

**United Nations Educational, Scientific and Cultural Organization
International Convention Against Doping in Sport,
done at Paris on 19 October 2005
[2005] ATNIF 24**

Documents tabled on 8 November 2005:

**National Interest Analysis [2005] ATNIA 16
with attachment on consultation**

Text of the proposed treaty action

**Background information:
Current status list**

NATIONAL INTEREST ANALYSIS: CATEGORY 1 TREATY

SUMMARY PAGE

United Nations Educational, Scientific and Cultural Organization International Convention Against Doping in Sport, done At Paris on 19 October 2005 [2005] ATNIF 24

Nature and timing of proposed treaty action

1. The proposed treaty action is for Australia to accede to the International Convention Against Doping In Sport (the Convention) pursuant to Article 36.
2. The Convention was unanimously adopted by Member States at the 33rd General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO), held in Paris in October 2005.
3. Since its adoption, Member States have moved to accede to the Convention. The Convention will come into force on the first day of the month that follows the end of a one month period after 30 states have submitted an instrument of ratification, acceptance, approval or accession to the UNESCO Director-General.
4. Given its strong international advocacy for measures to fight doping in sport, ideally Australia would like to be one of the first countries to accede to the Convention. In any case, to avoid potential international criticism, Australia should accede to the Convention prior to the commencement of the Melbourne Commonwealth Games on 15 March 2006.

Overview and national interest summary

5. In recent years there has been a concerted effort to harmonise anti-doping policies and practices internationally to ensure all athletes are subject to a comprehensive and fair testing regime. In March 2003, the World Anti-Doping Agency (WADA), established to coordinate anti-doping efforts worldwide, released the World Anti-Doping Code (the Code). The Code is the first document to harmonise anti-doping frameworks across all sports and all countries. The Code works in conjunction with four International Standards aimed at aligning the technical and operational aspects of countries' anti-doping programs.
6. Australia has been a key contributor to the development of the Code and International Standards. Australia also took a lead role in the development of, and was one of the first countries to sign, the *2003 Copenhagen Declaration on Doping in Sport*, a non-binding international instrument that recognises and supports the Code. The Declaration includes a commitment to develop a legally binding international convention with the expectation that such an instrument would be in place before the Turin Winter Olympics in February 2006.
7. At the meeting of the 32nd UNESCO General Conference held in October 2003, agreement was reached that drafting an international convention to support and enforce the Code should commence under the aegis of UNESCO. Australia was involved in the development of the Convention, and championed its adoption. The Convention aims to ensure that governments throughout the world take actions against doping in sport which are complementary to those already being undertaken by the sporting movement, including anti-doping activities at the national level, international cooperation, education and training, and research.

Reasons for Australia to take the proposed treaty action

8. Australia is acknowledged as being at the forefront of the fight against doping in sport, balancing a 'tough on drugs' approach with ensuring that all athletes are treated fairly and that athletes' rights are protected. Through its *Tough on Drugs in Sport Strategy*, launched in May 1999 in the lead up to the Sydney 2000 Games, the Government has ensured that Australia has a robust anti-doping framework that is world's best practice.
9. In its 2004 policy *Building Australian Communities through Sport*, the Government committed to strengthening its *Tough on Drugs in Sport Strategy* through enhancing the investigation of doping violations and establishing clear and consistent arrangements for hearing doping in sport matters.
10. In line with this commitment, the Government is establishing the Australian Sports Anti-Doping Authority (ASADA). ASADA will investigate doping allegations, present doping cases before sporting tribunals, take over the policy development, approval and monitoring role of the Australian Sports Commission, assume the existing functions of the Australian Sports Drug Agency and incorporate the Australian Sports Drug Medical Advisory Committee. ASADA will work together with sporting bodies to ensure that Australia remains at the forefront of the fight against doping in sport.
11. While Australia is already compliant with the mandatory provisions of the Code, and has fully operational and robust anti-doping programs in place, this is not the case for many other countries. It is in Australia's interests to encourage these countries to accede to the Convention and to assist them to improve their anti-doping policies and programs. Australia owes it to its athletes who train hard and play clean to minimise opportunities for sporting cheats to excel. The fundamental aim of the Code and of the Convention is to achieve a level international playing field where all athletes are subject to the same doping rules and sanctions.
12. Not acceding to the Convention would clearly undermine Australia's commitment to achieving a doping free sporting environment and our position as a world leader in this field.
13. As at 12 October 2005, 181 countries had signed the *Copenhagen Declaration on Doping in Sport*. Australia was one of the first countries to sign and we had significant involvement in the drafting of the document. It is expected that many of these countries will also move quickly to become parties to the Convention. Many of these countries are still moving to develop their anti-doping policies and programs, and look to countries such as Australia for leadership and direction.
14. The Convention will harmonise anti-doping policies and practices world-wide and ensure a consistent approach to eliminating doping in sport. It will also make sure elite athletes are educated on the risks presented by illicit drugs, and will assist in athletes remaining positive role models.
15. Acceding to the Convention will ensure that Australia's approach to anti-doping is in line with that of the rest of the world. It will also encourage support for the Convention, which, in turn, will ensure that Australian athletes are not disadvantaged by inconsistencies in anti-doping practices or an uneven playing field due to more lenient approaches to anti-doping in sport in other countries.
16. As host nation of the Melbourne 2006 Commonwealth Games, everything from Australia's sport programs and policies to our technical capabilities are likely to come under intense international scrutiny. Australia would attract widespread international criticism if not

a party to the Convention by the time of the Games, particularly as a number of countries competing at the Games will have already acceded to the Convention.

Obligations

17. Under the Convention governments will commit themselves to the principle of the Code (Article 4), and take specific action to:

- in abiding by the obligations contained in the Convention, adopt appropriate measures, which may include legislation, regulation, policies or administrative practices (Article 5);
- restrict the availability of prohibited substances or methods to athletes (except for legitimate medical purposes) including by taking measures against trafficking (Article 8);
- take measures or encourage sport organisations and anti-doping organisations 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 9);
- facilitate doping controls and support national testing programmes (Article 12);
- withhold any or all financial support from athletes and athlete support personnel who commit an anti-doping rule violation, or sporting organisations that are not in compliance with the Code and provide funding to support a national testing program (Article 11);
- where appropriate, and in accordance with domestic law and procedures:
 - facilitate the task of WADA and anti-doping organisations operating in compliance with the Code to conduct in or out of competition doping controls on the State Parties' athletes, whether on their territory or elsewhere;
 - facilitate the timely movement of authorised doping control teams across borders when conducting the doping control activities;
 - cooperate to expedite the timely shipping or carrying across borders of samples in such a way as to maintain their security and integrity;
 - assist in the international coordination of doping controls by various anti-doping organisations, and cooperate to this end with WADA;
 - promote cooperation between doping control laboratories within their jurisdiction and those within jurisdictions of other States Parties, including encouraging laboratories within their jurisdiction to assist other State Parties in enabling them to acquire the experience, skills and techniques necessary to establish their own laboratories should they wish to do so;
 - encourage and support reciprocal testing arrangements between designated anti-doping organisations, in conformity with the Code;
 - mutually recognise the doping control procedures and test results management, including the sport sanctions thereof, of any anti-doping organisation that are consistent with the Code (Article 16).
- 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 20);
- encourage and promote anti-doping research in cooperation with sports and other relevant organisations (Article 24);

- encourage producers and distributors of nutritional supplements to establish 'best practice' in the labelling, marketing and distribution of products which might contain prohibited substances (Article 10); and
- support the provision of anti-doping education to athletes and the wider sporting community (Article 19).

18. Pursuant to Article 28, the Convention establishes a Conference of Parties. Article 31 provides that Parties to the Convention must provide a report to the Conference of Parties every two years, on the measures they have in place for the purposes of complying with the Convention.

Implementation

19. Compliance with the Convention does not require further legislative amendment. The Australian Government has already taken action to implement the World Anti-Doping Code. Implementation of the Code is one part of a new policy framework for combating the use of illicit drugs in sport that includes the recent decision by the Australian Government to establish ASADA. The enabling legislation for ASADA will specifically provide that the new body will establish a National Anti-Doping Scheme consistent with the mandatory provisions of the Code. Assuming this legislation is passed, there will be no requirement for further legislation in order for Australia to be compliant with the Convention. ASADA is expected to become operational in 2006.

20. The *Australian Sports Drug Agency Act 1990* was amended in 2004 to enable the Australian Sports Drug Agency (ASDA) to adjust its policies and procedures to meet its obligations under the Code by the commencement of the Athens Olympic Games in August 2004. ASDA carries out its current drug testing program in accordance with the Code. The Australian Sports Commission (ASC) is also operationally compliant with the Code and requires sports in receipt of Government grants to have Code-compliant anti-doping policies.

21. Australia's obligations under the Convention will be met by the ASC and ASDA, and subsequently ASADA, through current programs and mechanisms, including funding agreements with National Sporting Organisations.

Costs

22. Costs of the Convention will be funded from the budget of UNESCO within existing resources or from a Voluntary Fund established under Article 17, or an appropriate combination of the two, to be determined at the UNESCO General Conference every two years.

23. Australia's annual contribution to UNESCO will not be affected by accession to the Convention. Australia may choose to make a contribution to the Voluntary Fund on an annual or less frequent basis. The amount of the contribution is unlikely to exceed \$US250,000 in any financial year.

24. Article 11(a) requires State Parties, where appropriate, to provide funding to support a national testing program or assist sports and anti-doping organisations to finance doping controls. Australia's obligations under the Convention, with the exception of any contribution to the Voluntary Fund, will be funded from within current appropriations to ASDA and the ASC, and subsequently ASADA.

Regulation Impact Statement

25. The Office of Regulation Review (Productivity Commission) has been consulted and confirms that a Regulation Impact Statement is not required.

Future treaty action

26. Under Article 33 of the Convention, each party to the Convention may propose amendments in writing to the Director-General of UNESCO. The Director-General then circulates the proposed amendments to all parties. If, within six months from the date of circulation, at least half of the parties give their consent, the Director-General shall present the proposed amendment to the next session of the Conference of Parties.

27. Amendments shall be adopted by the Conference of Parties with a two-thirds majority of States Parties present and voting. Once adopted, amendments will be submitted to parties for ratification, acceptance, approval or accession. With respect to parties that ratify or accept amendments, the amendment enters into force three months after the deposit of the instrument of ratification or acceptance by two thirds of parties. Any amendments would be subject to Australia's domestic treaty process, including the provision of a National Interest Analysis and consideration by JSCOT.

28. Article 34 of the Convention provides for a specific amendment procedure for the Annexes. Two of the International Standards that operate in conjunction with the Code, the Prohibited List and the Standard for Granting Therapeutic Use Exemptions, form Annexes to, and are an integral part, of the Convention.

29. The Prohibited List is reviewed by the World Anti-Doping Agency (WADA) on an annual basis. WADA may also change the List before the regular annual review if there is evidence that an existing or new substance/s or method is being used by athlete/s in a manner contrary to the Code. This regular revision could potentially cause a problem, as the WADA Prohibited List could then differ from the List annexed to the Convention. Thus, every time the Prohibited List is revised, the Annex to the Convention will need to be amended to reflect the new List.

30. Pursuant to Article 34, when WADA modifies either of the Annexes it may inform the Director-General of the change who should then notify all States Parties expeditiously of these proposed amendments. Amendments may be approved by a Conference of the Parties or through written consultation. Under Article 34, parties have 45 days to object to a proposed amendment to the Annexes. Unless two-thirds of parties object, the amendment is approved and will come into force 45 days after notification by the UNESCO Director-General, except for any State Party that has previously notified the Director-General that it does not accept the amendment.

31. While three months may appear to be an unusually short period before amendments take effect, it is based on the realities of how drugs in sport operate. The Prohibited List contains all substances and methods that meet at least two of the following three criteria outlined in the Code: it is performance enhancing; poses a danger to the health of an athlete; and its use is against the spirit of sport as defined in the Code. Unfortunately, governments and regulators are involved in a constant game of 'catch up'. Unscrupulous chemists, laboratories and related professionals manufacture new substances faster than regulators can devise tests to uncover doping abuse. It is essential that the Prohibited List is revised annually and that the new Prohibited List comes into force three months after it is published. This provides enough time to educate athletes but limits the time cheats have to avoid detection.

32. The timing of amendments to the Annexes may mean that Australia will become bound by the new Prohibited List, in the absence of an objection, before JSCOT has had time to consider the amendments. However it should be emphasised that the amendment procedures in Article 34 only relate to changes to the two Annexes, primarily the Prohibited List. Proposed amendments would be tabled in Parliament at the earliest opportunity, with an NIA, but the parliamentary timetable is unlikely to allow for 15 sitting days' tabling and the JSCOT report before Australia becomes bound by the amended international obligations to which it has not raised an objection. While this regrettably does not sit easily with regular current requirements of Australian practice on the parliamentary review of treaty actions, it is in the national interest that the Annexes to the Convention remain in congruence with the most recent list issued by WADA. It should be noted that the Australian Government is formally consulted on any proposed changes to the List and has a voice in the decisions of the WADA through its representation on both the WADA Foundation Board and Executive Committee.

33. The procedure for amending the Standards for Granting Therapeutic Use Exemptions (Annex 2) is the same as for the Prohibited List. As such the same issues regarding lack of time for Parliamentary review of treaty actions arise. However, the Exemptions Annex is more procedural in nature. It is envisaged that there will be less of a need to amend the Exemption Annex on a regular basis.

34. Article 34 provides that no reservations that are incompatible with the object and purpose of the Convention shall be permitted. Australia does not propose to make any reservation of any kind.

Withdrawal or denunciation

35. Under Article 39, any party may denounce the Convention. The denunciation must be made in writing to the Director-General of UNESCO. Parties must serve a six month period of notice following the receipt of their denunciation in writing. The denunciation then takes effect on the first day of the first month following the expiration of the six month notice period.

36. The financial obligations of a Party are not affected until the date on which the withdrawal takes effect.

37. Australian denunciation of the Convention would be subject to our domestic treaty process, including consideration by JSCOT.

Contact details

Anti-Doping Team

Arts and Sport Division

Department of Communications, Information Technology and the Arts

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CONSULTATION

Both the preliminary and final drafts of the International Convention Against Doping In Sport were provided to States and Territories through the Standing Committees On Treaties process.

Written comments on the preliminary draft were received from Victoria, Queensland, New South Wales, Tasmania and Western Australia. Only Victoria and Queensland raised specific issues in relation to the Convention and these were largely resolved between relevant state and federal agencies.

All States and Territories were provided with a copy of the final draft of the Convention and asked to provide written comments if they had any substantive concerns. Victoria was the only state that responded.

The Victorian Government noted that it was yet to be clearly articulated the extent to which the Code will be applied to sub-elite athletes who are not, in a technical sense, deemed to be subject to doping control programs.

The testing provisions of the Code apply to international athletes (as defined by each international sporting federation) and national athletes (as defined by each national anti-doping organisation). In practice, the pool of athletes covered by the Code is established between the Australian Sports Commission and each National Sporting Organisation in the context of finalisation of sports' anti-doping policies. The Australian Sports Drug Agency (ASDA) is funded to provide drug testing and education to athletes in this pool.

To the extent that States and Territories may wish to test any athletes outside this pool, this is a policy and resourcing matter for each jurisdiction (noting that jurisdictions may wish to contract ASDA for such testing).

The Government is working with the States and Territories to ensure a national approach to anti-doping and this issue is continuing to be progressed through the Standing Committee on Recreation and Sport and the Sport and Recreation Ministers' Council processes.

The Department of Communications, Information Technology and the Arts also held three Inter-Departmental Committee meetings to consult with key Australian Government agencies, including Customs, the Departments of Health and Aging, Agriculture, Forestry and Fisheries, Attorney-General's, the Australian Sports Commission and the Australian Sports Drug Agency.



The World Anti-Doping Code

THE 2005 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 2005.

THE 2005 PROHIBITED LIST WORLD ANTI-DOPING CODE

Valid 1 January 2005

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:

18 α -homo-17 β -hydroxyestr-4-en-3-one; bolasterone; boldenone; boldione; calusterone; clostebol; danazol; dehydrochloromethyl-testosterone; delta1-androstene-3,17-dione; delta1-androstenediol; delta1-dihydro-testosterone; drostanolone; ethylestrenol; fluoxymesterone; formebolone; furazabol; gestrinone; 4-hydroxytestosterone; 4-hydroxy-19-nortestosterone; mestanolone; mesterolone; metenolone; methandienone; methandriol; methyldienolone; methyltrienolone; methyltestosterone; mibolerone; nandrolone; 19-norandrostenediol; 19-norandrostenedione; norbolethone; norclostebol; norethandrolone; oxabolone; oxandrolone; oxymesterone; oxymetholone; quinbolone; stanozolol; stenbolone; tetrahydrogestrinone; trenbolone and other substances with a similar chemical structure or similar biological effect(s).

b. Endogenous** AAS:

androstenediol (androst-5-ene-3 β ,17 β -diol); androstenedione (androst-4-ene-3,17-dione); dehydroepiandrosterone (DHEA); dihydrotestosterone; testosterone.

and the following metabolites and isomers:

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

Where a *Prohibited Substance* (as listed above) is capable of being produced by the body naturally, a *Sample* will be deemed to contain such *Prohibited Substance* where the concentration of the *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 the *Athlete* proves by evidence 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 laboratory will report an *Adverse Analytical Finding* if, based on any reliable analytical method, it can show that the *Prohibited Substance* is of exogenous origin.

If the laboratory result is not conclusive and no concentration as referred to in the above paragraph is found, the relevant *Anti-Doping Organization* shall conduct a further investigation if there are serious indications, such as a comparison to reference steroid profiles, for a possible *Use of a Prohibited Substance*.

If the laboratory has reported the presence of a T/E ratio greater than four (4) to one (1) in the urine, further investigation is obligatory in order to determine whether the ratio is due to a physiological or pathological condition, except if the laboratory reports an *Adverse Analytical Finding* based on any reliable analytical method, showing that the *Prohibited Substance* is of exogenous origin.

In case of an investigation, it will include a review of any previous and/or subsequent tests. If previous tests are not available, the *Athlete* shall be tested unannounced at least three times within a three month period.

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, zeranol, zilpaterol.

For purposes of this section:

* "exogenous" refers to a substance which is not 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, including other substances with a similar chemical structure or similar biological effect(s), and their releasing factors, are prohibited:

- 1. Erythropoietin (EPO);**
- 2. Growth Hormone (hGH), Insulin-like Growth Factor (IGF-1), Mechano Growth Factors (MGFs);**
- 3. Gonadotrophins (LH, hCG);**
- 4. Insulin;**
- 5. Corticotrophins.**

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 so that it is unlikely to be consistent with normal endogenous production.

The presence of other substances with a similar chemical structure or similar biological effect(s), diagnostic marker(s) or releasing factors of a hormone listed above or of any other finding which indicate(s) that the substance detected is of exogenous origin, will be reported as an *Adverse Analytical Finding*.

S3. BETA-2 AGONISTS

All beta-2 agonists including their D- and L-isomers are prohibited. Their use requires a Therapeutic Use Exemption.

As an exception, formoterol, salbutamol, salmeterol and terbutaline, when administered by inhalation to prevent and/or treat asthma and exercise-induced asthma/broncho-constriction require an abbreviated Therapeutic Use Exemption.

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

S4. AGENTS WITH ANTI-ESTROGENIC ACTIVITY

The following classes of anti-estrogenic substances 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.**

S5. DIURETICS AND OTHER MASKING AGENTS

Diuretics and other masking agents are prohibited.

Masking agents include but are not limited to:

Diuretics*, epitestosterone, probenecid, alpha-reductase inhibitors (e.g. finasteride, dutasteride), plasma expanders (e.g. albumin, dextran, hydroxyethyl starch).

Diuretics include:

acetazolamide, amiloride, bumetanide, canrenone, chlortalidone, 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).

* 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:

- a. Blood doping, including the use of autologous, homologous or heterologous blood or red blood cell products of any origin, other than for medical treatment.
- b. 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

The following is prohibited:

Tampering, or attempting to tamper, in order to alter the integrity and validity of *Samples* collected in *Doping Controls*.

These include but are not limited to intravenous infusions*, catheterisation, and urine substitution.

* Except as a legitimate acute medical treatment, intravenous infusions are prohibited.

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

The following stimulants are prohibited, including both their optical (D- and L-) isomers where relevant:

Adrafinil, amfepramone, amiphenazole, amphetamine, amphetaminil, benzphetamine, bromantan, carphedon, cathine^{*}, clobenzorex, cocaine, dimethylamphetamine, ephedrine^{}, etilamphetamine, etilefrine, famprofazone, fencamfamin, fencamine, fenetylline, fenfluramine, fenproporex, furfenorex, mefenorex, mephentermine, mesocarb, methamphetamine, methylamphetamine, methylenedioxyamphetamine, methylenedioxymethamphetamine, methylephedrine^{**}, methylphenidate, modafinil, nikethamide, norfenfluramine, parahydroxyamphetamine, pemoline, phendimetrazine, phenmetrazine, phentermine, prolintane, selegiline, strychnine,** and other substances with a similar chemical structure or similar biological effect(s)^{***}.

* **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.

*** The substances included in the 2005 Monitoring Program (bupropion, caffeine, phenylephrine, phenylpropanolamine, pipradrol, pseudoephedrine, synephrine) are not considered as Prohibited Substances.

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

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.

All other routes of administration require an abbreviated Therapeutic Use Exemption.

Dermatological preparations are not prohibited.

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 for each Federation is reported in parenthesis.

- | | | | |
|--------------------|------------|------------------------------------|------------|
| • Aeronautic (FAI) | (0.20 g/L) | • Karate (WKF) | (0.10 g/L) |
| • Archery (FITA) | (0.10 g/L) | • Modern Pentathlon (UIPM) | (0.10 g/L) |
| • Automobile (FIA) | (0.10 g/L) | for disciplines involving shooting | |
| • Billiards (WCBS) | (0.20 g/L) | • Motorcycling (FIM) | (0.00 g/L) |
| • Boules (CMSB) | (0.10 g/L) | • Skiing (FIS) | (0.10 g/L) |

P2. BETA-BLOCKERS

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

- | | |
|---------------------------------------------------------------|----------------------------------------------------------------|
| • Aeronautic (FAI) | • Modern Pentathlon (UIPM) for disciplines involving shooting |
| • Archery (FITA) (also prohibited <i>out-of-competition</i>) | • Nine-pin bowling (FIQ) |
| • Automobile (FIA) | • Sailing (ISAF) for match race helms only |
| • Billiards (WCBS) | • Shooting (ISSF) (also prohibited <i>out-of-competition</i>) |
| • Bobsleigh (FIBT) | • Skiing (FIS) in ski jumping & free style snow board |
| • Boules (CMSB) | • Swimming (FINA) in diving & synchronised swimming |
| • Bridge (FMB) | • Wrestling (FILA) |
| • Chess (FIDE) | |
| • Curling (WCF) | |
| • Gymnastics (FIG) | |
| • Motorcycling (FIM) | |

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:

Ephedrine, L-methylamphetamine, methylephedrine;
Cannabinoids;
All inhaled Beta-2 Agonists, except clenbuterol;
Probenecid;
All Glucocorticosteroids;
All Beta Blockers;
Alcohol.

* *"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..."*

STANDARDS FOR GRANTING THERAPEUTIC USE EXEMPTIONS

Extract from «INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS» of the World Anti-Doping Agency (WADA); in force January 1st, 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 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:

- In 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 Clearinghouse

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 Clearinghouse shall guarantee strict confidentiality of all the medical information.

World Anti-Doping Code



2003

TABLE OF CONTENTS

INTRODUCTION

PURPOSE, SCOPE AND ORGANIZATION OF THE WORLD ANTI-DOPING PROGRAM AND THE <i>CODE</i>	1
THE WORLD ANTI-DOPING PROGRAM.....	1
THE <i>CODE</i>	1
<i>INTERNATIONAL STANDARDS</i>	2
MODELS OF BEST PRACTICE.....	2
FUNDAMENTAL RATIONALE FOR THE WORLD ANTI-DOPING <i>CODE</i>	3

PART ONE: DOPING CONTROL

INTRODUCTION	6
ARTICLE 1: DEFINITION OF DOPING	8
ARTICLE 2: ANTI-DOPING RULE VIOLATIONS	8
2.1.....THE PRESENCE OF A <i>PROHIBITED SUBSTANCE</i> OR ITS <i>METABOLITES</i> OR <i>MARKERS</i> IN AN <i>ATHLETE'S BODILY SPECIMEN</i>	8
2.2..... <i>USE</i> OR <i>ATTEMPTED USE</i> OF A <i>PROHIBITED</i> <i>SUBSTANCE</i> OR A <i>PROHIBITED METHOD</i>	10
2.3.....	10
2.4.....	11
2.5..... <i>TAMPERING</i> , OR <i>ATTEMPTING TO TAMPER</i> , WITH ANY PART OF <i>DOPING CONTROL</i>	11
2.6..... <i>POSSESSION</i> OF <i>PROHIBITED SUBSTANCES</i> AND <i>METHODS</i>	11
2.7..... <i>TRAFFICKING</i> IN ANY <i>PROHIBITED SUBSTANCE</i> OR <i>PROHIBITED METHOD</i>	12
2.8.....	12
ARTICLE 3: PROOF OF DOPING	12
3.1.....BURDENS AND STANDARDS OF PROOF.....	12
3.2.....METHODS OF ESTABLISHING FACTS AND PRESUMPTIONS.....	12

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ARTICLE 4: THE PROHIBITED LIST 14

4.1 PUBLICATION AND REVISION OF THE PROHIBITED LIST 14

4.2 PROHIBITED SUBSTANCES AND PROHIBITED METHODS IDENTIFIED ON THE PROHIBITED LIST 14

4.3 CRITERIA FOR INCLUDING SUBSTANCES AND METHODS ON THE PROHIBITED LIST 15

4.4 THERAPEUTIC USE 17

4.5 MONITORING PROGRAM 18

ARTICLE 5: TESTING 19

5.1 TEST DISTRIBUTION PLANNING 19

5.2 STANDARDS FOR TESTING 20

ARTICLE 6: ANALYSIS OF SAMPLES 20

6.1 USE OF APPROVED LABORATORIES 20

6.2 SUBSTANCES SUBJECT TO DETECTION 20

6.3 RESEARCH ON SAMPLES 20

6.4 STANDARDS FOR SAMPLE ANALYSIS AND REPORTING 21

ARTICLE 7: RESULTS MANAGEMENT 21

7.1 INITIAL REVIEW REGARDING ADVERSE ANALYTICAL FINDINGS 21

7.2 NOTIFICATION AFTER INITIAL REVIEW 21

7.3 FURTHER REVIEW OF ADVERSE ANALYTICAL FINDING WHERE REQUIRED BY PROHIBITED LIST 22

7.4 REVIEW OF OTHER ANTI-DOPING RULE VIOLATIONS 22

7.5 PRINCIPLES APPLICABLE TO PROVISIONAL SUSPENSIONS 23

ARTICLE 8 : RIGHT TO A FAIR HEARING 24

ARTICLE 9: AUTOMATIC DISQUALIFICATION OF INDIVIDUAL RESULTS 25

ARTICLE 10: SANCTIONS ON INDIVIDUALS 26

10.1 DISQUALIFICATION OF RESULTS IN EVENT DURING WHICH AN ANTI-DOPING RULE VIOLATION OCCURS 26

10.2 IMPOSITION OF INELIGIBILITY FOR PROHIBITED SUBSTANCES AND PROHIBITED METHODS 26

10.3 SPECIFIED SUBSTANCES 27

10.4 INELIGIBILITY FOR OTHER ANTI-DOPING RULE VIOLATIONS 28

10.5 ELIMINATION OR REDUCTION OF PERIOD OF INELIGIBILITY BASED ON EXCEPTIONAL CIRCUMSTANCES 29

10.6 RULES FOR CERTAIN POTENTIAL MULTIPLE VIOLATIONS 32

10.7 DISQUALIFICATION OF RESULTS IN COMPETITIONS SUBSEQUENT TO SAMPLE COLLECTION 34

10.8 COMMENCEMENT OF INELIGIBILITY PERIOD 34

10.9 STATUS DURING INELIGIBILITY 35

10.10 REINSTATEMENT TESTING 36

ARTICLE 11: CONSEQUENCES TO TEAMS 36

ARTICLE 12: SANCTIONS AGAINST SPORTING BODIES 37

ARTICLE 13: APPEALS 37

13.1 DECISIONS SUBJECT TO APPEAL 37

13.2 APPEALS FROM DECISIONS REGARDING ANTI-DOPING RULE VIOLATIONS, CONSEQUENCES, AND PROVISIONAL SUSPENSIONS 37

13.3 APPEALS FROM DECISIONS GRANTING OR DENYING A THERAPEUTIC USE EXEMPTION 39

13.4 APPEALS FROM DECISIONS IMPOSING CONSEQUENCES UNDER PART THREE OF THE CODE 40

13.5 APPEALS FROM DECISIONS SUSPENDING OR REVOKING LABORATORY ACCREDITATION 40

ARTICLE 14 : CONFIDENTIALITY AND REPORTING 40

14.1 INFORMATION CONCERNING ADVERSE ANALYTICAL FINDINGS AND OTHER POTENTIAL ANTI-DOPING RULE VIOLATIONS 40

14.2 PUBLIC DISCLOSURE 41

14.3 ATHLETE WHEREABOUTS INFORMATION 42

14.4 STATISTICAL REPORTING 42

14.5 DOPING CONTROL INFORMATION CLEARING HOUSE 42

ARTICLE 15: CLARIFICATION OF DOPING CONTROL RESPONSIBILITIES 43

15.1 EVENT TESTING 43

15.2 OUT-OF-COMPETITION TESTING 44

15.3 RESULTS MANAGEMENT, HEARINGS AND SANCTIONS 44

15.4 MUTUAL RECOGNITION 45

Contents

Contents

**ARTICLE 16: DOPING CONTROL FOR ANIMALS
COMPETING IN SPORT45**

16.145

16.246

ARTICLE 17: STATUTE OF LIMITATIONS46

PART TWO: EDUCATION AND RESEARCH

ARTICLE 18: EDUCATION50

18.1BASIC PRINCIPLE AND PRIMARY GOAL50

18.2PROGRAM AND ACTIVITIES50

18.3COORDINATION AND COOPERATION50

ARTICLE 19: RESEARCH51

19.1PURPOSE OF ANTI-DOPING RESEARCH51

19.2TYPES OF RESEARCH51

19.3COORDINATION51

19.4RESEARCH PRACTICES51

19.5ADMINISTRATION OF *PROHIBITED SUBSTANCES*
AND *PROHIBITED METHODS*51

19.6MISUSE OF RESULTS51

PART THREE: ROLES AND RESPONSIBILITIES

**ARTICLE 20: ADDITIONAL ROLES AND RESPONSIBILITIES
OF SIGNATORIES54**

20.1ROLES AND RESPONSIBILITIES OF THE
INTERNATIONAL OLYMPIC COMMITTEE54

20.2ROLES AND RESPONSIBILITIES OF THE
INTERNATIONAL PARALYMPIC COMMITTEE54

20.3ROLES AND RESPONSIBILITIES OF
INTERNATIONAL FEDERATIONS55

20.4ROLES AND RESPONSIBILITIES OF NATIONAL OLYMPIC
COMMITTEES AND NATIONAL PARALYMPIC COMMITTEES56

20.5ROLES AND RESPONSIBILITIES OF NATIONAL
ANTI-DOPING ORGANIZATIONS57

20.6ROLES AND RESPONSIBILITIES OF MAJOR
EVENT ORGANIZATIONS57

20.7ROLES AND RESPONSIBILITIES OF WADA57

**ARTICLE 21: ROLES AND RESPONSIBILITIES OF
PARTICIPANTS58**

21.1ROLES AND RESPONSIBILITIES OF *ATHLETES*58

21.2ROLES AND RESPONSIBILITIES OF *ATHLETE*
SUPPORT PERSONNEL58

ARTICLE 22: INVOLVEMENT OF GOVERNMENTS59

22.159

22.260

22.260

**PART FOUR: ACCEPTANCE, COMPLIANCE,
MODIFICATION & INTERPRETATION**

ARTICLE 23: ACCEPTANCE, COMPLIANCE AND MODIFICATION...64

23.1ACCEPTANCE OF THE *CODE*64

23.2IMPLEMENTATION OF THE *CODE*64

23.3ACCEPTANCE AND IMPLEMENTATION DEADLINES65

23.4MONITORING COMPLIANCE WITH THE *CODE*65

23.5CONSEQUENCES OF NONCOMPLIANCE WITH THE *CODE*66

23.6MODIFICATION OF THE *CODE*66

23.7WITHDRAWAL OF ACCEPTANCE OF THE *CODE*67

ARTICLE 24: INTERPRETATION OF THE *CODE*67

24.167

24.267

24.367

24.468

24.568

24.668

APPENDIX 1: DEFINITIONS72

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,

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.

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.

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

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*.

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

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

ARTICLE 1: DEFINITION OF DOPING

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

ARTICLE 2: ANTI-DOPING RULE VIOLATIONS

The following constitute anti-doping rule violations:

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

2.1.1 It is each *Athlete's* personal duty to ensure that no *Prohibited Substance* enters his or her body. *Athletes* are responsible for any *Prohibited Substance* or its *Metabolites* or *Markers* found to be present in their bodily *Specimens*. Accordingly, it is not necessary that intent, fault, negligence or knowing *Use* on the *Athlete's* part be demonstrated in order to establish an anti-doping violation under Article 2.1.

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

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

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;

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 not ensure that all of the appropriate specified because random *Testing*, or *Athletes* will be tested. (For example, even weighted random *Testing*, does 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*

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.*

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

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

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

10.6.3 Comment: *Article 10.6.3 deals with the situation where an Athlete commits two separate anti-doping rule violations, but one of the violations involves a specified substance governed by the lesser sanctions of Article 10.3. Without this Article in the Code, the second offense arguably could be governed by: the sanction applicable to a second violation for the Prohibited Substance involved in the second violation, the sanction applicable to a second offense for the substance involved in the first violation, or a combination of the sanctions applicable to the 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*

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.

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.

13.3 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

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

15.4 Mutual Recognition

Subject to the right to appeal provided in Article 13, the *Testing*, therapeutic use exemptions and hearing results or other final adjudications of any *Signatory* which are consistent with the *Code* and are within that *Signatory's* authority, shall be recognized and respected by all other *Signatories*. *Signatories* may recognize the same actions of other bodies which have not accepted the *Code* if the rules of those bodies are otherwise consistent with the *Code*.

ARTICLE 16: DOPING CONTROL FOR ANIMALS COMPETING IN SPORT

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

conducting hearings where a *National Anti-Doping Organization* tests a foreign national athlete over whom it would have had no jurisdiction but for the *Athlete's* presence in the *National Anti-Doping 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.

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 I 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* renounces 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.

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.



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.

TABLE OF CONTENTS

PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS . 4

1.0 Introduction, Scope and References	4
2.0 Code Provisions	7
3.0 Terms and definitions	8
3.1 Code defined Terms	8
3.2 Defined Terms from the International Standard for Laboratories.....	10

PART TWO: LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS 12

4.0 Requirements for WADA accreditation	12
4.1 Initial <i>WADA</i> accreditation	12
4.2 Maintaining <i>WADA</i> Accreditation	13
4.3 Special Requirements for Major <i>Events</i>	15
5.0 Application of ISO 17025 to the Analysis of Doping Control Samples ...	16
5.1 Introduction and Scope	16
5.2 Analytical and Technical Processes.....	17
5.3 Quality Management Processes	25
5.4 Support processes	28
6.0 Process of WADA Accreditation	37
6.1 Applying for a <i>WADA</i> Laboratory Accreditation	37
6.2 Preparing for <i>WADA</i> Laboratory Accreditation.....	38
6.3 Obtaining <i>WADA</i> Accreditation.....	39
6.4 Maintaining <i>WADA</i> Accreditation	40
6.5 Accreditation Requirements for Satellite Facilities for Major <i>Events</i>	44
7.0 Requirements for supporting an <i>Adverse Analytical Finding</i> in the Adjudication Process	46
7.1 Laboratory Documentation Package	46

PART THREE: ANNEXES 48

ANNEX A - WADA PROFICIENCY TESTING PROGRAM..... 48

1. Probationary period.....	48
2. Maintenance/Re-accreditation period.....	48
3. Proficiency Test Sample Composition.....	49
4. Evaluation of Proficiency Testing Results.....	50

ANNEX B - LABORATORY CODE OF ETHICS..... 54

1. Confidentiality	54
2. Research.....	54
3. Testing	54
4. Conduct Detrimental to the Anti-Doping Program.....	56

ANNEX C - LIST OF TECHNICAL DOCUMENTS 57

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., $\pm 20\%$ 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

$$z = \frac{\bar{x} - \hat{x}}{d}$$

Where \bar{x} is the value found

\hat{x} is the assigned value

d 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	<i>In progress</i>
Measurement of Uncertainty for Anti-Doping Analysis			<i>Future</i>
Reporting Guidance for Gas Chromatography/Combustion/ Isotope Ratio Mass Spectrometry			<i>Future</i>
Reporting Guidance for Salbutamol and other Beta-2 Agonists			<i>Future</i>

Valid July, 1st, 2004.

ADDENDUM TO THE INTERNATIONAL STANDARD FOR LABORATORIES

REQUIREMENTS FOR ANTI-DOPING ANALYSIS OF WHOLE BLOOD, PLASMA, SERUM OR OTHER BLOOD FRACTIONS.

Several anti-doping tests have now been developed on the blood matrix, and can be applied to whole blood or blood fractions (e.g. plasma, serum) to determine doping practices in sport.

As currently established, the World Anti-Doping *Code International Standard* for Laboratories does not specifically cover procedures to handle and analyze the blood matrix in anti-doping Laboratories. Provision 5.2.4.4.1 of the *International Standard* for Laboratories refers to specific requirements for the analysis of the blood matrix to be promulgated separately.

The present document is established to complement or amend the existing *International Standard* for Laboratories, to provide ad hoc requirements to the Laboratories for handling and analyzing blood *Samples* in the context of anti-doping analysis.

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

Specific Requirements for Whole Blood or Blood Fractions Analyses

In any Sections that refer to urine, and are carried over into this document by reference, the terms blood, plasma, or serum shall be substituted as appropriate. Unless otherwise stated, there is no blood, plasma, or serum equivalent to the urine integrity test or data, and any reference to this should be deleted.

The following sections of Section 5 of the *International Standard* for Laboratories apply to the analysis of blood *Samples* by reference:

5.1 and all subsections;

5.2.1 and all subsections;

5.2.2 and all subsections with the exception of subsections 5.2.2.5 and 5.2.2.6 which are replaced by the following:

Provisions 5.2.2.5 and 5.2.2.6 apply to plasma, serum or other blood fractions containing no blood cells. *Samples* shall be frozen on reception until analysis and as soon as practical after aliquots have been taken for analysis. The Laboratory shall retain the A and B *Samples* for a minimum of three (3) months after the Testing Authority receives a negative report. The *Samples* shall be retained frozen under appropriate conditions.

Samples with irregularities shall be held frozen for a minimum of three (3) months following the report to the Testing Authority.

Samples that consist of whole blood or blood fractions containing intact cells shall be stored at approximately 4 degree Celsius on reception and should be analyzed within 48 hours. As soon as practicable after aliquots have been taken for analysis, *Samples* should be returned to approximately 4 degree Celsius storage. The anti-doping Laboratory shall retain the A and B *Samples* with or without *Adverse Analytical Finding* for a minimum of 1 month after the Testing Authority receives the final analytical ("A" or "B" *Sample*) report.

5.2.3 and all subsections;

5.2.4 all subsections with the exception of subsections 5.2.4.1, 5.2.4.3.1.1, 5.2.4.2.1, 5.2.4.2.4, 5.2.4.3.1.2, 5.2.4.3.2.1, which are replaced or amended where needed by the following:

5.2.4.3.1.1 Screening and confirmation tests may be performed initially on the same aliquot of *Sample*. The test should be repeated on a fresh aliquot of the *Sample* to ensure that the initial test results are repeatable from the same *Sample* bottle.

Detection of blood transfusion relies upon the use of multiple antibodies and flow cytometry to reveal several red blood cell antigens. Consequently article 5.2.4.3.1.3 does not apply for this type of immunochemical analysis.

5.2.4.3.2.1 , for "B" *Sample* confirmation in whole blood or blood fraction with blood cells only, the "B" *Sample* analysis shall be completed within 30 days of notification of an "A" *Sample Adverse Analytical Finding*.

5.2.5 and all subsections;

5.2.6 and all subsections with the exception of 5.2.6.4, 5.2.6.7, and 5.2.6.8.

5.3 and all subsections;

5.4 and all subsections with the exception of 5.4.4.1, 5.4.4.2.2, 5.4.4.3, 5.4.6, and 5.4.7 which are amended, where applicable, by the following:

5.4.4.1 Selection of Methods

Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall develop, validate and document in-house methods for substances on the *Prohibited List* or their Metabolites or Markers. The methods shall be selected and validated so they are fit for the purpose.

5.4.4.3 The Laboratory should provide an estimation of the measurement uncertainty where applicable.

5.4.6.2 Reference Collection

A collection of *Samples* or isolates may be obtained from a biological matrix following an authentic and verifiable administration or traceable mixture of a *Prohibited Substance* or *Method*, providing that the analytical data are sufficient to justify the identity of the *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Metabolite* of a *Prohibited Substance* or *Marker* of a *Prohibited Substance* or *Method*.

5.4.7. Assuring the quality of test results

5.4.7.1. The performance of Laboratories for analysis on the blood matrix will be evaluated as deemed necessary by the *World Anti-Doping Agency* under the principles of the *International Standard for Laboratories* specifically applied to the blood matrix.

5.4.7.2 The Laboratory shall have in place a quality assurance system, including the submission of blind quality control samples, that challenges the entire scope of the testing process.

5.4.7.3 Analytical performance should be monitored by operating quality control schemes appropriate to the type and frequency of blood testing performed by the Laboratory.

Applicable Technical Documents for blood analysis:

Laboratory Documentation Packages.

Laboratory Internal Chain of Custody.



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.

TABLE OF CONTENT

PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS	4
1.0 Introduction and scope	4
2.0 Code Provisions	5
3.0 Terms and definitions	7
3.1 Defined terms from the <i>Code</i>	7
3.2 Defined Terms from the <i>International Standard for Testing</i>	10
PART TWO: STANDARDS FOR TESTING	12
4.0 Planning	12
4.1 Objective	12
4.2 General	12
4.3 Requirements for establishing the <i>Registered Testing Pool</i>	12
4.4 Requirements for collecting <i>Athlete</i> whereabouts information for the purposes of Out of Competition Testing	13
4.5 Requirements for test distribution planning	13
4.6 Requirements for selection of <i>Athletes</i>	14
5.0 Notification of Athletes	15
5.1 Objective	15
5.2 General	15
5.3 Requirements prior to notification of <i>Athletes</i>	16
5.4 Requirements for notification of <i>Athletes</i>	17
6.0 Preparing for the Sample Collection Session	19
6.1 Objective	19
6.2 General	20
6.3 Requirements for preparing for the <i>Sample</i> Collection Session	20
7.0 Conducting the Sample Collection Session	21
7.1 Objective	21
7.2 General	21
7.3 Requirements prior to <i>Sample</i> collection	21
7.4 Requirements for <i>Sample</i> collection	22
8.0 Security/Post test administration	23
8.1 Objective	23
8.2 General	24
8.3 Requirements for Security/post test administration	24
9.0 Transport of Samples and documentation	24
9.1 Objective	24
9.2 General	24
9.3 Requirements for transport of <i>Samples</i> and documentation	25
PART THREE: ANNEXES	26
Annex A - Investigating a possible failure to comply	26
Annex B - Modifications for <i>Athletes</i> with disabilities	28
Annex C - Collection of urine <i>Samples</i>	30
Annex D - Collection of blood <i>Samples</i>	33
Annex E - Urine <i>Samples</i> - Insufficient volume	36
Annex F - Urine <i>Samples</i> - Samples that do not meet laboratory pH or specific gravity guidelines	38
Annex G - Sample Collection Personnel Requirements	40

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 *Athletes* with disabilities.

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

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

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

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

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

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

C.4.12 Once a *Sample* collection kit has been selected, the DCO and the *Athlete* shall check that all code numbers match and that this code number is recorded accurately by the DCO.

If the *Athlete* or DCO finds that the numbers are not the same, the DCO shall instruct the *Athlete* to choose another kit in accordance with C.4.4. The DCO shall record the matter.

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

C.4.14 The *Athlete* shall seal the bottles as directed by the DCO. The DCO shall check, in full view of the *Athlete*, that the bottles have been properly sealed.

C.4.15 The DCO shall use the relevant laboratory's guidelines for pH and specific gravity to test the residual urine in the collection vessel to determine if the *Sample* is likely to meet the laboratory guidelines. If it is

not, then the DCO shall follow Annex F - Urine *Samples* - *Samples* that do not meet laboratory pH and specific gravity guidelines.

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

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 Samples* do not meet the laboratory's pH and specific gravity requirements for analysis and this is not related to natural causes, the ADO shall schedule another Sample Collection Session for the *Athlete* as *Target Testing* as soon as possible.

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

Annex G - Sample Collection Personnel Requirements

G.1 Objective

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

G.2 Scope

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

G.3 Responsibility

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 Officers 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.

Member States of the United Nations Education, Science and Cultural Organization

As at 1 November 2005, no Member States had acceded to the Convention Against Doping in Sport

1. Afghanistan
2. Albania
3. Algeria
4. Andorra
5. Angola
6. Antigua and Barbuda
7. Argentina
8. Armenia
9. Australia
10. Austria
11. Azerbaijan
12. Bahamas
13. Bahrain
14. Bangladesh
15. Barbados
16. Belarus
17. Belgium
18. Belize
19. Benin
20. Bhutan
21. Bolivia
22. Bosnia and Herzegovina
23. Botswana
24. Brunei Darussalam
25. Bulgaria
26. Burkina Faso
27. Burundi
28. Brazil
29. Cambodia
30. Cameroon
31. Canada
32. Cape Verde
33. Central African Republic
34. Chad
35. Chile
36. China
37. Colombia
38. Comoros
39. Congo

40. Cook Islands
41. Costa Rica
42. Côte d'Ivoire
43. Croatia
44. Cuba
45. Cyprus
46. Czech Republic
47. Democratic People's Republic of Korea
48. Democratic Republic of the Congo
49. Denmark
50. Djibouti
51. Dominica
52. Dominican Republic
53. Ecuador
54. Egypt
55. El Salvador
56. Equatorial Guinea
57. Eritrea
58. Estonia
59. Ethiopia
60. Fiji
61. Finland
62. France
63. Gabon
64. Gambia
65. Georgia
66. Germany
67. Ghana
68. Greece
69. Grenada
70. Guatemala
71. Guinea
72. Guinea-Bissau
73. Guyana
74. Haiti
75. Honduras
76. Hungary
77. Iceland
78. India
79. Indonesia
80. Iran (Islamic Republic of)
81. Iraq
82. Ireland

83. Israel
84. Italy
85. Jamaica
86. Japan
87. Jordan
88. Kazakhstan
89. Kenya
90. Kiribati
91. Kuwait
92. Kyrgyzstan
93. Lao People's Democratic Republic
94. Latvia
95. Lebanon
96. Lesotho
97. Liberia
98. Libyan Arab Jamahiriya
99. Lithuania
100. Luxembourg
101. Madagascar
102. Malawi
103. Malaysia
104. Maldives
105. Mali
106. Malta
107. Marshall Islands
108. Mauritania
109. Mauritius
110. Mexico
111. Micronesia (Federated States of)
112. Monaco
113. Mongolia
114. Morocco
115. Mozambique
116. Myanmar
117. Namibia
118. Nauru
119. Nepal
120. Netherlands
121. New Zealand
122. Nicaragua
123. Niger
124. Nigeria
125. Niue

126. Norway
127. Oman
128. Pakistan
129. Palau
130. Panama
131. Papua New Guinea
132. Paraguay
133. Peru
134. Philippines
135. Poland
136. Portugal
137. Qatar
138. Republic of Korea
139. Republic of Moldova
140. Romania
141. Russian Federation
142. Rwanda
143. Saint Kitts and Nevis
144. Saint Lucia
145. Saint Vincent and the Grenadines
146. Samoa
147. San Marino
148. Sao Tome and Principe
149. Saudi Arabia
150. Senegal
151. Serbia and Montenegro
152. Seychelles
153. Sierra Leone
154. Slovakia
155. Slovenia
156. Solomon Islands
157. Somalia
158. South Africa
159. Spain
160. Sri Lanka
161. Sudan
162. Suriname
163. Swaziland
164. Sweden
165. Switzerland
166. Syrian Arab Republic
167. Tajikistan
168. Thailand

169. The former Yugoslav Republic of Macedonia
170. Timor-Leste
171. Togo
172. Tonga
173. Trinidad and Tobago
174. Tunisia
175. Turkey
176. Turkmenistan
177. Tuvalu
178. Uganda
179. Ukraine
180. United Arab Emirates
181. United Kingdom of Great Britain and Northern Ireland
182. United Republic of Tanzania
183. United States of America
184. Uruguay
185. Uzbekistan
186. Vanuatu
187. Venezuela
188. Viet Nam
189. Yemen
190. Zambia
191. Zimbabwe

Associate Members

1. Aruba
2. British Virgin Islands
3. Cayman Islands
4. Macao, China
5. Netherlands Antille
6. Tokelau