2. "Anti-doping organization" means an entity 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, the World Anti-Doping Agency, international federations and national anti-doping organizations.

3. "Anti-doping rule violation" in sport means one or more of the following:

(a) the presence of a prohibited substance or its metabolites or markers in an athlete's bodily specimen;

(b) use or attempted use of a prohibited substance or a prohibited method;

(c) 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;

(d) violation of applicable requirements regarding athlete availability for out-of-competition testing, including failure to provide required whereabouts information and missed tests which are declared based on reasonable rules;

(e) tampering, or attempting to tamper, with any part of doping control;

(f) possession of prohibited substances or methods;

(g) trafficking in any prohibited substance or prohibited method;

(h) administration or attempted administration of a prohibited substance or prohibited method to any athlete, or assisting, encouraging, aiding, abetting, covering up or any other type of complicity involving an anti-doping rule violation or any attempted violation.

4. "Athlete" means, for the purposes of doping control, any person who participates in sport at the international or national level as defined by each national anti-doping organization and accepted by States Parties and any additional person who participates in a sport or event at a lower level accepted by States Parties. For the purposes of education and training programmes, "athlete" means any person who participates in sport under the authority of a sports organization.

5. "Athlete support personnel" means any coach, trainer, manager, agent, team staff, official, medical or paramedical personnel working with or treating athletes participating in or preparing for sports competition.

6. "Code" means the World Anti-Doping Code adopted by the World Anti-Doping Agency on 5 March 2003 at Copenhagen which is attached as Appendix 1 to this Convention.

ANTIGUA AND BARBUDA

RESOLUTION RATYFYING THE INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT 2005

STATUTORY INSTRUMENT

2010, No. 21

[Printed in the Official Gazette Vol. XXXI No.28 dated 26th May, 2011.]

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— By Authority, 2011.

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[Price $63.85]

Mindful also of the influence that elite athletes have on youth,

Aware of the ongoing need to conduct and promote research with the objectives of improving detection of doping and better understanding of the factors affecting use in order for prevention strategies to be most effective,

Aware also of the importance of ongoing education of athletes, athlete support personnel and the community at large in preventing doping,

Mindful of the need to build the capacity of States Parties to implement anti-doping programmes,

Aware that public authorities and the organizations responsible for sport have complementary responsibilities to prevent and combat doping in sport, notably to ensure the proper conduct, on the basis of the principle of fair play, of sports events and to protect the health of those that take part in them,

Recognizing that these authorities and organizations must work together for these purposes, ensuring the highest degree of independence and transparency at all appropriate levels,

Determined to take further and stronger cooperative action aimed at the elimination of doping in sport,

Recognizing that the elimination of doping in sport is dependent in part upon progressive harmonization of anti-doping standards and practices in sport and cooperation at the national and global levels,

Adopts this Convention on this nineteenth day of October 2005.

I. Scope

Article 1 – Purpose of the Convention

The purpose of this Convention, within the framework of the strategy and programme of activities of UNESCO in the area of physical education and sport, is to promote the prevention of and the fight against doping in sport, with a view to its elimination.

Article 2 – Definitions

These definitions are to be understood within the context of the World Anti-Doping Code. However, in case of conflict the provisions of the Convention will prevail. For the purposes of this Convention:

1. "Accredited doping control laboratories" means laboratories accredited by the World Anti-Doping Agency.

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT 2005

The General Conference of the United Nations Educational, Scientific and Cultural Organization, hereinafter referred to as "UNESCO", meeting in Paris, from 3 to 21 October 2005, at its 33rd session,

Considering that the aim of UNESCO is to contribute to peace and security by promoting collaboration among nations through education, science and culture,

Referring to existing international instruments relating to human rights,

Aware of resolution 58/5 adopted by the General Assembly of the United Nations on 3 November 2003, concerning sport as a means to promote education, health, development and peace, notably its paragraph 7,

Conscious that sport should play an important role in the protection of health, in moral, cultural and physical education and in promoting international understanding and peace,

Noting the need to encourage and coordinate international cooperation towards the elimination of doping in sport,

Concerned by the use of doping by athletes in sport and the consequences thereof for their health, the principle of fair play, the elimination of cheating and the future of sport,

Mindful that doping puts at risk the ethical principles and educational values embodied in the International Charter of Physical Education and Sport of UNESCO and in the Olympic Charter,

Recalling that the Anti-Doping Convention and its Additional Protocol adopted within the framework of the Council of Europe are the public international law tools which are at the origin of national anti-doping policies and of intergovernmental cooperation,

Recalling the recommendations on doping adopted by the second, third and fourth International Conferences of Ministers and Senior Officials Responsible for Physical Education and Sport organized by UNESCO at Moscow (1988), Punta del Este (1999) and Athens (2004) and 32 C/Resolution 9 adopted by the General Conference of UNESCO at its 32nd session (2003),

Bearing in mind the World Anti-Doping Code adopted by the World Anti-Doping Agency at the World Conference on Doping in Sport, Copenhagen, 5 March 2003, and the Copenhagen Declaration on Anti-Doping in Sport,

ANTIGUA AND BARBUDA

RESOLUTION RATIFYING THE INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT, 2005.

STATUTORY INSTRUMENT

2010, No. 21

RESOLUTION RATIFYING THE INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT, 2005.

WHEREAS the Ratification of the Treaties Act, Cap. 364 provides in section 3(10 *(c)* that where a Treaty to which Antigua and Barbuda becomes a party is one which affects or concern the relationship of Antigua and Barbuda with any international organization, agency, association or similar body, such Treaty shall not enter into force with respect to Antigua and Barbuda unless it has been ratified or its ratification has been authorized or approved in accordance with the provision of the Act; and

WHEREAS the International Convention Against Doping in Sport, 2005 is an international agreement to which Antigua and Barbuda is a party and is an agreement governed by international law and concern the relationship of Antigua and Barbuda and the State Parties to the Convention;

NOW, THEREFORE, BE IT RESOLVED by this Honourable House that the International Convention Against Doping in Sport, 2005 which was done at Paris, French Republic on 19th October, 2005 and attached hereto as a Schedule be ratified as a Treaty under section 3(1) *(c)* of the Ratification of Treaties Act, Cap. 364

Passed the House of Representatives this 2nd day of September, 2010.

Honourable D. Gisele Isaac-Arrindell
Speaker of the House of Representatives

Thelma Thomas (Miss)
Clerk to the House of Representatives

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

CONVENTION INTERNTIONALE CONTRE LE DOPAGE DANS LE SPORT

CONVENCIÓN INTERNA CIONAL CONTRA EL DOPAJE EN EL DEPORTE

МЕЖДУНАРОДНАЯ КОНВЕНЦИЯ О БОРЬБЕ С ДОПИНГОМ В СПОРТЕ

الاتفاقية الدولية لمكافحة المنشطات في مجال الرياضة

反对在体育运动中使用兴奋剂国 际 公 约

ED. 2005/CONVENTION ANTI-DOPING REV

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

Paris, 19 October, 2005

(a) doping control procedures;

(b) athletes' rights and responsibilities in regard to anti-doping, including information about the Code and the anti-doping policies of the relevant sports and anti-doping organizations. Such information shall include the consequences of committing an anti-doping rule violation;

(c) the list of prohibited substances and methods and therapeutic use exemptions;

(d) nutritional supplements.

ARTICLE 20
Professional codes of conduct

States Parties shall encourage relevant competent professional associations and institutions to develop and implement appropriate codes of conduct, good practice and ethics related to anti-doping in sport that are consistent with the Code.

ARTICLE 21
Involvement of athletes and athlete support personnel

States Parties shall promote and, within their means, support active participation by athletes and athlete support personnel in all facets of the anti-doping work of sports and other relevant organizations and encourage sports organizations within their jurisdiction to do likewise.

ARTICLE 22
Sports organizations and ongoing education and training on anti-doping

States Parties shall encourage sports organizations and anti-doping organizations to implement ongoing education and training programmes for all athletes and athlete support personnel on the subjects identified in Article 19.

ARTICLE 23
Cooperation in education and training

States Parties shall cooperate mutually and with the relevant organizations to share, where appropriate, information, expertise and experience on effective anti-doping programmes.

7. "Competition" means a single race, match, game or singular athletic contest.

8. "Doping control" means the process including test distribution planning, sample collection and handling, laboratory analysis, results management, hearings and appeals.

9. "Doping in sport" means the occurrence of an anti-doping rule violation.

10. "Duly authorized doping control teams" means doping control teams operating under the authority of international or national anti-doping organizations.

11. "In-competition" testing means, for purposes of differentiating between in-competition and out-of-competition testing, unless provided otherwise in the rules of an international federation or other relevant anti-doping organization, a test where an athlete is selected for testing in connection with a specific competition.

12. "International Standard for Laboratories" means the standard which is attached as Appendix 2 to this Convention.

13. "International Standard for Testing" means the standard which is attached as Appendix 3 to this Convention.

14. "No advance notice" means 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.

15. "Olympic Movement" means all those who agree to be guided by the Olympic Charter and who recognize the authority of the International Olympic Committee, namely the international federations of sports on the programme of the Olympic Games, the National Olympic Committees, the Organizing Committees of the Olympic Games, athletes, judges and referees, associations and clubs, as well as all the organizations and institutions recognized by the International Olympic Committee.

16. "Out-of-competition" doping control means any doping control which is not conducted in competition.

17. "Prohibited List" means the list which appears in Annex I to this Convention identifying the prohibited substances and prohibited methods.

18. "Prohibited method" means any method so described on the Prohibited List, which appears in Annex I to this Convention.

19. "Prohibited substance" means any substance so described on the Prohibited List, which appears in Annex I to this Convention.

20. "Sports organization" means any organization that serves as the ruling body for an event for one or several sports.

21. "Standards for Granting Therapeutic Use Exemptions" means those standards that appear in Annex II to this Convention.

22. "Testing" means the parts of the doping control process involving test distribution planning, sample collection, sample handling and sample transport to the laboratory.

23. "Therapeutic use exemption" means an exemption granted in accordance with Standards for Granting Therapeutic Use Exemptions.

24. "Use" means the application, ingestion, injection or consumption by any means whatsoever of any prohibited substance or prohibited method.

25. "World Anti-Doping Agency" (WADA) means the foundation so named established under Swiss law on 10 November 1999.

ARTICLE 3
Means to achieve the purpose of the Convention

In order to achieve the purpose of the Convention, States Parties undertake to:

(a) adopt appropriate measures at the national and international levels which are consistent with the principles of the Code;

(b) encourage all forms of international cooperation aimed at protecting athletes and ethics in sport and at sharing the results of research;

(c) foster international cooperation between States Parties and leading organizations in the fight against doping in sport, in particular with the World Anti-Doping Agency.

ARTICLE 4
Relationship of the Convention to the Code

1. In order to coordinate the implementation, at the national and international levels, of the fight against doping in sport, States Parties commit themselves to the principles of the Code as the basis for the measures provided for in Article 5 of this Convention. Nothing in this Convention prevents States parties from adopting additional measures Complementary to the Code.

(ii) organizations and programmes of the United Nations system, particularly the United Nations Development Programme, as well as other international organizations;

(iii) public or private bodies or individuals;

(c) any interest due on the resources of the Voluntary Fund;

(d) funds raised through collections, and receipts from events organized for the benefit of the Voluntary Fund;

(e) any other resources authorized by the Voluntary Fund's regulations, to be drawn up by the Conference of Parties.

3. Contributions into the Voluntary Fund by States Parties shall not be considered to be a replacement for States Parties' commitment to pay their share of the World Anti-Doping Agency's annual budget.

Article 18
Use and governance of the Voluntary Fund

Resources in the Voluntary Fund shall be allocated by the Conference of Parties for the financing of activities approved by it, notably to assist States Parties in developing and implementing anti-doping programmes, in accordance with the provisions of this Convention, taking into consideration the goals of the World Anti-Doping Agency, and may serve to cover functioning costs of this Convention. No political, economic or other conditions may be attached to contributions made to the Voluntary Fund.

IV. EDUCATION AND TRAINING

ARTICLE 19
General education and training principles

1. States Parties shall undertake, within their means, to support, devise or implement education and training programmes on anti-doping. For the sporting community in general, these programmes should aim to provide updated and accurate information on:

(a) the harm of doping to the ethical values of sport;

(b) the health consequences of doping.

2. For athletes and athlete support personnel, in particular in their initial training, education and training programmes should, in addition to the above, aim to provide updated and accurate information on:

(a) facilitate the task of the World Anti-Doping Agency and anti-doping organizations operating in compliance with the Code, subject to relevant host countries' regulations, of conducting in- or out-of-competition doping controls on their athletes, whether on their territory or elsewhere;

(b) facilitate the timely movement of duly authorized doping control teams across borders when conducting doping control activities;

(c) cooperate to expedite the timely shipping or carrying across borders of samples in such a way as to maintain their security and integrity;

(d) assist in the international coordination of doping controls by various anti-doping organizations, and cooperate to this end with the World Anti-Doping Agency;

(e) promote cooperation between doping control laboratories within their jurisdiction and those within the jurisdiction of other States Parties. In particular, States Parties with accredited doping control laboratories should encourage laboratories within their jurisdiction to assist other States Parties in enabling them to acquire the experience, skills and techniques necessary to establish their own laboratories should they wish to do so;

(f) encourage and support reciprocal testing arrangements between designated anti-doping organizations, in conformity with the Code;

(g mutually recognize the doping control procedures and test results management, including the sport sanctions thereof, of any anti-doping organization that are consistent with the Code.

Article 17 – Voluntary Fund

1. A "Fund for the Elimination of Doping in Sport", hereinafter referred to as "the Voluntary Fund", is hereby established. The Voluntary Fund shall consist of funds-in-trust established in accordance with the Financial Regulations of UNESCO. All contributions by States Parties and other actors shall be voluntary.

2. The resources of the Voluntary Fund shall consist of:

(a) contributions made by States Parties;

(b) contributions, gifts or bequests which may be made by:

(i) other States;

2. The Code and the most current version of Appendices 2 and 3 are reproduced for information purposes and are not an integral part of this Convention. The Appendices as such do not create any binding obligations under international law for States Parties.

3. The Annexes are an integral part of this Convention.

ARTICLE 5
Measures to achieve the objectives of the Convention

In abiding by the obligations contained in this Convention, each State Party undertakes to adopt appropriate measures. Such measures may include legislation, regulation, policies or administrative practices.

ARTICLE 6
Relationship to other international instruments

This Convention shall not alter the rights and obligations of States Parties which arise from other agreements previously concluded and consistent with the object and purpose of this Convention. This does not affect the enjoyment by other States Parties of their rights or the performance of their obligations under this Convention.

II. ANTI-DOPING ACTIVITIES AT THE NATIONAL LEVEL

ARTICLE 7
Domestic coordination

States Parties shall ensure the application of the present Convention, notably through domestic coordination. To meet their obligations under this Convention, States Parties may rely on anti-doping organizations as well as sports authorities and organizations.

ARTICLE 8
Restricting the availability and use in sport of prohibited substances and methods

1. States Parties shall, where appropriate, adopt measures to restrict the availability of prohibited substances and methods in order to restrict their use in sport by athletes, unless the use is based upon a therapeutic use exemption. These include measures against trafficking to athletes and, to this end, measures to control production, movement, importation, distribution and sale.

2. States Parties shall adopt, or encourage, where appropriate, the relevant entities within their jurisdictions to adopt measures to prevent and to restrict the use and possession of prohibited substances and methods by athletes in sport, unless the use is based upon a therapeutic use exemption.

3. No measures taken pursuant to this Convention will impede the availability for legitimate purposes of substances and methods otherwise prohibited or controlled in sport.

ARTICLE 9
Measures against athlete support personnel

States Parties shall themselves take measures or encourage sports organizations and anti-doping organizations to adopt measures, including sanctions or penalties, aimed at athlete support personnel who commit an anti-doping rule violation or other offence connected with doping in sport.

ARTICLE 10
Nutritional supplements

States Parties, where appropriate, shall encourage producers and distributors of nutritional supplements to establish best practices in the marketing and distribution of nutritional supplements, including information regarding their analytic composition and quality assurance.

ARTICLE 11
Financial measures

States Parties shall, where appropriate:

(a) provide funding within their respective budgets to support a national testing programme across all sports or assist sports organizations and anti-doping organizations in financing doping controls either by direct subsidies or grants, or by recognizing the costs of such controls when determining the overall subsidies or grants to be awarded to those organizations;

(b) take steps to withhold sport-related financial support to individual athletes or athlete support personnel who have been suspended following an anti-doping rule violation, during the period of their suspension;

(c) withhold some or all financial or other sport-related support from any sports organization or anti-doping organization not in compliance with the Code or applicable anti-doping rules adopted pursuant to the Code.

ARTICLE 12
Measures to facilitate doping control

States Parties shall, where appropriate:

(a) encourage and facilitate the implementation by sports organizations and anti-doping organizations within their jurisdiction of doping controls in a manner consistent with the Code, including no-advance notice, out-of-competition and in-competition testing;

(b) encourage and facilitate the negotiation by sports organizations and anti-doping organizations of agreements permitting their members to be tested by duly authorized doping control teams from other countries;

(c) undertake to assist the sports organizations and anti-doping organizations within their jurisdiction in gaining access to an accredited doping control laboratory for the purposes of doping control analysis.

III. INTERNATIONAL COOPERATION

ARTICLE 13
Cooperation between anti-doping organizations and sports organizations

States Parties shall encourage cooperation between anti-doping organizations, public authorities and sports organizations within their jurisdiction and those within the jurisdiction of other States Parties in order to achieve, at the international level, the purpose of this Convention.

ARTICLE 14
Supporting the mission of the World Anti-Doping Agency

States Parties undertake to support the important mission of the World Anti-Doping Agency in the international fight against doping.

ARTICLE 15
Equal funding of the World Anti-Doping Agency

States Parties support the principle of equal funding of the World Anti-Doping Agency's approved annual core budget by public authorities and the Olympic Movement.

ARTICLE 16
International cooperation in doping control

Recognizing that the fight against doping in sport can only be effective when athletes can be tested with no advance notice and samples can be transported in a timely manner to laboratories for analysis, States Parties shall, where appropriate and in accordance with domestic law and procedures:

V. RESEARCH

ARTICLE 24
Promotion of research in anti-doping

States Parties undertake, within their means, to encourage and promote anti-doping research in cooperation with sports and other relevant organizations on:

(a) prevention, detection methods, behavioural and social aspects, and the health consequences of doping;

(b) ways and means of devising scientifically-based physiological and psychological training programmes respectful of the integrity of the person;

(c) the use of all emerging substances and methods resulting from scientific developments.

ARTICLE 25
Nature of anti-doping research

When promoting anti-doping research, as set out in Article 24, States Parties shall ensure that such research will:

(a) comply with internationally recognized ethical practices;

(b) avoid the administration to athletes of prohibited substances and methods;

(c) be undertaken only with adequate precautions in place to prevent the results of anti-doping research being misused and applied for doping.

ARTICLE 26
Sharing the results of anti-doping research

Subject to compliance with applicable national and international law, States Parties shall, where appropriate, share the results of available anti-doping research with other States Parties and the World Anti-Doping Agency.

ARTICLE 27
Sport science research

States Parties shall encourage:

(a) members of the scientific and medical communities to carry out sport science research in accordance with the principles of the Code;

(b) sports organizations and athlete support personnel within their jurisdiction to implement sport science research that is consistent with the principles of the Code.

VI. MONITORING OF THE CONVENTION

ARTICLE 28
Conference of Parties

1. A Conference of Parties is hereby established. The Conference of Parties shall be the sovereign body of this Convention.

2. The Conference of Parties shall meet in ordinary session in principle every two years. It may meet in extraordinary session if it so decides or at the request of at least one third of the States Parties. 3. Each State Party shall have one vote at the Conference of Parties. 4. The Conference of Parties shall adopt its own Rules of Procedure.

ARTICLE 29
Advisory organization and observers to the Conference of Parties

The World Anti-Doping Agency shall be invited as an advisory organization to the Conference of Parties. The International Olympic Committee, the International Paralympic Committee, the Council of Europe and the Intergovernmental Committee for Physical Education and Sport (CIGEPS) shall be invited as observers. The Conference of Parties may decide to invite other relevant organizations as observers.

ARTICLE 30
Functions of the Conference of Parties

1. Besides those set forth in other provisions of this Convention, the functions of the Conference of Parties shall be to:

(a) promote the purpose of this Convention;

(b) discuss the relationship with the World Anti-Doping Agency and study the mechanisms of funding of the Agency's annual core budget. States non-Parties may be invited to the discussion;

(c) adopt a plan for the use of the resources of the Voluntary Fund, in accordance with Article 18;

(d) examine the reports submitted by States Parties in accordance with Article 31;

thereto. As the Depositary, the Director-General of UNESCO shall inform the States Parties to this Convention, as well as the other States Members of the Organization of:

(a) the deposit of any instrument of ratification, acceptance, approval or accession;

(b) the date of entry into force of this Convention in accordance with Article 37;

(c) any report prepared in pursuance of the provisions of Article 31;

(d) any amendment to the Convention or to the Annexes adopted in accordance with Articles 33 and 34 and the date on which the amendment comes into force;

(e) any declaration or notification made under the provisions of Article 38;

(f) any notification made under the provisions of Article 39 and the date on which the denunciation takes effect;

(g) any other act, notification or communication relating to this Convention.

ARTICLE 41
Registration

In conformity with Article 102 of the Charter of the United Nations, this Convention shall be registered with the Secretariat of the United Nations at the request of the Director-General of UNESCO.

ARTICLE 42
Authoritative texts

1. This Convention, including its Annexes, has been drawn up in Arabic, Chinese, English, French, Russian and Spanish, the six texts being equally authoritative.

2. The Appendices to this Convention are provided in Arabic, Chinese, English, French, Russian and Spanish.

ARTICLE 43
Reservations

No reservations that are incompatible with the object and purpose of the present Convention shall be permitted.

ARTICLE 37
Entry into force

1. This Convention shall enter into force on the first day of the month following the expiration of a period of one month after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession.

2. For any State that subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of one month after the date of deposit of its instrument of ratification, acceptance, approval or accession.

ARTICLE 38
Territorial extension of the Convention

1. Any State may, when depositing its instrument of ratification, acceptance, approval or accession, specify the territory or territories for whose international relations it is responsible and to which this Convention shall apply.

2. Any State Party may, at any later date, by a declaration addressed to UNESCO, extend the application of this Convention to any other territory specified in the declaration. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of one month after the date of receipt of such declaration by the depositary.

3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to UNESCO. Such withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of receipt of such a notification by the depositary.

ARTICLE 39
Denunciation

Any State Party may denounce this Convention. The denunciation shall be notified by an instrument in writing, deposited with the Director-General of UNESCO. The denunciation shall take effect on the first day of the month following the expiration of a period of six months after the receipt of the instrument of denunciation. It shall in no way affect the financial obligations of the State Party concerned until the date on which the withdrawal takes effect.

ARTICLE 40
Depositary

The Director-General of UNESCO shall be the Depositary of this Convention and amendments

(e) `examine, on an ongoing basis, the monitoring of compliance with this Convention in response to the development of anti-doping systems, in accordance with Article 31. Any monitoring mechanism or measure that goes beyond Article 31 shall be funded through the Voluntary Fund established under Article 17;

(f) examine draft amendments to this Convention for adoption;

(g) examine for approval, in accordance with Article 34 of the Convention, modifications to the Prohibited List and to the Standards for Granting Therapeutic Use Exemptions adopted by the World Anti-Doping Agency;

(h) define and implement cooperation between States Parties and the World Anti-Doping Agency within the framework of this Convention;

(i) request a report from the World Anti-Doping Agency on the implementation of the Code to each of its sessions for examination.

2. The Conference of Parties, in fulfilling its functions, may cooperate with other intergovernmental bodies.

ARTICLE 31
National reports to the Conference of Parties

States Parties shall forward every two years to the Conference of Parties through the Secretariat, in one of the official languages of UNESCO, all relevant information concerning measures taken by them for the purpose of complying with the provisions of this Convention.

ARTICLE 32
Secretariat of the Conference of Parties

1. The secretariat of the Conference of Parties shall be provided by the Director-General of UNESCO.

2. At the request of the Conference of Parties, the Director-General of UNESCO shall use to the fullest extent possible the services of the World Anti-Doping Agency on terms agreed upon by the Conference of Parties. 3. Functioning costs related to the Convention will be funded from the regular budget of UNESCO within existing resources at an appropriate level, the Voluntary Fund established under Article 17 or an appropriate combination thereof as determined every two years. The financing for the secretariat from the regular budget shall be done on a strictly minimal basis, it being understood that voluntary funding should also be provided to support the Convention. 4. The secretariat shall prepare the documentation of the Conference of Parties, as well as the draft agenda of its meetings, and shall ensure the implementation of its decisions.

ARTICLE 33
Amendments

1. Each State Party may, by written communication addressed to the Director-General of UNESCO, propose amendments to this Convention. The Director-General shall circulate such communication to all States Parties. If, within six months from the date of the circulation of the communication, at least one half of the States Parties give their consent, the Director-General shall present such proposals to the following session of the Conference of Parties.

2. Amendments shall be adopted by the Conference of Parties with a two-thirds majority of States Parties present and voting.

3. Once adopted, amendments to this Convention shall be submitted for ratification, acceptance, approval or accession to States Parties.

4. With respect to the States Parties that have ratified, accepted, approved or acceded to them, amendments to this Convention shall enter into force three months after the deposit of the instruments referred to in paragraph 3 of this Article by two thirds of the States Parties. Thereafter, for each State Party that ratifies, accepts, approves or accedes to an amendment, the said amendment shall enter into force three months after the date of deposit by that State Party of its instrument of ratification, acceptance, approval or accession.

5. A State that becomes a Party to this Convention after the entry into force of amendments in conformity with paragraph 4 of this Article shall, failing an expression of different intention, be considered:

(a) a Party to this Convention as so amended;

(b) a Party to the unamended Convention in relation to any State Party not bound by the amendments.

ARTICLE 34
Specific amendment procedure for the Annexes to the Convention

1. If the World Anti-Doping Agency modifies the Prohibited List or the Standards for Granting Therapeutic Use Exemptions, it may, by written communication addressed to the Director-General of UNESCO, inform her/him of those changes. The Director-General shall notify such changes as proposed amendments to the relevant Annexes to this Convention to all States Parties expeditiously. Amendments to the Annexes shall be approved by the Conference of Parties either at one of its sessions or through a written consultation.

2. States Parties have 45 days from the Director-General's notification within which to express their objection to the proposed amendment either in writing, in case of written consultation, to the Director-General or at a session of the Conference of Parties. Unless two thirds of the States Parties express their objection, the proposed amendment shall be deemed to be approved by the Conference of Parties.

3. Amendments approved by the Conference of Parties shall be notified to States Parties by the Director-General. They shall enter into force 45 days after that notification, except for any State Party that has previously notified the Director-General that it does not accept these amendments.

4. A State Party having notified the Director-General that it does not accept an amendment approved according to the preceding paragraphs remains bound by the Annexes as not amended.

VII. FINAL CLAUSES

ARTICLE 35
Federal or non-unitary constitutional systems

The following provisions shall apply to States Parties that have a federal or non-unitary constitutional system:

(a) with regard to the provisions of this Convention, the implementation of which comes under the legal jurisdiction of the federal or central legislative power, the obligations of the federal or central government shall be the same as for those States Parties which are not federal States;

(b) with regard to the provisions of this Convention, the implementation of which comes under the jurisdiction of individual constituent States, counties, provinces or cantons which are not obliged by the constitutional system of the federation to take legislative measures, the federal government shall inform the competent authorities of such States, counties, provinces or cantons of the said provisions, with its recommendation for their adoption.

ARTICLE 36
Ratification, acceptance, approval or accession

This Convention shall be subject to ratification, acceptance, approval or accession by Members States of UNESCO in accordance with their respective constitutional procedures. The instruments of ratification, acceptance, approval or accession shall be deposited with the Director-General of UNESCO.

A stimulant not expressly listed in this section is a Specified Substance.

(b) Specified Stimultants (examples):

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

*	The following substances included in the 2009 Monitoring Program (bupropion,caffeine, phenylephrine, phenylpropanolamine, pipradol, pseudoephedrine, 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.

S7. NARCOTICS

The following narcotics are prohibited:

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

S8. CANNABINOIDS

Cannabinoids (e.g. hashish, marijuana) are prohibited.

S9. GLUCOCORTICOSTEROIDS

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

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

Annex I - Standards for Granting Therapeutic Use Exemptions

Paris, 1 January, 2009

THE 2010 PROHIBITED LIST

WORLD ANTI-DOPING CODE

Valid 1 January 2010

The use of any drug should be limited to medically justifield indications.

All *Prohibited Substances* shall be considered as *"Specified Substances"* except Substances in classes S1, S2.1, 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.

S1.1 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** (18α-homo-pregna-4,9,11-trien-17β-ol-3-one); **trenbolone** and other substances with a similar chemical structure or similar biological effect(s).

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 catheterization, urine substitution and/or alteration.

2. Intravenous infusions are prohibited except in the management of surgical procedures, medical emergencies or clinical investigations.

M3. GENE DOPING

The transfer of cells or genetic elements or the use of cells, genetic elements or pharmacological agents to modulating expression of endogenous genes having the capacity to enhance athletic performance, is prohibited.

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-COMPETION

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 their D- & L- optical isomers whrere relevant) are prohibited, except imidazole derivatives for topical use and those stimulants included in the 2009 Monitoring Program.*

(a) Non-Specified Stimulants:

Adrafinil; amfepramone; amiphenazole; amphetamine; amphetaminil; benzphetamine; benzylpiperazine; bromantan; clobenzorex; cocaine; cropropamide; crotetamide; dimethylamphetamine; etilamphetamine; famprofazone; fencamine; fenetylline; fenfluramine; fenproporex; furfenorex; mefenorex; mephentermine; mesocarb; methamphetamine (D-), methylenedioxyamphetamine; methylenedioxymethamphetamine; methylamphetamine, modafinil, norfenfluramine, phendimetrazine, phenmetrazine, phentermine, 4-phenylpiracetam (carphedon), prolintane.

1. **Aromatase inhibitors** including, but not limited to**: anastrozole, letrozole, (aminoglutethimide), exemestane, formestane, 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. 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, and topical dorzolamide and brinzolamide, which are not prohibited).

[Comment to class S5: A Therapeutic Use Exemption is not valid if an *Athlete*'s urine contains a diuretic in association with threshold or subthreshold 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),

(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-androstene-dione** (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.**

Comment to class S1. 1 (b): Where an anabolic androgenic steroid is capable of being produced endogenously, a *Sample* will be deemed to contin such *Prohibited Substance* and and *Adverse Analytical Finding* will be reported where the concentration of such *Prohibited Substanc***e** or its metablolites or markers and/or any other relevant ratio(s) in the *Athlete's Sample* so deviates from the range of values normally found in humans that it is unlikely to be consistent with normal endogenous production. A *Sample* shall not be deemed to contain a *Prohibited Substance* in any such case where an *Athlete* proves that the concentration of the *Prohibited Substance* or its metabolites or markers and/or the relevant ratio(s) in the *Athlete's Sample* is attributable to a physiological or pathological condition.

In all cases, and at any concentration, the *Athlete's Sample* will be deemed to contain a *Prohibited Substance* and the Laboratory will report an *Adverse Analyticla Finding* if, based on any reliable analytical method (e.g. IRMS), the laboratory can show that the *Prohibited Substance* is of exogenerous origin. In such case, no further investigation is necessary.

When a value does not so deviate form the range of values normally found in humans and any reliable analytical method (e.g. IRMS) has not determined the exogenous origin of the substance, but if there are indications, such as a comparison to endogenous reference steroid profiles, of a possible Use of a *Prohibited Substance,* or when a laboratory has reported a T/E ratio greater than four (4) to one (1) and any reliable analytical method (e.g. IRMS) has not determined the exogenous origin of the substance, further investigation shall be conducted by the relevant *Anti-Doping Organization* by reviewing the results of any previous test(s) or by conducting subsequent test(s)

When such further investigation is required the result shall be reported by the laboratory as atypical and not as adverse. If a laboratory reports, using an additional reliable analytical method (e.g. IRMS), that the *Prohibited Substance* is of exogenous origin, no further investigation is necessary, and the *Sample* will be deemed to contain such *Prohibited Substance.*

When an additional reliabel analytical method (e.g. IRMS) has not been applied, and the minimum of three previous test results are not available, a longitudinal profile of the *Athlete* shall be established by performing three no advance notice tests in a period of three months by the relevant *Anti-Doping Organization.* The result that triggered this longitudinal study shall be reported as atypical. If the logitudinal profile of the *Athlete* established by the susequent tests is not physiologically normal, the result shall then be reported as an *Adverse Analytical Finding.*

In extremely rare individual cases, boldenone of endogenous origin can be consistently found at very low nanograms per milliliter (ng/mL) levels in urine. When such a very low concentration of boldenone is reported by a laboratory an the application of any reliable analytical method (e.g. IRMS) has nto determined the exogenous origin of the substance, further investigation may be conducted by subsequent test(s).

For 19-norandrosterone, an *Adverse Analytical Finding* reported by a laboratory is consisered to be scientifica and valied proof of exogenous origin of the *Prohibited Substance.* In such case, no further investigation is necessary.

Should an *Athlete* fail to cooperate in the investigations, the Athlete's Sample shall be deemed to contian a *Prohibited Substance.*]

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.*

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

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

S2. HORMONES AND RELATED SUBSTANCES

The following substances and their releasing factors are prohibited:

1. **Erythropoiesis-Stimulating Agents [e.g. erythropoietin (EPO), darbepoetin (dEPO), Hematide);**
2. **Growth Hormone (GH), Insulin-like Growth Factors (e.g. IGF-1), Mechano Growth Factors (MGFs);**
3. **Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH)** in males;
4. **Insulins;**
5. **Corticotrophins;**

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

[Comment to class S2: Unless the *Athlete* can demonstrate that the concentration was due to a physiological or pathological condition, a *Sample* will be deemed to contain a *Prohibited Substance* (as listed above) where the concentration of the *Prohibited Substance* or its metabolites and/or relevant ratios or markers in the *Athlete's Sample* satisfies positivity criteria established by WADA or otherwise so exceeds the range of values normally found in humans that it is unlikely to be consistent with normal endogenous production.

If a laboratory reports, using a reliable analytical method, that the *Prohibited Substance* is of exogenerous origin, the *Sample* will be deemed to contain a *Prohibited Substace* and shall be reported as an *Adverse Analytical Finding.]*

S3. BETA-2 AGONISTS

All beta-2 agonists including their D- and L-isomers where relevant) are prohibited.

Therefore, formoterol, salbutamol, salmeterol and terbutaline when administered by inhalation also require a Therapeutic Use Exemption in accordance with the relevant section of the International Standard for Therapeutic Use Exemptions.

Despite the granting of a Therapeutic Use Exemption, the presence of salbutamol in urine in excess of 1000 ng/mL will be considered as an A*dverse Analytical Finding* unless the *Athlete* proves, through a ocntrolled pharmacokinetic study, that the abnormal result was the consequence of the use of a therapeutic dose of inhaled salbutamol.

S4. HORMONE ANTAGONISTS AND MODULATORS

The following classes are prohibited:

submitted initially to the *Anti-Doping Organization* accompanied by an application fee. Until the review process has been completed, the original decision remains in effect. The process should not take longer than thirty (30) days following receipt of all the information by *WADA*.

(b) *WADA* can, on its own initiative, undertake a review at any time.

7.12 If the decision regarding the granting of 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 that the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the *Athlete*.

7.13 *Use* of inhaled Beta-2 Agonists:

— The *Use* of inhaled formoterol, salbutamol, salmeterol, terbutaline reflects current clinical practice. The *Use* of these substances should be declared on *ADAMS* where reasonably feasible and in accordance with the *Code* as soon as the product is used and must as well be declared on the *Doping Control* form at the time of *Testing*. Failure to declare will be taken into account in the result management process in particular in case of application for a Retroactive TUE.

— *Athletes* using the substances listed above by inhalation must have a medical file justifying this Use and meeting the minimum requirements outlined in Annex 1.

Depending upon the category of the *Athlete*, the medical file will be evaluated as follows:

— For all *Athletes* included in an International Federation *Registered Testing Pool* a regular TUE approved before the *Use* of the substance.

— For *Athletes* participating in an *International Event* but who are not included in an International Federation *Registered Testing Pool* either a TUE, or a Retroactive TUE in the case of an *Adverse Analytical Finding,* in accordance with the rule of the International Federation or of the *Major Event Organization.*

— For national-level *Athletes* who are not included in an International Federation *Registered Testing Pool,* whether or not they are part of a national *Registered Testing Pool,* either a TUE, or a Retroactive TUE in the case of an *Adverse Analytical Finding,* in accordance with the rules of the *National Anti-Doping Organization.*

— No Retroactive TUE will be granted if the requirements of Annex 1 are not met meaning that any *Adverse Analytical Finding* reported by the laboratory in these circumstances will result in an anti-doping rule violation.

— Any *Athlete* may apply for a TUE at any time if they wish.

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 neither require a Therapeutic Use Exemption nor a declaration of use.

SUBSTANCES PROHIBITED IN PARTICULAR SPORTS

P1. ALCOHOL

Alcohol (ethanol) is prohibited *In-Competition* only, in the following sports.Detection will be conducted by analysis of breath and/or blood. The doping violation threshold (haematological values) is 0.10 g/L.

- Aeronautic (FAI)
- Archery (FITA)
- Automobile (FIA)
- Boules (IPC bowls)
- Karate (WKF)
- Modern Pentathlon (UIPM) for disciplines involving shooting
- Motorcycling (FIM)
- Ninepin and Tenpin Bowling (FIQ)
- Powerboating (UIM)

P2. BETA-BLOCKERS

Unless otherwise specified, beta-blockers are prohibited *In-Competition* only, in the following sports.

- Aeronautic (FAI)
- Archery (FITA) (also prohibited *Out-of-Competition*)
- Automobile (FIA)
- Billiards and Snooker (WCBS)
- Bobsleigh (FIBT)

- Boules (CMSB)
- Bridge (FMB)
- Curling (WCF)
- Golf (IGF)
- Gymnastics (FIG)
- Motorcycling (FIM)
- Modern Pentathlon (UIPM) for disciplines involving shooting
- Ninepin and Tenpin Bowling (FIQ)
- Powerboating (UIM)
- Sailing (ISAF) for match race helms only
- Shooting (ISSF, IPC) (also prohibited *Out-of-Competition*)
- Skiing/Snowboarding (FIS) in ski jumping, freestyle aerials/halfpipe and snowboard halfpipe/ big air
- Wrestling (FILA)

Beta-blockers include, but are not limited to, the following:

Acebutolol, alprenolol, atenolol, betaxolol, bisoprolol, bunolol, carteolol, carvedilol, celiprolol, esmolol, labetalol, levobunolol, metipranolol, metoprolol, nadolol, oxprenolol, pindolol, propranolol, sotalol, timolol

7.3 The TUE application form(s) may be translated into other language(s) by *Anti-Doping Orgrmizations.* but English or French must remain on the application *form(s).*

7.4 An *Athlete* may not apply to more than one *Anti-Doping Organization* for a TUE. The application must identify the *Athlete's* sport and, where appropriate, discipline and specific position or role.

7.5 The application must list any previous and/or current requests for permission to use an otherwise *Prohibited Substance* or *Prohibited Method,* the body to whom that request was made, and the decision of that body.

7.6 The application must 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 follow the *WADA* "Medical Information to Support the Decisions of TUECs". For asthma, the specific requirement(s) set out in Annex 1 must be fulfilled.

7.7 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 or his/her national sport governing body.

7.8 The application must 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.

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

7.10 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.* Where a TUE has been granted to an *Athlete* in the *Anti-Doping Organization Registered Testing Pool,* the *Athlete* and *WADA* will be provided promptly with an approval which includes information pertaining to the duration of the exemption and any conditions associated with the TUE.

7.11 *(a)* Upon receiving a request by an *Athlete* for review, the *WADA* TUEC will, as specified in Article 4.4 of the *Code,* be able to reverse a decision on a TUE denied by an *Anti-Doping Organization.* The *Athlete* shall provide to the *WADA* TUEC all the information for a TUE as

involved 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 the TUEC or the *WADA* TUEC to obtain any health information on his/her behalf, the *Athlete* must 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.

6.0 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 *Athletes* 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 *Athletes* with disabilities, at least one TUEC member must possess specific experience with the care and treatment of *Athletes* 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 on its own initiative TUE decisions granted by *Anti-Doping Organizations.* As specified in Article 4.4 of the *Code,* the WADA TUEC, upon request by *Athletes* who have been denied TUEs by an *Anti-Doping Organization, will* review such decisions with the power to reverse them.

7.0 Therapeutic *Use* Exemption (TUE) Application Process

7.1 A TUE will only be considered following the receipt of a completed application form that must include all relevant documents (see Annex 2 - TUE form). The application process must be dealt with in accordance with the principles of strict medical confidentiality.

7.2 The TUE application form(s), as set out in Annex 2, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

Annex II - Standards for Granting Therapeutic Use Exemptions

Paris, 1 January, 2009

Extract from the INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS, 1 January 2009 of the World Anti-Doping Agency (WADA)

PART TWO: STANDARDS FOR GRANTING THERAPEUTIC USE EXEMPTIONS

4.0 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* contained in the *Prohibited List.* 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.* An exemption will be granted only in strict accordance with the following criteria:

[Comment: This Standard can apply to all Athletes as defined by and subject to the Code, i.e. able-bodied Athletes and Athletes with disabilities. 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.]

4.1 The *Athlete* should submit an application for a TUE no less than twenty-one (21) days before he/she needs the approval (for instance an *Event).*

4.2 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.

4.3 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.

4.4 There is no reasonable therapeutic alternative to the *Use of* the otherwise *Prohibited Substance* or *Prohibited, Method.*

4.5 The necessity for the *Use of* the otherwise *Prohibited Substance* or *Prohibited: Method* cannot be a consequence, wholly or in part, of prior non-therapeutic *Use of* any substance from the *Prohibited List.*

4.6 The TUE will be cancelled by the granting body, 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.*

(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.]

4.7 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,* or

(c) the conditions set forth under 7.13 apply.

[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 *dare to imminent competition are infrequent. Anti-Doping Organizations granting* TUES *should have internal procedures which permit such situations to be addressed.]*

5.0. Confidentiality of Information

5.1 The applicant must provide written consent for the transmission of all information pertaining to the application to members of the TUEC and, as required, other independent medical or scientific experts, or to all necessary staff involved in the management, review or appeal of TUEs.

Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the *Athlete* concerned. The applicant must also provide written consent for the decisions of the TUEC to be distributed to other relevant *Anti-Doping Organizations* under the provisions of the *Code.*

5.2 The members of the TUECs and the administration of the *Anti-Doping Organization* involved will conduct all of their activities in strict confidence. All members of a TUEC and all staff

Any *Athlete* who has applied for a TUE or a Retroactive TUE and who was denied such TUE may not use the substance without the prior granting of a TUE (no Retroactive TUE will be permitted).

8.0 Declaration of *Use* Process

8.1 It is acknowledged that some substances included on the List of *Prohibited Substances* are used to treat medical conditions frequently encountered in the athlete population. For monitoring purposes, these substances, for which the route of administration is not prohibited, will require a simple declaration of use. These are strictly limited to:

Glucocorticosteroids used by non systemic routes, namely intraarticular, periarticular, peritendinous, epidural intradermal injections and inhaled route.

8.2 For the mentioned substances, the declaration of *Use* should be done through *ADAMS* where reasonably feasible and in accordance with the *Code* by the *Athlete* at the same time as the *Use* starts. This declaration should mention the diagnosis, the name of the substance, the dose undertaken, the name and the contact details of the physician.

In addition, the *Athlete* must declare the *Use* of the substance in question on the *Doping Control* form.

9.0 Clearinghouse

9.1 *Anti-Doping Organizations* are required to provide *WADA* with all TUEs approved for *Athletes* who are part of a national or international *Registered Testing Pool,* and all supporting documentation, in accordance with section 7.

9.2 The declarations of use should be available to *WADA (ADAMS).*

9.3 The clearinghouse shall guarantee strict confidentiality of all the medical information.

10.0 Transitional Provision

Abbreviated Therapeutic Use Exemptions (ATUEs) delivered prior to December 31 2008, shall remain governed by the 2005 TUE Standard.

These ATUEs shall remain valid after January 1 2009, until the earliest of:

(a) The date on which they are cancelled by the competent TUEC following review in accordance with art. *8.6* of the 2005 TUE Standard;

(b) Their expiry date as mentioned on the ATUE;

(c) December 31 2009.

Annex I: Minimal requirements for the medical file to be used for the TUE process in the case of asthma and its clinical variants

The File must reflect current best medical practice to include:

(1) A complete medical history;

(2) A comprehensive report of the clinical examination with specific focus on the respiratory system;

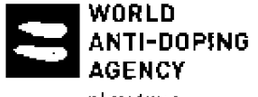
(3) A report of spirometry with the measure of the Forced Expiratory Volume in 1 second (FEVI);

(4) If airway obstruction is present, the spirometry will be repeated after inhalation of a short acting Beta-2 Agonist to demonstrate the reversibility of bronchoconstriction;

(5) In the absence of reversible airway obstruction, a bronchial provocation test is required to establish the presence of airway hyper-responsiveness;

(6) Exact name, speciality, address (including telephone, e-mail, fax) of examining physician.

World Anti-Doping Code



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specific rules have been violated. Most of the circumstances and conduct on this list of violations can be found in some form in the OMADC or other existing anti-doping rules.

***21.1 Comment:** For purposes of anti-doping violations involving the presence of a Prohibited Substance (or its Metabolites or Markers), the Code adopts the rule of strict liability which is found in the OMADC and the vast majority of existing anti-doping rules. Under the strict liability principle, an anti-doping rule violation occurs whenever a Prohibited Substance is found in an Athlete's bodily Specimen. 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).*

The strict liability rule for the finding of a Prohibited Substance in an Athlete's Specimen, with a possibility that sanctions may be modified based on specified criteria, provides a reasonable balance between effective anti-doping

2.1.2 Excepting those substances for which a quantitative reporting threshold is specifically identified in the Prohibited List, the detected presence of any quantity of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample shall constitute an anti-doping rule violation.

2.1.3 As an exception to the general rule of Article 2.1, the *Prohibited List* may establish special criteria for the evaluation of *Prohibited Substances* that can also be produced endogenously.

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 on the Athlete's part. It is important to emphasize that while determination of whether the anti-doping rule has been violated is based on strict liability, the imposition of a fixed period of Ineligibility is not automatic.

The rationale for the strict liability rule was well stated by the Court of Arbitration for Sport in the case of Quigley v, UIT.

INTRODUCTION

THE PURPOSE, SCOPE AND ORGANIZATION OF THE WORLD ANTI-DOPING PROGRAM AND THE CODE

The Purposes of the World Anti-Doping Program and the *Code* are:

To protect the *Athletes* fundamental right to participate in doping-free sport and thus promote health fairness and equality for *Athletes* worldwide: and

To ensure harmonized, coordinated and effective anti-doping programs at the international and national level with regard to detection, deterrence and prevention of doping.

THE WORLD ANTI-DOPING PROGRAM

The World Anti-Doping Program encompasses all of the elements needed in order to ensure optimal harmonization and best practice interanational and national anti-doping programs. The main elements are:

Level 1: The *Code*

Level 2: *International Standards*

Level 3: Models of Best Practice

THE *CODE*

The *Code* is the fundamental and universal document upon which the World Anti-Doping Program in sport is based. The purpose of the *Code* is to advance the anti-doping effort through universal harmonization of core anti-doping elements. It is intended to be specific enough to achieve complete harmonization on issues where uniformity is required, yet general enough in other areas to permit flexibility on how agreed on anti-doping principles are implemented.

INTERNATIONAL STANDARDS

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.

proceedings or employment matters. The policies and minimum standards set forth in the *Code* represent the consensus of a broad spectrum of stakeholders with an interest in fair sport and should be respected by all courts and adjudicating bodies.

Participants shall be bound to comply with the anti-doping rules adopted in conformance with the anti-doping rules adopted in conformance with the Code by the relevant *Anti-Doping Organizations*. Each *Signatory* shall establish rules and procedures to ensure that all *Participants* under the authority of the *Signatory* and its member organizations are informed of an agree to be bound by anti-doping rules in force of the relevant *Anti-Doping Organizations*.

Verbatim, as 13.2.2 establishes mandatory guiding principles that allow some flexibility in the formulation of rules by the Anti-Doping Organization.

Participants Comment. *By their participation in sport, Athletes are bound by the competitive rules of their sport. In the same manner, Athletes and Athlete Support Personnel should be bound by anti-doping rules based on Article 2 of the Code by virtue of their agreements for membership, accreditation, or participation in sports organizations or sports events subject to the Code. Each Signatory, however, shall take the necessary steps to ensure that all Athletes and Athlete Support Personnel within its authority are bound by the relevant Anti-Doping Organization's Anti-doping rules.*

ARTICLE 1: DEFINITION OF DOPING

Doping is defined as the occurrence of one or more of the anti-doping rule violations set forth in Article 2.1 through Article 2.8 of the *Code*.

ARTICLE 2: ANTI-DOPING RULE VIOLATIONS

The following constitute anti-doping rule violations:

2.1 *The presence of a Prohibited Substance or its Metabolites or Markers in an Athlete's bodily Specimen.*

2.1.1 It is each *Athlete's* personal duty to ensure that no *Prohibited Substance* enters his or her body. *Athletes* are responsible for any *Prohibited Substance* or its *Metabolites* or *Markers* found to be present in their bodily *Specimens*. 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.

2 Comment: *The purpose of Article 2 is to specify the circumstances and conduct which constitute violations of anti-doping rules. Hearings in doping cases will proceed based on the assertion that one or more of these*

INTRODUCTION

Part One of the *Code* sets forth specific anti-doping rules and principles that are to be followed by organizations responsible for adopting, implementing or enforcing anti-doping rules within their authority e.g., the international Olympic Committee, International Paralympic Committee, International Federations, *Major Event Organizations,* and *National Anti-Doping Organizations.* All of these organizations are collectively referred to as *Anti-Doping Organizations.*

Part One of the Code does not replace, or eliminate the need for, comprehensive anti-doping rules adopted by each of these *Anti-Doping Organizations.* While some provision of Part One of the *Code* must be incorporated essentially verbatim by each *Anti-Doping Organization* in its own anti-doping rules, other provisions of Part One establish mandatory guiding principles that allow flexibility in the formulation of rules by each Anti-Doping Organization or establish requirements that must be followed by each *Anti-Doping Organization* but need not be repeated in its own anti-doping rules. The following Articles, as applicable to the scope of anti-doping activity which the *Anti-Doping Organization* performs, must be incorporated into the rules of each Anti-Doping Organization without any substantive changes (allowing for necessary non-substantive editing

> ***Introduction Comment.*** *For example it is critical to harmonization that all Signatories base their decisions on the same list of anti-doping rules violations, the same burdens of proof and impose the same Consequences for the same anti-doping rule violations. These substantive rules must be the same whether a hearing takes place before an International Federation, at the national level or before CAS. On the other hand, it is not necessary for effective harmonization to force all Signatories to use one single results management and hearing process.*
>
> *At present, there are many different, yet equally effective processes for results management and hearings within different International Federations and different national bodies, The Code does not require absolute uniformity in results management and hearing procedures; it does, however, require that the diverse approaches of the Signatories satisfy principles stated in the Code.*
>
> *With respect to Articles 13, subpart 13.2.2 is not included in the provisions required to be adopted essentially*

changes to the language in order to refer to the organization's name, sport, section numbers, etc.): Articles 1 (Definition of Doping), 2 (Anti-Doping Rule Violations), 3 (Proof of Doping), 9 (Automatic *Disqualifications* of Individual Results), 10 (Sanctions on Individuals), 11 (*Consequences* to Teams), 13 (Appeals) with the exception of 13.2.2, 17 (Statute of Limitations) and Definitions.

Anti-doping rules, life competition rules, are sport rules governing the conditions under which sport is played. *Athletes* accept these rules as a condition of participation. Anti-doping rules are not intended to be subject to or limited by the requirements and legal standards applicable to criminal

MODELS OF BEST PRACTICE

Models of Best Practice based on the *Code* will be developed to provide state of the art solutions in different areas of anti-doping. The Models will be recommended by *WADA* and made available to *Signatories* upon request but will not be mandatory. In addition to providing models of anti-doping documentation, *WADA* will also make some training assistance available to the *Signatories.*

> **International Standards Comment**
> *International Standards will contain much of the technical detail necessary for implementing the Code. This would include, for example, the detailed requirements for sample collection, laboratory analysis and laboratory accreditation currently found in the Olympic Movement Anti-Doping Code 1999 ("OMADC"). International Standards, while expressly incorporated into the Code by reference, will in consultation with the Signatories and governments, be developed by experts and set forth in separate technical documents. It is important that the technical experts be able to make timely changes to the International Standards without requiring any amendment of the Code or individual stakeholder rules and regulations.*
>
> *All applicable International Standards will be in place by January 1, 2004.*
>
> ***Models of Best Practice Comment.***
>
> *WADA will prepare model anti-doping rules and regulations tailored to the needs of each of the major groups of Signatories (e.g. International Federations for individual sports,*

FUNDAMENTAL RATIONALE FOR THE WORLD ANTI-DOPING CODE

Anti-doping programs seek to preserve what is intrinsically valuable about sport. The intrinsic value is often referred to as "the spirit of sport"; it is the essence of Olympism; it is how we play true. The spirit of sport is the celebration of the human spirit, body and mind, and is characterized by the following values:

Ethics, fair play and honesty.
Health.
Excellence in performance.
Character and education.
Fun and joy.
Teamwork.
Dedication and commitment.
Respect for rules and laws.
Respect for self and other participants.
Courage.
Community and solidarity.

Doping is fundamentally contrary to the spirit of sport.

International Federations for team sports, National Anti-Doping Organizations, etc.). These model rules and regulations will conform with and be based on the Code, will be state of the art examples of best practices and will contain all of the detail (including reference to International Standards) necessary to conduct an effective anti-doping program.

These model rules and regulations will provide alternatives from which stakeholders may select. Some stakeholders may select. Some stakeholders may choose to adopt the model rules and regulations and other models of best practices verbatim. Others may decide to adopt the models with modifications. Still other stakeholders may choose to develop their own rules and regulations consistent with the general principles and specific requirements set forth in the Code.

Other model documents for specific parts of the anti-doping work may be developed based on generally recognized stakeholder needs and expectations. This could include models for national anti-doping programs, results management, Testing (beyond the specific requirements set forth in the International Standard for Testing), education programs., etc. All Models of Best Practice will be reviewed and approved by WADA before they are included in the World Anti-Doping Program.

PART ONE
DOPING CONTROL

WADA, on its own initiative, may review the granting of a therapeutic use exemption to any International-Level Athlete or national-level Athlete that is included in his or her National Anti-Doping Organization's Registered Testing Pool. Further, upon the request of any such Athlete that 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.

4.5 Monitoring Program

WADA, in consultation with other *Signatories* and governments, shall establish a monitoring program regarding substances which are not on the *Prohibited List*, but which *WADA* wishes to monitor in order to detect patterns of misuse in sport. *WADA* shall publish, in advance of any *Testing*, the substances that will be monitored. Laboratories will report the instances of reported *Use or* detected presence of these substances to WADA periodically on an aggregate basis by sport and whether the *Samples* were collected *In-Competition* or *Out-of-Competition.* Such reports shall not contain additional informaiton regarding specific *Samples. WADA* shall make available to International Federations and National Anti-Doping Organizations, on at least an annual basis, aggregate statistical information by sport regarding the additional substances. WADA shall implement measures to ensure that strict anonymity of individual *Athletes* is maintained with respect to such reports. The reported use or detected presence of the monitored substanes shall not constitute a doping violation.

ARTICLE 5: TESTING

5.1 Test Distribution Planning. *Anti-Doping Organizations* conducting *Testing* shall in coordination with other *Anti-Doping Organizations* conducting *Testing* on the same *Athlete pool:*

5.1.1 Plan and implement an effective number of *In-competition* and *Out-of-Co-mpetition* tests. 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* in its country. The national-level pool shall include *International-Level Athletes* from that country as well as other national-level Athletes. Each International Federation and *National Anti-Doping Organization* shall plan and conduct *In-Competition* and *Out-of-Competition Testing* on its *Registered Testing Pool.*

5.1.2 Made *No Advance Notice Testing* a priority.

5.1.3 Conduct *Target Testing.*

5.1.3 Comment: *Target Testing is specified because randomo Testing, or even weighted*

"It is true that a strict liability test is likely in some sense to be unfair in an individual case, such as that of Q., Where the Athlete may have taken medication as the result of mislabeling or faulty advice for which he or she is not responsible- particularly in the circumstances of sudden illness in a foreign country. But it is also in some sense "unfair" for an Athlete to get food poisoning on the eve of an important competition. Yet in neither case will the rules of the competition be altered to undo the unfairness. Just as the competition will not be postponed to await the Athlete's recovery, so the prohibition of banned substances will not be lifted in recognition of its accidental absorption. The vicissitudes of competition, like those of life generally, may create many types of unfairness, whether by accident or the negligence of unaccountable Persons, which the law cannot repair.

Furthermore, it appears to be a laudable policy objective not to repair an accidental unfairness to an individual by creating an intentional unfairness to the whole body of other competitors. This is what would happen if banned performance- enhancing substances were tolerated when absorbed inadvertently. Moreover, it is likely that even intentional abuse would in many cases escape sanction for lack of proof of guilty intent. And it is certain that a requirement of intent would invite costly litigation that may well cripple federations - particularly those run on modest budgets - in their fight against doping"

2.1.3 Comment: *For example, the Prohibited List might provide that a T/E ratio greater than 6:1 is doping unless a longitudinal analysis of prior or subsequent test results by the Anti-Doping Organization demonstrates a naturally elevated ratio or the Athlete otherwise establishes that the elevated ratio is the result of a physiological or pathological condition.*

2.2 *Use* or *Attempted Use* of a *Prohibited Substance* or a *Prohibited Method.*

2.2.1 The success or failure of the *Use* of a *Prohibited Substance* or *Prohibited Method* is not material. It is sufficient that the *Prohibited Substance* or *Prohibited Method* was *Used* or *Attempted* to be *Used* for an anti-doping rule violation to be committed.

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.

2.21 Comment: *The prohibition against "Use" has been expanded from the text in the OMADC to include Prohibited Substances as well as Prohibited Methods. With this inclusion there is no need to specifically delineate "admission of Use" as a separate anti-doping rule violation. "Use" can be proved, for example, through admissions, third party testimony or other evidence.*

Demonstrating the "Attempted Use" of a Prohibited Substance requires proof of intent on the Athlete's part. The fact that intent may be required to prove this particular anti-doping rule violation does not undermine the strict liability principle established for violations of Article 2.1 and Use of a Prohibited Substance or Prohibited Method.

An Athlete's Out-of-Competition Use of a Prohibited Substance that is not prohibited Out-of-Competition would not constitute and anti-doping rule violation.

2.3 Comment: *Failure or refusal to submit to Sample collection after notifications prohibited in almost all existing anti-doping rules. This Article expands the typical 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 who was attempting to conduct a test. 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 provided required whereabouts information and missed tests which are declared based on reasonable rules.

2.5 *Tampering,* or *Attempting* to tamper, with any part of *Doping Control.*

2.6 *Possession* of *Prohibited Substance*s and *Methods:*

2.6.1 *Possession* by an *Athlete* at any time or place of a substance that is prohibited in *Out-of -Competition Testing* or a *Prohibited Method* unless the *Athlete* establishes that the Possession is pursuant to a therapeutic use exemption granted in accordance with Article 4.4 (Therapeutic *Use*) or other Acceptable justification.

2.6.2 Possession of a substance that is prohibited in *Out-of-Competition Testing* or a *Prohibited Method* by *Athlete Support Personnel* in connection with an *Athlete, Competition* or training, unless the *Athlete Support Personnel* established that the *Possession* is pursuant to a therapeutic use exemption granted to an *Athlete* in accordance with Article 4.4 (Therapeutic *Use*) or other acceptable justification.

2.4 Comment: *Unannounced Out-of-Competition Testing is at the core of effective Doping Control. Without accurate Athlete location information such Testing is inefficient and sometimes impossible. This Article, which is not typically found in most existing anti-doping rules, requires Athletes that have been identified for Out-of-Competition Testing to be responsible for providing and updating infor-*

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. Each *National Anti-Doping Organization* slahll ensure, for all Athletes within its jurisdiction that are not *International-Level Athletes,* 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 exemptin. Such requests shall be evaluated in accordance with the international Standard on therapeutic use. International Federations and *National Anti-Doping Organizations* shall promptly report to *WADA* the granting of therapeutic use exemptions to any *International-Level Athlete* or national-level Athlete that is included in his or her *National Anti-Doping Organization's Registered Testing* Pool.

4.3.3 Comment: *The question of whether a substance meets the criteria in Article 4.3 (Criteria for Including Substances and Methods on the Prohibited List) in a particular case cannot be raised as a defense to an anti-doping rule violation. For example, it cannot be argued that the Prohibited Substance detected would not have been performance enhancing in that particular sport. Rather, doping occurs when a substance on the Prohibited List is found in an Athlete's bodily Speciment. The same principle is found in the OMADC.*

4.4 Comment*: It is important that the processes for granting therapeutic use exemptions become more harmonized. Athletes who use medically prescribed Prohibited Substances may be subject to sanctioning unless they have previously obtained a thereapeutic use exemption. However, currently many sporting bodies have no rules permitting therapeutic use exemptions; others follow unwritten policies incorprated into their anti-doping rules. This Article seeks to harmonize the basis upon which therapeutic use exemptions will be granted and gives responsibility for granting or denying exemptions to the International Federations for Internaitonal-Level Athletes and to the National Anti-Doping Organizations for national-level Athletes (that are not also International-Level Athletes) and other Athletes subject to Doping Control under the Code.*

Examples of commonly prescribed Prohibited Substances which might be specifically addressed in the Internaitonal Standard for therapeutic use exemptions are medications prescribed for acute severe asthma and inflammatory bowel disease. When a therapeutic use exemption has been denied or granted in contravention of the International Standard, that decision may be submitted to WADA for review as provided in the International Standard and thereafter appealed as provided in Article 13.3 (Appeals). If the granting of a therapeutic use exemption is reversed, the reversal shall not apply retroactively and shall not disqualify the Athlete's results during the time that the therapeutic use exemption was in effect.

the substance or method has the potential to enhance or enhances sport performance;

4.31.2. Medical or other scientific evidence, pharmacological effect, or experience that the *use* of the substance or method respresents an actual or potential health risk to the *Athlete;*

4.3.1.3 WADA'S determination that the *use* of the substance or method violates the spitit of sport described in the Introduction to the *Code.*

4.3.2 A substance or method shall also be included on the *Prohibited List* if *WADA* determines there is medical or other scientific evidence, pharmacological effect or experience that the substance or method has the potential to mask the *Use* of other *Prohibited Substances* and *Prohibited Methods.*

4.3.2 Comment: *A substance shall be considered for inclusion on the Prohibited List if the substance is a masking agent or meets two of the following three criteria: (1) if has the potential to enhance or enhances sport performance; (2) it represents a potential or actual health risk; or (3) it is contrary to the spirit of sport. None of the three criteria alone is a sufficient basis for adding a substance to the Prohibited List. Using the potential to enhance performances as the sole criteria would include, for example, physical and mental training, red meat, carbohydrate loading and training at altitude. Risk of harm would include smoking. Requiring all three criteria would also be unsatisfactory. For example the use of genetic transfer technology to dramatically enhance sport performance should be prohibited as contrary to the spirit of sport even if it is not harmful. Similary, the potentially unhealthy abuse of certain substances without the rapeutic justification based on the mistaken belief they enhance performance is certainly contrary to the spirit of sport regardless of whether the expectation of performance enhancemfent is realistic.*

4.3.3 *WADA'S* determination of the *Prohibited Substances* and *Prohibited Methods* that will be included on the *Prohibited List* shall be final and shall not be subject to challenge by an *Athlete* or other *Person* based on an argument that the substance or method was not a masking agent or did not have the potential to enhance performance, represent a health risk, or violate the spirit of sport.

4.4 Therapeutic *Use*

WADA shall adopt an International Standard for the process of granting therapeutic use exemptions.

Each Internaitonal Federation shall ensure, for *International-Level Athletes* or any other *Athlete* who is

mation on their whereabouts so that they can be located for No Advance Notice Out-of-Competition Testing. The "applicable requirements' are set by the Athlete's International Federation and National Anti-Doping Organization in order to allow some flexibility based upon varying circumstances encountered in diffferent sports and countries. A violation of this Article may be based on either intentional or negligent conduct by Athlete,

2.5 Comment: *This Article prohibits conduct which subverts the Doping Control process but which would not be included in the typical definition of Prohibited Methods. For example, altering identification numbers on a Doping Control form during Testing or breaking the B Bottle at the time of B Sample analysis.*

2.7 *Trafficking* in any *Prohibited Substanve* or *Prohibited Meth.*

2.8 Administration or *Attempted* Administration of a *Prohibited Substance* or *Prohibited Method* to any *Athlete*, or assisting, encouraging, adiding, abetting, covering up or any other type of complicity involving an anti-doping rule violatio or any *Attempted* violation.

ARTICLE 3: PROOF OF DOPING

3.1 Burdens and Standards of Proof.

The *Anti-Doping Organization* shall have the burden of establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether the *Anti-Doping Organization* has established an anti-doping rule violation to the compfortable satisfaction of the hearing body bearing in mind the seriousness of the allegation which 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. Where the *Code* places the burden of proof upon the *Athlete* or other *Person* alleged to have committed an anti-doping rule violationa to rebut a presumption or establish specified facts or circumstances, the standard of proof shall be by a balance of probability.

3.2 Methods of Establishing Facts and Presumptions.

Facts related to anti-doping rule violations may be established by any reliable means, including admissions. The following rules of proof shall be applicable in doping cases:

3.1 Comment*: This standard of proof required to be met by the Anti-Doping Organization is comparable to the standard which is applied in most countries to cases involving professional misconduct. It has also been widely applied by courts and tribunals in doping cases. See, for example, the CAS descision in N., J., W. v. FINA; V CAS 98/208, 22 December 1998.*

3.2.1 *WADA*-accredited laboratories are presumed to have conducted Sample analysis and custodia procedures in accordance with the *International Standard* for labioratory analysis. The *Athlete* may rebut this presumption by establishing that a departure from in *International Standard* occurred.

If the Athlete rebuts the preceding presumption by showing that a departure from the *International Standard* occurred, then the *Anti-Doping Organization* shall have the burden to establish that such departure did not cause the *Adverse Analytical Finding.*

3.2.2 Departures from the I*nternational Standard* for *Testing* which did not cause an *Adverse Analytical Finding* or other anti-doping rule violation shall nt invalidate such results. If the *Athlete* establisheds that departures from the *International Standard* occurred during *Testing* then the *Anti-Doping Organization* shall have the burden to establish that such departures ded not cause the *Adverse Analytical Finding* or the factual basis for the anti-doping rule violation.

> ***3.2.1 Comment:*** *The burden is on the Athlete to establish, by a preponderance cf the evidence, a departure from the evidence, a departure from the International Standard. ıf the Athlete does so, the burden shıfts to the Anti-Doping Organization to prove to the conıfortable statisfaction cf the hearing body that the departure did not change the test result.*

ARTICLE 4: THE PROHIBITED LIST

4.1 Publication and Revision of the Prohibited List.

WADA shall, as oftern as necessary and no less often than annually, publish the *Prohibited List* as an *International Standard.* The proposed content of the *Prohibited List* and all revisions shall be provided in writing promptly to all *Signatories* and governments for comment and consultation. Each annual version of the *Prohibited List* and all revisions shall be distributed promptly by *WADA* to each *Signatory* and government and shall be published on *WADA's* website, and each Signatory shall take appropriate steps to distribute the *Prohibited List* to its members and constituents. The rules of each *Anti-Doping Organization* shall specify that, unless provided otherwise in the Prohibited List or a revision, the *Prohibited List* and revisions shall go into effect under the *Anti-Doping Organization's* rules three months after publication of the *Prohibited List* by *WADA* without requiring any further action by the *Anti-Doping Organization.*

4.2 *Prohibited Substances and Prohibited Methods Identıfied on the Prohibited List.*

The *Prohibited List* shall identify those *Prohibited Substances* and *Prohibited Methods* which are prohibited as doping at all times (both *In-Competition* and *Out-cf- Competition*) because of their potential to enhance performance in future *Competitions* or their masking potential and those substances and methods which are prohibited *In-Competition* only. Upon the recommendation of an

International Federation, the *Prohibited List* may be expanded by *WADA* for that particular sport. *Prohibited Substances* and *Prohibited Methods* may be included in the *Prohibited List* by general category (e.g., anabolic agents) or by specific regerence to a particular substance or method.

> ***4.1 Comment:*** *The Prohibited List will be revised and published on an expedited basis whenever the need arises, Howevre, for the sake cf predictability, a new list will be published every year whether or not changes have been made. The virtue cf the IOC practice cf publishing a new list every January is that it avoids conıfustion over which list is the most current. To address this issue, WADA will always have the most current Prohibited List published on its website.*
>
> *It is anticipated that revised anti-doping rules adopted by Anti-Doping Organizations pursuant to the Code will not go into ɛjfect until January 1, 2004 with the publication cf the first Prohibited List adopted by WADA. The OMADC will continue to be applicable until the Code is accepted by the International Olympic Committee.*
>
> ***4.2 Comment:*** *There will be one Prohibited List. The substances which are prohibited at all times would include masking agents and those substances which, when used in training, may have long term peıformance enhancing ɛjfects such as anabolics. All substances and methods on the Prohibited List are prohibited In-Competition. This distinction between what is tested for In-Competition and what is tested for Out-cf-Competition is carried over from the OMADC.*
>
> *There will be only one document called the "Prohibited List." WADA may add additional substances or methods to the Prohibited List for particular sports (e.g. the inclusion cf beta-blockers for shootin) but this will also be reflected on the single Prohibited List. Having all Prohibited Substances on a single list will avoid some cf the current conıfusion related to identıfying which substances are prohibited in which sports. Individual sports are not permitted to seek exemption from the basic list cf Prohibited Substances (e.g. eliminating anabolics from the Prohibited List for "mind sports"). The premise cf this decision is that there are certain basic doping agents which anyone who chooses to call himseıf or hereseıf and Athlete should not take.*

4.3 Criteria for Including Substances and Methods on the *Prohibited List.*

WADA shall consider the following criteria in deciding wheterh to include a substance or method on the *Prohibited List.*

4.3.1 A substance or method shall be considered for inclusion on the Prohibited List if WADA determinies that the substance or method meets any two of the following three criteria:

4.3.1.1 Medical or other scientific evidence, pharmacological effect or experience that

However, the *Athlete* or other *Person* shall have the opportunity in each case, before a period of *Ineligibility* is imposed, to establish the basis for eliminating or reducing (in the case of a second or third violation) this sanction as provided in Article 10.5.

10.4 *Ineligibility* for Other Anti-Doping Rule Violations

The period of *Ineligibility* for other anti-doping rule violations shall be:

10.4.1 For violations of Article 2.3 (refusing or failing to submit to *Sample* collection) or Article 2.5 *(Tampering* with *Doping Control,* the *Ineligibility* periods set forth in Article 10.2 shall apply.

10.4.2 For violations of Articles 2.7 *(Trajficking)* or 2.8 (administration of *Prohibited Substance* or *Prohibited Method),* the period of *Ineligibility* imposed shall be a minimum of four (4) years up to

violation already builds in sujficient discretion to allow consideration cf the Person's degree cf fault.

10.41 Comment. *Those who are involved in doping Athletes or covering up doping should be subject to sanctions which are more severe than the Athletes who test positive.*

Since the authority cf sport organizations is generally limited to Ineligibility for credentials, membership and other sport benefits, reporting Athlete Support Personnel to competent authorities is an important step in the deterrence cf doping.

lifetime *Ineligibility.* An anti-doping rule violation involving a *Minor* shall be considered a particularly serious violation, and, if committed by *Athlete Support Personnel* for violations other than specified substances referenced in Article 10.3, shall result in lifetime *Ineligibility* for such *Athlete Support Personnel.* In addition, violations of such Articles which also violate non-sporting laws and regulations, may be reported to the competent administrative, professional or judicial authorities.

10.4.3 For violations of Article 2.4 (whereabouts violation or missed test), the period of *Ineligibility* shall be at a minimum 3 months and at a maximum 2 years in accordance with the rules established by the *Anti-Doping Organization* whose test was missed or whereabouts requirement was violated. The period of *Ineligibility* for subsequent violations of Article 2.4 shall be as established in the rules of the *Anti-Doping Organization* whose test was missed or whereabouts requirement was violated.

random Testing, does not ensure that all cf the appropriate Athletes will be tested. (For example: world class Athletes whose

5.2 Standards for Testing

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

ARTICLE 6: ANALYSIS OF SAMPLES

Doping Control Samples shall be analyzed in accordance with the following principles:

6.1 *Use* of Approved Laboratories

Doping Control Samples shall be analyzed only in *WADA*-accredited laboratories or as otherwise approved by WADA. The choice of the *WADA-accredited laboratory (or other method approved by WADA* used for the *Sample* analysis shall be determined exclusively by the *Anti-Doping Organization* responsible for results management.

6.2 Substances Subject to Detection

Doping Control Samples shall be analyzed to detect *Prohibited Substances* and *Prohibited Methods* identified on the *Prohibited List* and other substances as may be directed by *WADA* pursuant to Article 4.5 (Monitoring Program).

6.3 Research on *Samples*

No *Sample* may be used for any purpose other than the detection of substances (or classses of substances) or methods on the *Prohibited List*, or as otherwise identified

performances have dramatically improved over a short period cf 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. Similary, it does not impose any reasonable suspicion or probable cause requirement for Target Testing.

5.2 Comment: *The required methods and processes for the various types cf In-Competition and Out-cf-Competition Testing will be described in greater detail in the International Standard for Testing.*

6.1 Comment: *The phrase "or other method approved by WADA" is intended to cover, for example, mobile blood Testing procedures which WADA has reviewed and considers to be reliable.*

by *WADA* pursuant to Article 4.5 (Monitoring Program). without the *Athlete's* written consent.

6.4 Stnadards for *Sample* Analysis and Reporting

Laboratories shall analyze *Doping Control Samples* and report results in conformity with the *International Standard* for labouratory analysis.

ARTICLE 7: RESULTS MANAGEMENT

Each *Anti-Doping Organization*conducting results management shall establish a process for the pre-hearing administration of potential ant-doping rule violations that respects the following principles:

7:1 Initial Review Regarding *Adverse Analytical Findings*

Upon receipt of an A *Sample Adverse Analyticla Finding*, the *Anti-Doping Organization* responsible for results management shall conduct a review to determine whether: *(a)* and applicable therapeutic use exemption has been granted, or *(b)* there is any apparent departure from the *International Standards* for *Testing* or laboratory analysis that undermines the validity of the *Adverse Analytical Finding.*

7.2 Notification After Initial Review

If the initial review under Article 7.1 does not reveal and applicable therapeutic use exemption or departure that undermines the validity of the *Adverse Analytical Finding.*

7 Comment: *Various of the Signatories have created their own approaches to results managment for Adverse Analytical Findings. While the various approaches have not been entirely uniform, many have proven to be fair and effjective systems for results managment. The Code does not supplant each of the Signatories results management systems. This Article does, however, specify basic principles in order to ensure the fundamental fairness of the results managment process which must be observed by each Signatory. The Specific anti-doping rules of each Signatory shall be consistent with these basic principles.*

7.2 Comment: *Thre Athlete has a right to request a prompt B Sample analysis regardless of whether follow-up investigation may be required under Article 7.3 or 7.4.*

the *Anti-Doping Organization* shall promptly notify the *Athlete*, in the manner set out in its rules, of: (a) the A*dverse Analytical Finding*; *(b)* the anti-doping rule violated, or, in a case under Article 7.3, a description of the additional investigation that will be conducted as to whether there is an anti-doping rule violation; *(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

However, the *Athlete* or other *Person* shall have the opportunity in each case, before a period of *Ineligibility* is imposed, to establish the basis for eliminating or reducing this sanction as provided in Article 10.5

10.3 Specified Substances

The *Prohibited List* may identify specified substances which are particularly susceptible to unintentional anti-doping rules violations because of their general availability in medicinal products or which are less likely to be successfully abused as doping agents. Where an *Athlete* can establish that the *Use* of such a specified

much longer (e.g. equestrian and shooting): in individual sports, the Athlete is better able to maintain competitive skills through solitary practice during Disqualification than in other sports where practice as part of a team is more important A primary argument in favor of harmonization is that it is simply not right that two Athletes from the same country who test positive for the same Prohibited Substance under similar circumstances should receive diffferent sanctions only because they participate in different sports. In addition, flexibility in sanctioning has often been viewed as an unacceptable opportunity for some sporting bodies to be more lenient with dopers. The lack of harmonization of sanctions has also frequently been the source of International Federations and National Anti-Doping Organizations.

The consensus of the World Conference on Doping in Sport held in Lausanne in February 1999 supported a two year period of Ineligibility for a first serious anti-doping rule violation followed with a lifetime ban for a second violation. This consensus was reflected in the OMADC.

10.3 Comment: *This principle is carried over from the OMADCand allows, for example. some flexibility in disciplining Athletes who test positive as a result of the inadvertent use of a cold medicine containing a prohibited stimulant. "Reduction" of a sanction under Article 10.5.2 applies only to a second or third violation because the sanction for a first*

substance was not intended to enhance sport performance, the period of *Ineligibility* found in Article 10.2 shall be replaced with the following:

- First *violation:* At a minimum, a warning and reprimand and no period of *Ineligibility* from future *Events,* and at a maximum, one (1) year's *Ineligibility.*
- *Second violation:* Two (2) years' *Ineligibility.*
- *Third violation:* Lifetime *Ineligibility.*

An anti-doping rule violation occurring during or in connection with an *Event* may, upon the decision of the ruling body of the *Event,* lead to *Disqualification* of all of the *Athlete's* individual results obtained in that *Event* with all consequences, including forfeiture of all medals, points and prizes, except as provided in Article 10.1.1.

10.1.1 If the *Athlete* establishes that he or she bears *No Fault or Negligence* for the violation, the *Athlete's* individual results in the other *Competitions* shall not be *Disqualified* unless the *Athlete's* results in *Competitions* other than the *Competition* in which the anti-doping rule violation occurred were likely to have been affected by the *Athlete's* anti-doping rule violation.

10.2 *Imposition* of *Ineligibility* for *Prohibited Substances* and *Prohibited Methods*

Except for the specified substances identified in Article 10.3, the period of *Ineligibility* imposed for a violation of Articles 2.1 (presence of *Prohibited Substance* or its *Metabolites* or

10.1 Comment *Whereas Article 9 (Automatic Disqualification of Individual Results) Disqualifies the result in a single Competition in which the Athlete tested positive (e.g.. the 100 meter backstroke), this Article may lead to Disqualification of all results in all races during the Event (e.g., the FINA World Championships).*

Factors to be included in considering whether to Disqualify other results in an Event might include. for example, the severity of the Athlete's anti-doping rule violation and whether the Athlete tested negative in the other Competitions.

10.2 Comment *Harmonization of sanctions has been one of the most discussed and debated areas of anti-doping. Arguments against requiring harmonization of sanctions are based on differences between sports including for example the following: in some sports the Athletes are professionals making a sizable income from the sport and in others the Athletes are true amateurs: in those sports where an Athlete's career is short (e.g. artistic gymnastics) a two year Disqualification has a much more significant effect on the Athlete than in sports where careers are traditionally*

Markers). 2.2 (Use or *Attempted Use* of *Prohibited Substance* or *Prohibited Method)* and *2.6 (Possession* of *Prohibited Substances* and *Methods)* shall be:

- First violation: Two (2) years' *Ineligibility.*
- Second violation: Lifetime *Ineligibility.*

waived; (d) the right of the *Athlete* and/or the *Athlete's* representative to attend the B *Sample* opening and analysis if such analysis if such analysis is rquested; and (e) the *Athlete's* right to request copies of the A and B *Sample* laboratory documentation package which includes information as rquired by the *International Standard* for laboratory analysis.

7.3 Further Review of *Adverese Analytical Finding* Where Required by *Prohibited List*

The *Anti-Doping Organization* or other reviewing body established by such organization shll also conduct any follow-up investigation as may be required by the *Prohibited List.* Upon completion of such follow-up investigation, the *Anti-Doping Organization* shall promptly notify the *Athlete* regarding the results of the follow-up investigation and wheter or not the *Anti-Doping Organization* asserts that an anti-doping rule was violated.

7. 4 Review of Other Anti-Doping Rule Violations

The *Anti-Doping Organization* or other reviewing body established by such organization shall conduct any follow-up investigation as may be required under applicalbe anti-doping polices and rules adoped pursuant to the *Code* or which the *Anti-Doping Organization* otherwise considers appropriate. The *Anti-Doping Organization* shall promptly give the *Athlete* or other *Person* subject to sanction notice.

7.4 Comment: *As an example, an International Federation typically would notify the Athlete through the Athlete's national sports federation.*

in the manner set out in its rules, of the anti-doping rule which appears to have been violated, and the basis of the violation.

7.5 Principles Applicable to *Provisional Suspensions*

A *Sigatory* may adopt rules, applicable to any *Event* for which the *Signatory* is the ruling body or for any team selection process for which the *Signatory* is responsible, permitting *Provisional Suspensions* to be imposed after the review and notification described in Articles 7.1 and 7.2 but prior to a final hearing as described in Article 8 (Right to a Fair Hearing). Provided, however, that a *Provisional Suspension* may not be imposed unless the *Athlete* is given either: (a) an opportunity for a *Provisional Hearing* either before imposition of the *Provisional Suspension* or on a timely basis after imposition of the *Provisional Suspension* or on a timely basis after imposition of the *Provisional Suspension*; or (b) an opportunity for an expedited hearing in accordance with Article 8 (Right to a Fair Hearing) on a timely basis after imposition of a *Provisional Suspension.* If a *Provisioanl Suspension* is imposed based on an A *Sample Adverse Analyticla Finding* and an subsequent B *Sample* analysis does not confirm the A *Sample* analysis, then the *Athlete* shall not be subject to any further disciplinary action and any sanctiion previously imposed shall be rescinded. In circumstances where the *Athlete* or the *Athlete's* team has been removed from a *Competition* and the subsequent B *Sample* analysis does not

confirm the A *Sample* finding, if, without otherwise affecting the Competition, it is still possible for the Athlete or team to be reinserted, the *Athlete* or team may continue to take part in the *Competition.*

7.5 Comment: *This Article continues to permit the possibility of a Provisioanl Suspension before a final decision at a heraring under Article 8 (Right to a Fair Hearing). Provisional Suspensions have been authorized in the OMADC and by the rules of many Internaiotnl Federations. However, before a Provisional Suspension can be unilaterally imposed by an Anti-Doping Organization, the internal review specified in the Code must first be completed. In addition, a Signatory imposing a Provisional Suspension is required to give the Athlete an opportunity for a Provisional Hearing*

ARTICLE 8: RIGHT TO A FAIR HEARING

Each *Anti-Doping Organization* with responsibility for results management shall provide a hearing process for any *Person* who is asserted to have committed an anti-doping rule violation. Such hearing process shall address whether an anti-doping violation was committed and, if so, the appropriate *Consequences.* The hearing process shall respect the following principles:

- a timely hearing;
- fair and impartial hearing body;
- the right to be represented by counsel at the *Person's* own expense;
- the right to be fairly and timely informed of the asserted anti-doping rule violation;
- the right to respond to the asserted anti-doping rule violation and resulting *Consequences:*

either before or promptly after the imposition of the Provisional Suspension, or an expedited final hearing under Article B promptly after imposition of the Provisional Suspension. The Athlete has a right to appeal under Article 13.2. As an alternative to the process for imposing a Provisional Suspension under this Article, the Anti-Doping Organization may always elect to forego a Provisional Suspension and proceed directly to the final hearing utilizing an expedited process under Article 8.

In the rare circumstance where the B Sample analysis does not confirm the A Sample finding, the Athlete that had been provisionally suspended will be allowed. where circumstances permit. to participate in subsequent Competitions during the Event. Similarly, depending upon the relevant rules of the International Federation in a Team Sport, if the team is still in Competition. the Athlete may be able to take part in future Competitions.

8 Comment. *This Article contains basic principles relative to ensuring a fair hearing for Persons asserted to have violated anti-doping rules. This Article is not intended to supplant each Signatory's own rules for hearings but rather to ensure that each Signatory provides a hearing process consistent with these principles.*

- the right of each party to present evidence, including the right to call and question witnesses (subject to the hearing body's discretion to accept testimony by telephone or written submission);
- the *Person's* right to an interpreter at the hearing, with the hearing body to determine the identity, and responsibility for the cost, of the interpreter; and
- a timely, written, reasoned decision;

Hearings held in connection with Events may be conducted by an expedited process as permitted by the rules of the relevant Anti-Doping Organization and the hearing body.

ARTICLE 9: AUTOMATIC *DISQUALIFICATION OF* INDIVIDUAL RESULTS

An anti-doping rule violation in connection with an *In-Competition* test automatically leads to *Disqualification* of the individual result obtained in that *Competition* with all resulting consequences, including forfeiture of any medals, points and prizes.

The reference to CAS as an appellate body in Article 13 does not prevent a Signatory from also specifying CAS as the initial hearing body.

For example a hearing could be expedited on the eve of a major Event where the resolution of the anti-doping rule violation is necessary to determine the Athlete's eligibility to participate in the Event or during an Event where the resolution of the case will affect the validity of the Athlete's results or continued participation in the Event.

9 Comment: *This principle is found in the OMADC When an Athlete wins a gold medal with a Prohibited Substance in his or her system, that is unfair to the other Athletes in that Competition regardless of whether the gold medallist was at fault in any way. Only a "clean" Athlete should be allowed to benefit from his or her competitive results.*

For Team Sports, see Article 11 (Consequences to Teams).

ARTICLE 10: SANCTIONS ON INDIVIDUALS

10.1 *Disqualification* of Results in *Event* During which an Anti-Doping Rule Violation Occurs

In cases involving national-level *Athletes,* as defined by each *National Anti-Doping Organization,* that do not have a right to appeal under Article 13.2.1, the decision may be appealed to an independent and impartial body in accordance with rules established by the *National Anti-Doping Organization.* The rules for such appeal shall respect the following principles:

- A timely hearing;
- Fair, impartial and independent hearing body;
- The right to be represented by counsel at the Person'sown expense; and
- A timely, written, reasoned decision.

13.2.3 *Persons* Entitled to Appeal

In cases under Article 13.2.1, the following parties shall have the right to appeal to CAS: (a) the *Athlete*

13.21 Comment. *CAS decisions are final and binding except for any review required by law applicable to the annulment or enforcement of arbitral awards.*

13.2.2 Comment: *An Anti-Doping Organization may elect to comply with this Article by giving its national-level Athletes the right to appeal directly to CAS.*

or other *Person* who is the subject of the decision being appealed; (b) the other party to the case in which the decision was rendered; (c) the relevant International Federation and any other *Anti-Doping Organization* under whose rules a sanction could have been imposed; (d) the International Olympic Committee or International Paralympic Committee, as applicable, where the decision may have an effect in relation to the Olympic Games or Paralympic Games, including decisions affecting eligibility for the Olympic Games or Paralympic Games; and (e) *WADA.* In cases under Article 13.2.2, the parties having the right to appeal to the national-level reviewing body shall be as provided in the *National Anti-Doping Organization's* rules but, at a minimum, shall include: (a) the *Athlete* or other *Person* who is the subject of the decision being appealed; (b) the other party to the case in which the decision was rendered; (c) the relevant International Federation; and (d) *WADA.* For cases under Article 13.2.2, *WADA* and the International Federation shall also have the right to appeal to CAS with respect to the decision of the national-level reviewing body.

Notwithstanding any other provision herein, the only *Person* that may appeal from a *Provisional Suspension* is the *Athlete* or other *Person* upon whom the *Provisional Suspension* is imposed.

10.5 Elimination or Reduction of Period of *Ineligibility* Based on Exceptional Circumstances.

10.5.1 *No Fault or Negligence*

If the *Athlete* establishes in an individual case involving an anti-doping rule violation under Article

10.4.3 Comment: *The whereabouts and missed test policies of different Anti-Doping Organizations may vary considerably, particularly at the outset as these policies are being put into place. Thus, considerable flexibility has been provided for sanctioning these anti-doping rule violations. Those Anti-Doping Organizations with more sophisticated policies including built in safeguards. and those organizations with longer track records of Athlete experience with a whereabouts policy, could provide for Ineligibility periods at the longer end of the specified range*

10.51 Comment: *Article 10. S.1 applies only to violations underArticles 2.1 and 2.2 (presence and Use of Prohibited Substances) because fault or negligence is already required to establish an anti-doping rule violation under other anti-doping rules*

2.1 (presence of *Prohibited Substance* or its *Metabolites* or *Markers)* or *Use* of a *Prohibited Substance* or *Prohibited Method* under Article 2.2 that he or she bears *No Fault or Negligence* for the violation, the otherwise applicable period of *Ineligibility* shall be eliminated. When a *Prohibited Substance* or its *Markers* or *Metabolites is* detected in an Athlete's Specimen in violation of Article 2.1 (presence of *Prohibited Substance),* the *Athlete* must also establish how the *Prohibited Substance* entered his or her system in order to have the period of *Ineligibility* eliminated. In the event this Article is applied and the period of *Ineligibility* otherwise applicable is eliminated, the anti-doping rule violation shall not be considered a violation for the limited purpose of determining the period of *Ineligibility* for multiple violations under Articles 10.2,10.3and10.6.

10.5.2 *No Significant Fault or Negligence*

This Article 10.5.2 applies only to anti-doping rule violations involving Article 2.1 (presence of *Prohibited Substance* or its *Metabolites* or *Markers). Use* of a *Prohibited Substance* or

10.5.2 Comment. *The trend in doping cases has been to recognize that there must be some opportunity in the course of the hearing process to consider the unique facts and circumstances of each particular case in imposing sanctions. This principle was accepted at the World Conference on Doping in Sport 1999 and was incorpo-*

rated into the OMADC which provides that sanctions can be reduced in "exceptional circumstances. " The Code also provides for the possible reduction or elimination of the period of Ineligibility in the unique circumstance where the Athlete can establish that he or she had No Fault or Negligence, or No Significant Fault or Negligence, in connection with the violation. This approach is consistent with basic principles of human rights and provides a balance between those Anti-Doping Organizations that argue for a much narrower exception. or none at all, and those that would reduce a two year suspension based on a range of other factors even when the Athlete was admittedly at fault. These Articles apply only to the imposition of sanctions: they are not applicable to the determination of whether an anti-doping rule violation has occurred.

Prohibited Method under Article 2.2, failing to submit to *Sample* collection under Article 2.3, or administration of a *Prohibited Substance* or *Prohibited Method* under Article 2.8. If an *Athlete* establishes in an individual case involving such violations that he or she bears *No Significant Fault or Negligence,* then the period of *Ineligibility* may be reduced, but the reduced period of *Ineligibility* may not be less than one-half of the minimum 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 8 years. When a *Prohibited Substance* or its *Markers* or *Metabolites is* detected in an *Athlete's Specifnen* in violation of Article 2.1 (presence of *Prohibited Substance).* the *Athlete* must also establish how the *Prohibited Substance* entered his or her system in order to have the period of *Ineligibility* reduced.

Article 10.5 is meant to have an impact only in cases where the circumstances are truly exceptional and not in the vast majority of cases.

To illustrate the operation of Article 10.5. an example where No Fault or Negligence would result in the total elimination of a sanction is where an Athlete could prove that, despite all due care. he or she was sabotaged by a competitor. Conversely. a sanction could not be completely eliminated on the basis of No Fault or Negligence in the following circumstances: (a) a positive test resulting from a mislabeled or contaminated vitamin or nutritional supplement (Athletes are responsible for what they ingest (Article 2.1.1) and have been warned against the possibility of supplement contamination): (b) the administration of a prohibited substance by the Athlete's personal physician or trainer without disclosure to the Athlete (Athletes are responsible for their choice of medical personnel and for advising medical personnel that they cannot be given any prohibited substance): and (c) sabotage of the Athlete's food or drink by a spouse, coach or otherperson within the Athlete's circle of associates (Athletes are responsible for what they ingest and for the conduct of those persons to whom they entrust access to their food and drink). However, depending on the unique facts of a particular case, any of the referenced illustrations could result in a reduced sanction based on No Significant Fault or Negligence. (For example. reduction may well be appropriate in illustration (a) if the

ARTICLE 12 SANCTIONS AGAINST SPORTING BODIES

Nothing in this *Code* precludes any *Signatory* or government accepting the *Code* from enforcing its own rules for the purpose of imposing sanctions on another sporting body over which the *Signatory* or government has authority.

ARTICLE 13 APPEALS

13.1 Decisions Subject to Appeal

Decisions made under the *Code* or rules adopted pursuant to the *Code* may be appealed as set forth below in Articles 13.2 through 13.4. Such decisions shall remain in effect while under appeal unless the appellate body orders otherwise. Before an appeal is commenced, any post-decision review provided in the *Anti-Doping Organization's* rules must be exhausted, provided that such review respects the principles set forth in Article 13.2.2 below.

13.2 Appeals from Decisions Regarding Anti-Doping Rule Violations, *Consequences,* and *Provisional Suspensions*

A decision that an anti-doping rule violation was committed, a decision imposing *Consequences* for an anti-doping rule violation, a decision that no anti-doping rule violation was committed, a decision that an *Anti-Doping Organization* cacks jurisdiction to rule on an alleged anti-doping rule violation or its *Consequences.*

12 Comntent: *This Article makes it clear that the Code does not restrict whatever disciplinary rights between organizations may otherwise exist.*

13.1 Comment: *The comparable OMADC Article is broader in that it provides that any dispute arising out of the application of the OMADC may be appealed to CAS.*

and a decision to impose a *Provisional Suspension* as a result of a *Provisional Hearing* or in violation of Article 7.5 may be appealed exclusively as provided in this Article 13.2.

13.2.1 Appeals Involving *International-Level* Athletes

In cases arising from competition in an *International Event* or in cases involving *International-Level Athletes,* the decision may be appealed exclusively to the Court of Arbitration for Sport ("CAS") in accordance with the provisions applicable before such court.

13.2.2 Appeals Involving National-Level *Athletes*

those sports could still coach during the Ineligibility period. This Article adopts the position set forth in the OMADC that an Athlete who is made ineligible for doping should not participate in any capacity in an authorized Event or activity during the Ineligibility period. This would preclude, for example, practicing with a national team, or acting as a coach or sport official. Sanctions in one sport will also be recognized by other sports (see Article 15.4). This article would not prohibit the Person from participating in sport on a purely recreational level.

participate in local sport events in a sport other than the sport in which the *Person* committed the anti-doping rule violation, but only so long as the local sport event is not at a level that could otherwise qualify such *Person* directly or indirectly to compete in (or accumulate points toward) a national championship or *International Event.*

10.10 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.

ARTICLE 11 *CONSEQUENCES* TO TEAMS

Where more than one team member in a *Team Sport* has been notified of a possible anti-doping rule violation under Article 7 in connection with an *Event,* the Team shall be subject to T*arget Testing* for the *Event.* If more than one team member in a *Team Sport* is found to have committed an anti-doping rule violation during the *Event,* the team may be subject to *Disqualification* or other disciplinary action. In sports which are not *Team Sports* but

10.10 Comment: *On a related issue, the Code does not establish a rule, but rather leaves it to the various Anti-Doping Organizations to establish their own rules, addressing eligibility requirements forAthletes who are not ineligible and retire from sport while included in an Out-of-Competition pool and then seek to return to active participation in sport.*

where awards are given to teams, *Disqualification* or other disciplinary action against the team when one or more team members have committed an anti-doping rule violation shall be as provided in the applicable rules of the International Federation.

Athlete clearly establishes that the cause of the positive test was contamination in a common multiple vitamin purchased from a source with no connection to

10.5.3 *Athlete's* Substantial Assistance in Discovering or Establishing Anti-Doping Rule Violations by ***Athlete Support*** *Personnel* and Others.

An *Anti-Doping Organization* may also reduce the period of *Ineligibility* in an individual case where the Athlete has provided substantial assistance to the *Anti-Doping Organization* which results in the *Anti-Doping organization* discovering or establishing an anti-doping rule violation by another *Person* involving *Possession* under Article 2.6.2 *(Possession* by *Athlete Support Personne.* Article 2.7 *(Trafficking),* or Article 2.8 (administration to an Athlete). The reduced period of *Ineligibility* may not, however, be less than one-half of the minimum 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 8 years.

10.6 Rules for Certain Potential Multiple Violations

10.6.1 For purposes of imposing sanctions under Articles 10.2, 10.3 and 10.4, a second anti-doping rule violation may be considered for purposes of imposing sanctions only if the *Anti-Doping*

Prohibited Substances and the Athlete exercised care in not taking other nutritional supplements.)

Article 10.5.2 applies only to the identified anti-doping rule violations because these violations maybe based on conduct that is not intentional or purposeful. Violations under Article 24 (whereabouts information and missed tests) are not included. even though intentional conduct is not required to establish these violations, because the sanction for violations of Article 2.4 (from three months to two years) already builds in sufficient discretion to allow consideration of the Athlete's degree of fault.

10.6.1 Comment *Under this Article, an Athlete testing positive a second time before notice of the first positive test would only be sanctioned on the basis of a single anti-doping rule violation.*

Organization can establish that the *Athlete* or other Person committed the second anti-doping rule violation after the *Athlete* or other *Person* received notice, or after the *Anti-Doping Organization* made a reasonable Attempt to give notice, of the first anti-doping rule violation: if the *Anti-Doping Organization* cannot establish this, the violations shall be considered as one single first violation, and the sanction imposed shall be based on the violation that carries the more severe sanction.

10.6.2 Where an Athlete, based on the same *Doping Control,* is found to have committed an anti-doping rule violation involving both a specified substance under Article 10.3 and another *Prohibited Substance* or *Prohibited Method,* the *Athlete* shall be considered to have committed a single anti-doping rule violation, but the sanction imposed shall be based on the *Prohibited Substance* or *Prohibited Method* that carries the most severe sanction.

10.6.3 Where an *Athlete* is found to have committed two separate anti-doping rule violations, one involving a specified substance governed by the sanctions set forth in Article 10.3 (Specified Substances) and the

> ***10.6.3 Comment.*** *Article 10.6.3 deals with the situation where an Athlete commits two separate anti-doping rule violations. but one of the violations involves a specified substance governed by the lesser sanctions of Article 10.3. Without this Article in the Code, the second offense arguably could be governed by: the sanction applicable to a second violation for the Prohibited Substance involved in the second violation. the sanction applicable to a second offense for the substance involved in the first violation. or a combination of the sanctions applicable to the twooffenses. This Article irnposes a combined sanction calculated by adding together the sanctions for a first offense under 10.2 (two years) and a first offense under 10.3 (up to one year). This provides the same sanction to the Athlete that commits a first violation under 10.2 followed by a second violation involving a specified substance, and the Athlete that commits a first violation involving a specified substance followed by a second violation under 10.2. In both cases, the sanction shall be from two years to three years' Ineligibility.*

other involving a *Prohibited Substance* or *Prohibited Method* governed by the sanctions set forth in Article 10.2 or a violation governed by the sanctions in Article 10.4.1, the period of *Ineligibility* imposed for the second offense shall be at a minimum two years' *Ineligibility* and at a maximum three years' *Ineligibility.* Any *Athlete* found to have committed a third anti-doping rule violation involving any combination of specified substances under Article 10.3 and any other anti-doping rule violation under 10.2 or 10.4.1 shall receive a sanction of lifetime *Ineligibility.*

10.7 *Disqualification* of Results in Competitions Subsequent to Sample Collection

In addition to the automatic *Disqualification* of the results in the Competition which produced the positive *Sample* under Article 9 (Automatic *Disqualification* of Individual Results), all other competitive results obtained from the date a positive Sample was collected (whether *In-Competition* or *Out-of-Competition*). or other doping violation occurred, through the commencement of any *Provisional Suspension* or *Ineligibility* period, shall, unless fairness requires otherwise, be *Disqualified* with all of the resulting consequences including forfeiture of any medals, points and prizes.

10.8 Commencement of *Ineligibility* Period

The period of *Ineligibility* shall start on the date of the hearing decision providing for *Ineligibility* or, if the hearing is waived, on the date *Ineligibility* is accepted or otherwise imposed. Any period of *Provisional Suspension* (whether imposed or voluntarily accepted) shall be credited against the total period of *Ineligibility* to be served. Wherere required by fairness, such as delays in the hearing process or other aspects of *Doping Control* not attributable to the *Athlete,* the body imposing the sanction may start the period of *Ineligibility* at an earlier date commencing as early as the date of *Sample* collection.

10.9 Status During *Ineligibility*

No *Person* who has been declared *Ineligible* may, during the period of *Ineligibility*, participate in any capacity in a *Competition* or activity (other than authorized anti-doping education or rehabilitation programs) authorized or organized by any *Signatory* or *Signatory's* member organization. In addition, for any anti-doping rule violation not involving specified substances described in Article 10.3, some or all sport-related financial support or other sport-related benefits received by such *Person* will be withheld by *Signatories, Signatories* member organizations and governments. A *Person* subject to a period of *Ineligibility* longer than four years may, after completing four yers of the period of *Ineligibility,*

> ***10.8*** *Comment: Currently manyAnti-Doping Organizations start the two-year period of Ineligibility at the time a hearing decision is rendered. Those Anti-Doping Organizations also frequently invalidate results retroactively to the date a positive Sample was collected. OtherAnti-Doping Organizations simply start the two-year suspension on the date the positive Sample was collected. The OMADC, as clarified by its Explanatory Document, does not mandate either approach. The approach provided in the Code gives Athletes a strong disincentive to drag out the hearing process while they complete in the interim. It also encourages them to voluntarily accept Provisional Suspensions pending a hearing. On the other hand, the body imposing the sanction can start the sanction running before the date the hearing decision is reached so that an Athlete is not penalized by delays in the Doping Control process which are not his or her fault, for example, inordinate delay by the labouratory in reporting a positive test or delays in reporting a positive test or delays in scheduling the hearing caused by the Anti-Doping Organization.*

> ***10.9 Comment:*** *The rules of some Anti-Doping Organizations only ban an Athlete from "competing" during a period of Ineligibility. For example, and Athlete in*

13.3 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 Athletes* to CAS and by other *Athletes* 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.*

13.4 Appeals from Decisions Imposing *Consequences* under Part Three of the Code

With respect to *consequences* imposed under Part Three (Roles and Responsibilities) of the Code, the entity upon which *consequences* are imposed under Part Three of the Code shall have the right to appeal exclusively to CAS in accordance with the provisions applicable before such court.

13.5 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.

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 as provided below:

14.1 Information Concerning *Adverse Analytical Findings* and Other Potential Anti-Doping Rule Violations An *Athlete* whose *Sample* has resulted in an *Adverse Analytical Finding,* or an *Athlete* or other Person who may

> ***13.5 Comment:*** *The object of the Code is to have anti-doping matters resolved through fair and transparent internal processes with a final appeal. Anti-doping decisions by Anti-Doping Organizations are made transparent in Article 14. Specified Persons and organizations, including WADA, are then given the opportunity to appeal those decisions. Note, that the definition of interested Persons and organizations with a right to appeal underArticle 13 does not include Athletes, or their federations. who might benefit from having another competitor disqualified.*

have violated an anti-doping rule, shall be notified by the *Anti-Doping Organization* with results management responsibility as provided in Article 7 (Results Management). The

Athlete's National Anti-Doping Organization and International Federation and WADA shall also be notified not later than the completion of the process described in Articles 7.1 and 7.2. Notification shall include: the *Athlete's* name, country, sport and discipline within the sport, whether the test was *In-Competition* or *Out-of-Competition.* the date of *Sample* collection and the analytical result reported by the laboratory. The same *Persons* and *Anti-Doping Organizations* 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, in any case in which the period of *Ineligibility is* eliminated under Article 10.5.1 *(No Fault or Negligence),* or reduced under Article 10.5.2 *(No Significant Fault or Negligence).* shall be provided with a written reasoned decision explaining the basis for the elimination or reduction. The recipient organizations shall not disclose this information beyond those persons within the organization with a need to know 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.

14.2 Public Disclosure

The identity of *Athletes* whose *Samples* have resulted in *Adverse Analytical Findings.* or *Athletes* or other *Persons* who were alleged by an *Anti-Doping Organization* to have violated other anti-doping rules, may be publicly disclosed by the *Anti-doping Organization* with results management responsibility no earlier than completion of the administrative review described in Articles 7.1 and 7.2. No later than twenty days after it has been determined in a hearing in accordance with Article 8 that an anti-doping rule violation has occurred, or such hearing has been waived, or the assertion of an anti-doping rule violation has not been timely challenged, the *Anti-Doping Organization* responsible for results management must publicly report the disposition of the anti-doping matter.

14.3 ***Athlete* Whereabouts Information**

Athletes who have been identified by their International Federation or *National Anti-Doping Organization* for inclusion in an *Out-of-Competition 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 it to *WADA. WADA* shall make this information accessible to other *Anti-Doping Organizations* having authority 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.

14.4 Statistical Reporting

Anti-Doping Organizations shall, at least annually, publish publicly a general statistical report of their *Doping Control* activities with a copy provided to *WADA.*

PREAMBLE

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

The *International Standard* for *Testing* is extracted from the proposed ISO International Standard for Doping Control (ISO ISDC) which is being prepared by an expert group within the International Anti-Doping Arrangement (IADA) and WADA. The ISO ISDC is based on the IADA International Standard for Doping Control (ISDC)/ISO PAS 18873 (1999). *WADA* supports and is an active partner with IADA in developing the Proposed ISO ISDC to a full ISO standard. The ISO process is expected to be completed in mid 2004.

Version 1.0 of the *International Standard* for *Testing* was circulated to *Signatories* and governments for review and comments in November 2002. Version 2.0 was based on the comments and proposals received from *Signatories* and governments.

All *Signatories* and governments were consulted and have had the opportunity to review and provide comments on version 2.0. This draft version 3.0 will be presented for approval to the *WADA* Executive Committee on June 7th 2003.

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 ver-

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WORLD ANTI-DOPING AGENCY
play true

The World Anti-Doping Code

INTERNATIONAL STANDARD FOR TESTING

version 3.0

June 2003

14.5 *Doping* Control Information Clearing House

WADA shall act as a central clearing house for *Doping Control Testing* data and results for *International-Level Athletes* and national-level Athletes that 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. *WADA* shall make this information 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. Private information regarding an *Athlete* shall be maintained by *WADA* in strict confidence. *WADA* shall, at least annually, publish statistical reports summarizing such information.

ARTICLE 15: CLARIFICATION OF DOPING CONTROL RESPONSIBILRIES

15.1 Event Testing

The collection of *Samples* for *Doping Control* does and should take place at both *International Events* and National *Events.* However. only a single organization should be responsible for initiating and directing *Testing* during an *Event* 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 IOC for the Olympic Games. the International Federation for a World Championship, and PASO for the Pan American Games). If the international organization decides not to conduct any *Testing* at such an *Event.* the *National Anti-Doping Organization* for the country where the *Event* occurs may, in coordination with and with the approval of the international organization or *WADA,* initiate and conduct such *Testing.* 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 Comment: *To be effective. the anti-doping effort must involve many Anti-Doping Organizations conducting strong programs at both the international and national levels. Rather than limiting the responsibilities of one group in favor of the exclusive competency of the other. the Code manages potential problems associated with overlapping responsibilities. first by creating a much higher level of overall harmonization and second, by establishing rules of precedence and cooperation in specific areas.*

15.1 Comment: *The Anti-Doping Organization "initiating and directing testing" may, if it chooses, enter into agreements with other organizations to which it del-*

egates responsibility for Sample collection or other aspects of the Doping Control process.

15.2 Out-of-Competition Testing

Out-of-Competition Testing is and should be initiated and directed by both international and national organizations. *Out-of-Competition Testing* may be initiated and directed by: (a) *WADA:* (b) the IOC or [PC in connection with the Olympic Games or Paralympic Games; (c) the Athlete's International Federation; (d) the *Athlete's National* Anti-*Doping Organization: or (e)* the *National Anti-Doping Organization* of any country where the *Athlete* is present. *Out-of-Competition Testing* should be coordinated through *WADA* in order to maximize the effectiveness of the combined *Testing* effort and to avoid unnecessary repetitive *Testing* of individual *Athletes.*

15.3 Results Management, Hearings and Sanctions

Except as provided in Article 15.3.1 below, results management and hearings shall be the responsibility of and shall be governed by the procedural rules of the *Anti-Doping Organization* that initiated and directed *Sample* collection (or, if no *Sample* collection is involved, the organization which discovered the violation). Regardless of which organization conducts results management or hearings, the principles set forth in Articles 7 and 8 shall be respected and the rules identified in the Introduction to Part One to be incorporated without substantive change must be followed.

15.3.1 Results management and the conduct of hearings for an anti-doping rule violation arising from a test by, or discovered by, a *National Anti-Doping organization* involving an *Athlete* that is not a citizen

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

15.3 Comment *In some cases, the procedural rules of the Anti-Doping organization which initiated and directed the Sample collection may specify that results management will be handled by another organization (e.g.. the Athlete's national federation). to such event, it shall be the Anti-Doping Organization's responsibility to confirm that the other organization's rules are consistent with the Code.*

15.3.1 Comment *No absolute rule is established for managing results and*

or resident of that country shall be administered as directed by the rules of the applicable International Federation. Results management and the conduct of hearings from a test by the International Olympic Committee, the International Paralympic Committee, or *a major Event Organization,* shall be referred to the applicable International Federation as far as sanctions beyond *Disqualification* from the *Event or* the results of the *Event.*

15.4 Mutual Recognition

Subject to the right to appeal provided in Article 13, the *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. Signatories* may 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.*

ARTICLE 16: DOPING CONTROL FOR ANIMALS COMPETING IN SPORT

16.1 In any sport that includes animals in competition, the International Federation for that sport shall establish and implement anti-doping rules for the animals included in that sport. The anti-doping rules shall include a list of *Prohibited Substances,* appropriate *Testing* procedures and a list of approved laboratories for *Sample* analysis.

conducting hearings where a National Anti-Doping Organization tests a foreign national athlete over whom it would have had no jurisdiction but for the Athlete's presence in the National Anti-Doping Organizations country. Under this Article, it is left to the International Federation to determine under its own rules whether. for example, management of the case should be referred to the Athlete's National Anti-Doping Organization. remain with the Anti-Doping Organization that collected the Sample. or be taken over by the International Federation.

16.2 With respect to determining anti-doping rule violations, results management, fair hearings, *Consequences,* and appeals for animals involved in sport, the International Federation for that sport shall establish and implement rules that are generally consistent with Articles 1, 2, 3, 9, 10, 11, 13 and 17 of the *Code.*

ARTICLE 17: STATUTE OF LIMITATIONS

No action may be commenced against an *Athlete* or other *Person* for a violation of an anti-doping rule contained in the *Code* unless such action is commenced within eight years from the date the violation occurred.

17 Comment: *This does not restrict the Anti-Doping Organization from considering an earlier anti-doping violation for purposes of the sanction for a subsequent violation that occurs more than eight years later. In other words, a second violation ten years after a first violation is considered a second violation for sanction purposes.*

— Sealable and tamper-evident bottles and lids for securing the urine *Sample;*

- For blood Sample collection:

  — Needles for collecting the blood *Sample;*

  — Blood tubes with sealable and tamper-evident devices for holding the blood *Sample.*

Sample Collection Personnel: A collective term for qualified officials authorised 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 *Samples.*

Weighted: A ranking method of selecting *Athletes* using criteria where the ranking is based on the potential risk of doping and possible doping patterns.

PART TWO: STANDARDS FOR *TESTING*

4.0 Planning

4.1 Objective

The objective is to plan and implement an effective distribution of *Athlete* tests.

4.2 General

Planning starts with establishing criteria for *Athletes* to be included in a *Registered Testing Pool* and ends with selecting *Athletes* for *Sample* collection.

The main activities are information gathering, risk evaluation, and developing, monitoring, evaluating and modifying the test distribution plan.

4.3 Requirements for establishing the *Registered Testing* Pool

4.3.1 The *Anti-Doping Organization (ADO)* shall define and document the criteria for *Athletes* to be included in a *Registered Testing Pool.* This shall include as a minimum:

- For International Federations (IFs):
  Athletes who compete at a high level of international competition, and

- For *National Anti-Doping Organizations:*

PART ONE: INTRODUCTION, *CODE* PROVISIONS AND DEFINITIONS

1.0 Introduction and scope

The main purpose of *International Standard* for *Testing is* to plan for effective *Testing* and to maintain the integrity and identity of the *Samples,* from notifying the *Athlete* to transporting *Samples* 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.*

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."

The standards included in the *international Standard* for *Testing* are extracted from the ISO International Standard for Doping Control (ISO ISDC), which also includes management and support processes for *Testing* activities

Definitions specifield 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 *Code* directly address 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.

2.4 Violation of applicable requirements regarding *Athlete* availability for *Out-of-Competition Testing* including failure to provide required whereabouts information and missed tests which are declared based on reasonable rules.

2.5 *Tampering,* or *Attempt*ing to tamper, with any part of D*oping Control.*

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

Code **Article 3 Proof of Doping:**
3.2.2 Departures from the *International Standard* for *Testing* which did not cause an *Adverse Analytical Finding* or other anti-doping rule violation shall not invalidate such results. If the *Athlete* establishes that departures from the *International Standard* occurred during *Testing* then the *Anti-Doping Organization* shall have the burden to establish that such departures 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. *Anti-Doping Organizations* conducting *Testing* shall in coordination with other *Anti-Doping Organizations* conducting *Testing* on the same *Athlete* pool:

5.1.1 Plan and implement an effective number of *In-Competition* and *Out-of-Competition* tests. 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* in its country. The national-level pool shall include *International-Level Athletes* from that country as well as other national-level *Athletes.* Each International Federation and *National Anti-Doping Organization* shall plan and conduct *In-Competition* and *Out-of-Competition Testing* on its *Registered Testing Pool.*

5.1.2 Make *No Advance Notice Testing* a priority.

5.1.3 Conduct *Target 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 Organizations, National Anti-Doping Organizations,* and *WADA.*

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.

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 from the *International Standard* for *Testing*

Blood Collection Official: 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/specimen* from the provision of the sample/specimen until the *Sample/specimen* has been received for analysis.

Chaperone: An official who is trained and authorized by the *ADO* to carry out specific duties including 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: An official who has been trained and authorised 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* in Articles 2.3, 2.4, 2.5 and 2.8 of the Code.

Sample Collection Equipment: Containers or apparatus used to directly collect or hold the *Athlete's Specimen* 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 urine *Sample* as it leaves the *Athlete's* body;

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 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.

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. 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.

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.

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

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

Code **Article 7 Results Management:**
7.3 Further Review of *Adverse Analytical Finding* Where Required by *Prohibited List.* The *Anti-Doping Organization* or other reviewing body established by such organization shall also conduct any follow-up investigation as may be required by the *Prohibited List.* Upon completion of such follow-up investigation, the *Anti-Doping Organization* shall promptly notify the *Athlete* regarding the results of the follow-up investigation and whether or not the *Anti-Doping Organization* asserts that an anti-doping rule was violated.

Code **Article 10 Sanctions on Individuals:**
10.10 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. *Athletes* who have been identified by their International Federation or *National Anti-Doping Organization* for inclusion in an *Out-of-Competition 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 it to *WADA.*

WADA shall make this information accessible to other *Anti-Doping Organizations* having authority 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 Clearing House. *WADA* shall act as a central clearing house for *Doping Control Testing* data and results for *International-Level Athletes* and national-level *Athletes* that 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. *WADA* shall make this information accessible to the *Athlete,* the *Athlete's* National Federation, *National Olympic Committee* or National Paralympic Committee, *Na-*

tional Anti-Doping Organization, International Federation, and the International Olympic Committee or International Paralympic Committee. Private information regarding an *Athlete* shall be maintained by *WADA* in strict confidence. *WADA* shall, at least annually, publish statistical reports summarizing such information.

***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, only a single organization should be responsible for initiating and directing *Testing* during an *Event*. 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 IOC for the Olympic Games, the International Federation for a World Championship, and PASO for the Pan American Games). If the international organization decides not to conduct any *Testing* at such an *Event,* the *National Anti-Doping Organization* for the country where the *Event* occurs may, in coordination with and with the approval of the international organization or *WADA,* initiate and conduct such *Testing*. At National *Events,* the collection of *Doping Control Samples* shall be initiated and directed by the designated *National Anti-Doping Organization* of that country.

15.2 *Out-of-Competition Testing.* *Out-of-Competition Testing is* and should be initiated and directed by both international and national organizations. *Out-of-Competition Testing* may be initiated and directed by: (a) *WADA; (b)* the IOC or IPC in connection with the Olympic Games or Paralympic Games; (c) the *Athlete's* International Federation; (d) the *Athlete's National Anti-Doping Organization;* or (e) the *National Anti-Doping Organization* of any country where the *Athlete* is present. *Out-of-Competition Testing* should be coordinated through *WADA* in order to maximize the effectiveness of the combined *Testing* effort and to avoid unnecessary repetitive *Testing* of individual *Athletes.*

15.4 Mutual Recognition. Subject to the right to appeal provided in Article 13, the *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. Signatories* may 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.*

3.0 Terms and definitions

3.1 Defined terms from the *Code*

Adverse Analytical Finding; *A* report from a laboratory or other approved *Testing* entity that identifies in a *Specimen* 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: For purposes of *Doping Control,* any *Person* who participates in sport at the international level (as defined by each International Federation) or national level (as defined by each *National Anti-Doping Organization)* and any additional *Person* who participates in sport at a lower level if designated by the *Person's National Anti-Doping Organization.* 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.*

Code: The World Anti-Doping *Code.*

Competition: A single race, match, game or singular athletic contest. For example, 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 Rules 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: The process including test distribution planning, *Sample* collection and handling, laboratory analysis, results management, hearings and appeals.

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: For purposes of differentiating between *In-Competition* and *Out-of-Competition Testing,* unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization,* an *In-Competition* test is a test where an *Athlete is* selected for *Testing* in connection with a specific *Competition.*

Independent Observer Program: A team of observers, under the supervision of *WADA,* who observe the *Doping Control* process at certain *Events* and report on observations. If *WADA is Testing In-Competition* at an *Event,* the observers shall be supervised by an independent organization.

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

(e) Obtaining necessary medical treatment;

(f) Locating a representative and/or interpreter.

The DCO shall document the reasons for delay in reporting to the Doping Control Station and/or reasons for leaving the Doping Control Station once arriving that may require further investigation by the *ADO*.

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 When an *Athlete* notified of an advance notice *Sample* collection does not report to the Doping Control Station at the designated time, the DCO shall use his/her judgement whether to attempt to contact the *Athlete*. At a minimum, the DCO shall wait 30 minutes after the appointed time before departing. If the *Athlete* still has not reported by the time the DCO departs, the DCO shall follow the requirements of Annex A - Investigating a possible failure to comply.

5.4.8 If the *Athlete* reports to the Doping Control Station after the minimum waiting time and prior to the DCO's departure, the DCO shall decide as to 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.

5.4.9 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.

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 authorised to be present during a *Sample* Collection Session;

Athletes who are part of national teams in Olympic and Paralympic sports and recognised national federations.

The criteria shall be reviewed at least annually and updated if required.

4.3.2 The *ADO* shall include *Athletes* under their authority in *the Registered Testing Pool* who are serving periods of *Ineligibility* or *Provisional Suspensions* as *Consequences of Anti-Doping Rules Violations*.

4.3.3 The *Registered Testing Pool* shall be reviewed and updated regularly to reflect changes in *Athletes'* competing levels to ensure additions to or removals from the pool as required.

4.4 Requirements for collecting *Athlete* whereabouts information for the purposes of Out of Competition Testing

4.4.1 The *ADO* shall define procedures and/or systems for:

(a) Collecting, maintaining and monitoring sufficient whereabouts information to ensure that *Sample* collection can be planned and conducted at *No Advance Notice* for all *Athletes* included in the *Registered Testing Pool,* and

(b) When *Athletes* fail to provide accurate and timely whereabouts information, taking appropriate action to ensure the information stays up to date and complete.

4.4.2 As a minimum the following *Athlete* whereabouts information shall be collected:

(a) Name

(b) Sport/discipline,

(c) Home address

(d) Contact phone numbers

(e) Training times and venues

(f) Training camps

(g) Travel plans

(h) Competition schedule

(i) Disability if applicable, including the requirement for third party involvement in notification.

4.5 Requirements for test distribution planning

4.5.1 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) Physical demands of the sport and possible performance enhancing effect that doping may elicit;

(b) Available doping analysis statistics;

(c) Available research on doping trends;

(d) Training periods and *Competition* season.

4.5.2 The *ADO* shall develop and document a test distribution plan based on information determined in 4.5.1, the number of *Athletes* per sport/discipline in the *Registered Testing Pool* and the evaluation outcomes of previous test distribution planning cycles.

4.5.3 The *ADO* shall allocate the number of *Sample* collections by type of *Sample* collection for each sport/discipline, including *No Advance Notice, Out-of-Competition, In-Competition,* blood and urine *Sample* collection, as required to achieve effective deterrence.

4.5.4 The *ADO* shall establish a system whereby the 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 from *Athletes* in the *Registered* Testing *Pool* by other *ADOs.*

4.5.5 The ADO shall establish a system for maintaining test distribution planning data. Such data shall be used to assist with determining whether modifications to the plan are necessary. This information shall include as a minimum:

For each test:

(a) The sport/discipline;

(b) The country represented by the *Athlete* (if applicable);

(c) The type of *Sample* collection *(No Advance Notice,* Out-of-*Competition, In-Competition* or advance notice);

(d) The date of *Sample* collection; and

(e) The country in which the *Sample* collection occurred.

collection and 24 hours of receipt of notification for an advance notice *Sample* collection.

(f) Of the location of the Doping Control Station

5.4.2 When in-person contact is made, the DOC/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 their official *ADO* identification card/document;

(c) Confirm the *Athlete's* identity as per the criteria established in 5.3.4. Any failure to confirm the identity of the *Athlete* shall be documented. In such cases, the DCO responsible for conducting the *Sample* Collection Session shall decide whether it is appropriate to report the situation in accordance with Annex A - Investigating a possible failure to comply.

5.4.3 The 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 inform the *Athlete* of the consequences of failing to comply if possible, 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 and report the circumstances to the *ADO.* The DCO and *ADO* shall follow the steps prescribed in Annex A - Investigating a possible failure to comply.

5.4.4 The DCO/Chaperone shall consider any reasonable request by the *Athlete* to delay reporting to the Doping Control Station within 60 mins of acknowledgement and acceptance of notification and approve or reject such requests as appropriate in accordance with 5.4.5 and 5.4.6. The DCO shall document the reasons for any such delay that may require further investigation by the *ADO.* The first urine *Sample* post notification shall be collected.

5.4.5 A DCO may accept a request from an *Athlete* to delay reporting to the Doping Control Station beyond 60 mins, and/or once the athlete arrives at the Doping Control Station and wishes to leave if the *Athlete* can be continuously chaperoned during the delay and if the request relates to the following activities:

(a) Participation in a victory ceremony;

(b) Fulfilment of media commitments;

(c) Competing in further *competitions;*

(d) Performing a warm down;

5.3.12 The *ADO* shall not re-schedule or change a *Sample* collection from *No Advance Notice* to advance notice except where an unexpected situation forces the need for an advanced notice *Sample* collection. Any such decision shall be recorded.

5.3.13 Notification for advance notice *Sample* collection shall be by any means that indicates the *Athlete* received the notice.

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 5.3.10, 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 required, 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 sight of the DCO/Chaperone at all times from the first moment of in-person notificaiton by the DCO/Chaperone until the completion of the *Sample* collection procedure;

(ii) Produc identification in accordance with 5.3.4; and

(iii) Comply with *Sample* collection procedures and the possible consequences of failure to comply; and

(iv) Report to the Doping Control Station, unless delayed for valid reasons, as soon as possible and within 60 minutes of notification for a *No Advance Notice Sample*

In addition, for each *Adverse Analytical Finding:*

(a) Dates of *Sample* collection and analysis;

(b) Class of substance/s found;

(c) Actual substance/s detected;

(d) *Sanctions of Anti-Doping Rules Violations*, if any.

4.5.6 The ADO shall ensure that the athlete support personnel shall not be involved in the test distribution planning for their athletes.

4.5.7 In planning and conducting tests at *International Event, and where the relevant IF does not have a doping control program that complies with this standard,* the *National Anti-Doping Organization* shall be the preferred *Sample* collection supplier.

4.6 Requirements for selection of Athletes

4.6.1 In accordance with the number of *Sample* collections allocated to each sport/discipline in the test distribution plan, the *ADO* shall select *Athletes* for *Sample* collection using *Target Testing,* Weighted and random selection methods.

4.6.2 As a minimum, the ADO shall consider *Target Testing Athletes* based on the following information:

(a) Injury;

(b) Withdrawal or absence from expected *Competition;*

(c) Going into or coming out of retirement;

(d) Behaviour indicating doping;

(e) Sudden major improvements in performance;

(f) Changes in *Athlete* whereabouts information that can indicate a potential increase in the risk of doping, including moving to a remote location;

(g) *Athlete* sport performance history;

(h) Details of past *Doping Controls;*

(i) *Athlete* reinstatement after a period of *Ineligibility;* and

(j) Reliable information from a third party.

4.6.3 An ADO may select *Athletes under their authority* for *Sample* collection who are not included in the *Registered Testing Pool* defined in 4.3.1 and 4.3.2.

4.6.4 Where the ADO authorises a Doping Control Officer (DCO) to select *Athletes* for *Sample* collection, the *ADO* shall provide selection criteria to the DCO in accordance with the test distribution plan.

4.6.5 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

To ensure that the selected *Athlete* is notified, the rights of the *Athlete* are maintained, there are no opportunities to manipulate the *Sample* to be provided and the notification is documented.

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:

(a) Appointment of DCOs, Chaperones and other Sample Collection Personnel;

(b) Locating the *Athlete* and confirming his/her identity;

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

(d) 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

(e) Documenting the notification.

5.3 Requirements prior to notification of *Athletes*

5.3.1 *No Advance* Notice shall be the notification method for *Out-of-Competition Sample* collection whenever possible.

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 identification that is provided and controlled by the *ADO*. The minimum identification requirement is an official card/document naming the *ADO* through which they have been authorised. For DCOs, additional identification requirements shall include their name, their photograph and the card's/document's expiry date. For Blood Collection Officials additional identification requirements include evidence of their professional training in the collection of blood *Samples.*

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.

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* and the situation in question.

5.3.6 For *Out-of-Competition Sample* collection, the *ADO* shall establish criteria to ensure that reasonable attempts are made to notify *Athletes* of their selection for *Sample* collection.

5.3.7 Reasonable attempts shall be defined by the *ADO* and at a minimum shall consider alternative times of day/evening and alternative locations over a specified period of time from the initial notification attempt.

5.3.8 The *ADO* shall establish a system for logging *Athlete* notification attempt/s and outcome/s.

5.3.9 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 5.3.10.

5.3.10 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,* 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 for the notification.

5.3.11 If the *Athlete* can not be contacted after having made reasonable attempts using the information supplied in 4.4.2 and logging the attempts in accordance with 5.3.8, the DCO or *ADO*, as applicable, shall institute Annex A - Investigating a possible failure to comply.

B.4 Requirements

B.4.1 All aspects of notification and *Sample* collection for *Athletes* 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 *Athletes* 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*.

B.4.4 For *Athletes* with a physical disability or a sensorial disability, the *Athlete* 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 For *Athletes* with an intellectual disability, the *ADO* or DCO shall determine whether the Athlete must have a representative at the *Sample* Collection Session and the nature of the assistance that the representative must provide. Additional assistance can be provided by the representative or *Sample* Collection Personnel during the *Sample* Collection Session where authorised by the *Athlete* and agreed to by the DCO.

B.4.6 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.4.7 *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.

B.4.8 The DCO will record modifications made to the standard *Sample* collection procedures for *Athletes* with disabilities, including any applicable modifications specified in the above actions.

ANNEX C - COLLECTION OF URINE *SAMPLES*

C.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;

(c) Ensuring that the Doping Control Station meets the minimum criterial prescribed in 6.3.2;

(d) Ensuring that *Sample* Collection Equipment used by the ADO meets the minimum criteria prescribed in 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.

6.3.2 The DCO shall use a Doping Control Station which, at a minimum, ensures the *Athlete's* privacy and 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 authorised to be present during the *Sample* Collection Session in addition to the *Same* 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, and the witnessing DCO Chaperone's entitlement to have a representative observe the 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 *MinorAthlete*.

(c) An *Athlete* with a disability's entitlement to be accompanied by a representative as provided for in Annex B - Modifications for *Athletes* with disabilities.

(d) A WADA Independent Observer where applicabel under the *Independent Observer Program.* The WADA Independent Observer shall not directly observe the Passing of a urine *Sample*.

6.3.4 The DCO shall only use *Sample* Collection Equipment systems that are authorised by the *ADO,* which at a minimum, shall meet the following criteria. They shall:

(a) Have a unique numbering system incorporated into all bottles, containers, tubes or any other item used to seal the *Athlete's Sample;*

(b) Have a sealing system that is tamper evident;

(c) Ensure the identity of the *Athlete* is not evident from the equipment itself;

(d) Ensure that all equipment is clean and sealed prior to use by the *Athlete.*

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 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* is informed of his/her rights and responsibilities as specified in 5.4.1.

7.3.3 The DCO shall provide the *Athlete* with the opportunity to hydrate.

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 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:

(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).

(c) Appropriate documentation is completed to report any possible failure to comply.

A.3.2 *Sample* Collection Personnel are responsible for reporting to the DCO any matter with the potential to compromise a test, and the DCO is responsible for reporting such matters to the *ADO.*

A.4 Requirements

A.4.1 Any matters with the potential to compromise the test shall be reported as soon as practicable.

A.4.2 If the matter has potential to compromise the test, the *Athlete* shall be notified if possible:

(a) Of the possible consequences;

(b) That a possible failure to comply will be investigated by the *ADO* and appropriate follow-up action will be taken.

A.4.3 The necessary information about the possible failure to comply shall be obtained from all relevant sources as soon as possible and recorded.

A.4.4 If possible, the *Athlete's Sample* Collection Session shall be completed.

A.4.5 The *ADO* shall establish a system for ensuring that the outcomes of its investigation into the possible failure to comply are considered for results management action and, if applicable, for further planning and *Testing.*

ANNEX B - MODIFICATIONS FOR *ATHLETES* WITH DISABILITIES

B.1 Objective

To ensure that the special needs of *Athletes* with disabilities are provided as much as possible in relation to the provision of a *Sample.*

B.2 Scope

The scope of determining whether modifications need to be considered starts with identification of situations where *Sample* collection involves *Athletes* with disabilities and ends with the necessary modifications to *Sample* collection procedures and equipment as possible for these *Athletes.*

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 the *Sample* collection.

9.3.3 Sealed *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.

9.3.4 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.*

9.3.5 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.

9.3.6 Chain of Custody shall be checked by the *ADO* if receipt of either the *Samples* with accompanying documentation or *Sample* collection 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.

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, acted upon and documented.

A.2 Scope

Investigating a possible failure to comply begins when the *ADO* or a DCO becomes aware of a matter with the potential to compromise an *Athlete's* test and ends when the *ADO* takes appropriate follow-up action based on the outcomes of its investigation into the possible failure to comply.

A.3 Responsibility

A.3.1 The *ADO* is responsible for ensuring that:

(a) Any matters with the potential to compromise an Athlete's test are assessed to determine if a possible failure to comply has occurred;

(b) All relevant information, including information from the immediate surroundings when applicable, is obtained as soon as possible or when practicable to ensure that all knowledge of the matter can be reported and be presented as possible evidence; and

The DCO shall document this information and 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 C: Collection of urine *Samples*

(b) Annex D: 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. If appropriate, the *ADO* and/or DCO, as applicable, 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 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 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) Date and time of *Sample* provision;

(c) The name of the *Athlete;*

(d) The date of birth of the *Athlete;*

(e) The gender of the *Athlete;*

(f) The *Athlete's* home address and telephone number;

(g) The *Athlete's* sport and discipline;

(h) The *Sample* code number;

(i) The name and signature of the Chaperone who witnessed the urine *Sample* provision;

(j) The name and signature of the Blood Collection Official who collected the blood *Sample,* where applicable;

(k) Required laboratory information on the *Sample;*

(l) Medications and supplements taken and recent blood transfusion details if applicable, within the timeframe specified by the lab as declared by the *Athlete;*

(m) Any irregularities in procedures;

(n) *Athlete* comments or concerns regarding the conduct of the session, if provided;

(o) The name and signature of the *Athlete;*

(p) The name and signature of the *Athlete's* representative, if required; and

(q) The name and signature of the DCO.

7.4.6 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 shall sign on behalf of the Athlete 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 documentation for transport.

8.3 Requirements for Security/post test administration

8.3.1 The *ADO* shall define criteria ensuring that any sealed *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 sealed *Sample* is stored in accordance with these criteria.

8.3.2 Without exception, all Samples collected shall be sent for analysis to a WADA accredited laboratory or as otherwise approved by *WADA.*

8.3.3 The *ADO*/DCO shall develop a system to ensure that the documentation for each sealed Sample is completed and securely handled.

8.3.4 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 sealed *Samples* and documentation leave the Doping Control Station and ends with the confirmed receipt of the *Samples* and *Sample* collection 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 documentation to the *ADO.*

9.3 Requirements for transport 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 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 *Samples* and *Sample* collection documentation have arrived at their intended destinations.

The *ADO* has the responsibility for all activities defined in this Annex G.

G.4 Requirements - Qualifications and Training

G.4.1 The *ADO* shall determine the necessary competence and qualification requirements for the positions of Doping Control Officer, Chaperone and Blood Collection Official. The *ADO* shall develop duty statements for all Sample Collection Personnel that outline their respective responsibilities. As a minimum:

(a) Sample Collection Personnel shall be of adult age.

(b) Blood Collection Officials shall have adequate qualifications and practical skills required to perform blood collection from a vein.

G.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.

G.4.3 The *ADO* shall establish a system that ensures that *Sample* Collection Personnel are adequately qualified and trained to carry out their duties.

G.4.4 The training program for Chaperones and Blood Collection Officiers as a minimum shall include studies of all relevant requirements of the testing process and familiarization of relevant standard precautions in healthcare settings.

G.4.5 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) One observation of all doping control activities related to requirements in this standard, preferably on site;

(c) The satisfactory performance of one complete *Sample* collection on site under observation by a qualified Doping Control Officer or similar.

(b) The *Sample* is of a quality and quantity that meets laboratory guidelines;

(c) The *Sample* is clearly and accurately identified; and

(d) The *Sample* is securely sealed.

C.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.

C.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*.

C.4 Requirements

C.4.1 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 *Athletes* with disabilities.

C.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 *Athletes* with disabilities, the DCO shall inspect that equipment to ensure that it will not affect the identity or integrity of the *Sample*.

C.4.3 The DCO shall instruct the *Athlete* to select a collection vessel.

C.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 the selection, this shall be recorded by the DCO.

If the DCO does not agree with the *Athlete's* opinion 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 reasons put forward by 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.

C.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 *Athletes* with disabilities.

C.4.6 The DCO Chaperone who witnesses the passing of the Sample shall be of the same gender as the *Athlete* providing the *Sample.*

C.4.7 The DCO Chaperone and *Athlete* shall proceed to an area of privacy to collect a *Sample.*

C.4.8 The DCO Chaperone shall witness the *Sample* leaving the *Athlete's* body and record the witnessing in writing.

C.4.9 The DCO shall use the relevant laboratory's specifications to verify, in full view of the *Athlete,* that the volume of the urine *Sample* satisfies the laboratory's requirements for analysis.

C.4.10 Where the volume of urine is insufficient, the DCO shall conduct a partial Sample collection procedure as prescribed in Annex E - Urine *Samples* - insufficient volume.

C.4.11 The DCO shall instruct the *Athlete* to select a *Sample* collection kit containing A and B bottles in accordance with C.4.4.

C.4.12 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 C.4.4. The *DCO* shall record the matter.

C.4.13 The *Athlete* shall pour the relevant laboratory's prescribed minimum volume of urine into the B bottle, and then fill the A bottle as much as possible. The *Athlete* shall then fill the B bottle as much as possible with the remaining urine. The *Athlete* shall ensure that a small amount of urine is left in the collection vessel.

C.4.14 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.

C.4.15 The DCO shall use the relevant laboratory's guidelines for pH and specific gravity to test the residual urine in the collection vessel to determine if the *Sample* is likely to meet the laboratory guidelines. If it is not, then the DCO shall follow Annex F - Urine *Samples* - *Samples* that do not meet laboratory pH and specific gravity guidelines.

C.4.16 The DCO shall ensure any residual urine that will not be sent for analysis is discarded in full view of the *Athlete.*

F.4 Requirements

F.4.1 The *ADO* shall establish criteria for the number of additional *Samples* to be collected by the DCO when the DCO determines that an *Athlete's Sample* is unlikely to meet the relevant laboratory's pH or specific gravity guidelines.

F.4.2 The DCO shall inform the *Athlete* that he/she is required to provide a further *Sample.*

F.4.3 While waiting to provide an additional *Sample,* the *Athlete* shall remain under continuous observation.

F.4.4 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 C - Collection of urine *Sample* and in accordance with the *ADO's* criteria for the number of additional *Samples* to be collected as established in F.4.1.

F.4.5 The DCO shall record that the *Samples* collected belong to a single *Athlete* and the order in which the Samples were provided.

F.4.6 The DCO shall then continue with C.4.16.

F.4.7 If it is determined by the relevant laboratory that all of the *Athlete's Samples* do not meet the laboratory's pH and specific gravity requirements for analysis and this is not related to natural causes, the *ADO* shall schedule another *Sample* Collection Session for the *Athlete* as *Target Testing* as soon as possible.

F.4.8 If the *Target Testing Sample* Collection Session also results in *Samples* that do not meet the laboratory's pH and/or specific gravity requirements for analysis, the *ADO* shall investigate a possible anti-doping rule violation.

ANNEX G - SAMPLE COLLECTION PERSONNEL REQUIREMENTS

G.1 Objective

To ensure that *Sample* Collection Personnel have no conflict of interest and have adequate qualifications and experience to conduct *Sample* collection sessions.

G.2 Scope

Sample Collection Personnel requirements starts with the development of the necessary competencies for Sample Collection Personnel and ends with the provision of identifiable accreditation.

G.3 Responsibility

E.4.5 While waiting to provide an additional *Sample*, the *Athlete* shall remain under continuous observation and be given the opportunity to hydrate.

E.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 C - Collection of urine *Samples* until a sufficient volume of urine will be provided by combining the initial and additional *Sample/s*.

E.4.7 When the DCO is satisfied that a sufficient volume of urine has been provided, 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.

E.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 *Sample* collected until the required volume is met.

E.4.9 The DCO and *Athlete* shall then continue with C.4.11.

ANNEX F - URINE SAMPLES - SAMPLES THAT DO NOT MEET LABORATORY PH OR SPECIFIC GRAVITY GUIDELINES

F.1 Objective

To ensure that when the urine *Sample* does not meet the contracted laboratory pH or specific gravity guidelines, appropriate procedures are followed.

F.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 laboratory pH and specific gravity guidelines or appropriate follow-up action by the *ADO* if required.

F.3 Responsibility

The *ADO* is responsible for establishing criteria for the number of additional *Samples* to be collected at the *Athlete's Sample* Collection Session. If the additional *Samplels* collected do not meet the relevant laboratory's guidelines for analysis, the ADO is responsible for scheduling a new *Sample* Collection Session for the *Athlete* and, if required, taking subsequent appropriate action.

The DCO is responsible for collecting additional *Samplels* in accordance with the *ADO's* criteria.

ANNEX D - COLLECTION OF BLOOD SAMPLES

D.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* is clearly and accurately identified; and

(d) The *Sample* is securely sealed.

D.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*.

D.3 Responsibility

D.3.1 The DCO has the responsibility for ensuring that:

(a) Each *Sample* is properly collected, identified and sealed; and

(b) All *Samples* have been properly stored and dispatched in accordance with the relevant analytical guidelines.

D.3.2 The Blood Collection Official 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.

D.4 Requirements

D.4.1 Procedures involving blood shall be consistent with relevant principles of internationally recognised standard precautions in health care settings.

D.4.2 Blood *Sample* Collection Equipment shall consist of, either an A sample tube, or an A sample tube and a B sample tube. If the sample collection consists solely of blood then a B sample shall be collected and used as a confirmation if required.

D.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 *Athletes* with disabilities.

D.4.4 The DCO Chaperone and *Athlete* shall proceed to the area where the *Sample* will be provided.

D.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*.

D.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's* opinion 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 reasons put forward by 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.

D.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 in accordance with D.4.5. The DCO shall record the matter.

D.4.8 The Blood Collection Official 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 Official shall take the blood *Sample* from a superficial vein into the final collection container. The tourniquet, if applied, shall be immediately removed after the venipuncture has been made.

D.4.9 The amount of blood removed shall be adequate to satisfy the relevant analytical requirements for the *Sample* analysis to be performed.

D.4.10 If the amount of blood that can be removed from the Athlete at the first attempt is insufficient, the Blood Collection Official shall repeat the procedure. Maximum attempts shall be three. Should all attempts fail, then the Blood Collection Official shall inform the DCO. The DCO shall terminate the collection of the blood *Sample* and record this and the reasons for terminating the collection.

D.4.11 The Blood Collection Official shall apply a dressing to the puncture site/s.

D.4.12 The Blood Collection Official shall dispose of used blood sampling equipment not required for completing the *Sample* Collection Session.

D.4.13 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.

D.4.14 The sealed *Sample* shall be kept at a cool, but not freezing, temperature prior to analysis at the Doping Control Station or dispatch for analysis at the *WADA* accredited laboratory or as otherwise approved by *WADA*.

ANNEX E - URINE *SAMPLES* - INSUFFICIENT VOLUME

E.1 Objective

To ensure that where an insufficient volume of urine is provided, appropriate procedures are followed.

E.2 Scope

The procedure begins with informing the *Athlete* that the *Sample* is of insufficient volume and ends with the provision of a *Sample* of sufficient volume.

E.3 Responsibility

The DCO has the responsibility for declaring the *Sample* volume insufficient and for collecting the additional *Samples* to obtain a combined *Sample* of sufficient volume.

E.4 Requirements

E.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 relevant laboratory's volume requirements.

E.4.2 The DCO shall instruct the *Athlete* to select partial *Sample* Collection Equipment in accordance with C.4.4.

E.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.

E.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.*

European Union Decision 2002/657/EC Official Journal of the European Communities 17.8.2002; L 221: 8-36.

ISO/IEC 17025:1999. General requirements for the competence of testing and calibration laboratories.

International Laboratory Accreditation Cooperation (ILAC) Document G-7:1996. Accreditation Requirements and Operating Criteria for Horseracing Laboratories.

ILAC Document G-15:2001. Guidance for Accreditation to ISO/IEC 17025

ILAC Document G-17:2002. Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025.

ILAC Document G-19:2002. Guideline for Forensic Science Laboratories

ILAC Document P-10:2002. ILAC Policy on Traceability of Measurement Results.

National Clinical Chemistry Laboratory Standards Document C-43A, 2002 [ISBN 1- 56238-475-9]. "Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs; Approved Guideline."

Olympic Movement Anti-Doping Code (1999)

Society of Forensic Toxicology and American Academy of Forensic Sciences, Toxicology Section, 2002 (Draft). Forensic Toxicology Laboratory Guidelines.

Substance Abuse and Mental Health Services Administration (SAMHSA), United States Department of Health and Human Services (DHHS), 2001. Mandatory Guidelines for Federal Workplace Drug Testing Programs and Notice of Proposed Revisions (Federal Register 2001; 66: 43876-43882).

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The requirement related to actual passing of *Sample* shall not be included in the on site observations.
G.4.6 The *ADO* shall maintain records of education, training, skills and experience.

G.5 Requirements - Accreditation, re-accreditation and delegation

G.5.1 The *ADO* shall establish a system for accrediting and re-accrediting *Sample* Collection Personnel.

G.5.2 The *ADO* shall ensure that *Sample* Collection Personnel have completed the training program and are familiar with the requirements in this testing standard before granting accreditation.

G.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.

G.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.

G.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.

WORLD ANTI-DOPING AGENCY
play true

The World Anti-Doping Code

INTERNATIONAL STANDARD FOR LABORATORIES

Version 4.0

August 2004

The Laboratory accreditation framework consists of two main elements: Part Two of the standard: the Laboratory accreditation requirements and operating standards; and Part Three: the Annexes and Technical Documents. Part Two describes the requirements necessary to obtain *WADA* recognition and the procedures involved to fulfill the requirements. It also contains an application of the ISO/IEC 17025 standard to the field of *Doping Control*. The purpose of this section of the document is to facilitate consistent application and assessment of the ISO/IEC 17025 and the specific *WADA* requirements for *Doping Control* by accreditation bodies that operate in accordance with ISO/IEC Guide 58. The *International Standard* also sets forth the requirements for *Doping Control* Laboratories when adjudication results as a consequence of an *Adverse Analytical Finding*

Part Three of the Standard includes all Annexes. Annex A describes the *WADA* Proficiency Testing Program, including performance criteria necessary to maintain good standing in proficiency testing. Annex B describes the ethical standards required for continued *WADA* recognition of the **Laboratory.** Annex C is a list of Technical Documents. Technical Documents are issued, modified, and deleted by *WADA* from time to time and provide direction to the Laboratories on specific technical issues. Once promulgated, Technical Documents become part of the *International Standard* for Laboratories. The incorporation of the provisions of the 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 this standard, including the annexes, as a reference document in their accreditation audit process.

Terms defined in the *Code*, which are included in this standard, are written in italics.

Terms, which are defined in this standard, are underlined.

References

These following references were consulted in the development of this document. The specific requirements and concepts of these documents do not supersede or otherwise change the requirements stated in the *International Standard* for Laboratories

A2LA, 2001. Proficiency Testing Requirement for Accredited Testing and Calibration Laboratories.

EA-03/04 (August 2001). Use of Proficiency Testing as a Tool for Accreditation in Testing

Eurachem Proficiency Testing Mirror Group (2000). Selection, Use and Interpretation of Proficiency Testing (PT) Schemes by Laboratories.

Eurachem/CITAC Guide, 2nd Edition (2000) Quantifying Uncertainty in Analytical Measurement.

PART ONE: INTRODUCTION, *CODE* PROVISIONS AND DEFINITIONS

1.0 Introduction, Scope and References

The main purpose of the *International Standard* for Laboratories is to ensure laboratory production of valid test results and evidentiary data and to achieve uniform and harmonized results and reporting from all accredited *Doping Control* Laboratories.

The *International Standard* for Laboratories includes requirements for *WADA* accreditation of doping laboratories, operating standards for laboratory performance and description of the accreditation process.

The *International Standard* for Laboratories, 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 antidoping 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 antidoping 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.

This document sets out the requirements for *Doping Control* 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 of drugs and other substances deemed to be prohibited by the list of *Prohibited Substances* and *Prohibited Methods* (*The Prohibited List*) in human biological fluids or tissues.

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 basis for the *International Standard* for Laboratories is the relevant Sections in the Olympic Movement Anti-Doping *Code*. An expert group, together with a *WADA* Laboratory Accreditation Committee, has prepared the document and drafts have been circulated for initial review and comment from all IOC accredited doping Laboratories and the IOC Sub-Commission on Doping and Biochemistry of Sport.

Version 1.0 of the *International Standard* for Laboratories was circulated to *Signatories,* governments and accredited laboratories for review and comments in November 2002. Version 2.0 was based on the comments and proposals received from these stakeholders.

All *Signatories,* governments and Laboratories were consulted and have had the opportunity to review and provide comments to version 2.0. This draft version 3.0 was presented for approval to the *WADA* Executive Committee on June 7th 2003.

The *International Standard* for Laboratories will come into effect on January 1st 2004.

Currently, Laboratories are accredited by the International Olympic Committee (IOC). As part of the transition of the program from existing IOC accreditation to *WADA* accreditation, accreditation bodies shall require the Laboratories to which they grant and maintain accreditation to comply with the requirements of the *International Standard* for Laboratories and ISO/IEC 17025 by January 1st, 2004. For Laboratories moving from IOC to *WADA* accreditation (see Section 4.1.7), an internal audit before January 1st, 2004 shall be deemed compliant with the *International Standard* for Laboratories. The next ISO surveillance or reaccreditation audit conducted by the national accrediting body in 2004 shall document compliance with the *International Standard* for Laboratories. Laboratories seeking initial *WADA* accreditation shall have an on-site accreditation audit by their national accrediting body compliant with this standard before receiving *WADA* accreditation.

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.

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4.2 Maintaining *WADA* Accreditation

This section describes the specific requirements for a *WADA* re-accreditation of the Laboratory.

4.2.1 ISO/IEC 17025 accreditation
The Laboratory shall document a valid accreditation from the national accreditation body 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 Analysis of *Doping Control Samples* (Section 5).

4.2.2 Flexible Accreditation

WADA accredited Laboratories may add or modify scientific methods or add analytes without the need for approval by the body that completed the ISO/IEC 17025 accreditation of that Laboratory. Any analytical method or procedure must be properly selected and validated and included in the scope of the Laboratory at the next ISO audit if the method is used for analysis of *Doping Control Samples*.

4.2.3 Letter of support The Laboratory shall provide a renewed official letter of support from the relevant national public authority responsible for the national anti-doping program, if any, or a similar letter of support from the *National Olympic Committee* or *National Anti-Doping Organization* in years in which the Laboratory undergoes an ISO re-accreditation audit. The renewed letter of support shall contain as a minimum:

- Guarantee of sufficient financial support annually for a minimum of 3 years
- Guarantee of sufficient numbers of *Samples* annually
- Guarantee of provision of necessary analytical facilities and instrumentation, where applicable

Any explanation of exceptional circumstances shall be given due consideration by *WADA*. The letter of support does not in any way require exclusive support for only one Laboratory.

Letters of support from international sport organizations such as International Federations could also be provided in addition to the above mentioned letters.

If the Laboratory as an organization is linked to host organizations (e.g. university, hospital…), an official letter of support from the host organizations shall be renewed for each year in which the Laboratory undergoes a ISO re-accreditation audit and shall include the following information:

- Documentation of the administrative support for the Laboratory
- Financial support for the Laboratory, if relevant
- Guarantee of provision of necessary analytical facilities and instrumentation
- Support for the research activities

4.2.4 Minimum number of *testing Samples*

2.0 Code Provisions

The following articles in the *Code* directly address the *International Standard* for Laboratories:

***Code* Article 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 laboratory analysis. The *Athlete* may rebut this presumption by establishing that a departure from the *International Standard* occurred. If the *Athlete* rebuts the preceding presumption by showing that a departure from the *International Standard* occurred, then the *Anti-Doping Organization* shall have the burden to establish that such departure did not cause the *Adverse Analytical Finding*.

***Code* Article 6 Analysis of Samples**
Doping Control Samples shall be analyzed in accordance with the following principles:

6.1 Use of Approved Laboratories *Doping Control Samples* shall be analyzed only in *WADA*-accredited laboratories or as otherwise approved by *WADA*. The choice of the *WADA*accredited laboratory (or other method approved by *WADA*) used for the *Sample* analysis shall be determined exclusively by the *Anti-Doping Organization* responsible for results management.

[Comment: The phrase "or other method approved by WADA" is intended to cover, for example, mobile blood Testing procedures which WADA has reviewed and considers to be reliable.]

6.2 Substances Subject to Detection. *Doping Control Samples* shall be analyzed to detect *Prohibited Substances and Prohibited Methods* identified on the *Prohibited List* and other substances as may be directed by *WADA* pursuant to Article 4.5 (Monitoring Program).

6.3 Research on *Samples*. No *Sample* may be used for any purpose other than the detection of substances (or classes of substances) or methods on the *Prohibited List,* or as otherwise identified by *WADA* pursuant to Article 4.5 (Monitoring Program), without the *Athlete's* written consent.

6.4 Standards for *Sample* Analysis and Reporting. Laboratories shall analyze *Doping Control Samples* and report results in conformity with the *International Standard* for Laboratories analysis.

***Code* Article 13.5 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 14.1 Information Concerning *Adverse Analytical Findings* and Other Potential Anti-Doping Rule Violations.** An *Athlete* whose *Sample* has resulted in an *Adverse Analytical Finding*, or

an *Athlete* or other *Person* who may have violated an anti-doping rule, shall be notified by the *Anti-Doping Organization* with results management responsibility as provided in Article 7 (Results Management). The *Athlete*'s *National Anti-Doping Organization* and International Federation and *WADA* shall also be notified not later than the completion of the process described in Articles 7.1 and 7.2. Notification shall include: the *Athlete's* name, country, sport and discipline within the sport, whether the test was *In-Competition* or *Out-of-Competition*, the date of *Sample* collection and the analytical result reported by the laboratory. The same *Persons* and *Anti-Doping Organizations* 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, in any case in which the period of *Ineligibility* is eliminated under Article 10.5.1 (*No Fault or Negligence*), or reduced under Article 10.5.2 (*No Significant Fault or Negligence*), shall be provided with a written reasoned decision explaining the basis for the elimination or reduction. The recipient organizations shall not disclose this information beyond those *Persons* within the organization with a need to know 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.

3.0 Terms and definitions

3.1 Code defined Terms

Adverse Analytical Finding: A report from a Laboratory or other approved *Testing* entity that identifies in a *Specimen* 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, *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations.*

Athlete: For purposes of *Doping Control*, any *Person* who participates in sport at the international level (as defined by each International Federation) or national level (as defined by each *National Anti-Doping Organization*) and any additional *Person* who participates in sport at a lower level if designated by the *Person's National Anti- Doping Organization.* 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.*

Code: The World Anti-Doping Code.

Doping Control: The process including test distribution planning, *Sample* collection and handling, Laboratory analysis, results management, hearings and appeals.

Letters of support from international sport organizations such as International Federations could also be provided in addition to the above mentioned letters.

If the laboratory as an organization is linked to host organizations, (e.g. universities, hospitals…) an official letter of support from the host organizations shall be provided which should include the following information:

- 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

4.1.3 Code of Ethics
The laboratory shall sign and comply with the provision in the Code of Ethics (Annex B) which are relevant for a laboratory in the probationary period.

4.1.4 Proficiency testing program
During the probationary period the laboratory shall successfully analyze at a minimum four sets of proficiency testing samples containing at a minimum five samples per set.

The final accreditation test shall assess both the scientific competence and the capability of the laboratory to manage multiple *Samples.*

4.1.5 Sharing of knowledge
The laboratory shall demonstrate during the probationary period its willingness and ability to share knowledge with other *WADA* Accredited Laboratories. A description of this sharing is provided in the Code of Ethics (Annex B).

4.1.6 Research
The 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. The research activities can either be conducted by the laboratory or in cooperation with other *WADA*-accredited Laboratories or other research organizations.

4.1.7 Initial accreditation of Laboratories holding IOC accreditation
Laboratories accredited by the IOC in 2003 and which successfully complete the joint 2003 IOC/*WADA* re-accreditation test and at a minimum conduct an internal audit against Section 5 of the *Internal Standard* for Laboratories will receive *WADA* accreditation in 2004. The *International Standards* for Laboratories requirements will be fully in effect on January 1st, 2004. Laboratories that are downgraded or fail the 2003 IOC/*WADA* re-accreditation test will have their accreditation suspended or revoked by *WADA* in accordance with Section 6.4.8. Laboratories which have applied for, but have not received, IOC accreditation will complete their probationary period under the *International Standards* for Laboratories.

Testing Authority: 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* collection and transport either *In-Competition* or *Out-of-Competition* and/or for management of the test result.

Threshold Substance: A substance listed in the *Prohibited List* for which the detection 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 Requirements for WADA accreditation

4.1 Initial WADA accreditation

This section describes the specific requirements for the initial *WADA* accreditation of the laboratory. All the requirements must be fulfilled in order to obtain an initial *WADA* accreditation. For some of the requirements, the laboratory has to demonstrate compliance during the probationary period and for other requirements compliance will be checked and controlled based on an accreditation audit (ref. 5.1, 5.2 and 5.3).

4.1.1 ISO/IEC 17025

The laboratory shall be accredited by a relevant national accreditation body according to ISO/IEC 17025 with primary reference to the interpretations and applications of the ISO/IEC 17025 requirements as they are described in Application of ISO/IEC 17025 to the Analysis of *Doping Control Samples* (Section 5). The ISO/IEC 17025 accreditation must be obtained before the initial *WADA* accreditation will be given.

4.1.2 Letter of support

The laboratory shall provide an official letter of support from the relevant national public authority responsible for the national anti-doping program, if any, or a similar letter of support from the *National Olympic Committee* or *National Anti-Doping Organization*. The letter of support shall contain as a minimum:

- Guarantee of sufficient financial support annually for a minimum of 3 years
- Guarantee of sufficient numbers of *Samples* annually for 3 years
- Guarantee of provision of necessary analytical facilities and instrumentation, where applicable

In addition, any explanation of exceptional circumstances shall be given due consideration by *WADA*. The three year letter of support does not in any way require exclusive support for only one laboratory.

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: For purposes of differentiating between *In-competition* and *Out-of-Competition Testing*, unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, an *In-Competition* test is a test where an *Athlete* is drawn for *Testing* in connection with a specific *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 covered by the *International Standard* were performed properly.

Marker: A compound, group of compounds or biological parameters 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 antidoping 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 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 Substances* and *Prohibited Methods*.

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 Committees*, 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 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 Laboratories

Aliquot**:** A portion of the *Sample* of biological fluid or tissue (e.g., urine, blood, etc.) obtained from the *Athlete* used in the testing process.

Certified Reference Material: Reference Material, accompanied by a certificate, one or more whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence of a specific *Prohibited Substance* in a *Sample*. [*Comment: A* Confirmation Procedure may also indicate a quantity of *Prohibited Substance greater than a threshold value or quantify the amount of a Prohibited Substance in a Sample.*]

Flexible Accreditation: Approval for a Laboratory to make restricted modifications in the scope of the accreditation without the involvement of the national accreditation body before the modifications are implemented

Intermediate Precision, sZi: Variation in results observed when one or more factors, such as time, equipment, and operator are varied within a Laboratory with i denoting the number of factors varied.

Laboratory Internal Chain of Custody: Documentation of the sequence of *Persons* in possession of the *Sample* and any portions of the *Sample* taken for *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: An accredited laboratory applying test methods and processes to provide evidentiary data for the detection and, if applicable, quantification of a Threshold Substance on the *Prohibited List* in urine and other biological *Samples*.

Laboratory Documentation Packages: The material produced by the Laboratory to support the finding of an *Adverse Analytical Finding* as set forth in the *WADA* Technical Document for Laboratory Documentation Packages.

Minimum Required Performance Limit: A 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 in the routine daily operation of the Laboratory. See Technical Document Minimum Required Performance Limits for Detection of *Prohibited Substances*.

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 an adverse screening test, but a confirmation test has not 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 or substance one or more of whose properties are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method or for assigning values to materials.

Repeatability, sr: Variability observed within a laboratory, over a short time, using a single operator, item of equipment, etc.

Reproducibility, sR: Variability obtained when different laboratories analyze the same *Sample*.

Revocation: The permanent withdrawal of a Laboratory's *WADA* accreditation.

Screening Procedure: An analytical test procedure whose purpose is to identify those *Samples* which are suspicious with respect to containing a *Prohibited Substance* or *Metabolite* or *Marker* of a *Prohibited Method* and which require additional confirmation testing.

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.

5.2.4.4 Alternative biological matrices screening and confirmatory testing

5.2.4.4.1 Unless otherwise defined, this application applies only to the analysis of urine *Samples*. Blood, plasma, and serum are acceptable matrices for testing in certain circumstances. Specific requirements for the testing of these matrices are not included in the scope of this document and will be promulgated separately.

5.2.4.4.2 Any testing results of hair, nails, oral fluid or other biological material shall not be used to counter *Adverse Analytical Findings* 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 must independently review all *Adverse Analytical Findings* before a report is issued. The review process shall be documented.

5.2.5.1.2 At a minimum, the review shall include:

- Laboratory Internal Chain of Custody documentation
- Urine integrity data
- Validity of the analytical screening and confirmation data and calculations
- Quality control data
- Completeness of documentation supporting the reported analytical findings

5.2.5.1.3 When an *Adverse Analytical Finding* is rejected, the reason(s) must be documented.

5.2.6 Documentation and Reporting

5.2.6.1 The Laboratory must 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 must 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.

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).

The Laboratory shall periodically provide, at the request of *WADA* a report documenting all test results reported in a format to be specified by *WADA*.

In order to maintain proficiency, *WADA*-accredited Laboratories are required to analyze a minimum of 1500 *Doping Control Samples* per year that are provided by a Testing Authority. If the Laboratory fails to analyze this number of *Samples*, accreditation will be suspended or revoked, dependent on the circumstances.

4.2.5 Proficiency testing program

The Laboratories are required to successfully participate in the *WADA* Proficiency Testing program. The program is described in more detail in Annex A.

4.2.6 Reporting

The Laboratory shall simultaneously report to *WADA* and the relevant International Federation all *Adverse Analytical Findings* that have been reported to a Testing Authority. All reporting shall be in accord with the confidentiality requirements of the *Code*.

4.2.7 Code of Ethics

The Laboratory shall provide documentation of compliance with the provisions of the Code of Ethics (Annex B) relevant for a *WADA* accredited Laboratory. The Laboratory Director shall send a letter of compliance to *WADA* every year.

4.2.8 Sharing of knowledge

The Laboratory shall demonstrate their willingness and ability to share knowledge with other *WADA* Accredited Laboratories. A description of this sharing is provided in the Code of Ethics (Annex B).

4.2.9 Research

The Laboratory shall maintain an updated 3-year plan for research and development in the field of *Doping Control*, including an annual budget in this area.

The Laboratory should document the publication of results of the research in relevant scientific papers in the peer-reviewed literature. These documents 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.

4.3 Special Requirements for Major *Events*

The Laboratory support for the Olympic Games and other major *Events* may be such that the accredited Laboratory facilities are not adequate. This may require relocation of the Laboratory to a new facility, the addition of personnel, 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 the quality management system is maintained.

4.3.1 Satellite facility of an accredited Laboratory
If the Laboratory is required to move or extend its operation temporarily to a new physical location, the Laboratory must demonstrate a valid ISO/IEC 17025 accreditation with primary compliance with the Application of ISO/IEC 17025 to the Analysis of *Doping Control Samples* for the new facility ("satellite facility").

Any methods or equipment unique to the satellite facility must be validated prior to the satellite facility accreditation audit. Any changes to methods or other procedures in the quality manual must also be validated prior to the audit.

4.3.2 Personnel
The Laboratory shall report to *WADA* any senior personnel (e.g., certifying scientists, quality system management staff, supervisors, etc.) 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 should be maintained by the Laboratory.

4.3.3 Proficiency testing
WADA may, at its sole discretion, submit proficiency testing samples to the Laboratory for analysis. The samples shall be analyzed by the same methods used in the testing of *Samples* from a Testing Authority. These samples may be part of the ISO/IEC 17025 audit in conjunction with the national accrediting body. Failure(s) to successfully complete the proficiency test will be considered by *WADA* in deciding whether to accredit the Laboratory. In the event of an unacceptable report, the Laboratory shall document the changes instituted to remedy the failure.

The proficiency testing process should include any additional personnel that areadded to the staff for the major *Event*. The samples should be analyzed using the protocols and procedures that will be used for analysis of *Samples* for the *Event*.

4.3.4 Reporting
The Laboratory shall document that the reporting of test results maintains confidentiality.

5.0 Application of ISO 17025 to the Analysis of Doping Control Samples

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 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 and, where applicable, by ISO 9001. 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 *Doping*

is requested in the "B" *Sample*, the "B" *Sample* analysis should occur as soon as possible and should be completed within thirty (30) days of notification of an "A" *Sample Adverse Analytical Finding*.

5.2.4.3.2.2 The "B" *Sample* confirmation must be performed in the same Laboratory as the "A" *Sample* confirmation. A different analyst must perform the "B" analytical procedure. The same individual(s) that performed the "A" analysis may perform instrumental set up and performance checks and verify results.

5.2.4.3.2.3 The B *Sample* result must confirm the A *Sample* identification for the *Adverse Analytical Finding* to be valid. The mean value for the B *Sample* finding for Threshold Substances is required to exceed that threshold including consideration of uncertainty.

5.2.4.3.2.4 The *Athlete and/or a* 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.

In the absence of all of the above persons, the Testing Authority or the Laboratory shall appoint a surrogate (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.

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 that is interfering in the testing process. Any behavior resulting in removal should be reported to the Testing Authority and may be considered anti–*doping rule violation in accordance with Article 2.5 of the Code*, "*Tampering*, or *Attempting* to tamper, with any part of *Doping Control*".

5.2.4.3.2.5 Aliquots taken for analysis must be taken from the original "B" *Sample*.

5.2.4.3.2.6 The Laboratory must have a policy to define those circumstances when confirmation testing of the "B" *Sample* may be repeated. Each repeat confirmation should be performed on a new Aliquot of the "B" *Sample*.

5.2.4.3.2.7 If the "B" *Sample* confirmation does not provide analytical findings that confirm the "A" *Sample* result, the *Sample* shall be considered negative and the Testing Authority notified of the new analytical finding.

5.2.4.3 Urine confirmation testing

All Confirmation Procedures must be documented and meet applicable uncertainty requirements. The objective of a Confirmation Procedure is to ensure the identification and/or quantification and to exclude any technical deficiency in the Screening Procedure. Since the objective of the confirmation assay is to accumulate additional information regarding an adverse finding, a Confirmation Procedure should have greater selectivity/discrimination than a Screening Procedure.

5.2.4.3.1 "A" *Sample* Confirmation

5.2.4.3.1.1 Presumptive identification from a Screening Procedure of a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Method* must be confirmed using a second Aliquot(s) taken from the original "A" *Sample*.

5.2.4.3.1.2 Mass spectrometry coupled to either gas or liquid chromatography is the method of choice for confirmation of *Prohibited Substances*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Method*. GC/MS or HPLC/MS are acceptable for both Screening Procedures and Confirmation Procedures for a specific analyte.

5.2.4.3.1.3 Immunoassay for confirmation of prohibited proteins, peptides, mimetics, and analogues or *Marker*(s) of their *Use* is permitted. The immunoassay used for confirmation must use a procedure with a different antibody that should recognise a different epitope of the peptide/protein than the assay used for screening.

5.2.4.3.1.4 The Laboratory must have a policy to define those circumstances where the confirmation testing of an "A" *Sample* may be repeated (e.g., batch quality control failure). Each repeat confirmation must be documented and be completed on a new Aliquot of the "A" *Sample*.

5.2.4.3.1.5 The Laboratory is not required to confirm every *Prohibited Substance* that is identified by the Screening Procedures. The decision on the prioritization on order of confirmation(s) should be made in cooperation with the Testing Authority and the decision documented. In addition, no Certificate of Analysis or final written Test Report incorporating a Presumptive Analytical Finding shall be issued.

5.2.4.3.2 "B" *Sample* Confirmation

5.2.4.3.2.1 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 *Method*

Control Laboratory. These processes have been determined to be critical to the defined ISO 17025 criteria and are therefore determined to be significant in the evaluation and accreditation process.

This section introduces the specific performance standards for a *Doping Control* Laboratory. The conduct of testing is considered a process within the definitions of ISO 9001. Performance standards are defined according to a process model where the *Doping Control* 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 17025 document. The concepts of the quality management system, continuous improvement, and customer satisfaction included in ISO 9001 have been included.

5.2 Analytical and Technical Processes

5.2.1 Receipt of *Samples*

5.2.1.1 *Samples* may be received by any method authorized by *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 name and signature (or other means of identification and recording) of the *Person* delivering or transferring custody of the shipped *Samples*, the date, the time of receipt, and the name and signature of the Laboratory representative receiving the *Samples*, shall be documented as part of the Laboratory Internal Chain of Custody record.

5.2.2 Handling of *Samples*

5.2.2.1 The Laboratory shall have a system to uniquely identify the *Samples* 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 *Samples* from receipt through final disposition of the *Samples*. The procedures must incorporate the concepts presented in the *WADA* Technical Document for Laboratory Internal Chain of Custody (Annex C).

5.2.2.3 The Laboratory shall observe and document conditions that exist at the time of receipt that may impact on the integrity of a *Sample* report. 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 seal 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 extremely low

5.2.2.4 The Laboratory should notify and seek advice from the Testing Authority regarding rejection and testing of *Samples* for which irregularities are noted.

5.2.2.5 The Laboratory shall retain the A and B *Sample*(s) for a minimum of three (3) months after the Testing Authority receives a negative report. The *Samples* shall be retained frozen under appropriate conditions.

Samples with irregularities shall be held frozen for a minimum of three (3) months following the report to the Testing Authority.

5.2.2.6 The Laboratory shall retain the *Sample(s)* with an *Adverse Analytical Finding* for a minimum of three (3) months after the Testing Authority receives the final analytical (A or B *Sample*) report. The *Sample* shall be stored frozen under appropriate conditions during the long term storage.

5.2.2.7 If the Laboratory has been informed by the Testing Authority that the analysis of a *Sample* is challenged or disputed, the *Sample* shall be retained frozen under appropriate conditions and all the records pertaining to the *Testing* of that *Sample* shall be stored until completion of any challenges.

5.2.2.8 The Laboratory shall maintain a policy pertaining to retention, release, and disposal of *Samples* or Aliquots.

5.2.2.9 The Laboratory shall maintain custody information on the transfer of *Samples*, or portions thereof to another Laboratory.

5.2.3 Sampling and Preparation of Aliquots for Testing

5.2.3.1 The Laboratory shall maintain Laboratory Internal Chain of Custody procedures for control of and accountability for all Aliquots from preparation through disposal. The procedures must 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 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 Screening Procedure or Confirmation Procedure shall ensure that no risk of contamination of the *Sample* or Aliquot exists.

5.2.4 Testing

5.2.4.1 Urine integrity testing

5.2.4.1.1 The Laboratory must have a written policy establishing the procedures and criteria for *Sample* integrity tests.

5.2.4.1.2 The Laboratory should note any unusual condition of the urine – for example: color, odor, or foam. Any unusual conditions should be recorded and included as part of the report to the Testing Authority.

5.2.4.1.3 The Laboratory shall test for the pH and specific gravity as urine integrity parameters on the "A" *Sample*. Other tests may be performed if requested by the Testing Authority and approved by *WADA*

5.2.4.2 Urine screen testing

5.2.4.2.1 The Screening 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 *Method* for all substances listed in the *Out-of-Competition* or *In-competition* Section of the *Prohibited List as appropriate* for which there is a *WADA*-accepted screening method. *WADA* may make specific exceptions to this section.

5.2.4.2.2 The Screening Procedure shall be performed with a *WADA*-accepted validated method that is appropriate for the substance or method being tested. The criteria for accepting a screening result and allowing the testing of the *Sample* to proceed must be scientifically valid.

5.2.4.2.3 All screening assays shall include negative and positive controls in addition to the *Samples* being tested.

5.2.4.2.4 For analytes that must exceed a threshold for reporting as an *Adverse Analytical Finding*, appropriate controls shall be included in the screening assay. Screening Procedures for Threshold Substances are not required to meet quantitative or uncertainty requirements.

Laboratory Internal Chain of Custody; and proper remedial action to be taken in response to analytical problems. The qualifications for supervisor are:

- Bachelors 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 Gas Chromatography/Mass Spectrometry.
- 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 interruption or compromise of stored data.

5.4.3.1.1.2 All computers, peripherals, and communication devices 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 samples 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 must 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, which may include a threat and risk assessment.

5.2.6.4 Where instrumental analyses are conducted, the operating parameters for each run shall be recorded.

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 competitions may be substantially less than ten days. The reporting time may be modified by agreement between the Laboratory and the Testing Authority.

5.2.6.6 The Laboratory Certificate of Analysis or Test Report shall include, in addition to the items stipulated in ISO 17025, the following:

- *Sample* identification number
- Laboratory identification number (if any)
- Status of test (*Out of competition/In-competition*)
- Name of competition and/or sport
- Date of receipt of *Sample*
- Date of report
- Type of sample (urine, blood, etc.)
- Test results
- Signature of certifying individual
- Other information as specified by the Testing Authority.

5.2.6.7 The Laboratory is not required to measure or report a concentration for *Prohibited Substances* for a non-threshold analyte. The Laboratory should report the actual *Prohibited Substance*(s), *Metabolite*(s) of the *Prohibited Substance*(s) or *Method*(s), or *Marker*(s) detected in the *Sample*.

5.2.6.8 For Threshold Substances, the Laboratory report should establish that the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* of a *Prohibited Method* is present at a concentration greater than the threshold concentration taking into consideration the uncertainty in concluding that the concentration in the *Sample* exceeds the threshold. The estimate of uncertainty should not be included on the Certificate of Analysis or Test Report but must be included in Laboratory Documentation Packages.

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 Certificate of Analysis or 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 pharma-

cokinetics of a substance, 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 Findings* to *WADA* and the responsible International Federation. In the case where the sport or *Event* is not associated with an International Federation (e.g., college sports) or the *Athletes* are not members of an International Federation, the Laboratory is required to report *Adverse Analytical Findings* only to *WADA*. All reporting shall be in accord with the confidentiality requirements of the *Code*.

5.2.6.11 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 *Samples* rejected for testing and the reason for the rejection.

When the clearinghouse is in place, the Laboratory shall simultaneously report to *WADA* all 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.

5.2.6.12 Laboratory Documentation Packages shall contain material specified in the *WADA* Technical Document on Laboratory Documentation Packages.

5.2.6.13 *Athlete* confidentiality is a key concern for all Laboratories engaged in *Doping Control* cases. Confidentiality requires extra safeguards given the sensitive nature of these tests.

5.2.6.13.1 Testing Authority requests for information must be made in writing to the Laboratories.

5.2.6.13.2 *Adverse Analytical Findings* shall not be provided by telephone.

5.2.6.13.3 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.

5.2.6.13.4 Unencrypted email is not authorized for any reporting or discussion of *Adverse Analytical Findings* if the *Athlete* can be identified or if any information regarding the identity of the *Athlete* is included. 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

5.4.2 Personnel

5.4.2.1 Every person employed by, or under contract to, the Laboratory must have a personnel file accessible for auditors. The file must contain copies of the resumé, or qualification form, a description of the job, and documentation of initial and ongoing training. The Laboratory must maintain appropriate confidentiality of personal information.

5.4.2.2 All personnel should 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 certification should be documented in the individual's personnel file.

5.4.2.4 The *Doping Control* Laboratory must 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 medical or scientific degree with appropriate experience or training.
- Experience with the analysis of biological material for substances used in doping.
- Appropriate training or experience in forensic applications of *Doping Control.*

5.4.2.5 The *Doping Control* Laboratory must 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 Gas Chromatography/Mass Spectrometry.

5.4.2.6 Supervisory personnel should have a thorough understanding of the Quality Control procedures; the review, interpretation, and reporting of test results; maintenance of

5.3.12 Control of records

5.3.12.1 Technical Records

5.3.12.1.1 Analytical records on negative *Samples*, including Laboratory Internal Chain of Custody documentation and medical information (T/E ratio, steroid profiles, and blood parameters), must be retained in secure storage for at least two (2) years. Relevant records on *Samples* with irregularities or rejected *Samples* must be retained in secure storage for at least two (2) years.

5.3.12.1.2 All analytical records on *Specimens* with an *Adverse Analytical Finding* must be retained in secure storage at least five (5) years, unless otherwise specified by the Testing Authority or by contract.

5.3.12.1.3 The raw data supporting all analytical results must be retained in secure storage for five (5) years.

5.3.13 Internal Audits

5.3.13.1 Internal audits shall be completed in accordance with the requirements of ISO/IEC 17025 Section 4.13.

5.3.13.2 Internal Audit responsibilities may be shared amongst personnel provided that any *Person* does not audit his/her own area.

5.3.14 Management Reviews

5.3.14.1 Management reviews will be conducted to meet the requirements of ISO/IEC 17025 Section 4.14.

5.3.14.2 *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 should occur by the effective date.

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.

5.4 Support processes

5.4.1 General

General support shall be provided in accord with ISO/IEC 17025.

5.3.1.1 Within the framework of ISO/IEC 17025, the Laboratory shall be considered a testing laboratory (and not a calibration laboratory).

5.3.1.2 The Laboratory (Scientific) 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 Quality 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 should 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 Quality 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 Quality 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 documented. If this is not possible, *WADA* should 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 must meet the requirements of ISO/IEC 17025 Section 4.4.

The Laboratory shall ensure that the Testing Authority is informed concerning the tests that can be performed on *Samples* submitted for analysis.

5.3.5 Subcontracting of tests

A *WADA*-accredited Laboratory must perform all work with its own personnel and equipment within its accredited facility. In the case of specific technologies that may not be available in the Laboratory (e.g., GC/C/IRMS, Isoelectric focusing [EPO/NESP]), a *Sample* may be transferred to another *WADA*-accredited Laboratory in which the technology is within the scope of analysis.

In exceptional circumstances, *WADA* may elect to grant specific authorization for subcontracting part of the tasks. In such cases, assurance of maintaining the level of quality and the appropriate chain of custody throughout the entire process is the responsibility of the Laboratory Director of the *WADA*-accredited Laboratory.

5.3.6 Purchasing of services and supplies

5.3.6.1 Chemicals and reagents

Chemicals and reagents must be suitable for the purpose and be of established purity. Reference purity documentation must be obtained when available and retained in the quality system documents.

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 that no significant deterioration has occurred.

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 should be in place to protect the staff, the public, and the environment.

5.3.7 Service to the client

5.3.7.1 Service to clients 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 designee must:

- Ensure adequate communication.
- Report to *WADA* any unusual circumstances or information with regard to testing programs, patterns of irregularities in *Specimens*, 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 Testing Authority focus

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 should 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:

- Communicate with the Testing Authority concerning any significant question of testing needs or any unusual circumstance in the testing process (including delays in reporting).
- Act without bias regarding the national affiliation of the Testing Authority.
- Provide complete and timely explanations to the Testing Authority when requested or when there is a potential for misunderstanding the Test Report or Certificate of Analysis.
- Provide evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings.
- Respond 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 monitor Testing Authority satisfaction. There should be documentation that the Testing Authority concerns have been incorporated into the Laboratory Quality Management System, where appropriate.

5.3.7.3.4 The Laboratory shall develop a system, as required by ISO 17025, for monitoring key indicators of Laboratory service.

5.3.8 Complaints

Complaints shall be handled in accord 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 deviation from procedure or protocol involving a *Sample* testing shall be kept as part of the permanent record of that *Sample*.

5.3.10 Corrective action
Corrective action shall be taken in accord with ISO/IEC 17025 Section 4.10.

5.3.11 Preventive action
Preventive action shall be taken in accord with ISO/IEC 17025 Section 4.11.

submit a report to the laboratory. In the report *WADA* will make the necessary recommendations concerning giving the laboratory status as a *WADA* Probationary laboratory or if this is not the case, identifying needed improvements in order to be a *WADA* Probationary laboratory.

6.2 Preparing for *WADA* Laboratory Accreditation

A probationary period shall be defined for a *WADA* Probationary Laboratory. The period will range from 12 to 24 months depending on the status of the laboratory with regard to the defined requirements (refer to Section 4.1). The main purpose of this period is that the laboratory shall prepare for initial accreditation. During this period, *WADA* will provide appropriate feedback to assist the laboratory in improving the quality of its testing process. In this period the laboratory shall:

6.2.1 Obtain ISO 17025 accreditation

The laboratory shall prepare and establish the required documentation and system according to the requirements in Application of ISO 17025 to Analysis of *Doping Control Sample* (Section 5) and the ISO 17025. Based on this, the laboratory shall initiate and prepare for the accreditation process by consulting with a relevant national accreditation body. An audit team consisting of representatives from a national accreditation body, including independent technical assessors recommended by *WADA* will audit the laboratory. Copies of the Audit Report shall be sent to *WADA*. The laboratory has to correct any identified non-conformities within defined time-frames and document this accordingly. Copies of the documentation of the correction of the non-conformities should be sent to *WADA*.

6.2.2 Participate in the *WADA* Proficiency Testing Program

The laboratory must complete a minimum of one year of successful participation in the *WADA* Proficiency Testing program prior to achieving initial accreditation. (See Annex A for description of the Proficiency Testing program.)

As a final proficiency test, the laboratory shall analyze 20-50 urine *Samples* in the presence of a *WADA* representative. Costs associated with the *WADA* on-site visit shall be at the laboratory's expense. The laboratory shall successfully identify and/or document a concentration in excess of the threshold of all of *the Prohibited Substances*, *Metabolite*(s) of *Prohibited Substances*, or *Marker*(s) of *Prohibited Substances* or Methods within five (5) days of the laboratory opening the *Samples*.The laboratory shall provide a Certificate of Analysis for each of the *Samples* in the proficiency test. For negative *Samples*, *WADA* may request all or a portion of the negative screening data. For each of the *Samples* for which there is an *Adverse Analytical Finding*, the laboratory shall provide a Laboratory Documentation Package. This data shall be submitted within two (2) weeks of submission of the initial report.

6.2.3 Implement Code of Ethics

The laboratory shall communicate the Code of Ethics (Annex B) to all employees and ensure understanding of and commitment to the different aspects of the Code of Ethics.

5.4.3.2.2 Three levels of access should be considered in the quality manual or threat assessment plan:

- Reception zone. An initial point of control beyond which unauthorized individuals must be escorted.
- 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 must 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 It is advisable to have a separate Controlled Zone for *Sample* receipt and Aliquot preparation.

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 in-house methods for compounds present on the *Prohibited List* and for related substances. The methods shall be selected and validated so they are fit for the purpose.

5.4.4.1.1 Non-threshold Substances

Laboratories are not required to measure or report a concentration for Non-threshold Substances.

The Laboratory must 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 must demonstrate the ability to achieve the Minimum Required Performance Limits using a representative substance or substances if the appropriate standards are available. In case a Reference Collection is used for identification, an estimate of the limit of detection for the method must be provided by assessing a representative substance.

5.4.4.1.2 Threshold Substances

The Laboratory must develop methods with an acceptable uncertainty near the threshold concentration. The method must be capable of documenting both the relative concentration and the identity of the *Prohibited Substance* or *Metabolite(s)* or *Marker(s)*.

Confirmation methods for Threshold Substances must be performed on three Aliquots from the "A" bottle and three Aliquots from the "B" bottle, if the "B" sample confirmation is performed. 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 and include consideration of uncertainty with the coverage factor, k, reflecting the number of Aliquots analyzed and a level of confidence of 95%. Reports and documentation, where necessary, shall report the mean concentration.

5.4.4.1.3 Minimum Required Performance Limit
For both Non-threshold and Threshold Substances, the Laboratory will be required to meet a Minimum Required Performance Limit for detection, identification, and demonstration that a substance exceeds the threshold (if required).

5.4.4.2 Validation of Methods

5.4.4.2.1 Confirmation methods for Non-threshold Substances must be validated. Examples of factors relevant to determining if the method is fit for the purpose are:

- Specificity. The ability of the assay to detect only the substance of interest must be determined and documented. The assay must 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 identification of a substance representative of the class of *Prohibited Substance*s can be repeatedly identified and detected as present in the sample at a concentration near the MRPL.

- Robustness. The method must be determined to produce the same results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results must be controlled.

- Carryover. The conditions required to eliminate carryover of the substance of interest from sample to sample during processing or instrumental analysis must be determined and implemented.

This section describes the technical and financial requirements the laboratory must fulfill in the process of being accredited by *WADA*. The description of the steps in the accreditation process is linked to the defined requirement presented in Section 4.

6.1 Applying for a WADA Laboratory Accreditation

6.1.1 Submit Application Form
The laboratory must fill in the necessary information in the Application Form as provided by *WADA* and deliver this to *WADA* with the required documentation and applicable fee. The Application shall be signed by the Laboratory Director and, if relevant, by the Director of the host organization.

6.1.2 Description of Laboratory
As preparations for an initial visit by *WADA*, the laboratory shall complete a questionnaire provided by *WADA* and submit it to *WADA* no later than four weeks after the receipt of the questionnaire. The following information shall be submitted through the questionnaire:

- List of staff and their qualifications

- Description of physical facilities, including a description of the security considerations for *Samples* and records

- List of proposed and actual instrumental resources and equipment

- List of available Reference Materials or standards, or plans to acquire Reference Materials or standards, including properly validated biological *Sample* Reference Collections

- Financial or business plan for the laboratory *WADA* may require an update of this documentation during the process of accreditation.

6.1.3 Provide a letter of support
According to 4.1.2 the laboratory shall provide necessary letters of support containing the required information from the relevant national public authorities, or *National Olympic Committee*, or *National Anti-Doping Organization.*

6.1.4 Conduct Initial visit
If necessary, *WADA* shall conduct an initial visit (2-3 days) to the laboratory at the laboratory's expense. The purpose of this visit is to clarify issues with regard to the accreditation process and the defined requirements in *the International Standard* for Laboratories and to obtain information about different aspects of the laboratory relevant for the accreditation.

6.1.5 Issue final report and recommendation
Within eight (8) weeks after the initial visit or the receipt of the questionnaire, *WADA* will complete and

When a reference standard 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 samples or isolates may be obtained from a biological matrix following an authentic and verifiable administration of a *Prohibited Substance* or *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 Method

5.4.7 Assuring the quality of test results

5.4.7.1 The Laboratory must participate in the *WADA* Proficiency Testing Program.

5.4.7.2 The Laboratory shall have in place a quality assurance system, including the submission of blind quality control samples, that challenges the entire scope of the testing process (i.e, sample receipt and accessioning through result reporting).

5.4.7.3 Analytical performance should 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 includes:

- Positive and negative controls analyzed in the same analytical run as the Presumptive *Adverse Analytical Finding Sample.*
- The use of deuterated or other internal standards or standard addition.
- Comparison of mass spectra or ion ratios from selected on monitoring (SIM) to a Reference Material or Reference Collection sample analyzed in the same analytical run
- Confirmation of the "A" and "B" Split Samples.
- Quality control charts using appropriate control limits (e.g., ± 20% of the target value) depending on the analytical method employed.
- The quality control procedures should be documented in the Laboratory.

6.0 Process of *WADA* Accreditation

- 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 standards 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 must be validated. Examples of factors relevant to determining if the method is fit for the purpose are:

- Specificity. The ability of the assay to detect only the substance of interest must be determined and documented. The assay must be able to discriminate between compounds of closely related structures.
- Intermediate Precision. The method must allow for the reliable repetition of the results at different times and with different operators performing the assay. Intermediate Precision at the threshold must be documented.
- Robustness. The method must be determined to produce the same results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results must be controlled.
- Carryover. The conditions required to eliminate carryover of the substance of interest from sample to sample during processing or instrumental analysis must be determined and implemented
- Matrix interferences. The method must 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 standards should be used for quantification, if available. If there is no reference standard available, the use of data or sample from a validated Reference Collection is acceptable.
- Minimum Required Performance Limits (*MRPL*). The Laboratory must demonstrate that it can detect representative compounds of each prohibited class at defined MRPLs. The Laboratory should also determine the limit of detection and limit of quantification if the MRPL is close to these limits.
- Linearity must 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*. Thus, quantitative uncertainty as defined in ISO/IEC 17025 does not apply. In the identification of a compound by GC/MS or HPLC/MS, there are qualitative measures that substantially decrease the uncertainty of identification.

In the case of a Threshold Substance, uncertainty in both the identification and the finding that the substance is present in an amount greater than the threshold concentration must be addressed.

5.4.4.3.1 Uncertainty in identification
The appropriate analytical characteristics must be documented for a particular assay. The Laboratory must establish criteria for identification of a compound at least as strict as those stated in any relevant Technical Document.

5.4.4.3.2 Uncertainty in establishing that a substance exceeds a threshold.

The purpose of threshold reporting in *Doping Control* is to establish that the *Prohibited Substance* or its *Metabolite*(s) or *Marker*(s) are present at a concentration greater than the threshold value. The method, including selection of standards and controls, and report of uncertainty should be designed to fit the purpose.

5.4.4.3.2.1 Uncertainty of quantitative results, particularly at the threshold value, should be addressed during the validation of the assay through measurement of Repeatability, Intermediate Precision and bias, where possible.

5.4.4.3.2.2 The expression of uncertainty should use the expanded uncertainty using a coverage factor, k, to reflect a level of confidence of 95 %. The expression of uncertainty may also take the form of a one-sided t-test at 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 Access to computer terminals, computers, 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.

5.4.4.4.1.2 The operating software and all files shall be backed up on a regular basis and a current copy kept off site at a secure location.

5.4.4.4.1.3 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.

5.4.4.4.1.4 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, the information that was changed, 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 Laboratories shall operate a program for the maintenance and calibration of equipment according to ISO 17025 Section 5.5.

5.4.5.3 General service equipment 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 shall be established for items such as fume hoods, centrifuges, evaporators, etc, which are 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 must be documented.

5.4.6 Measurement Traceability

5.4.6.1 Reference Standards
Few of the available reference drug and drug *Metabolite*(s) are traceable to national or international standards. 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. When available, a certificate of analysis or authenticity shall be obtained.

In the event of a false positive, the Laboratory will immediately cease testing for the class of *Prohibited Substances and Methods*. The Laboratory shall apply corrective actions within 12 hours of notification of the false positive. All *Samples* analyzed prior to the false positive will be re-analyzed for the class of *Prohibited Substances and 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 *Samples* in appropriate number to ensure that the risk of false negatives is minimal will be re-analyzed for the class of *Prohibited Substances and 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.

7.0 Requirements for supporting an *Adverse Analytical Finding* in the Adjudication Process
This section describes the relevant procedures to be followed where an *Athlete* challenges an *Adverse Analytical Finding* in a hearing as provided for by the *Code*.

7.1 Laboratory Documentation Package
In support of any *Adverse Analytical Finding* the Laboratory is required to provide the Laboratory Documentation Package described in detail in the Technical Document on Laboratory Documentation Packages.

The Laboratory is not required to provide any documentation not specifically included in the Laboratory Documentation Package. Therefore, the Laboratory is not required to support an *Adverse Analytical Finding* by producing, either to the Testing Authority or in response to discovery requests related to the hearing, standard operating procedures, general quality management documents (e.g., ISO compliance documents) or any other documents not specifically required by Technical Document on Laboratory Documentation Packages. References in the *International Standard* for Laboratories to ISO requirements are for general quality control purposes only and have no applicability to any adjudication of any specific *Adverse Analytical* Finding.

PART THREE: ANNEXES
ANNEX A - *WADA* PROFICIENCY TESTING PROGRAM

The *WADA* Proficiency Testing (PT) Program is designed to evaluate Laboratory proficiency and to improve test result uniformity between Laboratories, and to provide educational opportunities for the *WADA*-accredited Laboratories. The purpose of the individual PT sample will determine its composition and form.

6.2.4 Plan and implement research activities
The 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. At least two research and development activities shall be initiated and implemented within the probationary period.

6.2.5 Plan and implement sharing of knowledge
The laboratory shall prepare and convey information and knowledge on at least two specific issues to the other *WADA* accredited Laboratories within the probationary period.

6.3 Obtaining *WADA* Accreditation

6.3.1 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 audit. Representatives of *WADA* will audit compliance of the defined requirements in the Application of ISO 17025 to Analysis of *Doping Control Samples* (Section 5) and the practice and documentation of the laboratory. If *WADA* has participated in the initial ISO audit, the final *WADA* audit may be a document audit. Otherwise, the audit can be conducted together with the national 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 needed, the laboratory will have to correct identified non-compliances within defined time-frames and report these to *WADA*.

6.3.2 *WADA* report and recommendation
Based on the relevant documentation from the laboratory, any *WADA* technical advisor feedback, and the relevant accreditation body (Audit Report), *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*.

6.3.3 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 published annually by *WADA*.

6.4 Maintaining *WADA* Accreditation

6.4.1 Provide a new letter of support
Letter(s) of Support from a national public authority or *National Olympic Committee or National Anti-Doping Organizatio*n 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 17025 reaccreditation audit.

A letter of support from the host organization renewing its commitment to the Laboratory shall also be required in conjunction with each ISO 17025 re-accreditation audit.

6.4.2 Document annual number of tests
The Laboratory shall periodically report the results of all tests performed to *WADA* in a specified format. *WADA* will monitor *Sample* test volume performed by the Laboratory. If the number of *Samples* falls below 1500 per year, *WADA* Laboratory accreditation will be suspended or revoked in accordance with Section 6.4.8.

6.4.3 Flexible Accreditation
WADA accredited Laboratories may add or modify scientific methods or add analytes to its scope of work without the need for approval by the body that completed the ISO/IEC 17025 accreditation of that Laboratory. Any analytical method or procedure must be properly selected and validated and included in the scope of the Laboratory at the next ISO audit if use is continued.

6.4.4 Document Compliance with the *WADA* Laboratory Code of Ethics
The Laboratory Director must send a letter of compliance to *WADA* every year. The Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics (Annex B).

6.4.5 Document implemented research activities
The Laboratory must 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.

6.4.6 Document implemented sharing of knowledge
The Laboratory must supply an annual report sharing of knowledge with all other *WADA*-accredited Laboratories.

6.4.7 Participate in WADA/ISO periodical audits and the re-accreditation audit
WADA reserves the right to inspect and audit the Laboratory at any time. The notice of the audit/inspection will be made in writing to the Laboratory Director. In exceptional circumstances, the audit/inspection may be unannounced.

6.4.7.1 *WADA*/ISO Re-accreditation audit
The Laboratory must receive ISO/IEC 17025 accreditation including compliance with the Application of ISO 17025 for Analysis of *Doping Control Samples* (Section 5 of this document). The audit team may include a *WADA* Consultant to augment the auditing team selected by the national accrediting body for the re-accreditation audit.

Copies of the audit summary report as well as the Laboratory responses must be sent to *WADA*. The Laboratory shall also provide a copy of the ISO 17025 certificate obtained from the national certifying body.

- List of Laboratory staff
- List of staff scientists not normally employed by the Laboratory (if required)
- Training plan for new staff scientists
- List of instrumental resources and equipment
- Procedure manual specific to the satellite facility including analytical methods
- Summary of results management process including criteria for determining positive and negative results
- Methods of reporting test results in a secure manner to the appropriate authorities

Any changes that occur prior to the *Event* should be immediately reported to *WADA*.

Even if the testing is to be done at the Laboratory's regular facility, the Pre-*Event* Report must be completed, particularly in regard to personnel changes and any additional equipment.

6.5.4 Participate in *WADA* accreditation audit
WADA may choose to perform an independent on-site audit or a document audit of the satellite facility. Should an on-site audit take place, *WADA* expenses related to the audit will be at the Laboratory's expense. This audit may include analysis of a set of proficiency testing samples. The full complement of staff must be in attendance. Particular emphasis will be placed on involvement of new staff members to assess their competence.

6.5.5 Review the reports and correct identified non-conformities
The Laboratory Director must address and correct any identified non-compliances. The audit report and documentation of the corrective actions must be submitted to *WADA*.

6.5.6 Issue and publication of a temporary and limited Accreditation certificate
Based on the documentation provided, *WADA* shall 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 *Event* and an appropriate time before and after the actual competition.

6.5.7 Monitoring and assessment during the *Event*
WADA may choose at its sole discretion to have an observer in the Laboratory during the *Event*. The Laboratory Director is expected to provide full cooperation to the observer.

WADA, in conjunction with the *Major Event Organization*, will submit double blind proficiency testing samples to the Laboratory.

accreditation process. The Laboratory shall assume the travel and accommodation expenses of the *WADA* representative(s) in the event of on-site inspections.

6.4.11 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 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.

6.5 Accreditation Requirements for Satellite Facilities for Major *Events*
In general, the reporting time requirements for a major *Event* require that the Laboratory facility be at the location in proximity to the competition such that *Samples* can be delivered by *Event Doping Control* staff. This may require relocation of an existing Laboratory for a period of time sufficient to validate operations at the satellite facility and perform the testing for the *Event*.

In extraordinary circumstances, *Samples* may be transferred to an existing Laboratory facility. There must be agreement between the *Major Event Organization* and *WADA* regarding whether testing requirements such as turn-around time and the *Athlete* rights are met for in any eventuality. If the Laboratory is functioning within its regular facility, the requirements stated below with respect to facilities do not apply. The Laboratory will, however, be required to report on staffing, equipment, and *Sample* transport issues.

The Laboratory shall be responsible for providing *WADA* with regular updates on the progress of the testing facilities.

6.5.1 Participate in an initial *WADA*/ISO visit/inspection
WADA may visit 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.

6.5.2 Document ISO/IEC 17025 accreditation of the satellite facility
At least one month prior to the major *Event*, the Laboratory must provide documentation that the national accrediting body has provided ISO/IEC accreditation for the satellite facility in compliance with the Application of ISO/IEC 17025 to the Analysis of *Doping Control Samples* (Section 5). *WADA* may require that a *WADA* consultant be present at the national accrediting body audit of the satellite facility. *WADA*'s expenses associated with such audit, will be at the Laboratory's expense.

6.5.3 Complete a Pre-*Event* Report on Facilities and Staff
At least one (1) month prior to the *Event*, the Laboratory must report:

6.4.7.2 ISO Periodical audit
In years when a periodical ISO/IEC 17025 audit is required, the Laboratory shall provide *WADA* with a copy of any external audits and evidence of corrective actions for any non-compliance.

6.4.8 *WADA* report and recommendation
WADA will annually review Laboratory compliance with the requirements listed in Sections 4 and 5. With the exception of re-accreditation and other required on-site audits, the annual review will consist of a documentation audit. *WADA* may require documentation from the Laboratory. Failure of the Laboratory to provide information requested in evaluating performance by the specified date shall be considered a refusal to cooperate and result in Suspension or Revocation of accreditation.

WADA will consider the overall performance of the Laboratory in making decisions regarding continued accreditation. Applicant Laboratory performance on aspects of the standards described in Section 5 (such as turn-around times, Documentation Package contents, and feedback from client organizations) may be considered in this auditing.

6.4.8.1 Maintenance of accreditation
In the event that the Laboratory has maintained satisfactory performance, *WADA* will recommend to the *WADA* Executive Committee that the Laboratory be re-accredited.

6.4.8.2 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 *WADA* and the Olympic movement, *WADA* may immediately suspend a Laboratory's accreditation. If necessary, such decision may be taken by the Chairman of the *WADA* Executive Committee.

Examples of actions that could result in Suspension of accreditation include:

- Suspension of ISO 17025 accreditation;
- failure to take appropriate corrective action after an unsatisfactory performance;
- lack of compliance with any of the requirements or standards listed in *WADA International Standard* for Laboratories (including Annex A. Proficiency Testing);
- failure to cooperate with *WADA* or the relevant Testing Authority in providing documentation;
- failure to comply with the *WADA* Laboratory Code of Ethics.

WADA may recommend a Suspension of accreditation at any time based on the results of the Proficiency Testing program.

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 noncompliance must be corrected. If the non-compliance is not corrected during the Suspension period, the Laboratory accreditation will be revoked.

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.

6.4.8.3 Revocation of accreditation

The *WADA* Executive Committee revokes accreditation of any Laboratory accredited under these provisions if *WADA* 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 17025 accreditation;
- Unsatisfactory performance in analyzing and reporting results of drug tests
- Unsatisfactory participation in performance evaluations or Laboratory on-site audits;
- Failure to take appropriate corrective action following an unsatisfactory performance either in *Testing* or in a proficiency test;
- A material violation of this standard or other condition imposed on the Laboratory by *WADA*;
- Failure to correct a lack of compliance with any of the requirements or standards listed in *WADA International Standard* for Laboratories (including Annex A. Proficiency Testing) during a Suspension period;
- Failure to cooperate with *WADA* or the relevant Testing Authority during the Suspension phase;
- A serious 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; or
- 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.

A Laboratory whose accreditation has been revoked is ineligible to perform testing *of Doping Control Samples* for any Testing Authority.

If a Laboratory whose accreditation has been revoked should seek 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 *WADA*. In the case of exceptional circumstances, *WADA* shall determine what steps shall be followed prior to granting a new accreditation.

6.4.9 Notification

6.4.9.1 Written Notice

When a Laboratory is suspended or *WADA* seeks to revoke accreditation, *WADA* must immediately serve the Laboratory with written notice of the Suspension or proposed Revocation by facsimile mail, personal service, 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.

6.4.9.2 Effective Date

A Suspension is immediately effective. A proposed Revocation is effective 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.

6.4.9.3 Public Notice

WADA will immediately notify all relevant national public authorities, *National Anti-Doping Organizations*, *National Olympic Committees*, International Federations, and the IOC 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.

6.4.10 Re-accreditation Costs

On an annual basis, *WADA* will invoice the Laboratory for a portion of the costs associated with the re-

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 must 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 testing or expert testimony that would call into question the integrity of the individual or the scientific validity of work performed in the anti-doping program.

3.4. Other Testing

If the Laboratory accepts *Samples* from an 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 should not engage in testing that undermines or is detrimental to the anti-doping program of *WADA*. The Laboratory should not provide results that in any way suggests endorsement of products or services for *Athletes* or sports authorities. The Laboratory should not provide testing services in defense of an *Athlete* in a *Doping Control* adjudication.

3.5. Sharing of Information and Resources

3.5.1 New Substances

The *WADA*-accredited Laboratories for *Doping Control* shall inform *WADA* when they detect a new or suspicious doping agent.

When possible, the Laboratories shall share information regarding the detection of potentially new or rarely detected doping agents

3.5.2 Sharing of Knowledge

Sharing of knowledge shall consist of, but not be limited to, dissemination of information about new *Prohibited Substances and Methods* and their detection within sixty (60) days of discovery. 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. An example of the latter would be in establishing reporting standards for determination of an *Adverse Analytical Finding*.

1. Probationary period

The Proficiency Testing (PT) program is a part of the initial evaluation of a Laboratory seeking accreditation. In addition to providing samples as part of quarterly PT samples, the *WADA* will provide upon request samples from past PT rounds in order to allow the applicant Laboratory with an opportunity to evaluate its performance against the recorded performance of accredited Laboratories.

All procedures associated with the handling and testing of the PT samples by the Laboratory are, to the greatest extent possible, to be carried out in a manner identical to that applied to routine Laboratory *Samples*, 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 PT samples unless it is a scheduled maintenance activity. Methods or procedures used in routine testing should be employed.

Successful participation in 12-24 months of PT sample rounds is required before a Laboratory is eligible to be considered for accreditation. The PT samples shall occur at least quarterly and will consist of a minimum of five (5) samples per challenge. At least four (4) PT samples will contain Threshold Substances. Blank and adulterated samples may also be included.

2. Maintenance/Re-accreditation period

After accreditation, Laboratories shall be challenged with at least five (5) PT samples each quarter. Each year at least two (2) samples will contain Threshold Substances. Blank and adulterated samples may be included.

All procedures associated with the handling and testing of the PT samples by the Laboratory are, to the greatest extent possible, to be carried out in a manner identical to that applied to routine Laboratory *Samples*, 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 PT samples unless it is a scheduled maintenance activity. Methods or procedures not used in routine testing should not be employed.

2.1 Open PT Samples

The Laboratory may be directed to analyze a PT sample for a specific *Prohibited Substance*. In general, this approach is used for educational purposes or for data gathering.

2.2 Blind PT Samples

The Laboratory will be aware that the sample is a PT sample, but will not be aware of the content of the sample. Performance on blind PT samples is to be at the same level as for the open or non-blind PT samples.

2.3 Reporting – Open and Blind Proficiency Samples

The Laboratory should report the results of open and blind PT samples to *WADA* in the same manner as specified for routine *Samples*. For some samples or PT sample sets, additional information may be requested from the Laboratory.

2.4 Double Blind Proficiency Sample
The Laboratory will receive PT sample sets which are indistinguishable from normal testing samples. The samples may consist of blank, adulterated or positive samples. 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 proficiency.

3. Proficiency Test Sample Composition

3.1 Description of the Drugs
PT samples contain those *Prohibited Substances*, *Metabolite*(s) of *Prohibited Substances*, and *Marker*(s) of *Prohibited Substances and Methods* which each accredited Laboratory must be prepared to assay in concentrations that allow detection of the analytes by commonly used screening techniques. These are generally concentrations that might be expected in the urine 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 PT samples supplied to different Laboratories in a particular PT sample may vary but, within any annual period, all Laboratories participating are expected to have analyzed the same total set of samples.

A sample may contain more than one *Prohibited Substance*, *Metabolite(s)*, or *Marker* of a *Prohibited Substance or Method*. A PT sample will not contain more than three substances or their *Metabolite(s)*, or *Markers* of *Prohibited Substances or Methods*. 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.

3.2 Concentrations
PT samples may be spiked with *Prohibited Substances* and/or their *Metabolites* or may be from authentic administration studies. For Threshold Substances, the concentration in the sample will be guided by, but not limited to, one of the following criteria:

(i) at least 20 percent above the threshold for either the initial assay or the confirmatory test, depending on which is to be evaluated;

(ii) near or below the 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 will not be considered for evaluation for the purposes of the PT program.

For Non-threshold Substances, the concentration will be guided by, but not limited to, one of the following criteria:

(i) the *Prohibited Substance* and/or its major *Metabolite(s)* will be present in quantities greater than the Minimum Required Performance Limit;

2.3. Controlled substances
The Laboratories are expected to comply with the relevant national laws regarding the handling and storage of controlled (illegal) substances.

3. Testing

3.1. Competitions
The Laboratories shall only accept and analyze *Samples* originating from known sources within the context of *Doping Control* programs conducted in competitions organized by national and international sports governing bodies. This includes national and international federations, *National Olympic Committees*, 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 *samples* are collected according to the World Anti-Doping *Code International Standard* for Testing or the International Standard for Doping Control (ISO/PAS 18873), or similar guidelines. These guidelines must include collection of Split Samples; appropriate *Sample* container security considerations; and formal chain of custody conditions.

3.2. *Out-of-competition*
The Laboratories shall accept *Samples* taken during training (or *Out-of-competition*) only if the following conditions are simultaneously met:

(a) That the *Samples* have been collected and sealed under the conditions generally prevailing in competitions themselves as in Section 3.1 above;

(b) If the collection is a part of an anti-doping program; and

(c) If appropriate sanctions will follow a positive case.

Laboratories shall not accept *Samples*, for the purposes of either screening or identification, from commercial or other sources when the conditions in the above paragraph are not simultaneously met.

Laboratories shall not accept *Samples* from individual *Athletes* on a private basis or from individuals or organizations acting on their behalf.

These rules apply to Olympic and non-Olympic sports.

3.3. Clinical or Forensic
Occasionally the Laboratory is 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 must explain the pre-testing

4.4 Laboratories failing a proficiency test round are informed immediately by *WADA*. Laboratories must take and report corrective action within 30 calendar days to *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* must be implemented in the routine operation of the Laboratory. Repeated failures of the same type will result in *WADA* requiring corrective action.

Laboratories failing two consecutive rounds of the PT scheme will be immediately suspended. The Laboratory is required to provide documentation of corrective action with 10 working days of notification of Suspension. Failure to do so will result in immediate Revocation of the accreditation. Lifting of the Suspension occurs only when corrective action has been taken and reported to the *WADA*. The *WADA* may choose, at its sole discretion, to submit additional PT 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 proficiency testing round.

4.5 *WADA* is to evaluate the annual performance of all accredited Laboratories.

ANNEX B - LABORATORY CODE OF ETHICS

1. 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 sample to the Laboratory and the organization that is asserting the *Adverse Analytical Finding* in adjudication.

2. 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.

2.1. 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*.

2.2. Human subjects

The Laboratories must follow the Helsinki Accords and any applicable national standards as they relate to the involvement of human subjects in research.

Voluntary informed consent must also be obtained from human subjects in any drug administration studies for the purpose of development of a Reference Collection or proficiency testing materials.

(ii) the *Prohibited Substance* and/or its major *Metabolite(s)* will be present near the limit of detection 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 will not be considered for evaluation for the purposes of the PT program.

These concentrations and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.

Negative samples do not contain concentrations of any of the target drugs above the Minimum Required Performance Limit when analyzed by the normally used methods.

3.3 Blank or Adulterated *Samples*

PT samples include those that do not contain prohibited drugs or samples 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.

4. Evaluation of Proficiency Testing Results

4.1 Evaluation of Quantitative Results

When a quantitative determination has been reported, the results can be scored based on the true 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 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 two (2) and three (3) is deemed **questionable** performance. A z-score greater than three (3) is deemed **unacceptable** performance.

In addition, re-scaled sum of score (RSZ) and re-scaled sum of squared scores (RSSZ) will be calculated. While the z-score gives an estimate of bias, the RSZ, by retaining the sign of the biases, will reflect consistent systematic bias. The RSSZ, by eliminating the possibility that positive and negative bias will cancel, provides another indicator of bias. The RSZ and RSSZ are calculated by the equations

$$RSZ = \sum \frac{Z}{\sqrt{m}}$$

$$RSSZ = \sum \frac{Z^2}{m}$$

where m is the number of tests.

4.2 Probationary Period

4.2.1 Any false positive reported automatically disqualifies a Laboratory from further consideration for accreditation. The Laboratory will be eligible for reinstatement upon providing documentation that satisfies *WADA* that remedial and preventative actions have been implemented.

4.2.2 An applicant Laboratory is to achieve an overall grade level of 90 percent for PT samples required during the probationary period, i.e., it must correctly identify and confirm 90 percent of the total drug challenges (qualitative including adulterated samples).

4.2.3 An applicant Laboratory is to obtain satisfactory Z-scores for any quantitative results reported based on the mean of three replicate determinations. For the purposes of accreditation a quantitative result is required for threshold drugs. The relative standard deviation is to be commensurate with the validation data.

Any Laboratory that fails to achieve a satisfactory score for at least 90% of the quantitative determinations during the probationary period will be disqualified from further consideration. If the Laboratory receives fewer than 10 samples for quantitation in the year, the Laboratory may be allowed a single unsatisfactory result in the quantitative portion of the PT program during a 12 month period. The Laboratory will be eligible for reinstatement upon providing documentation that satisfies *WADA* that remedial and preventative actions have been implemented.

4.3 Maintenance and Re-Accreditation Period

4.3.1 No false positive drug identification is acceptable for any drug and the following procedures are to be followed when dealing with such a situation:

(i) The Laboratory is immediately informed of a false positive error by the *WADA*.

(ii) The Laboratory is to provide the *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.

(iii) The *WADA* shall review the Laboratory's explanation promptly and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error (clerical, sample mix-up, etc), the *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 *Samples*.

(v) If the error is determined to be a technical or methodological error, the Laboratory may be required to re-test all *Samples* analyzed positive by the Laboratory from the time of final resolution of the error back to the time of the last satisfactory proficiency test 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 Methods*, or may include any prohibited drug. The Laboratory shall immediately notify the *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, the *WADA* may decide to take no further action.

(vi) 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 the *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.

4.3.2 An accredited Laboratory must correctly identify 100 percent of the *Prohibited Substances* to pass the round of PT samples. It must correctly identify and confirm 100 percent of the total PT samples (qualitative including adulterated samples).

4.3.3 An accredited Laboratory is to obtain satisfactory Z-scores for any quantitative results reported based on the mean of three replicate determinations. For the purposes of accreditation a quantitative result is required for threshold drugs.

The relative standard deviation is to be commensurate with the validation data.

Any Laboratory that fails to achieve a satisfactory score for quantitative determinations will be deemed to have failed that sample challenge. The Laboratory must achieve a satisfactory score on 90% of the quantitative samples during the year. If the Laboratory receives fewer than 10 samples for quantitation in the year, the Laboratory may be allowed a single unsatisfactory result in the quantitative portion of the PT program during a 12 month period.

5.2.2 and all subsections with the exception of subsections 5.2.2.5 and 5.2.2.6 which are replaced by the following:

Provisions 5.2.2.5 and 5.2.2.6 apply to plasma, serum or other blood fractions containing no blood cells. *Samples* shall be frozen on reception until analysis and as soon as practical after aliquots have been taken for analysis. The Laboratory shall retain the A and B *Samples* for a minimum of three (3) months after the Testing Authority receives a negative report. The *Samples* shall be retained frozen under appropriate conditions.

Samples with irregularities shall be held frozen for a minimum of three (3) months following the report to the Testing Authority.

Samples that consist of whole blood or blood fractions containing intact cells shall be stored at approximately 4 degree Celsius on reception and should be analyzed within 48 hours. As soon as practicable after aliquots have been taken for analysis, *Samples* should be returned to approximately 4 degree Celsius storage. The antidoping Laboratory shall retain the A and B *Samples* 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.

5.2.3 and all subsections;

5.2.4 all subsections with the exception of subsections 5.2.4.1, 5.2.4.3.1.1, 5.2.4.2.1, 5.2.4.2.4, 5.2.4.3.1.2, 5.2.4.3.2.1, which are replaced or amended where needed by the following:

5.2.4.3.1.1 Screening and confirmation tests may be performed initially on the same aliquot of *Sample*. The test should be repeated on a fresh aliquot of the *Sample* to ensure that the initial test results are repeatable from the same *Sample* bottle.

Detection of blood transfusion relies upon the use of multiple antibodies and flow cytometry to reveal several red blood cell antigens. Consequently article 5.2.4.3.1.3 does not apply for this type of immunochemical analysis.

5.2.4.3.2.1 , for "B" *Sample* confirmation in whole blood or blood fraction with blood cells only, the "B" *Sample* analysis shall be completed within 30 days of notification of an "A" *Sample Adverse Analytical Finding*.

5.2.5 and all subsections;

5.2.6 and all subsections with the exception of 5.2.6.4, 5.2.6.7, and 5.2.6.8.

4. 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 Organization* 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 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 Substances* or *Methods*.

ANNEX C - LIST OF TECHNICAL DOCUMENTS

Title	Document Number	Version Number	Effective Date
Laboratory Internal Chain of Custody	TD2003LCOC	1.2	Jan 1, 2004
Laboratory Documentation Packages	TD2003LDOC	1.3	Jan 1, 2004
Minimum Required Performance Limits for Detection of Prohibited Substances	TD2004MRPL	1.0	Feb15,2004
Identification Criteria for Qualitative Assays Incorporating Chromatography and Mass Spectrometry	TD2003IDCR	1.2	Jan 1, 2004
Reporting Norandrosterone Findings	TD2004NA	1.0	Aug13, 2004
Reporting and Evaluation Guidance for Testosterone, Epitestosterone, T/E Ratio and other Endogenous Steroids	TD2004EAAS	1.0	Aug13, 2004
Harmonization of the Method for the Identification of Epoetin Alfa and Beta (EPO) and Darbepoetin Alfa (NESP) by IEF-Double Blotting and Chemiluminescent Detection	TD2004EPO	1.0	*In progress*
Measurement of Uncertainty for Anti-Doping Analysis			*Future*
Reporting Guidance for Gas Chromatography/Combustion/ Isotope Ratio Mass Spectrometry			*Future*
Reporting Guidance for Salbutamol and other Beta-2 Agonists			*Future*

WORLD ANTI-DOPING AGENCY
play true

Valid July, 1st, 2004.

ADDENDUM TO THE INTERNATIONAL STANDARD FOR LABORATORIES

REQUIREMENTS FOR ANTI-DOPING ANALYSIS OF WHOLE BLOOD, PLASMA, SERUM OR OTHER BLOOD FRACTIONS.

Several anti-doping tests have now been developed on the blood matrix, and can be applied to whole blood or blood fractions (e.g. plasma, serum) to determine doping practices in sport.

As currently established, the World Anti-Doping *Code International Standard* for Laboratories does not specifically cover procedures to handle and analyze the blood matrix in anti-doping Laboratories. Provision 5.2.4.4.1 of the *International Standard* for Laboratories refers to specific requirements for the analysis of the blood matrix to be promulgated separately.

The present document is established to complement or amend the existing *International Standard* for Laboratories, to provide ad hoc requirements to the Laboratories for handling and analyzing blood *Samples* in the context of anti-doping analysis.

The official text of the Addendum to 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.

Specific Requirements for Whole Blood or Blood Fractions Analyses

In any Sections that refer to urine, and are carried over into this document by reference, the terms blood, plasma, or serum shall be substituted as appropriate. Unless otherwise stated, there is no blood, plasma, or serum equivalent to the urine integrity test or data, and any reference to this should be deleted.

The following sections of Section 5 of the *International Standard* for Laboratories apply to the analysis of blood *Samples* by reference:

5.1 and all subsections;

5.2.1 and all subsections;

5.3 and all subsections;

5.4 and all subsections with the exception of 5.4.4.1, 5.4.4.2.2, 5.4.4.3, 5.4.6, and 5.4.7 which are amended, where applicable, by the following:

5.4.4.1 Selection of Methods
Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall develop, validate and document inhouse methods for substances on the *Prohibited List* or their Metabolites or Markers. The methods shall be selected and validated so they are fit for the purpose.

5.4.4.3 The Laboratory should provide an estimation of the measurement uncertainty where applicable.

5.4.6.2 Reference Collection
A collection of *Samples* or isolates may be obtained from a biological matrix following an authentic and verifiable administration or traceable mixture of a *Prohibited Substance* or *Method*, providing that the analytical data are sufficient to justify the identity of the *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Marker* of a *Prohibited Substance* or Method.

5.4.7.Assuring the quality of test results

5.4.7.1. The performance of Laboratories for analysis on the blood matrix will be evaluated as deemed necessary by the *World Anti-Doping Agency* under the principles of the *International Standard* for Laboratories specifically applied to the blood matrix.

5.4.7.2 The Laboratory shall have in place a quality assurance system, including the submission of blind quality control samples, that challenges the entire scope of the testing process.

5.4.7.3 Analytical performance should be monitored by operating quality control schemes appropriate to the type and frequency of blood testing performed by the Laboratory.

Applicable Technical Documents for blood analysis:

Laboratory Documentation Packages.

5.3 and all subsections;

5.4 and all subsections with the exception of 5.4.4.1, 5.4.4.2.2, 5.4.4.3, 5.4.6, and 5.4.7 which are amended, where applicable, by the following:

5.4.4.1 Selection of Methods
Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall develop, validate and document inhouse methods for substances on the *Prohibited List* or their Metabolites or Markers. The methods shall be selected and validated so they are fit for the purpose.

5.4.4.3 The Laboratory should provide an estimation of the measurement uncertainty where applicable.

5.4.6.2 Reference Collection
A collection of *Samples* or isolates may be obtained from a biological matrix following an authentic and verifiable administration or traceable mixture of a *Prohibited Substance* or *Method*, providing that the analytical data are sufficient to justify the identity of the *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Marker* of a *Prohibited Substance* or Method.

5.4.7.Assuring the quality of test results

5.4.7.1. The performance of Laboratories for analysis on the blood matrix will be evaluated as deemed necessary by the *World Anti-Doping Agency* under the principles of the *International Standard* for Laboratories specifically applied to the blood matrix.

5.4.7.2 The Laboratory shall have in place a quality assurance system, including the submission of blind quality control samples, that challenges the entire scope of the testing process.

5.4.7.3 Analytical performance should be monitored by operating quality control schemes appropriate to the type and frequency of blood testing performed by the Laboratory.

Applicable Technical Documents for blood analysis:

Laboratory Documentation Packages.

Laboratory Internal Chain of Custody.