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INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

MESSAGE

FROM

THE PRESIDENT OF THE UNITED STATES

TRANSMITTING

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT, ADOPTED BY THE UNITED NATIONS EDUCATIONAL, SCIENTIFIC, AND CULTURAL ORGANIZATION ON OCTOBER 19, 2005

FEBRUARY 6, 2008.—Treaty was read the first time, and together with the accompanying papers, referred to the Committee on Foreign Relations and ordered to be printed for the use of the Senate

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U.S. GOVERNMENT PRINTING OFFICE

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LETTER OF TRANSMITTAL

THE WHITE HOUSE, *February 6, 2008.*

To the Senate of the United States:

With a view to receiving the advice and consent of the Senate to ratification, I transmit herewith the International Convention Against Doping in Sport, adopted by the United Nations Educational, Scientific, and Cultural Organization on October 19, 2005.

The United States supported the development of the Convention as a means to ensure equitable and effective application and promotion of anti-doping controls in international competition. The Convention will help to advance international cooperation on and promotion of international doping control efforts, and will help to protect the integrity and spirit of sport by supporting efforts to ensure a fair and doping-free environment for athletes.

The International Olympic Movement has been supportive of the promotion and adoption of this Convention by the international community. Ratification by the United States will demonstrate the United States' longstanding commitment to the development of international anti-doping controls and its commitment to apply and facilitate the application of appropriate anti-doping controls during international competitions held in the United States. Ratification will also ensure that the United States will continue to remain eligible to host international competitions. The Convention does not cover U.S. sports leagues.

I recommend that the Senate give prompt and favorable consideration to the Convention and give its advice and consent to ratification.

GEORGE W. BUSH.

LETTER OF SUBMITTAL

THE SECRETARY OF STATE,
Washington, October 30, 2007.

The PRESIDENT,
The White House.

THE PRESIDENT: I have the honor to submit to you, with a view to its transmittal to the Senate for advice and consent to ratification, the International Convention Against Doping in Sport, adopted by the United Nations Educational, Scientific, and Cultural Organization on October 19, 2005.

The United States supported the development of the Convention as a means to ensure equitable and effective application and promotion of anti-doping controls in international competition. The Convention will help to advance international cooperation on and promotion of international doping control efforts and will help to protect the integrity and spirit of sport by supporting efforts to ensure a fair and doping-free environment for athletes.

The International Olympic Movement supports the promotion and adoption of this Convention by the international community. Ratification by the United States will demonstrate the United States' longstanding commitment to the development of international anti-doping controls and its commitment to apply and facilitate the application of anti-doping controls consistent with the Convention during competitions held in the United States. Ratification will also ensure that the United States will continue to remain eligible to host international competitions. An overview of the provisions of the Convention is enclosed.

The Office of National Drug Control Policy and the Department of Health and Human Services participated in or otherwise supported the negotiation of the Convention and join me in recommending that it be transmitted to the Senate at an early date.

Respectfully submitted,

CONDOLEEZZA RICE.

Enclosures: As stated.

International Convention Against Doping in Sport 2005
Overview

The International Convention Against Doping in Sport was negotiated under the auspices of the United Nations Educational, Scientific, and Cultural Organization ("UNESCO") and adopted by its General Conference on October 19, 2005. The Convention entered into force on February 1, 2007. The United States participated in the negotiations and supported development of the Convention as a means of promoting anti-doping control efforts for international competition based on the World Anti-Doping Code (the "Code").

This Convention builds on longstanding efforts of the international community, supported by the United States, to develop a common approach and standards for equitable anti-doping control and enforcement for international competition. These efforts led to the creation and adoption by the World Anti-Doping Agency ("WADA") of the Code in 2003. The Convention was developed to build on these efforts and support them by providing a common instrument that countries could join to demonstrate their commitment to the Code as the basis for national anti-doping control and policy. The International Olympic Movement is committed to the Convention as a means of promoting anti-doping control in sport and has indicated that it may bar countries that do not support the Convention from participating in or hosting Olympic Games in the future.

The terms of the Convention recognize that, notwithstanding the need to provide a common framework for anti-doping controls, regulation of sport is a matter of national law and policy. The Convention is not structured to secure changes to national law or regulation, but rather to secure commitments by parties to promote international collaboration, research, education, and their own national efforts and awareness of anti-doping control efforts and of the Code. The Convention was developed for application to competitions regulated by national and international anti-doping organizations pursuant to the World Anti-Doping Code. The convention does not apply to professional sports organizations or other competitions outside the jurisdiction of the World Anti-Doping Code. There are no obligations in the Convention that require any changes to existing United States law or policy and nothing in the Convention which, upon ratification, would require implementing legislation for the United States to meet its obligations.

The Convention consists of its main text, two annexes (The Prohibited List-International Standard and Standards for Granting Therapeutic Use Exemptions), and three appendices (the World Anti-Doping Code, International Standards for

Laboratories, and International Standards for Testing). The following article-by-article analysis provides a detailed discussion of the Convention.

Article-by-Article Analysis

Preamble

The preamble describes the basis and context for the Convention. It notes the value of sport as a means of promoting international understanding and the need to encourage and coordinate international cooperation towards the elimination of doping in sport.

Article 1 – Purpose of the Convention

This article notes that the purpose of the Convention is to promote the prevention of and the fight against doping in sport, with a view to its elimination.

Article 2 – Definitions

This article contains the definitions of certain terms used in the Convention. Relevant aspects of these terms are addressed in connection with the substantive provisions that use the terms.

Several provisions in the Convention create obligations with respect to the application of doping control measures to "athletes," "anti-doping organizations," and "sports organizations." We interpret these definitions, consistent with the purpose of the Convention, to create obligations solely with respect to those individuals and entities engaged in internationally-regulated competition, and we intend to apply the Convention accordingly.

Article 3 – Means to achieve the purpose of the Convention

This article sets out the means by which Parties commit to achieve the purposes of the Convention.

Under Subsection (a), the Parties undertake to adopt "appropriate" measures at the national and international levels that are consistent with the principles of the Code. This provision does not create any obligation on Parties to take any actions beyond those set out elsewhere in the Convention, but it notes that actions taken by Parties to advance the purposes of the Convention should be consistent with the principles of the Code. Article 4(2) of the Convention, however, notes that the Code itself does not create any binding obligations. The United States supports the principles of the Code.

Under Subsection (b), the Parties undertake to encourage all forms of international cooperation aimed at protecting athletes and ethics in sport and at sharing anti-doping research.

Under Subsection (c), the Parties undertake to foster international cooperation between Parties and anti-doping organizations, in particular the WADA.

Article 4 – Relationship of the Convention to the Code

This provision confirms that the Code and the other appendices to the Convention are included for information purposes and do not create any binding obligations under the Convention. Notwithstanding this status, under this article Parties commit to the principles of the Code as the basis for measures under Article 5 of the Convention. United States anti-doping policy is consistent with the principles of the Code. This provision also makes it clear that nothing in the Convention restricts a Party from adopting additional measures that are complementary to the Code. This provision also states that, unlike the appendices, the two annexes to the Convention (The Prohibited List – International Standard and Standards for Granting Therapeutic Use Exemptions) are integral parts of the Convention.

Article 5 – Measures to achieve the objectives of the Convention

This article states that Parties undertake to adopt "appropriate" measures in abiding by the obligations under the Convention. It states that such measures may include legislation, regulation, policies, or administrative practices. Nothing in this article or elsewhere in the Convention interferes with a Party's sovereign authority to fulfill its obligations under the Convention by whatever means it chooses under its national system.

Article 6 – Relationship to other international instruments

This article establishes that nothing in the Convention affects the rights and obligations arising from any existing convention previously concluded and consistent with the object and purpose of this Convention.

Article 7 – Domestic coordination

This article provides that Parties shall ensure application of the Convention through domestic coordination. This article does not impose any obligation on Parties regarding domestic implementation of their obligations under the Convention, which remain governed by national systems and by Articles 5 and 35 of the Convention. The article notes that Parties may rely on anti-doping

organizations as well as sports authorities and organizations to meet their obligations under the Convention.

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

This article imposes general obligations that the United States can implement with no changes in law or policy. Paragraph 1 requires each Party to adopt measures where appropriate to restrict the availability of prohibited substances and methods in order to restrict their use in sport by athletes, unless their use is based on a therapeutic use exemption. Many substances on WADA's Prohibited List are controlled substances whose production, movement, importation, distribution, and sale are controlled by the Federal Controlled Substances Act. In addition, a number of the non-controlled substances on the Prohibited List are nevertheless subject to provisions of the Federal Food, Drug, and Cosmetic Act that restrict their use to legitimate medical activities and prohibit trafficking. These legal restrictions apply to athletes and athlete support personnel. In addition to the restrictions contained in the Federal Controlled Substances Act and Federal Food, Drug, and Cosmetic Act, states have parallel laws that address the trafficking, possession, and use of many of the substances on the Prohibited List. In addition, an increasing number of states have implemented student drug testing programs and education initiatives to prevent the use of doping substances on the Prohibited List. Federal resources are available to assist with such activities.

Paragraph 2 requires Parties to adopt or encourage, where appropriate, the adoption of measures to prevent and restrict the use and possession of prohibited substances and methods by athletes. The United States already takes such steps through, among other things, its financial and other support of the activities of the Office of National Drug Control Policy and support of the anti-doping control activities of the United States Anti-Doping Agency ("USADA") and the United States Olympic Committee.

Article 9 – Measures against athlete support personnel

This article requires Parties to take measures, or to encourage sports organizations and anti-doping organizations to take anti-doping measures, aimed at athlete support personnel. The United States already undertakes such measures through its support of the USADA, whose policies and testing protocols are consistent with the Code and contain provisions specifically addressing sanctions and penalties applicable to athlete support personnel.

Article 10 – Nutritional supplements

This article requires Parties, where appropriate, to 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. The United States could meet this obligation with no change in existing law or policy. The Dietary Supplement Health Education Act of 1994 ("DSHEA") requires that dietary supplement manufacturers must ensure that a dietary supplement is safe before it is marketed, and that its product label information is truthful and not misleading. The law sets forth post-marketing requirements that include monitoring safety, for example, adverse event reporting. In June 2007, the Federal Food and Drug Administration ("FDA") established regulations requiring good manufacturing practices for dietary supplements which are designed to ensure that such supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled. Through these and other measures, the United States currently meets the obligations that would arise under this article.

Article 11 – Financial measures

This article obligates Parties, where appropriate, to use certain financial measures to promote anti-doping control. Paragraph (a) requires Parties, where appropriate, to fund a national testing program across all sports or to provide financial assistance to sports organizations and anti-doping organizations through subsidies or grants. Paragraphs (b) and (c) obligate Parties, where appropriate, to withhold sport-related financial support from individual athletes and athlete support personnel who have been suspended following an anti-doping violation, or from any sports organization or anti-doping organization not in compliance with the Code.

The United States would currently meet the obligations of this article by virtue of its provision of annual funding to support the anti-doping testing program of the USADA. The testing protocols of the USADA are consistent with the Code, and sanctions under the program are consistent with the obligations of this article of the Convention.

Article 12 – Measures to facilitate doping control

This article obligates Parties, where appropriate, to undertake certain activities to facilitate the anti-doping control activities of sports organizations and anti-doping organizations.

Paragraph (a) obligates Parties to encourage and facilitate the implementation of doping controls by sports organizations and anti-doping

organizations, including no-advance notice, out-of-competition, and in-competition testing. By virtue of its annual funding of the USADA and policy coordination and collaboration with the USADA in support of its programs, the United States would currently meet this obligation as a matter of policy and practice.

Paragraph (b) obligates Parties to encourage and facilitate the negotiation by sports organizations and anti-doping organizations of agreements permitting their members to be tested by authorized anti-doping control teams from other countries. Paragraph (c) obligates Parties to assist sports organizations and anti-doping organizations within their jurisdictions to gain access to accredited doping control laboratories for the purpose of doping control analysis. The United States would currently meet the obligations set out in these paragraphs through its consistent and ongoing support of cooperation among anti-doping organizations, and through its support of the USADA and its extensive efforts in this area. The USADA is an active member of the Executive Committee of the Association of National Anti-doping Organizations (ANDO). ANDO members undertake cooperative action to promote compliance with the Code, including the facilitation of cooperation as set out in this article. USADA has also partnered with national anti-doping agencies and provided expert advice, administered out-of-competition testing, and conducted drug control officer training services. The United States has supported the USADA in its efforts to enter into agreements contemplated by this article, and the USADA has entered into such agreements, notably with WADA's Central American Regional Anti-Doping Organization, which performs Code-compliant testing in eight countries.

Article 13 – Cooperation between anti-doping organizations and sports organizations

This article obligates Parties to advance the purpose of the Convention by encouraging cooperation between anti-doping organizations, public authorities, and sports organizations within their jurisdiction and those of other countries. The United States would satisfy this obligation as a matter of current policy and practice. The United States collaborates with other public authorities and promotes collaboration with and among anti-doping organizations and sports organizations through its service on the Executive Committee, Foundation Board, and several key committees of WADA. The United States also advances public anti-doping support and public-private anti-doping control activities through its participation in regional anti-doping control bodies. It plays an active role in the Americas Sports Council, an informal organization of 42 governments from North, South, and Central America dedicated to advancing drug-free sport in the Americas, and participates in anti-doping activities of the Council of Europe and the Caribbean Community (CARICOM).

Article 14 – Supporting the mission of the World Anti-Doping Agency

The article affirms the general support by Parties of WADA in the international fight against doping.

Article 15 – Equal funding of the World Anti-Doping Agency

This article notes that Parties support the "principle" of equal funding of WADA's approved annual core budget by public authorities and the Olympic Movement. This provision reaffirms principles that have been agreed within the governance structures of WADA, including by the United States, but creates no separate legal obligation with respect to these principles. Funding of WADA is determined within its governance structures, and nothing in this Convention creates obligations or alters the right of Parties to adjust funding principles or structures of WADA in any manner they decide is appropriate.

Article 16 – International cooperation in doping control

This article obligates Parties to take certain steps to facilitate international cooperation in anti-doping testing and control. Parties are only obligated to take steps under this article to the degree they are "appropriate and in accordance with domestic law and procedures." No changes in existing U.S. law or policy would be necessary to meet the obligations that would arise under this article.

Paragraphs (a), (d), (e), (f), and (g) obligate Parties to facilitate, subject to relevant host countries' regulations, the work of the WADA and anti-doping organizations in conducting in- or out-of-competition doping controls on their athletes, on their territory, or elsewhere in a manner consistent with the Code, and to take other efforts to support and facilitate international cooperation on certain anti-doping control measures. The United States currently facilitates such activities through its support of the activities of the USADA. The USADA actively engages in anti-doping testing cooperation with appropriate Code-compliant anti-doping organizations. In 2006, the USADA established out-of-competition testing agreements to provide and/or request testing services with 21 anti-doping organizations and contracted to conduct testing on U.S. athletes training and competing in 19 countries. The USADA provided Code-compliant domestic in-competition testing services to a number of international sports federations and organizing committees of the Olympic games. The United States supports the mutual recognition of Code-compliant results management decisions and works with international federations, WADA, and national anti-doping organizations to ensure recognition of sanctions.

Under Paragraph (b), Parties commit to facilitate the timely movement of duly authorized doping control teams across their borders when conducting doping control activities. Because this provision is subject to domestic law and procedures and need only be implemented where appropriate, it does not require changes in U.S. border control law, nor does it require the United States to provide favorable immigration treatment to individuals engaged in doping control activities if it does not deem doing so appropriate as a matter of national policy.

Under Paragraph (c), Parties commit to cooperate to expedite the timely shipping or carrying across borders of samples in such a way as to maintain their security and integrity. As with Paragraph (b), because this provision is subject to domestic law and procedures and need only be implemented where appropriate, it does not require changes in United States border control law, nor does it require the United States to provide special treatment for anti-doping samples crossing its border.

Article 17 – Voluntary Fund

This article establishes a voluntary fund (the "Voluntary Fund") dedicated to providing assistance to Parties for the implementation of their obligations under the Convention. The article notes that any contributions to the Voluntary Fund are purely voluntary, sets out the type of entities that may contribute to the Voluntary Fund (and authorizes the Conference of Parties to broaden the category of resources which may comprise the Voluntary Fund), and notes that a Party's contributions to the Voluntary Fund do not offset any obligation it may have to contribute to the WADA annual budget. Nothing in this provision would impose any financial obligation on the United States.

Article 18 – Use and governance of the Voluntary Fund

This article sets out the terms of governance and use of the Voluntary Fund. The Voluntary Fund is to be allocated by the Conference of Parties for activities approved by it, notably the assistance of Parties in their anti-doping control efforts consistent with the Convention. Notwithstanding the control exercised by the Conference of Parties over the Voluntary Fund, the Convention limits that control by providing that no political, economic, or other conditions may be attached to contributions to the Voluntary Fund.

Article 19 – General education and training

This article obligates Parties, within their means, to support, devise, or implement education and training programs on anti-doping. The article further outlines the type of education and training programs that Parties "should" support in meeting its obligations under this provision. The United States currently funds a

number of programs that would fall within the scope of its obligations under this article.

The United States supports two research-derived school-based steroid education programs, the ATLAS (Adolescents Training and Learning to Avoid Steroids) program, and the ATHENA (Athletes Targeting Healthy Exercise and Nutrition Alternatives) program. The United States also supports anti-doping education through its support of the USADA, which traditionally directs more than 10 percent of its annual budget toward education programs targeting schoolchildren, emerging elite athletes, coaches, and parents. The United States also provides federal grant funds to operate student drug testing programs and education initiatives, such as activities undertaken by the Department of Education's Office of Safe and Drug-Free Schools.

Article 20 – Professional codes of conduct

This article obligates Parties to "encourage" 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. The United States would meet its obligations under this provision through its existing support of the activities of the USADA and the USOC in this area. The USADA and the USOC each work to ensure that various national sport governing bodies develop and implement codes of conduct and doping rules that are consistent with the Code, and excludes from competition any Olympic-recognized national sports federation that fails to implement such rules. The USADA also works with medical and health professional associations, such as the American Medical Association and the American College of Sports Medicine, on raising awareness of the health and ethical effects of doping.

Article 21 – Involvement of athletes and athlete support personnel

This article obligates Parties to 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. The United States would currently fulfill its obligations under this provision through its existing support of the USADA (which involves athletes and athlete support personnel in its governing bodies and anti-doping programs), the policies and practices of WADA (which has directly involved athletes in its anti-doping work), and through various outreach policies of the Office of National Drug Control Policy.

Article 22 – Sports organizations and ongoing education and training on anti-doping

Under this article Parties are obligated to "encourage" sports organizations and anti-doping organizations to implement ongoing education and training programs on the subjects identified in Article 19. The United States would currently meet its obligations under this article through its existing support of the USADA as well as through direct implementation of the federal programs discussed in connection with Article 19.

Article 23 – Cooperation in education and training

This article obligates Parties to share, where appropriate, information, expertise, and experience on effective anti-doping programs with other Parties and relevant anti-doping organizations. The United States already shares information collected and expertise accrued through its own education and training experience with its counterparts and with relevant anti-doping organizations. It does so through its participation and leadership in WADA and in collaboration with governments and organizations in organizations such as UNESCO, the Council of Europe, the Americas Sports Council, and CARICOM.

Article 24 – Promotion of research in anti-doping

Article 24 obligates Parties, "within their means," to encourage and promote anti-doping research in cooperation with sports and other relevant organizations on (a) prevention, detection methods, behavioral and social aspects, and the health consequences of doping, (b) ways and means of devising scientifically-based physiological and psychological training programs, and (c) the use of emerging substances and methods arising from scientific developments.

The United States may implement this obligation without any change in law or policy. The United States already funds significant research related to anti-doping, both directly and through the USADA. The USADA spends between 15 and 20 percent of its budget on research, and, among other research promotion activities, sponsors an annual international conference that brings together anti-doping researchers. The United States also supports anti-doping research activities through the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA) and the Drug Enforcement Administration (DEA).

Articles 25 and 26 – Nature of anti-doping research; Sharing the results of anti-doping research

Article 25 obligates Parties, while promoting anti-doping research, to ensure that such research will comply with internationally recognized ethical practices, avoid the administration to athletes of prohibited substances and methods, and be

undertaken with adequate precautions to prevent the results of the research from being used for doping purposes. Article 26 obligates Parties, where appropriate and subject to national and international law, to share the results of their research with other Parties and with WADA.

The United States currently promotes research in a manner consistent with the principles of these articles. It has, through ONDCP, promoted the sharing of research results by coordinating research collaboration between WADA's Science and Research Department and government officials from NIH, NIDA, and the FDA.

Article 27 – Sport science research

This article requires Parties to encourage members of the scientific and medical communities to carry out sport science research in accordance with the principles of the Code and to encourage sports organizations and athlete support personnel within their jurisdiction to implement such research. The United States already encourages and directly supports the sports science research of organizations such as the American College of Sports Medicine, the American Medical Association, and other medical and public health groups. Through its support of the USADA and its programs, the United States supports the dissemination of the results of this research and the implementation of policies and programs based on this research by sports organizations and athlete support personnel.

Article 28 – Conference of Parties

This article is a standard provision establishing the Conference of Parties (the "COP") of the Convention. The COP of this Convention meets once every two years, or more frequently if it so decides or if requested by one-third of the Parties. The Convention allows the COP to establish and amend its rules of procedure, as it deems appropriate, subject to the rule above on the frequency of meetings and the requirement that each Party shall have one vote.

Article 29 – Advisory organization and observers to the Conference of Parties

This article provides that the WADA will be invited as an advisory organization to the COP and that the following organizations shall have the right to participate as observers: the International Olympic Committee, the International Paralympic Committee, the Council of Europe, and the Intergovernmental Committee for Physical Education and Sport. It also provides that the COP may invite other relevant organizations as observers. The terms of participation by observers shall be determined by the rules of procedure of the COP, as provided under Article 28.

Article 30 – Functions of the Conference of Parties

This article enumerates specific functions of the COP, in addition to those provided elsewhere in the Convention, and notes that in implementing these functions the COP may cooperate with other intergovernmental bodies. These functions are the following:

(a) Promote the purpose of the Convention. Parties may undertake collective action through the COP and its Secretariat to promote the purpose of the Convention.

(b) Discuss the relationship with WADA and study the mechanisms of funding WADA's core budget (the Convention provides that State non-Parties may be invited to these discussions). Though this provision notes that the COP may discuss WADA funding, the COP is not authorized to take any action to determine WADA funding mechanisms, which remain within the governance structures of WADA.

(c) Adopt a plan for the use of resources of the Voluntary Fund, as provided for in Article 18.

(d) Examine bi-annual reports submitted by the Parties pursuant to Article 31 regarding measures they have undertaken to implement the Convention. Though the COP may examine these bi-annual implementation reports, the Convention does not provide a mechanism for the COP to take any formal action on these reports.

(e) Monitor compliance with the Convention in accordance with the reports submitted by Parties to the COP pursuant to Article 31.

(f) Examine draft amendments of the Convention for adoption under the procedures outlined in Articles 33 and 34.

(g) Examine, for approval, modifications to the Prohibited List and to the Standards for Granting Therapeutic Use Exemptions adopted by WADA pursuant to the procedures set out in Article 34.

(h) Define and implement cooperation between Parties and WADA within the framework of the Convention. This provision does not affect a Party's sovereign right to implement its obligations under the Convention, as it deems appropriate.

(i) Request a report from WADA on the implementation of the Code to each of its sessions for examination.

Article 31 – National reports to the Conference of Parties

Under this article Parties are obligated to report to the COP every two years on the measures taken by them to implement their obligations under the Convention. As provided in Article 30, the COP may examine these reports, but the Convention does not set out any formal action or sanction that the COP may take as a result of these reports.

Article 32 – Secretariat of the Conference of Parties

This article provides for the establishment of a Secretariat for the COP within (UNESCO). The Secretariat will be provided by UNESCO, and functioning costs related to the Convention will be funded from the UNESCO budget "within its existing resources at an appropriate level," the Voluntary Fund, or some combination of the two funding sources as determined by the COP every two years. Recognizing that the primary financial burden for operation of the COP Secretariat should be borne by Parties to the Convention, the article provides that funding from UNESCO core budget resources should be provided on a strictly minimal basis. The article notes that the Secretariat shall provide support to the COP and shall have the authority to ensure the implementation of its decisions.

Articles 33 and 34 – Amendments: Specific amendment procedure for the Annexes to the Convention

These articles contain provisions regarding the amendment procedure and the adoption of amendments to the annexes to the Convention that are common to several international agreements to which the United States is party. Article 33 provides that any Party may propose amendments to the Convention. Proposed amendments will be circulated to all Parties by the Director-General of UNESCO, and, if within six months of such circulation at least half of the Parties have consented, the Director-General will present the proposals to the following session of the COP. Amendments may be adopted by a two-thirds majority vote of the Parties present and voting.

Following adoption, amendments to the Convention shall enter into force, for those Parties that have accepted them, three months after the deposit of instruments of ratification, acceptance, approval, or accession by at least two-thirds of the Parties, and, for any other Party, three months after deposit of its instrument of ratification, acceptance, approval, or accession. A State that becomes a Party to the Convention after entry into force of an amendment shall, failing an expression

of different intention, become a Party to the Convention as amended or, with respect to the Parties not bound by the amendment, a Party to the unamended Convention.

Regarding the annexes to the Convention, Article 34 provides that if WADA amends the Prohibited List or the Standards for Granting Therapeutic Use Exemptions, it may inform the Director General of UNESCO of the changes. The Director General of UNESCO shall then notify the COP of the changes, which shall be considered for approval by the COP as proposed amendments to the relevant annex to the Convention at one of its sessions or through written consultation under a 45-day "no-objection" procedure. Unless two-thirds of the Parties express an objection within 45 days of the notification of the proposed amendment, the amendment will be deemed approved and, 45 days following approval, in force among all Parties who did not previously notify the Director-General that they do not accept the amendments. For Parties that have made such notifications, the Annexes will remain in force as unamended.

Articles 35-43 – Final clauses

Articles 35 through 43 are final clauses that are routinely included in conventions negotiated under the auspices of the United Nations and its specialized agencies.

Article 35 recognizes that Parties with federal systems may not have the constitutional authority at the national level to implement certain obligations under the Convention. It notes that such Parties are not obligated to implement those obligations at the federal level but must nevertheless inform the competent sub-national authorities of such obligations and recommend that the obligations be implemented by them at the sub-national level.

Articles 36 and 37 are standard provisions on ratification and entry into force. Article 36 provides that the Convention will be open to ratification, acceptance, approval, or accession by States that are members of UNESCO. Article 37 notes that the Convention will enter into force on the first day of the month following the deposit of the thirtieth such instrument. For States that subsequently express their consent to be bound, the Convention will enter into force on the first day of the month following one month after the deposit of its instrument. Article 38 allows for Parties who are the administering powers of a territory or territories, and who are responsible for their international relations, to specify the territories to which the Convention shall apply.

Article 39 provides for denunciation of the Convention by any Party, through an instrument deposited with the Director General of UNESCO. Such denunciation is effective on the first day of the month following a period of six months after the date of receipt of the instrument of denunciation.

Articles 40 through 42 are standard provisions which specify that UNESCO shall serve as the depository for the Convention and set out its administrative responsibilities, note that the Convention shall be registered at the Secretariat of the United Nations, and state that each of its texts are equally authoritative.

Article 43 states that no reservations may be made to the Convention that are incompatible with the object and purpose of the Convention. This provision preserves standard reservation practice in permitting reservations that are consistent with the object and purpose of the Convention.

Annexes I and II – The Prohibited List-International Standard and the Standards for Granting Therapeutic Use Exemptions

Annexes I (The Prohibited List – International Standard) and II (Standards for Granting Therapeutic Use Exemptions) are integral parts of the Convention. The Annexes as adopted in 2005 were approved and adopted by WADA, and the United States actively supported each Annex in its capacity as a member of WADA's Executive Committee and Foundation Board. Each Annex defines the scope of a Party's obligation to adopt control measures under Article 8 of the Convention by setting out the prohibited substances that are subject to control measures and applicable therapeutic use exemptions. Annex I was subsequently amended in accordance with the amendment procedure set out in Article 34 of the Convention to reflect modifications by WADA to its Prohibited List. The revised Annex I, effective 2007, and Annex II as adopted in 2005 have been adopted by USADA and serve as the basis of its anti-doping control measures. Upon ratification, the United States would be bound by the terms of Annex I as revised.

Appendices 1-3, The World Anti-Doping Code, International Standard for Laboratories, and International Standard for Testing

Pursuant to Article 4, Appendices 1, 2, and 3 are included for information purposes and are not integral parts of the Convention. They do not contain any binding obligations on Parties.

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

Paris, 19 October 2005

INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

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,

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.

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.

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.

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:

(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;

      (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) 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.

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;

   (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 States Members 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.

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 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.

Annex I – The Prohibited List – International Standard

Annex II – Standards for Granting Therapeutic Use Exemptions

Appendix 1 – World Anti-Doping Code

Appendix 2 – International Standard for Laboratories

Appendix 3 – International Standard for Testing

WORLD
ANTI-DOPING
AGENCY

The World Anti-Doping Code

THE 2008 PROHIBITED LIST

INTERNATIONAL STANDARD

The official text of the *Prohibited List* 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.

This List shall come into effect on 1 January 2008

The Prohibited List 2008
September 22, 2007

THE 2008 PROHIBITED LIST
WORLD ANTI-DOPING CODE

Valid 1 January 2008

The use of any drug should be limited to medically justified indications

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

PROHIBITED SUBSTANCES

S1. ANABOLIC AGENTS

Anabolic agents are prohibited.

1. Anabolic Androgenic Steroids (AAS)

a. Exogenous* AAS, including:

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

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

b. Endogenous** AAS:

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

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

Where an anabolic androgenic steroid is capable of being produced endogenously, a *Sample* will be deemed to contain such *Prohibited Substance* and an *Adverse Analytical Finding* will be reported where the concentration of such *Prohibited Substance* or its metabolites 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 Analytical Finding* if, based on any reliable analytical method (e.g. IRMS), the laboratory can show that the *Prohibited Substance* is of exogenous origin. In such case, no further investigation is necessary.

When a value does not so deviate from 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 reliable 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 longitudinal profile of the *Athlete* established by the subsequent 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 and the application of any reliable analytical method (e.g. IRMS) has not 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 considered to be scientific and valid 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 contain a *Prohibited Substance*.

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

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

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

S2. HORMONES AND RELATED SUBSTANCES

The following substances and their releasing factors, are prohibited:

1. **Erythropoietin (EPO);**
2. **Growth Hormone (hGH), Insulin-like Growth Factors (**e.g. **IGF-1), Mechano Growth Factors (MGFs);**
3. **Gonadotrophins (e.g. LH, hCG),** prohibited in males only;
4. **Insulins;**
5. **Corticotrophins.**

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

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* 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 exogenous origin, the *Sample* will be deemed to contain a *Prohibited Substance* and shall be reported as an *Adverse Analytical Finding*.

S3. BETA-2 AGONISTS

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

As an exception, formoterol, salbutamol, salmeterol and terbutaline when administered by inhalation, require an abbreviated Therapeutic Use Exemption.

Despite the granting of any form of Therapeutic Use Exemption, a concentration of salbutamol (free plus glucuronide) greater than 1000 ng/mL will be considered an *Adverse Analytical Finding* unless the *Athlete* proves that the abnormal result was the consequence of the therapeutic use of inhaled salbutamol.

S4. HORMONE ANTAGONISTS AND MODULATORS

The following classes are prohibited:

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*, epitestosterone, probenecid, alpha-reductase inhibitors (e.g. **finasteride, dutasteride), plasma expanders (**e.g. **albumin, dextran, hydroxyethyl starch)** 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 for drosperinone, which is not prohibited).

* A Therapeutic Use Exemption is not valid if an *Athlete*'s urine contains a diuretic in association with threshold or sub-threshold levels of a *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).

M2. CHEMICAL AND PHYSICAL MANIPULATION

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

2. Intravenous infusion is prohibited. In an acute medical situation where this method is deemed necessary, a retroactive Therapeutic Use Exemption will be required.

M3. GENE DOPING

The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance, is prohibited.

SUBSTANCES AND METHODS PROHIBITED IN-COMPETITION

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

PROHIBITED SUBSTANCES

S6. STIMULANTS

All stimulants (including both their (D- & L-) optical isomers where relevant) are prohibited, except imidazole derivatives for topical use and those stimulants included in the 2008 Monitoring Program*.

Stimulants include:

Adrafinil, adrenaline, amfepramone, amiphenazole, amphetamine, amphetaminil, benzphetamine, benzylpiperazine, bromantan, cathine***, clobenzorex, cocaine, cropropamide, crotetamide, cyclazodone, dimethylamphetamine, ephedrine****, etamivan, etilamphetamine, etilefrine, famprofazone, fenbutrazate, fencamfamin, fencamine, fenetylline, fenfluramine, fenproporex, furfenorex, heptaminol, isometheptene, levmethamfetamine, meclofenoxate, mefenorex, mephentermine, mesocarb, methamphetamine (D-), methylenedioxyamphetamine, methylenedioxymethamphetamine, p-methylamphetamine, methylephedrine****, methylphenidate, modafinil, nikethamide, norfenefrine, norfenfluramine, octopamine, ortetamine, oxilofrine, parahydroxyamphetamine, pemoline, pentetrazol, phendimetrazine, phenmetrazine, phenpromethamine, phentermine, 4-phenylpiracetam (carphedon), prolintane, propylhexedrine, selegiline, sibutramine, strychnine, tuaminoheptane** and other substances with a similar chemical structure or similar biological effect(s).

* The following substances included in the 2008 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.

A stimulant not expressly mentioned as an example under this section should be considered as a Specified Substance only if the *Athlete* can establish that the substance is particularly susceptible to unintentional anti-doping rule violations because of its general availability in medicinal products or is less likely to be successfully abused as a doping agent.

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 orally, rectally, intravenously or intramuscularly. Their use requires a Therapeutic Use Exemption approval.

Other routes of administration (intraarticular /periarticular/ peritendinous/ epidural/ intradermal injections and inhalation) require an Abbreviated Therapeutic Use Exemption except as noted below.

Topical preparations when used for dermatological (including iontophoresis/phonophoresis), auricular, nasal, ophthalmic, buccal, gingival and perianal disorders are not prohibited and do not require any form of Therapeutic Use Exemption.

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) for each Federation is reported in parenthesis.

- Aeronautic (FAI) (0.20 g/L)
- Archery (FITA, IPC) (0.10 g/L)
- Automobile (FIA) (0.10 g/L)
- Boules (IPC bowls) (0.10 g/L)
- Karate (WKF) (0.10 g/L)
- Modern Pentathlon (UIPM) (0.10 g/L) for disciplines involving shooting
- Motorcycling (FIM) (0.10 g/L)
- Powerboating (UIM) (0.30 g/L)

P2. BETA-BLOCKERS

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

- Aeronautic (FAI)
- Archery (FITA, IPC) (also prohibited *Out-of-Competition*)
- Automobile (FIA)
- Billiards (WCBS)
- Bobsleigh (FIBT)
- Boules (CMSB, IPC bowls)
- Bridge (FMB)
- Curling (WCF)
- Gymnastics (FIG)
- Motorcycling (FIM)
- Modern Pentathlon (UIPM) for disciplines involving shooting
- Nine-pin 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.

SPECIFIED SUBSTANCES*

"Specified Substances"* are listed below:

- All inhaled Beta-2 Agonists, except salbutamol (free plus glucuronide) greater than 1000 ng/mL and clenbuterol (listed under S1.2: Other Anabolic Agents);
- Alpha-reductase inhibitors, probenecid;
- Cathine, cropropamide, crotetamide, ephedrine, etamivan, famprofazone, heptaminol, isometheptene, levmethamfetamine, meclofenoxate, p-methylamphetamine, methylephedrine, nikethamide, norfenefrine, octopamine, ortetamine, oxilofrine, phenpromethamine, propylhexedrine, selegiline, sibutramine, tuaminoheptane, and any other stimulant not expressly listed under section S6 for which the Athlete establishes that it fulfils the conditions described in section S6;
- Cannabinoids;
- All Glucocorticosteroids;
- Alcohol;
- All Beta Blockers.

* *"The Prohibited List may identify specified substances which are particularly susceptible to unintentional anti-doping rule violations because of their general availability in medicinal products or which are less likely to be successfully abused as doping agents."* A doping violation involving such substances may result in a reduced sanction provided that the *"...Athlete can establish that the Use of such a specified substance was not intended to enhance sport performance..."*

ANNEX II

STANDARDS FOR GRANTING THERAPEUTIC USE EXEMPTIONS

Extract from "INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS" of the World Anti-Doping Agency (WADA); in force 1 January 2005

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 applies 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 21 days before participating in 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 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.*

[Comment: Medical Emergencies or acute medical situations requiring administration of an otherwise Prohibited Substance or Prohibited Method before an application for a TUE can be made, are uncommon. Similarly, circumstances requiring expedited consideration of an application for a TUE due to imminent competition are infrequent. Anti-Doping Organizations granting TUEs should have internal procedures 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* involved in the *Athlete*'s care. 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 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 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, a majority of the members of the TUEC should not have any official 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 Appendix 1 – 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 Appendix 1, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.

7.3 The TUE application form(s) may be translated into other language(s) by *Anti-Doping Organizations*, 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.

7.7 Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* 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.

7.10 Decisions of the TUEC, should be completed within 30 days of receipt of all relevant documentation and will be conveyed in writing to the *Athlete* by the relevant *Anti-Doping Organization*. 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, as specified in Article 4.4. of the Code, the *WADA* TUEC will, as specified in Article 4.4 of the *Code*, be able to reverse a decision on a TUE granted by an *Anti-Doping Organization*. The *Athlete* shall provide to the *WADA* TUEC all the information for a TUE as 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 30 days following receipt of the information by *WADA*.

(b) *WADA* can undertake a review at any time. The *WADA* TUEC will complete its review within 30 days.

7.12 If the decision regarding the granting of a TUE is reversed on 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 14 days following notification of the decision to the *Athlete*.

8.0 Abbreviated therapeutic use exemption (ATUE) application 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. In such cases, a full application as detailed in section 4 and section 7 is unnecessary. Accordingly an abbreviated process of the TUE is established.

8.2 The *Prohibited Substances* or *Prohibited Methods* which may be permitted by this abbreviated process are strictly limited to the following:

Beta-2 agonists (formoterol, salbutamol, salmeterol and terbutaline) by inhalation, and glucocorticosteroids by non-systemic routes.

8.3 To use one of the substances above, the *Athlete* shall provide to the *Anti-Doping Organization* a medical notification justifying the therapeutic necessity. Such medical notification, as contained in Appendix 2, shall describe the diagnosis, name of the drug, dosage, route of administration and duration of the treatment. When applicable any tests undertaken in order to establish the diagnosis should be included (without the actual results or details).

8.4 The abbreviated process includes:

(a) approval for use of *Prohibited Substances* subject to the abbreviated process is effective upon receipt of a complete notification by the *Anti-Doping Organization*. Incomplete notifications must be returned to the applicant;

(b) on receipt of a complete notification, the *Anti-Doping Organization* shall promptly advise the *Athlete*. As appropriate, the *Athlete*'s IF, NF and NADO shall also be advised. The *Anti-Doping Organization* shall advise *WADA* only upon receipt of a notification from an *International-level Athlete*;

(c) a notification for an ATUE will not be considered for retroactive approval except:

– if emergency treatment or treatment of an acute medical condition was necessary; or

– due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a TUEC to receive, an application prior to *Doping Control*.

8.5 (a) A review by the TUEC or the *WADA* TUEC can be initiated at any time during the duration of an ATUE.

(b) If an *Athlete* requests a review of a subsequent denial of an ATUE, the *WADA* TUEC will have the ability to request from the *Athlete* additional medical information as deemed necessary, the expenses of which should be met by the *Athlete*.

8.6 An ATUE may be cancelled by the TUEC or *WADA* TUEC at any time. The *Athlete*, his/her IF and all relevant *Anti-Doping Organizations* shall be notified immediately.

8.7 The cancellation shall take effect immediately following notification of the decision to the *Athlete*. The *Athlete* will nevertheless be able to apply under section 7 for a TUE.

9.0 Clearing house

9.1 *Anti-Doping Organizations* are required to provide *WADA* with all TUEs, and all supporting documentation, issued under section 7.

9.2 With respect to ATUEs, *Anti-Doping Organizations* shall provide *WADA* with medical applications submitted by *International-level Athletes* issued under section 8.4

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

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Stock Exchange Tower
800 Place Victoria (Suite 1700)
PO Box 120
Montreal, Quebec,
Canada H4Z 1B7

URL: www.wada-ama.org

Tel: +1.514.904.9232
Fax: +1.514.904.8650
E-mail: code@wada-ama.org

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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 in international 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 upon 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.

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, 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 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.

FUNDAMENTAL RATIONALE FOR THE WORLD ANTI-DOPING *CODE*

Anti-doping programs seek to preserve what is intrinsically valuable about sport. This 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.

PART ONE

DOPING CONTROL

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 provisions 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 rule 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 Article 13, subpart 13.2.2 is not included in the provisions required to be adopted essentially verbatim, as 13.2.2 establishes mandatory guiding principles that allow some flexibility in the formulation of rules by the Anti-Doping Organization.

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 *Disqualification* 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, like 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 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 *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 and agree to be bound by anti-doping rules in force of the relevant *Anti-Doping Organizations*.

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 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.*

2.1.1 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 the 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:

"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.

2.2.1 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 an anti-doping rule violation.

2.3 Comment: *Failure or refusal to submit to Sample collection after notification is 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 provide 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 Substances* 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* establishes 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 information 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 different sports and countries. A violation of this Article may be based on either intentional or negligent conduct by the 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 Substance* or *Prohibited Method.*

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.

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 comfortable 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 violation 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 decision in N., J., Y., W. v. FINA, CAS 98/208, 22 December 1998.*

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.*

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.

3.2.1 Comment: *The burden is on the Athlete to establish, by a preponderance of the evidence, a departure from the International Standard. If the Athlete does so, the burden shifts to the Anti-Doping Organization to prove to the comfortable satisfaction of 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 often 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* Identified 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-of-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 reference to a particular substance or method.

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

WADA shall consider the following criteria in deciding whether 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* determines 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 the substance or method has the potential to enhance or enhances sport performance;

4.1 Comment: *The Prohibited List will be revised and published on an expedited basis whenever the need arises. However, for the sake of predictability, a new list will be published every year whether or not changes have been made. The virtue of the IOC practice of publishing a new list every January is that it avoids confusion 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 effect until January 1, 2004 with the publication of 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 performance enhancing effects 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-of-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 of beta-blockers for shooting) but this will also be reflected on the single Prohibited List. Having all Prohibited Substances on a single list will avoid some of the current confusion related to identifying which substances are prohibited in which sports. Individual sports are not permitted to seek exemption from the basic list of Prohibited Substances (e.g. eliminating anabolics from the Prohibited List for "mind sports"). The premise of this decision is that there are certain basic doping agents which anyone who chooses to call himself or herself an Athlete should not take.*

4.3.1.2 Medical or other scientific evidence, pharmacological effect, or experience that the *Use* of the substance or method represents 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 spirit 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) it 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 performance 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. Similarly, the potentially unhealthy abuse of certain substances without therapeutic justification based on the mistaken belief they enhance performance is certainly contrary to the spirit of sport regardless of whether the expectation of performance enhancement 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 International Federation shall ensure, for *International-Level Athletes* or any other *Athlete* who is

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 Specimen. 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 therapeutic use exemption. However, currently many sporting bodies have no rules permitting therapeutic use exemptions; others follow unwritten policies; and only a few have written policies incorporated 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 International-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 International 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.

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* shall 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 exemption. 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*.

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 information 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 substances 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-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*.

5.1.3 Comment: *Target Testing is specified because random Testing, or even weighted random Testing, does not ensure that all of the appropriate Athletes will be tested. (For example: world class Athletes, 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 classes of substances) or methods on the *Prohibited List*, or as otherwise identified

performances have dramatically improved over a short period of time. Athletes whose coaches have had other Athletes test positive, etc.).

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

5.2 Comment: *The required methods and processes for the various types of In-Competition and Out-of-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 Standards for *Sample* Analysis and Reporting

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

ARTICLE 7: RESULTS MANAGEMENT

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

7.1 Initial Review Regarding *Adverse Analytical Findings*

Upon receipt of an *A Sample Adverse Analytical Finding*, the *Anti-Doping Organization* responsible for results management shall conduct a review to determine whether: (a) an applicable therapeutic use exemption has been granted, or (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 an 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 management for Adverse Analytical Findings. While the various approaches have not been entirely uniform, many have proven to be fair and effective systems for results management. 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 management 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: *The Athlete has a right to request a prompt B Sample analysis regardless of whether follow-up investigation may be required under Articles 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 *Adverse 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 waived; (d) the right of the *Athlete* and/or the *Athlete's* representative to attend the B *Sample* opening and analysis if such analysis is requested; and (e) the *Athlete's* right to request copies of the A and B *Sample* laboratory documentation package which includes information as required by the *International Standard* for laboratory analysis.

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.

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 applicable anti-doping policies and rules adopted 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 *Signatory* 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 (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 *Provisional Suspension* is imposed based on an A *Sample Adverse Analytical Finding* and a 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 sanction 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 Provisional Suspension before a final decision at a hearing under Article 8 (Right to a Fair Hearing). Provisional Suspensions have been authorized in the OMADC and by the rules of many International 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 8 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

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*.

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 different 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 jurisdictional conflicts between 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 OMADC and 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*.

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 (*Trafficking*) 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 sufficient discretion to allow consideration of the Person's degree of fault.

10.4.2 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 of 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 of 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.

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*

10.5.1 Comment: *Article 10.5.1 applies only to violations under Articles 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, 10.3 and 10.6.

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 incorporated 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 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* 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 other person 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 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 Personnel*), 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 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.

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 may be based on conduct that is not intentional or purposeful. Violations under Article 2.4 (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.*

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 two offenses. This Article imposes 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

10.8 Comment: *Currently, many Anti-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. Other Anti-Doping Organizations simply start the two-year suspension on the date the*

the total period of *Ineligibility* to be served. Where 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 years of the period of *Ineligibility*,

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 compete 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 laboratory 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, an Athlete in 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 *Target 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 for Athletes 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.

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* lacks jurisdiction to rule on an alleged anti-doping rule violation or its *Consequences*,

12 Comment: *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*

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's* own 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* 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.

13.2.1 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.*

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 under Article 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*.

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* 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 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 delegates 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 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*.

15.3 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). In 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 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 Organization's 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.*

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.

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.*

PART TWO

EDUCATION & RESEARCH

ARTICLE 18: EDUCATION

18.1 Basic Principle and Primary Goal

The basic principle for information and education programs shall be to preserve the spirit of sport as described in the Introduction to the *Code*, from being undermined by doping. The primary goal shall be to dissuade *Athletes* from using *Prohibited Substances* and *Prohibited Methods*.

18.2 Program and Activities

Each *Anti-Doping Organization* should plan, implement and monitor information and education programs. The programs should provide *Participants* with updated and accurate information on at least the following issues:

- Substances and methods on the *Prohibited List*
- Health consequences of doping
- *Doping Control* procedures
- *Athletes'* rights and responsibilities

The programs should promote the spirit of sport in order to establish an anti-doping environment which influences behavior among *Participants*.

Athlete Support Personnel should educate and counsel *Athletes* regarding anti-doping policies and rules adopted pursuant to the *Code*.

18.3 Coordination and Cooperation

All *Signatories* and *Participants* shall cooperate with each other and governments to coordinate their efforts in anti-doping information and education.

ARTICLE 19: RESEARCH

19.1 Purpose of Anti-Doping Research

Anti-doping research contributes to the development and implementation of efficient programs within *Doping Control* and to anti-doping information and education.

19.2 Types of Research

Anti-doping research may include, for example, sociological, behavioral, juridical and ethical studies in addition to medical, analytical and physiological investigation.

19.3 Coordination

Coordination of anti-doping research through *WADA* is encouraged. Subject to intellectual property rights, copies of anti-doping research results should be provided to *WADA*.

19.4 Research Practices

Anti-doping research shall comply with internationally recognized ethical practices.

19.5 Research Using *Prohibited Substances* and *Prohibited Methods*

Research efforts should avoid the administration of *Prohibited Substances* or *Prohibited Methods* to *Athletes*.

19.6 Misuse of Results

Adequate precautions should be taken so that the results of anti-doping research are not misused and applied for doping.

PART THREE

ROLES & RESPONSIBILITIES

ARTICLE 20: ADDITIONAL ROLES AND RESPONSIBILITIES OF *SIGNATORIES*

20.1 Roles and Responsibilities of the International Olympic Committee

20.1.1 To adopt and implement anti-doping policies and rules for the Olympic Games which conform with the *Code*.

20.1.2 To require as a condition of recognition by the International Olympic Committee, that International Federations within the Olympic Movement are in compliance with the *Code*.

20.1.3 To withhold some or all Olympic funding of sport organizations that are not in compliance with the *Code*.

20.1.4 To take appropriate action to discourage non-compliance with the *Code* as provided in Article 23.5.

20.1.5 To authorize and facilitate the *Independent Observer Program*.

20.2 Roles and Responsibilities of the International Paralympic Committee

20.2.1 To adopt and implement anti-doping policies and rules for the Paralympic Games which conform with the *Code*.

20.2.2 To require as a condition of recognition by the International Paralympic Committee, that National Paralympic Committees within the Olympic Movement are in compliance with the *Code*.

20 Comment: *Responsibilities for Signatories and Participants are addressed in various articles in the Code and the responsibilities listed in this part are additional to these responsibilities.*

20.2.3 To withhold some or all Paralympic funding of sport organizations that are not in compliance with the *Code*.

20.2.4 To take appropriate action to discourage non-compliance with the *Code* as provided in Article 23.5.

20.2.5 To authorize and facilitate the *Independent Observer Program*.

20.3 Roles and Responsibilities of International Federations

20.3.1 To adopt and implement anti-doping policies and rules which conform with the *Code*.

20.3.2 To require as a condition of membership that the policies, rules and programs of National Federations are in compliance with the *Code*.

20.3.3 To require all *Athletes* and *Athlete Support Personnel* within their jurisdiction to recognize and be bound by anti-doping rules in conformance with the *Code*.

20.3.4 To require *Athletes* who are not regularly members of the International Federation or one of its member National Federations to be available for *Sample* collection and provide accurate and up-to-date whereabouts information if required by the conditions for eligibility established by the International Federation or, as applicable, the *Major Event Organization*.

20.3.5 To monitor the anti-doping programs of National Federations.

20.3.4 Comment: *This would include, for example, Athletes from professional leagues.*

20.3.6 To take appropriate action to discourage non-compliance with the *Code* as provided in Article 23.5.

20.3.7 To authorize and facilitate the *Independent Observer* program at *International Events*.

20.3.8 To withhold some or all funding to its member National Federations that are not in compliance with the *Code*.

20.4 Roles and Responsibilities of *National Olympic Committees* and National Paralympic Committees

20.4.1 To ensure that their anti-doping policies and rules conform with the *Code*.

20.4.2 To require as a condition of membership or recognition that National Federations' anti-doping policies and rules are in compliance with the applicable provisions of the *Code*.

20.4.3 To require *Athletes* who are not regular members of a National Federation to be available for *Sample* collection and provide accurate and up-to-date whereabouts information on a regular basis if required during the year before the Olympic Games as a condition of participation in the Olympic Games.

20.4.4 To cooperate with their *National Anti-Doping Organization*.

20.4.5 To withhold some or all funding, during any period of his or her *Ineligibility*, to any *Athlete* or *Athlete Support Personnel* who has violated anti-doping rules.

20.4.6 To withhold some or all funding to its member or recognized National Federations that are not in compliance with the *Code*.

20.5 Roles and Responsibilities of *National Anti-Doping Organizations*

20.5.1 To adopt and implement anti-doping rules and polices which conform with the *Code*.

20.5.2 To cooperate with other relevant national organizations and other *Anti-Doping Organizations*.

20.5.3 To encourage reciprocal testing between *National Anti-Doping Organizations*.

20.5.4 To promote anti-doping research.

20.6 Roles and Responsibilities of *Major Event Organizations*

20.6.1 To adopt and implement anti-doping policies and rules for their *Events* which conform with the *Code*.

20.6.2 To take appropriate action to discourage non-compliance with the *Code* as provided in Article 23.5.

20.6.3 To authorize and facilitate the *Independent Observer Program*.

20.7 Roles and Responsibilities of *WADA*

20.7.1 To adopt and implement policies and procedures which conform with the *Code*.

20.7.2 To monitor the processing of *Adverse Analytical Findings*.

20.7.3 To approve *International Standards* applicable to the implementation of the *Code*.

20.7.4 To accredit laboratories to conduct *Sample* analysis or to approve others to conduct *Sample* analysis.

20.7.5 To develop and approve Models of Best Practice.

20.7.6 To promote, conduct, commission, fund and coordinate anti-doping research.

20.7.7 To conduct an effective *Independent Observer Program*.

20.7.8 To conduct *Doping Controls* as authorized by other *Anti-Doping Organizations*.

ARTICLE 21: ROLES AND RESPONSIBILITIES OF *PARTICIPANTS*

21.1 Roles and Responsibilities of *Athletes*

21.1.1 To be knowledgeable of and comply with all applicable anti-doping policies and rules adopted pursuant to the *Code*.

21.1.2 To be available for *Sample* collection.

21.1.3 To take responsibility, in the context of anti-doping, for what they ingest and use.

21.1.4 To inform medical personnel of their obligation not to *Use Prohibited Substances* and *Prohibited Methods* and to take responsibility to make sure that any medical treatment received does not violate anti-doping policies and rules adopted pursuant to the *Code*.

21.2 Roles and Responsibilities of *Athlete Support Personnel*

21.2.1 To be knowledgeable of and comply with all anti-doping policies and rules adopted pursuant to the *Code* and which are applicable to them or the *Athletes* whom they support.

21.2.2 To cooperate with the *Athlete Testing* program.

21.2.3 To use their influence on *Athlete* values and behavior to foster anti-doping attitudes.

ARTICLE 22: INVOLVEMENT OF GOVERNMENTS

Each government's commitment to the *Code* will be evidenced by its signing a Declaration on or before the first day of the Athens Olympic Games to be followed by a process leading to a convention or other obligation to be implemented as appropriate to the constitutional and administrative contexts of each government on or before the first day of the Turin Winter Olympic Games.

It is the expectation of the *Signatories* that the Declaration and the convention or other obligation will reflect the following major points:

22.1 Affirmative measures will be undertaken by each government in support of anti-doping in at least the following areas:

- Support for national anti-doping programs;
- The availability of *Prohibited Substances* and *Prohibited Methods*;
- Facilitate access for *WADA* to conduct *Out-of-Competition Doping Controls*;
- The problem of nutritional supplements which contain undisclosed *Prohibited Substances*; and
- Withholding some or all financial support from sport organizations and *Participants* that are not in compliance with the *Code* or applicable anti-doping rules adopted pursuant to the *Code*.

22 Comment: *Most governments cannot be parties to, or be bound by, private non-governmental instruments such as the Code. For that reason, governments are not asked to be Signatories to the Code. However, the effort to combat doping through the coordinated and harmonized program reflected in the Code is very much a joint effort between the sport movement and governments. An example of one type of obligation referred to above is the convention discussed in the Final Communiqué of the UNESCO Round Table of Ministers and Senior Officials Responsible for Physical Education and Sport held in Paris on 9/10 January 2003.*

22.2 All other governmental involvement with anti-doping will be brought into harmony with the *Code*.

22.3 Ongoing compliance with the commitments reflected in the convention or other obligation will be monitored as determined in consultation between *WADA* and the applicable government(s).

PART FOUR

ACCEPTANCE, COMPLIANCE, MODIFICATION & INTERPRETATION

ARTICLE 23: ACCEPTANCE, COMPLIANCE AND MODIFICATION

23.1 Acceptance of the *Code*

23.1.1 The following entities shall be *Signatories* accepting the *Code*: *WADA*, The International Olympic Committee, International Federations, The International Paralympic Committee, *National Olympic Committees*, National Paralympic Committees, *Major Event Organizations*, and *National Anti-Doping Organizations*. These entities shall accept the *Code* by signing a declaration of acceptance upon approval by each of their respective governing bodies.

23.1.2 Other sport organizations that may not be under the control of a *Signatory* may, upon *WADA's* invitation, also accept the *Code*.

23.1.3 A list of all acceptances will be made public by *WADA*.

23.2 Implementation of the *Code*

23.2.1 The *Signatories* shall implement applicable *Code* provisions through policies, statutes, rules or regulations according to their authority and within their relevant spheres of responsibility.

23.1.1 Comment: *Each accepting Signatory will separately sign an identical copy of the standard form common declaration of acceptance and deliver it to WADA. The act of acceptance will be as authorized by the organic documents of each organization. For example, an International Federation by its Congress and WADA by its Foundation Board.*

23.1.2 Comment: *Those professional leagues that are not currently under the jurisdiction of any government or International Federation will be encouraged to accept the Code.*

23.2.2 In implementing the *Code*, the *Signatories* are encouraged to use the Models of Best Practice recommended by *WADA*.

23.3 Acceptance and Implementation Deadlines

23.3.1 *Signatories* shall accept and implement the *Code* on or before the first day of the Athens Olympic Games.

23.3.2 The *Code* may be accepted after the above-referenced deadlines; however, *Signatories* shall not be considered in compliance with the *Code* until they have accepted the *Code* (and that acceptance has not been withdrawn).

23.4 Monitoring Compliance with the *Code*

23.4.1 Compliance with the *Code* shall be monitored by *WADA* or as otherwise agreed by *WADA*.

23.4.2 To facilitate monitoring, each *Signatory* shall report to *WADA* on its compliance with the *Code* every second year and shall explain reasons for noncompliance.

23.4.3 *WADA* shall consider explanations for non-compliance and, in extraordinary situations, may recommend to the International Olympic Committee, International Paralympic Committee, International Federations, and *Major Event Organizations* that they provisionally excuse the non-compliance.

23.4.3 Comment: *WADA recognizes that amongst Signatories and governments, there will be significant differences in anti-doping experience, resources, and the legal context in which anti-doping activities are carried out. In considering whether an organization is compliant, WADA will consider these differences.*

23.4.4 *WADA* shall, after dialogue with the subject organization, make reports on compliance to the International Olympic Committee, the International Paralympic Committee, International Federations, and *Major Event Organizations*. These reports shall also be made available to the public.

23.5 Consequences of Noncompliance with the *Code*

23.5.1 Noncompliance with the *Code* by either the government or *National Olympic Committee* of a country may result in consequences with respect to Olympic Games, Paralympic Games, World Championships or the *Events* of *Major Event Organizations* as determined by the ruling body for each *Event*. The imposition of such consequences may be appealed by the *National Olympic Committee* or government to CAS pursuant to Article 13.4.

23.6 Modification of the *Code*

23.6.1 *WADA* shall be responsible for overseeing the evolution and improvement of the *Code*. *Athletes* and all *Signatories* and governments shall be invited to participate in such process.

23.6.2 *WADA* shall initiate proposed amendments to the *Code* and shall ensure a consultative process to both receive and respond to recommendations and to facilitate review and feedback from *Athletes*, *Signatories* and governments on recommended amendments.

23.6.3 Amendments to the *Code* shall, after appropriate consultation, be approved by a two-thirds majority of the *WADA* Foundation Board including a majority of both the public sector and Olympic Movement members casting votes. Amendments shall, unless provided otherwise, go into effect three months after such approval.

23.6.4 *Signatories* shall implement any applicable amendment to the *Code* within one year of approval by the *WADA* Foundation Board.

23.7 Withdrawal of Acceptance of the *Code*

23.7.1 *Signatories* may withdraw acceptance of the *Code* after providing *WADA* six-month's written notice of their intent to withdraw.

ARTICLE 24: INTERPRETATION OF THE *CODE*

24.1 The official text of the *Code* 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.

24.2 The comments annotating various provisions of the *Code* are included to assist in the understanding and interpretation of the *Code*.

24.3 The *Code* shall be interpreted as an independent and autonomous text and not by reference to the existing law or statutes of the *Signatories* or governments.

24.4 The headings used for the various Parts and Articles of the *Code* are for convenience only and shall not be deemed part of the substance of the *Code* or to affect in any way the language of the provisions to which they refer.

24.5 The *Code* shall not apply retrospectively to matters pending before the date the *Code* is accepted by a Signatory and implemented in its rules.

24.6 APPENDIX 1 Definitions shall be considered an integral part of the *Code*.

24.5 Comment: *For example, conduct which is an anti-doping rule violation described in the Code, but which is not a violation under an International Federation's pre-Code rules, would not be a violation until the International Federation's rules are changed.*

Pre-Code anti-doping rule violations would continue to count as "First violations" or "Second violations" for purposes of determining sanctions under Article 10 for subsequent post-Code violations.

APPENDIX 1

DEFINITIONS

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.*

Athlete Support Personnel: Any coach, trainer, manager, agent, team staff, official, medical or para-medical personnel working with or treating *Athletes* participating in or preparing for sports competition.

Athlete Comment: *This definition makes it clear that all international and national-calibre athletes are subject to the anti-doping rules of the Code, with the precise definitions of international and national level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping control program beyond national-calibre athletes to athletes at lower levels of competition. Athletes at all levels of competition should receive the benefit of anti-doping information and education.*

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

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).

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

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.

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.

In-Competition Comment: *The distinction between "In-Competition" and "Out-of-Competition" testing is significant because the full Prohibited List is only tested for "In-Competition." Prohibited stimulants, for example, are not tested for Out-of-Competition because they have no performance enhancing benefit unless they are in the Athlete's system while the Athlete is actually competing. So long as the prohibited stimulant has cleared the Athlete's system at the time the Athlete competes, it makes no difference whether that stimulant could have been found in the Athlete's urine the day before or the day after the Competition.*

Major Event Organizations: This term refers to the continental associations of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.

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.

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

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.

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

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

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

Participant: Any *Athlete* or *Athlete Support Personnel*.

Person: A natural *Person* or an organization or other entity.

Possession: The actual, physical possession, or the constructive possession (which shall be found only if the *Person* has exclusive control over the *Prohibited Substance/Method* or the premises in which a *Prohibited Substance/Method* exists); provided, however, that if the *Person* does not have exclusive control over the *Prohibited Substance/Method* or the premises in which a *Prohibited Substance/Method* exists, constructive possession shall only be found if the *Person* knew about the presence of the *Prohibited Substance/Method* and intended to exercise control over it. Provided, however, there shall be no anti-doping rule violation based solely on *possession* if, prior to receiving

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

notification of any kind that the *Person* has committed an anti-doping rule violation, the *Person* has taken concrete action demonstrating that the *Person* no longer intends to have *Possession* and has renounced the *Person's* previous *Possession*.

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*.

Provisional Hearing: For purposes of Article 7.5, an expedited abbreviated hearing occurring prior to a hearing under Article 8 (Right to a Fair Hearing) that provides the *Athlete* with notice and an opportunity to be heard in either written or oral form.

Provisional Suspension: See *Consequences* above.

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.

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*.

Registered Testing Pool Comment: *Each International Federation shall clearly define the specific criteria for inclusion of Athletes in its Registered Testing Pool. For example, the criteria could be a specified world ranking cut-off, a specified time standard, membership on a national team, etc.*

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*.

Tampering: Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly to alter results or prevent normal procedures from occurring.

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

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

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

Trafficking: To sell, give, administer, transport, send, deliver or distribute a *Prohibited Substance* or *Prohibited Method* to an *Athlete* either directly or through one or more third parties, but excluding the sale or distribution (by medical personnel or by *Persons* other than an *Athlete's Support Personnel*) of a *Prohibited Substance* for genuine and legal therapeutic purposes.

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

WADA: The World Anti-Doping Agency.

WORLD
ANTI-DOPING
AGENCY

The World Anti-Doping Code

INTERNATIONAL STANDARD FOR LABORATORIES

Version 4.0

August 2004

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

In the introduction to the World Anti-Doping *Code (Code),* the purpose and implementation of *the* International *Standards* are summarized as follows:

> "*International Standards* for different technical and operational areas within the anti-doping program will be developed in consultation with the *Signatories* and governments and approved by *WADA*. The purpose of the *International Standards* is harmonization among *Anti-Doping Organizations* responsible for specific technical and operational parts of the anti-doping programs. Adherence to the *International Standards* is mandatory for compliance with the *Code*. The *International 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.

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.

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).

World Anti-Doping Code

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.

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 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.

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, s_{Zi}: 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, s_r: Variability observed within a laboratory, over a short time, using a single operator, item of equipment, etc.

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

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

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.

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.

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.

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*
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 re-location 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 are added 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 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.

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* 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.

5.2.4.4 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).

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 pharmacokinetics 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

5.3.1.1 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.

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.

5.4.2 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 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.

5.4.3.2.2 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 Substances* 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.
- Matrix interferences. The method should avoid interference in the detection of *Prohibited Substances* 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 Substances* 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.

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 ion monitoring (SIM) to a Reference Material or Reference Collection sample analyzed in the same analytical run
- Confirmation of the "A" and "B" Split Samples.

- 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

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 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.

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 Organization* 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 re-accreditation 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.

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 non-compliance 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-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 re-location 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:

- 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.

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.

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;
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.

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.

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 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*.

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

The World Anti-Doping Code

INTERNATIONAL STANDARD FOR TESTING

version 3.0

June 2003

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 versions, the English version shall prevail.

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

2.0 *Code* Provisions

The following articles in the *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 *Attempting* to tamper, with any part of *Doping 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.*

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, *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.

***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.

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*.

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;
  - 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 *Sample/s*.

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*:
  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.

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.

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 notification by the DCO/Chaperone until the completion of the *Sample* collection procedure;

ii. Produce 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* 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 DCO/Chaperone shall:

a) From this time until the *Athlete* leaves the Doping Control Station at the end of his/her *Sample* Collection Session, keep the *Athlete* under observation at all times.

b) Identify themselves to the *Athlete* using 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;

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;

c) Ensuring that the Doping Control Station meets the minimum criteria 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 *Sample* Collection Personnel. At a minimum the criteria shall include:

a) An *Athlete's* entitlement to be accompanied by a representative and/or interpreter during the *Sample* Collection Session except when the *Athlete* is passing a urine *Sample*.

b) A *Minor Athlete's* entitlement, 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 *Minor Athlete*.

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 applicable 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).

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.

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

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.

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;

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 *Athlete*s 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*.

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 *Sample*/s 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*.

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 *Sample/s* 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 *Sample/s* in accordance with the *ADO*'s criteria.

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 Sample*s 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 *Sample*s 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

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. 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.