ITF
International Tennis Federation

Tennis Anti-Doping Programme 2010

ATP
Sony Ericsson WTA TOUR

TENNIS
ANTI-DOPING PROGRAMME
2010

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A. Introduction

A.1 The purpose of this Tennis Anti-Doping Programme (the "**Programme**") is to maintain the integrity of tennis and to protect the health and rights of all tennis players.

A.2 The ITF is a signatory to the World Anti-Doping Code (the "**Code**"). This Programme is adopted and implemented pursuant to the mandatory provisions of the 2009 version of the Code, as part of the ITF's continuing efforts to keep doping out of the sport of tennis.

A.3 The Programme, which includes the appendices hereto, encompasses:

A.3.1 incorporation of the anti-doping rule violations identified in the Code, based on the List of Prohibited Substances and Prohibited Methods that is maintained by WADA, as described in Code Article 4.1 (the "**Prohibited List**");

A.3.2 collection of Samples both In-Competition and Out-of-Competition for Testing purposes;

A.3.3 review by an independent Review Board of Adverse Analytical Findings, Atypical Findings and other evidence of possible anti-doping rule violations, to confirm that there is a case to answer before anyone is charged with commission of such a violation;

A.3.4 the hearing and determination of any such charges by an independent Anti-Doping Tribunal, with the right to appeal from the decision of such tribunal to the Court of Arbitration for Sport in Lausanne, Switzerland; and

A.3.5 where it is found that an anti-doping rule violation has been committed under the Programme, imposition of Consequences of the nature and scope specified in the Code.

A.4 Terms in this Programme beginning with capital letters have the meaning ascribed to them in Appendix One to this Programme. The term 'anti-doping rule violation' shall have the meaning ascribed to it in Article C of this Programme.

A.5 The effective date of this Programme is 1 January 2010 (the "**Effective Date**").

A.6 Transitional provisions:

A.6.1 The Programme shall apply in full to all cases where the alleged anti-doping rule violation occurs after the Effective Date.

A.6.2 Any case pending prior to the Effective Date, or brought after the Effective Date but based on an anti-doping rule violation that occurred before the Effective Date, shall be governed by the predecessor version of the Programme in force at the time of the anti-doping rule violation, subject to any application of the principle of *lex mitior* by the Anti-Doping Tribunal hearing the case.

A.6.3 Any Filing Failure or Missed Test declared under a predecessor version of the Programme shall be carried forward and may be relied upon as one of the requisite elements of an anti-doping rule violation under Article C.4. However, a Filing Failure that occurred prior to 1 January 2009 may only be relied upon in combination with other Filing Failures; and a Missed Test that occurred prior to 1 January 2009 may only be relied upon in combination with other Missed Tests. No filing failure or missed test declared by any other Anti-Doping Organisation prior to 1 January 2009 may be combined with any Filing Failure or Missed Test declared under this Programme or under any predecessor version of the Programme.

A.6.4 Where a period of Ineligibility imposed under a version of the Programme pre-dating 1 January 2009 has not yet expired as of the Effective Date, the Participant in question may apply to the ITF to consider a reduction in the period of Ineligibility in light of the amendments to the Programme based on the 2009 version of the Code. The ITF's decision on such application is subject to appeal pursuant to Article O. To be valid, the application must be made before the period of Ineligibility has expired.

A.6.5 Anti-doping rule violations committed prior to the Effective Date, whether under predecessor versions of the Programme and/or other relevant rules, count as prior offences for purposes of determining sanctions under Article M.7. A prior offence involving a substance defined under this Programme as a Specified Substance, for which a period of Ineligibility of less than two years was imposed, shall be considered a Reduced Sanction offence for purposes of Article M.7.1.

A.7 The Programme shall be interpreted in a manner that is consistent with the Code. The Code shall be interpreted as an independent and autonomous text and not by reference to the existing law or statutes of any Signatory or government. The comments annotating various provisions of the Code may be used to assist in the understanding and interpretation of this Programme.

A.8 Subject to Article A.7, this Programme is governed by and shall be construed in accordance with English law. Strictly without prejudice to the arbitration provisions of Articles K and O of the Programme, disputes relating to the Programme shall be subject to the exclusive jurisdiction of the English courts.

A.9 The Board of Directors of the ITF may amend this Programme from time to time. Such amendments shall come into effect on the date specified by the Board of Directors.

B. Covered Players and Events

B.1 Any player who enters or participates in a Competition, Event or other activity organised, sanctioned or recognised by the ITF or who has an ATP Tour or WTA Tour ranking (a "**Player**") shall be bound by and shall comply with all of the provisions of this Programme, including making him/herself available upon request for Testing both In-Competition and Out-of-Competition.

B.2 The Events encompassed by Article B.1 include (without limitation) Grand Slam tournaments, Davis Cup and Fed Cup ties, the Olympic Tennis event, the Paralympic Tennis Event, other IOC-recognised International Events, WTA Tour tournaments and season-end championships, ATP World Tour tournaments and ATP World Tour Finals, ATP Challenger Tour tournaments, ITF Pro Circuit tournaments, ITF Juniors events, ITF Seniors events, ITF Wheelchair events, and ITF Beach Tennis Tour events ("**Covered Events**").

B.3 It is the sole responsibility of each Player:

B.3.1 to acquaint him/herself, and to ensure that each Person from whom he/she takes advice (including medical personnel) is acquainted, with all of the requirements of the Programme;

B.3.2 to know what constitutes an anti-doping rule violation under this Programme and what substances and methods have been included on the Prohibited List; and

B.3.3 to ensure that anything he/she ingests or uses, as well as any medical treatment he/she receives, does not give rise to an anti-doping rule violation under this Programme.

B.4 It is also the sole responsibility of each Player to ensure that the ITF is able to communicate with him/her efficiently and reliably in relation to matters arising under this Programme. To that end, each Player shall be deemed to be immediately contactable at the postal address and telephone number that he/she has specified on any Doping Control Form that he/she completes in relation to the Programme, and it shall be the Player's responsibility to complete such contact details (to be referred to herein as the "**Player's Nominated Address**") as necessary to ensure that he/she is immediately contactable at the Player's Nominated Address. Any notice required to be given to the Player under this Programme, if delivered to the Player by courier service to the Player's Nominated Address, shall be deemed to have been received by the Player on the date of delivery to such address reflected

in the confirmation of delivery provided by the courier service company. At its discretion, as an alternative to or in conjunction with such courier delivery, the ITF may use any other method of secure and confidential communication available, including but not limited to facsimile and/or e-mail; provided that if the Player denies receipt of such notice then (subject only to Article E.5.1) the burden will be on the ITF to prove that he/she did receive it.

B.5 A Player shall continue to be bound by and required to comply with the Programme unless and until the Player is deemed under the rules applicable to him/her to have retired from the sport, and the ITF shall continue to have jurisdiction over him/her after such retirement in respect of matters taking place prior to retirement. A Player who retires may not return to compete in a Covered Event unless he/she has made him/herself available for Out-of-Competition Testing (by notifying the ITF of his/her intent to return and by making him/herself available for Testing, including – if requested by the ITF -- by providing whereabouts information for the relevant period) for at least three months prior to the Covered Event in question.

B.6 Any coach, trainer, manager, agent, team staff, official, medical, paramedical personnel, parent or any other Person working with, treating or assisting a Player participating in or preparing for a Competition ("**Player Support Personnel**") shall also be bound by and shall comply with all of the provisions of this Programme.

B.7 It is the sole responsibility of each Player Support Personnel:

B.7.1 to acquaint him/herself with all of the provisions of the Programme;

B.7.2 to cooperate with the Testing of Players; and

B.7.3 to use his/her influence on Player values and behaviour to foster anti-doping attitudes.

C. <u>Anti-doping rule violations</u>

Doping is defined as the occurrence of one or more of the following (each, an "**anti-doping rule violation**"):

C.1 The presence of a Prohibited Substance or any of its Metabolites or Markers in a Player's Sample, unless the Player establishes that such presence is consistent with a therapeutic use exemption granted in accordance with Article E.

C.1.1 It is each Player's personal duty to ensure that no Prohibited Substance enters his/her body. A Player is responsible for any Prohibited Substance or any of its Metabolites or Markers found to be present in

his/her Sample. Accordingly, it is not necessary that intent, fault, negligence or knowing Use on the Player's part be demonstrated in order to establish an anti-doping rule violation under Article C.1; nor is the Player's lack of intent, fault, negligence or knowledge a defence to a charge that an anti-doping rule violation has been committed under Article C.1.

C.1.2 Excepting those substances for which a quantitative reporting threshold is specifically identified in the Prohibited List, and subject to the special criteria established in the Prohibited List (and/or other International Standards) to distinguish between endogenous and exogenous production of certain substances, the presence of any quantity of a Prohibited Substance or its Metabolites or Markers in a Player's Sample shall constitute an anti-doping rule violation under Article C.1, unless the Player establishes that such presence is consistent with a therapeutic use exemption granted in accordance with Article E.

C.2 Use or Attempted Use by a Player of a Prohibited Substance or a Prohibited Method, unless the Player establishes that such Use or Attempted Use is consistent with a therapeutic use exemption granted in accordance with Article E.

C.2.1 It is each Player's personal duty to ensure that he/she does not Use any Prohibited Substance or Prohibited Method. Accordingly, it is not necessary that intent, fault, negligence or knowing Use on the Player's part be demonstrated in order to establish an anti-doping rule violation of Use under Article C.2; nor is the Player's lack of intent, fault, negligence or knowledge a defence to a charge that an anti-doping rule violation of Use has been committed under Article C.2.

C.2.2 Without prejudice to Article C.2.1, it is necessary that intent on the Player's part be demonstrated in order to establish an anti-doping rule violation of Attempted Use under Article C.2.

C.2.3 The success or failure of the Use or Attempted Use of a Prohibited Substance or Prohibited Method is not material. For an anti-doping rule violation to be committed under Article C.2, it is sufficient that the Player Used or Attempted to Use the Prohibited Substance or Prohibited Method.

C.2.4 Notwithstanding Article C.2.3, however, a Player's Use of a substance Out-of-Competition shall not constitute an anti-doping rule violation under Article C.2 where the Use of that substance is not prohibited Out-of-Competition (see Article G.1.3).

C.3 Refusing or failing without compelling justification to submit to Sample collection after notification of Testing, or otherwise evading Sample collection.

C.4 For a Player in the International Registered Testing Pool, failure to comply with the requirements regarding Player availability for Out-of-Competition Testing set out in the International Standard for Testing, including any failure to file whereabouts information in accordance with Article 11.3 of the International Standard for Testing (a "**Filing Failure**") and any failure to be available for Testing at the declared whereabouts in accordance with Article 11.4 of the International Standard for Testing (a "**Missed Test**"). In accordance with Code Article 2.4 (but subject to Article A.6.3 of this Programme), any combination of three Filing Failures and/or Missed Tests committed within an eighteen-month period, whether declared by the ITF or any other Anti-Doping Organisation with jurisdiction over the Player, shall constitute an anti-doping rule violation under this Article C.4.

C.5 Tampering or Attempted Tampering with any part of Doping Control.

C.6 Possession of Prohibited Substances and/or Prohibited Methods:

C.6.1 Possession by a Player at any time or place of a substance that is prohibited at all times or of a Prohibited Method is an anti-doping rule violation under Article C.6, unless the Player establishes that such Possession is consistent with a therapeutic use exemption granted in accordance with Article E or other acceptable justification.

C.6.2 Possession by a Player In-Competition of any Prohibited Substance that is only prohibited In-Competition is an anti-doping rule violation under Article C.6, unless the Player establishes that such Possession is consistent with a therapeutic use exemption granted in accordance with Article E or other acceptable justification.

C.6.3 Possession by Player Support Personnel at any time or place of a substance that is prohibited at any time or of a Prohibited Method, in connection with a Player, Event or training, is an anti-doping rule violation under Article C.6, unless the Player Support Personnel establishes that such Possession is consistent with a therapeutic use exemption granted to the Player in accordance with Article E or other acceptable justification.

C.6.4 Possession by Player Support Personnel In-Competition of any Prohibited Substance that is only prohibited In-Competition, in connection with a Player, Event or training, is an anti-doping rule violation under Article C.6, unless the Player Support Personnel establishes that such Possession is consistent with a therapeutic use

exemption granted to a Player in accordance with Article E or other acceptable justification.

C.7 Trafficking or Attempted Trafficking in any Prohibited Substance or Prohibited Method.

C.8 Administration or Attempted administration to any Player at any time or place of a substance that is prohibited at all times or of a Prohibited Method, or administration or Attempted administration to any Player In-Competition of any Prohibited Substance that is only prohibited In-Competition, unless the Player establishes that such administration or Attempted administration was consistent with a therapeutic use exemption granted in accordance with Article E; or assisting, encouraging, aiding, abetting, covering up or any other type of complicity involving an anti-doping rule violation or any Attempted anti-doping rule violation.

C.9 Refusing or failing without compelling justification to comply with any other provision of this Programme.

D. **Prohibited Substances and Prohibited Methods**

D.1 Incorporation of the Prohibited List:

D.1.1 This Programme incorporates and is based upon the Prohibited List.

D.1.2 A copy of the Prohibited List effective as of 1 January 2010 is set out at Appendix Two to this Programme. WADA may amend the Prohibited List as set out in Code Article 4.1. Unless provided otherwise by WADA, amendments by WADA to the Prohibited List shall come into effect under this Programme automatically three months after publication of such amendments by WADA on its web-site, without the need for any further action by the ITF. It is the responsibility of each Player and each Player Support Personnel to be familiar with the most current version of the Prohibited List.

D.1.3 Without prejudice to the provisions of Article D.1.2, the ITF shall take reasonable steps to publicise any amendments made by WADA to the Prohibited List.

D.2 Criteria for Including Substances and Methods on the Prohibited List:

D.2.1 The criteria for including substances and methods on the Prohibited List are set out in Code Article 4.3. Such substances and methods may be included by general category (e.g. anabolic agents) or by specific reference to a particular substance or method. In accordance with Code Article 4.3.3, WADA's determination of the Prohibited Substances

and Prohibited Methods that will be included on the Prohibited List, and its classification of substances into categories on the Prohibited List (e.g., as prohibited at all times, or alternatively as prohibited only In-Competition; or as a Specified Substance or a non-Specified Substance), is final and shall not be subject to challenge by a Player or other Person.

D.2.2 Many of the substances on the Prohibited List may appear either alone or as part of a mixture within medications and/or supplements that may be available with or without a physician's prescription. Players are reminded that, as set out in Article C.1.1 of this Programme, they are strictly liable for any Prohibited Substances present in Samples collected from them. Players must ensure that Prohibited Substances do not enter or come to be present in their bodies and that Prohibited Methods are not Used.

D.3 Prohibited Substances and Prohibited Methods Identified on the Prohibited List:

As described in Code Article 4.2.1, WADA may expand the Prohibited List for the sport of tennis, and/or the ITF may request that WADA include additional substances or methods that have the potential for abuse in the sport of tennis in the monitoring programme described in Code Article 4.5.

D.4 Specified Substances:

D.4.1 For purposes of this Programme all Prohibited Substances shall be considered **"Specified Substances"** except (a) substances in the class of anabolic agents and hormones; and (b) those stimulants and hormone antagonists and modulators so identified on the Prohibited List. Prohibited Methods shall not be Specified Substances.

D.4.2 In the event that WADA expands the Prohibited List by adding a new class of Prohibited Substances, WADA's Executive Committee shall determine whether any or all of the Prohibited Substances within the new class of Prohibited Substances shall be considered Specified Substances within the meaning of Article D.4.1.

E. <u>Therapeutic Use Exemptions</u>

E.1 Players may be granted an exemption to Use one or more Prohibited Substances or Prohibited Methods for therapeutic purposes in the circumstances set out in the International Standard for Therapeutic Use Exemptions. In order to rely upon such an exemption to excuse the Use, the presence in a Sample, the Possession, or the administration of a Prohibited Substance or Prohibited Method that would otherwise amount to an anti-

doping rule violation under this Programme, such Use, presence, Possession or administration must be consistent with the provisions of a therapeutic use exemption (**"TUE"**) granted to the Player. Subject only to the limited provision in Article 4.7 of the International Standard for Therapeutic Use Exemptions for the retrospective grant of a TUE, such TUE must have been obtained by the Player prior to such Use, presence, Possession or administration.

E.2 The ITF is entitled, but not obliged, to recognise TUEs granted to Players by other Anti-Doping Organisations (such as National Anti-Doping Organisations). If a Player has such a TUE that he/she wishes to have recognised by the ITF for the purposes of Testing under the Programme, he/she must send a copy of the TUE to the APA requesting such recognition, and must provide such further information as the APA may request. Unless and until such recognition is given in writing, the Player uses the Prohibited Substance or Prohibited Method in issue entirely at his/her own risk.

E.3 Where a Player wishes the ITF to grant him/her a TUE, he/she should apply to the TUE Committee, c/o the APA, in accordance with the procedure set out in Article 8 of the International Standard for Therapeutic Use Exemptions. The request must be accompanied by all of the information specified in Article 8 of the International Standard for Therapeutic Use Exemptions, and the TUE Committee may require that further information be provided as necessary.

E.4 An application for a TUE shall be evaluated in accordance with the criteria set out in Article 4 of the International Standard for Therapeutic Use Exemptions. The application will be processed as quickly as is reasonably practicable, but Players should note that the procedure normally takes at least seventy-two hours from receipt of the complete application, and may take significantly longer. A Player may not assume that his/her application for a TUE (or for renewal of a TUE) will be granted. Any Player who uses the Prohibited Substance or Prohibited Method in issue prior to approval of his/her application for a TUE does so entirely at his/her own risk.

E.5 The APA shall notify the Player in writing of the grant or denial of the Player's application for a TUE. A copy of the decision will also be sent to WADA. If the application is granted, then the TUE will become effective as of the date that the Player receives notice of such grant. If the application is denied, the Player may apply to WADA to review that denial in accordance with Article E.6.

E.5.1 It shall be the Player's responsibility: (a) to ensure that the application for a TUE is complete and accurate; (b) to ensure that the application for a TUE contains an up-to-date and accurate postal address and facsimile number or e-mail to which notification of the approval or denial of the application can be communicated to the Player; and (c) to

make appropriate arrangements to ensure that any postal or facsimile communication made to the address or facsimile number specified by the Player on the TUE application comes to his/her immediate attention. For the avoidance of doubt, for the purposes of this Article E, any communication made by courier service to the postal address specified by the Player on his/her TUE application shall be deemed to have been received by the Player on the date of delivery to such address reflected in the confirmation of delivery provided by the courier service company, and any communication made to the facsimile number specified by the Player on his/her TUE application shall be deemed to have been received by the Player on the day of such transmission. In the event of a change of address or facsimile number while a TUE application is pending, it is the responsibility of the Player to notify the APA of the new details.

E.5.2 A TUE will be granted with effect for a specified period. It may also be granted subject to such conditions or restrictions as the TUE Committee may see fit. A Player who wishes to continue to use the Prohibited Substance or Prohibited Method in question beyond the period for which the TUE has been granted must make a new application for a further TUE in accordance with the provisions of this Article E. Any Player who wishes to have varied any conditions or restrictions imposed by the TUE Committee must apply to WADA in accordance with Article E.6.

E.6 Review by WADA:

E.6.1 At the request of a Player or on its own initiative, WADA may at any time review the TUE Committee's grant or denial of any application for a TUE. If WADA determines that the TUE Committee's grant or denial of a TUE does not comply with the International Standard for Therapeutic Use Exemptions in force at the time of the application, then WADA may reverse that decision.

E.6.2 If WADA reverses the grant of a TUE, that reversal shall not apply retroactively, but rather only from the point that the Player receives notice of the reversal. Therefore, the Player's results obtained from the date that the TUE came into effect until the date that the Player receives notice of WADA's reversal of the grant of the TUE shall not be Disqualified, nor shall the Player be subject to any other Consequences based on his/her Use of the Prohibited Substance or Prohibited Method in question during such period.

E.6.3 Decisions made by WADA further to Article E.6 may be appealed pursuant to Article O.3.

F. **In-Competition Testing**

F.1 Players shall be subject to Testing on behalf of the ITF at Covered Events. The selection of the Events at which Testing is to take place shall be made by the ITF, and shall remain confidential except to those Persons with a reasonable need to know of such selection in order to facilitate such Testing.

F.2 A Player may be notified that he/she has been selected for "In-Competition" Testing in conjunction with an Event in which he/she is participating at any time from 00.01 local time on the day of the first match of the main draw (or of the qualifying draw, if he/she is participating in the qualifying draw) of the Competition in question (a) until sixty (60) minutes after the completion of the Player's last match in the Event (120 minutes if the Player's last match in the Event is the final match in the Competition in question) (or, where he/she is participating in the Event as a nominated member of the team, sixty (60) minutes after the completion of his/her team's last match in the Event) (120 minutes if the team's last match in the Event is the final match in the Competition in question); or (b) further to Article F.4, until his/her withdrawal, no-show, retirement or default from the Competition. Such periods (and only such periods) shall be deemed **"In-Competition"** periods for purposes of this Programme and the Code. (For purposes of the Code, the "Event Period" shall be deemed to start at the same time as the "In Competition" period and to end at midnight on the day of the last match played in the Event).

F.3 The actual timing of the Testing at a selected Event, and the selection of Players to be tested at that Event, shall be at the discretion of the ITF. For the avoidance of doubt, the ITF may select Players for Target Testing (in accordance with the Code Article 5.1.3 requirement to make Target Testing a priority) so long as such Target Testing is not used for any purpose other than legitimate Doping Control purposes. However, in addition to any other Players that the ITF selects for Testing, all finalists and losing semi-finalists in each Competition at a selected Event will ordinarily be tested.

F.4 Any Player who retires, is a no-show, is defaulted from a match or withdraws from the Competition at any time after 00.01 local time on the day of the first match of the main draw (or qualifying draw, if he/she is participating in the qualifying draw) of the Competition must submit to Testing upon or after such retirement/no show/default/withdrawal if requested to do so. If the Competition in question is a doubles Competition, then his/her doubles partner must also submit to Testing at the same time if requested to do so. If the Player in question is not on-site at the time of the request, the ITF may require that the Player appear for Testing at a specified time and location, in which case the Player may be required to contribute to the cost of the test in an amount not exceeding US$5,000. All Samples collected in accordance with this Article F.4 – i.e., where collection of the Sample is triggered by the Player's retirement, no-show, default or withdrawal from Competition – that

are collected as part of a test commenced prior to midnight of the day following the Player's retirement, no-show, default or withdrawal from Competition will be deemed to have been collected In-Competition for purposes of this Programme, whether or not the Player has actually played a match or part of a match in the Competition.

F.5 Where a Sample is collected In-Competition, there shall be an anti-doping rule violation under Article C.1 if any substance on the Prohibited List (or any of its Metabolites or Markers) is present in the Sample.

F.6 In-Competition Testing shall be conducted on behalf of the ITF by qualified persons so authorised by the ITF. Such Testing shall be conducted in accordance with the International Standard for Testing and the Tennis Testing Protocols. Players must familiarise themselves with, and must comply with, all of the requirements of that Standard and those Protocols.

F.7 The ITF may authorise independent observers appointed by WADA to observe any In-Competition Testing conducted under the Programme as part of the Independent Observer Programme.

G. Out-of-Competition Testing

G.1 Ambit of Out-of-Competition Testing:

G.1.1 All Players must submit upon request to Testing under this Programme at any time and place.

G.1.2 Any period outside of an In-Competition period shall be deemed an **"Out-of-Competition"** period for purposes of this Programme and the Code. Any Testing of a Player outside of an In-Competition period shall therefore be considered Out-of-Competition Testing. Save in exceptional circumstances, such Testing shall be No Advance Notice Testing.

G.1.3 Where a Sample is collected during an Out-of-Competition period, there shall only be an anti-doping rule violation under Article C.1 if a substance (or any of its Metabolites or Markers) that is prohibited during Out-of-Competition periods - i.e. it is listed in the section of the Prohibited List entitled "Substances and Methods Prohibited At All Times (In- and Out-of-Competition)" - is present in the Sample.

G.1.4 A reasonable effort will be made to avoid inconvenience to a Player who is subjected to Out-of-Competition Testing. However, the ITF shall not be liable for any inconvenience or loss caused to the Player as a result of such Testing.

G.2 Additional Obligations on Players Included in the International Registered Testing Pool:

G.2.1 The ITF shall from time to time designate any Player or Players for inclusion in a pool of Players to be known as the "**International Registered Testing Pool**".

G.2.2 A Player in the International Registered Testing Pool is required:

(a) to advise the ITF (or, if the ITF agrees or WADA so specifies, his/her NADO) of his/her whereabouts on a quarterly basis, in the manner set out in Article 11.3 of the International Standard for Testing; and

(b) to be available for Testing at such whereabouts, in accordance with Article 11.4 of the International Standard for Testing.

G.2.3 Subject to the results management procedure referenced at Article G.2.5 of this Programme:

(a) a Player's failure to advise the ITF (or, if the ITF agrees or WADA so specifies, his/her NADO) of his/her whereabouts shall be deemed a Filing Failure for the purposes of this Programme where the conditions of Article 11.3.5 of the International Standard for Testing are met; and

(b) a Player's failure to be available for Testing at his/her declared whereabouts shall be deemed a Missed Test for the purposes of this Programme where the conditions of Article 11.4.3 of the International Standard for Testing are met.

G.2.4 Whereabouts information provided by a Player to the ITF pursuant to Article G.2.2 may be shared with WADA and other Anti-Doping Organisations in accordance with Article 11.7.1(d) of the International Standard for Testing.

G.2.5 Results management in relation to an anti-doping rule violation under Article C.4 of this Programme:

(a) Unless the ITF agrees (or WADA provides) that the Player's National Anti-Doping Organisation may take such responsibility, results management in respect of an apparent Filing Failure by a Player in the International Registered Testing Pool shall be conducted by the ITF in accordance with Article 11.6.2 of the International Standard for Testing (with the administrative review, if any, carried out by the Review Board in accordance with Article J.5.1) in order to determine

whether the failure should be declared a Filing Failure for purposes of Article C.4.

(b) Results management in respect of an apparent Missed Test by a Player in the International Registered Testing Pool as a result of an attempt to test the Player by or on behalf of the ITF under this Programme shall be conducted by the ITF in accordance with Article 11.6.3 of the International Standard for Testing (with the administrative review, if any, carried out by the Review Board in accordance with Article J.5.1) in order to determine whether the failure should be declared a Missed Test for purposes of Article C.4.

(c) Where, in any eighteen-month period, a Player in the International Registered Testing Pool is declared to have three Filing Failures, or three Missed Tests, or any combination of Filing Failures and Missed Tests adding up to three in total, whether under this Programme, or (in accordance with Article 11.1.5 of the International Standard for Testing) under the rules of any other relevant Anti-Doping Organisation, then (save only where Article 11.6.5(a) of the International Standard for Testing provides otherwise) the matter shall be referred to the Review Board to determine, in accordance with Article J.5.2 of this Programme and Article 11.6.5 of the International Standard for Testing, whether the Player has a case to answer under Article C.4.

G.2.6 A Player in the International Registered Testing Pool shall continue to be subject to the requirements of this Article G.2 unless and until:

(a) further to Article B.5, the Player is deemed under the rules applicable to him/her to have retired from the sport; or

(b) the Player is notified in writing that he/she no longer satisfies the criteria established by the ITF pursuant to Article G.2.1 for inclusion in the International Registered Testing Pool.

G.3 Selection of Players to be Tested Out-of-Competition:

A Player may be selected for Out-of-Competition Testing whether or not he/she has been included in the International Registered Testing Pool. The timing of Out-of-Competition Testing and the selection of Players to be tested shall be at the discretion of the ITF. For the avoidance of doubt, the ITF may select Players for Target Testing Out-of-Competition (in accordance with the Code Article 5.1.3 requirement to make Target Testing a priority) so long as such Target Testing is not used for any purpose other than legitimate Doping Control purposes. Decisions relating to timing and selection of Players for

Out-of-Competition Testing shall remain confidential except to those with a reasonable need to know of them in order to facilitate such Testing.

G.4 Out-of-Competition Testing shall be conducted on behalf of the ITF by qualified persons so authorised by the ITF. Such Testing shall be conducted in accordance with the International Standard for Testing and the Tennis Testing Protocols. Players must familiarise themselves with, and must comply with, all of the requirements of that Standard and those Protocols.

H. **Sample Analysis**

H.1 Use of Approved Laboratories:

H.1.1 For purposes of detecting the presence of a Prohibited Substance or its Metabolites or Markers and/or evidence of the Use of a Prohibited Method, the ITF shall send Samples for analysis only to WADA-accredited laboratories or as otherwise approved by WADA.

H.1.2 For purposes of screening of a blood (or other non-urine) Sample to determine whether the Player's corresponding urine Sample should be analysed, the ITF may send Samples either to a WADA-accredited laboratory or to such other entity as otherwise approved by WADA (e.g., a local hospital or a mobile testing unit).

H.1.3 Subject to Article H.1.1, the laboratory or laboratories used for the analysis of Samples collected under this Programme shall be chosen exclusively by the ITF.

H.2 Substances Subject to Detection:

Subject to Article G.1.3, Samples collected under this Programme shall be analysed (a) to detect Prohibited Substances (and/or their Metabolites or Markers) and Prohibited Methods identified on the Prohibited List and other substances as may be directed by WADA pursuant to the monitoring programme described in Article 4.5 of the Code, and/or (b) to assist the ITF in profiling relevant parameters in a Player's urine, blood or other matrix, including DNA profiling, for anti-doping purposes.

H.3 Restrictions on Use of Samples:

H.3.1 All Samples provided by a Player for the purposes of Testing under this Programme shall be the property of the ITF, and the ITF shall be entitled to determine all matters regarding the analysis and disposal of such Samples.

H.3.2 No Sample may be used for any purpose other than as described in Article H.2 without the Player's written consent. A Sample used (with the Player's consent) for purposes other than as described in Article H.2 shall have the identity code removed or shall be transferred into an anonymous container so that it cannot be traced back to the Player who provided it.

H.4 Standards for Sample Analysis and Reporting:

H.4.1 Laboratories shall analyse Samples and report results to the APA and the ITF Anti-Doping Manager in accordance with the International Standard for Laboratories.

H.4.2 Subject to Article F.4, the ITF shall pay the costs of collection and analysis of Samples under this Programme.

H.4.3 Any Adverse Analytical Findings reported by the laboratory shall be dealt with as set out in Article J.2.

H.4.4 Any Atypical Findings reported by the laboratory shall be dealt with as set out in Article J.3.

H.5 Re-Analysing Samples:

A Sample collected under this Programme may be re-analysed for the purposes described in Article H.2 at any time exclusively at the direction of the ITF or WADA. The circumstances and conditions for re-analysing Samples shall conform with the requirements of the International Standard for Laboratories.

I. **Investigations**

I.1 In addition to conducting the Testing referenced at Articles F and G of this Programme, the ITF shall have the power to conduct investigations in whatever manner it thinks fit into the activities of any Participant that the ITF believes may have committed an anti-doping rule violation. Such investigations may be conducted in conjunction with, and/or information obtained in such investigations may be shared with, other Signatories and/or other relevant authorities. The ITF shall have discretion, where it deems appropriate, to stay its own investigation pending the outcome of investigations being conducted by other Signatories and/or other relevant authorities.

I.2 In the event a Participant knows or suspects that any other Participant has committed an anti-doping rule violation, it shall be the Participant's obligation to report such knowledge or suspicion to the ITF Anti-Doping

Manager as soon as possible. A Participant shall have a continuing obligation to report any new knowledge or suspicion regarding any anti-doping rule violation to the ITF Anti-Doping Manager, even if the Participant's prior knowledge or suspicion has already been reported. Failure to comply with any of the foregoing without acceptable justification shall constitute an anti-doping rule violation within the meaning of Article C.9.

I.3 Participants must cooperate fully with investigations conducted pursuant to this Article I. Failure or refusal to do so without acceptable justification shall constitute an anti-doping rule violation within the meaning of Article C.9.

I.3.1 If the ITF Anti-Doping Manager believes that a Participant may have committed an anti-doping rule violation, the ITF Anti-Doping Manager may make a written demand to such Participant (a "**Demand**") to furnish to the ITF Anti-Doping Manager any information regarding the alleged anti-doping rule violation, including (without limitation) a written statement setting forth the facts and circumstances with respect to the alleged anti-doping rule violation; provided that the Review Board has agreed with the ITF Anti-Doping Manager, in accordance with Article J.6, that there is a good faith basis for the Demand. The Participant shall furnish such information within seven business days of the making of such Demand, or within such other time as may be set by the ITF Anti-Doping Manager. Any information furnished to the ITF Anti-Doping Manager shall be kept confidential except when it becomes necessary to disclose such information in furtherance of the prosecution of an anti-doping rule violation, or when such information is reported to administrative, professional, or judicial authorities pursuant to an investigation or prosecution of non-sporting laws or regulations.

I.3.2 Each Participant contractually agrees to waive and forfeit any rights, defences and privileges provided by any law in any jurisdiction to withhold information requested by the ITF Anti-Doping Manager. If a Participant fails to produce such information, the Participant's eligibility to compete in Covered Events (or, in the case of a Player Support Personnel, to assist Players competing in Covered Events) may be withdrawn, and he/she may be denied credentials and access to Covered Events, pending compliance with the Demand.

I.4 Where, as the result of an investigation under this Article I, the ITF forms the view that an anti-doping rule violation may have been committed, the ITF shall refer the matter to the Review Board, to be dealt with as set out in Article J.4.

J. **Review Board**

J.1 Responsibilities of the Review Board:

J.1.1 The Review Board shall carry out the functions assigned to it under this Article J and elsewhere in this Programme.

J.1.2 In a case involving an Adverse Analytical Finding or Atypical Finding, at no point during its deliberations should the Review Board be advised of the identity of the Player involved. Subject thereto, where necessary, where a matter is referred to the Review Board under this Programme the Review Board may request that the ITF provide additional information for the Review Board's consideration.

J.1.3 There shall be no obligation for the Review Board to meet in person to deliberate. However, any decision by the Review Board that the Participant has a case to answer under Article C of this Programme must be unanimous.

J.2 Review of Adverse Analytical Findings:

J.2.1 Upon receipt of an Adverse Analytical Finding in relation to an A Sample, then (save where an application for a retroactive TUE has been made to the ITF, in accordance with Article E of this Programme and 4.7 of the International Standard for TUEs, in which case no action shall be taken pending a decision on the application) the ITF shall, without delay:

(a) identify three Review Board members (who shall include one technical, one legal and one medical expert) to consider the matter; and

(b) send the relevant papers to the three Review Board members. Where it appears that the Adverse Analytical Finding may be consistent with a TUE previously granted to the Player, in the first instance only the laboratory's certificate of analysis of the A sample and anonymised copies of the TUE application and decision shall be sent to the three Review Board members. However, if there is no potentially applicable TUE, or if the Review Board determines that the Adverse Analytical Finding is not consistent with the TUE in question, the APA shall send the entire A Sample laboratory documentation package to the three Review Board members, along with any other relevant papers.

J.2.2 The three Review Board members shall conduct a review to determine whether:

(a) the Adverse Analytical Finding is consistent with a TUE that has been granted or recognised in accordance with Article E; or

(b) there is any departure from the International Standard for Testing or from the International Standard for Laboratories that caused the Adverse Analytical Finding.

J.2.3 If the Review Board determines that either (a) or (b) in Article J.2.2 applies, it shall advise the ITF that there is no case to answer. The ITF shall notify the Player, WADA and the Player's NADO and (subject to the rights of appeal set out at Article O) the matter shall not proceed any further.

J.2.4 If the Review Board determines that neither (a) nor (b) in Article J.2.2 applies, it shall advise the ITF that there is a case to answer, and the ITF shall send the Player a Notice of Charge in accordance with Article K.1.1.

J.3 Review of Atypical Findings:

J.3.1 In certain circumstances where a Prohibited Substance is detected in a Sample that may also be produced endogenously, the International Standards direct laboratories to report the presence of such substance as an Atypical Finding that should be investigated further.

J.3.2 If a laboratory reports an Atypical Finding in respect of a Sample collected from a Player under this Programme, the ITF shall refer it to three suitably qualified Review Board members, who shall conduct an initial review to determine whether:

(a) the Atypical Finding is consistent with a TUE that has been granted or recognised in accordance with Article E; or

(b) there is any departure from the International Standard for Testing or from the International Standard for Laboratories that caused the Atypical Finding.

J.3.3 If the Review Board determines that either (a) or (b) in Article J.3.2 applies, it shall advise the ITF that there is no case to answer. The ITF shall notify the Player, WADA and the Player's NADO, and (subject to the rights of appeal set out at Article O) the matter shall not proceed any further.

J.3.4 If the Review Board determines that neither of (a) or (b) in Article J.3.2 applies, the ITF shall conduct the follow-up investigation required by the International Standards.

J.3.5 If, following the investigation, the Review Board concludes that the Atypical Finding should be considered an Adverse Analytical Finding, and that there is a case to answer under Article C of the Programme, the matter shall proceed in accordance with Article J.2.4.

J.3.6 Pending the outcome of the investigation, the ITF will keep the Atypical Finding confidential, save that:

(a) if it determines that the B Sample should be analysed as part of the investigation, it shall notify the Player in accordance with Article K.1.1(c); and

(b) if requested by a Major Event Organisation in the lead-up to its Event, or by a sports organisation about to select Players for an International Event, it may confirm that the Player has a pending Atypical Finding, after telling the Player.

J.3.7 If the ITF decides not to pursue the Atypical Finding as an Adverse Analytical Finding, it shall so notify the Player, WADA and the Player's NADO and any other Anti-Doping Organisation with the right to appeal that decision under Article O.

J.4 Referrals to the Review Board that involve evidence other than Adverse Analytical Findings or Atypical Findings:

J.4.1 Where a matter is referred to the Review Board that involves evidence of an anti-doping rule violation other than an Adverse Analytical Finding or an Atypical Finding, whether pursuant to Article I of the Programme or otherwise:

(a) the ITF shall identify three Review Board members who have the expertise required by the nature of the particular case, to review the evidence to determine whether there is a case to answer under Article C of the Programme; and

(b) the ITF shall send the entire dossier of evidence to each of those three Review Board members.

J.4.2 Where they consider it appropriate to do so, the three Review Board members may give the Participant(s) implicated in the alleged anti-doping rule violation an opportunity, subject to a strict time-table set by the Review Board, to make any submissions that he/she may wish to make, and shall take such submissions (if any) into account in making its determination. The Review Board shall determine how the submissions should be made, such as (for example) in writing (copied to the ITF), or by telephonic conference (to which the ITF shall be a party). A formal hearing is not required to be held.

J.4.3 Where the Review Board concludes that there is no case to answer under Article C, then the ITF shall notify the Athlete, WADA, the Athlete's NADO and any other Anti-Doping Organisation with a right of appeal under Article O and (subject to the rights of appeal set out at Article O.2) the matter shall not proceed any further.

J.4.4 Where the Review Board concludes that there is a case to answer under Article C, the ITF shall send the Player a Notice of Charge in accordance with Article K.1.1.

J.5 Review of Whereabouts Failures:

J.5.1 Where (in accordance with Article 11.6.2 or Article 11.6.3 of the International Standard for Testing) a Player requests an administrative review of an alleged Filing Failure or Missed Test, the ITF Anti-Doping Manager shall refer the file to one or more suitably qualified members of the Review Board, who shall carry out that administrative review in accordance with the applicable IST Article.

J.5.2 (a) If the Review Board determines that such alleged Filing Failure or Missed Test should not be recorded against the Player, the ITF shall notify the Player, as well as WADA, the Player's National Anti-Doping Organisation, and any other Anti-Doping Organisation with a right of appeal against that decision under Article O. Subject to any such appeal, the matter shall not proceed any further.

(b) Where two whereabouts failures have already been recorded against the Player in the 18-month period prior to the alleged Filing Failure or Missed Test under administrative review, if the Review Board determines that the alleged Filing Failure or Missed Test under review should be recorded against the Player as well, then (subject to Article 11.6.5 of the International Standard for Testing) the ITF shall send the Player a Notice of Charge in accordance with Article K.1.1.

J.6 Review of Demands:

Where the ITF Anti-Doping Manager wishes to make a Demand of a Player in accordance with Article I.3, the ITF Anti-Doping Manager shall first refer the Demand to the Review Board to determine whether there is a good faith basis for the Demand, such that withdrawing eligibility for, access to and accreditation for Covered Events in the case of non-compliance with the Demand is justified. In considering the Demand, the Review Board shall have the discretion but not the obligation to invite such submissions from the ITF Anti-Doping Manager and the Participant in question as it sees fit. If the Review Board determines that there is no good faith basis for the Demand,

then (a) the ITF Anti-Doping Manager shall not pursue the Demand with the Player; and (b) there shall be no consequences imposed on the Player for not complying with the Demand.

J.7 Results Management for Tests Initiated During the Olympic Games or the Paralympic Games.

Where a Player commits an anti-doping rule violation at the Olympic Games, the International Olympic Committee shall determine the question of Disqualification from the Olympic Games. Where a Player commits an anti-doping rule violation at the Paralympic Games, the International Paralympic Committee shall determine the question of Disqualification from the Paralympic Games. In each case, however, the question of further Consequences, if any, to be imposed in relation to such anti-doping rule violation shall be determined in accordance with this Programme.

J.8 Results Management for Tests Initiated By Another Anti-Doping Organisation:

Unless otherwise agreed by the ITF, where another Anti-Doping Organisation tests a Player under its own rules, and that test results in an Adverse Analytical Finding, or if that Anti-Doping Organisation uncovers other evidence of an anti-doping rule violation by such Player, it shall be the responsibility of that Anti-Doping Organisation to pursue the matter, including bringing charges (if appropriate) under its rules, failing which it shall be the responsibility of the Player's National Association to pursue the matter.

K. <u>Proceedings Before an Anti-Doping Tribunal</u>

K.1 Notice of Charge:

K.1.1 When the Review Board determines, pursuant to Article J, that a Participant has a case to answer under Article C, the ITF Anti-Doping Manager shall appoint an Anti-Doping Tribunal to hear the matter and shall send a written notice to the Participant (the "**Notice of Charge**"), with a copy to the person designated as the Chairman of the Anti-Doping Tribunal, setting out:

(a) the anti-doping rule violation(s) alleged to have been committed, including the specific Article(s) of this Programme alleged to have been infringed, and a summary of the facts upon which such allegations are based (and if the charge has resulted from an Adverse Analytical Finding, a copy of the laboratory documentation pack supporting that Adverse Analytical Finding shall be enclosed with the Notice of Charge);

(b) the Consequences applicable under the Programme if it is determined that the alleged anti-doping rule violation has been committed;

(c) where the charge is under Article C.1, the right of the Player and/or the Player's representative to attend the opening and analysis of the B Sample, on a specified date (usually within seven working days of the Player's receipt of the Notice of Charge) and at a specified time and place, for purposes of Article K.2 (B Sample analysis);

(d) (where applicable) the matters relating to Provisional Suspension specified at Article K.3; and

(e) the Participant's entitlement to respond to the Notice of Charge in one of the following ways:

(i) to admit the anti-doping rule violation(s) charged, and accede to the Consequences specified in the Notice of Charge;

(ii) to admit the anti-doping rule violation(s) charged, but to dispute and/or seek to mitigate the Consequences specified in the Notice of Charge, and to have the Anti-Doping Tribunal determine the Consequences at a hearing conducted in accordance with Article K; or

(iii) to deny the anti-doping rule violation(s) charged, and to have the Anti-Doping Tribunal determine the charge and (if the charge is upheld) any Consequences, at a hearing conducted in accordance with this Article K;

provided that if the Participant wishes to exercise his/her right to a hearing before the Anti-Doping Tribunal, he/she must submit a written request for such a hearing so that it is received by the ITF Anti-Doping Manager as soon as possible, but in any event within ten (10) days of the Participant's receipt of the Notice. The request must also state how the Participant responds to the charge in the Notice and must explain (in summary form) the basis for such response. In the event no such response is received by that deadline, the Participant will be deemed to have admitted the anti-doping rule violation(s) charged, and to have acceded to the Consequences specified in the Notice of Charge.

K.1.2 In the Notice of Charge, or at any other time prior to the determination of the charge by the Anti-Doping Tribunal, the ITF may invite the

Participant to admit the anti-doping rule violation(s) charged and accede to specified Consequences.

K.1.3 In the event that the Participant admits the anti-doping rule violation(s) charged and accedes to the Consequences specified by the ITF (or is deemed to have done so in accordance with Article K.1.1), a hearing before the Anti-Doping Tribunal shall not be required. Instead the ITF shall promptly issue a decision confirming the commission of the anti-doping rule violation(s) and the imposition of the specified Consequences, and shall publish that decision in accordance with Article K.8.

K.2 B Sample Analysis:

K.2.1 If the Player admits the presence in his Sample of the Prohibited Substance (or any of its Metabolites or Markers) detected by the laboratory, the Player shall be deemed (a) to have waived his/her right to have the B Sample analysed; and (b) to have accepted the Adverse Analytical Finding based on the A Sample analysis only.

K.2.2 If the Player does not admit the presence in his Sample of the Prohibited Substance (or any of its Metabolites or Markers) detected by the laboratory, the analysis of the B Sample shall proceed on the date and at the time and venue specified pursuant to Article K1.1(c). The Player and/or his/her representative shall be entitled to be present at the analysis of the B Sample at the Player's cost. A representative of the ITF may also be present. There shall be no right to an adjournment of the date scheduled for analysis of the B Sample; instead, any such adjournment shall be at the absolute discretion of the ITF. In the event that neither the Player nor any representative of the Player attends the B Sample analysis, the laboratory shall appoint an independent witness, in accordance with the International Standard for Laboratories, to verify that the B Sample container shows no signs of tampering and that the identifying numbers correspond to those on the collection documentation.

K.2.3 If the analysis of B Sample does not confirm the Adverse Analytical Finding in respect of the A Sample, then unless the ITF charges the Player with Use under Article C.2, the entire test shall be considered negative and the Player shall be so informed. In such circumstances, the proceedings instituted against the Player shall be discontinued, any Provisional Suspension previously imposed shall be deemed vacated with immediate effect, in accordance with Article K.3.2, and no further action shall be taken against the Player.

K.2.4 If the analysis of the B Sample confirms the Adverse Analytical Finding in respect of the A Sample to the satisfaction of the ITF, then

the matter shall proceed to a hearing in accordance with the provisions of Article K.

K.3 Provisional Suspension:

K.3.1 If (and only if) each of the following conditions is met:

(a) analysis of an A Sample by a WADA-accredited laboratory has resulted (including after any further investigation of an Atypical Finding in accordance with Article J.3, where applicable) in an Adverse Analytical Finding for a Prohibited Substance that is not a Specified Substance; and

(b) the Review Board has completed its review in accordance with Article J.2 or Article J.3 (as applicable) and has concluded that the Player in question has a case to answer under Article C.1 (presence of a Prohibited Substance or its Metabolites or Markers in the Player's Sample);

then the ITF shall notify the Player, in the Notice of Charge sent to the Player in accordance with Article K.1, that he/she will be Provisionally Suspended with effect from the date ten days after the date of deemed receipt of the Notice of Charge, pending determination of the charge against him/her at a full hearing pursuant to Article K. However, the ITF shall at the same time notify the Player of his/her right, at his/her election, to make an application to the Chairman of the Anti-Doping Tribunal convened to hear his/her case, either immediately or at any time prior to the full hearing, showing cause why the Provisional Suspension should not be imposed (or, where it has been imposed, why it should be vacated) in advance of the full hearing.

K.3.2 If the B Sample analysis does not confirm the A Sample analysis, then Article K.2.3 shall apply, and no Provisional Suspension shall be imposed on the Player. If a Provisional Suspension was imposed on the Player prior to receipt of the results of the B Sample analysis, then in accordance with Article K.2.3 it shall be deemed automatically vacated with immediate effect, without any need for any further Order.

K.3.3 If, within ten days of the date of deemed receipt of the Notice of Charge, the results of the B Sample analysis are not received, or they are received and they confirm the A Sample results, and/or the Player does not exercise his/her right to apply for an order that a Provisional Suspension should not be imposed prior to 1700 (GMT) on the tenth day after the date of deemed receipt of the Notice of Charge, then the Provisional Suspension will come into effect automatically at that point and will remain in place (subject to the Player's right at any time

to apply to the Chairman of the Tribunal for it to be vacated) pending determination of the charge against the Player.

K.3.4 If the Player exercises his/her right to apply to the Chairman of the Anti-Doping Tribunal for an order that a Provisional Suspension should not be imposed (or, if already in place, that it should be vacated), then:

(a) any submissions that the Player wishes to make (personally or through a representative) in support of the application must be made in writing to the Chairman of the Tribunal at the same time as the application is made, with a copy sent simultaneously to the ITF Anti-Doping Manager;

(b) any submissions that the ITF Anti-Doping Manager wishes to make (personally or through a representative) must be made in writing to the Chairman of the Tribunal as soon as possible after receipt of the Player's submissions, with a copy sent simultaneously to the Player;

(c) the Chairman of the Anti-Doping Tribunal, sitting alone, will rule on the application as soon as reasonably practicable. The Chairman shall have discretion, where fairness requires, to invite or to allow the parties to make oral submissions, either by a telephone conference call or in person, prior to rendering his/her decision on the application. For the avoidance of doubt, however, neither party shall have the right to make such submissions if the Chairman in his/her discretion does not invite or allow such submissions;

(d) if the Player's application is received within ten days of the date of deemed receipt of the Notice of Charge, the Provisional Suspension will not come into effect unless and until that application is rejected;

(e) if the Player's application is made after the Provisional Suspension has come into effect, the Provisional Suspension will remain in effect pending the Chairman's decision on the application; and

(f) the Provisional Suspension shall be imposed (or shall not be vacated) unless the Player establishes to the comfortable satisfaction of the Chairman that, notwithstanding the matters set out in Article K.3.1(a) and (b):

(i) the charge has no reasonable prospect of being upheld, e.g. because of a material defect in the evidence on which the charge is based; or

(ii) the Player has a strong arguable case that he/she bears No Fault or Negligence for the anti-doping rule violation(s) charged, so that any period of Ineligibility that might otherwise be imposed for such offence is likely to be completely eliminated by application of Article M.5.1; or

(iii) some other facts exist that make it clearly unfair, in all of the circumstances of the case, to impose a Provisional Suspension prior to determination of the charge against the Player. This ground is to be construed narrowly, and applied only in truly exceptional circumstances. For example, the fact that the Provisional Suspension would prevent the Player competing in a particular Competition or Event shall not qualify as exceptional circumstances for these purposes.

K.3.5 Where the Chairman grants the Player's application and rules that no Provisional Suspension should be imposed on the Player, or that a Provisional Suspension previously imposed on the Player should be vacated, then (subject only to the possibility of reconsideration in light of new evidence) that decision will be final and binding on the parties, and the ITF shall have no right of appeal against it.

K.3.6 Where the Chairman rejects the Player's application (or no such application is made) and a Provisional Suspension is therefore imposed (or is not vacated), the Player has:

(a) a right to appeal immediately to CAS against the rejection of the application (if any) in accordance with Article O, provided however that the Provisional Suspension shall remain in effect pending a decision by CAS on the merits of the appeal;

(b) the right to have the proceedings before the Anti-Doping Tribunal expedited so that the hearing is held, and the charge against him/her is determined, as soon as possible, consistent with the requirements of due process; and

(c) the right, if the charge against him/her is upheld by the Anti-Doping Tribunal and a period of Ineligibility is imposed, to have the period of any Provisional Suspension that he/she has already served credited against that period of Ineligibility, in accordance with Article M.9.3(a).

K.3.7 Prohibition against Participation during Provisional Suspension:

A Player may not, during the period of any Provisional Suspension, play, coach or otherwise participate in any capacity in (a) a Covered Event, any other Event or Competition, or any other kind of function, event or activity (other than authorised anti-doping education or rehabilitation programmes) authorised, organised or sanctioned by the ITF, the ATP, the WTA, or any National Association or member of a National Association; or (b) any Event or Competition authorised or organised by any professional league or any other international or national-level Event organisation. Without prejudice to the generality of the foregoing, the Player shall not be given accreditation for, or otherwise granted access to, any Event or Competition, or other function, event or activity to which access is controlled by the ITF, any National Association or member of a National Association, the ATP, or the WTA, and any accreditation previously issued shall be withdrawn. In addition, the ITF will take the necessary steps to have the Provisional Suspension recognised and enforced by other relevant organisations in accordance with Article 15.4 (Mutual Recognition) of the Code.

K.3.8 For the avoidance of doubt, no Provisional Suspension may be imposed on a Player under this Programme except in the circumstances set out in Article K.3.1, and in accordance with the provisions of Articles K.3.2 – K.3.7. In other cases where a Notice of Charge is issued, however:

(a) if the Player voluntarily accepts a Provisional Suspension in writing in accordance with Article M.9.3 and thereby foregoes any form of involvement in any Covered Event or other Event or Competition that is authorised or organised by the ITF, any National Association, the ATP, the WTA or any Major Event Organisation pending determination of the charge against him/her (including but not limited to playing, coaching and/or participating in any capacity at such Events or Competitions), then in accordance with Article M.9.3(c) that period of voluntary Provisional Suspension will be credited against any period of Ineligibility subsequently imposed on the Player; and

(b) if the Player continues to compete in Events pending determination of the charge against him/her, where requested by the ITF the organisers of the relevant Events shall pay to the ITF upon demand the following proportions of any Prize Money won by the Player subsequent to his/her receipt of the Notice of Charge (taken in aggregate, across all of the relevant Events), to be held in escrow pending the determination of the charge:

Total aggregate prize money	Percentage withheld
US$0-7,500	0%
US$7,501-27,500	50%
US$27,501+	100%

If the final decision of the Anti-Doping Tribunal does not require the forfeiture of such escrowed Prize Money, then it shall be returned without delay to the Player, together with any interest earned on the money while it was in escrow. If such forfeiture is required, any interest earned shall be retained by the ITF.

K.3.9 No admission shall be inferred, or other adverse inference drawn, from (a) a Player's decision not to make an application under Article K.3.1 to avoid (or to vacate) a Provisional Suspension; or (b) a Player's decision to accept a voluntary Provisional Suspension under Article K.3.8(a).

K.4 Preliminary Meeting with the Chairman of the Anti-Doping Tribunal:

K.4.1 If the Participant charged exercises his/her right to a hearing, the Chairman of the Anti-Doping Tribunal shall convene a preliminary meeting with the ITF and its legal representatives, and with the Participant and/or his/her legal representatives (if any). The preliminary hearing should take place as soon as possible and (save in exceptional circumstances) no more than 21 days after the date of the Notice of Charge. The meeting may be held in person or by telephone conference call. The non-attendance of the Participant or his/her representative at the meeting, after proper notice of the meeting has been provided, shall not prevent the Chairman of the Anti-Doping Tribunal from proceeding with the meeting in the Participant's absence, whether or not any written submissions are made on the Participant's behalf.

K.4.2 The purpose of the preliminary meeting shall be to allow the Chairman to address any pre-hearing issues. In particular (but without limitation), the Chairman shall:

(a) consider any request by either party that the Chairman hear the matter sitting alone;

(b) determine the date(s) (which must be at least twenty-one days after the meeting, unless the parties consent to a shorter period) upon which the hearing shall be held. Subject to the foregoing sentence, the hearing shall be commenced as soon as practicable after the Notice of Charge is sent, and ordinarily

within sixty (60) days of the date that the Participant requests a hearing. It shall be completed expeditiously;

(c) establish dates reasonably in advance of the date of the hearing at which:

i. the ITF shall submit a brief with argument on all issues that the ITF wishes to raise at the hearing and a list of the witnesses that the ITF intends to call at the hearing (with each witness's address, telephone number and a summary of the subject areas of the witness's anticipated testimony), and enclosing copies of the documents that the ITF intends to introduce at the hearing;

ii. the Participant shall submit an answering brief, addressing the ITF's arguments and setting out argument on the issues that the Participant wishes to raise at the hearing, as well as a list of the witnesses that the Participant intends to call at the hearing (with each witness's address, telephone number and a summary of the subject areas of the witness's anticipated testimony), and enclosing copies of the documents that the Participant intends to introduce at the hearing; and

iii. the ITF may submit a reply brief, responding to the Participant's answer brief and listing any rebuttal witnesses or documents; and

(d) make such order as the Chairman shall deem appropriate in relation to the production of relevant documents and/or other materials between the parties; provided that save for good cause shown no documents and/or other materials shall be ordered to be produced in relation to any Adverse Analytical Finding beyond the documents that the International Standard for Laboratories requires to be included in the laboratory documentation pack.

K.4.3 The Participant shall be required to raise at the preliminary meeting any legitimate objection that he/she may have to any of the members of the Anti-Doping Tribunal convened to hear his/her case. Any unjustified delay in raising any such objection shall constitute a waiver of the objection. If any objection is made, the Chairman of the Anti-Doping Tribunal shall rule on its legitimacy.

K.4.4 If, because of a legitimate objection or for any other reason, a member of the Anti-Doping Tribunal is, or becomes, unwilling or unable to hear the case, then the Chairman of the Anti-Doping Tribunal may, at

his/her absolute discretion: (a) rule that a replacement member of the Anti-Doping Tribunal should be appointed (in which case the ITF Anti-Doping Manager shall appoint the replacement); or (b) authorise the remaining members to hear the case on their own.

K.5 Conduct of Hearings Before the Anti-Doping Tribunal:

K.5.1 Subject to the discretion of the Chairman of the Anti-Doping Tribunal to order otherwise for good cause shown by either party, hearings before the Anti-Doping Tribunal shall (a) take place in London; and (b) be conducted on a confidential basis.

K.5.2 Each of the ITF and the Participant has the right to be present and to be heard at the hearing. Each of the ITF and the Participant also has the right (at his/her/its own expense) to be represented at the hearing by legal counsel of his/her/its own choosing.

K.5.3 Subject strictly to Article K.7.5, the Participant may choose not to appear in person at the hearing, but rather to provide a written submission for consideration by the Anti-Doping Tribunal, in which case the Anti-Doping Tribunal shall consider the submission in its deliberations. However, the non-attendance of the Participant or his/her representative at the hearing, after proper notice of the hearing has been provided, shall not prevent the Anti-Doping Tribunal from proceeding with the hearing in his/her absence, whether or not any written submissions are made on his/ her behalf.

K.5.4 The procedure followed at the hearing shall be at the discretion of the Chairman of the Anti-Doping Tribunal, provided that the hearing is conducted in a fair manner with a reasonable opportunity for each party to present evidence (including the right to call and to question witnesses), address the Anti-Doping Tribunal and present his/her case.

K.5.5 Save where the Chairman orders otherwise for good cause shown by either party, the hearing shall be in English, and certified English translations shall be submitted of any non-English documents put before the Tribunal. The cost of the translation shall be borne by the party offering the document(s). If required by the Chairman, the ITF shall make arrangements to have the hearing recorded or transcribed (save for the private deliberations of the Anti-Doping Tribunal). If requested by the Participant, the ITF shall also arrange for a translator to attend the hearing to translate oral questions and/or answers. The costs of such transcription and translation shall be paid by the ITF, subject to any costs-shifting order that the Tribunal may make further to Article K.8.4.

K.6 Burdens and Standards of Proof:

K.6.1 The ITF shall have the burden of establishing that an anti-doping rule violation has been committed. The standard of proof shall be whether the ITF has established the commission of the alleged anti-doping rule violation to the comfortable satisfaction of the Anti-Doping Tribunal, bearing in mind the seriousness of the allegation that is made. This standard of proof in all cases is greater than a mere balance of probability but less than proof beyond a reasonable doubt.

K.6.2 Where this Programme places the burden of proof upon the Participant alleged to have committed an anti-doping rule violation to rebut a presumption or establish specified facts or circumstances, the standard of proof shall be by a balance of probability, except where the Programme specifically provides that the Participant must satisfy a higher standard of proof: see Article M.4.2 and Article M.6.1.

K.7 Methods of Establishing Facts and Presumptions:

The Anti-Doping Tribunal shall not be bound by judicial rules governing the admissibility of evidence. Instead, facts relating to an anti-doping rule violation may be established by any reliable means, including admissions. The following rules of proof shall be applicable at the hearing:

K.7.1 WADA-accredited laboratories shall be presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The Participant may rebut this presumption by establishing that a departure from the International Standard occurred that could reasonably have caused the Adverse Analytical Finding. In such an event, the ITF shall have the burden to establish that such departure did not cause the Adverse Analytical Finding.

K.7.2 Departures from any other International Standard or other anti-doping rule or policy that did not cause the facts alleged in support of a charge (e.g., an Adverse Analytical Finding) shall not invalidate such facts. If the Participant establishes that a departure from an International Standard or other anti-doping rule or policy occurred that could reasonably have caused the facts alleged in support of a charge, then the ITF shall have the burden to establish that such departure did not cause such facts.

K.7.3 Proof of an Adverse Analytical Finding in respect of a Player's A Sample is sufficient to establish an anti-doping rule violation under Article C.1 if (a) the Player waives analysis of the B Sample and the B Sample is therefore not analysed; or (b) the Player's B Sample is

analysed, and that analysis confirms the presence of the Prohibited Sample or its Metabolites or Markers found in the Player's A Sample.

K.7.4 The facts established by a decision of a court or professional disciplinary tribunal of competent jurisdiction that is not the subject of a pending appeal shall be irrebuttable evidence against the Participant to whom the decision pertained of those facts, unless that Participant establishes that the decision violated principles of natural justice.

K.7.5 The Anti-Doping Tribunal may draw an inference adverse to the Participant charged with an anti-doping rule violation based on the Participant's refusal, after a request made in a reasonable time in advance of the hearing, to appear at the hearing (either in person or telephonically as directed by the Tribunal) and to answer questions from the ITF or the Tribunal.

K.8 Decisions of the Anti-Doping Tribunal:

K.8.1 Once the parties have completed their respective submissions, the Anti-Doping Tribunal shall retire to deliberate in private as to whether an anti-doping rule violation has been committed and (if so) what the Consequence should be. Any decision that an anti-doping rule violation has been committed must be made unanimously, with no abstentions. Where Article M of this Programme specifies a range of possible sanctions for the anti-doping rule violation found to have been committed, the Anti-Doping Tribunal shall also fix the sanction within that range for the case at hand, after considering any submissions on the subject that the parties may wish to make.

K.8.2 The Anti-Doping Tribunal shall not make any verbal announcement of the decision but instead shall issue its decision in writing within 14 days after the conclusion of the hearing (or where, exceptionally, that deadline cannot be met, as soon thereafter as possible). Such decision will be sent to the parties and (subject strictly to the confidentiality provisions of Article P.4) to WADA and to any other party that has a right, further to Article O, to appeal the decision. The decision shall set out and explain:

(a) with reasons, the Anti-Doping Tribunal's findings as to whether any anti-doping rule violation(s) has/have been committed;

(b) with reasons, the Anti-Doping Tribunal's findings as to what Consequences, if any, are (or are not) to be imposed;

(c) with reasons, the date that such Consequences shall come into force and effect pursuant to Article M.9; and

(d) the rights of appeal applicable pursuant to Article O.

K.8.3 The ITF shall pay the costs of convening the Anti-Doping Tribunal and of staging the hearing, subject to any costs-shifting order that the Tribunal may make further to Article K.8.4.

K.8.4 The Anti-Doping Tribunal has the power to make a costs order against any party. If it does not exercise that power, each party shall bear its own costs, legal, expert, hearing, and otherwise.

K.8.5 Subject only to the rights of appeal under Article O, the Anti-Doping Tribunal's decision shall be the full, final and complete disposition of the case and will be binding on all parties. If the decision is that an anti-doping rule violation has been committed, (a) the decision shall be publicly reported in full without delay, and in any event no later than 20 days after its issue; and (b) the ITF may also publish such other parts of the proceedings before the Anti-Doping Tribunal as the ITF thinks fit. If the Participant is exonerated of all charges, then the decision shall not be published (save as set out in Article K.8.2 and Article O.6.4) and its confidentiality shall be strictly maintained by all parties.

L. **Disqualification of Results**

L.1 An anti-doping rule violation committed by a Player in connection with or arising out of an In-Competition test automatically leads to Disqualification of the results obtained by the Player in the Competition in question, with all resulting consequences, including forfeiture of any medals, titles, computer ranking points and Prize Money obtained in that Competition. In addition, further results obtained by the Player in the same or subsequent Events may be Disqualified, in accordance with Article M.1 (same Event) and/or Article M.8 (subsequent Events).

L.2 Where results obtained by a Player in a doubles Competition or Competitions are Disqualified because of that Player's anti-doping rule violation, that Player shall be required to forfeit his/her share of the Prize Money that was awarded to the doubles pair in which he/she competed in such Competition(s). In addition:

L.2.1 Where results obtained by a Player in a doubles Competition are Disqualified pursuant to Article L.1 because of that Player's anti-doping rule violation in connection with or arising out of that doubles Competition, the result of the Player's doubles partner in that Competition shall also be Disqualified, with all resulting consequences, including forfeiture of all medals, titles, computer ranking points and Prize Money.

L.2.2 Where results obtained by a Player in a doubles Competition are Disqualified pursuant to Article M.1 because of that Player's anti-doping rule violation in relation to another Competition at that Event, the result of the Player's doubles partner in that doubles Competition shall also be Disqualified, with all resulting consequences, including forfeiture of all medals, titles, computer ranking points and Prize Money, unless the doubles partner establishes at a hearing, on the balance of probabilities, (a) that he/she was not implicated in the first Player's anti-doping rule violation; and (b) that the result in the doubles Competition was not likely to have been affected by the first Player's anti-doping rule violation.

L.2.3 Where results obtained by a Player in doubles Competition(s) in an Event played subsequent to the Competition that produced the positive Sample are Disqualified pursuant to Article M.8 because of that Player's anti-doping rule violation, the result of the Player's doubles partner(s) in such subsequent Competition(s) shall not be Disqualified unless the ITF establishes, to the comfortable satisfaction of the Anti-Doping Tribunal, that the doubles partner(s) was implicated in the first Player's anti-doping rule violation.

L.3 There will be no readjustment of medals, titles, computer, ranking points or Prize Money for any Player who lost to a Player subsequently found to have committed an anti-doping rule violation, except where provision is made for such readjustment in the regulations of the relevant Competition.

M. **Further Sanctions**

M.1 Disqualification of Results in the Event during or in connection with which an Anti-Doping Rule Violation Occurs.

M.1.1 Subject to Article M.1.2, where a Player is found to have committed an anti-doping rule violation during or in connection with a Competition in an Event where the Player also participated in other Competitions (for example, the anti-doping rule violation was committed during or in connection with the doubles Competition and the Player also participated in the singles Competition at that Event), then in addition to the consequences set out at Article L (in relation to the Disqualification of results obtained in the particular Competition during or in connection with which the anti-doping rule violation was committed), the anti-doping rule violation will also lead to Disqualification of all of the Player's individual results obtained in the other Competitions in the Event, with all resulting consequences, including forfeiture of all medals, titles, computer ranking points and Prize Money.

M.1.2 If the Player establishes that he/she bears No Fault or Negligence for the anti-doping rule violation, the Player's results obtained in the Competition(s) other than the Competition during or in connection with which the anti-doping rule violation occurred shall not be Disqualified unless the ITF establishes that the Player's results in the other Competition(s) were likely to have been affected by his/her anti-doping rule violation.

M.2 Imposition of a Period of Ineligibility for Presence, Use or Attempted Use, or Possession of Prohibited Substances and Prohibited Methods:

The period of Ineligibility imposed for an anti-doping rule violation under Article C.1 (presence of Prohibited Substance or any of its Metabolites or Markers), Article C.2 (Use or Attempted Use of Prohibited Substance or Prohibited Method) or Article C.6 (Possession of Prohibited Substances and/or Prohibited Methods) that is the Participant's first offence shall be two years, unless the conditions for eliminating or reducing the period of Ineligibility (as specified in Articles M.4 and M.5) or the conditions for increasing the period of Ineligibility (as specified in Article M.6) are met.

M.3 Imposition of a Period of Ineligibility for Other Anti-Doping Rule Violations:

The period of Ineligibility imposed for anti-doping rule violations under provisions other than Articles C.1, C.2 and C.6 shall be as follows:

M.3.1 For an anti-doping rule violation under Article C.3 (refusing or failing to submit to or otherwise evading Sample collection) or Article C.5 (Tampering or Attempted Tampering with Doping Control) that is the Participant's first offence, the period of Ineligibility imposed shall be two years, unless the conditions specified in Article M.5 or in Article M.6 are met.

M.3.2 For an anti-doping rule violation under Article C.4 (Filing Failures and/or Missed Tests) that is the Player's first offence, the period of Ineligibility imposed shall be at a minimum one (1) year and at a maximum two (2) years, depending on the Player's degree of fault.

M.3.3 For an anti-doping rule violation under Article C.7 (Trafficking or Attempted Trafficking) or Article C.8 (administration or Attempted administration, etc.) that is the Participant's first offence, the period of Ineligibility imposed shall be a minimum of four (4) years up to lifetime Ineligibility, unless the conditions specified in Article M.5 are met. Provided that:

(a) an anti-doping rule violation involving a Minor shall be considered a particularly serious offence and, if committed by Player Support Personnel in relation to anti-doping rule

violations other than those involving Specified Substances, shall result in lifetime Ineligibility for such Player Support Personnel; and

(b) significant anti-doping rule violations under Article C.7 or Article C.8 that may also violate non-sporting laws and regulations shall be reported to the competent administrative, professional or judicial authorities.

M.3.4 For an anti-doping rule violation under Article C.9, the sanction(s) imposed shall be at the discretion of the Anti-Doping Tribunal.

M.4 Elimination or Reduction of the Period of Ineligibility for Specified Substances under Specified Circumstances:

M.4.1 Where the Participant can establish how a Specified Substance entered his/her body or came into his/her possession and that such Specified Substance was not intended to enhance the Player's sport performance or to mask the Use of a performance-enhancing substance, the period of Ineligibility established in Article M.2 shall be replaced (assuming it is the Participant's first offence) with, at a minimum, a reprimand and no period of Ineligibility, and at a maximum, a period of Ineligibility of two (2) years.

M.4.2 To qualify for any elimination or reduction under this Article, the Participant must produce corroborating evidence in addition to his/her word that establishes, to the comfortable satisfaction of the Anti-Doping Tribunal, the absence of an intent to enhance sport performance or to mask the Use of a performance-enhancing substance. The Participant's degree of fault shall be the criterion considered in assessing any reduction of the period of Ineligibility.

M.5 Elimination or Reduction of Period of Ineligibility Based on Exceptional Circumstances:

M.5.1 If a Participant establishes in an individual case that he/she bears No Fault or Negligence in respect of the anti-doping rule violation in question, the otherwise applicable period of Ineligibility shall be eliminated. When the anti-doping rule violation is an Article C.1 offence (presence of a Prohibited Substance or any of its Metabolites or Markers), the Player must also establish how the Prohibited Substance entered his/her system in order to have the period of Ineligibility eliminated. In the event that this Article is applied and the period of Ineligibility otherwise applicable is eliminated, the anti-doping rule violation shall not be considered an anti-doping rule violation for the limited purpose of determining the period of Ineligibility for multiple anti-doping rule violations under Article M.7.

M.5.2 If a Participant establishes in an individual case that he/she bears No Significant Fault or Negligence in respect of the anti-doping rule violation charged, then the period of Ineligibility may be reduced, but the reduced period of Ineligibility may not be less than one-half of the period of Ineligibility otherwise applicable. If the otherwise applicable period of Ineligibility is a lifetime, the reduced period under this section may be no less than eight (8) years. When the anti-doping rule violation is an Article C.1 offence (presence of Prohibited Substance or any of its Markers or Metabolites), the Player must also establish how the Prohibited Substance entered his/her system in order to have the period of Ineligibility reduced.

M.5.3 In any individual case where a period of Ineligibility has been imposed, the ITF may suspend a part of that period of Ineligibility where the Participant has provided Substantial Assistance to the ITF or other Anti-Doping Organisation, a criminal authority or a professional disciplinary body that results in the ITF or other Anti-Doping Organisation discovering or establishing an anti-doping rule violation by another Person or that results in a criminal authority or disciplinary body discovering or establishing a criminal offence or the breach of professional rules by another Person; provided that if the decision to suspend a part of the period of Ineligibility is made after a final appellate decision under Article O or the expiration of time to appeal, then WADA's approval is required for such suspension. The extent to which the otherwise applicable period of Ineligibility may be suspended shall be based on the seriousness of the anti-doping rule violation committed by the Participant and the significance of the Substantial Assistance provided by the Participant to the effort to eliminate doping in sport. No more than three quarters (¾) of the otherwise applicable period of Ineligibility may be suspended. If the otherwise applicable period of Ineligibility is a lifetime, the non-suspended period under this Article must be no less than 8 years. If the ITF suspends any part of the otherwise applicable period of Ineligibility under this Article, it shall promptly provide a written justification for its decision to each Anti-Doping Organisation having a right to appeal the decision under Article O. If the ITF subsequently reinstates any part of the suspended period of Ineligibility because the Participant has failed to provide the Substantial Assistance that was anticipated, the Participant may appeal the reinstatement pursuant to Article O.2.

M.5.4 Reduction of Period of Ineligibility Based on Admission of an Anti-Doping Rule Violation in the Absence of Other Evidence:

Where a Participant voluntarily admits the commission of an anti-doping rule violation before having received either (a) notification of a Sample collection that could establish the anti-doping rule violation (in

the case of an anti-doping rule violation under Article C.1), or (b) a Notice of Charge (in the case of any other anti-doping rule violation), and that admission is the only reliable evidence of the offence at the time of the admission, then the otherwise applicable period of Ineligibility may be reduced, but not by more than 50%.

M.5.5 Where a Participant Establishes Entitlement to Reduction of Suspension in Sanction Under More than One Provision of this Article M.5:

Before applying any reduction or suspension under Articles M.5.2, M.5.3 or M.5.4, the otherwise applicable period of Ineligibility shall be determined in accordance with Articles M.2, M.3, M.4 and M.6. If the Participant establishes entitlement to a reduction or suspension of the period of Ineligibility under two or more of Articles M.5.2, M.5.3 or M.5.4, then the period of Ineligibility may be reduced or suspended, but not below one-quarter (¼) of the period of Ineligibility otherwise applicable.

M.6 Aggravating Circumstances That May Increase the Period of Ineligibility:

M.6.1 If the ITF establishes in an individual case involving an anti-doping rule violation other than under Article C.7 (Trafficking or Attempted Trafficking) or Article C.8 (administration or Attempted administration) that aggravating factors are present that justify the imposition of a period of Ineligibility greater than the standard period, then the period of Ineligibility otherwise applicable shall be increased up to a maximum of four years, unless the Participant can prove to the comfortable satisfaction of the Anti-Doping Tribunal that he/she did not knowingly commit the anti-doping rule violation.

M.6.2 A Participant can avoid the application of Article M.6.1 by admitting his/her anti-doping rule violation promptly after being confronted with it by the ITF.

M.7 Multiple Anti-Doping Rule Violations:

M.7.1 Second Anti-Doping Rule Violation:

For a Participant's first anti-doping rule violation, the period of Ineligibility is set out in Articles M.2 and M.3 (subject to elimination, reduction or suspension under Articles M.4 or M.5 or to an increase

under Article M.6). For a second anti-doping rule violation, the period of Ineligibility shall be within the range set out in the following table:[1]

First offence \ Second offence	**RS**	**FFMT**	**NSF**	**St**	**AS**	**TRA**
RS	1-4	2-4	2-4	4-6	8-10	10-life
FFMT	1-4	4-8	4-8	6-8	10-life	life
NSF	1-4	4-8	4-8	6-8	10-life	life
St	2-4	6-8	6-8	8-life	life	life
AS	4-5	10-life	10-life	life	life	life
TRA	8-life	life	life	life	life	life

The definitions for purposes of the second anti-doping rule violation table are as follows:

RS (Reduced sanction for Specified Substance under Article M.4): The anti-doping rule violation was or should be sanctioned by a reduced sanction under Article M.4 because it involved a Specified Substance and the other conditions under Article M.4 were met.

FFMT (Filing Failures and/or Missed Tests): The anti-doping rule violation was or should be sanctioned under Article M.3.2 (Filing Failures and/or Missed Tests).

NSF (Reduced sanction for No Significant Fault or Negligence): The anti-doping rule violation was or should be sanctioned by a reduced sanction under Article M.5.2 because No Significant Fault or Negligence under Article M.5.2 was established by the Participant.

St (Standard sanction under Article M.2 or M.3.1): The anti-doping rule violation was or should be sanctioned by the standard sanction of two years under Article M.2 or M.3.1.

[1] The table is applied by locating the Participant's first anti-doping rule violation in the left-hand column and then moving across the table to the right to the column representing the second anti-doping rule violation. By way of example, assume a Participant receives the standard period of Ineligibility for a first anti-doping rule violation under Article M.2 and then commits a second anti-doping rule violation for which he/she receives a reduced sanction under Article M.4. The table is used to determine the period of Ineligibility for the second anti-doping rule violation. The table is applied to this example by starting in the left-hand column and going down to the fourth row (which is "St" for standard sanction), then moving across the table to the first column (which is "RS" for reduced sanction for a Specified Substance), thus resulting in a 2-4 year range for the period of Ineligibility for the second anti-doping rule violation. The Participant's degree of fault shall be the criterion used in assessing a period of Ineligibility within the applicable range.

AS (Aggravated sanction): The anti-doping rule violation was or should be sanctioned by an aggravated sanction under Article M.6 because the ITF established the conditions set out under Article M.6.

TRA (Trafficking or Attempted Trafficking and administration or Attempted administration): The anti-doping rule violation was or should be sanctioned by a sanction under Article M.3.3.

M.7.2 Application of Articles M.5.3 and M.5.4 to Second anti-doping rule violation:

Where a Participant who has committed a second anti-doping rule violation establishes an entitlement to suspension or reduction of a portion of the period of Ineligibility under Article M.5.3 or Article M.5.4, the Anti-Doping Tribunal shall first determine the otherwise applicable period of Ineligibility within the range established in the table at Article M.7.1, and then apply the appropriate reduction or suspension, provided that the remaining period of Ineligibility after such reduction or suspension must be at least one-fourth of the otherwise applicable period of Ineligibility.

M.7.3 Third Anti-Doping Rule Violation:

A third anti-doping rule violation will always result in a lifetime period of Ineligibility, unless the third anti-doping rule violation fulfils the conditions for elimination or reduction of the period of Ineligibility under Article M.4 or is a anti-doping rule violation under Article C.4 (Filing Failures and/or Missed Tests), in which case the period of Ineligibility shall be from eight years to life.

M.7.4 Additional Rules for Certain Potential Multiple Offences:

(a) For purposes of imposing sanctions under Article M.7, an anti-doping rule violation will only be considered a second anti-doping rule violation if the ITF can establish that the Participant committed the second anti-doping rule violation after the Participant received notice, or after the ITF made a reasonable attempt to give notice, of the first alleged anti-doping rule violation. If the ITF cannot establish this, the anti-doping rule violations shall be considered together as one single anti-doping rule violation for sanctioning purposes, and the sanction imposed shall be based on the anti-doping rule violation that carries the more severe sanction. However, the occurrence of multiple anti-doping rule violations may be considered as a factor in determining aggravated circumstances under Article M.6.

(b) If, after the resolution of a first anti-doping rule violation, the ITF discovers a second anti-doping rule violation by the same Participant that occurred prior to notification of the first anti-doping rule violation, then an additional sanction shall be imposed based on the sanction that could have been imposed if the two anti-doping rule violations had been adjudicated at the same time. Results in all Competitions dating back to the earlier anti-doping rule violation will be subject to Disqualification in accordance with Article M.8. To avoid the possibility of a finding of aggravating circumstances (Article M.6) on account of the earlier-in-time but later-discovered anti-doping rule violation, the Participant must voluntarily admit the earlier anti-doping rule violation on a timely basis after being charged with notice of the subsequent anti-doping rule violation for which he/she is first charged. The same rule shall also apply when the ITF discovers another prior anti-doping rule violation after the resolution of a second anti-doping rule violation.

M.7.5 Multiple Anti-Doping Rule Violations During an Eight-Year Period:

Any prior anti-doping rule violation shall only be taken into account for purposes of Article M.7 if it took place within eight (8) years of the anti-doping rule violation under consideration.

M.7.6 For the avoidance of doubt, where a Player is found to have committed two or more separate anti-doping rule violations, the Ineligibility periods for the separate offences shall run sequentially, not concurrently.

M.8 Disqualification of Results in Competitions Subsequent to Sample Collection or commission of an Anti-Doping Rule Violation:

In addition to the automatic Disqualification, pursuant to Article L, of the results in the Competition that produced the Adverse Analytical Finding, all other competitive results obtained from the date the Sample in question was collected (whether In-Competition or Out-of-Competition) or other anti-doping rule violation occurred through to the start of any Ineligibility period shall, unless the Anti-Doping Tribunal determines that fairness requires otherwise, be Disqualified with all of the resulting consequences, including forfeiture of any medals, titles, computer ranking points and Prize Money. The lack of any evidence that the Player's performance was enhanced during subsequent Competitions shall not of itself be sufficient to trigger the Anti-Doping Tribunal's discretion under Article M.8.

M.9 Commencement of Consequences:

Any Consequences imposed under this Programme shall come into force and effect on the date that the decision imposing the Consequences is issued, save that:

M.9.1 For purposes of forfeiture of computer ranking points, the decision shall come into effect at midnight on the Sunday nearest to the date that the decision is issued.

M.9.2 The ITF shall have absolute discretion, and in addition the Anti-Doping Tribunal shall have discretion where fairness requires, to establish an instalment plan for repayment of any Prize Money forfeited pursuant to Articles L and/or M of this Programme and/or for payment of any costs awarded further to Article K.8.4. For the avoidance of doubt, the schedule of payments pursuant to such plan may extend beyond any period of Ineligibility imposed upon the Player, provided however that in accordance with Article M.11.4 default in payment under such plan shall automatically trigger a further period of Ineligibility until such default is cured.

M.9.3 The period of Ineligibility shall start on the date that the decision is issued, provided that:

(a) any period of Provisional Suspension served by the Player (whether imposed in accordance with Article K.3 or voluntarily accepted by the Player in accordance with Article K.3.8(a)) shall be credited against the total period of Ineligibility to be served. To get credit for any period of voluntary Provisional Suspension, however, the Player must have given written notice at the beginning of such period to the ITF, in a form acceptable to the ITF (and the ITF shall copy that notice to every other Person entitled to receive notice of a potential anti-doping rule violation by that Player under Article P.4). No credit against a period of Ineligibility shall be given for any time period before the effective date of the Provisional Suspension or voluntary Provisional Suspension, regardless of the Player's status during such period;

(b) where the Participant promptly (which means, in any event, before he/she competes again) admits the anti-doping rule violation after being confronted with it by the ITF, the period of Ineligibility subsequently imposed on him/her may be back-dated so that it is deemed to have commenced as far back as the date of last occurrence of the anti-doping rule violation (which, in the case of an Article C.1 anti-doping rule violation, would be on the date of Sample collection). However, this discretion

to back-date is subject to the following limit: the Participant must actually serve at least one-half of the period of Ineligibility, i.e., the commencement date of that period of Ineligibility cannot be back-dated such that he/she actually serves less than one-half of that period; and

(c) where there have been substantial delays in the hearing process or other aspects of Doping Control not attributable to the Participant, the period of Ineligibility may be deemed to have started at an earlier date, commencing as early as the date of last occurrence of the anti-doping rule violation (e.g., under Article C.1, the date of Sample collection), taking into account any such period of delay.

M.10 Status During Ineligibility:

M.10.1 Prohibition Against Participation During Ineligibility:

No Participant who has been declared Ineligible may, during the period of Ineligibility, play, coach or otherwise participate in any capacity in (a) a Covered Event, any other Event or Competition, or any other kind of function, event or activity (other than authorised anti-doping education or rehabilitation programmes) authorised, organised or sanctioned by the ITF, the ATP, the WTA, or any National Association or member of a National Association; or (b) any Event or Competition authorised or organised by any professional league, or any international or national-level Event or Competition organisation.

M.10.2 Without prejudice to the generality of the foregoing, such Participant shall not be given accreditation for, or otherwise granted access to, any Event, competition, function, event or activity of the type referred to at Article M.10.1(a) and any such accreditation previously issued shall be withdrawn. Furthermore, the ITF will take all necessary steps to have the Ineligibility recognised and enforced by other relevant organisations in accordance with Code Article 15.4 (Mutual Recognition).

M.10.3 Where an Event that will take place after the period of Ineligibility has an entry deadline that falls during the period of Ineligibility, the Player may submit an application for entry in the Event in accordance with that deadline, notwithstanding that at the time of such application he/she is Ineligible.

M.10.4 A Player subject to a period of Ineligibility shall remain subject to Testing. If a Participant commits an anti-doping rule violation during a period of Ineligibility (including but not limited to an anti-doping

rule violation under Article C.1), this shall be treated as a separate anti-doping rule violation under the Programme.

M.10.5 If a Participant who has been declared Ineligible participates in any capacity, during such period of Ineligibility, in a Covered Event or any other Event or Competition, or other function, event or activity (other than authorised anti-doping education or rehabilitation programs) of the type referred to at Article M.10.1(a) or Article M.10.1(b), the period of Ineligibility that was originally imposed shall start over again as of the date of such participation. The new period of Ineligibility may be reduced under Article M.5.2 if the Player establishes that he/she bears No Significant Fault or Negligence for such participation. The determination of whether a Player has violated the prohibition against participation while Ineligible, and whether a reduction under Article M.5.2 is appropriate, shall be made by the ITF, and such decision shall be subject to appeal in accordance with Article O. In any case, any results obtained by the Participant in such Event(s), with all resulting consequences, including forfeiture of any medals, titles, computer ranking points and Prize Money obtained in such Event(s), shall be automatically Disqualified.

M.10.6 In addition, for any anti-doping rule violation not involving an eliminated or reduced period of Ineligibility pursuant to Article M.4, some or all sport-related financial support or other sport-related benefits received by such Participant will be withheld by the ITF or any National Association.

M.11 Conditions of Reinstatement:

M.11.1 As a condition to regaining eligibility at the end of a period of Provisional Suspension or Ineligibility, a Player must make him/herself available for Out-of-Competition Testing by the ITF and any other Anti-Doping Organisation with jurisdiction to test him/her during that period of Provisional Suspension or Ineligibility, and must provide current and accurate whereabouts information to the ITF upon request, in accordance with Article G.2.2, for that purpose.

M.11.2 If a Player who is subject to a period of Ineligibility retires from sport and so is not available for Testing, and later seeks reinstatement, the Player shall not be eligible for reinstatement until he/she has notified the ITF of such request for reinstatement and has been available for Testing for a period of time equal to the period of Ineligibility remaining as at the date he/she retired.

M.11.3 The ITF may also make reinstatement subject to the review and approval of a Player's medical condition by the Review Board in order to establish the Player's fitness to be reinstated.

M.11.4 Once the period of a Player's Ineligibility has expired, and the Player has fulfilled the foregoing conditions of reinstatement, then provided that the Player has paid in full all amounts forfeited under the Programme, and has satisfied in full any award of costs made against the Player by the Anti-Doping Tribunal further to Article K.8.4 and/or by the Court of Arbitration for Sport following any appeal made pursuant to Article O.2, the Player will become automatically re-eligible and no application by the Player for reinstatement will be necessary. If, however, further amounts become due after a Player's period of Ineligibility has expired (as a result of an instalment plan established pursuant to Article M.9.2), then any failure by the Player to pay all outstanding amounts on or before their respective due dates shall render the Player automatically Ineligible to participate in further Covered Events until all amounts due are paid in full.

M.11.5 Even if no period of Ineligibility is imposed, a Player may not participate in a Covered Event while any Prize Money ordered or agreed to be forfeit under the Programme, and/or any award of costs against the Player, remains unpaid, unless an instalment plan has been established pursuant to Article M.9.2 and the Player has made all payments due under that plan. If any instalment(s) become(s) overdue under that plan, the Player may not participate in any Covered Event until such overdue instalments are paid in full.

N. **Consequences for Teams**

The consequences for a team entered in a Competition of the commission of an anti-doping rule violation by a Player in his/her capacity as the member of that team shall be as set out in the rules relating to that Competition, in accordance with Code Article 11.

O. **Appeals**

O.1 Decisions Subject to Appeal:

Decisions made under this Programme may be appealed as set out in this Article O. Such decisions shall remain in effect while under appeal unless CAS orders otherwise.

O.2 Appeals from Decisions Regarding anti-doping rule violations and Consequences.

O.2.1 A decision that an anti-doping rule violation has been committed, a decision imposing (or not imposing) Consequences for an anti-doping rule violation, a decision that no anti-doping rule violation has been committed, a decision that a charge cannot go forward for procedural reasons (including, for example, because too much time has passed), a decision not to record an alleged Filing Failure or Missed Test, a decision under Article M.10.4 in relation to participation while Ineligible, a decision that the ITF lacks jurisdiction to rule on an alleged anti-doping rule violation or its Consequences, a decision by the ITF not to pursue an Adverse Analytical Finding or an Atypical Finding as an anti-doping rule violation, and a decision by the ITF not to bring a charge after an investigation under Article I, may each be appealed by any of the following parties exclusively to CAS:

(a) the Participant who is the subject of the decision being appealed;

(b) the ITF;

(c) the National Anti-Doping Organisation(s) of the Participant's country of residence or of countries where the Participant is a national or licence-holder;

(d) the International Olympic Committee, where the decision may have an effect in relation to the Olympic Games, including decisions affecting eligibility for the Olympic Games;

(e) the International Paralympic Committee, where the decision may have an effect in relation to the Paralympic Games, including decisions affecting eligibility for the Paralympic Games; and/or

(f) WADA.

O.2.2 The only Person who may appeal a decision to impose (or not to vacate) a Provisional Suspension is the Player affected by the Provisional Suspension. In accordance with Article K.3.6(a), the Player may appeal that decision exclusively to CAS.

O.3 Appeals from Decisions Granting or Denying a Therapeutic Use Exemption:

O.3.1 Decisions by WADA further to Article E.6, reversing the grant or denial of a TUE by the TUE Committee, may be appealed exclusively to CAS by the Player or the ITF.

O.3.2 The denial of a TUE by the TUE Committee, if not reversed by WADA, may be appealed to CAS by the Player.

O.3.3 When the ITF fails to take action on a properly submitted TUE application within a reasonable time, the ITF's failure may be considered a denial for purposes of the appeal rights provided in this Article O.3.

O.4 Failure to Render a Timely Decision:

Where, in a particular case, the ITF fails to decide whether an anti-doping rule violation was committed within a reasonable deadline set by WADA, WADA may elect to appeal directly to CAS as if the ITF had rendered a decision finding no anti-doping rule violation. If CAS determines that an anti-doping rule violation was committed and that WADA acted reasonably in electing to appeal directly to CAS, then WADA's reasonable costs and legal fees in prosecuting the appeal shall be reimbursed to WADA by the ITF.

O.5 Time for Filing Appeals:

O.5.1 The deadline for filing an appeal to CAS shall be twenty-one (21) days from the date of receipt of the decision by the appealing party. Where the appellant is a party other than the ITF, to be a valid filing under this Article O.5.1 a copy of the appeal must be filed on the same day with the ITF.

O.5.2 Notwithstanding Article O.5.1, the filing deadline for an appeal filed by WADA shall be the later of:

(a) twenty-one (21) days after the last day on which any other party in the case could have appealed; and

(b) twenty-one (21) days after WADA's receipt of the complete file relating to the decision.

O.6 Appeal Procedure:-

O.6.1 CAS's Code of Sports-related Arbitration as modified or supplemented herein, shall apply to all appeals filed pursuant to this Article O.

O.6.2 Any party filing an appeal shall be entitled to assistance from CAS to obtain all relevant information from the parties to the decision being appealed, and the information shall be provided if CAS so directs.

O.6.3 In all appeals to CAS pursuant to this Article O, the governing law shall be English law and the appeal shall be conducted in English, unless the parties agree otherwise.

O.6.4 The decision of CAS shall be final and binding on all parties, and no right of appeal shall lie from the CAS decision. Subject to Article P.4, the CAS decision shall be published by the ITF within 20 days of receipt.

P. **Confidentiality**

P.1 Details of all Testing carried out under this Programme, (i.e. date of test, name of Player tested, and whether the test was In-Competition or Out-of-Competition) shall be entered onto the WADA Database, and made available via that database to WADA and other Anti-Doping Organisations that have jurisdiction to test Players, so that duplication of anti-doping efforts may be avoided.

P.2 All communications with a laboratory in relation to Testing carried out under this Programme must be conducted in such a way that the laboratory is not advised of the identity of the Players involved, save where required as part of the investigation of a potential case and/or the presentation of evidence to an Anti-Doping Tribunal.

P.3 The ITF shall use its reasonable endeavours to ensure that Persons under its control do not publicly identify Participants whose Samples have resulted in Adverse Analytical Findings or Atypical Findings, or who have a Provisional Suspension imposed on them, or are alleged to have committed an anti-doping rule violation under this Programme, unless and until an Anti-Doping Tribunal has determined that an anti-doping rule violation has been committed, and/or the anti-doping rule violation has been admitted. However, the ITF in its discretion may at any time disclose to other organisations such information as the ITF may consider necessary or appropriate to facilitate administration or enforcement of this Programme (including, without limitation, national associations selecting teams for the Davis Cup or Fed Cup Events), provided that each organisation provides assurance satisfactory to the ITF that the organisation will maintain all such information in confidence. The ITF will not comment publicly on the specific facts of a pending case (as opposed to general description of process and science) except in response to public comments attributed to the Participant or his/her representatives.

P.4 Subject strictly to Article P.3, the ITF shall send a copy of the Notice of Charge to both WADA and the Participant's National Anti-Doping Organisation (and, where agreed by the Player, the ATP or WTA) and shall thereafter keep each of them informed in relation to the status of the case under Article K. WADA and the National Anti-Doping Organisation (and, where applicable, the ATP or WTA) shall keep the contents of the Notice of Charge, and any further information supplied to them pursuant to this Article P.4, strictly confidential unless and until a decision that an anti-doping rule violation has been committed is published pursuant to Article K.8.5; provided

that, if the decision exonerates the Participant, that confidentiality shall be strictly maintained unless and until the decision is overturned on appeal.

P.5 Subject strictly to Article P.3, the ITF may release information about the Programme for public consumption, including, but not limited to, the names of Players who have been tested and the frequency with which they have been tested; the numbers of tests conducted on Players within certain ranking groups or categories; and the identity of Events where Testing has been carried out.

P.6 Whereabouts information provided to the ITF by a Player pursuant to Article G.2.2 shall be entered onto the WADA Database on the basis that it shall be maintained in the strictest confidence at all times, it shall be used by WADA and other Anti-Doping Organisations only for Doping Control purposes, and it shall be destroyed when no longer relevant for such purposes.

P.7 All Players subject to this Programme shall be deemed to have agreed, for purposes of applicable data protection and other laws and for all other purposes, to have consented to the collection, processing, disclosure and use of information relating to them, including personal information relating to them, in accordance with the provisions of the International Standard for the Protection of Privacy, as required to implement this Programme.

Q. **Recognition of Decisions Made by Other Organisations**

Q.1 The provisions of this Programme shall be without prejudice to any jurisdiction that the Code may give to any other Anti-Doping Organisation over a Player.

Q.2 The Testing, TUE decisions and hearing results or other final adjudications of any Signatory to the Code that are consistent with the Code and are within the Signatory's authority shall be recognised and respected by the ITF and the National Associations automatically upon receipt of notice of same, without the need for any further formality. Each of the ITF and the National Associations shall take all steps available to it to enforce and give effect to such decisions.

Q.3 The Testing, TUE decisions and hearing results or other final adjudications of other bodies that have not accepted the Code shall also be recognised and respected by the ITF and the National Associations if the ITF is satisfied that the rules of those bodies are otherwise consistent with the Code.

R. **Statute of Limitations**

No action may be commenced under this Programme against a Player or other Person for an anti-doping rule violation unless such action is commenced within eight years from the date that the anti-doping rule violation occurred.

S. **National Associations**

S.1 Incorporation of the Programme:

S.1.1 It shall be a condition of membership of the ITF that all National Associations shall comply with this Programme. This Programme shall also be incorporated either directly or by express reference into each National Association's rules and regulations. The rules of each National Association shall specifically provide that all players, player support personnel and other Persons under the jurisdiction of the National Association shall be bound by the Programme as so incorporated. All National Federations shall include in their rules and regulations the rules necessary to implement this Programme effectively against such Persons within their jurisdiction, and shall enforce the Programme diligently with respect to such Persons.

S.1.2 All players under the jurisdiction of a National Association and participating in a national-level event may be subjected to Testing by the ITF, the National Association and/or any other Anti-Doping Organisation responsible for Testing at that event. Where a National Association decides that an Adverse Analytical Finding or other evidence of a possible anti-doping rule violation does not give rise to a case to answer, it shall report that decision to the ITF and to WADA within 14 days, and thereafter shall answer any queries that the ITF or WADA may have on the matter fully and without delay. Where the National Association determines that there is a case to answer, it shall send to the ITF and WADA a copy of the notice of charge that it sends to the participant involved, and thereafter will keep the ITF and WADA informed of the status of the matter, including permitting them to attend hearings as observers upon request. The ITF and WADA shall have the rights of appeal specified in the Code in relation to decisions taken in such proceedings.

S.1.3 The ITF shall have the right to withhold some or all funding otherwise due to a National Association that has failed to comply with Article S.1.1 and/or S.1.2.

S.2 Statistical Reporting:

S.2.1 National Associations shall report to the ITF at the end of every calendar year results of all Doping Controls within their respective jurisdictions, sorted by Player and identifying each date on which the Player was tested, the entity conducting the test, and whether the test was In-Competition or Out-of-Competition. The ITF may periodically publish such data received from National Associations.

S.2.2 The National Association shall regularly update the ITF and WADA on the status and findings of any review or proceedings conducted by the National Association in relation to alleged anti-doping rule violations.

S.3 Recognition of Decisions Made Pursuant to the Programme:

Any decision made under this Programme shall be recognised by all National Associations, which shall take all necessary action to render such decision effective.

APPENDICES

APPENDIX ONE

DEFINITIONS

Adverse Analytical Finding. A report from a laboratory or other WADA-approved entity that, consistent with the International Standard for Laboratories and related Technical Documents, identifies in a Sample the presence of a Prohibited Substance or any of its Metabolites or Markers (including elevated quantities of endogenous substances) or evidence of the Use of a Prohibited Method.

Anti-Doping Organisation. A Signatory that is responsible for adopting rules for initiating, implementing or enforcing any part of the Doping Control process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other Major Event Organisations that conduct Testing at their Events, WADA, International Federations and National Anti-Doping Organisations.

Anti-Doping Programme Administrator, or "APA". A person appointed by the ITF to perform various functions on its behalf under the Programme. References to the APA shall be deemed to encompass any designee of the APA.

Anti-Doping Tribunal. A panel of three persons (subject to Article K.4.2(a)) appointed by the ITF consisting of a Chair (who shall be legally qualified), and other lawyers and/or a medical expert and/or a technical expert with experience in anti-doping, to perform the functions assigned to the Anti-Doping Tribunal under the Programme. Each member of the Anti-Doping Tribunal shall be independent of the ITF, which may provide reasonable compensation and reimbursement of expenses to such members.

APA. See Anti-Doping Programme Administrator.

Attempt. Purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an anti-doping rule violation. Provided, however, that there shall be no anti-doping rule violation based solely on an Attempt to commit an anti-doping rule violation if the Person renounces the Attempt prior to it being discovered by a third party not involved in the Attempt.

Atypical Finding. A report from a laboratory or other WADA-approved entity that requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an Adverse Analytical Finding.

CAS. The Court of Arbitration for Sport in Lausanne, Switzerland.

Code. As defined in Article A.2.

Competition. Any stand-alone part of an Event, such as a singles competition or a doubles or mixed doubles competition.

Consequences. An anti-doping rule violation may result in one or more of the following: (a) Disqualification means the Player's results in a particular Competition or Event are invalidated, with all resulting consequences, including forfeiture of any medals, computer ranking points and Prize Money; (b) Ineligibility means the Participant is barred for a specified period of time from participation in the sport, as provided in Article M.10; and (c) Provisional Suspension means the Participant is temporarily barred from participation in the sport pending a decision on the charge(s) against him/her, as provided in Article K.3.6.

Covered Event(s). As defined in Article B.2.

Disqualification. See Consequences.

Doping Control. All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, Sample collection and handling, laboratory analysis, TUEs, results management and hearings.

Effective Date. As defined in Article A.5.

Event. A series of individual Competitions conducted together under one organising ruling body (e.g., the Olympic Games, FINA World Championships, or Grand Slam).

Filing Failure. As defined in Article C.4.

In-Competition. The period described in Article F.2.

Independent Observer Programme. A team of observers, under the supervision of WADA, who observe the Doping Control process at certain Events and report on observations.

Ineligibility. See Consequences.

International Event. An Event where the International Olympic Committee, the International Paralympic Committee, an International Federation, a Major Event Organisation or another international sport organisation is the ruling body for the Event or appoints the technical officials for the Event.

International Registered Testing Pool. As defined in Article G.2.1.

International Standard. A standard adopted by WADA in support of the Code, as revised from time to time. Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude

that the procedures addressed by the International Standard were performed properly. The International Standards in force as of the Effective Date are set out in the appendices to the Programme. However, WADA's Executive Committee may approve revisions to an International Standard at any time, and such revisions shall become effective in relation to the Programme on the date specified by WADA, without the need for any further action by the ITF. In the case of any difference between the International Standards as set out in the appendices to the Programme and the International Standards in effect and published on WADA's website, the latter shall prevail.

International Standard for Laboratories. The International Standard of the same name adopted by WADA in support of the Code, the current version of which (as of the Effective Date) is set out at Appendix Five to the Programme.

International Standard for the Protection of Privacy and Personal Information. The International Standard of the same name adopted by WADA in support of the Code, the current version of which (as of the Effective Date) is set out at Appendix Six to the Programme.

International Standard for Testing. The International Standard of the same name adopted by WADA in support of the Code, the current version of which (as of the Effective Date) is set out at Appendix Four to the Programme.

International Standard for Therapeutic Use Exemptions. The International Standard of the same name adopted by WADA in support of the Code, the current version of which (as of the Effective Date) is set out in Appendix Three to the Programme.

ITF. ITF Limited (t/a the International Tennis Federation) or its designee, which (in the context of the Programme) may be the APA.

ITF Anti-Doping Manager. An appointee of the ITF with supervisory responsibilities in relation to the Programme.

Major Event Organisations. The continental associations of National Olympic Committees and other international multi-sport organisations that function as the ruling body for any continental, regional or other International Event.

Marker. A compound, group of compounds or biological parameter(s) that indicates the presence and/or Use of a Prohibited Substance or Prohibited Method.

Metabolite. Any substance produced by a biotransformation process.

Minor. A natural Person who has not reached the age of majority as established by the applicable laws of his/her country of residence.

Missed Test. As defined in Article C.4.

NADO. See National Anti-Doping Organisation.

National Anti-Doping Organisation. The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of Samples, the management of test results, and the conduct of hearings, all at the national level. If this designation has not been made by the competent public authority(ies), the entity shall be the country's National Olympic Committee or its designee.

National Association. A national or regional entity which is a member of the ITF or is recognised by the ITF as the entity governing the sport of tennis in that nation or region.

National Olympic Committee. The organisation recognised by the International Olympic Committee. The term National Olympic Committee shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical National Olympic Committee responsibilities in the anti-doping area.

No Advance Notice. A Doping Control that takes place with no advance warning to the Player and where the Player is continuously chaperoned from the moment of notification through Sample provision.

No Fault or Negligence. The Participant establishing that he/she did not know or suspect, and could not reasonably have known or suspected even with the exercise of utmost caution, that he/she had Used or been administered the Prohibited Substance or Prohibited Method.

No Significant Fault or Negligence. The Participant establishing that his/her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the anti-doping rule violation in issue.

Notice of Charge. The document described in Article K.1.1.

Out-of-Competition. The period(s) described in Article G.1.2.

Participant. Any Player or Player Support Personnel.

Person. A natural Person or an organisation or other entity.

Player. As defined in Article B.1.

Player's Nominated Address. As defined in Article B.4.

Player Support Personnel. As defined in Article B.6.

Possession. Actual, physical possession, or constructive possession, provided, however, that if the Person does not have exclusive control over the Prohibited Substance/Method or the premises in which a Prohibited Substance/Method exists, constructive possession shall only be found if the Person knew about the presence of the Prohibited Substance/Method and intended to exercise control over it. Provided, however, that there shall be no anti-doping rule violation based solely on Possession if, prior to receiving notification of any kind that the Person has committed an anti-doping rule violation, the Person has taken concrete action demonstrating that the Person never intended to have Possession and has renounced Possession by explicitly declaring it to an Anti-Doping Organisation. Notwithstanding anything to the contrary in this definition, the purchase (including by any electronic or other means) of a Prohibited Substance or Prohibited Method constitutes Possession by the Person who makes the purchase.

Prize Money. All of the consideration provided by the organiser of a Competition as a reward for performance in the Competition, whether monetary (i.e. cash) or non-monetary (e.g. a trophy, vehicle or other prize). Where the reward is attributable to performance as part of a team, the rules of the Competition may provide for how much of the reward is to be allocated to a Player for purposes of forfeiture under the Programme. Such rules shall be without prejudice to the provisions of Article L with respect to doubles Prize Money. Any Prize Money forfeited shall be repaid without deduction for tax paid by or on behalf of the Player, unless the Player shows by means of independent and verifiable evidence that such tax has been paid and is not recoverable by the Player. All Prize Money forfeited under the Programme shall be retained by the ITF to defray the costs of its anti-doping efforts.

Programme. As defined in Article A.1.

Prohibited List. As defined in Article A.3.1.

Prohibited Method. Any method so described on the Prohibited List.

Prohibited Substance. Any substance so described on the Prohibited List.

Provisional Suspension. See Consequences.

Review Board. A standing panel appointed by the ITF, consisting of persons with medical, technical and/or legal experience in anti-doping, to perform the functions assigned to the Review Board in the Programme. Each member of the Review Board panel shall be independent of the ITF, which may provide reasonable compensation and reimbursement of expenses to such members.

Sample. Any biological material collected for the purposes of Doping Control. The terms “A Sample” and “B Sample” shall have the meanings ascribed to them in the International Standard for Testing.

Signatories. Those entities signing the Code and agreeing to comply with the Code, including the International Olympic Committee, International Federations, International Paralympic Committee, National Olympic Committees, National Paralympic Committees, Major Event Organisations, National Anti-Doping Organisations and WADA.

Specified Substances. As defined in Article D.4.

Substantial Assistance. For purposes of Article M.5.3, a Person providing Substantial Assistance must: (1) fully disclose in a signed written statement all information he/she possesses in relation to anti-doping rule violations; and (2) fully cooperate with the investigation and adjudication of any case related to that information, including (for example) by testifying at a hearing if requested to do so by the ITF or the Anti-Doping Tribunal. Further, the information provided must be credible and must comprise an important part of any case which is initiated or, if no case is initiated, must have provided a sufficient basis on which a case could have been brought.

Tampering. Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures from occurring; or providing fraudulent information to an Anti-Doping Organisation.

Target Testing. Selection of Players for Testing where specific Players or groups of Players are selected on a non-random basis for Testing at a specified time.

Tennis Testing Protocols. The supplementary Testing protocols set out at Appendix Seven.

Testing. The parts of the Doping Control process involving test distribution planning, Sample collection, Sample handling, and Sample transport to the laboratory.

Trafficking. Selling, giving, administering, transporting, sending, delivering or distributing a Prohibited Substance or Prohibited Method (either physically or by any electronic or other means) by a Player or Player Support Personnel to any third party; provided, however, that this definition shall not include (a) the actions of bona fide medical personnel involving a Prohibited Substance used for genuine and legal therapeutic purposes or other acceptable justification; or (b) actions involving Prohibited Substances which are not prohibited in Out-of-Competition Testing unless the circumstances as a whole demonstrate that such Prohibited Substances were not intended for genuine and legal therapeutic purposes.

TUE. As defined in Article E.1.

TUE Committee. A panel appointed by the ITF and composed of at least three physicians with experience in the care and treatment of Players and a sound knowledge of clinical and exercise medicine. In all cases involved a Player with a disability, one of the physicians must have experience with the care and treatment of Players with disabilities.

Use. The utilisation, application, ingestion, injection or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method.

WADA. The World Anti-Doping Agency.

WADA Database. An on-line database, with a state-of-the-art security system, maintained by WADA for purposes of collating anti-doping information.

APPENDIX TWO

THE 2010 PROHIBITED LIST
(Valid from 1 January 2010)

All *Prohibited Substances* shall be considered as "Specified Substances" except Substances in classes S1, S2.1 to S2.5, S.4.4 and S6.a, and *Prohibited Methods* M1, M2 and M3.

SUBSTANCES AND METHODS PROHIBITED AT ALL TIMES (IN- AND OUT-OF-COMPETITION)

PROHIBITED SUBSTANCES

S1. ANABOLIC AGENTS

Anabolic agents are prohibited.

1. Anabolic Androgenic Steroids (AAS)

a. Exogenous* AAS, including:

1-androstendiol (5α-androst-1-ene-3β,17β-diol)**; 1-androstendione** (5α-androst-1-ene-3,17-dione)**; bolandiol** (19-norandrostenediol)**; bolasterone; boldenone; boldione** (androsta-1,4-diene-3,17-dione)**; calusterone; clostebol; danazol** (17α-ethynyl-17β-hydroxyandrost-4-eno[2,3-d]isoxazole)**; dehydrochlormethyltestosterone** (4-chloro-17β-hydroxy-17α-methylandrosta-1,4-dien-3-one)**; desoxymethyltestosterone** (17α-methyl-5α-androst-2-en-17β-ol)**; drostanolone; ethylestrenol** (19-nor-17α-pregn-4-en-17-ol)**; fluoxymesterone; formebolone; furazabol** (17β-hydroxy-17α-methyl-5α-androstano[2,3-c]-furazan)**; gestrinone; 4-hydroxytestosterone** (4,17β-dihydroxyandrost-4-en-3-one)**; mestanolone; mesterolone; metenolone; methandienone** (17β-hydroxy-17α-methylandrosta-1,4-dien-3-one)**; methandriol; methasterone** (2α, 17α-dimethyl-5α-androstane-3-one-17β-ol)**; methyldienolone** (17β-hydroxy-17α-methylestra-4,9-dien-3-one)**; methyl-1-testosterone** (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one)**; methylnortestosterone** (17β-hydroxy-17α-methylestr-4-en-3-one)**; methyltestosterone; metribolone** (methyltrienolone, 17β-hydroxy-17α-methylestra-4,9,11-trien-3-one)**; mibolerone; nandrolone; 19-norandrostenedione** (estr-4-ene-3,17-dione)**; norboletone; norclostebol; norethandrolone; oxabolone; oxandrolone; oxymesterone; oxymetholone; prostanozol** (17β-hydroxy-5α-androstano[3,2-c] pyrazole); **quinbolone; stanozolol; stenbolone; 1-testosterone** (17β-hydroxy-5α-androst-1-en-3-one)**; tetrahydrogestrinone** (18a-homo-pregna-4,9,11-trien-17β-ol-3-one)**; trenbolone** and other substances with a similar chemical structure or similar biological effect(s).

b. Endogenous[**] AAS when administered exogenously:

androstenediol (androst-5-ene-3β,17β-diol)**; androstenedione** (androst-4-ene-3,17-dione)**; dihydrotestosterone** (17β-hydroxy-5α-androstan-3-one) **; prasterone** (dehydroepiandrosterone, DHEA)**; testosterone**
and the following metabolites and isomers:

5α-androstane-3α,17α-diol; 5α-androstane-3α,17β-diol; 5α-androstane-3β,17α-diol; 5α-androstane-3β,17β-diol; androst-4-ene-3α,17α-diol; androst-4-ene-3α,17β-diol; androst-4-ene-3β,17α-diol; androst-5-ene-3α,17α-diol; androst-5-ene-3α,17β-diol; androst-5-ene-3β,17α-diol; 4-androstenediol (androst-4-ene-3β,17β-diol)**; 5-androstenedione** (androst-5-ene-3,17-dione)**; epi-dihydrotestosterone; epitestosterone; 3α-hydroxy-5α-androstan-17-one; 3β-hydroxy-5α-androstan-17-one; 19-norandrosterone; 19-noretiocholanolone.**

2. Other Anabolic Agents, including but not limited to:

Clenbuterol, selective androgen receptor modulators (SARMs), tibolone, zeranol, zilpaterol.

For purposes of this section:
[*] "exogenous" refers to a substance which is not ordinarily capable of being produced by the body naturally.
[**] "endogenous" refers to a substance which is capable of being produced by the body naturally.

S2. PEPTIDE HORMONES, GROWTH FACTORS AND RELATED SUBSTANCES

The following substances and their releasing factors are prohibited:

1. **Erythropoiesis-Stimulating Agents [**e.g. **erythropoietin (EPO), darbepoetin (dEPO), methoxy polyethylene glycol-epoetin beta (CERA), hematide];**
2. **Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH)** in males;
3. **Insulins;**
4. **Corticotrophins;**
5. **Growth Hormone (GH), Insulin-like Growth Factor-1 (IGF-1), Mechano Growth Factors (MGFs), Platelet-Derived Growth Factor (PDGF), Fibroblast Growth Factors (FGFs), Vascular-Endothelial Growth Factor (VEGF) and Hepatocyte Growth Factor (HGF)** as well as any other growth factor affecting muscle, tendon or ligament protein synthesis/degradation, vascularisation, energy utilization, regenerative capacity or fibre type switching;
6. **Platelet-derived preparations (e.g. Platelet Rich Plasma, "blood spinning")** administered by intramuscular route. Other routes of

administration require a declaration of *Use* in accordance with the International Standard for Therapeutic Use Exemptions.

and other substances with similar chemical structure or similar biological effect(s).

S3. BETA-2 AGONISTS

All beta-2 agonists (including both optical isomers where relevant) are prohibited except salbutamol (maximum 1600 micrograms over 24 hours) and salmeterol by inhalation which require a declaration of *Use* in accordance with the International Standard for Therapeutic Use Exemptions.

The presence of salbutamol in urine in excess of 1000 ng/mL is presumed not to be an intended therapeutic use of the substance and will be considered as an *Adverse Analytical Finding* unless the *Athlete* proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of a therapeutic dose (maximum 1600 micrograms over 24 hours) of inhaled salbutamol.

S4. HORMONE ANTAGONISTS AND MODULATORS

The following classes are prohibited:

1. **Aromatase inhibitors** including, but not limited to: **aminoglutethimide, anastrozole, androsta-1,4,6-triene-3,17-dione (androstatrienedione), 4-androstene-3,6,17 trione (6-oxo), exemestane, formestane, letrozole, testolactone.**

2. **Selective estrogen receptor modulators (SERMs)** including, but not limited to**: raloxifene, tamoxifen, toremifene.**

3. **Other anti-estrogenic substances** including, but not limited to: **clomiphene, cyclofenil, fulvestrant.**

4. **Agents modifying myostatin function(s)** including but not limited to: **myostatin inhibitors.**

S5. DIURETICS AND OTHER MASKING AGENTS

Masking agents are prohibited. They include:
Diuretics, probenecid, plasma expanders (e.g. **glycerol**; intravenous administration of **albumin, dextran, hydroxyethyl starch** and **mannitol)** and other substances with similar biological effect(s).

Diuretics include:
Acetazolamide, amiloride, bumetanide, canrenone, chlorthalidone, etacrynic acid, furosemide, indapamide, metolazone, spironolactone, thiazides (e.g.

bendroflumethiazide, chlorothiazide, hydrochlorothiazide), triamterene, and other substances with a similar chemical structure or similar biological effect(s) (except drosperinone, pamabrom and topical dorzolamide and brinzolamide, which are not prohibited).

A Therapeutic Use Exemption for diuretics and masking agents is not valid if an *Athlete*'s urine contains such substance(s) in association with threshold or sub-threshold levels of an exogenous *Prohibited Substance*(s).

PROHIBITED METHODS

M1. ENHANCEMENT OF OXYGEN TRANSFER

The following are prohibited:

1. Blood doping, including the use of autologous, homologous or heterologous blood or red blood cell products of any origin.

2. Artificially enhancing the uptake, transport or delivery of oxygen, including but not limited to perfluorochemicals, efaproxiral (RSR13) and modified haemoglobin products (e.g. haemoglobin-based blood substitutes, microencapsulated haemoglobin products), excluding supplemental oxygen.

M2. CHEMICAL AND PHYSICAL MANIPULATION

1. *Tampering,* or attempting to tamper, in order to alter the integrity and validity of *Samples* collected during *Doping Controls* is prohibited. These include but are not limited to catheterisation, urine substitution and/or adulteration (e.g. proteases).

2. Intravenous infusions are prohibited except for those legitimately received in the course of hospital admissions or clinical investigations.

M3. GENE DOPING

The following, with the potential to enhance athletic performance, are prohibited:

1- The transfer of cells or genetic elements (e.g. DNA, RNA);

2- The use of pharmacological or biological agents that alter gene expression.

Peroxisome Proliferator Activated Receptor δ (PPARδ) agonists (e.g. GW 1516) and PPARδ-AMP-activated protein kinase (AMPK) axis agonists (e.g. AICAR) are prohibited.

SUBSTANCES AND METHODS
PROHIBITED IN-COMPETITION

In addition to the categories S1 to S5 and M1 to M3 defined above, the following categories are prohibited in competition:

PROHIBITED SUBSTANCES

S6. STIMULANTS

All stimulants (including both optical isomers where relevant) are prohibited, except imidazole derivatives for topical use and those stimulants included in the 2010 Monitoring Program[*].

Stimulants include:

a: Non-Specified Stimulants:

Adrafinil; amfepramone; amiphenazole; amphetamine; amphetaminil; benfluorex; benzphetamine; benzylpiperazine; bromantan; clobenzorex; cocaine; cropropamide; crotetamide; dimethylamphetamine; etilamphetamine; famprofazone; fencamine; fenetylline; fenfluramine; fenproporex; furfenorex; mefenorex; mephentermine; mesocarb; methamphetamine(*d*-); p-methylamphetamine; methylenedioxyamphetamine; methylenedioxymethamphetamine; methylhexaneamine (dimethylpentylamine); modafinil; norfenfluramine; phendimetrazine; phenmetrazine; phentermine; 4-phenylpiracetam (carphedon); prenylamine; prolintane.
A stimulant not expressly listed in this section is a Specified Substance.

b: Specified Stimulants (examples):

Adrenaline[**]**; cathine**[***]**; ephedrine**[****]**; etamivan; etilefrine; fenbutrazate; fencamfamin; heptaminol; isometheptene; levmetamphetamine; meclofenoxate; methylephedrine**[****]**; methylphenidate; nikethamide; norfenefrine; octopamine; oxilofrine; parahydroxyamphetamine; pemoline; pentetrazol; phenpromethamine; propylhexedrine; pseudoephedrine**[*****]**; selegiline; sibutramine; strychnine; tuaminoheptane** and other substances with a similar chemical structure or similar biological effect(s).

[*] The following substances included in the 2010 Monitoring Program (bupropion, caffeine, phenylephrine, phenylpropanolamine, pipradol, synephrine) are not considered as *Prohibited Substances*.

[**] **Adrenaline** associated with local anaesthetic agents or by local administration (e.g. nasal, ophthalmologic) is not prohibited.

[***] **Cathine** is prohibited when its concentration in urine is greater than 5 micrograms per milliliter.

**** Each of **ephedrine** and **methylephedrine** is prohibited when its concentration in urine is greater than 10 micrograms per milliliter.
***** **Pseudoephedrine** is prohibited when its concentration in urine is greater than 150 micrograms per milliliter.

S7. NARCOTICS

The following narcotics are prohibited:

Buprenorphine, dextromoramide, diamorphine (heroin), fentanyl and its derivatives, hydromorphone, methadone, morphine, oxycodone, oxymorphone, pentazocine, pethidine.

S8. CANNABINOIDS

Natural or synthetic Δ9-tetrahydrocannabinol (THC) and THC-like cannabinoids (e.g. hashish, marijuana, HU-210) are prohibited.

S9. GLUCOCORTICOSTEROIDS

All glucocorticosteroids are prohibited when administered by oral, intravenous, intramuscular or rectal routes.

In accordance with the International Standard for Therapeutic Use Exemptions, a declaration of *Use* must be completed by the *Athlete* for glucocorticosteroids administered by intraarticular, periarticular, peritendinous, epidural, intradermal and inhalation routes, except as noted below.

Topical preparations when used for auricular, buccal, dermatological (including iontophoresis/phonophoresis), gingival, nasal, ophthalmic and perianal disorders are not prohibited and require neither a Therapeutic Use Exemption nor a declaration of *Use*.

APPENDIX THREE

INTERNATIONAL STANDARDS FOR THERAPEUTIC USE EXEMPTIONS
(Valid from 1 January 2010)

PREAMBLE

The World Anti-Doping *Code International Standard* for Therapeutic Use Exemptions (TUE) is a Level 2 mandatory *International Standard* developed as part of the World Anti-Doping Program.

The official text of the *International Standard* for TUE shall be maintained by WADA and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

The *International Standard* for TUE (version 4.0) will come into effect on 1 January 2010.

PART ONE: INTRODUCTION, *CODE* PROVISIONS AND DEFINITIONS

1 INTRODUCTION AND SCOPE

The purpose of the *International Standard* for Therapeutic Use Exemptions is to ensure that the process of granting therapeutic use exemptions is harmonized across sports and countries.

The *Code* permits *Athletes* to apply for therapeutic use exemptions (TUE) i.e. permission to use, for therapeutic purposes, substances or methods contained in the List of *Prohibited Substances* or *Methods* where *Use* would otherwise be prohibited.

The *International Standard* for TUE includes criteria for granting a TUE, confidentiality of information, the formation of Therapeutic Use Exemptions Committees and the TUE application process.

This Standard applies to all *Athletes* as defined by and subject to the *Code* i.e. able-bodied *Athletes* and *Athletes* with disabilities.

[Comment: This Standard will be applied according to an individual's circumstances. For example, an exemption that is appropriate for an Athlete with a disability may be inappropriate for other Athletes.]

The World Anti-Doping Program encompasses all of the elements needed in order to ensure optimal harmonization and best practice in international and national anti-

doping programs. The main elements are: the *Code* (Level 1), *International Standards* (Level 2), and Models of Best Practice (Level 3).

In the introduction to the *Code,* the purpose and implementation of the *International Standards* are summarized as follows:

> "*International Standards* for different technical and operational areas within the anti-doping program will be developed in consultation with the *Signatories* and governments and approved by *WADA*. The purpose of the *International Standards* is harmonization among *Anti-Doping Organizations* responsible for specific technical and operational parts of the anti-doping programs. Adherence to the *International Standards* is mandatory for compliance with the *Code*. The *International Standards* may be revised from time to time by the *WADA* Executive Committee after reasonable consultation with the *Signatories* and governments. Unless provided otherwise in the *Code, International Standards* and all revisions shall become effective on the date specified in the *International Standard* or revision."

Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the *International Standard* were performed properly.

Definitions specified in the *Code* are written in italics. Additional definitions specific to the *International Standard* for TUE are underlined.

2 CODE PROVISIONS

The following articles in the 2009 *Code* are directly relevant to the *International Standard* for TUE:

Code Article 4.4 Therapeutic Use

WADA has adopted an *International Standard* for the process of granting therapeutic use exemptions.

Each International Federation shall ensure, for *International*-Level *Athletes* or any other *Athlete* who is entered in an *International Event*, that a process is in place whereby *Athletes* with documented medical conditions requiring the *Use* of a *Prohibited Substance* or a *Prohibited Method* may request a therapeutic use exemption. *Athletes* who have been identified as included in their International Federation's *Registered Testing Pool* may only obtain therapeutic use exemptions in accordance with the rules of their International Federation. Each International Federation shall publish a list of those *International Events* for which a therapeutic use exemption from the International Federation is required. Each *National Anti-Doping Organization* shall ensure, for all *Athletes* within its jurisdiction that have not been included in an International Federation *Registered Testing Pool,* that a process is in place whereby *Athletes* with documented medical conditions requiring the *Use* of a *Prohibited Substance* or a *Prohibited Method* may request a therapeutic

use exemption. Such requests shall be evaluated in accordance with the *International Standard* for Therapeutic Use Exemptions. International Federations and *National Anti-Doping Organizations* shall promptly report to *WADA* through *ADAMS* the granting of any therapeutic use exemption except as regards national-level *Athletes* who are not included in the *National Anti-Doping Organization's Registered Testing Pool*.

WADA, on its own initiative, may review at any time the granting of a therapeutic use exemption to any *International-Level Athlete* or national-level *Athlete* who is included in his or her *National Anti-Doping Organization's Registered Testing Pool*. Further, upon the request of any such *Athlete* who has been denied a therapeutic use exemption, *WADA* may review such denial. If *WADA* determines that such granting or denial of a therapeutic use exemption did not comply with the *International Standard* for Therapeutic Use Exemptions, *WADA* may reverse the decision.

If, contrary to the requirement of this Article, an International Federation does not have a process in place where *Athletes* may request therapeutic use exemptions, an *International-Level Athlete* may request *WADA* to review the application as if it had been denied.

Presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (Article 2.1), *Use* or *Attempted Use* of a *Prohibited Substance* or a *Prohibited Method* (Article 2.2), *Possession of Prohibited Substances* and *Prohibited Methods* (Article 2.6) or Administration or *Attempted* Administration of a *Prohibited Substance* or *Prohibited Method* (Article 2.8) consistent with the provisions of an applicable therapeutic use exemption issued pursuant to the *International Standard* for Therapeutic Use Exemptions shall not be considered an anti-doping rule violation.

***Code* Article 13.4 Appeals from Decisions Granting or Denying a Therapeutic Use Exemption**

Decisions by *WADA* reversing the grant or denial of a therapeutic use exemption may be appealed exclusively to *CAS* by the *Athlete* or the *Anti-Doping Organization* whose decision was reversed. Decisions by *Anti-Doping Organizations* other than *WADA* denying therapeutic use exemptions, which are not reversed by *WADA*, may be appealed by *International-Level Athlete*s to *CAS* and by other *Athlete*s to the national-level reviewing body described in Article 13.2.2. If the national-level reviewing body reverses the decision to deny a therapeutic use exemption, that decision may be appealed to *CAS* by *WADA*.

When an *Anti-Doping Organization* fails to take action on a properly submitted therapeutic use exemption application within a reasonable time, the *Anti-Doping Organization's* failure to decide may be considered a denial for purposes of the appeal rights provided in this Article.

***Code* Article 14.5 *Doping Control* Information Clearinghouse**

WADA shall act as a central clearinghouse for *Doping Control Testing* data and results for *International-Level Athlete*s and national-level *Athlete*s who have been

included in their *National Anti-Doping Organization's Registered Testing Pool*. To facilitate coordinated test distribution planning and to avoid unnecessary duplication in *Testing* by the various *Anti-Doping Organizations*, each *Anti-Doping Organization* shall report all *In-Competition* and *Out-of-Competition* tests on such *Athlete*s to the *WADA* clearinghouse as soon as possible after such tests have been conducted. This information will be made accessible to the *Athlete*, the *Athlete*'s National Federation, *National Olympic Committee* or National Paralympic Committee, *National Anti-Doping Organization*, International Federation, and the International Olympic Committee or International Paralympic Committee.

To enable it to serve as a clearinghouse for *Doping Control Testing* data, *WADA* has developed a database management tool, *ADAMS*, that reflects emerging data privacy principles. In particular, *WADA* has developed *ADAMS* to be consistent with data privacy statutes and norms applicable to *WADA* and other organizations using *ADAMS*.

Private information regarding an *Athlete*, *Athlete Support Personnel*, or others involved in anti-doping activities shall be maintained by *WADA*, which is supervised by Canadian privacy authorities, in strict confidence and in accordance with the *International Standard* for the protection of privacy. *WADA* shall, at least annually, publish statistical reports summarizing the information that it receives, ensuring at all times that the privacy of *Athlete*s is fully respected and make itself available for discussions with national and regional data privacy authorities.

***Code* Article 15.4 Mutual Recognition**

15.4.1 Subject to the right to appeal provided in Article 13, *Testing*, therapeutic use exemptions and hearing results or other final adjudications of any *Signatory* which are consistent with the *Code* and are within that *Signatory*'s authority, shall be recognized and respected by all other *Signatories*.

[Comment to Article 15.4.1: There has in the past been some confusion in the interpretation of this Article with regard to therapeutic use exemptions. Unless provided otherwise by the rules of an International Federation or an agreement with an International Federation, National Anti-Doping Organizations do not have "authority" to grant therapeutic use exemptions to International-Level Athletes.]

15.4.2 *Signatories* shall recognize the same actions of other bodies which have not accepted the *Code* if the rules of those bodies are otherwise consistent with the *Code*.

[Comment to Article 15.4.2: Where the decision of a body that has not accepted the Code is in some respects Code compliant and in other respects not Code compliant, Signatories should attempt to apply the decision in harmony with the principles of the Code. For example, if in a process consistent with the Code a non-Signatory has found an Athlete to have committed an anti-doping rule violation on account of the presence of a Prohibited Substance in his body but the period of Ineligibility applied is shorter than the period provided for in the Code, then all Signatories should

recognize the finding of an anti-doping rule violation and the Athlete's National Anti-Doping Organization should conduct a hearing consistent with Article 8 to determine whether the longer period of Ineligibility provided in the Code should be imposed.]

3 TERMS AND DEFINITIONS

3.1 Defined Terms from the Code

***ADAMS*:** The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.

Adverse Analytical Finding: A report from a laboratory or other *WADA*-approved entity that, consistent with the *International Standard* for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use* of a *Prohibited Method*.

Anti-Doping Organization: A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations*.

Athlete: Any Person who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization*, including but not limited to those Persons in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and therapeutic use exemptions, shall be applied to international- and national-level competitors. Some *National Anti-Doping Organizations* may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national caliber competitors. *National Anti-Doping Organizations* are not required, however, to apply all aspects of the *Code* to such *Persons*. Specific national rules may be established for *Doping Control* for non-international-level or non-national-level competitors without being in conflict with the *Code*. Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempted* Administration) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all international- and national-caliber Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes shall be included in a National Anti-Doping Organization's Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-caliber Athletes to competitors at lower levels of competition. Competitors at all levels of competition should receive the benefit of anti-doping information and education.]

Code: The World Anti-Doping *Code*.

Competition: A single race, match, game or singular athletic contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other athletic contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

Doping Control: All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, therapeutic use exemptions, results management and hearings.

Event: A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

Event Period: The time between the beginning and end of an *Event*, as established by the ruling body of the *Event*.

In-Competition: Unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, "In-Competition" means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

International Event: An *Event* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization*, or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event*.

International-Level Athlete: *Athlete*s designated by one or more International Federations as being within the *Registered Testing Pool* for an International Federation.

International Standard: A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard*.

National Anti-Doping Organization: The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of test results, and the conduct of hearings, all at the national level. This includes an entity which may be designated by multiple countries to serve as regional *Anti-Doping Organization* for such countries. If this designation has not been made by the competent public authority(ies), the entity shall be the country's *National Olympic Committee* or its designee.

National Event: A sport *Event* involving international- or national-level *Athlete*s that is not an *International Event*.

Out-of-Competition: Any *Doping Control* which is not *In-Competition*.

***Possession*:** The actual, physical *Possession*, or the constructive *Possession* (which shall be found only if the *Person* has exclusive control over the *Prohibited Substance* or *Prohibited Method* or the premises in which a *Prohibited Substance* or *Prohibited Method* exists); provided, however, that if the Person does not have exclusive control over the *Prohibited Substance* or *Prohibited Method* or the premises in which a *Prohibited Substance* or *Prohibited Method* exists, constructive *Possession* shall only be found if the Person knew about the presence of the *Prohibited Substance* or *Prohibited Method* and intended to exercise control over it. Provided, however, there shall be no anti-doping rule violation based solely on *Possession* if, prior to receiving notification of any kind that the *Person* has committed an anti-doping rule violation, the *Person* has taken concrete action demonstrating that the *Person* never intended to have *Possession* and has renounced *Possession* by explicitly declaring it to an Anti-Doping Organization. Notwithstanding anything to the contrary in this definition, the purchase (including by any electronic or other means) of a *Prohibited Substance* or *Prohibited Method* constitutes *Possession* by the *Person* who makes the purchase.

[Comment to Possession: Under this definition, steroids found in an Athlete's car would constitute a violation unless the Athlete establishes that someone else used the car; in that event, the Anti-Doping Organization shall establish that, even though the Athlete did not have exclusive control over the car, the Athlete knew about the steroids and intended to have control over the steroids. Similarly, in the example of

steroids found in a home medicine cabinet under the joint control of an Athlete and spouse, the Anti-Doping Organization shall establish that the Athlete knew the steroids were in the cabinet and that the Athlete intended to exercise control over the steroids.]

Prohibited List: The List identifying the *Prohibited Substance*s and *Prohibited Method*s.

Prohibited Method: Any method so described on the *Prohibited List*.

Prohibited Substance: Any substance so described on the *Prohibited List*.

Registered Testing Pool: The pool of top-level *Athlete*s established separately by each International Federation and *National Anti-Doping Organization* who are subject to both *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or *National Anti-Doping Organization*'s test distribution plan. Each International Federation shall publish a list which identifies those *Athlete*s included in its *Registered Testing Pool* either by name or by clearly defined, specific criteria.

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, including the International Olympic Committee, International Federations, International Paralympic Committee, *National Olympic Committee*s, National Paralympic Committees, *Major Event Organizations*, *National Anti-Doping Organizations*, and *WADA*.

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

Use: The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

WADA: The World Anti-Doping Agency.

3.2 Defined Terms from the *International Standard for* TUE

Personal Information: As defined in the *International Standard* for the Protection of Privacy and Personal Information, information, including without limitation sensitive Personal Information, relating to an identified or identifiable *Participant* or relating to other *Persons* whose information is processed solely in the context of an Anti-Doping Organization's anti-doping activities.

[Comment: It is understood that Personal Information includes, but is not limited to, information relating to an Athlete's contact details and sporting affiliations, Whereabouts, designated therapeutic use exemptions (if any), anti-doping test results, and results management (including disciplinary hearings, appeals and sanctions). Personal Information also includes personal details and contact

information relating to other Persons, such as medical professionals and other Persons working with, treating or assisting an Athlete in the context of anti-doping activities.]

Therapeutic: Of or relating to the treatment of a medical condition by remedial agents or methods; or providing or assisting in a cure.

TUE: Therapeutic *Use* exemption approved by a Therapeutic Use Exemption Committee based on a documented medical file and obtained before *Use* or *Possession* of, a substance or method that would otherwise be prohibited by the *Code*.

TUEC: Therapeutic Use Exemption Committee is the panel established by the relevant *Anti-Doping Organization*.

WADA TUEC: *WADA* Therapeutic Use Exemption Committee is the panel established by *WADA*.

PART TWO: STANDARDS FOR GRANTING THERAPEUTIC *USE* EXEMPTIONS

4 CRITERIA FOR GRANTING A THERAPEUTIC *USE* EXEMPTION

A Therapeutic *Use* exemption (TUE) may be granted to an *Athlete* permitting the *Use* of a *Prohibited Substance* or *Prohibited Method.* An application for a TUE will be reviewed by a Therapeutic *Use* Exemption Committee (TUEC). The TUEC will be appointed by an *Anti-Doping Organization*.

4.1 A TUE will be granted only in strict accordance with the following criteria:

a. The *Athlete* would experience a significant impairment to health if the *Prohibited Substance* or *Prohibited Method* were to be withheld in the course of treating an acute or chronic medical condition.

b. The Therapeutic *Use* of the *Prohibited Substance* or *Prohibited Method* would produce no additional enhancement of performance other than that which might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition. The *Use* of any *Prohibited Substance* or *Prohibited Method* to increase "low-normal" levels of any endogenous hormone is not considered an acceptable Therapeutic intervention.

c. There is no reasonable Therapeutic alternative to the *Use* of the otherwise *Prohibited Substance* or *Prohibited Method*.

d. The necessity for the *Use* of the otherwise *Prohibited Substance* or *Prohibited Method* cannot be a consequence, wholly or in part, of the prior

Use, without a TUE, of a substance or method which was prohibited at the time of *Use*.

4.2 The TUE will be cancelled, if:

a. The *Athlete* does not promptly comply with any requirements or conditions imposed by the *Anti-Doping Organization* granting the exemption.

b. The term for which the TUE was granted has expired.

c. The *Athlete* is advised that the TUE has been withdrawn by the *Anti-Doping Organization.*

d. A decision granting a TUE has been reversed by WADA or CAS.

[Comment: Each TUE will have a specified duration as decided upon by the TUEC. There may be cases when a TUE has expired or has been withdrawn and the Prohibited Substance subject to the TUE is still present in the Athlete's body. In such cases, the Anti-Doping Organization conducting the initial review of an Adverse Analytical Finding will consider whether the finding is consistent with expiry or withdrawal of the TUE.]

4.3 An application for a TUE will not be considered for retroactive approval except in cases where:

a. Emergency treatment or treatment of an acute medical condition was necessary, or

b. Due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a TUEC to consider, an application prior to *Doping Control*.

[Comment: Medical emergencies or acute medical situations requiring administration of an otherwise Prohibited Substance or Prohibited Method before an application for a TUE can be made, are uncommon. Similarly, circumstances requiring expedited consideration of an application for a TUE due to imminent competition are infrequent. Anti-Doping Organizations granting TUEs should have internal procedures that permit such situations to be addressed.]

5 CONFIDENTIALITY OF INFORMATION

5.1 The collection, storage, processing, disclosure and retention of Personal Information in the TUE process by *Anti-Doping Organizations* and *WADA* shall comply with the *International Standard* for the Protection of Privacy and Personal Information.

5.2 An *Athlete* applying for a TUE shall provide written consent for the transmission of all information pertaining to the application to members of all TUECs with authority under the *Code* to review the file and, as required, other

independent medical or scientific experts, and to all necessary staff involved in the management, review or appeal of TUEs, and WADA. The applicant shall also provide written consent for the decision of the TUEC to be distributed to other relevant *Anti-Doping Organizations* and National Federations under the provisions of the *Code*.

[Comment to 5.2: Prior to collecting Personal Information or obtaining consent from an Athlete, the Anti-Doping Organization shall communicate to the Athlete the information set forth in Article 7.1 of the International Standard for the Protection of Privacy and Personal Information.]

Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the *Athlete* concerned.

5.3 The members of the TUECs, independent experts and the staff of the *Anti-Doping Organization* involved, will conduct all of their activities in strict confidence and will sign confidentiality agreements. In particular they will keep the following information confidential:

a. All medical information and data provided by the *Athlete* and physician(s) involved in the *Athlete*'s care.

b. All details of the application including the name of the physician(s) involved in the process.

Should the *Athlete* wish to revoke the right of any TUEC to obtain any health information on his/her behalf, the *Athlete* shall notify his/her medical practitioner in writing of the fact. As a consequence of such a decision, the *Athlete* will not receive approval for a TUE or renewal of an existing TUE.

5.4 *Anti-Doping Organizations* shall ensure that Personal Information obtained in the TUE process is retained for a period of eight (8) years, and thereafter only for as long as necessary to fulfill their obligations under the *Code* or where otherwise required by applicable law, regulation or compulsory legal process.

6 THERAPEUTIC *USE* EXEMPTION COMMITTEES (TUECS)

TUECs shall be constituted and act in accordance with the following guidelines:

6.1 TUECs should include at least three (3) physicians with experience in the care and treatment of *Athlete*s and a sound knowledge of clinical, sports and exercise medicine. In order to ensure a level of independence of decisions, the majority of the members of any TUEC should be free of conflicts of interest or political responsibility in the *Anti-Doping Organization*. All members of a TUEC will sign a conflict of interest agreement. In applications involving *Athlete*s with disabilities, at least one TUEC member shall possess specific experience with the care and treatment of *Athlete*s with disabilities.

6.2 TUECs may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.

6.3 The *WADA* TUEC shall be composed following the criteria set out in Article 6.1. The *WADA* TUEC is established to review the granting or denial of TUEs for *International-Level Athletes,* Athletes entered in an International event as described under 7.1(b), or *Athletes* in their *National Anti-Doping Organization's Registered Testing* Pool as set forth in Article 4.4 of the *Code*. In normal circumstances, the WADA TUEC shall render a decision within 30 days of receipt of all requested information.

7 RESPONSIBILITIES OF INTERNATIONAL FEDERATIONS AND *NATIONAL ANTI-DOPING ORGANIZATIONS*

7.1 Each International Federation shall:

a. Establish a TUEC as provided in Article 6.

b. Publish a list of *International Events* for which a TUE granted pursuant to the International Federation's rules is required.

c. Establish and publish a TUE process whereby any *Athlete* who is in the International Federation's *Registered Testing Pool* or who is entered in an *International Event* described in Article 7.1(b) may request a TUE for a documented medical condition requiring the *Use* of a *Prohibited Substance* or a *Prohibited Method.* Such TUE process shall comply with Article 4.4 of the *Code,* this *International Standard* and the *International Standard* for the Protection of Privacy and Personal Information.

d. Publish any rule pursuant to which the International Federation will accept *TUEs* granted by other *Anti-Doping Organizations.*

e. Promptly report to *WADA,* through *ADAMS*, the granting of all TUEs, including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.

f. Promptly report the granting of a TUE to the relevant *National Anti-Doping Organization* and National Federation.

g. At *WADA's* request, promptly provide its entire file on any TUE which has been denied.

7.2 Each *National Anti-Doping Organization* shall:

a. Establish a TUEC as provided in Article 6.

b. Identify and publish those categories of *Athletes* within its jurisdiction who are required to obtain a TUE before *Using* a *Prohibited Substance* or a *Prohibited Method.* At a minimum, this shall include all *Athletes* in the

National Anti-Doping Organization's Registered Testing Pool and other national-level *Athletes* as defined by the *National Anti-Doping Organization*.

c. Establish and publish a TUE process whereby any *Athlete* who is in the *National Anti-Doping Organization's Registered Testing Pool* or who is described in 7.2(b) may request a TUE for a documented medical condition requiring the *Use* of a *Prohibited Substance* or a *Prohibited Method.* Such TUE process shall comply with Article 4.4 of the *Code,* this *International Standard* and the *International Standard* for the Protection of Privacy and Personal Information.

[Comment to 7.2(b): National Anti-Doping Organizations will not grant TUEs to Athletes in an International Federation's Registered Testing Pool except in those instances where the International Federation's rules recognize or give authority to National Anti-Doping Organizations to grant TUEs to such Athletes.]

d. Promptly report to *WADA*, through *ADAMS,* the granting of a TUE to any *Athlete* in its *Registered Testing Pool*, and if applicable, to an Athlete in an International Federation's *Registered Testing Pool* or entered in an *International Event* described in Article 7.1(b), including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.

e. At *WADA's* request, promptly provide its entire file on any TUE that has been denied.

f. Promptly report the granting of a TUE to the relevant National Federation and International Federation where the rules of the International Federation authorize NADO to grant TUEs to International-Level Athletes.

g. Recognize TUEs granted by International Federations to *Athletes* in the International Federation's *Registered Testing Pool* or entered in an International Event as described under 7.1(b).

[As used in this Article 7, the term "publish" means: An *Anti-Doping Organization* shall Publish information by providing the information in a conspicuous place on its website and by sending the information to each National Federation which is subject to its rules.]

8 TUE APPLICATION PROCESS

8.1 Unless the rules of their International Federation provide otherwise, the following *Athletes* shall obtain a TUE from their International Federation:

a. *Athletes* in the International Federation's *Registered Testing Pool;* and

b. *Athletes* participating in an *International Event* for which a TUE granted pursuant to the International Federation's rules is required.

8.2 *Athletes* not identified in Article 8.1 shall obtain a TUE from their *National Anti-Doping Organization.*

[Comment to 8.1 and 8.2: Unless the rules of an International Federation provide otherwise, an Athlete who already has a TUE from a National Anti-Doping Organization, but later becomes a member of the International Federation's Registered Testing Pool or seeks to participate in an International Event which the International Federation has identified as requiring an International Federation TUE, shall obtain a new TUE from the International Federation.

The phrase "unless the rules of an International Federation provide otherwise" takes into account the fact that some International Federations, through their rules, are willing to recognize TUEs granted by National Anti-Doping Organizations and do not require a new TUE application at the International Federation level. Where such rules are in place, the Athlete should obtain a TUE from the Athlete's National Anti-Doping Organization.]

8.3 The *Athlete* should submit an application for a TUE no less than thirty (30) days before he/she needs the approval (for instance, an *Event).*

8.4 A TUE will only be considered following the receipt of a completed application form that shall include all relevant documents (see Annex 1 - TUE form). The application process shall be dealt with in accordance with the principles of strict medical confidentiality.

8.5 The TUE application form(s), as set out in Annex 1, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.

8.6 The TUE application form(s) may be translated into other language(s) by *Anti-Doping Organizations*, but the English or French text shall remain on the application form(s).

8.7 The application shall identify the *Athlete*'s level of competition (e.g., International Federation *Registered Testing Pool),* sport and, where appropriate, discipline and specific position or role.

8.8 The application shall list any previous and/or current TUE requests, the body to whom that request was made, the decision of that body, and the decisions of any other body on review or appeal.

8.9 The application shall include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis and treatment, as well as duration of validity, should be guided by the *WADA* "Medical Information to Support the Decisions of TUECs".

8.10 Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* before approval will be undertaken at the expense of the applicant.

[Comment to 8.10: In some cases, the applicant's National Federation may elect to pay this expense.]

8.11 The application shall include a statement by an appropriately qualified physician attesting to the necessity of the otherwise *Prohibited Substance* or *Prohibited Method* in the treatment of the *Athlete* and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.

8.12 The substance or method, dose, frequency, route and duration of administration of the otherwise *Prohibited Substance* or *Prohibited Method* in question shall be specified. In case of change, a new application shall be submitted.

8.13 In normal circumstances, decisions of the TUEC should be completed within thirty (30) days of receipt of all relevant documentation and will be conveyed in writing to the *Athlete* by the relevant *Anti-Doping Organization*. In case of a TUE application made in a reasonable time limit prior to an *Event* the TUEC should use its best endeavors to complete the TUE process before the start of the *Event*.

[Comment to 8.13: When an Anti-Doping Organization has failed to act on an Athlete's TUE application within a reasonable time, the Athlete may seek review by WADA as if the application was denied.]

9 DECLARATION OF USE

9.1 The List identifies certain substances and methods that are not prohibited but for which an Athlete is required to file a declaration of Use. An athlete should satisfy this requirement by declaring the Use on a Doping Control Form and when available by filing a declaration of use through ADAMS.

9.2 An *Athlete's* failure to declare *Use* on a *Doping Control Form* and through ADAMS when available, as stated in Article 9.1, shall not be an anti-doping rule violation.

[Comment to 9.2: The rules of Anti-Doping Organizations with jurisdiction over an Athlete may impose consequences ***other than*** *an anti-doping rule violation for a failure to declare.]*

10 REVIEW OF TUE DECISIONS BY WADA

10.1 The *WADA* TUEC may, at any time, review the grant of a TUE to an *Athlete* in the International Federation *Registered Testing Pool,* entered in an international event as described in 7.1(b), or a *National Anti-Doping Organization Registered Testing Pool*. In addition to the information to be provided as set forth in Articles 7.1 and 7.2, the *WADA* TUEC may also seek additional information from the *Athlete*, including further studies as described in Article 8.10. If a decision granting

a TUE is reversed by *WADA* upon review, the reversal shall not apply retroactively and shall not disqualify the *Athlete's* results during the period for which the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the *Athlete*.

10.2 An *Athlete* in an International Federation *Registered Testing* Pool, entered in an international event as described in 7.1(b), or *National Anti-Doping Organization Registered Testing Pool* may request that *WADA* review the denial of a TUE by submitting a written request for review to WADA within twenty-one (21) days of the date of the denial. An *Athlete* submitting such a request for review to *WADA* shall pay an application fee as established by *WADA* and shall provide to the *WADA* TUEC copies of all information that the *Athlete* submitted to the *Anti-Doping* Organization in connection with the TUE application. The *WADA* TUEC will assess the request based on the file that was available to the ADO that has denied the TUE but may, for the sake of clarification, seek additional information from the *Athlete*, including further studies as described in Article 8.10. Until the *WADA* review process has been completed, the original TUE denial remains in effect. If *WADA* reverses the denial of a TUE, the TUE shall immediately go into effect in accordance with the conditions set forth in the *WADA* decision.

10.3 Decisions by *WADA* to affirm or reverse the TUE decisions of an *Anti-Doping Organization* may be appealed to CAS as provided in Article 13 of the *Code*.

11 PREVIOUSLY GRANTED ABBREVIATED THERAPEUTIC *USE* EXEMPTIONS (ATUES)

11.1 All previously granted ATUEs that have not already expired or been cancelled shall expire on December 31, 2009.

ANNEX 1:

Therapeutic use exemption application form

Identification of Anti-Doping Organization
(Logo or Name of the ADO)

Application form

Therapeutic Use Exemptions
TUE

Please complete all sections <u>in capital letters or typing</u>

1. Athlete Information

Surname: _____ Given Names: _____

Female □ Male □ Date of Birth (d/m/y)_____

Address: _____

City:_____ Country:_____

Postcode:_____

Tel.: _____ E-mail: _____
(*with international code*)

Sport: _____ Discipline/Position: _____

International or National Sport Organization: _____

Please mark the appropriate box:

□ I am part of an International Federation Registered Testing Pool
□ I am part of a National Anti-Doping Organization Testing Pool
□ I am participating in an International Federation event for which a TUE granted pursuant to the International Federation's rules is required[1] - Name of the competition:_____
□ None of the above

If athlete with disability, indicate disability: _____

[1] Refer to your International Federation for the list of designated events

2. Medical information

Diagnosis with sufficient medical information (see note 1):

_____
_____
_____
_____

If a permitted medication can be used to treat the medical condition, provide clinical justification for the requested use of the prohibited medication

_____
_____
_____

3. Medication details

Prohibited substance(s): Generic name	**Dose**	**Route**	**Frequency**
1.			
2.			
3.			

Intended duration of treatment: (Please tick appropriate box)	once only □ emergency □ or duration (week/month):_____

Have you submitted any previous TUE application: **yes** □ **no** □

For which substance? _____

To whom? _____

When? _____

Decision: Approved □ Not approved □

4. Medical practitioner's declaration

I certify that the above-mentioned treatment is medically appropriate and that the use of alternative medication not on the prohibited list would be unsatisfactory for this condition.

Name: _____
Medical specialty: _____
Address: _____
Tel.: _____
Fax: _____
E-mail:_____
Signature of Medical Practitioner:_____
Date: _____

5. Athlete's declaration

I, _____, certify that the information under 1. is accurate and that I am requesting approval to use a Substance or Method from the WADA Prohibited List. I authorize the release of personal medical information to the Anti-Doping Organization (ADO) as well as to WADA authorized staff, to the WADA TUEC (Therapeutic Use Exemption Committee) and to other ADO TUECs and authorized staff that may have a right to this information under the provisions of the Code.

I understand that my information will only be used for evaluating my TUE request and in the context of possible anti-doping violation investigations and procedures. I understand that if I ever wish to (1) obtain more information about the use of my information; (2) exercise my right of access and correction or (3) revoke the right of these organizations to obtain my health information, I must notify my medical practitioner and my ADO in writing of that fact. I understand and agree that it may be necessary for TUE-related information submitted prior to revoking my consent to be retained for the sole purpose of establishing a possible anti-doping rule violation, where this is required by the Code.

I understand that if I believe that my personal information is not used in conformity with this consent and the International Standard for the Protection of Privacy and Personal Information I can file a complaint to WADA or CAS.

Athlete's signature: _____ Date: _____

Parent's/Guardian's signature: _____ Date: _____

(if the athlete is a minor or has a disability preventing him/her to sign this form, a parent or guardian shall sign together with or on behalf of the athlete)

6. Note:

Note 1	**Diagnosis** *Evidence confirming the diagnosis shall be attached and forwarded with this application. The medical evidence should include a comprehensive medical history and the results of all relevant examinations, laboratory investigations and imaging studies. Copies of the original reports or letters should be included when possible. Evidence should be as objective as possible in the clinical circumstances and in the case of non-demonstrable conditions independent supporting medical opinion will assist this application.*

Incomplete Applications will be returned and will need to be resubmitted.
Please submit the completed form to the ADO and keep a copy for your records.

APPENDIX FOUR

INTERNATIONAL STANDARD FOR TESTING
(Valid from 1 January 2009)

PREAMBLE

World Anti-Doping Code *International Standard* for *Testing* is a mandatory *International Standard* (Level 2) developed as part of the World Anti-Doping Program.

Version 3.0 of the 2003 *International Standard for Testing* was approved by the *WADA* Executive Committee on June 7th 2003. In concert with revisions to the 2003 *World Anti-Doping Code*, a consultation process was initiated with *Signatories* in order to revise the *International Standard* for *Testing*. Version 1.0 of the revised *International Standard* for *Testing* was circulated to *Signatories* and governments for review and comments in August 2006. Versions 2.0 (2007), 3.0 (2007) and 4.0 (2008) were also drafted based on the comments and proposals received from *Signatories* and governments during this consultation process. The *International Standard* for *Testing* (January 2009) was approved by the WADA Executive Committee in May 2008.

The official text of the *International Standard* for *Testing* shall be maintained by *WADA* and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

PART ONE: INTRODUCTION, *CODE* PROVISIONS AND DEFINITIONS

1.0 Introduction and scope

The main purpose of the *International Standard* for *Testing* is to plan for effective *Testing*, both *In-Competition* and *Out-of-Competition*, and to maintain the integrity and identity of the *Samples* collected, from the point the *Athlete* is notified of the test to the point the *Samples* are transported to the laboratory for analysis.

The *International Standard* for *Testing* includes standards for test distribution planning, notification of *Athletes*, preparing for and conducting *Sample* collection, security/post test administration and transport of *Samples*.

In addition, Section 11.0 of the *International Standard* for *Testing* sets out mandatory standards to be implemented by IFs and *NADOs* (as well as recognised and applied by other *Anti-Doping Organizations*) as the whereabouts requirements applicable to *Athletes* in their respective *Registered Testing Pools*. Failure to comply with such requirements three times in an 18-month period shall constitute an anti-doping rule violation under Article 2.4 of the *Code*.

The *International Standard* for *Testing*, including all annexes, is mandatory for all *Signatories* to the *Code*.

The World Anti-Doping Program encompasses all of the elements needed in order to ensure optimal harmonization and best practice in international and national anti-doping programs. The main elements are: the *Code* (Level 1), *International Standards* (Level 2), and Models of Best Practice (Level 3).

In the introduction to the *Code,* the purpose and implementation of the *International Standards* are summarized as follows:

> *"International Standards* for different technical and operational areas within the anti-doping program will be developed in consultation with the *Signatories* and governments and approved by *WADA*. The purpose of the *International Standards* is harmonization among *Anti-Doping Organizations* responsible for specific technical and operational parts of the anti-doping programs. Adherence to the *International Standards* is mandatory for compliance with the *Code*. The *International Standards* may be revised from time to time by the *WADA* Executive Committee after reasonable consultation with the *Signatories* and governments. Unless provided otherwise in the *Code*, *International Standards* and all revisions shall become effective on the date specified in the *International Standard* or revision."

Definitions specified in the *Code* are written in italics. Additional definitions specific to the *International Standard* for *Testing* are underlined.

2.0 *Code* Provisions

The following articles in the 2009 *Code* are directly relevant to the *International Standard* for *Testing*:

***Code* Article 2 Anti-Doping Rule Violations**

2.3 Refusing or failing without compelling justification to submit to *Sample* collection after notification as authorized in applicable anti-doping rules or otherwise evading *Sample* collection.

[Comment to Article 2.3: Failure or refusal to submit to Sample collection after notification was prohibited in almost all pre-Code anti-doping rules. This Article expands the typical pre-Code rule to include "otherwise evading Sample collection" as prohibited conduct. Thus, for example, it would be an anti-doping rule violation if it were established that an Athlete was hiding from a Doping Control official to evade notification or Testing. A violation of "refusing or failing to submit to Sample collection" may be based on either intentional or negligent conduct of the Athlete, while "evading" Sample collection contemplates intentional conduct by the Athlete.]

2.4 Violation of applicable requirements regarding *Athlete* availability for *Out-of-Competition Testing*, including failure to file required whereabouts information and missed tests which are declared based on rules which comply with the *International Standard* for *Testing*. Any combination of three missed tests

and/or filing failures within an eighteen-month period as determined by *Anti-Doping Organizations* with jurisdiction over the *Athlete* shall constitute an anti-doping rule violation.

[Comment to Article 2.4: Separate whereabouts filing failures and missed tests declared under the rules of the Athlete's International Federation or any other Anti-Doping Organization with authority to declare whereabouts filing failures and missed tests in accordance with the International Standard for Testing shall be combined in applying this Article. In appropriate circumstances, missed tests or filing failures may also constitute an anti-doping rule violation under Article 2.3 or Article 2.5.]

2.5 ***Tampering*****, or** ***Attempted Tampering***, with any part of *Doping Control*.
[Comment to Article 2.5: This Article prohibits conduct which subverts the Doping Control process but which would not otherwise be included in the definition of Prohibited Methods. For example, altering identification numbers on a Doping Control form during Testing, breaking the B Bottle at the time of B Sample analysis or providing fraudulent information to an Anti-Doping Organization.]

2.8 Administration or *Attempted* administration to any *Athlete In-Competition* of any *Prohibited Method* or *Prohibited Substance,* or administration or *Attempted* administration to any *Athlete Out-of-Competition* of any *Prohibited Method* or any *Prohibited Substance* that is prohibited *Out-of-Competition*, or assisting, encouraging, aiding, abetting, covering up or any other type of complicity involving an anti-doping rule violation or any *Attempted* anti-doping rule violation.

[Comment to Article 2: The Code does not make it an anti-doping rule violation for an Athlete or other Person to work or associate with Athlete Support Personnel who are serving a period of Ineligibility. However, a sport organization may adopt its own rules which prohibit such conduct.]

Code **Article 3 Proof of Doping**
3.2.2 Departures from any other *International Standard* or other anti-doping rule or policy which did not cause an *Adverse Analytical Finding* or other anti-doping rule violation shall not invalidate such results. If the *Athlete* or other *Person* establishes that a departure from another *International Standard* or other anti-3doping rule or policy which could reasonably have caused the *Adverse Analytical Finding* or other anti-doping rule violation occurred, then the *Anti-Doping Organization* shall have the burden to establish that such departure did not cause the *Adverse Analytical Finding* or the factual basis for the anti-doping rule violation.

Code **Article 5** ***Testing***
5.1 Test Distribution Planning. Subject to the jurisdictional limitations for *In-Competition Testing* in Article 15.1, each *National Anti-Doping Organization* shall have *Testing* jurisdiction over all *Athletes* who are present in that *National Anti-Doping Organization's* country or who are nationals, residents, license-holders or members of sport organizations of that country. Each International Federation shall

have *Testing* jurisdiction over all *Athletes* who are members of their member National Federations or who participate in their *Events*. All *Athletes* must comply with any request for *Testing* by any *Anti-Doping Organization* with *Testing* jurisdiction. In coordination with other *Anti-Doping Organizations* conducting *Testing* on the same *Athletes*, and consistent with the *International Standard* for *Testing,* each *Anti-Doping Organization* shall:

5.1.1 Plan and conduct an effective number of *In-Competition* and *Out-of-Competition* tests on *Athletes* over whom they have jurisdiction, including but not limited to *Athletes* in their respective *Registered Testing Pools*. Each International Federation shall establish a *Registered Testing Pool* for *International-Level Athletes* in its sport, and each *National Anti-Doping Organization* shall establish a national *Registered Testing Pool* for *Athletes* who are present in that *National Anti-Doping Organization's* country or who are nationals, residents, license-holders or members of sports organizations of that country. In accordance with Article 14.3, any *Athlete* included in a *Registered Testing Pool* shall be subject to the whereabouts requirements set out in the *International Standard* for *Testing*.

5.1.2 Except in exceptional circumstances all *Out-of-Competition Testing* shall be *No Advance Notice*.

5.1.3 Make *Target Testing* a priority.

5.1.4 Conduct *Testing* on *Athletes* serving a period of *Ineligibility* or a *Provisional Suspension.*

[Comment to Article 5.1.3: Target Testing is specified because random Testing, or even weighted random Testing, does not ensure that all of the appropriate Athletes will be tested (e.g., world-class Athletes, Athletes whose performances have dramatically improved over a short period of time, Athletes whose coaches have had other Athletes test positive, etc.).

Obviously, Target Testing must not be used for any purpose other than legitimate Doping Control. The Code makes it clear that Athletes have no right to expect that they will be tested only on a random basis. Similarly, it does not impose any reasonable suspicion or probable cause requirement for Target Testing.]

5.2 Standards for Testing *Anti-Doping Organizations* with *Testing* jurisdiction shall conduct such *Testing* in conformity with the *International Standard* for *Testing*.

5.3 Retired *Athletes* Returning to *Competition*

Each *Anti-Doping Organization* shall establish a rule addressing eligibility requirements for *Athletes* who are not *Ineligible* and retire from sport while included in a *Registered Testing Pool* and then seek to return to active participation in sport.

Code Article 7 Results Management

7.1 Initial Review Regarding *Adverse Analytical Findings* Upon receipt of an A *Sample Adverse Analytical Finding*, the *Anti-Doping Organization* responsible for results management shall conduct a review to determine whether: (a) an applicable therapeutic use exemption has been granted or will be granted as provided in the *International Standard* for Therapeutic Use Exemptions, or (b) there is any apparent departure from the *International Standard* for *Testing* or *International Standard* for Laboratories that caused the *Adverse Analytical Finding*.

7.2 Notification After Initial Review Regarding *Adverse Analytical Findings* If the initial review of an *Adverse Analytical Finding* under Article 7.1 does not reveal an applicable therapeutic use exemption or entitlement to a therapeutic use exemption as provided in the *International Standard* for Therapeutic Use Exemptions, or departure that caused the *Adverse Analytical Finding*, the *Anti-Doping Organization* shall promptly notify the *Athlete*, in the manner set out in its rules, of: (a) the *Adverse Analytical Finding*; (b) the anti-doping rule violated; (c) the *Athlete's* right to promptly request the analysis of the B *Sample* or, failing such request, that the B *Sample* analysis may be deemed waived; (d) the scheduled date, time and place for the B *Sample* analysis if the *Athlete* or *Anti-Doping Organization* chooses to request an analysis of the B *Sample*; (e) the opportunity for the *Athlete* and/or the *Athlete's* representative to attend the B *Sample* opening and analysis within the time period specified in the *International Standard* for Laboratories if such analysis is requested; and (f) the *Athlete's* right to request copies of the A and B *Sample* laboratory documentation package which includes information as required by the International Standard for Laboratories. The *Anti-Doping Organization* shall also notify the other *Anti-Doping Organizations* described in Article 14.1.2. If the *Anti-Doping Organization* decides not to bring forward the *Adverse Analytical Finding* as an anti-doping rule violation, it shall so notify the *Athlete* and the *Anti-Doping Organizations* as described in Article 14.1.2.

7.3 Review of *Atypical Findings*
As provided in the *International Standards*, in some circumstances laboratories are directed to report the presence of *Prohibited Substances*, which may also be produced endogenously, as *Atypical Findings* subject to further investigation. Upon receipt of an A *Sample Atypical Finding*, the *Anti-Doping Organization* responsible for results management shall conduct a review to determine whether: (a) an applicable therapeutic use exemption has been granted, or (b) there is any apparent departure from the *International Standard* for *Testing* or *International Standard* for Laboratories that caused the *Atypical Finding*. If that review does not reveal an applicable therapeutic use exemption or departure that caused the *Atypical Finding*, the *Anti-Doping Organization* shall conduct the required investigation. After the investigation is completed, the *Athlete* and other *Anti-Doping Organizations* identified in Article 14.1.2 shall be notified whether or not the *Atypical Finding* will be brought forward as an *Adverse Analytical Finding*. The *Athlete* shall be notified as provided in Article 7.2.

7.3.1 The *Anti-Doping Organization* will not provide notice of an *Atypical Finding* until it has completed its investigation and decided whether it will bring the *Atypical Finding* forward as an *Adverse Analytical Finding* unless one of the following circumstances exist:

(a) If the *Anti-Doping Organization* determines the B *Sample* should be analyzed prior to the conclusion of its investigation under Article 7.3, the *Anti-Doping Organization* may conduct the B *Sample* analysis after notifying the *Athlete*, with such notice to include a description of the *Atypical Finding* and the information described in Article 7.2(b)-(f).

(b) If the *Anti-Doping Organization* receives a request, either from a *Major Event Organization* shortly before one of its *International Events* or a request from a sport organization responsible for meeting an imminent deadline for selecting team members for an *International Event*, to disclose whether any *Athlete* identified on a list provided by the *Major Event Organization* or sport organization has a pending *Atypical Finding*, the *Anti-Doping Organization* shall so identify any such *Athlete* after first providing notice of the *Atypical Finding* to the *Athlete.*

[Comment to Article 7.3.1(b): Under the circumstance described in Article 7.3.1(b), the option to take action would be left to the Major Event Organization or sport organization consistent with its rules.]

7.4 Review of Other Anti-Doping Rule Violations Not Covered by Articles 7.1–7.3

The *Anti-Doping Organization* or other reviewing body established by such organization shall conduct any follow-up investigation into a possible anti-doping rule violation as may be required under applicable anti-doping policies and rules adopted pursuant to the *Code* or which the *Anti-Doping Organization* otherwise considers appropriate. At such time as the *Anti-Doping Organization* is satisfied that an anti-doping rule violation has occurred, it shall promptly give the *Athlete* or other *Person* subject to sanction notice, in the manner set out in its rules, of the anti-doping rule violated, and the basis of the violation. Other *Anti-Doping Organizations* shall be notified as provided in Article 14.1.2.

7.6 Retirement from

If an *Athlete* or other *Person* retires while a results management process is underway, the *Anti-Doping Organization* conducting the results management process retains jurisdiction to complete its results management process. If an *Athlete* or other *Person* retires before any results management process has begun, the *Anti-Doping Organization* which would have had results management jurisdiction over the *Athlete* or other *Person* at the time the *Athlete* or other *Person* committed an anti-doping rule violation, has jurisdiction to conduct results management.

[Comment to Article 7.6: Conduct by an Athlete or other Person before the Athlete or other Person was subject to the jurisdiction of any Anti-Doping Organization

would not constitute an anti-doping rule violation but could be a legitimate basis for denying the Athlete or other Person membership in a sports organization.]

Code **Article 10 Sanctions on Individuals**

10.3.3 For violations of Article 2.4 (Whereabouts Filing Failures and/or Missed Tests), the period of *Ineligibility* shall be at a minimum one (1) year and at a maximum two (2) years based on the *Athlete's* degree of fault.

[Comment to Article 10.3.3: The sanction under Article 10.3.3 shall be two years where all three filing failures or missed tests are inexcusable. Otherwise, the sanction shall be assessed in the range of two years to one year, based on the circumstances of the case.]

10.11 Reinstatement *Testing*

As a condition to regaining eligibility at the end of a specified period of *Ineligibility*, an *Athlete* must, during any period of *Provisional Suspension* or *Ineligibility*, make him or herself available for *Out-of-Competition Testing* by any *Anti-Doping Organization* having Testing jurisdiction, and must, if requested, provide current and accurate whereabouts information. If an *Athlete* subject to a period of *Ineligibility* retires from sport and is removed from *Out-of-Competition Testing* pools and later seeks reinstatement, the *Athlete* shall not be eligible for reinstatement until the *Athlete* has notified relevant *Anti-Doping Organizations* and has been subject to *Out-of-Competition Testing* for a period of time equal to the period of *Ineligibility* remaining as of the date the *Athlete* had retired.

Code **Article 14 Confidentiality and Reporting:**

14.3 *Athlete* Whereabouts Information

As further provided in the *International Standard* for *Testing*, *Athletes* who have been identified by their International Federation or *National Anti-Doping Organization* for inclusion in a *Registered Testing Pool* shall provide accurate, current location information. The International Federations and *National Anti-Doping Organizations* shall coordinate the identification of *Athletes* and the collecting of current location information and shall submit these to *WADA*. This information will be accessible, through *ADAMS* where reasonably feasible, to other *Anti-Doping Organizations* having jurisdiction to test the *Athlete* as provided in Article 15. This information shall be maintained in strict confidence at all times; shall be used exclusively for purposes of planning, coordinating or conducting *Testing*; and shall be destroyed after it is no longer relevant for these purposes.

14.5 *Doping Control* Information Clearinghouse

WADA shall act as a central clearinghouse for *Doping Control Testing* data and results for *International-Level Athletes* and national-level *Athletes* who have been included in their *National Anti-Doping Organization's Registered Testing Pool*. To facilitate coordinated test distribution planning and to avoid unnecessary duplication in *Testing* by the various *Anti-Doping Organizations*, each *Anti-Doping*

Organization shall report all *In-Competition* and *Out-of-Competition* tests on such *Athletes* to the *WADA* clearinghouse as soon as possible after such tests have been conducted. This information will be made accessible to the *Athlete*, the *Athlete's* National Federation, *National Olympic Committee* or National Paralympic Committee, *National Anti-Doping Organization*, International Federation, and the International Olympic Committee or International Paralympic Committee.

To enable it to serve as a clearinghouse for *Doping Control Testing* data, WADA has developed a database management tool, *ADAMS*, that reflects emerging data privacy principles. In particular, *WADA* has developed *ADAMS* to be consistent with data privacy statutes and norms applicable to *WADA* and other organizations using *ADAMS*. Private information regarding an *Athlete, Athlete Support Personnel,* or others involved in anti-doping activities shall be maintained by *WADA,* which is supervised by Canadian privacy authorities, in strict confidence and in accordance with the *International Standard* for the protection of privacy. *WADA* shall, at least annually, publish statistical reports summarizing the information that it receives, ensuring at all times that the privacy of *Athletes* is fully respected and make itself available for discussions with national and regional data privacy authorities.

14.6 Data Privacy

When performing obligations under the Code, *Anti-Doping Organizations* may collect, store, process or disclose personal information relating to *Athletes* and third parties. Each *Anti-Doping Organization* shall ensure that it complies with applicable data protection and privacy laws with respect to their handling of such information, as well as the *International Standard* for the protection of privacy that *WADA* shall adopt to ensure *Athletes* and non-athletes are fully informed of and, where necessary, agree to the handling of their personal information in connection with anti-doping activities arising under the Code.

***Code* Article 15 Clarification of *Doping Control* Responsibilities:**

15.1 *Event Testing*

The collection of *Samples* for *Doping Control* does and should take place at both *International Events* and *National Events*. However, except as otherwise provided below, only a single organization should be responsible for initiating and directing *Testing* during the *Event Period*. At *International Events*, the collection of *Doping Control Samples* shall be initiated and directed by the international organization which is the ruling body for the *Event* (e.g., the International Olympic Committee for the Olympic Games, the International Federation for a World Championship, and Pan-American Sports Organization for the Pan American Games). At *National Events*, the collection of *Doping Control Samples* shall be initiated and directed by the designated *National Anti-Doping Organization* of that country.

15.1.1 If an *Anti-Doping Organization* which is not responsible for initiating and directing *Testing* at an *Event* nevertheless desires to conduct additional *Testing* of *Athletes* at the *Event* during the *Event Period*, the *Anti-Doping Organization* shall first confer with the ruling body of the *Event* to obtain permission to conduct, and to

coordinate, any additional *Testing*. If the *Anti-Doping Organization* is not satisfied with the response from the ruling body of the *Event*, the *Anti-Doping Organization* may ask *WADA* for permission to conduct additional *Testing* and to determine how to coordinate such additional *Testing*. *WADA* shall not grant approval for such additional *Testing* before consulting with and informing the ruling body for the *Event*.

[Comment to Article 15.1.1: Before giving approval to a National Anti-Doping Organization to initiate and conduct Testing at an International Event, WADA shall consult with the international organization which is the ruling body for the Event. Before giving approval to an International Federation to initiate and conduct Testing at a National Event, WADA shall consult with the National Anti-Doping Organization of the country where the Event takes place. The Anti-Doping Organization "initiating and directing Testing" may, if it chooses, enter into agreements with other organizations to which it delegates responsibility for Sample collection or other aspects of the Doping Control process.]

15.2 *Out-of-Competition Testing*

Out-of-Competition Testing shall be initiated and directed by both international and national organizations. *Out-of-Competition Testing* may be initiated and directed by: (a) *WADA*; (b) the International Olympic Committee or International Paralympic Committee in connection with the Olympic Games or Paralympic Games; (c) the *Athlete's* International Federation; or (d) any other *Anti-Doping Organization* that has *Testing* jurisdiction over the *Athlete* as provided in Article 5.1 (Test Distribution Planning). *Out-of-Competition Testing* shall be coordinated through *ADAMS* where reasonably feasible in order to maximize the effectiveness of the combined *Testing* effort and to avoid unnecessary repetitive *Testing* of individual *Athletes*.

[Comment to Article 15.2: Additional authority to conduct Testing may be authorized by means of bilateral or multilateral agreements among Signatories and governments.]

15.4.1 *Mutual Recognition*.

Subject to the right to appeal provided in Article 13, *Testing*, therapeutic use exemptions and hearing results or other final adjudications of any *Signatory* which are consistent with World Anti-Doping Code 2007 Version 1.0 46 the *Code* and are within that *Signatory's* authority, shall be recognized and respected by all other *Signatories*.

[Comment to Article 15.4.1: There has in the past been some confusion in the interpretation of this Article with regard to therapeutic use exemptions. Unless provided otherwise by the rules of an International Federation or an agreement with an International Federation, National Anti-Doping Organizations do not have "authority" to grant therapeutic use exemptions to International-Level Athletes.]

15.4.2 *Signatories* shall recognize the same actions of other bodies which have not accepted the *Code* if the rules of those bodies are otherwise consistent with the *Code*.

[Comment to Article 15.4.2: Where the decision of a body that has not accepted the Code is in some respects Code compliant and in other respects not Code compliant, Signatories should attempt to apply the decision in harmony with the principles of the Code. For example, if in a process consistent with the Code a non-Signatory has found an Athlete to have committed an anti-doping rule violation on account of the presence of a Prohibited Substance in his body but the period of Ineligibility applied is shorter than the period provided for in the Code, then all Signatories should recognize the finding of an anti-doping rule violation and the Athlete's National Anti-Doping Organization should conduct a hearing consistent with Article 8 to determine whether the longer period of Ineligibility provided in the Code should be imposed.]

3.0 Terms and definitions, and interpretation

3.1 Defined terms from the 2009 *Code*

ADAMS: The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.

Adverse Analytical Finding: A report from a laboratory or other *WADA*-approved *Testing* entity that, consistent with the *International Standard* for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use* of a *Prohibited Method.*

Anti-Doping Organization (ADO): A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations.*

***Athlete*:** Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization,* including but not limited to those *Persons* in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and therapeutic use exemptions, must be applied to international- and national-level competitors. Some *National Anti-Doping Organizations* may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national

caliber competitors. *National Anti-Doping Organizations* are not required, however, to apply all aspects of the *Code* to such *Persons.* Specific national rules may be established for Doping Control for non-international-level or non-national-level competitors without being in conflict with the *Code.* Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempted* Administration) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all international- and national-caliber athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national- level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes must be included in a National Anti-Doping Organization's Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-caliber athletes to competitors at lower levels of competition. Competitors at all levels of competition should receive the benefit of anti-doping information and education.]

Atypical Finding: A report from a laboratory or other *WADA*-approved entity which requires further investigation as provided by the *International Standard* for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding*.

Code: The World Anti-Doping *Code*.

Competition: A single race, match, game or singular athletic contest. For example, a basketball game or the finals of the Olympic 100-meter dash. For stage races and other athletic contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

Consequences of Anti-Doping Rule Violations: An *Athlete*'s or other *Person's* violation of an anti-doping rule may result in one or more of the following: (a) *Disqualification* means the *Athlete's* results in a particular *Competition* or *Event* are invalidated, with all resulting Consequences including forfeiture of any medals, points and prizes; (b) *Ineligibility* means the *Athlete* or other *Person* is barred for a specified period of time from participating in any *Competition* or other activity or funding as provided in Article 10.9; and (c) *Provisional Suspension* means the

Athlete or other Person is barred temporarily from participating in any *Competition* prior to the final decision at a hearing conducted under Article 8 (Right to a Fair Hearing).

***Doping Control*:** All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, therapeutic use exemptions, results management and hearings.

Event: A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games of the Olympiad and the Winter Games, FINA World Championships, or Pan American Games).

***In-Competition*:** Unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, "*In-Competition"* means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

***Independent Observer Program*:** A team of observers, under the supervision of *WADA*, who observe and may provide guidance on the *Doping Control* process at certain *Events* and report on their observations.

Ineligibility: See *Consequences of Anti-Doping Rule Violations* above.

International Event: An *Event* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization,* or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event.*

International-Level Athlete: *Athletes* designated by one or more International Federations as being within the *Registered Testing* P*ool* for an International Federation.

International Standard: A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard.*

Minor: A natural *Person* who has not reached the age of majority as established by the applicable laws of his or her country of residence.

National Anti-Doping Organization: The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of test results, and

the conduct of hearings, all at the national level. This includes an entity which may be designated by multiple countries to serve as regional *Anti-Doping* Organization for such countries. If this designation has not been made by the competent public authority(ies), the entity shall be the country's *National Olympic Committee* or its designee.

National Olympic Committee (NOC): The organization recognized by the International Olympic Committee. The term *National Olympic Committee* shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical *National Olympic Committee* responsibilities in the anti-doping area.

No Advance Notice: A *Doping Control* which takes place with no advance warning to the *Athlete* and where the *Athlete* is continuously chaperoned from the moment of notification through *Sample* provision.

Out-of-Competition: Any *Doping Control* which is not *In-Competition*.

Prohibited List: The List identifying the *Prohibited Substances* and *Prohibited Methods*.

Provisional Suspension: See *Consequences* above.

***Registered Testing Pool*:** The pool of top level *Athletes* established separately by each International Federation and *National Anti-Doping Organization* who are subject to both *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or Organization's Test Distribution Plan. Each International Federation shall publish a list which identifies those *Athletes* included in its *Registered Testing Pool* either by name or by clearly defined, specific criteria.

Sample or Specimen: Any biological material collected for the purposes of *Doping Control*.

[Comment: It has sometimes been claimed that the collection of blood Samples violates the tenets of certain religious or cultural groups. It has been determined that there is no basis for any such claim.]

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, including the International Olympic Committee, International Federations, International Paralympic Committee, *National Olympic Committee*s, National Paralympic Committees, *Major Event Organizations*, *National Anti-Doping Organizations*, and *WADA*.

***Tampering*:** Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures

from occurring; or providing fraudulent information to an *Anti-Doping Organization*.

Target Testing: Selection of *Athletes* for *Testing* where specific *Athletes* or groups of *Athletes* are selected on a non-random basis for *Testing* at a specified time.

Team Sport: A sport in which the substitution of players is permitted during a *Competition.*

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

WADA: The World Anti-Doping Agency.

3.2 Defined terms specific to the *International Standard* for *Testing*

Blood Collection Officer (BCO): An official who is qualified to and has been authorized by the *ADO* to collect a blood *Sample* from an *Athlete.*

Chain of Custody: The sequence of individuals or organizations who have the responsibility for a *Sample* from the provision of the *Sample* until the *Sample* has been received for analysis.

Chaperone: An official who is trained and authorized by the *ADO* to carry out specific duties including one or more of the following: notification of the *Athlete* selected for *Sample* collection; accompanying and observing the *Athlete* until arrival at the Doping Control Station; and/or witnessing and verifying the provision of the *Sample* where the training qualifies him/her to do so.

Doping Control Officer (DCO): An official who has been trained and authorized by the *ADO* with delegated responsibility for the on-site management of a *Sample* Collection Session.

Doping Control Station: The location where the *Sample* Collection Session will be conducted.

Failure to Comply: A term used to describe anti-doping rule violations under *Code* Articles 2.3, 2.5 and 2.8.

Filing Failure: A failure by the *Athlete* (or by a third party to whom the *Athlete* has delegated this task, in accordance with Clause 11.3.6 or Clause 11.5.4) to make an accurate and complete Whereabouts Filing in accordance with Clause 11.3 or Clause 11.5.6.

International Federation (IF): An international non-governmental organization administering one or more sports at world level.

Missed Test: A failure by the *Athlete* to be available for *Testing* at the location and time specified in the 60-minute time slot identified in his/her Whereabouts Filing for the day in question, in accordance with Clause 11.4 or Clause 11.5.6.

National Federation: A national non-governmental organization administering one or more sports at a national level.

Random Selection: Selection of *Athletes* for *Testing* which is not *Target Testing*. Random Selection may be: completely random (where no pre-determined criteria are considered, and *Athletes* are chosen arbitrarily from a list or pool of *Athlet*e names); or weighted (where *Athletes* are ranked using pre-determined criteria in order to increase or decrease the chances of selection).

Responsible ADO: The *Anti-Doping Organization* with responsibility for a particular whereabouts matter, as specified in Clause 11.5.

***Sample* Collection Equipment:** Containers or apparatus used to directly collect or hold the *Sample* at any time during the *Sample* collection process. *Sample* Collection Equipment shall, as a minimum, consist of:

- For urine *Sample* collection:
  - Collection vessels for collecting the *Sample* as it leaves the *Athlete's* body;
  - Sealable and tamper-evident bottles and lids for securing the *Sample*;
  - Partial *Sample* kit;

- For blood *Sample* collection:
  - Needles for collecting the *Sample*;
  - Blood tubes with sealable and tamper-evident devices for holding the *Sample*.

***Sample* Collection Personnel:** A collective term for qualified officials authorized by the *ADO* who may carry out or assist with duties during the *Sample* Collection Session.

***Sample* Collection Session:** All of the sequential activities that directly involve the *Athlete* from notification until the *Athlete* leaves the Doping Control Station after having provided his/her *Sample/s*.

Suitable Specific Gravity for Analysis: Specific gravity measured at 1.005 or higher with a refractometer, or 1.010 or higher with lab sticks.

Suitable Volume of Urine for Analysis: A minimum of 90 mL for full or part menu analysis.

Team Activity: As defined in Clause 11.5.3.

Test Distribution Plan: As defined in Clause 4.2.1.

Unsuccessful Attempt Report: A detailed report of an unsuccessful *Testing* attempt, as more fully described in Clause 11.6.3(a).

Whereabouts Failure: A Filing Failure or a Missed Test.

Whereabouts Filing: Information provided by or on behalf of an *Athlete* in a *Registered Testing Pool* that sets out the *Athlete's* whereabouts during the following quarter, in accordance with Clause 11.3 (or optionally, in the case of a *Team Sport*, in accordance with Clause 11.5).

3.3 Interpretation of the *International Standard* for *Testing*

3.3.1 Unless otherwise specified, references in this document to Clauses are references to clauses of this *International Standard* for *Testing*.

3.3.2 The comments annotating various provisions of the *International Standard* for *Testing* are included to assist in the understanding and interpretation of the *International Standard.*

PART TWO: STANDARDS FOR *TESTING*

4.0 Planning

4.1 Objective

The objective is the development of Test Distribution Plans that are specific to the relevant sport (in the case of an IF) or the relevant nation (in the case of a *NADO*). The common objective in each case is to plan and implement an effective distribution of *Sample* collections both *In-Competition* and *Out-of-Competition* in each nation, sport, or discipline within the sport (as applicable), resulting in the effective detection, deterrence and prevention of doping practices in such sport/discipline/nation.

4.2 General

4.2.1 Each *ADO* with *Testing* jurisdiction must develop a plan for the efficient and effective allocation of its *Testing* resources across the different sports under its jurisdiction (in the case of a *NADO*), across the different countries within its jurisdiction (in the case of an IF) and across the different disciplines within a sport under its jurisdiction (in the case of an IF and a *NADO*). Such plan, which should be monitored, evaluated, modified and updated periodically as required, is referred to in this *International Standard* as the "Test Distribution Plan".

[4.2 Comment: Any other ADO that (like a NADO) has Testing jurisdiction over a significant number of different and otherwise unrelated sports (e.g., a Major Event Organizer) shall be treated under this International Standard in the same manner as a NADO in relation to test distribution planning and allocation of Testing resources across those different sports. (See Clauses 4.3.1, 4.3.6 and 4.4.4).]

4.2.2 Planning starts with the gathering of information (e.g., in relation to the number of relevant *Athletes* in a particular sport/discipline/nation, as well as the basic structure of the season for the sport/discipline in question, including standard competition schedules and training patterns for each sport/discipline); evaluating the potential risk of doping and possible doping pattern for each sport/discipline/nation; and then developing a Test Distribution Plan that deploys the available resources in the most efficient and effective way to address those risks.

4.2.3 The main activities are therefore information-gathering, monitoring and follow up; risk evaluation; and developing, monitoring, evaluating, modifying and updating the Test Distribution Plan.

4.2.4 The *ADO* shall ensure that *Athlete Support Personnel* and/or any other person with a conflict of interest shall not be involved in test distribution planning for their *Athlete*s or in the process of selection of *Athletes* for *Testing*.

4.3 Requirements for test distribution planning

4.3.1 The basis of the Test Distribution Plan must be a considered evaluation of the risk of doping and possible doping pattern for the sport/discipline/nation in question. In the case of an IF, in addition to conducting a risk evaluation for each discipline within its sport, it should also take into account the strength of the national anti-doping programme within each nation under its jurisdiction, so as to ensure proper coordination and efficiency in the use of *Testing* resources. In the case of a *NADO*, in addition to conducting its own risk evaluations for each relevant sport/discipline under its jurisdiction, it may also take into account the relative risks of doping as between the different sports under its jurisdiction, as well as any national anti-doping policy requirements and priorities that it may follow as between those different sports.

[4.3.1 Comment: It is understood and expected that different NADOs will have different national policy requirements and priorities. For example, one NADO may have legitimate reasons to prioritize (some or all) Olympic sports while another may have legitimate reasons, because of different characteristics of that sporting nation, to prioritize (for example) certain professional sports. These national policy imperatives are a relevant consideration in the NADO's test distribution planning, alongside the NADO's assessment of the relative risks of doping in the various sports played within its national jurisdiction. They may lead, for example, to a NADO deciding, in its Test Distribution Plan for a particular period, (1) not to allocate any Testing to one or more sports within its jurisdiction; and/or (2) to allocate Testing to a particular sport in its Test Distribution Plan but not to include any Athletes from that sport in its national Registered Testing Pool for purposes of triggering the whereabouts requirements of Section 11 of this International Standard. (See further Clause 4.4.4(b)). Such decisions should be reviewed regularly: See Clause 4.3.11.]

4.3.2 The *ADO* shall, as a minimum, evaluate the potential risk of doping and possible doping pattern for each sport and/or discipline based on:

a) The physical demands of the sport and/or discipline and possible performance-enhancing effect that doping may elicit;
b) Available doping analysis statistics;
c) Available research on doping trends;
d) The history of doping in the sport and/or discipline;
e) Training periods and the *Competition* calendar; and
f) Information received on possible doping practices.

4.3.3 The *ADO* shall develop and document a Test Distribution Plan based on the information referred to in Clause 4.3.2; the number of *Athletes* involved in the sport/discipline; the *Competition* calendar; the anti-doping activities of other *ADOs* with responsibility for *Testing* in respect of the sport/discipline; the evaluation outcomes of previous test distribution planning cycles; (in the case of IFs) the strength of the national anti-doping programme from nation to nation; and (in the case of *NADOs*) the national anti-doping policy imperatives referenced in Clause 4.3.1.

4.3.4 The *ADO* shall allocate the number of *Sample* collections that it has at its disposal for each sport/discipline/nation (as relevant), including between urine and blood *Testing* and between *Out-of-Competition Testing* and *In-Competition Testing*. The allocation of resources between urine and blood *Testing* and between *Out-of-Competition Testing* and *In-Competition Testing* shall take into account the relative risks of doping in such periods for each sport/discipline under evaluation.

4.3.5 Each IF shall evaluate the relative merits of *Out-of-Competition* and *In-Competition Testing* in its sport and in the various disciplines within that sport. In sports and/or disciplines with a high risk of doping *Out-of-Competition*, *Out-of-Competition Testing* shall be made a priority, and a substantial portion of *Testing* shall be conducted *Out-of-Competition*. However, some material amount of *In-Competition Testing* shall still take place. For those sports and/or disciplines where there is a low risk of doping *Out-of-Competition*, *In-Competition Testing* shall be made a priority, and a significant amount of *Testing* shall be conducted *In-Competition*. However, some material amount of *Out-of-Competition Testing* shall still take place.

4.3.6 Each *NADO* shall first determine how it will allocate the *Sample* collections at its disposal among the various sports under its jurisdiction, based on an analysis of the relative risks of doping between those sports as well as the national anti-doping policy imperatives referenced in Clause 4.3.1. Having identified in this way the "priority" sports to which its *Testing* resources are to be allocated, the *NADO* shall then make its own evaluation of the relative merits of *Out-of-Competition* and *In-Competition Testing* in those "priority" sports. In those sports and/or disciplines where it assesses that there is a high risk of doping in the *Out-of-Competition* period, the *NADO* shall ensure that *Out-of-Competition Testing* is made a priority, and that a

substantial portion of annual *Testing* is conducted *Out-of-Competition*. However, some material amount of *In-Competition Testing* shall still take place. For those sports and/or disciplines where the *NADO* assesses that there is a low risk of doping *Out-of-Competition*, *In-Competition Testing* shall be made a priority, and a substantial amount of *Testing* shall be conducted *In-Competition.* However, some material amount of *Out-of-Competition Testing* shall still take place.

4.3.7 In order to develop a Test Distribution Plan that takes into account in a coordinated manner the *Testing* activities of other relevant *ADOs*:

a) *ADO*s shall coordinate *Testing* activities to avoid duplication. Clear agreement on roles and responsibilities for *Event Testing* shall be agreed in advance in accordance with *Code* Article 15.1.

b) *ADO*s shall, without any unnecessary delay, share information on its *Testing* with other relevant *ADOs*, ideally via ADAMS or another centralized database of similar functionality and security, in accordance with *Code* Article 14.5.

4.3.8 As part of the Test Distribution Plan, the *ADO* shall allocate the type of test for each sport/discipline/nation, as relevant, including as between urine and blood *Sample* collection, based on an analysis of the risks of doping for the particular sport/discipline in question, as explained in Clause 4.3.4.

4.3.9 The *ADO* shall ensure that the timing of *Testing* is planned to ensure optimum deterrence and detection of doping practices.

4.3.10 Save in exceptional and justifiable circumstances, all *Testing* shall be *No Advance Notice*:

a) For *In-Competition Testing*, placeholder selection may be known in advance. However, random *Athlete*/placeholder selection shall not be revealed to the *Athlete* until notification.

b) All *Out-of-Competition Testing* shall be *No Advance Notice* save in exceptional and justifiable circumstances.

4.3.11 The *ADO* shall document its Test Distribution Plan and shall establish a system whereby that Test Distribution Plan is reviewed and, if necessary, updated on a regular basis in order to incorporate new information and take into account *Sample* collection by other *ADOs.* Such data shall be used to assist with determining whether modifications to the plan are necessary.

4.4 Requirements for selection of *Athletes* for *Testing*

4.4.1 In implementing the Test Distribution Plan, the *ADO* shall select *Athletes* for *Sample* collection using *Target Testing* and Random Selection methods.

4.4.2 *ADOs* shall ensure that a significant amount of *Testing* undertaken pursuant to the Test Distribution Plan is *Target Testing*, based on the intelligent assessment of the risks of doping and the most effective use of resources to ensure optimum detection and deterrence. The factors that will be relevant to determining who should be made the subject of *Target Testing* will vary as between different sports, but could include (without limitation) some or all of the following factors:

a) Abnormal biological parameters (blood parameters, steroid profiles, etc);
b) Injury;
c) Withdrawal or absence from expected *Competition*;
d) Going into or coming out of retirement;
e) Behaviour indicating doping;
f) Sudden major improvements in performance;
g) Repeated failure to provide Whereabouts Filings;
h) Whereabouts Filings that may indicate a potential increase in the risk of doping, including moving to a remote location;
i) *Athlete* sport performance history;
j) *Athlete* age, e.g. approaching retirement, move from junior to senior level;
k) *Athlete* test history;
l) *Athlete* reinstatement after a period of *Ineligibility*;
m) Financial incentives for improved performance, such as prize money or sponsorship opportunities;
n) *Athlete* association with a third party such as coach or doctor with a history of involvement in doping; and
o) Reliable information from a third party.

4.4.3 *Testing* which is not *Target Testing* shall be determined by Random Selection, which shall be conducted using a documented system for such selection. Random Selection which is weighted shall be conducted according to clear criteria and may take into account the factors listed in Clause 4.4.2 (as applicable) in order to ensure that a greater percentage of 'at risk' *Athletes* is selected.

4.4.4 As set out in Clause 11.2:

a. In addition to developing a Test Distribution Plan that is specific to its sport, an IF must define criteria for the inclusion of certain *Athletes* from its sport in an international *Registered Testing Pool*, to whom the whereabouts requirements of Section 11 of this *International Standard* will apply. For the avoidance of doubt, however, the IF's Test Distribution Plan must encompass all relevant *Athletes*, not just *Athletes* included in the international *Registered Testing Pool*, and accordingly the IF should select *Athletes* for *Testing* (including *Out-of-Competition Testing*) who are not included in its international *Registered Testing Pool.* However, an appropriate proportion of the *Out-of-Competition* tests specified in the Test Distribution Plan must be conducted on *Athletes* in the international *Registered Testing Pool.*

b. In addition to developing a Test Distribution Plan that allocates its *Testing* resources among some or all of the sports within its jurisdiction, a *NADO* must identify criteria for the inclusion of certain *Athletes* from some or all of those sports in a national *Registered Testing Pool*, to whom the whereabouts requirements of Section 11 of this *International Standard* will apply. For the avoidance of doubt, however, the *NADO's* Test Distribution Plan must encompass all relevant *Athletes* from the sports in question, not just *Athletes* included in the national *Registered Testing Pool*, and accordingly the *NADO* should select *Athletes* for *Testing* (including *Out-of-Competition Testing*) who are not included in the national *Registered Testing Pool.* However, where *Athletes* from a particular sport have been included in the national *Registered Testing Pool*, an appropriate proportion of the *Out-of-Competition* tests allocated to that sport in the *NADO's* Test Distribution Plan must be conducted on those *Athletes.*

[4.4.4 Comment: As further explained in Section 11 of this International Standard, the main purpose of the Registered Testing Pool is to identify those Athletes from the relevant sport(s) who should be made subject to the whereabouts requirements of Section 11 of this International Standard. That decision will depend principally on an evaluation of the risk of Out-of-Competition doping in the sport(s) or discipline(s) in question: the greater that risk, the larger the Registered Testing Pool should be; the smaller that risk, the smaller the Registered Testing Pool can be. Accordingly, the number of Athletes in a Registered Testing Pool may vary considerably from sport to sport. In accordance with Clause 11.2, however, there are certain minimum requirements for populating Registered Testing Pools, and pursuant to Clause 4.4.4 an appropriate number of the Out-of-Competition tests specified in the Test Distribution Plan must be carried out on Athletes in the Registered Testing Pool.

In the case of a NADO, the relevant sports for purposes of Clause 4.4.4(b) shall be those sports within its jurisdiction that it decides, based on the national policy requirements and priorities referenced in Clause 4.3.1, as well as the risk assessment and other factors referred to in Clause 4.3.3, to treat as "priority" sports for purposes of Out-of-Competition Testing. Based on those factors, a NADO may decide not to include any Athletes from a particular sport or sports in the national Registered Testing Pool. That decision should be reviewed regularly in accordance with Clause 4.3.11. However, where the NADO does decide to include Athletes from a particular sport in the national Registered Testing Pool, an appropriate number of the Out-of-Competition tests allocated to that sport in the Test Distribution Plan must be conducted on those Athletes.]

4.4.5 Where the *ADO* authorizes a DCO to select *Athletes* for *Sample* collection, the *ADO* shall provide selection criteria to the DCO in accordance with the Test Distribution Plan.

4.4.6 Following the selection of an *Athlete* for *Sample* collection and prior to notification of the *Athlete*, the *ADO* and/or DCO shall ensure *Athlete* selection

decisions are disclosed only to those who need to know, in order to ensure the *Athlete* can be notified and tested on a *No Advance Notice* basis.

5.0 Notification of *Athletes*

5.1 Objective

The objective is to ensure that reasonable attempts are made to locate the *Athlete,* the selected *Athlete* is notified as outlined in Clause 5.4.1, the rights of the *Athlete* are maintained, there are no opportunities to manipulate the *Sample* to be provided, and the notification is documented.

[5.1 Comment: WADA will produce guidelines to assist ADOs in determining what constitutes reasonable attempts to locate an Athlete in the specific context of Section 11 (Whereabouts).]

5.2 General

Notification of *Athletes* starts when the *ADO* initiates the notification of the selected *Athlete* and ends when the *Athlete* arrives at the Doping Control Station or when the *Athlete's* possible failure to comply is brought to the *ADO's* attention. The main activities are:

Appointment of DCOs, Chaperones and other *Sample* Collection Personnel;

Locating the *Athlete* and confirming his/her identity;

Informing the *Athlete* that he/she has been selected to provide a *Sample* and of his/her rights and responsibilities;

For *No Advance Notice Sample* collection, continuously chaperoning the *Athlete* from the time of notification to the arrival at the designated Doping Control Station; and

Documenting the notification, or notification attempt.

5.3 Requirements prior to notification of *Athletes*

5.3.1 Other than by exception, *No Advance Notice* shall be the notification method for *Sample* collection.

5.3.2 To conduct or assist with *Sample* Collection Sessions, the *ADO* shall appoint and authorise *Sample* Collection Personnel who have been trained for their assigned responsibilities, who do not have a conflict of interest in the outcome of the *Sample* collection, and who are not *Minors*.

5.3.3 *Sample* Collection Personnel shall have official authorisation documentation that is provided and controlled by the *ADO*. In the case of DCOs, such documentation shall identify them by name. DCOs shall also carry complementary identification which includes their name and photograph (i.e., *ADO*

identification card, driver's licence, health card, passport or similar valid identification) and the expiry date of the identification.

[5.3.3 Comment: Chaperones do not have to carry documentation that identifies them by name or photograph. They only have to produce official authorisation documentation that is provided by the ADO, such as a Mission Order or an Authorisation Letter.]

5.3.4 The *ADO* shall establish criteria to validate the identity of an *Athlete* selected to provide a *Sample.* This ensures the selected *Athlete* is the *Athlete* who is notified. The method of identification of the *Athlete* shall be documented on the doping control documentation.

5.3.5 The *ADO*, DCO or Chaperone, as applicable, shall establish the location of the selected *Athlete* and plan the approach and timing of notification, taking into consideration the specific circumstances of the sport/*Competition*/training session/etc and the situation in question.

5.3.6 The *ADO* shall establish a system for the detailed recording of *Athlete* notification attempt/s and outcome/s.

5.3.7 The *Athlete* shall be the first one notified that he/she has been selected for *Sample* collection except where prior contact with a third party is required as specified in Clause 5.3.8.

5.3.8 The *ADO*/DCO/Chaperone, as applicable, shall consider whether a third party is required to be notified prior to notification of the *Athlete* when the *Athlete* is a *Minor* (as provided for in Annex C – Modifications for *Athletes* who are Minors), or where required by an *Athlete's* disability (as provided for in Annex B - Modifications for *Athletes* with disabilities), or in situations where an interpreter is required and available for the notification.

[5.3.8 Comment: In the case of In-Competition Testing, it is permissible to notify third parties that Testing will be conducted, where required to help the Sample Collection Personnel to identify the Athlete(s) to be tested and to notify such Athlete(s) that he/she is required to provide a Sample. However, there is no requirement to notify any third party (e.g. a team doctor) of the Doping Control mission where such assistance is not needed.]

5.4 Requirements for notification of *Athletes*

5.4.1 When initial contact is made, the *ADO*, DCO or Chaperone, as applicable, shall ensure that the *Athlete* and/or a third party (if required in accordance with Clause 5.3.8) is informed:

a) That the *Athlete* is required to undergo a *Sample* collection;

b) Of the authority under which the *Sample* collection is to be conducted;

c) Of the type of *Sample* collection and any conditions that need to be adhered to prior to the *Sample* collection;

d) Of the *Athlete's* rights, including the right to:

i. Have a representative and if available, an interpreter;

ii. Ask for additional information about the *Sample* collection process;

iii. Request a delay in reporting to the Doping Control Station for valid reasons; and

iv. Request modifications as provided for in Annex B – Modifications for *Athletes* with disabilities.

e) Of the *Athlete's* responsibilities, including the requirement to:

i. Remain within direct observation of the DCO/Chaperone at all times from the point of notification by the DCO/Chaperone until the completion of the *Sample* collection procedure;

ii. Produce identification in accordance with Clause 5.3.4;

iii. Comply with *Sample* collection procedures (and the *Athlete* should be advised of the possible consequences of Failure to Comply); and

iv. Report immediately for a test, unless there are valid reasons for a delay, as determined in accordance with Clause 5.4.4.

f) Of the location of the Doping Control Station.

g) That should the *Athlete* choose to consume food or fluids prior to providing a *Sample*, he/she does so at his/her own risk, and should in any event avoid excessive rehydration, having in mind the requirement to produce a *Sample* with a Suitable Specific Gravity for Analysis.

h) That the *Sample* provided by the *Athlete* to the *Sample* Collection Personnel should be the first urine passed by the *Athlete* subsequent to notification, i.e., he/she should not pass urine in the shower or otherwise prior to providing a *Sample* to the *Sample* Collection Personnel.

5.4.2 When contact is made, the DCO/Chaperone shall:

a) From this time until the *Athlete* leaves the Doping Control Station at the end of his/her *Sample* Collection Session, keep the *Athlete* under observation at all times.

b) Identify themselves to the *Athlete* using the documentation referred to in Clause 5.3.3.

c) Confirm the *Athlete's* identity as per the criteria established in Clause 5.3.4. Confirmation of the *Athlete's* identity by any other method, or failure to confirm the identity of the *Athlete*, shall be documented and reported to the *ADO*.

d) In cases where the *Athlete's* identity cannot be confirmed as per the criteria established in Clause 5.3.4, the *ADO* shall decide whether it is appropriate

to follow up in accordance with Annex A – Investigating a possible failure to comply.

5.4.3 Chaperone/DCO shall then have the *Athlete* sign an appropriate form to acknowledge and accept the notification. If the *Athlete* refuses to sign that he/she has been notified, or evades the notification, the Chaperone/DCO shall if possible inform the *Athlete* of the consequences of refusing or failing to comply, and the Chaperone (if not the DCO) shall immediately report all relevant facts to the DCO. When possible the DCO shall continue to collect a *Sample*. The DCO shall document the facts in a detailed report and report the circumstances to the *ADO*. The *ADO* shall follow the steps prescribed in Annex A – Investigating a Possible Failure to Comply.

5.4.4 The DCO/Chaperone may at their discretion consider any reasonable third party requirement or any request by the *Athlete* for permission to delay reporting to the Doping Control Station following acknowledgement and acceptance of notification, and/or to leave the Doping Control Station temporarily after arrival, and may grant such permission if the *Athlete* can be continuously chaperoned and kept under direct observation during the delay and if the request relates to the following activities:

For *In-Competition Testing*:

a) Participation in a victory ceremony;
b) Fulfilment of media commitments;
c) Competing in further *Competitions*;
d) Performing a warm down;
e) Obtaining necessary medical treatment;
f) Locating a representative and/or interpreter;
g) Obtaining photo identification; or
h) Any other exceptional circumstances which may be justified, and which shall be documented.

For *Out-of-Competition Testing*:

a) Locating a representative;
b) Completing a training session;
c) Receiving necessary medical treatment;
d) Obtaining photo identification;
e) Any other exceptional circumstances which can be justified, and which shall be documented.

5.4.5 The DCO or other authorised *Sample* Collection Personnel shall document any reasons for delay in reporting to the Doping Control Station and/or reasons for leaving the Doping Control Station that may require further investigation by the

ADO. Any failure of the *Athlete* to remain under constant observation should also be recorded.

5.4.6 A DCO/Chaperone shall reject a request for delay from an *Athlete* if it will not be possible for the *Athlete* to be continuously chaperoned.

5.4.7 If the *Athlete* delays reporting to the Doping Control Station other than in accordance with Clause 5.4.4 but arrives prior to the DCO's departure, the DCO shall decide whether to process a possible Failure to Comply. If at all possible the DCO shall proceed with collecting a *Sample*, and shall document the details of the delay in the *Athlete* reporting to the Doping Control Station.

5.4.8 If, while keeping the *Athlete* under observation, *Sample* Collection Personnel observe any matter with potential to compromise the test, the circumstances shall be reported to and documented by the DCO. If deemed appropriate by the DCO, the DCO shall follow the requirements of Annex A – Investigating a Possible Failure to Comply, and/or consider if it is appropriate to collect an additional *Sample* from the *Athlete*.

6.0 Preparing for the *Sample* Collection Session

6.1 Objective

To prepare for the *Sample* Collection Session in a manner that ensures that the session can be conducted efficiently and effectively.

6.2 General

Preparing for the *Sample* Collection Session starts with the establishment of a system for obtaining relevant information for effective conduct of the session and ends when it is confirmed that the *Sample* Collection Equipment conforms to the specified criteria.

The main activities are:

a) Establishing a system for collecting details regarding the *Sample* Collection Session;

b) Establishing criteria for who may be present during a *Sample* Collection Session;

c) Ensuring that the Doping Control Station meets the minimum criteria prescribed in Clause 6.3.2;

d) Ensuring that the *Sample* Collection Equipment used by the *ADO* meets the minimum criteria prescribed in Clause 6.3.4.

6.3 Requirements for preparing for the *Sample* Collection Session

6.3.1 The *ADO* shall establish a system for obtaining all the information necessary to ensure that the *Sample* Collection Session can be conducted effectively, including special requirements to meet the needs of *Athletes* with disabilities (as

provided in Annex B – Modifications for *Athletes* with disabilities) as well as the needs of *Athletes* who are *Minors* (as provided in Annex C – Modifications for *Athletes* who are Minors).

6.3.2 The DCO shall use a Doping Control Station which, at a minimum, ensures the *Athlete's* privacy and where possible is used solely as a Doping Control Station for the duration of the *Sample* Collection Session. The DCO shall record any significant deviations from these criteria.

6.3.3 The *ADO* shall establish criteria for who may be authorized to be present during the *Sample* Collection Session in addition to the *Sample* Collection Personnel. At a minimum the criteria shall include:

a) An *Athlete's* entitlement to be accompanied by a representative and/or interpreter during the *Sample* Collection Session except when the *Athlete* is passing a urine *Sample;*

b) A *Minor Athlete's* entitlement (as provided for in Annex C – Modifications for Athletes who are Minors), and the witnessing DCO/Chaperone's entitlement to have a representative observe the witnessing DCO/Chaperone when the *Minor Athlete* is passing a urine *Sample*, but without the representative directly observing the passing of the *Sample* unless requested to do so by the *Minor Athlete*;

c) The entitlement of an *Athlete* with a disability to be accompanied by a representative as provided for in Annex B - Modifications for *Athletes* with disabilities;

d) A *WADA* Independent Observer where applicable under the *Independent Observer Program*. The *WADA* Independent Observer shall not directly observe the passing of a urine *Sample*.

6.3.4 The ADO shall only use *Sample* Collection Equipment systems which, at a minimum, meet the following criteria. They shall:

a) Have a unique numbering system incorporated into all bottles, containers, tubes or other item used to seal the *Sample*;

b) Have a sealing system that is tamper evident;

c) Ensure the identity of the *Athlete* is not evident from the equipment itself; and

d) Ensure that all equipment is clean and sealed prior to use by the *Athlete.*

6.3.5 The *ADO* shall develop a system for recording the Chain of Custody of the *Samples* and *Sample* collection documentation which includes confirming that both the S*ample*s and *Sample* collection documentation have arrived at their intended destinations.

[6.3.5 Comment: Information as to how a Sample is stored prior to departure from the Doping Control Station may be recorded on (for example) a post-mission report. When the Sample is taken from the Doping Control Station, each

transfer of custody of the Sample from one person to another, e.g. from the DCO to the courier, or from the DCO to the laboratory, should be documented, up until the Sample arrives at its intended destination.]

7.0 Conducting the *Sample* Collection Session

7.1 Objective

To conduct the *Sample* Collection Session in a manner that ensures the integrity, security and identity of the *Sample* and respects the privacy of the *Athlete.*

7.2 General

The *Sample* Collection Session starts with defining overall responsibility for the conduct of the *Sample* Collection Session and ends once the *Sample* collection documentation is complete.

The main activities are:

a) Preparing for collecting the *Sample*;

b) Collecting and securing the *Sample;* and

c) Documenting the *Sample* collection.

7.3 Requirements prior to *Sample* collection

7.3.1 The *ADO* shall be responsible for the overall conduct of the *Sample* Collection Session, with specific responsibilities delegated to the DCO.

7.3.2 The DCO shall ensure that the *Athlete* has been informed of his/her rights and responsibilities as specified in Clause 5.4.1.

7.3.3 The DCO shall provide the *Athlete* with the opportunity to hydrate. The *Athlete* should avoid excessive rehydration, having in mind the requirement to provide a *Sample* with a Suitable Specific Gravity for Analysis.

7.3.4 The *Athlete* shall only leave the Doping Control Station under continuous observation by the DCO/Chaperone and with the approval of the DCO. The DCO shall consider any reasonable request by the *Athlete* to leave the Doping Control Station, as specified in Clauses 5.4.5 and 5.4.6, until the *Athlete* is able to provide a *Sample*.

7.3.5 If the DCO gives approval for the *Athlete* to leave the Doping Control Station, the DCO shall agree with the *Athlete* on the following conditions of leave:

a) The purpose of the *Athlete* leaving the Doping Control Station; and

b) The time of return (or return upon completion of an agreed activity); and

c) That the *Athlete* must remain under observation at all times; and

d) That the *Athlete* shall not pass urine until he/she gets back to the Doping Control Station; and

the DCO shall document the actual time of the *Athlete's* departure and return.

7.4 Requirements for *Sample* collection

7.4.1 The DCO shall collect the *Sample* from the *Athlete* according to the following protocol/s for the specific type of *Sample* collection:

a) Annex D: Collection of urine *Samples*;

b) Annex E: Collection of blood *Samples.*

7.4.2 Any behaviour by the *Athlete* and/or persons associated with the *Athlete* or anomalies with potential to compromise the *Sample* collection shall be recorded in detail by the DCO. If appropriate, the *ADO* shall institute Annex A – Investigating a possible Failure to Comply.

7.4.3 If there are doubts as to the origin or authenticity of the *Sample*, the *Athlete* shall be asked to provide an additional *Sample*. If the *Athlete* refuses to provide an additional *Sample*, the DCO shall document in detail the circumstances around the refusal, and the ADO shall institute Annex A – Investigating a possible Failure to Comply.

7.4.4 The DCO shall provide the *Athlete* with the opportunity to document any concerns he/she may have about how the *Sample* Collection Session was conducted.

7.4.5 In conducting the *Sample* Collection Session the following information shall be recorded as a minimum:

a) Date, time and type of notification (*No Advance Notice*, advance notice*, In-Competition* or *Out-of-Competition*);

b) Arrival time at Doping Control Station;

c) Date and time of *Sample* provision;

d) The name of the *Athlete*;

e) The date of birth of the *Athlete;*

f) The gender of the *Athlete*;

g) The *Athlete's* home address and telephone number;

h) The *Athlete's* sport and discipline;

i) The name of the *Athlete's* coach and doctor;

j) The *Sample* code number;

k) The name and signature of the witnessing DCO/Chaperone;

l) The name and signature of the Blood Collection Officer (where applicable);

m) Required laboratory information on the *Sample;*

n) Medications and supplements taken and recent blood transfusion details (if applicable) within the timeframe specified by the laboratory, as declared by the *Athlete;*

o) Any irregularities in procedures;

p) *Athlete* comments or concerns regarding the conduct of the *Sample* Collection Session, if provided;

q) *Athlete* consent for the processing of test data in ADAMS;

r) *Athlete* consent or otherwise for the use of the *Sample*(s) for research purposes;

s) The name and signature of the *Athlete's* representative (if applicable), as per Clause 7.4.6;

t) The name and signature of the *Athlete*; and

u) The name and signature of the DCO.

7.4.6 At the conclusion of the *Sample* Collection Session the *Athlete* and DCO shall sign appropriate documentation to indicate their satisfaction that the documentation accurately reflects the details of the *Athlete's Sample* Collection Session, including any concerns recorded by the *Athlete.* The *Athlete's* representative (if any) and the *Athlete* shall both sign the documentation if the *Athlete* is a *Minor.* Other persons present who had a formal role during the *Athlete's Sample* Collection Session may sign the documentation as a witness of the proceedings.

7.4.7 The DCO shall provide the *Athlete* with a copy of the records of the *Sample* Collection Session that have been signed by the *Athlete*.

8.0 Security/Post test administration

8.1 Objective

To ensure that all *Samples* collected at the Doping Control Station and *Sample* collection documentation are securely stored prior to their departure from the Doping Control Station.

8.2 General

Post test administration begins when the *Athlete* has left the Doping Control Station after providing his/her *Sample/s*, and ends with preparation of all of the collected *Samples* and *Sample* collection documentation for transport.

8.3 Requirements for security/post test administration

8.3.1 The *ADO* shall define criteria ensuring that any *Sample* will be stored in a manner that protects its integrity, identity and security prior to transport from the

Doping Control Station. The DCO shall ensure that any *Sample* is stored in accordance with these criteria.

8.3.2 The *ADO*/DCO shall develop a system to ensure that the documentation for each *Sample* is completed and securely handled.

8.3.3 The *ADO* shall develop a system to ensure that, where required, instructions for the type of analysis to be conducted are provided to the *WADA*- accredited laboratory or as otherwise approved by *WADA*.

9.0 Transport of *Samples* and documentation

9.1 Objective

a) To ensure that *Samples* and related documentation arrive at the *WADA*-accredited laboratory or as otherwise approved by *WADA* in proper condition to do the necessary analysis, and

b) To ensure the *Sample* Collection Session documentation is sent by the DCO to the *ADO* in a secure and timely manner.

9.2 General

Transport starts when the *Samples* and related documentation leave the Doping Control Station and ends with the confirmed receipt of the *Samples* and *Sample* Collection Session documentation at their intended destinations.

The main activities are arranging for the secure transport of *Samples* and related documentation to the *WADA*-accredited laboratory or as otherwise approved by *WADA*, and arranging for the secure transport of *Sample* Collection Session documentation to the *ADO*.

9.3 Requirements for transport and storage of *Samples* and documentation

9.3.1 The *ADO* shall authorise a transport system that ensures *Samples* and documentation will be transported in a manner that protects their integrity, identity and security.

9.3.2 *Samples* shall always be transported to the *WADA*-accredited laboratory (or as otherwise approved by *WADA*), using the *ADO's* authorised transport method, as soon as practicable after the completion of the *Sample* Collection Session. *Samples* shall be transported in a manner which minimizes the potential for *Sample* degradation due to factors such as time delays and extreme temperature variations.

[9.3.2 Comment: ADOs should discuss transportation requirements for particular missions with the laboratory they are using for analysis of the Samples, to establish what is necessary (e.g., whether refrigeration or freezing of Samples is necessary) in the particular circumstances of such mission(s).]

9.3.3 Documentation identifying the *Athlete* shall not be included with the *Samples* or documentation sent to the *WADA*-accredited laboratory or as otherwise approved by *WADA*.

9.3.4 The DCO shall send all relevant *Sample* Collection Session documentation to the *ADO* using the *ADO's* authorised transport method as soon as practicable after the completion of the *Sample* Collection Session.

9.3.5 Chain of Custody shall be checked by the *ADO* if receipt of either the *Samples* with accompanying documentation or *Sample* Collection Session documentation is not confirmed at their intended destination or a *Sample*'s integrity or identity may have been compromised during transport. In this instance, the *ADO* shall consider whether the *Sample* should be voided.

9.3.6 Documentation related to a *Sample* Collection Session and/or an anti-doping rule violation shall be stored by the *ADO* for a minimum of 8 years as per *Code* Article 17.

10.0 Ownership of Samples

10.1 The *ADO* which initiates *Testing* on the *Athlete* owns the *Samples* collected from the *Athlete*.

10.2 The *ADO* which initiates *Testing* on the *Athlete* may transfer ownership of the *Samples* to the *ADO* exercising results management authority in relation to such *Testing*.

11.0 *Athlete* Whereabouts Requirements

11.1 Objective/general principles

11.1.1 It is recognised and accepted that (a) *No Advance Notice Out-of-Competition Testing* is at the core of effective *Doping Control*; and (b) without accurate information as to an *Athlete's* whereabouts, such *Testing* can be inefficient and often impossible.

[11.1.1 Comment: Such recognition is the fundamental rationale underlying Code Article 2.4 and this Section 11 of the International Standard for Testing.]

11.1.2 Therefore, in addition to developing a Test Distribution Plan in accordance with Section 4 of this *International Standard*, each IF and *NADO* shall create a *Registered Testing Pool* of *Athletes* meeting criteria specified by the IF/*NADO* (as applicable): see Clause 11.2 and, in relation to *Team Sports*, Clause 11.5. *Athletes* in a *Registered Testing Pool* shall be subject to and required to comply with the *Athlete* whereabouts requirements set out in this Section 11: see *Code* Article 14.3.

11.1.3 An *Athlete* in a *Registered Testing Pool* is required to make a quarterly Whereabouts Filing that provides accurate and complete information about the *Athlete's* whereabouts during the forthcoming quarter, including identifying where

he/she will be living, training and competing during that quarter, so that he/she can be located for *Testing* at any time during that quarter: see Clause 11.3. A failure to do so amounts to a Filing Failure and therefore a Whereabouts Failure for purposes of *Code* Article 2.4.

11.1.4 An *Athlete* in a *Registered Testing Pool* is also required to specify in his/her Whereabouts Filing, for each day in the forthcoming quarter, one specific 60-minute time slot where he/she will be available at a specified location for *Testing*: see Clause 11.4. This does not limit in any way the *Athlete's* obligation to be available for *Testing* at any time and place. Nor does it limit his/her obligation to provide the information specified in Clause 11.3 as to his/her whereabouts outside of that 60-minute time slot. However, if the *Athlete* is not available for *Testing* at such location during the 60-minute time slot specified for that day in his/her Whereabouts Filing, and has not updated his/her Whereabouts Filing prior to that 60-minute time slot to provide an alternative time slot/location for that day, that failure shall amount to a Missed Test and shall therefore constitute a Whereabouts Failure for purposes of *Code* Article 2.4.

[11.1.4 Comment: The purpose of the 60-minute time slot is to strike a balance between the need to locate the Athlete for Testing and the impracticality and unfairness of making Athletes potentially accountable for a Missed Test every time they depart from their previously-declared routine. ADOs that implemented whereabouts systems in the period up to 2008 reflected that tension in different ways. Some demanded "24/7" whereabouts information, but did not declare a Missed Test if an Athlete was not where he/she had said he/she would be unless (a) he/she could still not report for Testing despite being given notice in the form of a phone call; or (b) the following day he/she was still not where he/she had said he/she would be. Others asked for details of the Athlete's whereabouts for only one hour per day, but held the Athlete fully accountable during that period, which gave each side certainty but limited the ADO's ability to test the Athlete outside that hour. After extensive consultation with stakeholders with substantial whereabouts experience, the view was taken that the best way to maximize the chances of finding the Athlete at any time, while providing a reasonable and appropriate mitigation of "24/7" Missed Test liability, was to combine the best elements of each system, i.e. requiring disclosure of whereabouts information on a "24/7" basis, while limiting exposure to a Missed Test to a 60-minute time slot. (For discussion of how this will work in practice, see the comment to Clause 11.4.1).]

11.1.5 More than one *ADO* may have jurisdiction to test an *Athlete* in a *Registered Testing Pool* (see *Code* Article 15) and therefore (where an attempt to test the *Athlete* is unsuccessful and the requirements of Clause 11.5.3 are satisfied) to record a Missed Test against that *Athlete.* That Missed Test shall be recognized by other *ADOs* in accordance with *Code* Article 15.4.

11.1.6 An *Athlete* in a *Registered Testing Pool* shall be deemed to have committed an anti-doping rule violation under *Code* Article 2.4 if he/she commits a total of three Whereabouts Failures (which may be any combination of Filing Failures

and/or Missed Tests adding up to three in total) within any 18 (eighteen) month period, irrespective of which *ADO(s)* has/have declared the Whereabouts Failures in question.

[11.1.6 Comment: While a single Whereabouts Failure will not amount to an anti-doping rule violation under Code Article 2.4, it may, if the circumstances are particularly flagrant, amount to an anti-doping rule violation under Code Article 2.3 (evading Sample collection) and/or Code Article 2.5 (Tampering or Attempted Tampering with Doping Control). Nothing in this International Standard is intended to prevent an ADO from treating a Whereabouts Failure as an anti-doping rule violation under one or both such Articles where the circumstances warrant (without prejudice to the ability subsequently to rely on it as a Whereabouts Failure under Code Article 2.4).

Only Athletes who have been designated for inclusion in a Registered Testing Pool, in accordance with Code Article 14.3, are subject to the whereabouts requirements set out in this Section 11. Other Athletes are not subject to those whereabouts requirements. However, nothing in this International Standard prevents an ADO developing different whereabouts requirements for Athletes outside the Registered Testing Pool. For example:

a. *where the circumstances warrant, an ADO may identify certain "high risk" Athletes under its jurisdiction who should be subject to stricter whereabouts requirements (such as an expansion of the time slots during which an Athlete may be held liable for a missed test if he/she is not available for Testing, e.g. to incorporate regular training periods); and/or*

b. *an ADO may identify a pool of Athletes (e.g. those Athletes who were in a larger Registered Testing Pool that it maintained prior to the introduction of IST v.4.0) who may be made subject to lesser whereabouts requirements (e.g. filing of place of residence and regular training, competing and other regular activities, but no specific 60-minute time slot requirement).*

In this manner, a range (or pyramid) of different testing pools may be established by an ADO, with different whereabouts requirements applying to each pool. And any failure to comply with such requirements may be deemed a Whereabouts Failure for purposes of Code Article 2.4.

The difference arises when it comes to combining Whereabouts Failures declared under different rules. Where an Athlete is in a Registered Testing Pool, only Whereabouts Failures declared against him/her based on rules consistent with this Section 11 are to be combined for purposes of Code Article 2.4. Where the Athlete is in a different testing pool, to which other whereabouts requirements apply, then the rules of the ADO that put him/her in that pool shall determine to what extent Whereabouts Failures declared against the Athlete under other rules shall be combined with Whereabouts Failures declared under that ADO's rules for purposes of Code Article 2.4.]

11.1.7 The 18-month period referred to in Clause 11.1.6 starts to run on the date that an *Athlete* commits a Whereabouts Failure. It is not affected by any successful *Sample* collection conducted with respect to that *Athlete* during the 18-month period, i.e., if three Whereabouts Failures occur during the 18-month period then a *Code* Article 2.4 anti-doping rule violation is committed, irrespective of any *Samples* successfully collected from the *Athlete* during that 18-month period. However, if an *Athlete* who has committed one Whereabouts Failure does not go on to commit a further two Whereabouts Failures within 18 months of the first, at the end of that 18-month period the first Whereabouts Failure "expires" for purposes of Clause 11.1.6.

[11.1.7 Comment: If an Athlete commits two Whereabouts Failures, but then does not commit a third within 18 months of the first, then the first Whereabouts Failure "expires" and a new 18-month period begins to run from the date of the second Whereabouts Failure.

For purposes of determining whether a Whereabouts Failure has occurred within the 18-month period referred to in Clause 11.1.6:

a. a Filing Failure will be deemed to have occurred on the first day of the quarter for which the Athlete fails to make the required filing, or (in the case of any subsequent Filing Failure in the same quarter) on the day that the deadline specified in accordance with Clause 11.3.8 expires; and

b. a Missed Test will be deemed to have occurred on the date that the Sample collection was unsuccessfully attempted.]

11.1.8 Transitional arrangements:

a. This January 2009 version of the *International Standard* for *Testing*, including (without limitation) the provisions relating to the combination of Whereabouts Failures declared by different *ADOs* for the purposes of *Code* Article 2.4, shall apply in full to all Whereabouts Failures occurring after 1 January 2009.

[11.1.8(a) Comment: Nothing in this Standard precludes an ADO prior to 1 January 2009 establishing its Registered Testing Pool for purposes of this Section 11, notifying Athletes that they have been included in that pool, and collecting Whereabouts Filings from them for the quarter beginning 1 January 2009.]

b. Where an *Athlete* has failed to comply with any whereabouts requirements declared in accordance with the then-applicable rules of the *ADO* in question in the 18-month period up to 1 January 2009, questions about whether such failures may be combined with each other and/or with post-1 January 2009 Whereabouts Failures for purposes of *Code* Article 2.4 shall be determined by reference to *Code* Article 25.2.

[11.1.8(b) Comment: Nothing in this Standard precludes an ADO providing in its rules that it will recognise whereabouts violations declared by other ADOs, even prior to 1 January 2009, where such whereabouts violations are made public by the ADO(s) in question. Furthermore, an ADO may put an Athlete on notice that whereabouts failures committed subsequent to the notice but prior to 1 January 2009 will be combined with Whereabouts Failures committed after 1 January 2009 for purposes of Code Article 2.4.]

11.2 Requirements for establishing the *Registered Testing Pool*

11.2.1 Each IF shall define the criteria for *Athletes* to be included in the international *Registered Testing Pool* for its sport, and shall publish those criteria as well as a list of the *Athletes* meeting those criteria (and so included in the international *Registered Testing Pool*) for the period in question. The criteria used should reflect the IF's evaluation of the risks of *Out-of-Competition* doping in that sport: see Clause 4.2. While such criteria (and therefore the number of *Athletes* in the *Registered Testing Pool*) may vary from sport to sport, an IF must be able to demonstrate it has made a proper assessment of the relevant risks and has adopted appropriate criteria based on the results of that assessment.

[11.2.1 Comment: As a general principle, it is expected that an international Registered Testing Pool will include Athletes who compete regularly at the highest level of international competition (e.g. candidates for Olympic, Paralympic or World Championship medals), determined by rankings or other suitable criteria. In accordance with Clause 4.4.4, an appropriate proportion of the Out-of-Competition tests specified in the IF's Test Distribution Plan must be carried out on Athletes in the international Registered Testing Pool.

In relation to options for the fixing of the Registered Testing Pool in a Team Sport, see Clause 11.5.1.]

11.2.2 Each *NADO* shall define the criteria for *Athletes* to be included in its national *Registered Testing Pool* from the sports that it has included in its Test Distribution Plan, and shall publish those criteria as well as a list of the *Athletes* meeting those criteria (and so included in the national *Registered Testing Pool*) for the period in question. The criteria used should reflect the *NADO's* evaluation of the risks of *Out-of-Competition* doping in such sports (see Clause 4.3), as well as the national anti-doping policy imperatives referenced in Clause 4.3.1. While such criteria may vary from nation to nation, a *NADO* must be able to demonstrate it has made a proper assessment of the relevant risks and has adopted appropriate criteria based on the results of that assessment.

[11.2.2 Comment: As a general principle, unless good reason exists otherwise, it is expected that the national Registered Testing Pool will include (i) Athletes over which the NADO has jurisdiction that have been included in an international Registered Testing Pool; (ii) Athletes who are part of national teams in Olympic, Paralympic or other sports of high national priority (or who may be selected for

such teams); and (iii) Athletes who train independently but perform at Olympic/Paralympic or World Championship level and may be selected for such events.

An example of a reason why a particular Athlete in one of these categories might not be included in the national Registered Testing Pool would be if such inclusion was inconsistent with the NADO's national anti-doping policy imperatives, as referenced in Clause 4.3.1.

In accordance with Clause 4.4.4, where Athletes from a particular sport are included in a national Registered Testing Pool, an appropriate proportion of the Out-of-Competition tests allocated to that sport in the NADO's Test Distribution Plan must be carried out on such Athletes.]

11.2.3 The *ADO* should include in its *Registered Testing Pool* (a) those *Athletes* under its jurisdiction who are serving periods of *Ineligibility* (see *Code* Article 10.11); and (b) those *Athletes* under its jurisdiction who retired at a time when they were in its *Registered Testing Pool* and who wish to return from that period of retirement to active participation in the sport (see *Code* Article 5.4). The *ADO* may also include in its *Registered Testing Pool* those *Athletes* under its jurisdiction whom it wishes to target for *Testing*.

11.2.4 The *ADO* shall periodically review and update as necessary its criteria for including *Athletes* in its *Registered Testing Pool.* In addition, the *ADO* shall periodically review its published list of *Athletes* in its *Registered Testing Pool* to ensure that each listed *Athlete* continues to meet such criteria. *Athletes* who no longer meet the criteria should be removed from the *Registered Testing Pool* and *Athletes* who meet the criteria should be added to the *Registered Testing Pool*. The *ADO* must advise such *Athletes* of the change in their status, and publish a new list of *Athletes* in the *Registered Testing Pool*, without delay.

[11.2.4 Comment: see Clause 11.5.2 for a discussion of the application of this Clause 11.2.4 in the context of Registered Testing Pools defined by reference to teams.]

11.2.5 An *Athlete* who has been included in a *Registered Testing Pool* shall continue to be subject to the whereabouts requirements set out in this Section 11 unless and until:

a. he/she has been given written notice by the Responsible ADO that he/she is no longer designated for inclusion in its *Registered Testing Pool*; or

b. he/she retires from competition in the sport in question in accordance with the applicable rules and gives written notice to his/her IF or *NADO* or both (as applicable) to that effect.

[11.2.5(a) Comment: The applicable rules may also require that notice of retirement be sent to the Athlete's National Federation.

Where an Athlete retires from but then returns to sport, his/her period of retirement/non-availability for Out-of-Competition Testing shall be disregarded for purposes of calculating the 18-month period referred to in Code Article 2.4 and Clause 11.1.5. As a result, Whereabouts Failures committed by the Athlete prior to retirement may be combined, for purposes of Code Article 2.4, with Whereabouts Failures committed by the Athlete after his/her return from retirement/non-availability for Out-of-Competition Testing. For example, if an Athlete committed two Whereabouts Failures in the 12 months prior to his/her retirement, then if he/she commits another Whereabouts Failure in the first six months after his/her return from retirement/non-availability for Out-of-Competition Testing, this amounts to a Code Article 2.4 anti-doping rule violation.]

11.2.6 For co-ordination purposes, the *ADO* shall make available to other relevant *ADOs* and *WADA* the criteria that the *ADO* has established for inclusion of *Athletes* in its *Registered Testing Pool,* the current list of *Athletes* in its *Registered Testing Pool,* and updates as necessary: see *Code* Article 14.3.

11.3 Whereabouts Filing Requirements

[11.3 Comment: ADOs are encouraged to use the ADAMS system to facilitate the information-sharing required under this Section 11.

See Clause 11.5.5 for a discussion of the application of this Clause 11.3 in the context of Team Sports.]

11.3.1 On a date specified by the Responsible ADO that is prior to the first day of each quarter (i.e. 1 January, 1 April, 1 July and 1 October, respectively), an *Athlete* in a *Registered Testing Pool* must file a Whereabouts Filing with his/her IF (if the *Athlete* has been included in its international *Registered Testing Pool*) or his/her *NADO* (if the *Athlete* has been included in its national *Registered Testing Pool*) that contains at least the following information:

[11.3.1 Comment: If an Athlete is included in both an international Registered Testing Pool and a national Registered Testing Pool, then his/her IF and NADO should seek to agree on who will be responsible for receiving his/her Whereabouts Filings and advise the Athlete accordingly. In the absence of any such agreement, WADA shall determine whether the IF or the NADO shall be responsible. The Athlete should file his/her Whereabouts Filing only with the Responsible ADO, who will then share that information with the Athlete's IF/NADO (as applicable) and other ADOs with jurisdiction to test the Athlete, in accordance with Clause 11.7.3(c). In such cases, it will still be necessary for the IF/NADO (as applicable) that is not the Responsible ADO to notify the Athlete that he/she is also in its Registered Testing Pool, in accordance with Clause 11.7.1(b).]

a. a complete mailing address where correspondence may be sent to the *Athlete* for formal notice purposes. Any notice or other item mailed to that

address will be deemed to have been received by the *Athlete* five working days after it was deposited in the mail;

[11.3.1(a) Comment: For these purposes, the Athlete should specify an address where he/she lives or otherwise knows that mail received there will be immediately brought to his/her attention. An ADO is encouraged also to supplement this basic provision with other notice and/or "deemed notice" provisions in its rules (for example, permitting use of fax, email, SMS text or other methods of service of notice; permitting proof of actual receipt as a substitute for deemed receipt; allowing notice to be served on the Athlete's National Federation if it is returned undelivered from the address supplied by the Athlete). The aim of such provisions should be to shorten the results management timelines set out in Clause 11.6.]

b. details of any disability of the *Athlete* that may affect the procedure to be followed in conducting a *Sample* collection session;

c. specific confirmation of the *Athlete's* consent to the sharing of his/her Whereabouts Filing with other *ADOs* having authority to test him/her: see *Code* Article 14.6;

d. for each day during the following quarter, the full address of the place where the *Athlete* will be residing (e.g. home, temporary lodgings, hotel, etc);

e. for each day during the following quarter, the name and address of each location where the *Athlete* will train, work or conduct any other regular activity (e.g. school), as well as the usual time-frames for such regular activities; and

[11.3.1(e) Comment: This requirement applies only to regular activities, i.e. activities that are part of the Athlete's regular routine. For example, if the Athlete's regular routine includes training at the gym, the pool and the track, and regular physio sessions, then the Athlete should provide the name and address of the gym, track, pool and physio in his or her Whereabouts Filing, and then set out his/her usual routine, e.g. "Mondays: 9-11 gym, 13-17 gym; Tuesdays: 9-11 gym, 16–18 gym; Wednesdays: 9–11 track, 3-5 physio; Thursdays: 9-12 gym 16-18 track; Fridays: 9-11 pool 3-5 physio; Saturdays: 9-12 track, 13-15 pool; Sundays: 9-11 track, 13-15 pool".

If the Athlete is not currently training, he/she should specify that in his/her Whereabouts Filing and detail any other routine that he/she will be following in the forthcoming filing period, e.g. his/her work routine, or school schedule, or rehab routine, or other routine, and identify the name and address of each location where that routine is conducted and the time-frame during which it is conducted.]

f. the *Athlete's* competition schedule for the following quarter, including the name and address of each location where the *Athlete* is scheduled to

compete during the quarter and the date(s) on which he/she is scheduled to compete at such location(s).

11.3.2 The Whereabouts Filing must also include, for each day during the following quarter, one specific 60-minute time slot between 6 a.m. and 11 p.m. each day where the *Athlete* will be available and accessible for *Testing* at a specific location.

[11.3.2 Comment: The Athlete can choose which location to identify for this 60-minute time slot. It could be the Athlete's place of residence, training or competition, or it could be another location (e.g. work or school). A failure to be available for Testing at the specified location during the specified time slot will be pursued as an apparent Missed Test, in accordance with Clause 11.6.3.]

11.3.3 When making a Whereabouts Filing, it is the *Athlete's* responsibility to ensure that he/she provides all of the information required accurately and in sufficient detail to enable any *ADO* wishing to do so to locate the *Athlete* for *Testing* on any given day in the quarter, including but not limited to during the 60-minute time slot specified for that day in the Whereabouts Filing.

[11.3.3 Comment: The Responsible ADO shall make ADAMS (or another centralized database of similar functionality and security) available to the Athlete or else provide other electronic filing form(s) or paper form(s) to use in making an Whereabouts Filing. WADA will make a template form available for use/adaptation by ADOs.

Where an Athlete does not know precisely what his/her whereabouts will be at all times during the forthcoming quarter, he/she must provide his/her best information, based on where he/she expects to be at the relevant times, and then update that information as necessary in accordance with Clause 11.4.2. ADOs should provide appropriate mechanisms (e.g. phone, fax, Internet, email, SMS) to facilitate the filing of such updates.

When specifying a location in his/her Whereabouts Filing (whether in his/her original quarterly filing or in an update), the Athlete must provide sufficient information to enable the DCO to find the location, to gain access to the location, and to find the Athlete at the location. For example, declarations such as "running in the Black Forest" are insufficient and are likely to result in a Whereabouts Failure. Similarly, specifying a location that the DCO cannot access (e.g. a "restricted-access" building or area) is likely to result in an unsuccessful attempt to test the Athlete and therefore a Whereabouts Failure.

In such circumstances, there are several possibilities:

a. *Where the ADO is able to determine the insufficiency of the information from the Whereabouts Filing itself, the ADO should pursue such insufficiency as an apparent Filing Failure, in accordance with Clause 11.6.2.*

b. Where the ADO only discovers the insufficiency of the information when it attempts to test the Athlete and is unable to locate him/her:

i. if the insufficient information relates to the 60-minute time slot, the ADO should pursue the matter as an apparent Missed Test, in accordance with Clause 11.6.3, and/or (where the circumstances warrant) as an evasion of Sample collection under Code Article 2.3, and/or as Tampering or Attempted Tampering with Doping Control under Code Article 2.5; and

ii. if the insufficient information relates to periods outside the 60-minute time slot, then the ADO should pursue the matter as an apparent Filing Failure, in accordance with Clause 11.6.4, and/or (where the circumstances warrant) as an evasion of Sample collection under Code Article 2.3, and/or as Tampering or Attempting to Tamper with Doping Control under Code Article 2.5.]

11.3.4 Any *Athlete* who provides fraudulent information in his/her Whereabouts Filing, whether in relation to his/her location during the specified daily 60-minute time slot, or in relation to his/her whereabouts outside that time slot, or otherwise, thereby commits an anti-doping rule violation under *Code* Article 2.3 (evading *Sample* collection) and/or *Code* Article 2.5 (*Tampering* or *Attempting* to *Tamper* with *Doping Control*).

[11.3.4 Comment: Any decision to treat an incident as evading Sample collection under Code Article 2.3 and/or as Tampering or Attempting to Tamper with Doping Control under Code Article 2.5 shall be without prejudice to the ADO's ability to treat the same incident as a Whereabouts Failure under Code Article 2.4; and vice versa.]

11.3.5 An *Athlete* may only be declared to have committed a Filing Failure where the Responsible ADO, following the results management procedure set out in Clause 11.6.2, can establish each of the following:

a. that the *Athlete* was duly notified (i) that he/she was designated for inclusion in a *Registered Testing Pool*, (ii) of the consequent requirement to make Whereabouts Filings; and (iii) of the consequences of any failure to comply with that requirement;

b. that the *Athlete* failed to comply with that requirement by the applicable deadline;

[11.3.5(a) Comment: An Athlete fails to comply with the requirement to make Whereabouts Filings in the following circumstances:

i. when he/she does not make any such filing; or

ii. *where he/she makes the filing (i.e. either the original quarterly filing or an update) but does not include all of the required information (e.g. he/she does not include the place where he/she will be residing for each day in the following quarter, or for each day covered by the update, or omits to declare a regular activity that he/she will be pursuing during the quarter, or during the period covered by the update); or*

iii. *where he/she includes information (whether in the original quarterly filing or an update) that is inaccurate (e.g. an address that does not exist) or insufficient to enable the ADO to locate him/her for Testing (e.g. "running in the Black Forest"). As noted in the comment to Clause 11.3.3, if the inaccuracy or insufficiency relates to the 60-minute time slot, and is only discovered when an attempt is made to test the Athlete during that time slot, that may be pursued as a Missed Test. In other circumstances, such inaccuracy or insufficiency should be pursued as a Filing Failure.]*

c. (in the case of a second or third Filing Failure in the same quarter) that he/she was given notice of the previous Filing Failure in accordance with Clause 11.6.2(a) and failed to rectify that Filing Failure by the deadline specified in that notice; and

[11.3.5(c) Comment: The purpose of this requirement is to ensure fairness to the Athlete. In the notice of the first Filing Failure that the Responsible ADO sends to the Athlete in accordance with Clause 11.6.2(a), the Responsible ADO must advise the Athlete that, in order to avoid a further Filing Failure, he/she must file the required Whereabouts Filing by the deadline specified in the notice. That deadline may be set by the ADO but it must be no less than 24 hours after receipt of the notice and not later than the end of the month in which the notice is received.]

d. that the *Athlete's* failure to comply was at least negligent. For these purposes, the *Athlete* will be presumed to have committed the failure negligently upon proof that he/she was notified of the requirement yet failed to comply with it. That presumption may only be rebutted by the *Athlete* establishing that no negligent behaviour on his/her part caused or contributed to the failure.

[11.3.5(d) Comment: In the event that a Code Article 2.4 anti-doping rule violation is established, the actual degree of fault involved on the part of the Athlete (i.e. negligence or greater) will be relevant to the assessment, under Code Article 10.3.3, of the period of Ineligibility to be imposed.]

11.3.6 An *Athlete* in a *Registered Testing Pool* may choose to delegate the making of some or all of his/her Whereabouts Filings required under Clauses 11.3.1 and 11.3.2 (and/or any updates to his/her Whereabouts Filings required under Clause 11.4.3) to a third party, such as (for example, and depending on the rules of the Responsible ADO) a coach, a manager or a National Federation, provided that the third party agrees to such delegation.

[11.3.6 Comment: See Clause 11.5.4 for a discussion of the application of this Clause 11.3.6 in the specific context of a Team Sport. For the avoidance of doubt, however, an Athlete in a sport that is not a Team Sport may also delegate the making of his/her Whereabouts Filings to a third party for some or all relevant periods, provided that the third party agrees.

The Responsible ADO may require written notice of any agreed delegation pursuant to Clause 11.3.6 to be filed with it, signed by both the Athlete in question and the third party delegate.]

11.3.7 In all cases, however, including in *Team Sports*:

a. each *Athlete* in an *Registered Testing Pool* remains ultimately responsible at all times for making accurate and complete Whereabouts Filings as required by this Clause 11.3, whether he/she makes each filing personally or delegates it to a third party (or a mixture of the two). It shall not be a defence to an allegation of a Filing Failure under *Code* Article 2.4 that the *Athlete* delegated such responsibility to a third party and that third party failed to comply with the applicable requirements; and

b. such *Athlete* remains personally responsible at all times for ensuring he/she is available for *Testing* at the whereabouts declared on his/her Whereabouts Filings, whether he/she made that filing personally or delegated it to a third party (or a mixture of the two). It shall not be a defence to an allegation of a Missed Test under *Code* Article 2.4 that the *Athlete* had delegated responsibility for filing his/her whereabouts information for the relevant period to a third party and that third party had failed to file the correct information or failed to update previously-filed information so as to ensure that the whereabouts information in the Whereabouts Filing for the day in question was current and accurate.

11.4 Availability for *Testing*

11.4.1 An *Athlete* in a *Registered Testing Pool* must specifically be present and available for *Testing* on any given day in the relevant quarter for the 60-minute time slot specified for that day in his/her Whereabouts Filing, at the location that the *Athlete* has specified for that time slot in such filing.

[11.4.1 Comment: This specific requirement is without prejudice to the Athlete's basic obligation to provide information as to his/her whereabouts generally during the forthcoming quarter, and to submit to Testing at any time and any place during that quarter.

To achieve Testing that is effective in deterring and detecting cheating, best practice requires test distribution planning that makes the timing of Testing unpredictable. To achieve this, Testing needs to be attempted at different times of the day. Thus,

the intent behind the 60-minute time slot is not to limit Testing to that period, or to create a 'default' period for Testing, but rather:

a. *to make it very clear when an unsuccessful attempt to test an Athlete will count as a Missed Test (which helps the Athlete to avoid a Missed Test and helps an ADO, as well as a hearing panel, to determine when there has been a Missed Test);*

b. *to guarantee that the Athlete can be found, and a Sample can be collected, at least once per day (which should deter cheating, or, as a minimum, make it far more difficult);*

c. *to increase the reliability of the rest of the whereabouts information provided by the Athlete, and so to assist the ADO in locating the Athlete for Testing outside the 60-minute time slot:*

   i. *The 60-minute time slot "anchors" the Athlete to a certain location for a particular day. Combined with the information that the Athlete must provide as to where he/she is residing, training, competing and conducting other 'regular' activities during that day, the ADO should be able to locate the Athlete for Testing outside the 60-minute time slot, or alternatively to determine whether the information provided as to his/her whereabouts outside that time slot is incomplete and/or inaccurate (which may be pursued, depending on the circumstances, as a Filing Failure under Code Article 2.4, a sample evasion case under Code Article 2.3, and/or a Tampering case under Code Article 2.5).*

   ii. *It is of course in the interests of the Athlete to provide as much information as possible about his/her whereabouts outside the 60-minute time slot, so that ADOs are able to test him/her outside the 60-minute time slot and therefore he/she never risks liability for a Missed Test; and*

d. *to generate useful anti-doping intelligence, e.g. if the Athlete regularly specifies time slots with large gaps between them, and/or changes his time slot and/or location at the last minute. Such intelligence can be relied upon as a basis for the Target Testing of such Athlete.]*

11.4.2 It is the *Athlete's* responsibility to ensure (including by updates, where necessary) that the whereabouts information provided in his/her Whereabouts Filing is sufficient to enable any *ADO* to locate him/her for *Testing* on any given day in the quarter, including but not limited to during the 60-minute time slot specified for that day in his/her Whereabouts Filing. Where any change in circumstances means that the information previously provided by or on behalf of the *Athlete* (whether in the initial Whereabouts Filing or in any subsequent update) is no longer accurate or complete (i.e. it is not sufficient to enable any *ADO* to locate the *Athlete* for *Testing*

on any given day in the relevant quarter, including but not limited to during the 60-minute time slot that he/she has specified for that day), the *Athlete* must update his/her Whereabouts Filing so that the information on file is again accurate and complete. He/she must make such update as soon as possible, and in any event prior to the 60-minute time slot specified in his/her filing for that day. A failure to do so shall have the following consequences:

a. if, as a result of such failure, an *ADO's* attempt to test the *Athlete* during the 60-minute time slot is unsuccessful, then the unsuccessful attempt shall be pursued as an apparent Missed Test in accordance with Clause 11.6.3; and

b. if the circumstances so warrant, the failure may be pursued as evasion of Sample collection under *Code* Article 2.3, and/or Tampering or Attempted Tampering with Doping Control under *Code* Article 2.5; and

c. in any event, the ADO shall consider Target Testing of the Athlete.

[11.4.2 Comment: It is the responsibility of the ADO to ensure that it checks for any updates filed by the Athlete prior to attempting to collect a Sample from the Athlete based on his/her Whereabouts Filing. For the avoidance of doubt, however, an Athlete who updates his/her 60-minute time slot for a particular day prior to the original 60-minute slot must still submit to Testing during the original 60-minute time slot, if he/she is located for Testing during that original 60-minute time slot.

An update of the 60-minute time slot may be made at any time up until the beginning of the time slot. In appropriate circumstances, however, last-minute updates by an Athlete may be pursued as a possible anti-doping rule violation of evading Sample collection under Code Article 2.3 and/or Tampering (or Attempting to Tamper) with Doping Control under Code Article 2.5.

If an update is filed by the Athlete, but the updated information filed is incomplete, or inaccurate, or insufficient to enable the ADO to locate the Athlete, then it may be pursued as a Filing Failure in accordance with Clause 11.3.5(b).]

11.4.3 An *Athlete* may only be declared to have committed a Missed Test where the Responsible ADO, following the results management procedure set out in Clause 11.6.3, can establish each of the following:

a. that when the *Athlete* was given notice that he/she had been designated for inclusion in a *Registered Testing Pool*, he/she was advised of his/her liability for a Missed Test if he/she was unavailable for *Testing* during the 60-minute time slot specified in his/her Whereabouts Filing at the location specified for that time slot;

b. that a DCO attempted to test the *Athlete* on a given day in the quarter, during the 60-minute time slot specified in the *Athlete's* Whereabouts Filing for that day, by visiting the location specified for that time slot;

[11.4.3(b) Comment: If the Athlete is not available for Testing at the beginning of the 60-minute time slot, but becomes available for Testing later on in the 60-minute time slot, the DCO should collect the Sample and should not process the attempt as an unsuccessful attempt to test, but should include full details of the delay in availability of the Athlete in the DCO's Sample collection report. Any pattern of behaviour of this type should be investigated by the Responsible ADO as a possible anti-doping rule violation of evading Sample collection under Code Article 2.3 or Code Article 2.5. It may also prompt Target Testing of the Athlete.

If located for Testing, the Athlete must remain with the DCO until the Sample collection has been completed, even if this takes longer than the 60-minute time slot.

If an Athlete is not available for Testing during his/her specified 60-minute time slot at the location specified for that time slot for that day, he/she will be liable for a Missed Test even if he/she is located later that day and a Sample is successfully collected from him/her.]

c. that during that specified 60-minute time slot, the DCO did what was reasonable in the circumstances (i.e. given the nature of the specified location) to try to locate the *Athlete*, short of giving the *Athlete* any *Advance Notice* of the test;

[11.4.3(c) Comment: Once the DCO has arrived at the location specified for the 60-minute time slot, if the Athlete cannot be located immediately then the DCO should remain at that location for whatever time is left of the 60-minute time slot and during that remaining time he/she should do what is reasonable in the circumstances to try to locate the Athlete.]

d. that the provisions of Clause 11.4.4 (if applicable) have been met; and

e. that the *Athlete's* failure to be available for *Testing* at the specified location during the specified 60-minute time slot was at least negligent. For these purposes, the *Athlete* will be presumed to have been negligent upon proof of the matters set out at sub-Clauses 11.4.3(a) to (d). That presumption may only be rebutted by the *Athlete* establishing that no negligent behaviour on his/her part caused or contributed to him/her (i) being unavailable for *Testing* at such location during such time slot; and (ii) failing to update his/her most recent Whereabouts Filing to give notice of a different location where he/she would instead be available for *Testing* during a specified 60-minute time slot on the relevant day.

[11.4.3(e) Comment: In the event that a Code Article 2.4 anti-doping rule violation is established, the actual degree of fault involved on the part of the Athlete (i.e. whether negligence or greater) will be relevant to the assessment, under Code Article 10.3.3, of the period of Ineligibility to be imposed.]

11.4.4 To ensure fairness to the *Athlete*, where an unsuccessful attempt has been made to test an *Athlete* during one of the 60-minute time slots specified in his/her Whereabouts Filing, any subsequent attempt to test that *Athlete* (by the same or any other *ADO*) may only be counted as a Missed Test against that *Athlete* if that subsequent attempt takes place after the *Athlete* has received notice, in accordance with Clause 11.6.3(b), of the original unsuccessful attempt.

11.5 Team Sports

[11.5 Comment: During the 2007-08 consultation phase on revisions to the 2007 Version 3.0 of the International Standard for Testing, a common theme of many of the submissions made by Team Sports was that any harmonised whereabouts system needs to be flexible enough to reflect the fact that Team Sports are organized and carried out on a team basis rather than on an individual basis, with most of the activities carried out in pursuit of that sport being conducted on a collective basis rather than on an individual basis. The purpose of this Clause 11.5 is to reflect that characteristic of Team Sports by allowing for a Registered Testing Pool to be defined by reference to teams. It also allows for whereabouts information in relation to Athletes on such teams to be submitted on a collective basis, with information as to the team's collective activities being supplemented by submission of individual whereabouts information for periods when the Athletes are not with the team. In line with the systems implemented in 2004-2007 in Team Sports such as water polo and rugby union, the individual Athlete remains personally responsible at all times for the accuracy of that whereabouts information and for making him/herself available for Testing at such whereabouts.]

11.5.1 An IF of a *Team Sport* may define its *Registered Testing Pool* by reference to teams, i.e. so that the *Athletes* in its *Registered Testing Pool* are some or all of the *Athletes* on particular teams within the relevant period.

[11.5.1 Comment: For example, an IF may choose to define its Registered Testing Pool by reference to its top-ranked national representative teams at any given time. In a year in which that IF's World Championships are played, it may choose to expand its Registered Testing Pool to include all of the national representative teams that have qualified to compete in the World Championships. In accordance with Clause 11.7.5, the IF may delegate the responsibility for collecting such Athletes' whereabouts information to the relevant National Federations.

A NADO that includes a Team Sport within its national Registered Testing Pool may take the same approach.]

11.5.2 In such circumstances, in accordance with Clause 11.2.4, to reflect the fact that membership of a team may change regularly, the IF shall issue rules addressing changes in the composition of the *Registered Testing Pool* during the relevant period.

[11.5.2 Comment: For example, in a Team Sport where a Registered Testing Pool is identified by reference to national representative teams, the IF might fix membership by reference to the Athletes included in the last national representative squad selected prior to the quarter in question. If a new squad is selected during the quarter that is different in composition from the prior squad, the IF's rules will determine whether the changes are reflected immediately (e.g., any Athlete from the first squad who is not in the second squad drops out of the Registered Testing Pool with immediate effect) or alternatively as of the beginning of the next quarter (i.e., the Athlete not in the second squad remains in the Registered Testing Pool until the end of the quarter).]

11.5.3 In a *Team Sport* where the *Registered Testing Pool* is defined by reference to teams, *Athletes* on the designated teams are likely to carry out most of their sporting activities (e.g., training, travelling, tactical sessions) on a collective basis. Accordingly, much of the whereabouts information required under Clause 11.3 will be the same for all of the *Athletes* on the team. Furthermore, on occasions when an *Athlete* on a team is not participating in a scheduled team collective activity (e.g. because of injury), he/she is likely to be pursuing other activities under the supervision of his/her team (e.g. treatment by a team doctor). Such team-based activities, collective or otherwise, shall be known, for purposes of this *International Standard* for *Testing*, as "Team Activity".

11.5.4 An Athlete who is included in a *Registered Testing Poo*l by reference to the fact that he/she plays for a particular team is subject to the same individual whereabouts requirements set out in this Section 11 as an *Athlete* who is included in a *Registered Testing Pool* by reference to some other criterion. In accordance with Clauses 11.3.6 and 11.3.7, however, in the circumstances outlined in Clause 11.5.3 the *Athlete* may delegate the task of making some or all of the Whereabouts Filings required under Clauses 11.3.1 and 11.3.2 (and/or any updates to Whereabouts Filings required under Clause 11.4.2) to the team, to be carried out by (for example, depending on the rules of the Responsible ADO) a coach, a manager or a National Federation.

[11.5.4 Comment: For the avoidance of doubt, for the sake of convenience and efficiency, an Athlete in a Team Sport may delegate the making of his/her Whereabouts Filings to his/her team not only in respect of periods of Team Activity but also in respect of periods where he/she is not with the team, provided the team agrees. In such circumstances, it will be necessary for the Athlete to provide the information as to his/her individual whereabouts for the period in question to the team, to supplement the information it provides in relation to Team Activities.

In those Team Sports where an Athlete may play for more than one team, and therefore may be involved in Team Activity for more than one team in any given filing period, clear provision should be made in the relevant rules for the collection and submission of the information required under Clause 11.3. For example, where an IF defines its Registered Testing Pool by reference to national representative teams, the Athletes on such teams may spend much of their time with their national

representative teams, competing in International Events, but they may also spend a significant amount of time with their clubs, competing in domestic and/or regional Events. In such circumstances, the National Federation should collect the information as to the Athlete's Team Activities for his/her club and include it in the Whereabouts Filing alongside the information as to the national representative team's Team Activities and the Athlete's individual whereabouts information for the relevant period.]

11.5.5 In the circumstances identified in Clause 11.5.4, the team (e.g. the National Federation) may make the Whereabouts Filing on behalf of its *Athletes*, providing the information required under Clause 11.3, as follows:

a. a complete mailing address for formal notice purposes, in accordance with Clause 11.3.1(a). Where agreed with the *Athlete*, this notice may be sent care of the team.

b. the information specified in Clauses 11.3.1(b), (c), (d) and (f);

c. for each day in the following quarter, the time(s) each day of any Team Activity, whether that is a collective activity (e.g. training) or an individual activity under the supervision of the team (e.g. medical treatment), along with the venue and any other details required in order for the Athlete to be located during the time(s) in question; and

[11.5.5(c) Comment: If the Athlete conducts other regular activities outside Team Activities (e.g., he is an amateur Athlete and therefore also works or goes to school), then the locations and time-frames of such other regular activities should also be disclosed, in accordance with Clause 11.3.1(e).]

d. for each day in the following quarter, one specific 60-minute time slot between 6 a.m. and 11 p.m. where the *Athlete* will be available and accessible for *Testing* at a specific location. For the avoidance of doubt, this 60-minute time slot may be during any Team Activity conducted on the day in question.

11.5.6 For *Athletes* in *Registered Testing Pools* in *Team Sports*, liability for Filing Failures shall be determined in accordance with Clause 11.3.5, and liability for Missed Tests shall be determined in accordance with Clause 11.4.2. In accordance with Clause 11.3.7:

a. if the team does not make a required Whereabouts Filing, or makes the Whereabouts Filing but does not include all of the required information, then (subject to the requirements of Clause 11.3.5) the *Athlete* will be liable for a Filing Failure under *Code* Article 2.4; and

b. if any of the required information changes after a Whereabouts Filing is made, then in accordance with Clause 11.4.2 an update must be filed so that

the Whereabouts Filing remains accurate at all times. If an update is not made, and as a result an attempt to test the *Athlete* during the 60-minute time slot is unsuccessful, then (subject to the requirements of Clause 11.4.3) the *Athlete* will be liable for a Missed Test under *Code* Article 2.4.

[11.5.6 Comment: For example, if an attempt to test an Athlete during a 60-minute time slot designated within a particular Team Activity period is unsuccessful due to a team official filing the wrong information in relation to the Team Activity, or failing to update previously-filed information where the details of the Team Activity have subsequently changed, the team may be liable for sanction under the applicable rules of the IF for such failure, but the Athlete him/herself will still be liable (assuming that the requirements of Clause 11.4.3 are satisfied) for a Missed Test. This must be the case because if an Athlete is able to blame his/her team if he/she is not available for Testing at a location declared by his team, then he/she will be able to avoid accountability for his/her whereabouts for Testing. Of course the team has the same interest as the Athlete in ensuring the accuracy of the Whereabouts Filing and avoiding any Whereabouts Failures on the part of the Athlete.]

11.5.7 In accordance with Clause 11.1.6, in addition to maintaining a *Registered Testing Pool* in accordance with the foregoing provisions of this Clause 11.5, an *ADO* in a *Team Sport* may establish one or more further testing pool(s) for other teams/*Athletes* under its jurisdiction, and may apply different whereabouts requirements to such pool(s) for purposes of *Code* Article 2.4.

[11.5.7 Comment: A good example of such an additional pool is the whereabouts pool maintained by the Football Association in England in the period 2006-08, consisting of all Athletes playing for certain teams. Under the FA's approach, which has been identified by FIFA and the IFs of certain other Team Sports as a useful model, a team designated for inclusion in such pool is responsible for making periodic whereabouts filings with the Football Association, declaring the names of the Athletes registered with the team and the team's training and competition schedule for the following period. In other words, the Football Association is advised of the collective whereabouts of the team during the Team Activities referred to in Clause 11.5.3. If an attempt is then made to test an Athlete on that team during such a Team Activity and the Athlete in question is not available for Testing at the specified location, then the Athlete is investigated for a potential Missed Test. If upon investigation it is determined that the Athlete was not available for Testing because the team failed to provide accurate information as to the Athlete's participation in and/or the location of the relevant Team Activity to the Football Association, then the team rather than the Athlete is subject to sanction. Otherwise, however, absent exceptional circumstances a Missed Test is declared against the Athlete.

Nothing in this Standard is intended to prevent ADOs in Team Sports from maintaining pools of this type, applying whereabouts requirements of this type. For the avoidance of doubt, this is to be done in addition to (not instead of) maintaining

a Registered Testing Pool in accordance with the foregoing provisions of this Clause 11.5, to which the full requirements of this Section 11 apply.]

11.6 Results Management

11.6.1 Annex A of the *International Standard* for *Testing* ("Investigating a possible Failure to Comply") shall not apply with respect to Whereabouts Failures. Instead, the provisions of this Clause 11.6 shall apply.

11.6.2 The results management process in respect of an apparent Filing Failure shall be as follows:

a. If it appears that all of the Clause 11.3.5 requirements relating to Filing Failures are satisfied, then no later than 14 (fourteen) days after the date of discovery of the apparent Filing Failure the Responsible ADO must send notice to the *Athlete* in question of the apparent Filing Failure, inviting a response within 14 (fourteen) days of receipt of the notice. In the notice, the Responsible ADO should warn the *Athlete*:

   i. that unless the *Athlete* persuades the Responsible ADO that there has not been any Filing Failure, then (subject to the remainder of the results management process set out below) an alleged Whereabouts Failure will be recorded against the *Athlete*; and

   ii. of the consequences to the *Athlete* if a hearing panel upholds the alleged Whereabouts Failure.

[11.6.2(a)(ii) Comment: The notice should advise the Athlete whether any other Whereabouts Failures have been alleged against him/her in the 18-month period prior to this alleged Whereabouts Failure.]

b. Where the *Athlete* disputes the apparent Filing Failure, the Responsible ADO must re-assess whether all of the Clause 11.3.5 requirements are met. The Responsible ADO must advise the *Athlete*, by letter sent no later than 14 (fourteen) days after receipt of the *Athlete's* response, whether or not it maintains there has been a Filing Failure.

[11.6.2(b) Comment: Any notice sent to an Athlete pursuant to Clause 11.6.2(b) agreeing that there has not been any Filing Failure shall also be sent to WADA and any other party/ies with a right of appeal under Code Article 13, and may be appealed by WADA and/or such other party/ies in accordance with that Article.]

c. If no response is received from the *Athlete* by the relevant deadline, or if the Responsible ADO maintains (notwithstanding the *Athlete's* response) that there has been a Filing Failure, the Responsible ADO shall send notice to the *Athlete* that an alleged Filing Failure is to be recorded against him/her.

The Responsible ADO shall at the same time advise the *Athlete* that he/she has the right to an administrative review of that decision;

d. Where it is requested by the *Athlete*, such administrative review shall be conducted by a designee of the Responsible ADO who was not involved in the previous assessment of the alleged Filing Failure. The review shall be based on written submissions only, and shall consider whether all of the requirements of Clause 11.3.5 are met. The review shall be completed within 14 (fourteen) days of receipt of the *Athlete's* request and the decision shall be communicated to the *Athlete* by letter sent no more than 7 (seven) days after the decision is made;

[11.6.2(d) Comment: Nothing in this Article prevents a sufficiently resourced ADO using a panel of up to three persons to conduct such administrative review, provided that none of those persons has been involved in the previous assessment of the alleged Filing Failure.]

e. If it appears, upon such review, that the requirements of Clause 11.3.5 have not been met, then the alleged Filing Failure shall not be treated as a Whereabouts Failure for any purpose; and

[11.6.2(e) Comment: Any notice sent to an Athlete pursuant to Clause 11.6.3(e), agreeing that there has been no Filing Failure, shall also be sent to WADA and any other party/ies with a right of appeal under Code Article 13, and may be appealed by WADA and/or such party/ies in accordance with that Article.]

f. If the *Athlete* does not request an administrative review of the alleged Filing Failure by the relevant deadline, or if the administrative review leads to the conclusion that all of the requirements of Clause 11.3.5 have been met, then the Responsible ADO shall record an alleged Filing Failure against the *Athlete* and shall notify the *Athlete* and (on a confidential basis) *WADA* and all other relevant *ADOs* of that alleged Filing Failure and the date of its occurrence.

[11.6.2(f) Comment: For the avoidance of doubt, the Responsible ADO is not precluded from notifying other relevant ADOs (on a strictly confidential basis) of the alleged Filing Failure at an earlier stage of the results management process. Rather, the Responsible ADO is entitled to do so, where it considers it appropriate (for test planning purposes or otherwise).

The Clause 11.6.2(f) notice should again advise the Athlete whether any other Whereabouts Failures have been alleged against him/her in respect of the 18-month period prior to this alleged Filing Failure.]

11.6.3 The results management process in the case of an apparent Missed Test shall be as follows:

a. The DCO shall file an Unsuccessful Attempt Report with his/her *ADO*, setting out the details of the attempted *Sample* collection, including the date of the attempt, the location visited, the exact arrival and departure times at the location, the step(s) taken at the location to try to find the *Athlete*, including details of any contact made with third parties, and any other relevant details about the attempted *Sample* collection.

[11.6.3(a) Comment: WADA will make a template Unsuccessful Attempt Report available for use/adaptation by ADOs. When commissioning another ADO to conduct a test on its behalf, the commissioning ADO may specify a deadline for the submission to it of an Unsuccessful Attempt Report.]

b. If it appears that all of the Clause 11.4.3 requirements relating to Missed Tests are satisfied, then no later than 14 (fourteen) days after the date of the unsuccessful attempt, the Responsible ADO (i.e. the *ADO* on whose behalf the test was attempted) must send notice to the *Athlete* of the unsuccessful attempt, inviting a response within 14 (fourteen) days of receipt of the notice. In the notice, the Responsible ADO should warn the *Athlete*:

   i. that unless the *Athlete* persuades the Responsible ADO that there has not been any Missed Test, then (subject to the remainder of the results management process set out below) an alleged Missed Test will be recorded against the *Athlete*; and

   ii. of the consequences to the *Athlete* if a hearing panel upholds the alleged Missed Test.

[11.6.3(b)(ii) Comment: The notice should also advise the Athlete whether any other Whereabouts Failures have been declared against him/her in the 18-month period prior to this alleged Missed Test. (See also comment to Clause 11.6.3(d)).]

c. Where the *Athlete* disputes the apparent Missed Test, the Responsible ADO must re-assess whether all of the Clause 11.4.3 requirements are met. The Responsible ADO must advise the *Athlete*, by letter sent no later than 14 (fourteen) days after receipt of the *Athlete's* response, whether or not it maintains that there has been a Missed Test.

[11.6.3(c) Comment: WADA intends to issue guidelines relating to the assessment of unsuccessful attempts, including what explanations may or may not excuse an apparent Missed Test.

Any notice sent to an Athlete pursuant to Clause 11.6.3(c), agreeing that there has been no Missed Test, shall also be sent to WADA and any other party/ies with a right of appeal under Code Article 13, and may be appealed by WADA and/or such party/ies in accordance with that Article.]

d. If no response is received from the *Athlete* by the relevant deadline, or if the Responsible ADO maintains (notwithstanding the *Athlete's* response) that there has been a Missed Test, the Responsible ADO shall send notice to the *Athlete* that an alleged Missed Test is to be recorded against him/her. The Responsible ADO shall at the same time advise the *Athlete* that he/she has the right to request an administrative review of the alleged Missed Test. The Unsuccessful Attempt Report must be provided to the *Athlete* at this point if it has not been provided earlier in the process.

[11.6.3(d) Comment: The ADO may provide the Unsuccessful Attempt Report to the Athlete prior to this stage if it so chooses (i.e. when it sends the initial notice in accordance with Clause 11.6.3(b)), or it may initially provide only the basic details of the apparent Missed Test, holding back the full Unsuccessful Attempt Report to be provided only at this stage.]

e. Where requested, such administrative review shall be conducted by a designee of the Responsible ADO who was not involved in the previous assessment of the alleged Missed Test, shall be based on written submissions alone, and shall consider whether all of the requirements of Clause 11.4.3 are met. If necessary, the relevant DCO may be asked to provide further information to the designee. The review shall be completed within 14 (fourteen) days of receipt of the *Athlete's* request and the decision shall be communicated to the *Athlete* by letter sent no more than 7 (seven) days after the decision is made.

[11.6.3(e) Comment: Nothing in this Article prevents a sufficiently resourced ADO setting up a panel of up to three persons to conduct such administrative review, provided that none of those persons has been involved in the previous assessment of the alleged Missed Test.]

f. If it appears to the designee that the requirements of Clause 11.4.3 have not been met, then the unsuccessful attempt to test the *Athlete* shall not be treated as a Missed Test for any purpose; and

[11.6.3(f) Comment: Any notice sent to an Athlete pursuant to Clause 11.6.3(f), agreeing that there has been no Missed Test, shall also be sent to WADA and any other party/ies with a right of appeal under Code Article 13, and may be appealed by WADA and/or such party/ies in accordance with that Article.]

g. If the *Athlete* does not request an administrative review of the alleged Missed Test by the relevant deadline, or if the administrative review leads to the conclusion that all of the requirements of Clause 11.4.3 have been met, then the Responsible ADO shall record an alleged Missed Test against the *Athlete* and shall notify the *Athlete* and (on a confidential basis) *WADA* and all other relevant *ADOs* of that alleged Missed Test and the date of its occurrence.

[11.6.3(g) Comment: For the avoidance of doubt, the ADO that attempted the test is not precluded from notifying other relevant ADOs (on a strictly confidential basis) of the alleged Missed Test at an earlier stage of the results management process. Rather, it is entitled to do so, where it considers it appropriate (for test planning purposes or otherwise).

The Clause 11.6.3(g) notice should again advise the Athlete whether any other Whereabouts Failures have been alleged against him/her in respect of the 18-month period prior to this alleged Missed Test.

Whenever such notice is received, if the ADO with results management responsibility, as determined by Clause 11.7.5, is different from the ADO that attempted the test, then the ADO with results management responsibility is encouraged to review the file immediately to determine whether, in its view, the evidence in relation to the Missed Test declared by the ADO that attempted the test is sufficient to establish a Whereabouts Failure under Code Article 2.4. The reviewing ADO should raise any issues of concern with the notifying ADO as soon as possible, i.e. it should not wait until an Athlete has amassed three alleged Whereabouts Failures within any one 18-month period before raising any concern. Any decision by the reviewing ADO that a Whereabouts Failure recorded by another ADO should be disregarded for lack of sufficient evidence shall be communicated to the other ADO and to WADA, shall be without prejudice to WADA's right of appeal under Code Article 13, and in any event shall not affect the validity of any other Whereabouts Failures declared against the Athlete in question.]

11.6.4 An *ADO* that declares, or that receives notice of, a Whereabouts Failure in respect of an *Athlete* shall not disclose that information beyond those persons with a need to know unless and until that *Athlete* is found to have committed an anti-doping rule violation under *Code* Article 2.4 based on (among other things) such Whereabouts Failure. Such persons who need to know shall also maintain the confidentiality of such information until the same point.

[11.6.4 Comment: This shall not preclude an ADO from publishing a general statistical report of its activities that discloses in general terms the number of Whereabouts Failures that have been declared in respect of Athletes under its jurisdiction during a particular period, provided that it does not publish any information that might reveal the identity of the Athletes involved. An ADO should not disclose that a particular Athlete does (or does not) have any Whereabouts Failures alleged against him/her (or that a particular sport does, or does not, have Athletes with Whereabouts Failures alleged against them).]

11.6.5 The Responsible ADO shall keep a record of all Whereabouts Failures alleged in respect of each *Athlete* within its *Registered Testing Pool.* Where it is alleged that such an *Athlete* has committed 3 (three) Whereabouts Failures within any 18-month period:

a. Where two or more of those Whereabouts Failures were alleged by an *ADO* that had the *Athlete* in its *Registered Testing Pool* at the time of those failures, then that *ADO* (whether the IF or a *NADO*) shall be the Responsible ADO for purposes of bringing proceedings against the *Athlete* under *Code* Article 2.4. If not (for example, if the Whereabouts Failures were alleged by three different *ADOs*), then the Responsible ADO for these purposes will be the *ADO* whose *Registered Testing Pool* the *Athlete* was in as of the date of the third Whereabouts Failure. If the *Athlete* was in both the international and a national *Registered Testing Pool* as of that date, the Responsible ADO for these purposes shall be the IF.

[11.6.5(a) Comment: The Responsible ADO shall have the right to receive, from any other ADO that has recorded one of the alleged Whereabouts Failures, such further information about that alleged Whereabouts Failure as the Responsible ADO may reasonably require in order to assess the strength of the evidence of such alleged Whereabouts Failure and to bring proceedings under Code Article 2.4 in reliance thereon. If the Responsible ADO decides in good faith that the evidence in relation to such alleged Whereabouts Failure(s) is insufficient to support such proceedings under Code Article 2.4, then it may decline to bring proceedings based on such alleged Whereabouts Failure(s). Any decision by a Responsible ADO that a declared Whereabouts Failure should be disregarded for lack of sufficient evidence shall be communicated to the other ADO and to WADA, shall be without prejudice to WADA's right of appeal under Code Article 13, and in any event shall not affect the validity of the other Whereabouts Failures alleged against the Athlete in question.]

b. Where the Responsible ADO fails to bring proceedings against an *Athlete* under *Code* Article 2.4 within 30 (thirty) days of *WADA* receiving notice of that *Athlete's* third alleged Whereabouts Failure in any 18-month period, then it shall be deemed that the Responsible ADO has decided that no anti-doping rule violation was committed, for purposes of triggering the appeal rights set out at *Code* Article 13 (in particular Article 13.2).

[11.6.5(b) Comment: In such circumstances, the ADO(s) that alleged such Whereabouts Failure(s) must provide to WADA, upon request, such further information about the alleged Whereabouts Failure(s) as WADA shall reasonably require in order to assess the strength of the evidence of such alleged Whereabouts Failure(s) and (where it deems it appropriate) to bring an appeal in accordance with Code Article 13.]

11.6.6 An *Athlete* alleged to have committed an anti-doping rule violation under *Code* Article 2.4 shall have the right to have such allegation determined at a full evidentiary hearing in accordance with *Code* Article 8. The hearing panel shall not be bound by any determination made during the results management process, whether as to the adequacy of any explanation offered for a Whereabouts Failure or otherwise. Instead, the burden shall be on the *ADO* bringing the proceedings to establish all of the requisite elements of each alleged Whereabouts Failure.

[11.6.6 Comment: Nothing in Clause 11.6.6 is intended to prevent the ADO challenging an argument raised on the Athlete's behalf at the hearing on the basis that it could have been but was not raised at an earlier stage of the results management process.

The ADO that brings proceedings against an Athlete under Code Article 2.4 should also consider in good faith whether or not a Provisional Suspension should be imposed on the Athlete pending determination of the proceedings, in accordance with Code Article 7.5.2.

If the hearing panel decides that one (or two) alleged Whereabouts Failures have been established to the required standard, but that the third alleged Whereabouts Failure has not, then no Code Article 2.4 anti-doping rule violation shall be found to have occurred. However, if the Athlete then commits one (or two) further Whereabouts Failures within the relevant 18-month period, new proceedings may be brought based on a combination of the Whereabouts Failure(s) established to the satisfaction of the hearing panel in the previous proceedings (in accordance with Code Article 3.2.3) and the Whereabouts Failure(s) subsequently committed by the Athlete.

(A)A finding that an Athlete has committed an anti-doping rule violation under Code Article 2.4 of the Code has the following Consequences:

a. imposition of a period of Ineligibility in accordance with Code Article 10.3.3 (first violation) or Code Article 10.7 (second violation); and

b. in accordance with Code Article 10.8, Disqualification (unless fairness requires otherwise) of all individual results obtained by an Athlete from the date of the anti-doping rule violation through to the date of commencement of any Provisional Suspension or Ineligibility period, with all of the resulting consequences, including forfeiture of any medals, points and prizes. For these purposes, the anti-doping rule violation shall be deemed to have occurred on the date of the third Whereabouts Failure found by the hearing panel to have occurred.

The impact of any Code Article 2.4 anti-doping rule violation by an individual Athlete on the results of any team for which that Athlete has played during the relevant period shall be determined in accordance with Code Article 11.]

11.7 Whereabouts Responsibilities of *Anti-Doping Organizations*

11.7.1 The IF is responsible for the following:

a. designating *Athletes* for inclusion in the international *Registered Testing Pool*, and revising the list of designated *Athletes* as appropriate from time to time, all in accordance with *Code* Article 14.3 and Clause 11.2;

b. notifying each *Athlete* designated for inclusion in the international *Registered Testing Pool,* either directly or through the National Federation or Olympic/Paralympic Committee to which the IF has delegated the responsibility to provide notification to the *Athlete*:

   i. of the fact that he/she has been designated for inclusion in the international *Registered Testing Pool*;

   ii. of the whereabouts requirements with which he/she must comply as a result of such inclusion; and

   iii. of the potential consequences if he/she fails to comply with such requirements;

c. agreeing with the *NADO*, in accordance with Clause 11.3.1, which of them shall take responsibility for receiving the Whereabouts Filings of *Athletes* who are in both the *NADO's* national *Registered Testing Pool* and the IF's international *Registered Testing Pool*;

d. establishing a workable system for the collection, maintenance and sharing of Whereabouts Filings, preferably using an on-line system (capable of recording who enters information and when) or at least fax, e-mail and/or SMS text messaging, to ensure that:

   i. the information provided by the *Athlete* is stored safely and securely (ideally in ADAMS or another centralized database system of similar functionality and security);

   ii. the information can be accessed by (A) authorized individuals acting on behalf of the IF on a need-to-know basis only; (B) *WADA*; and (C) other *ADOs* with *Testing* jurisdiction over the *Athlete*, in accordance with *Code* Article 14.3; and

   iii. the information is maintained in strict confidence at all times, is used by the IF exclusively for the purpose of planning, coordinating or conducting *Testing*, and is destroyed in accordance with relevant confidentiality requirements after it is no longer relevant;

e. conducting results management in accordance with Clause 11.6 in respect of:

   i. any apparent Filing Failure on the part of an *Athlete* in the international *Registered Testing Pool* (unless the *Athlete* is also in a national *Registered Testing Pool* and files his/her Whereabouts Filing with the *NADO*, in which case it will be the *NADO* that conducts results management in respect of any apparent Filing Failure by that *Athlete*); and

ii. any apparent Missed Test in respect of such *Athlete*, where the unsuccessful attempt to test the *Athlete* was made on behalf of the IF; and

f. in the circumstances specified in Clause 11.6.5(a), bringing disciplinary proceedings against an *Athlete* under *Code* Article 2.4.

11.7.2 Notwithstanding Clause 11.7.1:

a. an IF may propose, and a *NADO* may agree to, the delegation of some or all of the responsibilities set out in sub-Clauses 11.7.1(b) to (e) to the *NADO*;

b. an IF may delegate some or all of the responsibilities set out in Clause 11.7.1 to the *Athlete's* National Federation; or

c. where *WADA* determines that the IF is not discharging some or all of its responsibilities set out in Clause 11.7.1, *WADA* may delegate some or all of those responsibilities to any other appropriate *ADO*.

11.7.3 The *NADO* is responsible for the following:

a. designating *Athletes* for inclusion in the national *Registered Testing Pool*, and revising the list of designated *Athletes* as appropriate from time to time, all in accordance with *Code* Article 14.3 and Clause 11.2;

b. notifying each *Athlete* designated for inclusion in the national *Registered Testing Pool*:

i. of the fact that he/she has been designated for inclusion in the national *Registered Testing Pool*;

ii. of the whereabouts requirements with which he/she must comply as a result of such inclusion; and

iii. of the potential consequences if he/she fails to comply with such requirements;

c. agreeing with the IF, in accordance with Clause 11.3.1, which of them shall take responsibility for receiving the Whereabouts Filings of *Athletes* who are in both the *NADO's* national *Registered Testing Pool* and the IF's international *Registered Testing Pool*;

d. establishing a workable system for the collection, maintenance and sharing of Whereabouts Filings made by *Athletes* in the national *Registered Testing Pool*, preferably using an on-line system (capable of recording who enters

information and when) or at least fax, e-mail and/or SMS text messaging, to ensure that:

i. the information is stored safely and securely (ideally in ADAMS or another centralized database system of similar functionality and security);
ii. the information can be accessed by (A) authorized individuals acting on behalf of the *NADO* on a need-to-know basis only; (B) *WADA*; and (C) other *ADOs* with authority to test the *Athlete(s)* in question, in accordance with *Code* Article 14.3; and

iii. the information is maintained in strict confidence at all times, is used by the *NADO* exclusively for the purpose of planning, coordinating or conducting *Testing*, and is destroyed in accordance with relevant confidentiality requirements after it is no longer relevant;

e. conducting results management in accordance with Clause 11.6 in respect of:

i. any apparent Filing Failure on the part of an *Athlete* in the national *Registered Testing Pool* (unless the *Athlete* is also in an international *Registered Testing Pool* and files his/her Whereabouts Filing with the IF, in which case it will be the IF that conducts results management in respect of any apparent Filing Failure by that *Athlete*); and

ii. any apparent Missed Test in respect of such *Athlete*, where the unsuccessful attempt to test the *Athlete* was made on behalf of the *NADO*; and

f. in the circumstances specified in Clause 11.6.5(a), bringing disciplinary proceedings against an *Athlete* under *Code* Article 2.4.

11.7.4 Notwithstanding Clause 11.7.3:

a. a *NADO* may delegate some or all of the responsibilities set out in Clause 11.7.3 to the relevant *Athlete's* National Federation or other appropriate *ADO* with authority over the *Athlete* in question;

b. where no appropriate *NADO* exists, the *National Olympic Committee* shall assume the responsibilities of the *NADO* set out in Clause 11.7.3; and

c. where *WADA* determines that the responsibilities set out in Clause 11.7.3 are not being properly exercised, *WADA* may delegate some or all of those responsibilities to any other appropriate *ADO*.

11.7.5 In addition to any specific responsibilities delegated to it in accordance with Clause 11.7.2 or Clause 11.7.4, a National Federation must use its best efforts to

assist the Responsible ADO in collecting Whereabouts Filings from *Athletes* within that National Federation's jurisdiction, including (without limitation) making special provision in its rules for that purpose.

11.7.6 Any *ADO* with *Testing* jurisdiction over an *Athlete* in a *Registered Testing Pool* (see *Code* Article 15):

a. may access that *Athlete's* Whereabouts Filings, as filed with his/her IF or *NADO*, for use in conducting such *Testing*, in accordance with *Code* Article 14.3, provided that:

   i. it shall ensure that such information is accessed by authorized individuals acting on behalf of the *ADO* on a need-to-know basis only, is maintained in strict confidence at all times, is used exclusively for the purpose of planning, coordinating or conducting *Testing*, and is destroyed in accordance with relevant confidentiality requirements after it is no longer relevant; and

   ii. it shall have due regard, in accordance with *Code* Article 15.2, to the need to co-ordinate its *Sample* collection activities with the *Sample* collection activities of other *ADOs*, in order to maximize the effectiveness of the combined *Testing* effort and to avoid unnecessary repetitive testing of individual *Athletes*;

b. it must provide information from the most current Whereabouts Filing to the DCO charged with testing the *Athlete*, and must issue the DCO with clear instructions as to how he/she should go about attempting to locate the *Athlete*, in accordance with Clause 11.4.3(d);

c. it must conduct results management in respect of any apparent Missed Test arising out of its attempt to test the *Athlete*, in accordance with Clause 11.6.3;

11.7.6(c) Comment: Where the ADO attempts the test by agreement with another ADO, that agreement may specify that the requesting ADO will conduct results management with respect to any apparent Missed Test arising out of the attempt.

d. it must report unsuccessful attempts promptly to the Responsible ADO for the *Athlete* in question, in accordance with Clause 11.4.3(h); and

e. it must cooperate as reasonably requested with the Responsible ADO and/or *WADA* in its investigation of any such Whereabouts Failures and in its pursuit of any proceedings brought in reliance on such Whereabouts Failures, including providing any further information requested and producing witnesses and/or documentation as required to evidence, in any disciplinary or related proceedings, any facts within its knowledge on which the charge is based.

PART THREE: ANNEXES

Annex A - Investigating a possible Failure to Comply

A.1 Objective

To ensure that any matters occurring before, during or after a *Sample* Collection Session that may lead to a determination of a Failure to Comply are assessed, documented and acted upon.

A.2 Scope

Investigating a possible Failure to Comply begins when the *ADO* or a DCO becomes aware of a possible Failure to Comply and ends when the *ADO* takes appropriate follow-up action based on the outcomes of its investigation.

A.3 Responsibility

A.3.1 The *ADO* is responsible for ensuring that:

a) An investigation of the possible Failure to Comply is instigated based on all relevant information and documentation.

b) The *Athlete* or other party is informed of the possible Failure to Comply in writing and has the opportunity to respond.

c) The evaluation process is documented.

d) The final determination is made available to other *ADO*s in accordance with the *Code*.

A. 3.2 The DCO is responsible for:

a) Informing the Athlete or other party of the consequences of a possible Failure to Comply.

b) Completing the Athlete's *Sample* Collection Session where possible.

c) Providing a detailed written report of any possible Failure to Comply.

A.3.3 *Sample* Collection Personnel are responsible for:

a) Informing the *Athlete* or other party of the consequences of a possible Failure to Comply.

b) Reporting to the DCO any possible Failure to Comply.

A.4 Requirements

A.4.1 Any potential Failure to Comply shall be reported by the DCO and/or followed up by the *ADO* as soon as practicable.

A.4.2 If the *ADO* determines that there has been a potential Failure to Comply, the *Athlete* or other party shall be promptly notified in writing:

a) Of the possible consequences;

b) That a potential Failure to Comply will be investigated by the *ADO* and appropriate follow-up action will be taken.

A.4.3 Any additional necessary information about the potential Failure to Comply shall be obtained from all relevant sources, including the *Athlete* or other party as soon as possible and recorded.

A.4.4 The *ADO* shall establish a system for ensuring that the outcomes of its investigation into the potential Failure to Comply are considered for results management action and, if applicable, for further planning and *Target Testing*.

Annex B – Modifications for *Athletes* with disabilities

B.1 Objective

To ensure that the special needs of *Athlete*s with disabilities are considered, where possible, in relation to the provision of a *Sample,* without compromising the integrity of the *Sample* Collection Session.

B.2 Scope

Determining whether modifications are necessary starts with identification of situations where *Sample* collection involves *Athlete*s with disabilities and ends with modifications to *Sample* collection procedures and equipment where necessary and where possible.

B.3 Responsibility

The *ADO* has responsibility for ensuring, when possible, that the DCO has any information and *Sample* Collection Equipment necessary to conduct a *Sample* Collection Session with an *Athlete* with a disability.
The DCO has responsibility for *Sample* collection.

B.4 Requirements

B.4.1 All aspects of notification and *Sample* collection for *Athlete*s with disabilities shall be carried out in accordance with the standard notification and *Sample* collection procedures unless modifications are necessary due to the *Athlete*'s disability.

B.4.2 In planning or arranging *Sample* collection, the *ADO* and DCO shall consider whether there will be any *Sample* collection for *Athlete*s with disabilities that may require modifications to the standard procedures for notification or *Sample* collection, including *Sample* Collection Equipment and facilities.

B.4.3 The DCO shall have the authority to make modifications as the situation requires when possible and as long as such modifications will not compromise the

identity, security or integrity of the *Sample*. All such modifications must be documented.

B.4.4 An *Athlete* with an intellectual, physical or sensorial disability can be assisted by the *Athlete*'s representative or *Sample* Collection Personnel during the *Sample* Collection Session where authorised by the *Athlete* and agreed to by the DCO.

B.4.5 The DCO can decide that alternative *Sample* Collection Equipment or facilities will be used when required to enable the *Athlete* to provide the *Sample* as long as the *Sample*'s identity, security and integrity will not be affected.

B.4.6 *Athletes* who are using urine collection or drainage systems are required to eliminate existing urine from such systems before providing a urine *Sample* for analysis. Where possible, the existing urine collection or drainage system should be replaced with a new, unused catheter or drainage system.

B.4.7 The DCO will record modifications made to the standard *Sample* collection procedures for *Athlete*s with disabilities, including any applicable modifications specified in the above actions.

Annex C – Modifications for *Athletes* who are *Minors*

C.1 Objective

To ensure that the needs of *Athlete*s who are *Minors* are met, in relation to the provision of a *Sample,* without compromising the integrity of the *Sample* Collection Session.

C.2 Scope

Determining whether modifications are necessary starts with identification of situations where *Sample* collection involves *Athlete*s who are *Minors* and ends with modifications to *Sample* collection procedures where necessary and where possible.

C.3 Responsibility

The *ADO* has responsibility for ensuring, when possible, that the *DCO* has any information necessary to conduct a *Sample* Collection Session with an *Athlete* who is a *Minor*. This includes confirming wherever necessary that parental consent clauses are in place when arranging *Testing* at an *Event*..

C.4 Requirements

C.4.1 All aspects of notification and *Sample* collection for *Athlete*s who are *Minors* shall be carried out in accordance with the standard notification and *Sample* collection procedures unless modifications are necessary due to the *Athlete* being a *Minor*.

C.4.2 In planning or arranging *Sample* collection, the *ADO* and DCO shall consider whether there will be any *Sample* collection for *Athlete*s who are *Minors*

that may require modifications to the standard procedures for notification or *Sample* collection.

C.4.3 The DCO and the *ADO* shall have the authority to make modifications as the situation requires when possible and as long as such modifications will not compromise the identity, security or integrity of the *Sample*.

C.4.4 *Athlete*s who are *Minors* may be accompanied by a representative throughout the entire *Sample* Collection Session. The representative shall not witness the passing of a urine *Sample* unless requested to do so by the *Minor*. The objective is to ensure that the *DCO* is observing the *Sample* provision correctly. Even if the *Minor* declines a representative, the *ADO*, DCO or Chaperone, as applicable, shall consider whether a third party ought to be present during notification of and/or collection of the *Sample* from the *Athlete.*

C.4.5 For *Athlete*s who are *Minors*, the DCO shall determine who, in addition to the *Sample Collection Personnel*, may be present during the *Sample Collection Session*, namely a *Minor's* representative to observe the *Sample* Collection Session (including observing the DCO when the *Minor* is passing the urine *Sample*, but not to directly observe the passing of the urine *Sample* unless requested to do so by the *Minor*) and the DCO's/Chaperone's representative, to observe the DCO/Chaperone when a *Minor* is passing a urine *Sample*, but without the representative directly observing the passing of the *Sample* unless requested by the *Minor* to do so.

C.4.6 Should a *Minor* decline to have a representative present during the *Sample* Collection Session, this should be clearly documented by the DCO. This does not invalidate the test, but must be recorded. If a *Minor* declines the presence of a representative, the representative of the DCO/Chaperone must be present.

C.4.7 Should a *Minor* fall within a *Registered Testing Pool*, the preferred venue for all *Out-of-Competition Testing* is a location where the presence of an adult is most likely, e.g. training venue.

C.4.8 The *ADO* shall consider the appropriate course of action when no adult is present at the *Testing* of an *Athlete* who is a *Minor* and shall accommodate the *Athlete* in locating a representative in order to proceed with *Testing*.

Annex D - Collection of urine *Samples*

D.1 Objective

To collect an *Athlete*'s urine *Sample* in a manner that ensures:

a) Consistency with relevant principles of internationally recognised standard precautions in healthcare settings so that the health and safety of the *Athlete* and *Sample* Collection Personnel are not compromised;

b) The *Sample* meets the Suitable Specific Gravity for Analysis and the Suitable Volume of Urine for Analysis. Failure of a *Sample* to meet these requirements in no way invalidates the suitability of the *Sample* for analysis. The determination

of a *Sample's* suitability for analysis is the decision of the relevant laboratory, in consultation with the *ADO.*

c) The *Sample* has not been manipulated, substituted, contaminated or otherwise tampered with in any way.

d) The *Sample* is clearly and accurately identified; and

e) The *Sample* is securely sealed in a tamper-evident kit.

D.2 Scope

The collection of a urine *Sample* begins with ensuring the *Athlete* is informed of the *Sample* collection requirements and ends with discarding any residual urine remaining at the end of the *Athlete's* *Sample* Collection Session.

D.3 Responsibility

The DCO has the responsibility for ensuring that each *Sample* is properly collected, identified and sealed.

The DCO/Chaperone has the responsibility for directly witnessing the passing of the urine *Sample*.

D.4 Requirements

D.4.1 The DCO shall ensure that the *Athlete* is informed of the requirements of the *Sample* Collection Session, including any modifications as provided for in Annex B – Modifications for *Athlete*s with disabilities.

D.4.2 The DCO shall ensure that the *Athlete* is offered a choice of appropriate equipment for collecting the *Sample*. If the nature of an *Athlete*'s disability requires that he/she must use additional or other equipment as provided for in Annex B – Modifications for *Athlete*s with disabilities, the DCO shall inspect that equipment to ensure that it will not affect the identity or integrity of the *Sample*.

D.4.3 The DCO shall instruct the *Athlete* to select a collection vessel.

D.4.4 When the *Athlete* selects a collection vessel and for selection of all other *Sample* Collection Equipment that directly holds the urine *Sample*, the DCO will instruct the *Athlete* to check that all seals on the selected equipment are intact and the equipment has not been tampered with. If the *Athlete* is not satisfied with the selected equipment, he/she may select another. If the *Athlete* is not satisfied with any of the equipment available for selection, this shall be recorded by the DCO.

If the DCO does not agree with the *Athlete* that all of the equipment available for the selection is unsatisfactory, the DCO shall instruct the *Athlete* to proceed with the *Sample* Collection Session.

If the DCO agrees with the *Athlete* that all of the equipment available for the selection is unsatisfactory, the DCO shall terminate the collection of the *Athlete*'s urine *Sample* and this shall be recorded by the DCO.

D.4.5 The *Athlete* shall retain control of the collection vessel and any *Sample* provided until the *Sample* is sealed, unless assistance is required by an *Athlete*'s disability as provided for in Annex B – Modifications for *Athlete*s with disabilities. Additional assistance may be provided in exceptional circumstances to any *Athlete* by the *Athlete's* representative or *Sample* Collection Personnel during the *Sample* Collection Session where authorised by the *Athlete* and agreed to by the DCO.

D.4.6 The DCO/Chaperone who witnesses the passing of the *Sample* shall be of the same gender as the *Athlete* providing the *Sample*.

D.4.7 The DCO/Chaperone should where practicable ensure the *Athlete* thoroughly washes his or her hands prior to the provision of the *Sample*.

D.4.8 The DCO/Chaperone and *Athlete* shall proceed to an area of privacy to collect a *Sample*.

D.4.9 The DCO/Chaperone shall ensure an unobstructed view of the *Sample* leaving the *Athlete*'s body and must continue to observe the *Sample* after provision until the *Sample* is securely sealed, and the DCO/Chaperone shall record the witnessing in writing. In order to ensure a clear and unobstructed view of the passing of the *Sample*, the DCO/Chaperone shall instruct the *Athlete* to remove or adjust clothing which restricts the clear view of *Sample* provision. Once the Sample has been provided, the DCO/Chaperone shall also ensure that no additional volume is passed by the athlete at the time of provision, which could have been secured in the collection vessel.

D.4.10 The DCO shall verify, in full view of the *Athlete*, that the Suitable Volume of Urine for Analysis has been provided.

D.4.11 Where the volume of urine is insufficient, the DCO shall conduct a partial *Sample* collection procedure as prescribed in Annex F – Urine *Samples* – insufficient volume.

D.4.12 The DCO shall instruct the *Athlete* to select a *Sample* collection kit containing A and B bottles in accordance with Clause C.4.4.

D.4.13 Once a *Sample* collection kit has been selected, the DCO and the *Athlete* shall check that all code numbers match and that this code number is recorded accurately by the DCO.

If the *Athlete* or DCO finds that the numbers are not the same, the DCO shall instruct the *Athlete* to choose another kit in accordance with Clause C.4.4. The DCO shall record the matter.

D.4.14 The *Athlete* shall pour the minimum Suitable Volume of Urine for Analysis into the B bottle (to a minimum of 30 mL), and then pour the remainder of the urine into the A bottle (to a minimum of 60 mL). If more than the minimum Suitable Volume of Urine for Analysis has been provided, the DCO shall ensure that the *Athlete* fills the A bottle to capacity as per the recommendation of the equipment manufacturer. Should there still be urine remaining, the DCO shall ensure that the *Athlete* fills the B bottle to capacity as per the recommendation of the equipment manufacturer. The DCO shall instruct the *Athlete* to ensure that a small amount of

urine is left in the collection vessel, explaining that this is to enable the DCO to test that residual urine in accordance with Clause D.4.17.

D.4.15 Urine should only be discarded when both the A and B bottles have been filled to capacity in accordance with Clause D.4.14, and after the residual urine has been tested in accordance with Clause D.4.17. The Suitable Volume of Urine for Analysis shall be viewed as an absolute minimum.

D.4.16 The *Athlete* shall seal the bottles as directed by the DCO. The DCO shall check, in full view of the *Athlete*, that the bottles have been properly sealed.

D.4.17 The DCO shall test the residual urine in the collection vessel to determine if the *Sample* has a Suitable Specific Gravity for Analysis. If the DCO's field reading indicates that the *Sample* does not have a Suitable Specific Gravity for Analysis, then the DCO shall follow Annex G (Urine Samples that do not meet requirement for Suitable Specific Gravity for Analysis).

D.4.18 The DCO shall ensure that the *Athlete* has been given the option of requiring that any residual urine that will not be sent for analysis is discarded in full view of the *Athlete*.

Annex E – Collection of blood *Samples*

E.1 Objective

To collect an *Athlete*'s blood *Sample* in a manner that ensures:

a) The health and safety of the *Athlete* and *Sample* Collection Personnel are not compromised;

b) The *Sample* is of a quality and quantity that meets the relevant analytical guidelines;

c) The *Sample* has not been manipulated, substituted, contaminated or otherwise tampered with in any way;

d) The *Sample* is clearly and accurately identified; and

e) The *Sample* is securely sealed.

E.2 Scope

The collection of a blood *Sample* begins with ensuring the *Athlete* is informed of the *Sample* collection requirements and ends with properly storing the *Sample* prior to dispatch for analysis at the *WADA* accredited laboratory or as otherwise approved by *WADA*.

E.3 Responsibility

E.3.1 The DCO has the responsibility for ensuring that:

Each *Sample* is properly collected, identified and sealed; and

All *Samples* have been properly stored and dispatched in accordance with the relevant analytical guidelines.

E.3.2 The Blood Collection Officer has the responsibility for collecting the blood *Sample*, answering related questions during the provision of the *Sample*, and proper disposal of used blood sampling equipment not required for completing the *Sample* Collection Session.

E.4 Requirements

E.4.1 Procedures involving blood shall be consistent with the local standards and regulatory requirements regarding precautions in health care settings.

E.4.2 Blood *Sample* Collection Equipment shall consist of (a) a single sample tube for blood profiling purposes; or (b) both an A and a B sample tube for blood analysis; or (c) as otherwise specified by the relevant laboratory.

E.4.3 The DCO shall ensure that the *Athlete* is informed of the requirements of the *Sample* collection, including any modifications as provided for in Annex B – Modifications for *Athlete*s with disabilities.

E.4.4 The DCO/Chaperone and *Athlete* shall proceed to the area where the *Sample* will be provided.

E.4.5 The DCO shall ensure the *Athlete* is offered comfortable conditions including being in a relaxed position for at least 10 minutes prior to providing a *Sample*.

E.4.6 The DCO shall instruct the *Athlete* to select the *Sample* collection kit/s required for collecting the *Sample* and to check that the selected equipment has not been tampered with and the seals are intact. If the *Athlete* is not satisfied with a selected kit, he/she may select another. If the *Athlete* is not satisfied with any kits and no others are available, this shall be recorded by the DCO.

If the DCO does not agree with the *Athlete* that all of the available kits are unsatisfactory, the DCO shall instruct the *Athlete* to proceed with the *Sample* Collection Session.

If the DCO agrees with the *Athlete* that all available kits are unsatisfactory, the DCO shall terminate the collection of the *Athlete*'s blood *Sample* and this shall be recorded by the DCO.

E.4.7 When a *Sample* collection kit has been selected, the DCO and the *Athlete* shall check that all code numbers match and that this code number is recorded accurately by the DCO.

If the *Athlete* or DCO finds that the numbers are not the same, the DCO shall instruct the *Athlete* to choose another kit. The DCO shall record the matter.

E.4.8 The Blood Collection Officer shall clean the skin with a sterile disinfectant wipe or swab in a location unlikely to adversely affect the *Athlete* or his/her performance and, if required, apply a tourniquet. The Blood Collection Officer shall take the blood *Sample* from a superficial vein into the tube. The tourniquet, if applied, shall be immediately removed after the venipuncture has been made.

E.4.9 The amount of blood removed shall be adequate to satisfy the relevant analytical requirements for the *Sample* analysis to be performed.

E.4.10 If the amount of blood that can be removed from the *Athlete* at the first attempt is insufficient, the Blood Collection Officer shall repeat the procedure. Maximum attempts shall be three. Should all attempts fail, then the Blood Collection Officer shall inform the DCO. The DCO shall terminate the collection of the blood *Sample* and record this and the reasons for terminating the collection.

E.4.11 The Blood Collection Officer shall apply a dressing to the puncture site/s.

E.4.12 The Blood Collection Officer shall dispose of used blood sampling equipment not required for completing the Sample Collection Session in accordance with the required local standards for handling blood.

E.4.13 If the *Sample* requires further on-site processing, such as centrifugation or separation of serum, the *Athlete* shall remain to observe the *Sample* until final sealing in secure, tamper-evident kit.

E.4.14 The *Athlete* shall seal his/her *Sample* into the *Sample* collection kit as directed by the DCO. In full view of the *Athlete*, the DCO shall check that the sealing is satisfactory.

E.4.15 The sealed *Sample* shall be stored in a manner that protects its integrity, identity and security prior to transport from the Doping Control Station to the *WADA* accredited laboratory or as otherwise approved by *WADA*.

Annex F – Urine *Samples* – Insufficient volume

F.1 Objective

To ensure that where a Suitable Volume of Urine for Analysis is not provided, appropriate procedures are followed.

F.2 Scope

The procedure begins with informing the *Athlete* that the *Sample* is not of Suitable Volume of Urine for Analysis and ends with the provision of a *Sample* of sufficient volume.

F.3 Responsibility

The DCO has the responsibility for declaring the *Sample* volume insufficient and for collecting the additional *Sample*/s to obtain a combined *Sample* of sufficient volume.

F.4 Requirements

F.4.1 If the *Sample* collected is of insufficient volume, the DCO shall inform the *Athlete* that a further *Sample* shall be collected to meet the Suitable Volume of Urine for Analysis requirements.

F.4.2 The DCO shall instruct the *Athlete* to select partial *Sample* Collection Equipment in accordance with Clause D.4.4.

F.4.3 The DCO shall then instruct the *Athlete* to open the relevant equipment, pour the insufficient *Sample* into the container and seal it as directed by the DCO. The DCO shall check, in full view of the *Athlete*, that the container has been properly sealed.

F.4.4 The DCO and the *Athlete* shall check that the equipment code number and the volume and identity of the insufficient *Sample* are recorded accurately by the DCO. Either the *Athlete* or the DCO shall retain control of the sealed partial *Sample*.

F.4.5 While waiting to provide an additional *Sample*, the *Athlete* shall remain under continuous observation and be given the opportunity to hydrate.

F.4.6 When the *Athlete* is able to provide an additional *Sample*, the procedures for collection of the *Sample* shall be repeated as prescribed in Annex D – Collection of urine *Samples* until a sufficient volume of urine will be provided by combining the initial and additional *Sample*/s.

F.4.7 When the DCO is satisfied that the requirements for Suitable Volume of Urine for Analysis have been met, the DCO and *Athlete* shall check the integrity of the seal(s) on the partial *Sample* container(s) containing the previously provided insufficient *Sample*(s). Any irregularity with the integrity of the seal/s will be recorded by the DCO and investigated according to Annex A – Investigating a Possible Failure to Comply.

F.4.8 The DCO shall then direct the *Athlete* to break the seal/s and combine the *Samples*, ensuring that additional *Samples* are added sequentially to the first entire *Sample* collected until, as a minimum, the requirement for Suitable Volume of Urine for Analysis is met.

F.4.9 The DCO and *Athlete* shall then continue with Clause D.4.12 or Clause D.4.14 as appropriate.

F.4.10 The DCO shall check the residual urine to ensure that it meets the requirement for Suitable Specific Gravity for Analysis.

F.4.11 Urine should only be discarded when both the A and B bottles have been filled to capacity in accordance with Clause D.4.1.4. The Suitable Volume of Urine for Analysis shall be viewed as an absolute minimum.

Annex G – Urine *Samples* that do not meet the requirement for Suitable Specific Gravity for Analysis

G.1 Objective

To ensure that when the urine *Sample* does not meet the requirement for Suitable Specific Gravity for Analysis, appropriate procedures are followed.

G.2 Scope

The procedure begins with the DCO informing the *Athlete* that a further *Sample* is required and ends with the collection of a *Sample* that meets the requirements for Suitable Specific Gravity for Analysis, or appropriate follow-up action by the *ADO* if required.

G.3 Responsibility

The *ADO* is responsible for establishing procedures to ensure that a suitable *Sample* is collected. If the original *Sample* collected does not meet the requirement for Suitable Specific Gravity for Analysis, the DCO is responsible for collecting additional *Samples* until a suitable *Sample* is obtained.

G.4 Requirements

G.4.1 The DCO shall determine that the requirements for Suitable Specific Gravity for Analysis have not been met.

G.4.2 The DCO shall inform the *Athlete* that he/she is required to provide a further *Sample*.

G.4.3 While waiting to provide additional *Samples*, the *Athlete* shall remain under continuous observation.

G.4.4 The *Athlete* shall be encouraged not to hydrate excessively, since this may delay the production of a suitable *Sample*.

G.4.5 When the *Athlete* is able to provide an additional *Sample*, the DCO shall repeat the procedures for collection of the *Sample* as prescribed in Annex D – Collection of urine *Samples.*

G.4.6 The DCO should continue to collect additional *Samples* until the requirement for Suitable Specific Gravity for Analysis is met, or until the DCO determines that there are exceptional circumstances which mean that for logistical reasons it is impossible to continue with the *Sample* Collection Session. Such exceptional circumstances shall documented accordingly by the DCO.

G.4.6 Comment: It is the responsibility of the Athlete to provide a Sample with a Suitable Specific Gravity for Analysis. If his/her first Sample is too dilute, he/she should not need further hydration and therefore should avoid drinking as far as possible until a Sample with a Suitable Specific Gravity for Analysis is provided. The DCO should wait as long as necessary to collect such a Sample. The ADO may produce guidelines to be followed by the DCO in determining whether exceptional circumstances exist that make it impossible to continue with the Sample Collection Session.

G.4.7 The DCO shall record that the *Sample*s collected belong to a single *Athlete* and the order in which the *Sample*s were provided.

G.4.8 The DCO shall then continue with the *Sample* Collection Session in accordance with Clause D.4.16.

G.4.9 If it is determined that none of the *Athlete's Sample*s meets the requirement for Suitable Specific Gravity for Analysis and the DCO determines that for logistical reasons it is impossible to continue with the *Sample* Collection Session, the DCO may end the *Sample* Collection Session. In such circumstances, if appropriate the *ADO* may investigate a possible anti-doping rule violation.

G.4.10 The DCO shall send to the laboratory for analysis all *Samples* which were collected, irrespective of whether or not they meet the requirement for Suitable Specific Gravity for Analysis.

G.4.11 The laboratory shall, in conjunction with the *ADO,* determine which *Samples* shall be analyzed.

Annex H – *Sample* Collection Personnel Requirements

H.1 Objective

To ensure that Sample Collection Personnel have no conflict of interest and have adequate qualifications and experience to conduct *Sample* Collection Sessions.

H.2 Scope

Sample Collection Personnel requirements start with the development of the necessary competencies for Sample Collection Personnel and end with the provision of identifiable accreditation.

H.3 Responsibility

The *ADO* has the responsibility for all activities defined in this Annex H.

H.4 Requirements - Qualifications and Training

H.4.1 The *ADO* shall determine the necessary competence and qualification requirements for the positions of Doping Control Officer, Chaperone and Blood Collection Officer. The *ADO* shall develop duty statements for all *Sample* Collection Personnel that outline their respective responsibilities. As a minimum:

a) Sample Collection Personnel shall not be *Minors*.

b) Blood Collection Officers shall have adequate qualifications and practical skills required to perform blood collection from a vein.

H.4.2 The *ADO* shall ensure that Sample Collection Personnel that have an interest in the outcome of the collection or testing of a *Sample* from any *Athlete* who might provide a *Sample* at a session are not appointed to that *Sample* Collection

Session. *Sample* Collection Personnel are deemed to have an interest in the collection of a *Sample* if they are:

a) Involved in the planning of the sport for which *Testing* is being conducted; or

b) Related to, or involved in the personal affairs of, any *Athlete* who might provide a *Sample* at that session.

H.4.3 The *ADO* shall establish a system that ensures that Sample Collection Personnel are adequately trained to carry out their duties.

H.4.3.1 The training program for Blood Collection Officers as a minimum shall include studies of all relevant requirements of the *Testing* process and familiarization with relevant standard precautions in healthcare settings.

H.4.3.2 The training program for Doping Control Officers as a minimum shall include:

a) Comprehensive theoretical training in different types of *Testing* activities relevant to the Doping Control Officer position;
b) Observation of all Doping Control activities related to requirements in this standard, preferably on site;
c) The satisfactory performance of one complete *Sample* Collection Session on site under observation by a qualified Doping Control Officer or similar. The requirement related to actual passing of *Sample* shall not be included in the on-site observations.

H.4.3.3 The training program for Chaperones shall include studies of all relevant requirements of the *Sample* collection process.

H 4.4 The *ADO* shall maintain records of education, training, skills and experience.

H.5 Requirements - Accreditation, re-accreditation and delegation

H.5.1 The *ADO* shall establish a system for accrediting and re-accrediting Sample Collection Personnel.

H.5.2 The *ADO* shall ensure that *Sample* Collection Personnel have completed the training program and are familiar with the requirements of this *International Standard* for *Testing* before granting accreditation.

H.5.3 Accreditation shall only be valid for a maximum of two years. *Sample* Collection Personnel shall be required to repeat a full training program if they have not participated in *Sample* collection activities within the year prior to re-accreditation.

H.5.4 Only *Sample* Collection Personnel that have an accreditation recognised by the *ADO* shall be authorised by the *ADO* to conduct *Sample* collection activities on behalf of the *ADO*.

H.5.5 Doping Control Officers may personally perform any activities involved in the *Sample* Collection Session, with the exception of blood collection unless particularly qualified, or they may direct a Chaperone to perform specified activities that fall within the scope of the Chaperone's authorised duties.

APPENDIX FIVE

INTERNATIONAL STANDARD FOR LABORATORIES

(Valid from 1 January 2009)

PREAMBLE

The *World Anti-Doping Code International Standard* for Laboratories is a mandatory level 2 *International Standard* developed as part of the *World Anti-Doping* Program.

The *International Standard* for Laboratories version 6.0 will come into effect on January 01, 2009.

The official text of the *International Standard* for Laboratories shall be maintained by *WADA* and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS

1.0 Introduction, Scope and References

The main purpose of the *International Standard* for Laboratories (ISL) is to ensure laboratory production of valid test results and evidentiary data and to achieve uniform and harmonized results and reporting from all Laboratories.

The ISL includes requirements for obtaining and maintaining *WADA* accreditation of Laboratories, operating standards for laboratory performance and a description of the accreditation process.

WADA will publish, from time to time, specific technical recommendations in a Technical Document. Implementation of the technical recommendations described in the Technical Documents is mandatory and shall occur by the effective date specified in the Technical Document. Technical Documents supersede any previous publication on a similar topic, or if applicable, this document. The document in effect will be that Technical Document whose effective date most recently precedes that of *Sample* receipt date. The current version of the Technical Document will be available on *WADA*'s website.

The ISL, including all Annexes and Technical Documents, is mandatory for all *Signatories* to the *Code*.

The *World Anti-Doping* Program encompasses all of the elements needed in order to ensure optimal harmonization and best practice in international and national anti-doping programs. The main elements are: the *Code* (Level 1), *International Standards* (Level 2), and Models of Best Practice (Level 3).

In the introduction to the *World Anti-Doping Code (Code),* the purpose and implementation of *the International Standards* are summarized as follows:

> "*International Standards* for different technical and operational areas within the anti-doping program will be developed in consultation with the *Signatories* and governments and approved by *WADA*. The purpose of the *International Standards* is harmonization among *Anti-Doping Organizations* responsible for specific technical and operational parts of the anti-doping programs. Adherence to the *International Standards* is mandatory for compliance with the *Code*. The *International Standard*s may be revised from time to time by the *WADA* Executive Committee after reasonable consultation with the *Signatorie*s and governments. Unless provided otherwise in the *Code, International Standards* and all revisions shall become effective on the date specified in the *International Standard* or revision."

Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the *International Standard* were performed properly.

This document sets out the requirements for Laboratories that wish to demonstrate that they are technically competent, operate an effective quality management system, and are able to produce forensically valid results. *Doping Control* testing involves the detection, identification, and in some cases demonstration of the presence greater than a threshold concentration or ratio of measured analytical values (e.g. concentrations, chromatogram peak height or area, etc.) of drugs and other substances in human biological fluids or tissues as identified on the List of *Prohibited Substances* and *Prohibited Methods* (*The Prohibited List*). Laboratories may undertake other forms of testing, within the limits of the Code of Ethics, which are not under the scope of *WADA* Accreditation (e.g. Equine testing, Forensic testing). Any such testing shall not be covered by *WADA* Accreditation.

The Laboratory accreditation framework consists of two main elements: Part Two of the ISL: the Laboratory accreditation requirements and operating standards; and Part Three: the Annexes. Part Two describes the requirements necessary to obtain *WADA* recognition and the procedures involved to fulfill the requirements. It also contains an application of ISO/IEC 17025[1] to the field of *Doping Control*. The purpose of this section of the document is to facilitate consistent application and assessment of ISO/IEC 17025 and the specific *WADA* requirements for *Doping Control* by accreditation bodies that operate in accordance with ISO/IEC 17011. The *International Standard* also sets forth the requirements for Laboratories when adjudication results as a consequence of an *Adverse Analytical Finding.*

Part Three of the ISL includes all Annexes. Annex A describes the *WADA* External Quality Assessment Scheme (EQAS), including performance criteria necessary to maintain *WADA* accreditation. Annex B describes the ethical standards required for continued *WADA* recognition of the Laboratory. Technical Documents are issued, modified, and deleted by *WADA* from time to time and provide direction to the Laboratories and other stakeholders on specific technical issues. Once promulgated, Technical Documents become part of the ISL. The incorporation of the provisions of the approved *WADA* Technical Documents into the Laboratory*'s* quality management system is mandatory for *WADA* accreditation.

In order to harmonize the accreditation of Laboratories to the requirements of ISO/IEC 17025 and the *WADA*-specific requirements for recognition, it is expected that national accreditation bodies will use the ISL, including the Annexes and Technical Documents, as reference documents in their assessment process.

Terms defined in the *Code*, which are included in this standard, are written in *italics*. Terms, which are defined in the ISL, are underlined.

[1] Current version of ISO/IEC 17025

2.0 *Code* Provisions

The following articles in the *Code* directly address the ISL:

Code Article 2 ANTI-DOPING RULE VIOLATIONS

2.1 Presence of a *Prohibited Substance* or its *Metabolite*s or *Marker*s in an *Athlete*'s *Sample*

2.1.1 It is each *Athlete*'s personal duty to ensure that no *Prohibited Substance* enters his or her body. *Athlete*s are responsible for any *Prohibited Substance* or its *Metabolite*s or *Marker*s found to be present in their *Samples*. Accordingly, it is not necessary that intent, fault, negligence or knowing *Use* on the *Athlete*'s part be demonstrated in order to establish an anti-doping violation under Article 2.1.

[Comment to Article 2.1.1: For purposes of anti-doping rule violations involving the presence of a Prohibited Substance (or its Metabolites or Markers), the Code adopts the rule of strict liability which was found in the Olympic Movement Anti-Doping Code ("OMADC") and the vast majority of pre-Code anti-doping rules. Under the strict liability principle, an Athlete is responsible, and an anti-doping rule violation occurs, whenever a Prohibited Substance is found in an Athlete's *Sample. The violation occurs whether or not the Athlete intentionally or unintentionally Used a Prohibited Substance or was negligent or otherwise at fault. If the positive Sample came from an In-Competition test, then the results of that Competition are automatically invalidated (Article 9 (Automatic Disqualification of Individual Results)). However, the Athlete then has the possibility to avoid or reduce sanctions if the Athlete can demonstrate that he or she was not at fault or significant fault (Article 10.5 (Elimination or Reduction of Period of Ineligibility Based on Exceptional Circumstances)) or in certain circumstances did not intend to enhance his or her sport performance (Article 10.4 (Elimination or Reduction of the Period of Ineligibility for Specified Substances under Specific Circumstances)).*

The strict liability rule for the finding of a Prohibited Substance in an Athlete's *Sample, with a possibility that sanctions may be modified based on specified criteria, provides a reasonable balance between effective anti-doping enforcement for the benefit of all "clean" Athletes and fairness in the exceptional circumstance where a Prohibited Substance entered an Athlete's system through No Fault or Negligence or No Significant Fault or Negligence on the Athlete's part. It is important to emphasize that while the determination of whether the anti-doping rule violation has occurred is*

based on strict liability, the imposition of a fixed period of Ineligibility is not automatic. The strict liability principle set forth in the Code has been consistently upheld in the decisions of CAS.]

2.1.2 Sufficient proof of an anti-doping rule violation under Article 2.1 is established by either of the following: presence of a *Prohibited Substance* or its *Metabolites* or *Markers* in the *Athlete*'s A *Sample* where the *Athlete* waives analysis of the B *Sample* and the B *Sample* is not analyzed; or, where the *Athlete*'s B *Sample* is analyzed and the analysis of the *Athlete*'s B *Sample* confirms the presence of the *Prohibited Substance* or its *Metabolite*s or *Marker*s found in the Athlete's A Sample.

[Comment to Article 2.1.2: The Anti-Doping Organization with results management responsibility may in its discretion choose to have the B Sample analyzed even if the Athlete does not request the analysis of the B Sample.]

2.1.3 Excepting those substances for which a quantitative threshold is specifically identified in the *Prohibited List*, the presence of any quantity of a *Prohibited Substance* or its *Metabolite*s or *Marker*s in an *Athlete*'s *Sample* shall constitute an anti-doping rule violation.

2.1.4 As an exception to the general rule of Article 2.1, the *Prohibited List* or *International Standard*s may establish special criteria for the evaluation of *Prohibited Substance*s that can also be produced endogenously.

***Code* Article 3 PROOF OF DOPING**

3.2 Methods of Establishing Facts and Presumptions

3.2.1 *WADA*-accredited laboratories are presumed to have conducted *Sample* analysis and custodial procedures in accordance with the *International Standard* for Laboratories. The *Athlete* or other *Person* may rebut this presumption by establishing that a departure from the *International Standard* for Laboratories occurred which could reasonably have caused the *Adverse Analytical Finding*.

If the *Athlete* or other *Person* rebuts the preceding presumption by showing that a departure from the *International Standard* for Laboratories occurred which could reasonably have caused the *Adverse Analytical Finding*, then the *Anti-Doping Organization* shall have the burden to establish that such departure did not cause the *Adverse Analytical Finding*.

[Comment to Article 3.2.1: The burden is on the Athlete or other Person to establish, by a balance of probability, a departure from the International Standard for Laboratories that could reasonably have caused the Adverse Analytical Finding. If the Athlete or other Person does so, the burden shifts to the Anti-Doping Organization to prove to the comfortable satisfaction of the hearing panel that the departure did not cause the Adverse Analytical Finding.]

Code Article 6 ANALYSIS OF *SAMPLES*

*Doping Control Sample*s shall be analyzed in accordance with the following principles:

6.1 Use of Approved Laboratories

For purposes of Article 2.1 (Presence of a *Prohibited Substance* or its *Metabolite*s or *Marker*s), *Sample*s shall be analyzed only in *WADA*-accredited laboratories or as otherwise approved by *WADA*. The choice of the *WADA*-accredited laboratory (or other laboratory or method approved by *WADA*) used for the *Sample* analysis shall be determined exclusively by the *Anti-Doping Organization* responsible for results management.

[Comment to Article 6.1: Violations of Article 2.1 (Presence of a Prohibited Substance or its Metabolites or Markers) may be established only by Sample analysis performed by a WADA-approved laboratory or another laboratory specifically authorized by WADA. Violations of other Articles may be established using analytical results from other laboratories so long as the results are reliable.]

6.2 Purpose of Collection and Analysis of *Sample*s

*Sample*s shall be analyzed to detect *Prohibited Substance*s and *Prohibited Method*s identified on the *Prohibited List* and other substances as may be directed by *WADA* pursuant to Article 4.5 (Monitoring Program), or to assist an *Anti-Doping Organization* in profiling relevant parameters in an *Athlete*'s urine, blood or other matrix, including DNA or genomic profiling, for anti-doping purposes.

[Comment to Article 6.2: For example, relevant profile information could be used to direct Target Testing or to support an anti-doping rule violation proceeding under Article 2.2 (Use or Attempted Use of a Prohibited Substance), or both.]

6.3 Research on *Sample*s

No *Sample* may be used for any purpose other than as described in Article 6.2 without the *Athlete*'s written consent. *Sample*s used for purposes other than Article 6.2 shall have any means of identification removed such that they cannot be traced back to a particular *Athlete*.

6.4 Standards for *Sample* Analysis and Reporting

Laboratories shall analyze *Doping Control Sample*s and report results in conformity with the *International Standard* for Laboratories.

6.5 Retesting *Sample*s

A *Sample* may be reanalyzed for the purpose of Article 6.2 at any time exclusively at the direction of the *Anti-Doping Organization* that collected the *Sample* or *WADA*. The circumstances and conditions for retesting *Sample*s shall conform with the requirements of the *International Standard* for Laboratories.

[Comment to Article 6.5: Although this Article is new, Anti-Doping Organizations have always had the authority to reanalyze Samples. The International Standard for Laboratories or a new technical document which is made a part of the International Standard will harmonize the protocol for such retesting.]

Code Article 13 APPEALS

13.6 Appeals from Decisions Suspending or Revoking Laboratory Accreditation

Decisions by *WADA* to suspend or revoke a laboratory's *WADA* accreditation may be appealed only by that laboratory with the appeal being exclusively to *CAS*.

Code Article 14 CONFIDENTIALTIY AND REPORTING

14.1 Information Concerning *Adverse Analytical Finding*s, *Atypical Finding*s, and Other Potential Anti-Doping Rule Violations.

14.1.1 Notice to *Athlete*s and Other *Person*s

An *Athlete* whose *Sample* is brought forward as an *Adverse Analytical Finding* after the initial review under Articles 7.1 or 7.3, or an *Athlete* or other *Person* who is asserted to have committed an anti-doping rule violation after the initial review under Article 7.4, shall be notified by the *Anti-Doping Organization* with results management responsibility as provided in Article 7 (Results Management).

14.1.2 Notice to *National Anti-Doping Organization*s, International Federations and *WADA*

The same *Anti-Doping Organization* shall also notify the *Athlete*'s *National Anti-Doping Organization*, International Federation and *WADA* not later than the completion of the process described in Articles 7.1 through 7.4.

14.1.3 Content of Notification

Notification shall include: the *Athlete*'s name, country, sport and discipline within the sport, the *Athlete*'s competitive level, whether the test was *In-Competition* or *Out-of-Competition*, the date of *Sample* collection and the analytical result reported by the laboratory.

14.1.4 Status Reports

The same *Person*s and *Anti-Doping Organization*s shall be regularly updated on the status and findings of any review or proceedings conducted pursuant to Articles 7 (Results Management), 8 (Right to a Fair Hearing) or 13 (Appeals) and shall be provided with a prompt written reasoned explanation or decision explaining the resolution of the matter.

14.1.5 Confidentiality

The recipient organizations shall not disclose this information beyond those *Person*s with a need to know (which would include the appropriate personnel at the applicable *National Olympic Committee*, National Federation, and team in a *Team Sport*) until the *Anti-Doping Organization* with results management

responsibility has made public disclosure or has failed to make public disclosure as required in Article 14.2 below.

[Comment to Article 14.1.5: Each Anti-Doping Organization shall provide, in its own anti-doping rules, procedures for the protection of confidential information and for investigating and disciplining improper disclosure of confidential information by any employee or agent of the Anti-Doping Organization.]

3.0 Terms and definitions

3.1 *Code* defined Terms

ADAMS: The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their anti-doping operations in conjunction with data protection legislation.

Adverse Analytical Finding: A report from a laboratory or other *WADA*-approved entity that, consistent with the *International Standard* for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolite*s or *Marker*s (including elevated quantities of endogenous substances) or evidence of the *Use* of a *Prohibited Method*.

Anti-Doping Organization: A *Signatory* that is responsible for adopting rules for, initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the *International Olympic Committee*, the International Paralympic Committee, *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations.*

Athlete: Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization,* including but not limited to those *Person*s in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and therapeutic use exemptions, must be applied to international- and national-level competitors. Some *National Anti-Doping Organization*s may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national caliber competitors. *National Anti-Doping Organization*s are not required, however, to apply all aspects of the *Code* to such *Person*s. Specific national rules may be established for *Doping Control* for non-international-level or non-national-level competitors without being in conflict with the *Code.* Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempt*ed Administration) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all international- and national-caliber athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes must be included in a National Anti-Doping Organization's Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-caliber athletes to competitors at lower levels of competition. Competitors at all levels of competition should receive the benefit of anti-doping information and education.]

***Atypical Finding**:* A report from a laboratory or other *WADA*-approved entity which requires further investigation as provided by the *International Standard* for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding*.

***Code**:* The *World Anti-Doping Code*.

Competition: A single race, match, game or singular athletic contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other athletic contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

***Doping Control**:* All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, therapeutic use exemptions, results management and hearings.

***Event**:* A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

***In-Competition**:* Unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, "*In-Competition"* means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

***International Standard**:* A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standard*s shall include any Technical Documents issued pursuant to the *International Standard.*

Marker: A compound, group of compounds or biological parameter(s) that indicates the *Use* of a *Prohibited Substance* or *Prohibited Method.*

Metabolite: Any substance produced by a biotransformation process.

National Anti-Doping Organization: The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Sample*s, the management of test results, and the conduct of hearings, all at the national level. This includes an entity which may be designated by multiple countries to serve as regional *Anti-Doping Organization* for such countries. If this designation has not been made by the competent public authority(ies), the entity shall be the country's *National Olympic Committee* or its designee.

National Olympic Committee: The organization recognized by the International Olympic Committee. The term *National Olympic Committee* shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical *National Olympic Committee* responsibilities in the anti-doping area.

Out-of-Competition: Any *Doping Control* which is not *In-Competition*.

Person: A natural person or an organization or other entity.

Prohibited List: The List identifying the *Prohibited Substance*s and *Prohibited Method*s.

Prohibited Method: Any method so described on the *Prohibited List*.

Prohibited Substance: Any substance so described on the *Prohibited List*.

Publicly Disclose or Publicly Report: To disseminate or distribute information to the general public or *Persons* beyond those *Persons* entitled to earlier notification in accordance with Article 14.

Sample/Specimen: Any biological material collected for the purposes of *Doping Control*.

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, including the International Olympic Committee, International Federations, International Paralympic Committee, *National Olympic Committee*s, National Paralympic Committees, *Major Event Organizations*, *National Anti-Doping Organizations*, and *WADA*.

Tampering: Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures from occurring; or providing fraudulent information to an *Anti-Doping Organization*.

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the Laboratory.

Use: The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method.*

WADA: The *World Anti-Doping* Agency.

3.2 ISL Defined Terms

Aliquot: A portion of the *Sample* of biological fluid or tissue (e.g., urine, blood, etc.) obtained from the *Athlete* used in the analytical process.

Analytical Testing: The parts of the *Doping Control* process involving *Sample* handling, analysis and reporting following receipt in the Laboratory.

Certified Reference Material: Reference Material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or concentration of one or more specific *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Method* in a *Sample*. [*Comment: A Confirmation Procedure may also indicate a quantity of Prohibited Substance greater than a threshold value and quantify the amount of a Prohibited Substance in a Sample.*]

Flexible Scope of Accreditation: Process for a Laboratory to make and implement restricted modifications in the scope of the accreditation prior to the assessment by the national accreditation body. Please see section 4.4.11 for a detailed description of Flexible Scope of Accreditation.

Initial Testing Procedure (Screen Testing Procedure): An analytical test procedure whose purpose is to identify those *Sample*s which may contain a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* or the quantity of a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* in excess of a defined threshold.

Intermediate Precision: Variation in results observed when one or more factors, such as time, equipment, and operator are varied within a Laboratory.

International Standard for Laboratories (ISL): The *International Standard* applicable to Laboratories as set forth herein.

Laboratory Internal Chain of Custody: Documentation of the sequence of *Persons* in custody of the *Sample* and any Aliquot of the *Sample* taken for Analytical Testing. *[Comment: Laboratory Internal Chain of Custody is generally documented by a written record of the date, location, action taken, and the individual performing an action with a Sample or Aliquot.]*

Laboratory(ies): (A) WADA-accredited laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of Prohibited *Substances, Methods* and *Markers* on the *Prohibited List*, and if applicable, quantification of a Threshold Substance, in urine and other biological *Sample*s in the context of anti-doping activities.

Laboratory Documentation Packages: The material produced by the Laboratory to support an analytical result such as an *Adverse Analytical Finding* as set forth in the *WADA* Technical Document for Laboratory Documentation Packages.

Major *Event*: A series of individual international *Competitions* conducted together under an international multi-sport organization functioning as a ruling body (e.g., the Olympic Games, Pan American Games) and for which a significant increase of resources and capacity is required to conduct *Doping Control* for the *Event* as determined by *WADA*.

Minimum Required Performance Level (MRPL): concentration of a *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Marker* of a *Prohibited Substance* or *Method* that a doping Laboratory is expected to reliably detect and confirm in the routine daily operation of the Laboratory. See Technical Document Minimum Required Performance Levels for Detection of *Prohibited Substance*s.

Non-Threshold Substance: A substance listed on the *Prohibited List* for which the documentable detection of any amount is considered an anti-doping rule violation.

Presumptive Analytical Finding: The status of a *Sample* test result for which there is a suspicious result in the Initial Testing Procedure, but for which a confirmation test has not yet been performed.

Reference Collection: A collection of samples of known origin that may be used in the determination of the identity of an unknown substance. For example, a well characterized sample obtained from a verified administration study in which scientific documentation of the identity of *Metabolite(s)* can be demonstrated.

Reference Material: Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Repeatability, s_r: Variability observed within a laboratory, over a short time, using a single operator, item of equipment, etc.

Reproducibility, s_R: Variability obtained when different Laboratories analyze the same *Sample*.

Revocation: The permanent withdrawal of a Laboratory's *WADA* accreditation.

Split Sample: Division of a *Sample* taken for testing into two portions at collection, usually designated "A" and "B".

Suspension: The temporary withdrawal of a Laboratory's *WADA* accreditation.

Testing Authority(ies): The International Olympic Committee, *World Anti-Doping* Agency, International Federation, National Sport Organization, *National Anti-Doping Organization*, *National Olympic Committee*, Major *Event Organization*, or other authority defined by the *Code* responsible for *Sample* Testing either *In-Competition* or *Out-of-Competition* and/or for management of the test result.

Threshold Substance: A substance listed on the *Prohibited List* for which the detection and quantification of an amount in excess of a stated threshold is considered an *Adverse Analytical Finding*.

PART TWO: LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS

4.0 Process and Requirements for *WADA* accreditation

This section describes the specific requirements that a laboratory shall fulfill in the process of applying, obtaining, and maintaining *WADA* accreditation including requirements for Major *Event*s.

4.1 Applying for a *WADA* Laboratory Accreditation

4.1.1 Expression of Interest

The candidate laboratory shall officially contact *WADA* in writing to express its interest in the *WADA* accreditation process.

4.1.2 Submit initial Application Form

The candidate laboratory shall complete the necessary information in the Application Form as provided by *WADA* and deliver this to *WADA*. The Application shall be signed by the Laboratory Director and, if relevant, by the Director of the host organization.

At this stage, *WADA* will verify the existence of a National Anti-Doping Program (compliant with the Anti-Doping *International Standard*s) in the country where the candidate laboratory is located, the ratification of the UNESCO Convention against Doping in Sport by the host country of the candidate laboratory, as well as the payment of the nation's financial contributions to *WADA*.

4.1.3 Provide letter(s) of support

Upon successful completion of the above, the candidate laboratory shall be requested by *WADA* to provide an official letter of support from the responsible National *Anti-Doping Organization* or, if not established, the *National Olympic Committee*. The letter of support shall contain as a minimum:

- Guarantee of sufficient annual financial support for a minimum of 3 years;
- Guarantee that, within two (2) years of obtaining accreditation, a minimum of 3000 *Sample*s from *Code*-compliant clients (as determined by *WADA*) will be provided annually to the laboratory for 3 years;
- Guarantee that the necessary analytical facilities and instrumentation will be provided.

Any additional information regarding the above shall be given due consideration by *WADA*. The authority providing the three year letter of support is not restricted to provide exclusive support for only one laboratory.

Letters of support from international sport organizations such as International Federations may also be provided in addition to the above-mentioned letters.

If the candidate laboratory, as an organization, is linked to host organizations (e.g. universities, hospitals, private organization…) and/or supported by a public authority, an official letter of support from such authority shall be provided. In addition to the above-mentioned letter from the NADO or NOC, the following information should be provided:

- Documentation of the administrative support for the laboratory;
- Financial support for the laboratory, if relevant;
- Support for the research and development activities;
- Guarantee of provision of necessary analytical facilities and instrumentation.

4.1.4 Description of the Candidate Laboratory

The candidate laboratory shall then complete a detailed questionnaire provided by *WADA* and submit it to *WADA* no later than eight weeks following the receipt of the questionnaire. The questionnaire will include, but is not limited to, the following:

- Staff list and their qualifications;
- Description of physical facilities, including a description of the security considerations for *Sample*s and records;
- List of proposed and actual instrumental resources and equipment;
- Method validation data;
- List of available Reference Materials and/or standards, or plans to acquire Reference Materials and/or standards, including properly validated biological *Sample* Reference Collections;
- Business plan for the laboratory demonstrating commitment to analyse 3000 *Samples* from *Code*-compliant Testing Authorities (as determined by WADA) annually, within two (2) years of receiving accreditation;
- List of sponsors of the laboratory.

WADA may require an update of this documentation during the process of accreditation.

4.1.5 Conduct Initial visit

WADA usually conducts an initial visit (2-3 days) to the candidate laboratory at the candidate laboratory's expense. The purpose of this visit is to clarify issues with regard to the accreditation process and the defined requirements in the ISL and to obtain information about different aspects of the laboratory relevant for the accreditation. Such a visit could be conducted prior to or during the accreditation process.

4.1.6 Issue final report and recommendation

Within approximately twelve (12) weeks after the initial visit or the receipt of the questionnaire, *WADA* will complete and submit a report to the candidate laboratory. In

the report *WADA* will make the necessary recommendations with respect to granting the candidate laboratory the status of *WADA* probationary laboratory or if this is not the case, identifying needed improvements in order to be considered a *WADA* probationary laboratory.

4.1.7 Initial accreditation fee

Prior to entering the probationary period, the candidate laboratory shall pay to *WADA* a one time non-refundable fee to cover the costs related to the laboratory initial accreditation process. This fee shall be determined by *WADA*.

4.1.8 Compliance with the Code of Ethics

The candidate laboratory shall implement and comply with the provision(s) in the Code of Ethics (Annex B) which are relevant for a laboratory in the probationary period. The laboratory shall communicate the Code of Ethics to all employees and ensure understanding of and commitment to the different aspects of the Code of Ethics. The candidate laboratory shall provide to *WADA* a letter of compliance with the Code of Ethics, signed by the laboratory Director.

4.2 Preparing for *WADA* Laboratory Accreditation

Prior to entering the probationary period, the candidate laboratory may be required to participate in a pre-probationary test, consisting of at least ten (10) EQAS samples in order to assess its competence at that time. The pre-probationary test may be conducted in conjunction with an initial site visit as described in 4.1.5. The candidate laboratory shall successfully identify and document concentrations in excess of the threshold(s) or Minimum Required Performance Levels (MRPL), as applicable, of the *Prohibited Substances*, *Metabolite*(s) of *Prohibited Substances*, or *Marker(s)* of *Prohibited Substances* or *Prohibited Methods* within a time frame of 10 to 15 working days as determined by *WADA*. The candidate laboratory shall provide a test report for each of the samples in the pre-probationary test. For negative samples, *WADA* may request all or a portion of the negative Initial Testing Procedure data. For selected samples for which there is an *Adverse Analytical Finding*, the candidate laboratory shall provide a Laboratory Documentation Package. Additional data to be provided upon *WADA*'s request. The candidate laboratory's performance in the pre-probationary test shall be taken into consideration by *WADA* to gauge the laboratory's competence as well as allow *WADA* to provide feedback on areas in need of improvement. Corrective actions, if any, shall be conducted and reported upon request. Such testing will be taken into account in the overall review of the candidate laboratory's application and may affect the timeliness of the candidate laboratory's entry into the probationary phase of accreditation.

Upon successful completion of the provisions of section 4.1 and following official notification by *WADA*, a candidate laboratory enters the probationary phase of *WADA* accreditation as a *WADA* probationary laboratory. The probationary period shall incorporate at least twenty (20) EQAS samples, typically distributed over multiple EQAS rounds, in order to prepare the probationary laboratory for the initial accreditation. During this period, *WADA* shall provide appropriate feedback to assist

the laboratory in improving the quality of its testing process. In this period the laboratory shall successfully complete provisions 4.2.1 to 4.2.5.

4.2.1 Obtain Laboratory ISO/IEC 17025 accreditation

The laboratory shall be accredited by a relevant accreditation body to ISO/IEC 17025 with primary reference to the interpretations and applications of the ISO/IEC 17025 requirements as described in the Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s (Section 5.0) and the Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s (Section 6.0). The relevant accreditation body shall be an International Laboratory Accreditation Cooperation (ILAC) full member that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA). The laboratory shall prepare and establish the required documentation and system according to the requirements in Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s (Section 5.0) and, if necessary, the Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s (Section 6.0). Based on this, the laboratory shall initiate and prepare for the accreditation process by consulting with a relevant accreditation body. An assessment by the representative(s) of a relevant accreditation body, including an ISL-trained assessor, shall be conducted. The laboratory shall correct any identified non-conformities within defined time-frames and document this accordingly.

Summaries of the Assessment Report and any documentation of correction of non-conformities, in English or French, should be sent to *WADA* by the relevant accreditation body. Should the laboratory prefer to send the information directly to *WADA*, the laboratory shall do so within a reasonable time frame.

The ISO/IEC 17025 accreditation shall be obtained before the end of the probationary period.

4.2.2 Participate in the *WADA* External Quality Assessment Scheme

During the probationary period the laboratory shall successfully analyze at least twenty (20) EQAS samples in multiple rounds containing a minimum of five samples per set (See Annex A for a description of the EQAS).

After successful completion of the probationary period, as a final proficiency test, the laboratory shall analyze a minimum of 20 EQAS samples in the presence of *WADA* representatives. The final accreditation test shall assess both the scientific competence and the capability of the laboratory to manage multiple *Sample*s. Costs associated with the *WADA* on-site visit shall be at the laboratory's expense. The probationary laboratory shall successfully identify and/or document a concentration in excess of the threshold or Minimum Required Performance Level (MRPL) of *the Prohibited Substances*, *Metabolite*(s) of *Prohibited Substances*, or *Marker(s)* of *Prohibited Substances* or *Prohibited Methods* within five (5) calendar days of opening the samples. The probationary laboratory shall provide a Test Report for each of the samples in the proficiency test. For negative samples, *WADA* may request all or a portion of the negative Initial Testing Procedure data. For selected samples for which there is an *Adverse Analytical Finding*, the probationary laboratory shall provide a

Laboratory Documentation Package. This documentation shall be submitted within two (2) weeks of *WADA*'s request.

It is understood that some laboratories already perform routine anti-doping activities under national legislation not yet in line with the UNESCO convention. Such laboratories entering *WADA* probationary phase shall report *Adverse Analytical Finding*s and provide annual statistics to *WADA* as per provisions 4.5.1.5, 5.2.6.10, and 5.2.6.11.

4.2.3 Plan and implement research activities

The probationary laboratory shall develop a plan for its research and development activities in the field of *Doping Control* within a 3 year period including a budget. The probationary laboratory shall demonstrate in its budget an allocation to research and development activities in the field of *Doping Control* of at least 7% of the annual budget for the initial 3-year period. At least two research and development activities shall be initiated and implemented within the probationary period. The research activities can either be conducted by the laboratory or in cooperation with other *WADA* accredited Laboratories or other research organizations.

4.2.4 Plan and implement sharing of knowledge

The probationary laboratory shall demonstrate during the probationary period its willingness and ability to share knowledge with other *WADA* accredited Laboratories. The probationary laboratory shall prepare and convey information and knowledge on at least two specific issues to the other *WADA* accredited Laboratories within the probationary period. A description of this sharing is provided in the Code of Ethics (Annex B).

4.2.5 Professional liability insurance coverage

Probationary laboratories shall provide documentation to *WADA* that professional liability risk insurance coverage has been obtained to cover liability to an amount of no less than 2 million USD annually.

4.3 Obtaining *WADA* Accreditation

4.3.1 Participate in a *WADA* accreditation audit

In the last phase of the probationary period *WADA* will prepare in cooperation with the laboratory a final *WADA* accreditation assessment. Compliance with the defined requirements in the Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s (Section 5.0) and if necessary, the Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s (Section 6.0) and the practice and documentation of the laboratory will be assessed. If *WADA* has participated in the initial ISO/IEC 17025 assessment, the final *WADA* assessment may only consist of a document audit. Otherwise, the audit can be conducted together with the relevant accreditation body or separately if more practical. Should an on-site audit take place by *WADA*, the associated cost shall be at the laboratory's expense. Based on the audit,

WADA will issue an Audit Report and submit this to the laboratory. If applicable, the laboratory shall correct identified non-compliances within defined time-frames and report these to *WADA*.

4.3.2 *WADA* report and recommendation

Based on the relevant documentation from the laboratory, the Audit Report(s) from *WADA* representative(s) and the Audit Report(s) from the relevant accreditation body, *WADA* will make a final report including a recommendation concerning the accreditation of the laboratory. The report and recommendation will be submitted to the *WADA* Executive Committee for approval. In case that the recommendation is that the laboratory should not be accredited, the laboratory will have a maximum of six (6) months to correct and improve specific parts of their operation, at which time a further report will be made by *WADA*.

4.3.3 Issue and publication of Accreditation certificate

A certificate signed by a duly authorized representative of *WADA* shall be issued in recognition of an accreditation. Such certificate shall specify the name of the Laboratory and the period for which the certificate is valid. Certificates may be issued after the effective date, with retroactive effect. A list of accredited Laboratories will be available on *WADA*'s website.

4.4 Maintaining *WADA* Accreditation

In order for the Laboratory to maintain its accreditation status, the National Anti-Doping Organization and/or NOC shall be declared *Code*-compliant (as determined by *WADA*) and the Laboratory host country shall have ratified the UNESCO Convention against Doping in Sport.

4.4.1 Maintain ISO/IEC 17025 accreditation

The Laboratory shall hold an accreditation from the relevant accreditation body, ILAC full member, signatory to ILAC MRA, according to ISO/IEC 17025 with primary reference to the interpretations and applications of the ISO/IEC 17025 requirements as described in the Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s (Section 5.0) and if necessary, Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s (Section 6.0).

4.4.2 Participate in the *WADA* External Quality Assessment Scheme

The *WADA* accredited Laboratories are required to successfully participate in the *WADA* EQAS which is described in more detail in Annex A.

4.4.3 Document Compliance with the *WADA* Laboratory Code of Ethics

The Laboratory shall annually provide to *WADA* a letter of compliance with the provisions of the Code of Ethics (Annex B), signed by the Laboratory Director. The

Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics (Annex B).

4.4.4 Document implemented research activities

The Laboratory shall maintain a plan for research and development in the field of *Doping Control*, including an annual budget in this area of at least 7% of the total annual budget.

The Laboratory should document the publication of results of the research in relevant scientific papers in the peer-reviewed literature (at least one publication every two (2) years). The list of scientific papers shall be made available to *WADA* upon request. The Laboratory may also demonstrate a research program by documenting successful or pending applications for research grants (at least one application submitted every three (3) years).

The Laboratory shall supply an annual progress report to *WADA* documenting research and development results in the field of *Doping Control* and dissemination of the results. The Laboratory should also relate research and development plans for the next year.

4.4.5 Document implemented sharing of knowledge

The Laboratory shall demonstrate their willingness and ability to share knowledge with other *WADA* accredited Laboratories. The Laboratory should make at least one annual contribution to an anti-doping symposium or conference. The Laboratory shall supply an annual report on sharing of knowledge with all other *WADA* accredited Laboratories. A description of this sharing is provided in the Code of Ethics (Annex B).

4.4.6 Maintain professional liability insurance coverage

Laboratories shall provide documentation to *WADA* that professional liability risk insurance coverage is maintained to an amount no less than 2 million USD annually.

4.4.7 Provide renewed letter(s) of support

Letter(s) of support, as described in Section 4.1.3, from a *National Anti-Doping Organization* or *National Olympic Committee* responsible for a national *Doping Control* program or an International Federation responsible for an international *Doping Control* program shall be required in years in which there is an ISO/IEC 17025 re-assessment. For any commitment of less than three years, the *National Anti-Doping Organization* or *National Olympic Committee* responsible for a national *Doping Control* program or an International Federation responsible for an international *Doping Control* program shall be required to provide letter(s) of support for the Laboratory every year.

A letter of support from the host organization renewing its three (3) year commitment to the Laboratory shall also be required in conjunction with each ISO/IEC 17025 re-assessment or be generated and sent to *WADA* at least every two (2) years.

4.4.8 Minimum number of *Sample*s

In order to maintain proficiency, *WADA* accredited Laboratories are required, within two (2) years of the effective date of the current version of the ISL, to analyze a minimum of 3000 *Doping Control Sample*s provided annually by *Code*-compliant Testing Authorities (as determined by *WADA*)**.** *WADA* will monitor the number of *Sample*s tested by the Laboratory. If the number of *Sample*s falls below 3000 per year, *WADA* Laboratory accreditation may be suspended or revoked in accordance with sections 4.4.12.2, 4.4.12.3 and 4.4.13.

4.4.9 Participate in *WADA*/Accreditation Body re-assessments and surveillance assessments

WADA reserves the right to inspect and assess the Laboratory at any time. The notice of the assessment/inspection will be made in writing to the Laboratory Director. In exceptional circumstances, the assessment/inspection may be unannounced.

4.4.9.1 *WADA*/Accreditation Body re-assessment

The Laboratory must receive ISO/IEC 17025 accreditation including compliance with the Application of ISO/IEC 17025 for the Analysis of *Urine Doping Control Sample*s (Section 5.0) and if necessary, Application of ISO/IEC 17025 for the Analysis of *Blood Doping Control Sample*s (Section 6.0). The assessment team shall include an ISL-trained assessor within the assessment team selected by the accreditation body for the re-assessment.

Copies of the assessment summary report in English or French as well as the Laboratory responses should be sent in a timely fashion to *WADA* by the relevan*t* accreditation body. Should the Laboratory prefer sending this information directly to WADA, the Laboratory shall do so within a reasonable time frame.

The Laboratory shall provide a copy of the ISO/IEC 17025 certificate as soon as obtained from the relevant accreditation body.

4.4.9.2 Accreditation Body surveillance assessment

In years when a surveillance ISO/IEC 17025 assessment is required, a copy of the assessment summary report and evidence of corrective actions for any non-compliance(s), in English or French, should be sent to *WADA* by the relevan*t* accreditation body. Should the Laboratory prefer sending this information directly to WADA, the Laboratory shall do so within a reasonable time frame.

4.4.10 Flexible Scope of Accreditation

WADA accredited Laboratories may modify or add analytes to existing scientific methods to expand their scope or develop new methods that involve technology already within the scope of accreditation without the need for approval by the body that completed the ISO/IEC 17025 accreditation of that Laboratory. To have a Flexible Scope of Accreditation, the laboratory must have within its quality

management documentation processes for method validation/acceptance, competence of key personnel, record keeping and reporting.

Any new analytical method or procedure to *Doping control* requiring expertise and technology outside the Laboratory scope of accreditation shall be properly validated by the Laboratory and be determined as Fit-for-purpose by *WADA* prior to first implementation by any Laboratory into the field of anti-doping analysis. *WADA* shall use whatever means deemed appropriate, including formal consultation with scientific expert working groups, and/or publication(s) in peer-reviewed scientific journal(s) to evaluate whether the test is Fit-for-purpose prior to providing approval. Before applying such a new method or procedure to the analysis of *Doping Control Sample*s, but after the approval by *WADA,* the Laboratory shall obtain an extension of the scope of accreditation by a relevant accreditation body.

4.4.11 *WADA* report and recommendation

WADA will annually review Laboratory compliance with the requirements listed in the ISL. With the exception of re-accreditation and other required on-site assessments, the annual review may consist of a documentation assessment. *WADA* may require documentation from the Laboratory. Failure of the Laboratory to provide timely information requested in evaluating performance by the specified date shall be considered a refusal to cooperate and may result in Suspension or Revocation of accreditation.

WADA will consider the overall, EQAS and routine performance of the Laboratory in making decisions regarding continued accreditation. The Laboratory's performance on aspects of the standards described in Section 5.0 and/or Section 6.0 (such as turn-around times, Documentation Package contents, and feedback from customer organizations) may be considered in formulating such recommendation.

4.4.11.1 Maintenance of accreditation

In the event that the Laboratory has maintained satisfactory performance, *WADA* will maintain the accreditation of the Laboratory.

4.4.11.2 Suspension of accreditation

Whenever *WADA* has reason to believe that Suspension may be required and that immediate action is necessary in order to protect the interests of the Anti-Doping Community, *WADA* may immediately suspend a Laboratory*'s* accreditation. If necessary, such a decision may be taken by the Chairman of the *WADA* Executive Committee.

Suspension of accreditation may be based on, but not limited to, the following considerations:

- Suspension of ISO/IEC 17025 accreditation;
- Failure to take appropriate corrective action after an unsatisfactory performance either in routine Analytical Testing or in an EQAS test;

- Failure to comply with any of the requirements or standards listed in *WADA* ISL and/or Technical Documents;
- Failure to cooperate with *WADA* or the relevant Testing Authority in providing documentation;
- Lack of compliance with the *WADA* Laboratory Code of Ethics;
- Major changes in key staff without proper and timely notification to *WADA*;
- Failure to cooperate in any *WADA* enquiry in relation to the activities of the Laboratory;
- Non-compliances identified from laboratory on-site assessments;
- Loss of support jeopardizing the quality and/or viability of the Laboratory.

WADA may decide upon a Suspension of accreditation at any time based on the results of the EQAS or other evidence of serious deviation(s) of the ISL arising from the routine analysis of *Doping Control Sample*s.

Violations of Laboratory routine performance will be assessed by *WADA* on a case-by-case basis considering severity and consequences to the Anti-Doping System. In the event of serious violations, *WADA* reserves the right to organize unannounced audits which may include national accreditation body- and ISL-trained assessors and/or *WADA* experts.

The period and terms of Suspension shall be proportionate to the seriousness of the non-compliance(s) or lack of performance and the need to ensure accurate and reliable drug testing of *Athletes*. A period of Suspension shall be up to 6 months, during which time any non-compliance must be corrected, documented and reported to *WADA* at least six (6) weeks before the end of the Suspension period. Delay in submitting the proper corrective actions may lead to an extension of the Suspension period. If the non-compliance is not corrected during the Suspension period, the Laboratory accreditation will be revoked, unless an extension not to exceed two (2) months is granted by *WADA*.

In the case of a non-compliance, *WADA* may suspend the Laboratory from performing analyses for any *Prohibited Substances*. If *WADA* determines that the non-compliance is limited to a class of *Prohibited Substances*, *WADA* may limit the Suspension to analysis for the class of compounds in which the non-compliance occurred.

4.4.11.3 Revocation of accreditation

The *WADA* Executive Committee shall revoke the accreditation of any Laboratory accredited under these provisions if it determines that Revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results. Revocation of accreditation may be based on, but not limited to, the following considerations:

- Loss of ISO/IEC 17025 accreditation or repeated Suspensions of ISO/IEC 17025 accreditation;
- Systematic failure to comply with the ISL and/or Technical Documents;
- Serious Laboratory non-compliances identified (e.g. on-site assessments, documented client complaints, other enquiries);
- Repeated failure to take appropriate corrective action following unsatisfactory performance either in routine Analytical Testing or in an EQAS test;
- A serious or repeated violation of the ISL;
- Failure to correct a lack of compliance with any of the requirements or standards listed in the *WADA* ISL (including Annex A External Quality Assessment Scheme) during a Suspension period;
- Failure to cooperate with *WADA* or the relevant Testing Authority during the Suspension phase;
- Recurrent non-compliances with the ISL and/or Technical Documents and lack of cooperation with *WADA*;
- Failure to inform clients of Suspension of accreditation;
- A serious or repeated violation of the Code of Ethics;
- Conviction of any key personnel for any criminal offence committed that is related to the operation of the Laboratory;
- Any other cause that materially affects the ability of the Laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results;
- Repeated and/or continuous failure to cooperate in any *WADA* inquiry in relation to the activities of the Laboratory;
- Loss of support jeopardizing the quality and/or viability of the Laboratory.

A Laboratory whose accreditation has been revoked is ineligible to perform testing *of Doping Control Sample*s for any Testing Authority.

If a Laboratory, whose accreditation has been revoked, should seek a new accreditation, it shall begin the process as a new laboratory as described in Section 4.1; unless there are exceptional circumstances or justifications as determined solely by the *WADA* Executive Committee. In the case of exceptional circumstances, the *WADA* Executive Committee shall determine what steps shall be followed prior to granting a new accreditation.

4.4.12 Notification

4.4.12.1 Written Notice

When a Laboratory is suspended or *WADA* seeks to revoke accreditation, *WADA* shall immediately serve the Laboratory with written notice of the Suspension or proposed Revocation by facsimile, hand delivery, or registered or certified mail, return receipt requested. This notice shall state the following:

1) The reason for Suspension or proposed Revocation;
2) The terms of the Suspension or proposed Revocation; and
3) The period of Suspension.

4.4.12.2 Effective Date

A Suspension is immediately effective. A proposed Revocation is effective thirty (30) calendar days after the date on the written notice or, if review is requested, upon *WADA*'s decision to uphold the proposed Revocation. A Laboratory who has received notice that its accreditation is in the process of being revoked shall be suspended until the Revocation is made final or is rescinded by *WADA*. If *WADA* decides not to uphold the Suspension or proposed Revocation, the Suspension is terminated immediately and any proposed Revocation shall not take place.

4.4.12.3 Public Notice

WADA will immediately notify all relevant national public authorities, National Accreditation Bodies, *National Anti-Doping Organizations*, *National Olympic Committees*, International Federations, and the International Olympic Committee of the name and address of any Laboratory that has had its accreditation suspended or revoked, and the name of any Laboratory that has had its Suspension lifted.

WADA will provide to any Testing Authority, upon written request, *WADA*'s written decision which upholds or denies the Suspension or proposed Revocation.

WADA's website will be updated regarding a Laboratory's accreditation status.

4.4.13 Re-accreditation Costs

On an annual basis, *WADA* will invoice the Laboratory for a portion of the costs associated with the re-accreditation process. The Laboratory shall assume the travel and accommodation expenses of the *WADA* representative(s) in the event of on-site assessments.

4.4.14 Issue and publication of Accreditation certificate

If maintenance of accreditation is approved, the Laboratory shall receive a certificate signed by a duly authorized representative of *WADA* issued in recognition of such accreditation. Such a certificate shall specify the name of the Laboratory and the period for which the certificate shall be valid. Certificates may be issued after the effective date, with retroactive effect.

4.5 Accreditation Requirements for Major *Event*s

Primarily, Major *Event* Organizers should consider transporting *Sample*s to the existing facilities of an accredited Laboratory.

In some cases, the reporting time requirements for a Major *Event* may require that the Laboratory facility be located in proximity to the *Competition* such that *Sample*s can be delivered by *Event Doping Control* staff. This may require re-location of an existing Laboratory for a period of time which shall start sufficiently in advance to validate operations at the satellite facility and perform the testing for the *Event*.

In addition, the Laboratory support for a Major *Event* may be such that the existing accredited Laboratory facilities are not adequate. This may require re-location of the Laboratory to a new facility, the addition of personnel, and/or the acquisition of additional equipment. The Laboratory Director of the *WADA* accredited Laboratory designated to perform the testing shall be responsible to ensure that proper quality management system, performance, security and safety are maintained.

In some circumstances, where *Sample*s will be transferred to an existing Laboratory facility, there must be agreement between the Major *Event* Organizer and the *WADA* accredited Laboratory in regards whether testing requirements such as turn-around time and the *Athlete* rights are met for in any eventuality. The Laboratory will, however, be required to report on staffing and equipment issues as required by *WADA*.

If the Laboratory is required to move or extend its operation temporarily to a new physical location, the Laboratory shall demonstrate a valid ISO/IEC 17025 accreditation with primary compliance with the Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s (Section 5.0) and if necessary, the Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s (Section 6.0) for the new facility or satellite facility.

Any methods or equipment unique to the satellite facility shall be validated prior to the satellite facility accreditation assessment. Any changes to methods or other procedures in the quality manual shall also be validated prior to the assessment.

The Laboratory shall be responsible for providing *WADA* with regular and timely updates on the progress of the testing facilities.

4.5.1 Major *Event* Testing in the Laboratory Facilities

4.5.1.1 Participate in an initial *WADA*/Accreditation Body assessment

WADA may perform one or more site visit(s) to the Laboratory facility as soon as it is available to determine whether the facility is adequate. Expenses related to such a visit shall be at the Laboratory's expense. Particular emphasis will be placed on the adequacy of security considerations, the physical layout of the space to ensure that adequate separation of various parts of the Laboratory are maintained, and to provide a preliminary review of other key support elements and to assess compliance with the ISL.

4.5.1.2 Complete a Pre-*Event* Report on Facilities and Staff

The Laboratory shall report to *WADA* all senior personnel temporarily working in the Laboratory. The Laboratory Director shall ensure that these personnel are

adequately trained in the methods, policies, and procedures of the Laboratory. Particular emphasis should be given to the Code of Ethics and the confidentiality of the results management process. Adequate documentation of training of these temporary employees shall be maintained by the Laboratory.

At least one (1) month prior to start of testing for the *Event*, the Laboratory shall provide a report to *WADA* consisting of the following:

- A valid signed contract between the Laboratory and the responsible Testing Authority / Major *Event* organizer including the schedule and number of testing to be performed;
- An organizational chart including Laboratory staff and temporary staff scientists employed by the Laboratory for the *Event*. Supporting information such as job titles and responsibilities shall be included;
- A training plan with timelines for new staff scientists;
- A list of instrumental resources and equipment including identification of ownership;
- A summary of the results management process including criteria for determining analytical results (*Adverse Analytical Findings*, Atypical Findings, etc.);
- Method(s) of reporting the test results in a secure manner to the appropriate authorities.

Any changes that occur prior to the start of *Testing* for the Major *Event* should be immediately reported to *WADA*.

Even if the testing is to be done at the Laboratory*'s* existing facility, the Pre-*Event* Report shall be completed, particularly in regard to personnel changes and any additional equipment.

4.5.1.3 Review the reports and correct identified non-conformities

The Laboratory shall address and correct all identified non-compliances. The assessment report and documentation of the corrective actions shall be submitted to *WADA* prior to start of scheduled testing for the Major *Event.*

4.5.1.4 External Quality Assessment Scheme

WADA may, at its sole discretion, submit EQAS samples to the Laboratory for analysis. The samples shall be analyzed by the same methods used in the testing of *Sample*s from a Major *Event* Organizer. The use of these EQAS samples may be part of the ISO/IEC 17025 assessment by the relevant accreditation body.

Failure to successfully complete the EQAS will be considered by *WADA* in deciding whether to accredit the Laboratory for the Major *Event*. In such event, the Laboratory shall implement, document, and provide to *WADA* proper corrective action.

The EQAS process should include any additional personnel that are added to the staff for the Major *Event*. The samples shall be analyzed using the same methods and procedures that will be used for the analysis of *Sample*s for the Major *Event*.

4.5.1.5 Reporting

All test result reporting shall be in accordance with the confidentiality requirements of the *Code*.

4.5.1.6 Monitoring and assessment during the Major *Event*

WADA may choose at its sole discretion to have an observer in the Laboratory during the Major *Event*. The Laboratory Director and staff are expected to provide full cooperation to the observer.

WADA, in conjunction with the Major *Event Organization* or relevant International Federation, may submit Double Blind EQAS samples to the Laboratory.

In the event of a false positive, the Laboratory will immediately cease testing for that class of *Prohibited Substances and Prohibited Methods*. The Laboratory shall apply corrective actions within 12 hours of notification of the false positive. All *Sample*s analyzed prior to the false positive will be re-analyzed for the class of *Prohibited Substances and Prohibited Methods* for which the non-compliance occurred. The results of the investigation and analysis will be presented to *WADA* within 24 hours unless otherwise agreed in writing.

In the event of a false negative, the Laboratory will be required to investigate the root cause and apply corrective actions within 24 hours of notification of the false negative result. A representative group of *Sample*s in appropriate number to ensure that the risk of false negatives is minimal will be re-analyzed for the class of *Prohibited Substances and Prohibited Methods* for which the non-compliance occurred. The results of the investigation and analysis will be presented to *WADA* within 48 hours unless otherwise agreed in writing.

4.5.2 Major *Event Testing* in satellite Laboratory facilities

In addition to the accreditation requirements for Major *Event*s, satellite laboratories shall also meet the following requirements:

4.5.2.1 Participate in an initial *WADA*/Accreditation Body assessment

WADA may perform one or more site visit(s) to the Laboratory facility as soon as it is available to determine whether the facility is adequate. Expenses related to such a visit(s) shall be at the Laboratory's expense. Particular emphasis will be placed on the adequacy of security considerations, the physical layout of the space to ensure that adequate separation of various parts of the Laboratory are

maintained, and to provide a preliminary review of other key support elements and to assess compliance to the ISL and ISO/IEC 17025.

4.5.2.2 Document ISO/IEC 17025 accreditation of the satellite facility

At least one month prior to the start of scheduled *Testing* for the Major *Event*, the Laboratory must provide documentation that the relevant accreditation body has accredited the satellite facility in compliance with the Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s (Section 5.0) and if necessary, the Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s (Section 6.0). It is a *WADA* requirement that an ISL trained assessor shall be present at the accreditation body assessment of the satellite facility. Expenses associated with such assessment will be at the Laboratory's expense.

4.5.2.3 Participate in *WADA* accreditation assessment

WADA may choose to perform an on-site assessment or a document assessment of the satellite facility. Should an on-site assessment take place, *WADA* expenses related to the assessment will be at the Laboratory's expense. This assessment may include analysis of a set of EQAS samples. Particular emphasis will be placed on involvement of new staff members to assess their competence.

4.5.2.4 Issue and publication of a temporary and limited Accreditation certificate

Based on the documentation provided, *WADA* reserves the right to make a decision regarding accreditation of the Laboratory. In the event that accreditation is awarded, *WADA* shall issue an accreditation for the period of the Major *Event* and an appropriate time before and after the actual *Competition*.

In the event that the accreditation is not awarded, it is the responsibility of the Testing Authority/ Major *Event Organizer* to activate a contingency plan in order to ensure analysis of *Sample*s in compliance with ISL requirements.

5.0 Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Sample*s

5.1 Introduction and Scope

This section of the document is intended as an application as described in Annex B.4 (Guidelines for establishing applications for specific fields) of ISO/IEC 17025 to the field of *Doping Control*. Any aspect of testing or management not specifically discussed in this document shall be governed by ISO/IEC 17025. The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as a *WADA*-accredited laboratory and are therefore determined to be significant in the evaluation and accreditation process.

This section introduces the specific performance standards for a *WADA*-accredited laboratory. The conduct of testing is considered a process within the definitions of

ISO 17000. Performance standards are defined according to a process model where the Laboratory practice is structured into three main categories of processes:

- Analytical and technical processes;
- Management processes;
- Support processes.

Wherever possible, the application will follow the format of the ISO/IEC 17025 document. The concepts of the quality management system, continuous improvement, and customer satisfaction have been included.

5.2 Analytical and Technical Processes

5.2.1 Receipt of *Sample*s

5.2.1.1 *Sample*s may be received by any method acceptable within the concepts of *the International Standard* for *Testing*.

5.2.1.2 The transport container shall first be inspected and any irregularities recorded.

5.2.1.3 The transfer of the *Sample*s from the courier or other person delivering the *Sample*s shall be documented including at a minimum, the date, the time of receipt, and the name and signature of the Laboratory representative receiving the *Sample*s. This information shall be included into the Laboratory Internal Chain of Custody record.

5.2.2 Handling and Retention of *Sample*s

5.2.2.1 The Laboratory shall have a system to uniquely identify the *Sample*s and associate each *Sample* with the collection document or other external chain of custody.

5.2.2.2 The Laboratory shall have Laboratory Internal Chain of Custody procedures to maintain control of and accountability for *Sample*s from receipt through final disposition of the *Sample*s. The procedures shall incorporate the concepts presented in the applicable *WADA* Technical Document for Laboratory Internal Chain of Custody.

5.2.2.3 The Laboratory shall observe and document conditions that exist at the time of receipt that may adversely impact on the integrity of a *Sample*. For example, irregularities noted by the Laboratory should include, but are not limited to:

- *Sample tampering* is evident;
- *Sample* is not sealed with tamper-resistant device or not sealed upon receipt;

- *Sample* is without a collection form (including *Sample* identification code) or a blank form is received with the *Sample*;
- *Sample* identification is unacceptable. For example, the number on the bottle does not match the *Sample* identification number on the form;
- *Sample* volume is inadequate to perform the requested testing menu;
- *Sample* transport conditions are not consistent with preserving the integrity of the *Sample* for anti-doping analysis.

5.2.2.4 The Laboratory shall notify and seek instructions from the Testing Authority regarding rejection or testing of *Sample*s for which irregularities are noted. If applicable, any agreement between a Testing Authority and Laboratory that establishes *Sample* rejection criteria shall be documented.

5.2.2.5 In cases where the Laboratory receives more than two *Sample*s, which are linked to a single *Athlete* according to the *Doping control* form(s), the Laboratory should prioritize the analysis of the first and last *Sample*s collected.

- The Laboratory may conduct further analyses on the intermediary *Sample*s collected if deemed necessary in consultation with the Testing Authority.
- The Laboratory may combine Aliquots from multiple *Sample*s, which are linked to a single *Athlete* according to the *Doping Control* form(s), if necessary to conduct a proper analysis.

5.2.2.6 The Laboratory shall retain the "A" and "B" *Sample(s)* without an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of three (3) months after the final analytical ("A" *Sample*) report is transmitted to the Testing Authority. The *Sample*(s) shall be stored frozen during the long term storage.

*Sample*s with irregularities shall be stored frozen for a minimum of three (3) months following the report to the Testing Authority.

After the applicable storage period, from a minimum of three (3) months, or up to a maximum of eight (8) years if and as requested by the Testing Authority, the Laboratory shall either make the *Sample*s anonymous for research purposes (with proper consent from the *Athlete*) or dispose of the *Sample*s. *Sample*s used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular *Athlete*. Disposal of *Sample*s shall be conducted and recorded under the Laboratory Internal Chain of Custody.

5.2.2.7 The Laboratory shall retain frozen the "A" and "B" *Sample(s)* with an *Adverse Analytical Finding* for a minimum of three (3) months after the final analytical report is transmitted to the Testing Authority or as long as necessary pending the conclusion of a longitudinal study.

5.2.2.8 If the Laboratory has been informed by the Testing Authority that the analysis of a *Sample* is challenged, disputed or under longitudinal investigation, the *Sample* shall be stored frozen and all the records pertaining to the *Testing* of that *Sample* shall be stored until completion of any challenges.

5.2.2.9 The Laboratory shall maintain a policy pertaining to retention, release, and disposal of *Sample*s and Aliquots.

5.2.2.10 The Laboratory shall maintain custody information on the transfer of *Sample*s, or portions thereof to another Laboratory.

5.2.2.11 In cases where both "A" and "B" *Sample*s have been analyzed as part of the anti-doping procedure and the reporting of an *Adverse Analytical Finding(s)*, the Laboratory shall either make the *Sample*s anonymous for research purposes (with proper consent from the *Athlete*) or dispose of the *Sample*s. *Sample*s used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular *Athlete*. Disposal of *Sample*s shall be conducted and recorded under the Laboratory Internal Chain of Custody.

5.2.2.12 Re-sealing of *Sample*s for long-term storage and re-testing

5.2.2.12.1 *Sample*s which have tested negative

5.2.2.12.1.1 Where sufficient urine remains in "A" *Sample* for possible re-testing.

In cases where a *Sample* has been reported negative by the Laboratory following the analysis of the "A" *Sample*, the remainder of the "A" *Sample* and the sealed "B" *Sample* shall be stored frozen by the Laboratory in a secure location under a continuous chain of custody for the purpose of possible re-testing. The re-testing in such cases shall follow the regular *Testing* procedure.

5.2.2.12.1.2 Where no urine remains of "A" *Sample* for possible re-testing.

After a *Sample* has been reported negative by the Laboratory following the analysis of the "A" *Sample*, and there is no remainder of the "A" *Sample*, the sealed "B" *Sample* shall remain stored frozen by the Laboratory in a secure location, under a continuous chain of custody, for the purpose of re-testing.

The opportunity shall be offered to the A*thlete*, or to the representative of the *Athlete* to be present at the opening of the sealed "B" bottle. If the *Athlete* declines to be present or the *Athlete*'s representative does not respond to the invitation or if

the *Athlete* or the *Athlete*'s representative continuously claim not to be available on the date of the opening, despite reasonable attempts by the Laboratory to accommodate their dates, over a period not to exceed 7 working days, the Laboratory shall proceed regardless and appoint an independent witness to verify the opening of the sealed "B" *Sample*.

When opening the "B" *Sample,* the Laboratory will divide the *Sample* into two bottles and the *Athlete* or the *Athlete's* representative will be invited to seal one of the bottles using a tamper proof evident method. If the analysis of the first bottle reveals an *Adverse Analytical Finding*, a confirmation shall be undertaken, if requested by the *Athlete* or his/her representative, using the second bottle.

5.2.2.12.2 *Sample* where the "A" and the "B" bottles have been opened and not re-sealed according to procedure as per 5.2.2.12.1.2.

The *Sample*s shall be handled as per ISL section 5.2.2.11.

5.2.3 Sampling and Preparation of Aliquots for Analysis

5.2.3.1 The Laboratory shall maintain paper or electronic Laboratory Internal Chain of Custody procedures for control of and accountability for all Aliquots and other subsamples and transfers from preparation through disposal. The procedures shall incorporate the concepts presented in the *WADA* Technical Document for Laboratory Internal Chain of Custody.

5.2.3.2 Before the initial opening of a *Sample* bottle, the device used to ensure the integrity of the *Sample* (e.g., security tape or a bottle sealing system) shall be inspected and the integrity documented.

5.2.3.3 The Aliquot preparation procedure for any Initial Testing Procedure or Confirmation Procedure shall ensure that no risk of contamination of the *Sample* or Aliquot exists.

5.2.4 Analytical Testing

5.2.4.1 Urine analysis for adulteration or manipulation

5.2.4.1.1 The Laboratory shall only note any unusual condition of the urine – for example: color, odor, turbidity or foam. Any unusual conditions should be recorded and included as part of the report to the Testing Authority.

5.2.4.1.2 The Laboratory shall measure the pH and specific gravity. Other tests that may assist in the evaluation of adulteration or manipulation may be performed if deemed necessary.

5.2.4.2 Urine Initial Testing Procedure

5.2.4.2.1 The Initial Testing Procedure(s) shall detect the *Prohibited Substance*(s) or *Metabolite(s)* of *Prohibited Substance*(s), or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* for all substances covered by the *Prohibited List* for which there is a method that is Fit-for-purpose. *WADA* may make specific exceptions to this section for specialized techniques that are not required to be within the scope of accreditation of all Laboratories.

5.2.4.2.2 The Initial Testing Procedure shall be performed with a Fit-for-purpose method for the *Prohibited Substance* or *Prohibited Method* being tested. A characteristic of the Initial Testing Procedure is to obtain information about the potential presence of *Prohibited Substance*(s) or *Metabolite(s)* of *Prohibited Substance*(s), or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method.* Results from Initial Testing Procedures can be included as part of longitudinal studies (such as endogenous steroid profiles) provided that the method is appropriately validated.

5.2.4.2.3 All batches undergoing the Initial Testing Procedure shall include appropriate negative and positive controls in addition to the *Sample*s being tested.

5.2.4.2.4 For Threshold Substances, appropriate controls near the threshold shall be included in the Initial Testing Procedures. Initial Testing Procedures are not required to consider uncertainty of measurement.

5.2.4.3 Urine Confirmation Procedure

All Confirmation Procedures shall be documented. The objective of the Confirmation Procedure is to accumulate additional information to support an *Adverse Analytical Finding*. A Confirmation Procedure shall have equal or greater selectivity/discrimination than the Initial Testing Procedure.

5.2.4.3.1 "A" *Sample* Confirmation

5.2.4.3.1.1 A Presumptive Analytical Finding from an Initial Testing Procedure of a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* shall be confirmed using an additional Aliquot(s) taken from the original "A" *Sample*.

For sections S.3 Beta-2 Agonists and S.9 Glucucorticosteroids of the *Prohibited List* only, and if requested by the Testing Authority, a Laboratory may report a Presumptive Analytical

Finding to enquire whether an approved Therapeutic Use Exemption (TUE) exists for the *Prohibited Substance(s)* detected. Decision by the Testing Authority shall be retained as part of the record.

5.2.4.3.1.2 Mass spectrometry (MS) coupled to either gas (GC) or liquid chromatography (LC) is the analytical technique of choice for confirmation of *Prohibited Substances*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method*. GC or High Performance Liquid Chromatography (HPLC) coupled with MS or MS-MS are acceptable for both Initial Testing Procedures and Confirmation Procedures for a specific analyte.

5.2.4.3.1.3 Immunoassays are also routinely used for detection of macromolecules in urine samples. Immunoassays applied for the Initial Testing Procedures and Confirmation Procedures shall use antibodies recognizing different epitopes of the macromolecule analyzed, unless a purification or separation method is used prior to application of the immunoassay to eliminate the potential of cross-reactivity.

In assays which include multiple antibodies (such as sandwich immunoassays), only one of the antibodies (either capture or detection) used in the immunoassays applied for the Initial Testing Procedures and Confirmation Procedures must differ for antigenic epitope specificity. The other antibody may be used in both immunoassays.

For analytes that are too small to have two independent antigenic epitopes, two different purification methods or two different analytical methods shall be applied.

Multiplexed immunoassays, protein chips, and similar simultaneous multi-analyte testing approaches may be used. The Initial Testing Procedures and Confirmation Procedures may be performed simultaneously in the same Aliquot providing that the same preconditions described above for assay antibody specificity or methods of purification or separation are met.

5.2.4.3.1.4 The Laboratory shall have a policy to define those circumstances where the Confirmation Procedure for an "A" *Sample* may be repeated (e.g., batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and be completed on a new Aliquot of the "A" *Sample*.

5.2.4.3.1.5 If more than one *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* is identified by the Initial Testing

Procedures, the Laboratory shall confirm as many of the Presumptive Analytical Findings as possible. The decision on the prioritization for the confirmation(s) shall be made to give precedent to non-specified substance(s) and the decision should be made in cooperation with the Testing Authority and documented. In addition, no final written Test Report incorporating a Presumptive Analytical Finding shall be issued unless authorized by the Testing Authority in relation to the existence of an approved Therapeutic Exemption (TUE) for the *Prohibited Substance*.

5.2.4.3.1.6 The mean value of the results of three Aliquots for the "A" *Sample* finding for Threshold Substances minus the value of the measurement uncertainty determined by the Laboratory must exceed the relevant Threshold. If insufficient *Sample* volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed. *Adverse Analytical Finding* or *Atypical Finding* decisions shall be based on the mean of the measured concentrations or ratios of measured analytical values (e.g. concentrations, chromatogram peak heights or areas, etc.), taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. Reports and documentation shall give the mean concentration or ratio of measured analytical values with the associated uncertainty.

5.2.4.3.2 "B" *Sample* Confirmation

5.2.4.3.2.1 The "B" *Sample* analysis should occur as soon as possible and shall take place no later than seven (7) working days starting the first working day following notification of an "A" *Sample Adverse Analytical Finding* by the Laboratory. If the Laboratory is unable to perform the "B" analysis within this time frame for technical or logistical reason(s), this shall not be considered as a deviation from the ISL susceptible to invalidate the analytical procedure and analytical results. The Laboratory shall proceed as described above unless informed within the seven (7) working day time frame that the *Athlete* has waived his/her right to the "B" confirmation analysis and accepts the findings of the "A" confirmation analysis.

5.2.4.3.2.2 The "B" *Sample* confirmation shall be performed in the same Laboratory as the "A" *Sample* confirmation.

5.2.4.3.2.3 If the "B" *Sample* confirmation proves negative, the entire test shall be considered negative.

5.2.4.3.2.4 For exogenous Threshold Substances, the "B" *Sample* results need only confirm the "A" *Sample* identification for the *Adverse Analytical Finding* to be valid.

5.2.4.3.2.5 For endogenous Threshold Substances, the mean value of the results of three Aliquots for the "B" *Sample* finding minus the value of estimated measurement uncertainty determined by the Laboratory, must exceed the relevant threshold. *Adverse Analytical Finding* or *Atypical Finding* decisions shall be based on the mean of the measured concentrations and/or ratio of measured analytical values, taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. If insufficient *Sample* volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

5.2.4.3.2.6 The *Athlete and/or* his/her representative, a representative of the entity responsible for *Sample* collection or results management, a representative of the *National Olympic Committee*, National Sport Federation, International Federation, and a translator shall be authorized to attend the "B" confirmation.

If the *Athlete* declines to be present or the *Athlete*'s representative does not respond to the invitation or if the *Athlete* or the *Athlete*'s representative continuously claim not to be available on the date of the opening, despite reasonable attempts by the Laboratory to accommodate their dates, over a period not to exceed 7 working days, the Testing Authority or the Laboratory shall proceed regardless and appoint an independent witness to verify that the "B" *Sample* container shows no signs of *Tampering* and that the identifying numbers match that on the collection documentation. At a minimum, the Laboratory Director or representative and the *Athlete* or his/her representative or the independent witness shall sign Laboratory documentation attesting to the above.

The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations.

The Laboratory Director may remove, or have removed by proper authority, any *Athlete* or representative(s) interfering with the testing process. Any behavior resulting in removal shall be reported to the Testing Authority and may be considered an anti–doping rule violation in accordance with Article 2.5 of the *Code*, "*Tampering*, or Attempting to tamper, with any part of *Doping Control*".

5.2.4.3.2.7 Aliquots taken for "B" Confirmation Procedure shall be taken from the original "B" *Sample*.

The Laboratory shall ensure that the "B" *Sample* is properly resealed as per provision 5.2.2.12.

5.2.4.3.2.8 The Laboratory shall have a policy to define those circumstances when Confirmation Procedure for the "B" *Sample* may be repeated (e.g. batch quality control failure) and the first test result shall be nullified. Each repeat confirmation should be performed on a new Aliquot of the "B" *Sample* and new controls.

5.2.4.3.2.9 If the "B" *Sample* confirmation proves negative, the *Sample* shall be considered negative and the Testing Authority, *WADA* and the International Federation notified of the new analytical finding.

5.2.4.4 Alternative biological matrices.

Any testing results obtained from hair, nails, oral fluid or other biological material shall not be used to counter *Adverse Analytical Finding*s or *Atypical Finding*s from urine.

5.2.5 Results Management

5.2.5.1 Review of results

5.2.5.1.1 A minimum of two certifying scientists shall independently review all *Adverse Analytical Finding*s and *Atypical Finding*s before a report is issued. The review process shall be recorded.

5.2.5.1.2 At a minimum, the review shall include:

- Laboratory Internal Chain of Custody documentation;
- Validity of the analytical initial and confirmatory data and calculations;
- Quality control data;
- Completeness of documentation supporting the reported analytical findings.

5.2.5.1.3 When an *Adverse Analytical Finding* or *Atypical Finding* is rejected, the reason(s) shall be recorded.

5.2.6 Documentation and Reporting

5.2.6.1 The Laboratory shall have documented procedures to ensure that it maintains a coordinated record related to each *Sample* analyzed. In the case of an *Adverse Analytical Finding* or *Atypical Finding*, the record shall include the data necessary to support the conclusions reported. In general, the record should be such that in the absence of the analyst, another competent analyst could evaluate what tests had been performed and interpret the data.

5.2.6.2 Each step of testing shall be traceable to the staff member who performed that step.

5.2.6.3 Significant variance from the written procedure shall be documented as part of the record (e.g., memorandum for the record).

5.2.6.4 Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.

5.2.6.5 Reporting of "A" *Sample* results should occur within ten (10) working days of receipt of the *Sample*. The reporting time required for specific *Competition*s may be substantially less than ten days. The reporting time may be altered by agreement between the Laboratory and the Testing Authority.

5.2.6.6 A single, distinct Test Report shall be generated to document the *Adverse Analytical Finding(s)* or *Atypical Finding*(s) of an individual *Sample*. The Laboratory Test Report shall include, in addition to the items stipulated in ISO/IEC 17025, the following:

- Customer *Sample* identification code;
- Laboratory identification code;
- Type of test (*Out of Competition/In-Competition*);
- Sport and/or discipline
- Name of *Competition* and/or Customer reference code (for example: *ADAMS* test mission code), if provided;
- Date of receipt of *Sample;*
- Date of report;
- Sex of the *Athlete*;
- Type of *Sample* (urine, blood, etc.);
- Test results (for Threshold Substances: the mean value, units, uncertainty details and reporting threshold shall be included);
- Signature of authorized individual;
- Other information as specified by the Testing Authority and/or *WADA*.

At a minimum, labelling and information provided by the Laboratory related to the type of test, sport/discipline, test results (including comments/opinions) and client to whom the report is addressed shall also be provided in English on the test report.

5.2.6.7 The Laboratory is not required to measure or report a concentration for *Prohibited Substances* for a non-threshold analyte in urine *Sample*s. The Laboratory shall report the actual *Prohibited Substance*(s), *Metabolite*(s) of the *Prohibited Substance*(s) or *Prohibited Method*(s), or *Marker(s)* detected in the urine *Sample*.

For Threshold Substances in urine *Sample*s, the Laboratory report shall establish that the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* of a *Prohibited Method* is present at a concentration and/or ratio of measured analytical values greater than the threshold (taking into consideration the

value of measurement uncertainty for the "A" *Sample* confirmation and also the "B" *Sample* confirmation of endogenous Threshold Substances).

5.2.6.8 The Laboratory should qualify the result(s) in the Test Report as an *Adverse Analytical Finding* or "No *Prohibited Substance(s)* on Test menu detected". For substances requiring follow-up and that cannot be confirmed as coming from an exogenous source, the Laboratory shall qualify the result as an *Atypical Finding* in the Test Report.

5.2.6.9 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented.

Note: An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, whether the observed results may suggest the need for additional *Testing* and whether an observed result is consistent with a set of reported conditions.

5.2.6.10 In addition to reporting to the Testing Authority, the Laboratory shall simultaneously report any *Adverse Analytical Finding*s ("A" and "B" results) to *WADA* and the responsible International Federation (and/or to the owner of the *Event* in the case of Major *International Events*). *Atypical Finding*s shall be simultaneously reported to the Testing Authority and *WADA*. Documented instructions from the Testing Authority, with regard to a Presumptive Analytical Finding, shall also be reported to *WADA*. In the case where the sport or *Event* is not associated with an International Federation (e.g., Professional Leagues, University and College sports) the Laboratory shall report *Adverse Analytical Finding*s to the Testing Authority and to *WADA*. All reporting shall be in accord with the confidentiality requirements of the *Code*.

5.2.6.11 The Laboratory, upon request by Testing Authorities, may be asked to review data from longitudinal studies which include an *Atypical Finding*(s). Following review of the applicable data, a report and recommendation shall be made by the Laboratory to the Testing Authority as to whether the data supports an *Adverse Analytical Finding* or not. If the Testing Authority has concluded an *Adverse Analytical Finding*, the Laboratory will be informed and shall conduct the "B" confirmation analysis according to 5.2.4.3.2.1.

5.2.6.12 The Laboratory shall report quarterly to *WADA*, in a format specified by *WADA*, a summary of the results of all tests performed. No information that could link an *Athlete* with an individual result will be included. The report will include a summary of any *Sample*s rejected for testing and the reason for the rejection.

When the clearinghouse (*ADAMS*) is in place, the Laboratory shall simultaneously report via such system to *WADA* all material information

reported to the Testing Authority, according to the requirements listed in Section 5.2.6.6, in lieu of the paragraph above. The information will be used to generate summary reports.

5.2.6.13 The documentation package should be provided by the Laboratory only to the relevant result management authority upon request and should be provided within 10 working days of the request. Laboratory Documentation Packages shall be in compliance with the *WADA* Technical Document on Laboratory Documentation Packages.

5.2.6.14 *Athlete* confidentiality shall be a key concern for all Laboratories engaged in *Doping Control* cases.

5.2.6.14.1 Testing Authority requests for information shall be made in writing to the Laboratories.

5.2.6.14.2 *Adverse Analytical Finding*s and *Atypical Finding*s shall not be provided by telephone.

5.2.6.14.3 Information sent by a facsimile is acceptable if the security of the receiving facsimile machine has been verified and procedures are in place to ensure that the facsimile has been transmitted to the correct facsimile number.

5.2.6.14.4 Unencrypted email is not authorized for any reporting or discussion of *Adverse Analytical Finding*s or *Atypical Finding*s if the *Athlete* can be identified or if any information regarding the identity of the *Athlete* is included.

5.2.6.14.5 The Laboratory shall also provide any information requested by *WADA* in conjunction with the Monitoring Program, as set forth in Article 4.5 of the *Code*.

5.3 Quality Management Processes

5.3.1 Organization

5.3.1.1 Within the framework of ISO/IEC 17025, the Laboratory shall be considered as a testing Laboratory.

5.3.1.2 The administrative and operational activities of the Laboratory, as well as the hosting facility, should be independent from the Anti-Doping Organization(s) providing support (e.g. financial, *Sample*s, facilities) to the Laboratory.

5.3.1.3 The Laboratory Director shall have the responsibilities of the Chief Executive, unless otherwise noted.

5.3.2 Quality Policy and Objectives

5.3.2.1 The Quality Policy and implementation shall meet the requirements of ISO/IEC 17025 Section 4.2 Management System and shall include a quality manual that describes the quality system.

5.3.2.2 A single staff member should be appointed as the Quality Manager and shall have responsibility and authority to implement and ensure compliance with the quality system.

5.3.3 Document Control

The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025 Section 4.3 Document Control.

5.3.3.1 The Laboratory Director (or designee) shall approve the Quality Manual and all other documents used by staff members in completing testing.

5.3.3.2 The Management System shall ensure that the contents of *WADA* Technical Documents are incorporated into the appropriate manuals by the effective date and that training is provided and recorded. If this is not possible, *WADA* shall be contacted with a written request for an extension.

5.3.4 Review of requests, tenders, and contracts

Review of legal documents or agreements related to testing shall meet the requirements of ISO/IEC 17025 Section 4.4.

The Laboratory shall ensure that the Testing Authority is informed concerning the *Prohibited Substances* that can be detected under the scope of accreditation in *Sample*s submitted for analysis.

5.3.5 Subcontracting of tests

A *WADA* accredited Laboratory shall perform all work with qualified personnel and equipment within its accredited facility.

In the case of specific technologies that may not be available in the Laboratory, a *Sample* may be transferred to another *WADA* accredited Laboratory where the specific technology is within the scope of its accreditation. In exceptional circumstances, *WADA* may elect to grant specific authorization for subcontracting parts of the tasks. In such cases, assurance of the maintenance of the level of quality and the appropriate chain of custody throughout the entire process is the responsibility of the Laboratory Director. Such arrangements shall be clearly documented as part of the permanent *Sample* record and included in the Laboratory Documentation Package, if applicable.

5.3.6 Purchasing of services and supplies

5.3.6.1 Chemicals and reagents

Chemicals and reagents shall be suitable for the purpose of the analysis and be of established purity. Reference purity documentation shall be obtained when

available and retained in the quality system documents. Chemicals, reagents and kits labelled "Research Only" may be utilized for the purposes of *Doping Control* as long as they are validated by the Laboratory.

In the case of rare or difficult to obtain reagents, Reference Materials, or Reference Collections, particularly for use in qualitative methods, the expiration date of the solution can be extended if adequate documentation exists confirming that no significant deterioration that would preclude obtaining an acceptable mass spectrum has occurred or that purification has been performed.

5.3.6.2 Waste disposal shall be in accord with national laws and other relevant regulations. This includes biohazard materials, chemicals, controlled substances, and radioisotopes, if used.

5.3.6.3 Environmental health and safety policies shall be in place to protect the staff, the public, and the environment.

5.3.7 Service to the customer

5.3.7.1 Service to customers shall be handled in accord with ISO/IEC 17025 Section 4.7.

5.3.7.2 Ensuring responsiveness to *WADA*

The Laboratory Director or his/her designee shall:

- Ensure adequate communication;
- Report to *WADA* any unusual circumstances or information with regard to testing programs, patterns of irregularities in *Sample*s, or potential use of new substances;
- Provide complete and timely explanatory information to *WADA* as appropriate and as requested to provide quality accreditation.

5.3.7.3 Ensuring responsiveness to Testing Authority

5.3.7.3.1 The Laboratory Director shall be familiar with the Testing Authority rules and the *Prohibited List.*

5.3.7.3.2 The Laboratory Director shall interact with the Testing Authority with respect to specific timing, report information, or other support needs. These interactions should include, but are not limited to, the following:

- Communicating with the Testing Authority concerning any significant question of testing needs or any unusual circumstance in the testing process (including delays in reporting);

- Acting without bias regarding the national affiliation of the Testing Authority;
- Providing complete and timely explanations to the Testing Authority when requested or when there is a potential for misunderstanding the Test Report or Laboratory Documentation Package;
- Providing evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings;
- Responding to any comment or complaint submitted by a Testing Authority or *Anti-Doping Organization* concerning the Laboratory and its operation.

5.3.7.3.3 The Laboratory shall actively monitor the quality of the services provided to the relevant anti-doping authorities. There should be documentation that the Testing Authority concerns have been incorporated into the Laboratory Management System where appropriate.

5.3.7.3.4 The Laboratory shall develop a system, as required by ISO/IEC 17025 for monitoring Laboratory service.

5.3.8 Complaints

Complaints shall be handled in accordance with ISO/IEC 17025 Section 4.8.

5.3.9 Control of nonconforming testing work

5.3.9.1 The Laboratory shall have policies and procedures that shall be implemented when any aspect of its testing or a result from its testing does not comply to set procedures.

5.3.9.2 Documentation of any non-compliance or departure from procedure or protocol involving a *Sample* testing shall be kept as part of the permanent record of that *Sample*.

5.3.10 Improvement

The Laboratory shall continually improve the effectiveness of its management system in accordance with ISO/IEC 17025 Section 4.10.

5.3.11 Corrective action

Corrective action shall be taken in accordance with ISO/IEC 17025 Section 4.11.

5.3.12 Preventive action

Preventive action shall be taken in accordance with ISO/IEC 17025 Section 4.12.

5.3.13 Control of records

5.3.13.1 Technical Records

5.3.13.1.1 Analytical records on negative *Sample*s, including Laboratory Internal Chain of Custody documentation and the endogenous steroid profile, shall be retained in secure storage for at least two (2) years. Analytical records on *Sample*s with irregularities or on rejected *Sample*s shall be retained in secure storage for at least two (2) years.

5.3.13.1.2 All analytical records on *Sample*s with an *Adverse Analytical Finding,* as described in Section 5.2.5.1.2, shall be retained in secure storage for at least eight (8) years.

5.3.13.1.3 The raw data supporting all analytical results shall be retained in secure storage for at least eight (8) years.

5.3.14 Internal Audits

5.3.14.1 Internal audits shall be completed in accordance with the requirements of ISO/IEC 17025 Section 4.14.

5.3.14.2 Internal Audit responsibilities may be shared amongst personnel provided that any *Person* does not audit his/her own area.

5.3.15 Management Reviews

Management reviews will be conducted to meet the requirements of ISO/IEC 17025 Section 4.15.

5.4 Support processes

5.4.1 General

General support shall be provided in accordance with the requirements of ISO/IEC 17025 (Section 5.0).

5.4.2 Personnel

5.4.2.1 Every person employed by, or under contract to, the Laboratory shall have an accessible personnel file which shall contain copies of the curriculum vitae or qualification form, a job description, and records of initial and ongoing training. The Laboratory shall maintain appropriate confidentiality of personal information.

5.4.2.2 All personnel shall have a thorough knowledge of their responsibilities including the security of the Laboratory, confidentiality of results, Laboratory Internal Chain of Custody protocols, and the standard operating procedures for any method that they perform.

5.4.2.3 The Laboratory Director is responsible for ensuring that Laboratory personnel are adequately trained and have experience necessary to perform their duties. The approval, as well as supporting training records, shall be retained in the individual's personnel file.

5.4.2.4 The Laboratory shall have a qualified *Person* as the Laboratory Director to assume professional, organizational, educational, and administrative responsibility. The Laboratory Director qualifications are:

- Ph.D. (or equivalent) in one of the natural sciences or training comparable to a Ph.D. in one of the natural sciences such as a scientific or medical degree with appropriate experience or training;
- Experience and competence in the analysis of biological material for substances used in doping;
- Appropriate training or experience in forensic applications of *Doping Control*. It is acknowledged that the Laboratory Director plays an essential role in the anti-doping Laboratory operations and that the *WADA* accreditation is delivered based upon such qualification as well as the Laboratory operational performance. *WADA* shall be immediately informed of the appointment of a new Laboratory Director. *WADA* reserves the right to review the credentials of such appointments in accordance with the above qualifications;
- Any personnel changes to this position shall be communicated to *WADA* no later than one month prior to the scheduled date the Laboratory Director vacates his/her position. A succession plan shall be forwarded to *WADA*.

5.4.2.5 The Laboratory shall have qualified personnel to serve as Certifying Scientist(s) to review all pertinent data, quality control results, and to attest to the validity of the Laboratory's test reports. The qualifications are:

- Bachelors Degree in Medical Technology, Chemistry, Biology, or related natural science or equivalent. Documented experience of 8 years or more in a *Doping Control* Laboratory is equivalent to a Bachelor's degree for this position;
- Experience in the analysis of doping materials in biological fluids;
- Experience in the use of relevant analytical techniques such as chromatography, immunoassay, and mass spectrometric techniques.

5.4.2.6 Supervisory personnel shall have a thorough understanding of the quality control procedures including, the review, interpretation and reporting of test results, maintenance of Laboratory Internal Chain of Custody and proper remedial action to be taken in response to analytical problems. The qualifications for supervisor are:

- Bachelor's Degree in Medical Technology, Chemistry, Biology, or related natural science or equivalent. Documented experience of 5 years

or more in a *Doping Control* Laboratory is equivalent to a Bachelor's degree for this position;

- Experience in relevant analytical testing including the analysis of *Prohibited Substances* in biological material;
- Experience in the use of analytical techniques such as chromatography, immunoassay, and mass spectrometric techniques;
- Ability to ensure compliance with quality management systems and quality assurance processes.

5.4.3 Accommodation and environmental conditions

5.4.3.1 Environmental Control

5.4.3.1.1 Maintain appropriate electrical services

5.4.3.1.1.1 The Laboratory shall ensure that adequate electrical service is available so that there is no compromise of stored data.

5.4.3.1.1.2 All Laboratory instrumentation and equipment critical to Laboratory operations should be supported in such a way that service is not likely to be interrupted.

5.4.3.1.1.3 The Laboratory shall have policies in place to ensure the integrity of refrigerated and/or frozen stored *Sample*s in the event of an electrical failure.

5.4.3.1.2 The Laboratory shall have a written safety policy and compliance with Laboratory safety policies shall be enforced.

5.4.3.1.3 The storage and handling of controlled substances shall follow a risk assessment and comply with applicable national legislation.

5.4.3.2 Security of the facility

5.4.3.2.1 The Laboratory shall have a policy for the security of its facilities, equipment and system against unauthorized access which may include a threat and risk assessment by expert(s) in relevant field.

5.4.3.2.2 Three levels of access shall be considered in the quality manual or threat assessment plan:

- Reception zone. An initial point of control beyond which unauthorized individuals shall be escorted by laboratory personnel;
- Common operational zones;
- Controlled zones. Access to these areas should be monitored and records maintained of access by visitors.

5.4.3.2.3 The Laboratory shall restrict access to Controlled Zones to only authorized *Persons*. A staff member should be assigned as the security officer who has overall knowledge and control of the security system.

5.4.3.2.4 Unauthorized *Persons* shall be escorted within Controlled Zones. A temporary authorization may be issued to individuals requiring access to the Controlled Zones such as auditing teams and individuals performing service or repair.

5.4.3.2.5 The Laboratory should have a separate Controlled Zone for *Sample* receipt and Aliquot preparation.

5.4.3.3 Relocation of Laboratory Facilities

In cases where a Laboratory is to relocate, on a permanent or semi-permanent basis to a new physical space, a report containing the following information shall be provided to *WADA* no later than three months prior to the relocation:

- Description of circumstances for moving Laboratory operations into a new space and anticipated effect on capabilities;
- Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;
- Date of ISO/IEC 17025 inspection(s) of new facilities (evidence of continued accreditation required when made available by the Accreditation Body);
- New Laboratory contacts;
- Assessment of the effect of the relocation to Laboratory client operations.

5.4.4 Test Methods and Method Validation

5.4.4.1 Selection of Methods

Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall develop, validate and document methods for the detection of substances present on the *Prohibited List* and for associated *Metabolites* or *Markers* or related substances. Note that for many substances, the associated *Metabolites* are detected, thereby confirming the metabolism and the administration of a *Prohibited Substance*. The methods shall be selected and validated so they are Fit-for-purpose. *WADA* shall supply feedback to the Laboratories regarding the suitability of the assay principle.

5.4.4.1.1 Non-Threshold Substances

Laboratories are not required to measure or report a concentration for Non-Threshold Substances.

The Laboratory shall develop, as part of the method validation process, acceptable standards for identification of *Prohibited Substances*. (See the Technical Document on Identification Criteria for Qualitative Assays).

The Laboratory shall demonstrate the ability to successfully identify 100% of the time representative substances in the class of *Prohibited Substances* at the Minimum Required Performance Levels (for example twenty urines spiked at MRPL). The Laboratory shall establish, in routine practice, the use of control samples containing representative substance(s) at the MRPL if the appropriate standards are available. A Reference Collection may be used for identification and in such cases an estimate of the detection capability for the method may be provided by assessing a representative substance.

5.4.4.1.2 Threshold Substances

The Laboratory shall develop methods that are Fit-for-purpose. The method shall be capable of determining both the relative mean concentration or ratio of measured analytical values and the identity of the *Prohibited Substance* or *Metabolite(s)* or *Marker(s).*

Confirmation methods for Threshold Substances shall be performed on three Aliquots. If insufficient *Sample* volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed. *Adverse Analytical Finding* decisions shall be based on the mean of the measured concentrations or ratio of measured analytical values taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. Reports and documentation, where necessary, shall report the mean concentration or ratio of measured analytical values, including the relevant uncertainty details.

In the case of substances which are capable of being produced endogenously (for example testosterone, peptide hormones) and at any concentration (including below relevant thresholds), the *Athlete*'s *Sample* will be deemed to contain a *Prohibited Substance* and the Laboratory will report an *Adverse Analytical Finding* if, based on any reliable analytical method (e.g. IRMS), the Laboratory can show that the *Prohibited Substance* is of exogenous origin.

5.4.4.2 Validation of Methods

5.4.4.2.1 Confirmation methods for Non-Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-purpose include but are not limited to:

- Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between compounds of closely related structures;
- Identification capability. Since the results for Non- Threshold Substances are not quantitative, the Laboratory should establish criteria for ensuring that a substance representative of the class of *Prohibited Substance*s can be repeatedly identified and detected as present in the *Sample* at the MRPL;
- Robustness. The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;
- Carryover. The conditions required to eliminate carryover of the substance of interest from *Sample* to *Sample* during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method should avoid interference in the detection of *Prohibited Substance*s or their *Metabolites* or *Markers* by components of the *Sample* matrix;
- Standards. Reference Materials should be used for identification, if available. If there is no reference standard available, the use of data or *Sample* from a validated Reference Collection is acceptable.

5.4.4.2.2 Confirmation methods for Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-purpose include but are not limited to:

- Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between compounds of closely related structures;
- Intermediate Precision. The method shall allow for the reliable repetition of the results at different times and with different operators performing the assay. Intermediate Precision at the threshold shall be recorded;
- Robustness. The method shall be determined to produce the similar results with respect to minor variations in analytical

conditions. Those conditions that are critical to reproducible results shall be controlled;

- Carryover. The conditions required to eliminate carryover of the substance of interest from *Sample* to *Sample* during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method shall limit interference in the measurement of the amount of *Prohibited Substance*s or their *Metabolites* or *Markers* by components of the *Sample* matrix;
- Standards. Reference Materials should be used for quantification, if available;
- Limit of quantitation (LOQ). The Laboratory shall demonstrate that a threshold method has an established LOQ of no more than 50% of the threshold value for Threshold Substances;
- Linearity shall be documented at 50% to 200% of the threshold value, unless otherwise stipulated in a Technical Document.

5.4.4.3 Estimate of Uncertainty of Method

In most cases an identification of a *Prohibited Substance*, its *Metabolite*(s) or *Marker(s)*, is sufficient to report an *Adverse Analytical Finding*.

5.4.4.3.1 Uncertainty in identification

The appropriate analytical characteristics shall be documented for a particular assay. The Laboratory shall establish criteria for identification of a compound at least as rigorous as stated in the relevant Technical Document.

5.4.4.3.2 Uncertainty in establishing that a substance exceeds a threshold.

The purpose of threshold reporting is to establish that the *Prohibited Substance* or its *Metabolite*(s) or *Marker(s)* are present at a concentration/ratio of measured analytical values greater than the threshold taking into consideration the applicable uncertainty. The method, including selection of standards and controls, and estimation of uncertainty shall be Fit-for-purpose.

5.4.4.3.2.1 Uncertainty of quantitative results, particularly at the threshold value, shall be addressed during the validation of the assay.

5.4.4.3.2.2 The expression of uncertainty shall use the expanded uncertainty using a coverage factor, k, to reflect a level of confidence of 95%.

5.4.4.3.2.3 Uncertainty may be further addressed in Technical Documents in order to reflect the purpose of analysis for the specific substances.

5.4.4.4 Control of Data

5.4.4.4.1 Data and Computer Security

5.4.4.4.1.1 All reasonable measures shall be taken to prevent intrusion and copy of data from computer systems.

5.4.4.4.1.2 Access to computer terminals, computers, servers or other operating equipment shall be controlled by physical access and by multiple levels of access controlled by passwords or other means of employee recognition and identification. These include, but are not limited to account privileges, user identification codes, disk access, and file access control.

5.4.4.4.1.3 The operating software and all files shall be backed up on a regular basis and a current copy shall be either stored in a fire and water proof environment or kept off site at a secure location.

5.4.4.4.1.4 The software shall prevent the changing of results unless there is a system to document the *Person* doing the editing and that editing can be limited to users with proper level of access.

5.4.4.4.1.5 All data entry, recording of reporting processes and all changes to reported data shall be recorded with an audit trail. This shall include the date and time, retention of original data, reason for change to original data and the individual performing the task.

5.4.5 Equipment

5.4.5.1 A List of available equipment is to be established and maintained.

5.4.5.2 As part of a quality system, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025 Section 5.5.

5.4.5.3 General Laboratory equipment (fume hoods, centrifuges, evaporators, etc) that is not used for making measurements should be maintained by visual examination, safety checks and cleaning as necessary. Calibrations are only required where the setting can significantly change the test result. A maintenance schedule, at least to manufacturer's recommendations or local regulations if available, shall be established for general Laboratory equipment which is used in the test method.

5.4.5.4 Equipment or volumetric devices used in measuring shall have periodic performance checks along with servicing, cleaning, and repair.

5.4.5.5 Qualified subcontracted vendors may be used to service, maintain, and repair measuring equipment.

5.4.5.6 All maintenance, service, and repair of equipment shall be documented.

5.4.6 Measurement Traceability

5.4.6.1 Reference Materials

When available, reference drug or drug *Metabolite*(s) traceable to a national standard or certified by a body of recognized status, such as USP, BP, Ph.Eur. or WHO, should be used. At a minimum, an analysis report must be obtained.

When a Reference Material is not certified, the Laboratory shall verify its identity and purity by comparison with published data or by chemical characterization.

5.4.6.2 Reference Collections

A collection of *Sample* or isolates may be obtained from a biological matrix following an authentic and verifiable administration of a *Prohibited Substance* or *Prohibited Method*, providing that the analytical data are sufficient to justify the identity of the relevant chromatographic peak or isolate as a *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Marker* of a *Prohibited Substance* or *Prohibited Method*.

5.4.7 Assuring the quality of test results

5.4.7.1 The Laboratory shall participate in the *WADA* EQAS.

5.4.7.2 The Laboratory shall have in place a quality control system, including the submission of blind quality control samples that challenges the entire scope of the analytical process (i.e., *Sample* receipt and accessioning through result reporting).

5.4.7.3 Analytical performance shall be monitored by operating quality control schemes appropriate to the type and frequency of testing performed by the Laboratory. The range of quality control activities should include:

- Positive and negative controls analyzed in the same analytical run as the Presumptive Analytical Finding *Sample*;
- The use of deuterated or other internal standards or standard addition;
- Comparison of mass spectra or ion ratios from selected ion monitoring (SIM) to a Reference Material or Reference Collection *Sample* analyzed in the same analytical run;
- Confirmation of the "A" and "B" Split *Samples*;

- For Threshold Substances, quality control charts referring to appropriate control limits depending on the analytical method employed (e.g., ± 10 % of the target value; +/- 3SD), should be used;
- The quality control procedures shall be documented by the Laboratory.

6.0 Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Sample*s

6.1 Introduction and Scope

This section of the document is intended as an application as described in Annex B.4 (Guidelines for establishing applications for specific fields) of ISO/IEC 17025 for the field of *Doping Control*. Any aspect of testing or management not specifically discussed in this document shall be governed by ISO/IEC 17025. The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as a *WADA*-accredited Laboratory and are therefore determined to be significant in the evaluation and accreditation process.

This section introduces the specific performance standards for a *WADA*-accredited Laboratory. The conduct of testing is considered a process within the definitions of ISO 17000. Performance standards are defined according to a process model where the Laboratory practice is structured into three main categories of processes:

- Analytical and technical processes;
- Management processes;
- Support processes.

Wherever possible, the application will follow the format of the ISO/IEC 17025 document. The concepts of the quality management system, continuous improvement, and customer satisfaction have been included. In some circumstances, measurements of blood parameters may be conducted according to ISO 15189.

6.2 Analytical and Technical Processes

6.2.1 Receipt of *Sample*s

6.2.1.1 *Sample*s may be received by any method acceptable under the concepts of the *International Standard* for *Testing*.

6.2.1.2 The transport container shall first be inspected and any irregularities recorded.

6.2.1.3 The transfer of the *Sample*s from the courier or other person delivering the *Sample*s shall be documented including at a minimum, the date, the time of receipt, and the name and signature of the Laboratory representative receiving the *Sample*. This information shall be included into the Laboratory Internal Chain of Custody record.

6.2.2 Handling and Retention of *Sample*s

6.2.2.1 The Laboratory shall have a system to uniquely identify the *Sample*s and associate each *Sample* with the collection document or other external chain of custody.

6.2.2.2 The Laboratory shall have Laboratory Internal Chain of Custody procedures to maintain control of and accountability for *Sample*s from receipt through to final disposition of the *Sample*s. The procedures shall incorporate the concepts presented in the applicable *WADA* Technical Document for Laboratory Internal Chain of Custody.

6.2.2.3 The Laboratory shall observe and document conditions that exist at the time of receipt that may adversely impact on the integrity of a *Sample*. For example, irregularities noted by the Laboratory should include, but are not limited to:

- *Sample Tampering* is evident;
- *Sample* is not sealed with tamper-resistant device or not sealed upon receipt;
- *Sample* is without a collection form (including *Sample* identification code) or a blank form is received with the *Sample*;
- *Sample* identification is unacceptable. For example, the number on the bottle does not match the *Sample* identification number on the form;
- *Sample* volume is inadequate to perform the requested testing menu;
- *Sample* transport conditions are not consistent with preserving the integrity of the *Sample* for anti-doping analysis.

6.2.2.4 The Laboratory shall notify and seek advice from the Testing Authority regarding rejection and testing of *Sample*s for which irregularities are noted (e.g. a *Sample* sent as whole blood for blood transfusion testing has coagulated). If applicable, any agreement between a Testing Authority and Laboratory that establishes *Sample* rejection criteria shall be documented.

6.2.2.5 *Sample*s for which Analytical Testing is to be performed on serum/plasma fraction only (not on cellular components).

*Sample*s should be centrifuged immediately after Laboratory reception to obtain the serum or plasma fraction. When analyzed shortly after centrifugation (within 48 hours), *Sample*s and/or Aliquots may be stored refrigerated at approximately 4 degrees Celsius until analysis. For longer term analyses, *Sample*s shall be frozen according to established protocols and thawed before analysis. In all circumstances, the appropriate steps to ensure the integrity of the *Sample* shall be taken by the Laboratory. The Laboratory shall retain the "A" and "B" *Sample*s with or without *Adverse Analytical Finding(s)* for a minimum of three (3) months after the Testing Authority receives the final analytical ("A" or "B" *Sample*) report. The *Sample*s shall be retained frozen under appropriate conditions. *Sample*s with irregularities shall

be held under appropriate conditions for a minimum of three (3) months following the report to the Testing Authority.

After the applicable storage period, from a minimum of three (3) months, or up to a maximum of eight (8) years if and as requested by the Testing Authority, the Laboratory shall either make the *Sample*s anonymous for research purposes (with proper consent from the *Athlete*) or dispose of the *Sample*s. *Sample*s used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular *Athlete*. Disposal of *Sample*s shall be conducted and recorded under the Laboratory Internal Chain of Custody.

6.2.2.6 *Sample*s that consist of whole blood or blood fractions for which tests on cellular components are to be performed.

When analyzed shortly after reception, *Samples* shall be stored at approximately 4 degrees Celsius as soon as practicable after Aliquots have been taken for analysis. If it is necessary to delay the analysis, *Sample*s shall be stored at approximately 4 degrees Celsius on reception and should be analyzed within 48 hours. As soon as practicable after Aliquots have been taken for analysis, *Sample*s should be returned to approximately 4 degrees Celsius storage. In all circumstances, the appropriate steps to ensure the integrity of the *Sample* shall be taken by the Laboratory. The Laboratory shall retain the "A" and "B" *Sample*s with or without *Adverse Analytical Finding* for a minimum of 1 month after the Testing Authority receives the final analytical ("A" or "B" *Sample*) report. *Sample*s with irregularities shall be held under appropriate conditions for a minimum of one (1) month following the report to the Testing Authority.

After the applicable storage period, from a minimum of one (1) month, or longer if requested by the Testing Authority, the Laboratory shall either make the *Sample*s anonymous for research purposes (with proper consent from the *Athlete*) or dispose of the *Sample*s. *Sample*s used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular *Athlete*. Disposal of *Sample*s shall be conducted and recorded under the Laboratory Internal Chain of Custody.

6.2.2.7 If the Laboratory has been informed by the Testing Authority that the analysis of a *Sample* is challenged or disputed, the *Sample* shall be stored under appropriate conditions and all the records pertaining to the testing of that *Sample* shall be stored until completion of any challenges.

6.2.2.8 The Laboratory shall maintain a policy pertaining to retention, release, and disposal of *Sample*s or Aliquots.

6.2.2.9 The Laboratory shall maintain custody information on the transfer of *Sample*s, or portions thereof to another Laboratory.

6.2.2.10 In cases where both "A" and "B" *Sample*s have been analyzed as part of the anti-doping procedure and led to a maximum sanction of the *Athlete*, the Laboratory shall either make the *Sample*s anonymous for research purposes (with proper consent from the *Athlete*) or dispose of the *Sample*s. *Sample*s used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular *Athlete*. Disposal of *Sample*s shall be conducted and recorded under the Laboratory Internal Chain of Custody.

6.2.2.11 Re-sealing of *Sample*s for long-term storage and re-Testing

Re-sealing of *Sample*s for future re-testing as listed in ISL Section 5.2.2.12 shall apply.

6.2.3 Sampling and Preparation of Aliquots for Analysis

The sampling and preparation of Aliquots for analysis listed under ISL section 5.2.3 shall apply.

6.2.4 Analytical Testing

6.2.4.1 Blood Initial Testing Procedure

6.2.4.1.1 The Initial Testing Procedure(s) shall detect the *Prohibited Substance*(s) or *Metabolite(s)* of *Prohibited Substance*(s), or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* for substances covered by the *Prohibited List* for which there is a method that is Fit-for-Purpose. *WADA* may make specific exceptions to this section for specialized techniques that are not required to be within the scope of accreditation of all Laboratories.

6.2.4.1.2 The Initial Testing Procedure shall be performed with a Fit-for-purpose method for the *Prohibited Substance* or *Prohibited Method* being tested. A characteristic of the Initial Testing Procedure is to obtain information about the potential presence of *Prohibited Substance*(s) or *Metabolite(s)* of *Prohibited Substance*(s), or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method*. Results from Initial Testing Procedures can be included as part of longitudinal studies provided that the method is appropriately validated.

6.2.4.1.3 All batches undergoing the Initial Testing Procedure shall include appropriate negative and positive controls in addition to the *Sample*s being tested.

6.2.4.1.4 Initial Testing Procedure results are not required to consider uncertainty of measurement.

6.2.4.2 Blood Confirmation Procedure

All Confirmation Procedures shall be documented. The objective of the Confirmation Procedure is to accumulate additional information to support an *Adverse Analytical Finding*.

6.2.4.2.1 "A" *Sample* confirmation

6.2.4.2.1.1 A Presumptive Analytical Finding from an Initial Testing Procedure of a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* shall be confirmed using an additional Aliquot(s) taken from the original "A" *Sample*.

6.2.4.2.1.2 Immunoassays applied for the Initial Testing Procedures and Confirmation Procedures shall use antibodies recognizing different epitopes of the macromolecule analyzed, unless a properly validated purification or separation method is incorporated into the confirmation method to eliminate the potential for cross-reactivity prior to the application of "A" confirmation immunoassay.

In assays which include multiple antibodies (such as sandwich immunoassays), only one of the antibodies (either capture or detection) used in the immunoassays applied for the Initial Testing Procedures and Confirmation Procedures must differ for antigenic epitope specificity. The other antibody may be used in both immunoassays.

For peptide/protein analytes that are too small to have two independent epitopes, two different purification methods or two different analytical methods shall be applied.

Multiplexed immunoassays, protein chips, and similar simultaneous multi-analyte testing approaches may be used. The Initial Testing Procedures and Confirmation Procedures may be performed simultaneously in the same Aliquot, although it is required that the test be repeated as described in Section 6.2.4.2.1.1 and that the same preconditions described above for assay antibody specificity or methods of purification or separation are met.

6.2.4.2.1.3 Antibodies may also be used for specific labelling of cell components and other cellular characteristics. When the purpose of the test is to identify populations of blood constituents, the detection of multiple *Markers* on the cells as the criteria for an *Adverse Analytical Finding* replaces the requirement for two antibodies recognizing different antigenic epitopes.

Note: An example is the detection of surface Markers on red blood cells (RBCs) using flow cytometry. The flow cytometer is

set up to selectively recognize RBCs. The presence on the RBC of more than one surface Marker (as determined by antibody labelling) as a criterion for an Adverse Analytical Finding may be used as an alternative to multiple antibodies to the same Marker.

6.2.4.2.1.4 The Laboratory shall have a policy to define those circumstances where the Confirmation Procedure of an "A" *Sample* may be repeated (e.g., batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and be completed on a new Aliquot of the "A" *Sample*.

6.2.4.2.1.5 If more than one *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* is identified by the Initial Testing Procedures, the Laboratory shall confirm as many of the Presumptive Analytical Findings as possible. The decision on the prioritization for the confirmation(s) shall be made to give precedent to non-specified substance(s) and the decision should be made in cooperation with the Testing Authority and documented.

6.2.4.2.1.6 The mean value of the results of three Aliquots for the "A" *Sample* finding for Threshold Substances minus the value of the measurement uncertainty determined by the Laboratory must exceed the relevant Threshold. If insufficient *Sample* volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed. *Adverse Analytical Finding* decisions shall be based on the mean of the measured concentrations or ratio of measured analytical values (e.g. concentrations, chromatogram peak height or area, etc.), taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. Reports and documentation, shall give the mean concentration with the associated uncertainty.

6.2.4.2.2 "B" *Sample* confirmation

6.2.4.2.2.1 *Sample*s that consist of plasma, serum or other blood fractions for which no tests on cellular components are to be performed: In those cases where confirmation of a *Prohibited Substance*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* is requested in the "B" *Sample*, the "B" *Sample* analysis should occur as soon as possible and shall take place no later than seven (7) working days starting the first working day following notification of an "A" *Sample Adverse Analytical Finding* by the Laboratory.

*Sample*s that consist of whole blood or blood fractions for which tests on cellular components are to be performed: For "B" *Sample*

confirmation in whole blood or blood fraction with blood cells only, the "B" *Sample* analysis shall take place no later than seven (7) working days starting the first working day following notification of an "A" *Sample Adverse Analytical Finding* by the Laboratory.

If the Laboratory is unable to perform the "B" analysis within this time frame for technical or logistical reason(s), this shall not be considered as a deviation from the ISL susceptible to invalidate the analytical procedure and analytical results.

The Laboratory shall proceed as described above unless informed within the seven (7) working day time frame that the *Athlete* has waived his/her right to the "B" confirmation analysis and accepts the finding(s) of the "A" confirmation analysis.

6.2.4.2.2.2 The "B" *Sample* confirmation shall be performed in the same Laboratory as the "A" *Sample* confirmation.

6.2.4.2.2.3 If the "B" *Sample* confirmation proves negative, the entire test shall be considered negative.

6.2.4.2.2.4 For exogenous Threshold Substances, the "B" *Sample* results need only confirm the "A" *Sample* identification for the *Adverse Analytical Finding* to be valid.

6.2.4.2.2.5 For endogenous Threshold Substances, the mean value of the results of three Aliquots for the B *Sample* finding minus the value of the estimated measurement uncertainty, determined by the Laboratory, must exceed the relevant Threshold. *Adverse Analytical Finding* decisions shall be based on the mean of the measured concentrations or ratio of measured analytical values, taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. If insufficient *Sample* volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

6.2.4.2.2.6 The *Athlete* and/or his/her representative, a representative of the entity responsible for *Sample* collection or results management, a representative of the *National Olympic Committee*, National Sport Federation, International Federation, and a translator shall be authorized to attend the "B" confirmation.

If the *Athlete* declines to be present or the *Athlete*'s representative does not respond to the invitation or if the *Athlete* or the *Athlete*'s representative continuously claim not to be available on the date of the opening, despite reasonable attempts by the Laboratory to accommodate their dates, over a period not to exceed 7 working

days, the Testing Authority or the Laboratory shall proceed regardless and appoint an independent witness to verify that the "B" *Sample* container shows no signs of *Tampering* and that the identifying numbers match that on the collection documentation. At a minimum, the Laboratory Director or representative and the *Athlete* or his/her representative or the independent witness shall sign Laboratory documentation attesting to the above.

The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations.

The Laboratory Director may remove, or have removed by proper authority, any *Athlete* or representative(s) interfering with the testing process. Any behavior resulting in removal shall be reported to the Testing Authority and may be considered an anti–*doping* rule violation in accordance with Article 2.5 of the *Code*, "*Tampering*, or *Attempting* to tamper, with any part of *Doping Control*".

6.2.4.2.2.7 Aliquots taken for "B" Confirmation Procedure shall be taken from the original "B" *Sample*. Refer to urine section 5.2.4.3.2.7.

6.2.4.2.2.8 The Laboratory shall have a policy to define those circumstances when confirmation testing of the "B" *Sample* may be repeated (eg batch quality control failure) and the first test result shall be nullified. Each repeat confirmation should be performed on a new Aliquot of the "B" *Sample* and new controls.

6.2.4.2.2.9 If the "B" *Sample* confirmation proves negative, the *Sample* shall be considered negative and the Testing Authority, *WADA* and the International Federation notified of the new analytical finding.

6.2.4.3 Alternative biological matrices

Any testing results of hair, nails, oral fluid or other biological material shall not be used to counter *Adverse Analytical Finding*s from blood.

6.2.5 Results Management

6.2.6.1 Review of results

6.2.6.1.1 A minimum of two certifying scientists shall independently review all *Adverse Analytical Finding*s before a report is issued. The review process shall be recorded.

6.2.6.1.2 At a minimum, the review shall include:

- Laboratory Internal Chain of Custody documentation;

- Validity of the analytical Initial Testing and confirmation data and calculations;
- Quality control data;
- Completeness of documentation supporting the reported analytical findings.

6.2.6.1.3 When an *Adverse Analytical Finding* is rejected, the reason(s) shall be recorded.

6.2.6 Documentation and Reporting

6.2.6.2 The Laboratory shall have documented procedures to ensure that it maintains a coordinated record related to each *Sample* analyzed. In the case of an *Adverse Analytical Finding*, the record shall include the data necessary to support the conclusions reported (as set forth in the Technical Document, Laboratory Documentation Packages). In general, the record should be such that in the absence of the analyst, another competent analyst could evaluate what tests had been performed and interpret the data.

6.2.6.3 Each step of testing shall be traceable to the staff member who performed that step.

6.2.6.3 Significant variance from the written procedure shall be documented as part of the record (e.g., memorandum for the record).

6.2.6.4 Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.

6.2.6.5 Reporting of "A" *Sample* results should occur within ten (10) working days of receipt of the *Sample*. The reporting time required for specific *Competition*s may be substantially less than ten (10) days. The reporting time may be altered by agreement between the Laboratory and the Testing Authority.

6.2.6.6 A single, distinct Test Report shall be generated to document the *Adverse Analytical Finding(s)* of an individual *Sample*. The Laboratory Test Report shall include, in addition to the items stipulated in ISO/IEC 17025, the following:

- Customer *Sample* identification number;
- Laboratory identification number;
- Type of test (*Out of Competition/In-Competition*);
- Sport and/or discipline;
- Name of *Competition* and/or client reference code (for example: *ADAMS* test mission code), if provided;
- and sport and/or discipline;
- Date of receipt of *Sample*;

- Date of report;
- Sex of the *Athlete*;
- Type of *Sample* (urine, blood, etc.);
- Test results (for Threshold Substances, the mean value, units, uncertainty details and reporting threshold shall be included);
- Signature of authorized individual;
- Other information as specified by the Testing Authority or *WADA*.

At a minimum, labelling and information provided by the Laboratory related to the type of test, sport/discipline, test results (including comments/opinions) and client to whom the report is addressed shall also be provided in English on the test report.

6.2.6.7 The Laboratory is not required to measure or report a concentration for *Prohibited Substances* for a non-threshold analyte in blood *Sample*s. The Laboratory shall report the actual *Prohibited Substance*(s), *Metabolite*(s) of the *Prohibited Substance*(s) or *Prohibited Method*(s), or *Marker(s)* detected in the blood *Sample*.

For Threshold Substances in blood *Sample*s, the Laboratory report shall establish that the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* of a *Prohibited Method* is present at a concentration and/or ratio of measured analytical values greater than the threshold (taking into consideration the value of measurement uncertainty for the "A" *Sample* confirmation and also "B" *Sample* confirmation of Threshold Substances) in concluding that the concentration and/or ratio of measured analytical values in the *Sample* exceeds the threshold. The estimated value of measurement uncertainty should be included in the Test Report and in the Laboratory Documentation Packages, if provided.

6.2.6.8 The Laboratory should qualify the result(s) in the Test Report as an *Adverse Analytical Finding* or "no *Prohibited Substance(s)* on test menu detected".

6.2.6.9 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented.

Note: An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, and whether an observed result is consistent with a set of reported conditions.

6.2.6.10 In addition to reporting to the Testing Authority, the Laboratory shall simultaneously report any *Adverse Analytical Finding*s ("A" and "B" results) to *WADA* and the responsible International Federation (and/or to the owner of the *Event* in the case of Major *International Event*s). In the case where the

sport or *Event* is not associated with an International Federation (e.g., professional leagues, University and college sports) the Laboratory shall report *Adverse Analytical Finding*s to the Testing Authority and to *WADA*. All reporting shall be in accord with the confidentiality requirements of the *Code*.

6.2.6.11 The Laboratory shall report quarterly to *WADA*, in a format specified by *WADA*, a summary of the results of all tests performed. No information that could link an *Athlete* with an individual result will be included. The report will include a summary of any *Sample*s rejected for testing and the reason for the rejection.

When the clearinghouse (*ADAMS*) is in place, the Laboratory shall simultaneously report to *WADA* all information reported to the Testing Authority, according to the requirements listed in Section 6.2.6.6 in lieu of the paragraph above. The information will be used to generate summary reports.

6.2.6.12 The documentation package should be provided by the Laboratory only to the relevant result management authority upon request and should be provided within 10 working days of the request. Laboratory Documentation Packages shall be in compliance with the *WADA* Technical Document on Laboratory Documentation Packages.

6.2.6.13 *Athlete* confidentiality shall be a key concern for all Laboratories engaged in *Doping Control* cases.

6.2.6.13.1.1 Testing Authority requests for information shall be made in writing to the Laboratories.

6.2.6.13.1.2 *Adverse Analytical Finding*s shall not be provided by telephone.

6.2.6.13.1.3 Information sent by a facsimile is acceptable if the security of the receiving facsimile machine has been verified and procedures are in place to ensure that the facsimile has been transmitted to the correct facsimile number.

6.2.6.13.1.4 Unencrypted email is not authorized for any reporting or discussion of *Adverse Analytical Finding*s if the *Athlete* can be identified or if any information regarding the identity of the *Athlete* is included.

6.2.6.13.1.5 The Laboratory shall also provide any information by *WADA* in conjunction with the Monitoring Program, as set forth in Article 4.5 of the *Code*.

6.3 Quality Management Processes

The Laboratory management requirements listed under ISL Section 5.3 shall apply.

6.4 Support processes

Except as modified below, the Laboratory support requirements listed under ISL Section 5.4 shall apply. Accordingly, numbering below is not consecutive, but instead, only those sections where changes from Section 5.4 have been made are included.

6.4.4 Test Methods and Method Validation

6.4.4.1 Selection of Methods

Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall develop, validate and document methods for the detection of substances present on the *Prohibited List* and for associated *Metabolites* or *Markers* or related substances. Note that for many substances, the associated *Metabolites* are detected; thereby confirming the metabolism and the administration of a *Prohibited Substance*. The methods shall be selected and validated so they are Fit-for-purpose. *WADA* will supply feedback to the Laboratories regarding the Fit–for-purpose of the assay principle.

For Non-Threshold Substances refer to section 5.4.4.1.1.

For Threshold Substances refer to section 5.4.4.1.2.

6.4.4.2 Validation of Methods

For Non-Threshold Substances refer to section 5.4.4.2.1.

For Threshold Substances refer to section 5.4.4.2.2.

6.4.4.3 Estimate of Uncertainty of Method

The Laboratory shall provide an estimation of the measurement uncertainty where applicable.

6.4.4.3.1 Uncertainty in identification

The appropriate analytical characteristics shall be documented for a particular assay. The Laboratory shall establish criteria for identification of a compound.

6.4.4.3.2 Uncertainty in establishing that a substance exceeds a threshold.

The purpose of threshold reporting is to establish that the *Prohibited Substance* or its *Metabolite*(s) or *Marker(s)* are present at a concentration/ratio of measured analytical values greater than the threshold value taking into consideration the applicable uncertainty. The method, including selection of standards and controls, and estimation of uncertainty shall be Fit-for-purpose.

PART THREE: ANNEXES

ANNEX A - *WADA* EXTERNAL QUALITY ASSESSMENT SCHEME (EQAS)

The *WADA* External Quality Assessment Scheme (EQAS) is designed to continuously monitor the capabilities of the Laboratories to evaluate Laboratory proficiency and to improve test result uniformity between Laboratories. At the same time the EQAS also represents, via the educational program, a source of continuous improvement for the effectiveness of the anti-doping testing procedures. The purpose of the individual EQAS sample will determine its composition and form.

1.0 *WADA* External Quality Assessment Scheme

All procedures associated with the handling and testing of the EQAS samples by the probationary laboratory and Laboratory are, to the greatest extent possible, to be carried out in a manner identical to that applied to routine Laboratory *Sample*s, unless otherwise specified by *WADA*. No effort should be made to optimize instrument (e.g., change multipliers or chromatographic columns) or method performance prior to analyzing the EQAS samples unless it is a regularly scheduled maintenance activity. Only methods or procedures used in routine testing should be employed.

1.1 Open (Educational) EQAS

The Laboratory may be directed to analyze an EQAS sample for a specific *Prohibited Substance*. In general, this approach is used for educational purposes or for data gathering.

The Laboratory shall report the results of open EQAS samples in a format specified by *WADA*.

1.2 Blind EQAS

The Laboratory will be aware that the sample is an EQAS sample, but will not be aware of the content of the sample.

The Laboratory shall report the results of blind EQAS samples to *WADA* in the same manner as specified for routine *Sample*s unless otherwise notified by *WADA*. For some EQAS samples or EQAS sample sets, additional information may be requested from the Laboratory.

1.3 Double Blind EQAS

The Laboratory will receive EQAS samples which are indistinguishable from normal testing *Sample*s. The EQAS samples may consist of blank, adulterated or samples with *Adverse Analytical Finding*(s). These samples may be used to assess turn-around time, compliance with documentation package requirements, and other non-analytical performance criteria as well as Laboratory competence in detection and identification of *Prohibited Substances*, *Metabolite*(s) of *Prohibited Substances*, and *Marker(s)* of *Prohibited Substances and Prohibited Methods*.

2.0 External Quality Assessment Scheme Sample Composition

2.1 Blank EQAS Samples

Blank EQAS samples include those samples that do not contain *Prohibited Substances* or their *Metabolites*.

2.2 Adulterated EQAS Samples

Adulterated samples are those which have been deliberately adulterated by the addition of extraneous substances designed to dilute the sample, degrade the analyte or to mask the analyte during the analytical determination.

2.3 EQAS Samples containing *Adverse Analytical Finding*(s)

2.3.1 EQAS Sample Composition

These EQAS samples contain target substances such as those *Prohibited Substances*, *Metabolite*(s) of *Prohibited Substances*, and *Marker(s)* of *Prohibited Substances and Prohibited Methods* which each accredited Laboratory must be prepared to assay in order to allow detection of the analytes by commonly used screening techniques. These are generally concentrations that might be expected in the urine or blood of drug users. For some analytes, the sample composition may consist of the parent drug as well as major *Metabolites*. The actual composition of the EQAS samples supplied to different Laboratories in a particular EQAS sample may vary but, within any annual period, all Laboratories participating in the EQAS are expected to have analyzed the same total number of samples.

A sample may contain more than one *Prohibited Substance*, *Metabolite(s)*, or *Marker* of a *Prohibited Substance or Prohibited Method*. It is possible that the sample will contain multiple *Metabolites* of a single substance, which would represent the presence of a single *Prohibited Substance*. All *Metabolites* detected should be reported according to the Laboratory*'s* standard operating procedures.

2.3.2 EQAS Sample Content

EQAS samples may be spiked with *Prohibited Substances* and/or their *Metabolites* and/or may be from authentic administration studies.

For Non-Threshold Substances, the concentration will be guided by, but not limited to, one of the following criteria:

- The *Prohibited Substance* and/or its major *Metabolite*(s) will be present in quantities greater than the Minimum Required Performance Level (MRPL);
- The *Prohibited Substance* and/or its major *Metabolite*(s) will be present near or below the applicable MRPL for special purposes. In this case, the Laboratory would be directed to analyze the sample for a particular *Prohibited Substance* as part of an educational challenge and the results will not be considered for evaluation for the purposes of the EQAS.

For Threshold Substances, the concentration in the sample will be guided by, but not limited to, one of the following criteria:

- At least 20 percent above the threshold or above the threshold plus the applicable target measurement uncertainty;
- Near or below the applicable threshold limit for special purposes. In this case, the Laboratory would be directed to analyze the sample for a particular *Prohibited Substance* as part of an educational challenge and the results will not be considered for evaluation for the purposes of the EQAS.

These concentrations and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.

Concentrations of any of the *Prohibited Substances* (or *Metabolites*) found below the threshold or the MRPL in the EQAS samples are considered to be negative for the purposes of the EQAS.

3.0 Evaluation of External Quality Assessment Scheme

Overall and individual round Laboratory EQAS performance will be assessed in accordance with the point system table in section 3.5 of this Annex.

3.1 Evaluation of Qualitative EQAS Samples

When a qualitative determination has been reported, the result will be judged to have properly reported the presence or absence of an *Adverse Analytical Finding*, or evidence of adulteration, as intended in the preparation of the EQAS sample.

3.2 Evaluation of Quantitative EQAS Samples

When a quantitative determination has been reported, the results can be scored based on the nominal or consensus value of the sample analyzed and a standard deviation which may be set either by the group results or according to the expected precision of the measurement. The z-score is calculated using the equation:

$$z = \frac{\bar{x} - \hat{x}}{\delta}$$

Where $\bar{x}$ is the value found

$\hat{x}$ is the assigned value

δ is the target value for standard deviation

The target relative standard deviation will be set in such a way that:

- An absolute z-score between zero (0) and two (2.0), inclusive, is deemed **satisfactory** performance;

- An absolute z-score between greater than two (2.0) to less than three (3.0) is deemed to be **questionable** performance;

- An absolute z-score equal to or greater than three (3.0) is deemed to be **unsatisfactory** performance.

3.3 Probationary Period and Probationary Laboratory Evaluation

The probationary EQAS is a part of the initial evaluation of a probationary laboratory seeking *WADA* accreditation. In addition to providing EQAS samples, *WADA* may provide, upon request, samples from past EQAS rounds in order to allow the probationary laboratory an opportunity to evaluate its performance against the recorded performance of accredited Laboratories.

Successful participation in *WADA* probationary EQAS is required before a probationary laboratory is eligible to be considered for accreditation (usually a minimum of 12 months). The EQAS samples shall occur in multiple rounds per year and will consist of a minimum of twenty (20) samples per year. At least four (4) EQAS samples will contain Threshold Substances. Blank and adulterated samples may also be included.

3.3.1 Methods Utilized

All procedures associated with the handling and testing of the EQAS samples by the laboratory are, to the greatest extent possible, to be carried out in a manner identical to that expected to be applied to routine *Sample*s, unless otherwise specified by *WADA*. No effort should be made to optimize instrument (e.g., change multipliers or chromatographic columns) or method performance prior to analyzing the EQAS samples unless it is a regularly scheduled maintenance activity. Methods or procedures to be utilized in routine testing should be employed.

3.3.2 False Positive result

Any false positive reported automatically disqualifies a probationary laboratory from further consideration for accreditation. The laboratory will only be eligible for re-instatement upon providing documentation to *WADA* that appropriate remedial and preventive actions have been implemented. *WADA* may decide to send a set of EQAS samples and/or audit the laboratory prior to reinstatement.

3.3.3 False Negative result

Probationary laboratories reporting a false negative in a Blind EQAS round, e.g. failure to identify a *Prohibited Substance* and/or its *Metabolites*, are informed as soon as possible by *WADA*. The laboratory shall take and report proper corrective action within 30 calendar days of the date of the letter to *WADA* (unless informed otherwise by *WADA*). Probationary laboratories may otherwise be advised by *WADA* to take corrective action for a given reason or to change a corrective action which has previously been reported to *WADA*. The corrective action reported to *WADA* shall be implemented in the routine operation of the laboratory.

3.3.4 Threshold Substance result

A probationary laboratory is to achieve satisfactory z-scores for quantitative results reported based on the mean of three independent determinations. The relative standard deviation is to be commensurate with the validation data and the uncertainty of the procedure should be such as to ensure a positive result in all of the cases for concentrations at 20% above the threshold level. Appropriate corrective action reported to *WADA* is mandatory in all cases of unsatisfactory z-scores.

3.3.5 Overall Probationary Laboratory Evaluation

During the probationary period other elements of the EQAS scheme, which are part of the generally applied procedures, will be considered to assess the competence of the laboratory.

These elements include, but are not limited to: determination of the specific gravity of the samples, the initial determination of the testosterone/epitestosterone (T/E) ratio and the presentation of necessary documentation (test reports and the documentation package to support an *Adverse Analytical Finding*).

For laboratories already in operation prior to the *WADA* probationary phase, all routine laboratory services will also be factors for evaluation purposes including, but not limited to:

- False negative(s);
- False positive(s);
- Questionable results for prohibited Threshold Substance(s);
- Unsatisfactory results for prohibited Threshold Substance(s);
- Improper implementation of corrective action;
- Responsiveness to *WADA*;
- T/E ratio or specific gravity;
- Test Report(s);
- Documentation package(s).

A probationary laboratory is to achieve a passing score based on the EQAS table in section 3.5 for the EQAS samples supplied during the probationary period.

Upon successful completion of the probationary phase, the laboratory will participate in the final accreditation test. The probationary laboratory is to achieve a passing score based on the EQAS table in section 3.5 for the EQAS samples supplied for the final accreditation test.

Appropriate corrective action reported to *WADA* is mandatory in all cases of non-compliance.

An assessment will be made on the overall performance of the laboratory after each EQAS round and also over the length of the laboratory probationary period based on a points system as shown in the point system table in section 3.5.

Probationary laboratories failing the requirements of the probationary EQAS shall have their status as a probationary laboratory suspended.

A suspended probationary laboratory wishing to re-enter the probationary EQAS is required to provide documentation of corrective action no later than thirty (30) working days prior to the end of the Suspension (unless informed otherwise by *WADA*). Failure to do so will prohibit the laboratory from re-entering the probationary EQAS. Lifting of the Suspension occurs only when proper corrective action has been implemented and reported to *WADA*. *WADA* may choose, at its sole discretion, to submit additional EQAS samples to the laboratory or to require that the laboratory be re-audited, at the expense of the laboratory. Laboratories re-entering the probationary EQAS shall be considered as a candidate laboratory and are subject to provide the applicable fee and the required documentation to *WADA*.

3.4 Accreditation Maintenance and Laboratory Evaluation

Laboratories shall be challenged with at least twenty (20) EQAS samples each year distributed in multiple rounds per year. Each year at least two (2) samples will contain Threshold Substances. Blank and adulterated samples may be included.

3.4.1 Methods utilized in EQAS

All procedures associated with the handling and testing of the EQAS samples by the Laboratory are, to the greatest extent possible, to be carried out in a manner identical to that applied to routine Laboratory *Sample*s, unless otherwise specified. No effort should be made to optimize instrument (e.g., change multipliers or chromatographic columns) or method performance prior to analyzing the EQAS samples unless it is a scheduled maintenance activity. Methods or procedures described in the standard operating procedures are to be employed in the initial analysis of these samples. Should a sample be suspected of containing a *Prohibited Substance* a confirmatory analysis is to be performed using the methods and procedures applied in routine testing. However, since many substances are rarely seen by the Laboratories, their routine procedures may not always cover all contingencies. It may be that the usual methodology is not found to be satisfactory, e.g. due to matrix background, and so the methods may be modified in a way to allow for confirmation of identification. This must be documented.

3.4.2 False Positive result

No false positive result is acceptable as part of the Blind or the Double Blind EQAS. The following procedures are to be followed when faced with such a situation:

- The Laboratory will be informed by *WADA* of a false positive finding as soon as possible;

- The Laboratory is to provide *WADA* with a written explanation of the reasons for the error within five (5) working days. This explanation is to include the submission of all quality control data from the batch of samples that included the false positive sample if the error is deemed to be technical/scientific;
- *WADA* shall review the Laboratory*'s* explanation promptly and decide what further action, if any, to take;
- If the error is determined to be an administrative error (clerical, sample mix-up, etc), *WADA* may direct the Laboratory to take corrective action to minimize the occurrence of the particular error in the future and, if there is reason to believe the error could have been systematic, may require the Laboratory to review and re-analyze previously run *Sample*s;
- If the error is determined to be a technical or methodological error, the Laboratory may be required to re-test all *Sample*s analyzed positive by the Laboratory from the time of final resolution of the error back to the time of the last satisfactory EQAS round. A statement signed by the Laboratory Director shall document this re-testing. The Laboratory may also be required to notify all clients whose results may have been affected of the error as part of its quality management system. Depending on the type of error that caused the false positive, this retesting may be limited to one analyte, a class of *Prohibited Substances or Prohibited Methods*, or may include any prohibited drug. The Laboratory shall immediately notify *WADA* if any result on a *Sample* that has been reported to a client is detected as a false positive. *WADA* may suspend or revoke the Laboratory*'s* accreditation. However, if the case is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, *WADA* may decide to take no further action;
- During the time required to resolve the error, the Laboratory remains accredited but has a designation indicating that a false positive result is pending resolution. If *WADA* determines that the Laboratory*'s* accreditation must be suspended or revoked, the Laboratory*'s* official status becomes "Suspended" or "Revoked" until the Suspension or Revocation is lifted or any process complete.

3.4.3 False Negative result

Laboratories reporting a false negative in a Blind EQAS round or Double Blind proficiency sample, e.g. failure by a Laboratory to identify a *Prohibited Substance* and/or its *Metabolites or a Prohibited Method*, are informed as soon as possible by *WADA*. Laboratories must take and report proper corrective action within thirty (30) calendar days of the date of the letter to *WADA* (unless informed otherwise by *WADA*). Laboratories may otherwise be advised by *WADA* to take corrective action for a given reason or to change a corrective action which has previously been reported to *WADA*. The corrective action reported to *WADA* shall be implemented in the routine operation of the Laboratory.

3.4.4 Threshold Substance result

A Laboratory is to achieve satisfactory z-scores for quantitative results reported based on the mean of three independent determinations. The relative standard deviation is to

be commensurate with the validation data and the uncertainty of the procedure should be such as to ensure a positive result at the 100% probability level for concentrations at 20% above the threshold level. Appropriate corrective action reported to *WADA* is mandatory in all cases of unsatisfactory z-scores.

A Laboratory with an unsatisfactory result based on the z-score or an unacceptably high uncertainty will receive a warning and will be required to furnish *WADA* with documentation of the corrective action taken within thirty (30) days of the date of the warning letter (unless informed otherwise by *WADA*).

3.4.5 Overall Laboratory evaluation

WADA is to evaluate, as per section 3.5, the performance of all Laboratories based on the results in the *WADA* EQAS (Blind and Double Blind EQAS) as well as on issues brought to *WADA*'s attention in relation to the Laboratory's routine testing services. The factors for consideration include, but are not limited to:

- False negative(s);
- False Positive(s)
- Questionable results for prohibited Threshold Substance(s);
- Unsatisfactory results for prohibited Threshold Substance(s);
- Improper implementation of corrective action;
- Responsiveness to *WADA*;
- T/E ratio or specific gravity;
- Test Report(s);
- Documentation package(s).

Persistent failure by a Laboratory to take appropriate action to remedy procedures, to comply with the requirements of Technical Documents and recommendations made or requested by *WADA* will result in a warning such that if documented evidence of effective corrective action is not received within thirty (30) working days, then Suspension immediately follows. The documentation, describing the corrective action taken will be assessed for acceptability by *WADA*. If considered to be unsatisfactory then Suspension will result.

The Laboratory is required to provide documentation of corrective action no later than thirty (30) working days prior to the end of the Suspension (unless informed otherwise by *WADA*). Failure to do so will result in immediate Revocation of the accreditation. Lifting of the Suspension occurs only when proper corrective action has been taken and reported to *WADA*. *WADA* may choose, at its sole discretion, to submit additional EQAS samples to the Laboratory or to require that the Laboratory be re-audited, at the expense of the Laboratory after having furnished satisfactory results for another EQAS round.

An assessment will be made on the overall performance of the Laboratory after each EQAS round and over a period of 12 months based on the points system shown in the

table in section 3.5. The points received by a Laboratory over a 12 month period will be taken into account for the purpose of re-accreditation for the next year.

3.5 Point Scale for Assessment of Laboratory Performance

Scoring	**Prohibited Substances**	**False positive**	**25**	**Immediate Suspension**
		False negative	**10**	**Corrective Action Report**
	Threshold Substances	**z-score ≥ 3.0**	**10**	**Corrective Action Report**
		2.0 < z-score < 3.0	**5**	**Internal investigation**
	Sample Parameters	**SG z-score ≥ 3.0**	**1**	**Internal investigation**
		T/E z-score ≥ 3.0	**1**	**Internal investigation**
	Documentation*	**ISL Non-conformity**	**2**	**Corrective Action Report**
	Technical Issue	**ISL Non-conformity**	**2**	**Corrective Action Report**
Evaluation	**Point Total for single EQAS round**		**≥ 20**	**Suspension**
	Point Total per 12 month period		**≥ 30**	**Suspension or Revocation of accreditation**

* Documentation includes but is not limited to Documentation Packages, Corrective Action Reports and Test Reports.

ANNEX B - LABORATORY CODE OF ETHICS

1.0 Confidentiality

The heads of Laboratories, their delegates and Laboratory staff shall not discuss or comment to the media on individual results prior to the completion of any adjudication without consent of the organization that supplied the *Sample* to the Laboratory and the organization that is asserting the *Adverse Analytical Finding* in adjudication.

2.0 Research

Laboratories are entitled to participate in research programs provided that the Laboratory Director is satisfied with the *bona fide* nature and the programs have received proper ethical (e.g. human subjects) approval.

3.0 Research in Support of *Doping Control*

The Laboratories are expected to develop a program of research and development to support the scientific foundation of *Doping Control*. This research may consist of the development of new methods or technologies, the pharmacological characterization of a new doping agent, the characterization of a masking agent or method, and other topics relevant to the field of *Doping Control*.

3.1 Human subjects

The Laboratories shall follow the Helsinki Accords and any applicable national standards as they relate to the involvement of human subjects in research.

Voluntary informed consent shall also be obtained from human subjects in any drug administration studies for the purpose of development of a Reference Collection or proficiency testing materials.

3.2 Controlled substances

The Laboratories are expected to comply with the relevant national laws regarding the handling and storage of controlled (illegal) substances.

4.0 Analysis

4.1 *Competition*s

The Laboratories shall only accept and analyze *Sample*s originating from known sources within the context of *Doping Control* programs conducted in *Competition*s organized by national and international sports governing bodies. This includes national and international federations, *National Olympic Committee*s, national associations, universities, and other similar organizations. This rule applies to Olympic and non-Olympic sports.

Laboratories should exercise due diligence to ascertain that the *Sample*s are collected according to the *World Anti-Doping Code International Standard* for *Testing* or similar guidelines. These guidelines shall include collection of Split Samples; appropriate *Sample* container security considerations; and formal chain of custody conditions. Laboratories shall ensure that *Sample*s received are tested in accordance with all the ISL rules.

4.2 *Out-of-Competition*

The Laboratories shall accept *Sample*s taken during training (or *Out-of-Competition*) only if the following conditions are simultaneously met:

- That the *Sample*s have been collected and sealed under the conditions generally prevailing in *Competition*s themselves as in Section 3.1 above;
- If the collection is a part of an anti-doping program; and
- If appropriate sanctions will follow a positive case.

Laboratories shall not accept *Sample*s, for the purposes of either Initial Testing or identification, from commercial or other sources when the conditions in the above paragraph are not simultaneously met.

Laboratories shall not accept *Sample*s from individual *Athletes* on a private basis or from individuals or organizations acting on their behalf.

These rules apply to all sports.

4.3 Clinical or Forensic

Occasionally the Laboratory may be requested to analyze a sample for a banned drug or endogenous substance allegedly coming from a hospitalized or ill *Person* in order to assist a physician in the diagnostic process. Under this circumstance, the Laboratory Director shall explain the pre-testing issue to the requester and agree subsequently to analyze the sample only if a letter accompanies the sample and explicitly certifies that the sample is for medical diagnostic or therapeutic purposes.

The letter shall also explain the medical reason for the test.

Work to aid in forensic investigations may be undertaken but due diligence should be exercised to ensure that the work is requested by an appropriate agency or body. The Laboratory should not engage in analytical activities or expert testimony that would intentionally question the integrity of the individual or the scientific validity of work performed in the anti-doping program.

4.4 Other analytical activities

If the Laboratory accepts *Sample*s from any entity that is not a Testing Authority recognized by the *World Anti-Doping Code*, it is the responsibility of the Laboratory Director to ensure that any *Adverse Analytical Finding* will be processed according to

the *Code* and that the results cannot be used in any way by an *Athlete* or associated *Person* to avoid detection.

The Laboratory shall not engage in any analysis that undermines or is detrimental to the anti-doping program of *WADA*. The Laboratory should not provide analytical services in a *Doping Control* adjudication, unless specifically requested by the responsible Testing Authority or a Hearing Body.

The Laboratory shall not engage in analyzing commercial material or preparations (e.g. dietary supplements) unless specifically requested by an *Anti-Doping Organization* as part of a doping case investigation. The Laboratory shall not provide results, documentation or advice that, in any way, suggests endorsement of products or services.

4.5 Sharing of Information and Resources

4.5.1 New Substances

The *WADA* accredited Laboratories for *Doping Control* shall inform *WADA* immediately when they detect a new or suspicious doping agent.

When possible, the Laboratories shall share information with *WADA* regarding the detection of potentially new or rarely detected doping agents.

4.5.2 Sharing of Knowledge

When information on new substance(s), method(s), or practise(s) is known to the Laboratory Director, such information shall be shared with *WADA* within sixty (60) calendar days. This can occur by participation in scientific meetings, publication of results of research, sharing of specific details of methodology necessary for detection, and working with *WADA* to distribute information by preparation of a reference substance or biological excretion study or information regarding the chromatographic retention behaviour and mass spectra of the substance or its *Metabolites*. The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of testing in the *WADA* accredited Laboratory system.

5.0 Conduct Detrimental to the Anti-Doping Program

The Laboratory personnel shall not engage in conduct or activities that undermine or are detrimental to the anti-doping program of *WADA*, an International Federation, a *National Anti-Doping Organization*, a *National Olympic Committee*, a Major *Event* Organizing Committee, or the International Olympic Committee. Such conduct could include, but is not limited to, conviction for fraud, embezzlement, perjury, etc. that would cast doubt on the integrity of the anti-doping program.

No Laboratory employee or consultant shall provide counsel, advice or information to *Athletes* or others regarding techniques or methods to mask detection of, alter metabolism of, or suppress excretion of a *Prohibited Substance* or *Marker* of a *Prohibited Substance* or *Prohibited Method* in order to avoid an *Adverse Analytical Finding*. No Laboratory staff shall assist an *Athlete* in avoiding collection of a *Sample*.

This paragraph does not prohibit presentations to educate *Athletes*, students, or others concerning anti-doping programs and *Prohibited Substance*s or *Prohibited Methods*. Such provision shall remain valid for a minimum of five (5) years following termination of the contractual link of any employee to a Laboratory.

If Laboratory staff is requested by either party or the tribunal to appear before an arbitration or court hearing, they are expected to provide independent, scientifically-valid expert testimony. Laboratory experts should not be an advocate to either party.

APPENDIX SIX

INTERNATIONAL STANDARD FOR THE PROTECTION OF PRIVACY AND PERSONAL INFORMATION (Valid from 1 June 2009)

PREAMBLE

The World Anti-Doping *International Standard* for the Protection of Privacy and Personal Information is a level 2 mandatory *International Standard* developed as part of the World Anti-Doping Program.

WADA and *Anti-Doping Organizations* share responsibility for ensuring that Personal Information Processed in connection with Anti-Doping Activities is protected as required by data protection and privacy laws, principles and standards. The main purpose of this *International Standard* is to ensure that organizations and persons involved in anti-doping in sport apply appropriate, sufficient and effective privacy protections to Personal Information that they Process, regardless of whether this is also required by applicable laws.

A *WADA* expert reference group reviewed, discussed and prepared this document, and specifically took into account the Organization for Economic Cooperation and Development's (OECD) 1980 Guidelines on the Protection of Privacy and Transborder Flows of Personal Data; the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS. No. 108); Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the processing of personal data and on the free movement of such data, and other international and regional data privacy rules and standards.

The official text of the *International Standard* for Privacy and Personal Information shall be maintained by *WADA* and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall be controlling.

The *International Standard* for the Protection of Privacy and Personal Information version 2.0 shall come into effect on 1 June 2009. It shall be updated from time to time, as needed, to reflect developments in applicable laws and anti-doping practices.

PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS

1.0 Introduction and Scope

The purpose of the *International Standard* for the Protection of Privacy and Personal Information is to ensure that *Anti-Doping Organizations* apply appropriate,

sufficient and effective privacy protections to the Personal Information they Process when conducting anti-doping programs, in recognition of the fact that Personal Information gathered in the anti-doping context can impinge upon and implicate the privacy rights and interests of persons involved in and associated with organized sport.

The *Code*, in particular, requires *Athletes* and *Athlete Support Personnel* to furnish a significant amount of Personal Information to *Anti-Doping Organizations*. As a result, it is essential that *Anti-Doping Organizations* appropriately protect the Personal Information that they collect both to meet legal standards and to ensure the continued confidence and trust of those who participate in organized sport.

The *Code* recognizes and affirms the importance of ensuring that the privacy interests of persons participating in anti-doping programs based on the *Code* are fully respected. In support of this commitment, this *International Standard* provides mandatory rules and standards relating to the protection of Personal Information by *Anti-Doping Organizations*.

Consistent with other *International Standards* that have been developed and implemented to date, this *International Standard* sets forth a minimum, common set of rules to which *Anti-Doping Organizations* must conform when collecting and handling Personal Information pursuant to the *Code*. In some cases, *Anti-Doping Organizations* may be required by applicable laws to apply rules or standards that exceed those set forth in this *Standard*. For purposes of this *International Standard*, definitions appearing in the *Code* shall be *italicized*, and additional definitions created for purposes of this *International Standard* shall be underlined.

2.0 *Code* Provisions

The following articles of the *Code* are directly relevant to this *International Standard* for the Protection of Privacy and Personal Information:

- **Code Article 14 Confidentiality and Reporting**

The *Signatories* agree to the principles of coordination of anti-doping results, public transparency and accountability and respect for the privacy interests of individuals alleged to have violated anti-doping rules.

- **Code Article 14.1.5**

The recipient organizations shall not disclose this information beyond those *Persons* with a need to know (which would include the appropriate personnel at the applicable *National Olympic Committee*, National Federation, and team in a *Team Sport*) until the *Anti-Doping Organization* with results management responsibility has made public disclosure or has failed to make public disclosure as required in Article 14.2. below.

- **Code Article 14.2 Public Disclosure**

➢ **Code Article 14.2.1**

The identity of any *Athlete* or other *Person* who is asserted by an *Anti-Doping Organization* to have committed an anti-doping rule violation, may be *Publicly Disclosed* by the *Anti-Doping Organization* with results management responsibility only after notice has been provided to the *Athlete* or other *Person* in accordance with Articles 7.2, 7.3 or 7.4, and to the applicable *Anti-Doping Organizations* in accordance with Article 14.1.2.

➢ **Code Article 14.2.3**

In any case where it is determined, after a hearing or appeal, that the *Athlete* or other *Person* did not commit an anti-doping rule violation, the decision may be disclosed publicly only with the consent of the *Athlete* or other *Person* who is the subject of the decision. The *Anti-Doping Organization* with results management responsibility shall use reasonable efforts to obtain such consent, and if consent is obtained, shall publicly disclose the decision in its entirety or in such redacted form as the *Athlete* or other *Person* may approve.

➢ **Code Article 14.2.4**

For purposes of Article 14.2, publication shall be accomplished at a minimum by placing the required information on the *Anti-Doping Organization's* Web site and leaving the information up for at least one (1) year.

➢ **Code Article 14.2.5**

No *Anti-Doping Organization* or *WADA*-accredited laboratory, or official of either, shall publicly comment on the specific facts of a pending case (as opposed to general description of process and science) except in response to public comments attributed to the *Athlete*, other *Person* or their representatives.

- **Code Article 14.3 *Athlete* Whereabouts Information**

As further provided in the *International Standard* for *Testing*, *Athletes* who have been identified by their International Federation or *National Anti-Doping Organization* for inclusion in a *Registered Testing Pool* shall provide accurate, current location information. The International Federations and *National Anti-Doping Organizations* shall coordinate the identification of *Athletes* and the collecting of current location information and shall submit these to *WADA*. This information will be accessible, through *ADAMS* where reasonably feasible, to other *Anti-Doping Organizations* having jurisdiction to test the *Athlete* as provided in Article 15. This information shall be maintained in strict confidence at all times; shall be used exclusively for purposes of planning, coordinating or conducting *Testing*; and shall be destroyed after it is no longer relevant for these purposes.

- **Code Article 14.5 *Doping Control* Information Clearinghouse**

WADA shall act as a central clearinghouse for *Doping Control Testing* data and results for *International-Level Athletes* and national-level *Athletes* who have been included in their *National Anti-Doping Organization's Registered Testing Pool*. To facilitate coordinated test distribution planning and to avoid unnecessary duplication in *Testing* by the various *Anti-Doping Organizations*, each *Anti-Doping Organization* shall report all *In-Competition* and *Out-of-Competition* tests on such *Athletes* to the *WADA* clearinghouse as soon as possible after such tests have been conducted. This information will be made accessible to the *Athlete*, the *Athlete's* National Federation, *National Olympic Committee* or National Paralympic Committee, *National Anti-Doping Organization*, International Federation, and the International Olympic Committee or International Paralympic Committee.

To enable it to serve as a clearinghouse for *Doping Control Testing* data, *WADA* has developed a database management tool, *ADAMS*, that reflects emerging data privacy principles. In particular, *WADA* has developed *ADAMS* to be consistent with data privacy statutes and norms applicable to *WADA* and other organizations using *ADAMS*. Private information regarding an *Athlete, Athlete Support Personnel*, or others involved in anti-doping activities shall be maintained by *WADA,* which is supervised by Canadian privacy authorities, in strict confidence and in accordance with the *International Standard* for the protection of privacy. *WADA* shall, at least annually, publish statistical reports summarizing the information that it receives, ensuring at all times that the privacy of *Athletes* is fully respected and make itself available for discussions with national and regional data privacy authorities.

- **Code Article 14.6 Data Privacy**

When performing obligations under the *Code*, *Anti-Doping Organizations* may collect, store, process or disclose personal information relating to *Athletes* and third parties. Each *Anti-Doping Organization* shall ensure that it complies with applicable data protection and privacy laws with respect to their handling of such information, as well as the *International Standard* for the protection of privacy that *WADA* shall adopt to ensure *Athletes* and non-athletes are fully informed of and, where necessary, agree to the handling of their personal information in connection with anti-doping activities arising under the *Code*.

3.0 Terms and Definitions

3.1 Selected Defined Terms from the Code

***Anti-Doping Organization*:** A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events, WADA*, International Federations, and *National Anti-Doping Organizations.*

***Athlete*:** Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization,* including but not limited to those *Persons* in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing*, and therapeutic use exemptions must be applied to international- and national-level competitors. Some *National Anti-Doping Organizations* may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national caliber competitors. *National Anti-Doping Organizations* are not required, however, to apply all aspects of the *Code* to such *Persons.* Specific national rules may be established for *Doping Control* for non-international-level or non-national-level competitors without being in conflict with the *Code.* Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempted* Administration) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

***Athlete Support Personnel*:** Any coach, trainer, manager, agent, team staff, official, medical, paramedical personnel, parent or any other *Person* working with, treating or assisting an *Athlete* participating in or preparing for sports *Competition*.

Participant: Any *Athlete* or *Athlete Support Personnel*.

3.2 Defined Terms from the *International Standard* on Privacy and Personal Information

Anti-Doping Activities: Activities specified by the *Code* and the *International Standards* to be carried out by *Anti-Doping Organizations*, and their Third-Party Agents, for the purpose of establishing whether anti-doping rule violations took place, including collecting whereabouts information, conducting *Testing*, performing results management, determining whether an *Athlete*'s use of a prohibited substance or method is strictly limited to legitimate and documented therapeutic purposes, educating *Participants* on their rights and responsibilities, conducting investigations into anti-doping rule violations and initiating legal proceedings against those who are alleged to have committed such a violation.

Personal Information: Information, including without limitation Sensitive Personal Information, relating to an identified or identifiable *Participant* or relating to other persons whose information is Processed solely in the context of an *Anti-Doping Organization*'s Anti-Doping Activities.

[3.2 Comment: It is understood that Personal Information includes, but is not limited to, information relating to an Athlete's contact details and sporting

affiliations, Whereabouts, designated therapeutic use exemptions (if any), anti-doping test results, and results management (including disciplinary hearings, appeals and sanctions). Personal Information also includes personal details and contact information relating to other persons, such as medical professionals and other persons working with, treating or assisting an Athlete in the context of Anti-Doping Activities.]

Processing (and its cognates, Process and Processed): Collecting, retaining, storing, disclosing, transferring, transmitting, amending, deleting or otherwise making use of Personal Information.

Sensitive Personal Information: Personal Information relating to a *Participant's* racial or ethnic origin, commission of offences (criminal or otherwise), health (including information derived from analyzing an *Athlete's Samples* or *Specimens*) and genetic information.

Third Party: Any natural person or legal entity other than the natural person to whom the relevant Personal Information relates, *Anti-Doping Organizations* and Third-Party Agents.

Third-Party Agent: The natural or legal person, public authority, agency or body, including without limitation subcontractors and their subcontractors, that Processes Personal Information for or on behalf of an *Anti-Doping Organization*.

PART TWO: STANDARDS FOR HANDLING PERSONAL INFORMATION

4.0 Processing Personal Information in Accordance with *International Standard* and Applicable Law

4.1 This *International Standard* sets forth a minimum set of requirements for the Processing of Personal Information by *Anti-Doping Organizations* and their Third-Party Agents in the context of their Anti-Doping Activities. All *Anti-Doping Organizations* must comply with this Standard, even when its requirements exceed those arising under the *Anti-Doping Organization*'s applicable data protection and privacy laws, reflecting the vital need to protect the privacy of *Participants* and other persons involved in and associated with anti-doping in sport.

[4.1 Comment: Anti-Doping Organizations, along with any Third-Party Agents that Process Personal Information for or on behalf of Anti-Doping Organizations, minimally must comply with the requirements set forth in this International Standard, provided that such compliance does not breach other applicable laws. In cases where compliance with this International Standard may cause an Anti-Doping Organization to breach other applicable laws, those laws shall prevail, which will not lead to a determination of non-compliance with the World Anti-Doping Code.]

4.2 *Anti-Doping Organizations* may be subject to data protection and privacy laws and regulations that impose requirements that exceed those arising under this

International Standard. In such circumstances, *Anti-Doping Organizations* must ensure that their Processing of Personal Information complies with all such data protection and privacy laws and regulations.

[4.2 Comment: Anti-Doping Organizations in certain countries may be subject to laws and regulations that govern their Processing of Personal Information relating to natural persons in addition to Participants, such as their own employees or staff employed by other Anti-Doping Organizations, or impose additional restrictions going beyond this International Standard. In all such cases, Anti-Doping Organizations will be expected to comply with applicable data protection laws and regulations.]

5.0 Processing Relevant and Proportionate Personal Information

5.1 *Anti-Doping Organizations* shall only Process Personal Information where necessary and appropriate to conduct their Anti-Doping Activities under the *Code* (such as those identified in Articles 2, 4.4, 5-8, 10-16 and 18-20) and International Standards, or where otherwise required by applicable law, regulation or compulsory legal process, provided such Processing does not conflict with applicable privacy and data protection laws.

5.2 *Anti-Doping Organizations* shall not Process Personal Information that is irrelevant or unnecessary in the context of their Anti-Doping Activities as identified in Article 5.1.

[5.2 Comment: Anti-Doping Organizations shall examine the different contexts in which they Process Personal Information to ensure that the Processing of the Personal Information in any given case is required in order to satisfy one of the purposes identified in Article 5.1. Where Anti-Doping Organizations cannot satisfy themselves that the Processing is necessary, they shall refrain from Processing the Personal Information.]

5.3 In particular, except as otherwise required by the *Code* or expressly required by law:

a. *Anti-Doping Organizations* Processing Personal Information (which will involve Processing Sensitive Personal Information related to *Athletes* and Processing non-Sensitive Personal Information related to *Participants* and potentially other persons) to determine whether an *Athlete*'s *Use or Possession* of a prohibited substance or method is strictly limited to legitimate and documented therapeutic purposes shall Process only the Personal Information needed for making this determination as required by the *International Standard* for Therapeutic Use Exemptions.

b. *Anti-Doping Organizations* Processing Personal Information related to *Participants* and other persons in order to perform *Testing*, shall Process only the Personal Information (including whereabouts information) needed to conduct *Testing* (e.g., test distribution planning, *Sample* collection, *Sample* handling, and

Sample transport to the laboratory) in accordance with the *Code* (such as Articles 2, 5 and 15) or the *International Standard* for Testing.

c. *Anti-Doping Organizations* Processing Personal Information related to *Participants* and other persons in order to engage in investigation and results management, including associated disciplinary hearings, appeals and adjudications, shall Process only the Personal Information needed for investigating and establishing one or more anti-doping rule violations.

5.4 Personal Information Processed by *Anti-Doping Organizations* shall be accurate, complete and kept up-to-date. *Anti-Doping Organizations* shall where possible, and taking into account the responsibilities of *Participants* such as under Article 14.3 of the *Code* and Article 11 of the *International Standard* for Testing, correct or amend any Personal Information that they affirmatively know to be incorrect or inaccurate as soon as possible.

[5.4 Comment: Where Participants are responsible for providing Personal Information about themselves directly to Anti-Doping Organizations and for keeping it accurate, complete and up-to-date, they should be informed of this obligation and, whenever practicable, offered reasonable means to fulfill it. For instance, this could involve furnishing Individuals with access to their Personal Information via the Internet through online tools and resources.]

6.0 Processing Personal Information in Accordance with Law or with Consent

6.1 *Anti-Doping Organizations* shall only Process Personal Information:

- on valid legal grounds which can include compliance with legal obligations, fulfillment of a contract or to protect the vital interests of the *Participant* and other persons; or
- where permitted, with a *Participant*'s or other person's informed consent, subject to the exceptions in Article 6.3.b and 6.4 of this *International Standard*.

[6.1 Comment: This International Standard envisions that Personal Information will be Processed in cases where the law expressly provides for its Processing or with the consent of Participants, subject to appropriate exceptions to avoid Participants or other persons undermining the Code. Principal responsibility for obtaining the consent of an Athlete, and his or her associated Athlete Support Personnel, shall rest with the Anti-Doping Organization(s) that places the relevant Athlete in its Registered Testing Pool.]

6.2 Where, in accordance with Article 6.1, it is possible for *Anti-Doping Organizations* to Process Sensitive Personal Information with consent, the express and written consent of the *Participant* or person to whom the Personal Information relates shall be obtained. The Processing of Sensitive Personal Information shall

occur in accordance with any specific safeguards or procedures established under locally applicable data protection laws and regulations.

[6.2 Comment: This International Standard imposes additional restrictions where Anti-Doping Organizations Process Sensitive Personal Information, reflecting the greater sensitivities surrounding the Processing of such information. Although the Standard defines Sensitive Personal Information to expressly include different classes of information, this is not to suggest that such information should be Processed by Anti-Doping Organizations, as required by Article 5.1.]

6.3 Where, in accordance with Article 6.1, it is possible for *Anti-Doping Organizations* to Process Personal Information with consent, Anti-Doping Organizations shall, in order to obtain an informed consent, as required by Article 6.2, ensure that adequate information is furnished to the *Participant* or person to whom the Personal Information relates as described more fully in Article 7.

a. *Anti-Doping Organizations* shall inform *Participants* of the negative consequences that could arise from their refusal to participate in doping controls, including *Testing*, and of the refusal to consent to the Processing of Personal Information as required for this purpose.

[6.3.a. Comment: For the avoidance of doubt, Participants shall be informed that their refusal to participate in doping controls, when requested to do so, could prevent their continued involvement in organized sport and, for Athletes, constitute a violation of the Code and invalidate competition results, among other things. A Participant who believes that an Anti-Doping Organization does not comply with this International Standard may notify WADA pursuant to Article 11.5, which shall, without prejudice to any other rights the Participant may have under applicable law, consider the grounds for the complaint.]

b. *Anti-Doping Organizations* shall inform *Participants* that regardless of any refusal to grant or subsequent withdrawal of consent, the Processing of their Personal Information by *Anti-Doping Organizations* still may be required, unless otherwise prohibited by applicable law, where necessary to enable *Anti-Doping Organizations*:

- to commence or pursue investigations involving suspected anti-doping rule violations relating to the *Participant*;
- to conduct or participate in proceedings involving suspected anti-doping rule violations relating to the *Participant*; or
- to establish, exercise or defend against legal claims relating to the *Anti-Doping Organization*, the *Participant* or both.

[6.3.b. Comment: In certain limited circumstances, Anti-Doping Organizations must have the ability to Process Personal Information in the absence of the Participant's consent. These exceptions are necessary to avoid situations where Participants

refuse to grant consent or withdraw consent in order to circumvent anti-doping efforts and procedures and evade detection for a doping violation.]

6.4 In cases where a *Participant* is incapable of furnishing their informed consent by virtue of their age, mental capacity or other legitimate reason recognized in law, the *Participant's* legal representative, guardian or other competent representative may furnish consent on the *Participant's* behalf for purposes of this *International Standard*, as well as exercise the *Participant's* rights arising under Article 11 below. *Anti-Doping Organizations* shall ensure that obtaining consents under such circumstances is permitted by applicable law.

7.0 Ensuring Appropriate Information is Furnished to *Participants* and Other Persons

7.1 An *Anti-Doping Organization* shall inform *Participants* or person to whom the Personal Information relates about the Processing of their Personal Information. This information shall include:

- the identity of the *Anti-Doping Organization* collecting the Personal Information;
- types of Personal Information that may be Processed;
- the purposes for which the Personal Information may be used and how long it may be retained;
- other potential recipients of the Personal Information, including *Anti-Doping Organizations* located in other countries where the *Participant* may compete, train or travel;
- the possibility and circumstances under which Personal Information may, where permitted by applicable law, be publicly disclosed (such as the disclosure of test results and tribunal decisions);
- the *Participant's* rights with respect to the Personal Information under this *International Standard* and the means to exercise those rights, including the procedure for submitting complaints pursuant to Article 11.5; and
- any other information necessary to ensure that the handling of the Personal Information remains fair, such as information about regulatory authorities or bodies that oversee the *Anti-Doping Organization's* Processing of Personal Information.

7.2. *Anti-Doping Organizations* shall communicate the above information to *Participants* or other persons prior to or at the time that they collect Personal Information from *Participants* or other persons, and *Anti-Doping Organizations* shall be responsive to the questions or concerns of *Participants* relating to the Processing of their Personal Information by the *Anti-Doping Organization*. Where *Anti-Doping Organizations* receive Personal Information from Third Parties, and not

directly from the *Participant*, they shall communicate the above information as soon as possible and without unnecessary delay, unless it previously has been furnished to the *Participant* or other person by other parties.

[7.2 Comment: Anti-Doping Organizations should recognize that basic principles of fairness require that where a Participant's Personal Information is Processed in the context of Anti-Doping Activities, he or she should receive or have reasonable access to information that explains the purpose and procedures for the collection and processing of their Personal Information in simple terms. This International Standard aspires to ensure that Participants acquire a basic grasp of the roles and responsibilities performed by the different organizations involved in anti-doping in sport, as those relate to the Processing of Personal Information. Under no circumstances should Anti-Doping Organizations seek to mislead or misinform Participants in order to collect or use their Personal Information.

Each Anti-Doping Organization should ensure that its Processing of Personal Information is reasonably transparent to Participants, notwithstanding the fact that certain information relating to Anti-Doping Activities, notably information concerning scheduled Testing and investigations and proceedings relating to anti-doping rule violations, may need to be temporarily withheld from Participants in order to maintain the integrity of the anti-doping process. The prompt provision of appropriate information to Participants pursuant to this Article 7 is essential given the serious, adverse consequences that might arise if Participants are found to have committed an anti-doping rule violation.]

7.3 *Anti-Doping Organizations* shall provide the above information in a manner and format, whether written, oral or otherwise, that *Participants* or person to whom the Personal Information relates can easily comprehend, taking into account local practices, customs and the particular circumstances surrounding the Processing of the Personal Information.

[*7.3 Comment: Anti-Doping Organizations need to determine the most effective means of providing information in particular cases, recognizing that furnishing Participants with written notice is to be preferred whenever practicable. This also may include furnishing notices through generally available sources, such as brochures and Internet websites, alone or preferably in combination with more succinct notices on forms and other documentation provided directly to Participants.*]

8.0 Disclosures of Personal Information to other *Anti-Doping Organizations* and Third Parties

8.1 *Anti-Doping Organizations* shall not disclose Personal Information to other *Anti-Doping Organizations* except where such disclosures are necessary to allow the *Anti-Doping Organizations* receiving the Personal Information to fulfill obligations under the *Code* and in accordance with applicable privacy and data protection laws.

[8.1 Comment: In many instances required by the Code, it is necessary for Anti-Doping Organizations to share certain Personal Information relating to Participants with other Anti-Doping Organizations so that they may engage in Code-mandated Testing. For instance, this may occur in order to subject Athletes to In-Competition and Out-of-Competition Testing. In such cases, Anti-Doping Organizations shall cooperate with one another to ensure that the participation by Participants in such Testing remains suitably transparent to Participants and complies with the rules set out in this International Standard and applicable laws.]

8.2 *Anti-Doping Organizations* shall not disclose Personal Information to other *Anti-Doping Organizations*: (i) where the recipient *Anti-Doping Organizations* cannot establish a right, authority or need to obtain the Personal Information; (ii) where there is evidence that the recipient *Anti-Doping Organizations* do not or cannot comply with this *International Standard*; (iii) where the *Anti-Doping Organization* is prohibited from disclosing the Personal Information by applicable law or restrictions imposed by a competent supervisory authority; or (iv) where the disclosure would seriously compromise the status of an ongoing investigation into anti-doping rule violations. Where an *Anti-Doping Organization* has concerns that another *Anti-Doping Organization* is incapable of complying with this *International Standard*, it shall make its concerns known to the *Anti-Doping Organization* and *WADA* as soon as possible.

8.3 *Anti-Doping Organizations* may disclose Personal Information to Third Parties, besides *Anti-Doping Organizations*, where such disclosures:

a. are required by law;

b. take place with the informed, express and written consent of the relevant *Participant*; or

c. are necessary to assist law enforcement or governmental authorities in the detection, investigation or prosecution of a criminal offence or breach of the *Code*, provided that the Personal Information requested is directly relevant to the offence in question and otherwise cannot reasonably be obtained by the authorities.

9.0 Maintaining the Security of Personal Information

9.1 *Anti-Doping Organizations* shall designate a person who is accountable for compliance with this *International Standard* and all locally applicable privacy and data protection laws. They shall take reasonable measures to ensure that the name and contact information of the person so designated is made readily available to *Participants* should they request it.

9.2 *Anti-Doping Organizations* shall protect Personal Information that they Process by applying all necessary security safeguards, including physical, organizational, technical, environmental and other measures, to prevent the loss, theft, or unauthorized access, destruction, use, modification or disclosure (including disclosures made via electronic networks) of Personal Information.

[9.2 Comment: Anti-Doping Organizations shall ensure that any access to Personal Information by their own personnel shall take place on a need-to-know basis only and where consistent with assigned roles and responsibilities. Personnel accessing Personal Information should be informed of the need to hold Personal Information in confidence.]

9.3 *Anti-Doping Organizations* shall apply security measures that take into account the sensitivity of the Personal Information being Processed. *Anti-Doping Organizations* shall apply a higher level of security to the Sensitive Personal Information that they Process, reflecting the correspondingly greater risk that the unlawful or unauthorized disclosure of such information presents to the *Participant* or person to whom the Personal Information relates.

9.4 *Anti-Doping Organizations* disclosing Personal Information to Third-Party Agents in connection with their Anti-Doping Activities shall ensure that such Third-Party Agents are subject to appropriate controls, including contractual controls, in order to protect the confidentiality and privacy of the Personal Information and to ensure that the Personal Information is only Processed for and on behalf of the *Anti-Doping Organization*.

[9.4 Comment: Anti-Doping Organizations have an ongoing responsibility to protect any Personal Information under their effective control or in their possession, including Personal Information Processed by their Third-Party Agents, such as IT-service providers, laboratories and external Doping Control Officers.]

9.5 *Anti-Doping Organizations* are required to choose Third-Party Agents that provide sufficient guarantees, in accordance with applicable law and this *Standard*, in respect of the technical security measures and organizational measures governing the Processing to be carried out.

10.0 Retaining Personal Information Only as Necessary and Ensuring Its Destruction

10.1 As a general rule, retaining Sensitive Personal Information requires stronger or more compelling reasons and justifications than retaining non-Sensitive Personal Information.

10.2 *Anti-Doping Organizations* shall ensure that Personal Information is only retained for as long as necessary to fulfill their obligations under the *Code* or where otherwise required by applicable law, regulation or compulsory legal process. Once Personal Information no longer serves the above purposes, it shall be deleted, destroyed or permanently anonymized.

10.3 In order to ensure the effective application of Article 10.1, *Anti-Doping Organizations* shall establish clear retention times to govern their Processing of Personal Information consistent with the above-described limitations. *Anti-Doping Organizations* shall develop specific plans and procedures to ensure the secure retention and eventual destruction of Personal Information.

10.4 Different retention times shall apply to different types of Personal Information and take into account the purposes for which the Personal Information is Processed in the context of Anti-Doping Activities, including the granting of *Therapeutic Use Exemptions*, *Testing*, the investigation of doping violations, and the sanctioning of such violations**.**

[*10.4 Comment: WADA shall undertake to develop guidelines setting forth more specific retention times for the different types of Personal Information Processed in the anti-doping context.]*

11.0 Rights of *Participants* and Other Persons with Respect to Personal Information

11.1 *Participants* or person to whom the Personal Information relates shall have the right to obtain from *Anti-Doping Organizations*: (a) confirmation of whether or not *Anti-Doping Organizations* Process Personal Information relating to them, (b) the information as per Article 7.1, and (c) a copy of the relevant Personal Information within a reasonable timeframe, in a readily intelligible format, and without excessive cost, unless to do so in a particular case plainly conflicts with the *Anti-Doping Organization*'s ability to plan or conduct *No Advance Notice Testing* or to investigate and establish anti-doping rule violations.

11.2 *Anti-Doping Organizations* have to respond to requests from *Participants* or person to whom the Personal Information relates seeking access to their Personal Information, except if doing so imposes a disproportionate burden on the *Anti-Doping Organizations* in terms of cost or effort given the nature of the Personal Information in question.

11.3 In the event an *Anti-Doping Organization* refuses to allow a *Participant* access to his or her Personal Information, it shall inform the *Participant* and explain in writing the grounds for refusing the request as soon as practicable. *Anti-Doping Organizations* shall ensure that *Participants* only obtain Personal Information relating to themselves, and not relating to other *Participants* or third persons, where they seek to obtain access to Personal Information pursuant to this Article 11.

11.4 Where an *Anti-Doping Organization*'s Processing of Personal Information is shown to be inaccurate, incomplete, or excessive, it shall, as appropriate, rectify, amend or delete the relevant Personal Information as soon as possible. If the *Anti-Doping Organization* has disclosed the Personal Information in question to another *Anti-Doping Organization* that to its knowledge or belief continues to Process the Personal Information, it shall inform that *Anti-Doping Organization* of the change as soon as possible, unless this proves impossible or involves a disproportionate effort.

11.5 Without prejudice to any other rights a *Participant* may have under applicable laws, a *Participant* shall be entitled to initiate a complaint with an *Anti-Doping Organization* where he or she has a reasonable, good-faith belief that an *Anti-Doping Organization* is not complying with this *International Standard* and

each *Anti-Doping Organization* shall have a procedure in place for dealing with such complaints in a fair and impartial manner. In the event that the complaint cannot be satisfactorily resolved, the *Participant* may notify *WADA* and/or submit a complaint to *CAS*, which will determine whether a violation occurred. Where the *International Standard* is not being adhered to, the relevant *Anti-Doping Organization* will be required to rectify the breach.

APPENDIX SEVEN

TENNIS TESTING PROTOCOLS

The following protocols are designed to supplement the International Standard for Testing as necessary to reflect the specificities of tennis. They are not intended to amend or contradict the International Standard for Testing. In the event of any conflict between these protocols and the International Standard for Testing, the latter shall prevail.

1. Collection of urine Samples

1.1 If a Sample collected from a Player does not have a Suitable Specific Gravity for Analysis (as defined in the IST), the DCO shall inform the Player that he/she is required to provide a further Sample or Samples, until a Sample that has a Suitable Specific Gravity for Analysis is provided. (See IST Annex G). To facilitate this, the Player should fully void his/her bladder when providing a Sample, and any further Sample should not be collected for at least one hour after the previous Sample was collected. In the meantime, the Player should avoid unnecessary hydration (drinking liquids).

2. Collection of blood Samples

2.1 Prior to providing a blood Sample (see IST Annex E), the Player should sit down (not lie down) for thirty minutes.

3. Collection of urine Samples and/or blood Samples

3.1 The persons authorised to be present during the Sample collection session are:

a. The DCO and his/her assistant(s).

b. The persons identified at IST 6.3.3.

c. The ITF Anti-Doping Manager and/or his/her designee(s).

4. Storage of Samples and documentation

4.1 Storage of Samples prior to dispatch from collection site (IST Article 8.3.1):

a. The DCO is responsible for ensuring that all Samples are stored in a manner that protects their identity, integrity and security whilst at the collection site.

b. The DCO shall keep the Samples secured and under his/her control until they are passed to a third party (e.g., the laboratory, or a courier to take them to the laboratory). Samples must not be left unattended,

unless they are locked away in a refrigerator or cupboard, for example. In the absence of a secure area where the Samples may be left, the DCO shall keep the Samples under his/her control. Access to Samples shall be restricted at all times to authorised personnel.

c. Where possible, samples shall be stored in a cool environment. Warm conditions should be avoided.

4.2 Secure handling of documentation for each Sample (IST Article 8.3.3):

a. The DCO is responsible for ensuring that the documentation for each Sample is securely handled after completion.

b. Those parts of the Sample collection documentation that identify the Player and can be used to identify which Player provided a particular Sample shall be kept separately from the Samples themselves. Where a separate secure storage site is available at the collection site itself (lockable and/or accessible only by authorised personnel), the documentation may be stored there. Otherwise, it shall be kept by the DCO and taken away from the site overnight.

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