International Standards for Doping Control (ISDC)

Prepared for the International Organisation for Standardisation (ISO)

By the International Anti-Doping Arrangement (IADA)

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Contents

Preamble

Australia, Canada, the Netherlands, New Zealand, Norway, Sweden and the United Kingdom have established an international alliance in the area of anti-doping in sport. At the government level they have signed a memorandum of understanding, the International Anti-Doping Arrangement (IADA), outlining their commitment to co-operatively pursue and promote anti-doping in sport.

The IADA mission is to ensure the development and harmonisation of the domestic doping control programmes of the seven signatories and through this concrete example of good practice, positively influence the broader international sports community.

The IADA Strategic Plan for 1995-1998 emphasised the need for developing and implementing quality systems for national anti-doping programmes. Such systems will contribute to uniform practices and also increase world-wide confidence in doping control procedures.

At the July 1995 IADA meeting in Oslo, Norway, the IADA countries agreed to take part in the IADA Quality Project with the goals of developing and implementing quality systems for the participating countries' domestic doping control programmes, and having the quality systems certified by an internationally recognised and accredited ISO certifying agency. The ISO 9002 standard in the ISO 9000 series was recommended to be the reference standard for establishing quality systems in each IADA country.

The IADA Standard for Doping Control, version 2.0, was approved by the members of the IADA Steering Group at their March 1998 meeting in Sydney**,** Australia. In the IADA Standard for Doping Control, the IADA member countries have defined the overall quality policy for doping control programmes as follows:

«Through the implementation of quality systems for doping control which satisfy the requirements in the IADA Standard for Doping Control, the doping control procedures and practices will be consistent, secure and reliable in all phases of the doping control process.»

The IADA Standard for Doping Control shall be reviewed according to the «Procedure for Changing and Controlling the Quality Manual» which was approved by the IADA Steering Group in Canberra**,** Australia on 10 February, 1997.

Any departure from the policies and/or standards set out in the IADA Standard for Doping Control shall not invalidate the finding of a positive test result or failure to comply with a request to provide a sample unless such a departure casts real doubt on the reliability of the finding.

The IADA Quality Concept

The IADA Quality Concept presents a comprehensive approach for managing and improving quality control in doping control programmes.

By setting policies and standards for carrying out the doping control process and by ensuring that the doping control procedures in different anti-doping organisations are in compliance with these policies and standards, it will be possible to develop high quality, harmonised doping control practices world wide.

The IADA Quality Concept is comprised of the following elements:

The IADA Standard for Doping Control
ISO Certified Quality Systems for Doping Control
Guidelines for Implementing ISO Certified Quality Systems.

The IADA Standard for Doping Control

The objectives for the IADA Standard for Doping Control are to improve and harmonise doping control practices, particularly as they directly affect the athlete.

The IADA Standard for Doping Control prescribes policies and standards for the doping control process and for the quality management of doping control procedures and programmes. The IADA Standard for Doping Control was designed and developed at the international level with the support and joint commitment of the IADA countries. The Standard includes:

Policies and Standards for the Doping Control Process
Frame Conditions for Anti-Doping Organisations
Policies and Standards for Applying ISO 9002 to Doping Control.

<u>Policies and Standards for the Doping Control Process</u>
represent world best practices for doping control in sport and will be essential in harmonising doping control procedures and practices in the international sport community.

The doping control process has been divided into seven phases. Each of these phases focuses on activities that have a strong impact on the overall quality of the doping control process. The seven phases are: test distribution planning; selection and notification of athletes; preparing for and conducting the sample collection session; handling of samples; sample analysis; results management; and disciplinary procedures, sanctions and appeals. These seven phases represent a natural activity flow in the doping control process.

The main customers of the doping control process are the athletes.

Frame Conditions for Anti-Doping Organisations
include areas that have a considerable influence on the various phases in the doping control process. Frame conditions are not part of the natural activity flow in the doping control process but are prerequisites for conducting doping control programmes and procedures. Every anti-doping organisation must have these prerequisites in place in order to carry out doping controls in compliance with the policies and standards for the doping control process prescribed in the following chapter.

The frame conditions will vary depending on the type of organisation conducting doping controls. The IADA Standard for Doping Control distinguishes between frame conditions for anti-doping organisations at the national level, anti-doping organisations acting on behalf of international sport organisations and anti-doping organisations acting on behalf of major international event organisers.

Policies and Standards for Applying ISO 9002 to the Doping Control Process
introduce quality management principles. The objective of these policies and standards is to manage the doping control process using quality systems that are developed at the national or organisational level and that are in compliance with ISO 9002.

Through the implementation of quality systems for doping control that satisfy requirements in the IADA Standard for Doping Control, doping control procedures and practices will be consistent, secure and reliable in all phases of the doping control process. In turn**,** by applying the requirements in the ISO 9002 standard to the doping control process, a quality system will be developed that ensures the effective implementation of the IADA Standard for Doping Control at the national or organisational level. The ISO 9000 series standards are widely recognised and have been adopted by more than 70 countries. There is a growing interest in international quality standards in many industries, including the service sector. Quality systems developed in compliance with the ISO 9000 series will increase both the impact of doping control programmes and confidence in doping control practices.

The IADA Standard for Doping Control is the main reference document in the IADA Quality Concept. Therefore, any country or organisation participating in the IADA Quality Concept is committed to following the policies and standards prescribed in the IADA Standard for Doping Control.

ISO Certified Quality Systems for Doping Control

The policies and standards for applying ISO 9002 to the doping control process define the requirements for the development and implementation of quality systems that are in compliance with the IADA Quality Concept. Anti-doping organisations must implement quality systems according to these standards in order to be part of the IADA Quality Concept.

The quality systems shall be certified in accordance with ISO 9002 by an accredited certifying agency. Doping control is a new area of application for ISO 9000 quality systems. It is therefore necessary to adapt the requirements of the ISO 9002 standard in a manner that is appropriate for the doping control process.

The quality systems represent the operational level in the IADA Quality Concept. The development and implementation of required quality system documentation such as the quality manual, quality policies, procedures, work instructions, specifications, etc. are critical for the effective application of the IADA Standard for Doping Control. The quality system documentation is the main tool for ensuring that doping control activities are carried out in accordance with the prescribed standards.

The quality systems shall be audited and reviewed according to specific procedures in order to confirm that the critical activities in the doping control process are controlled, assured, improved and properly managed.

Guidelines for Implementing ISO Certified Quality Systems

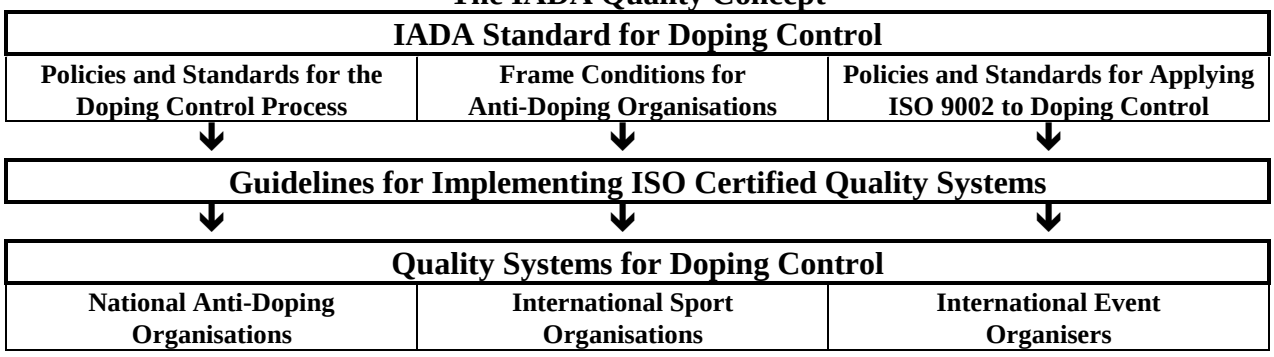
In order to have a certified quality system, the IADA Quality Concept requires quality systems to be in compliance with the standards prescribed in the IADA Standard for Doping Control and the ISO 9002 standard.

The objectives of these guidelines are to ensure the effective and homogeneous implementation of quality systems within different anti-doping organisations such as national anti-doping organisations, international sport organisations and international event organisers, and to ensure that the quality systems are appropriately adapted to meet each anti-doping organisation's specific needs and requirements.

The guidelines describe the process of developing a quality system and provide direction on how to establish a quality system in practice.

The following model demonstrates the various elements in the IADA Quality Concept and how they interrelate:

The IADA Quality Concept



2.0 Policies and Standards for the Doping Control Process

2.1 Test Distribution Planning

Policy Statement
The objective is to plan and implement an independent and effective distribution of athlete tests.

This phase starts with developing criteria for the distribution of athlete tests and ends prior to the selection of individual athletes for testing.

The main activities are consultations with relevant stakeholders, information gathering, development of test distribution criteria, development of the test distribution plan, and monitoring, evaluation and modification of the plan.

The ADO is responsible for the development of the test distribution plan.

Standards
2.1.1 The ADO shall consult, at least annually, with priority sports about the effectiveness of the test distribution plan and document the outcome of those consultations.

2.1.2 The ADO shall establish a system for collecting information necessary to develop an effective test distribution plan (eg., NSO information, historical information, research information and information from other relevant organisations).

2.1.3 The ADO shall develop and document a comprehensive set of criteria which will give direction to the test distribution plan. These criteria shall include:

- in a systematic way, assigning all sports to be tested into (i) high (ii) medium and (iii) low risk categories;
- giving high priority to high level athletes with a focus on high risk sports and high risk situations;
- in a systematic way, assigning the most effective testing method for each sport;
- giving priority to no-notice testing as the main testing method, particularly for high risk athletes with a focus on high risk sports and high risk situations;
- giving priority to «out of competition» testing.

2.1.4 The ADO shall develop and document an annual test distribution plan.

2.1.5 The ADO shall maintain testing statistics and monitor progress against the test distribution plan, and make modifications if necessary.

2.2 Selection and Notification of Athletes for Doping Controls

Policy Statement - Selection of Athletes

The objective of selecting athletes for sample collection is to detect and deter the use of banned substances and methods through an independent and unpredictable selection process.

The scope of the selection activities starts with requiring specific athlete contact information and event details from NSOs and other sources, and ends with deciding which athletes will be tested.

The main activities are: the continuous updating of athlete contact and event information from the NSOs and other sources, determining the criteria for selecting athletes, and the final selection of athletes.

The ADO has the main responsibility for determining the selection criteria and for selecting athletes, taking into account requirements from sport federations. The DCO has responsibility for applying the criteria when selecting the athletes for testing. The NSOs are responsible for providing the ADO with updated athlete contact information and information about events, competitions and training camps and programmes. NSOs are also responsible for requiring their athletes to provide updated contact information on a regular basis.

Standards - Selection of Athletes

2.2.1 The ADO shall define criteria and procedures for collecting event and athlete contact information (eg., the athlete's name, home address, alternate addresses, home and work telephone numbers, coach's name and contact telephone numbers, etc.) from the NSOs.

2.2.2 The ADO shall establish a system that requires NSOs to provide the ADO with athlete contact information in an appropriate and timely manner. This system shall require NSOs for high risk sports and specific athlete target groups to immediately provide updated contact information for any athlete in their respective athlete pools who change address for a period of 5 or more days.

2.2.3 A system shall be established to enforce the availability and provision of updated athlete contact information to the ADO, wherein non-compliance by NSOs or athletes will be investigated and appropriate action taken.

2.2.4 The ADO shall define the criteria for athletes to be registered in an athlete testing pool.

2.2.5 The ADO shall establish a system for testing athletes who are suspended or disqualified because of a doping infraction during their period of suspension and/or disqualification.

2.2.6 The ADO shall establish a system for testing athletes who are coming out of retirement or who are seeking reinstatement during a designated period before they can return to competition.

2.2.7 The ADO and the DCOs shall ensure that the athlete selection decisions are not disclosed to any unauthorised person before notification of the selected athletes.

2.2.8 When defining selection criteria, the following elements shall be included:

- national level athletes
- athletes with unusual improvement in performance
- athletes with behaviour indicating doping
- gender
- sport
- minimum level of testing
- the competition cycle.

2.2.9 The ADO shall review the specific selection criteria annually.

2.2.10 The ADO shall give written authorisation to the DCOs specifying the selection criteria, and the DCOs shall select athletes according to these criteria.

Policy Statement - Notification of Athletes

The objective of the notification process is to ensure that the selected athlete is notified, that the rights of the athlete are observed, that opportunities to manipulate the sample are minimised and that the notification is documented.

Notification of athletes starts with locating and identifying the selected athletes, and ends prior to starting the registration procedure for collecting the samples.

The main activities are:

- locating and identifying the athlete
- informing the athlete that he/she has been selected for doping control testing
- informing the athlete of his/her rights and responsibilities
- for testing where no advance notice is given, escorting the athlete from the time of notification to the arrival at the designated doping control station
- documenting the notification.

The DCO has the main responsibility for managing the notification process, including assigning responsibilities to the chaperones. The DCO also is responsible for seeking assistance from event organisers, coaches or team leaders in locating athletes.

Standards - Notification of Athletes

2.2.11 No-notice notification shall be the main notification method, particularly for high risk sports and high risk situations. Notification by telephone, fax or post can be used only in specified circumstances. Notification by telephone, fax or post shall be documented through a log system.

2.2.12 The ADO shall establish a system to confirm that the athlete selected is the athlete notified.

2.2.13 At the time of notification, the DCO shall ensure that the athlete is informed:
that he/she is required to provide a sample
of his/her rights and responsibilities, including the right to have a representative
of the possible consequences of failure to comply
that he/she has access to more detailed information about the doping control process.

2.2.14 A written notification form shall be presented to the athlete by a person authorised by the ADO and signed by the athlete.

2.2.15 If the athlete refuses to sign the notification form, the DCO shall provide the ADO with written documentation of the refusal, and the ADO shall deal with the refusal according to the procedures prescribed in 2.6 Results Management.

2.2.16 Sample collection shall take place as soon as possible after the notification process has been completed.

- For no-notice notification in both «in competition» and «out of competition» testing, the sample collection procedure shall begin as soon as possible but no later than 60 minutes after notification.
- For notification by telephone, fax or post, the sample collection procedure shall begin as soon as possible but no later than 24 hours after notification.

2.2.17 From the time of notification for a no-notice test until provision of the sample, the athlete shall be escorted to the designated doping control station by a person authorised by the ADO in such a way that the athlete is always within sight and not able to manipulate the sample to be given.

2.2.18 Following notification by telephone, fax or post, the athlete shall be escorted by a person authorised by the ADO in such a way that the athlete is always within sight and not able to manipulate the sample to be given from the time of the athlete's arrival at the designated doping control station until provision of the sample.

2.2.19 The DCO reserves the right to allow the athlete to accommodate special circumstances that may arise during the sample collection session. Should the athlete be required to leave the doping control station, he/she must be observed at all times by an ADO authorised person. The DCO shall record all such circumstances and report these circumstances to the ADO.

2.3 Preparing for and Conducting the Sample Collection Session

Policy Statement
The objective is to prepare and conduct the sample collection session in a manner that ensures the integrity, validity and identity of the sample.

The scope of this objective starts with the selection and preparation of the area in which the samples are to be collected, and ends with sealing the samples in their transport bag at the doping control station and completing associated doping control documentation.

The main activities can be subdivided into three areas: pre-collection administration, collection procedures and post-collection administration.

General responsibility for the preparation and conduct of the sample collection session lies with the ADO, while specific responsibility to fulfill these duties is delegated to the DCO. The NSOs and relevant authorities have a responsibility to assist with the provision of facilities and access to athletes.

Standards

2.3.1 The ADO shall establish a system for obtaining all the information necessary to ensure that the sample collection session can be conducted effectively.

2.3.2 The ADO shall appoint one or more DCOs to be responsible for managing the sample collection session. Where more than one DCO will be conducting tests at a sample collection session, the ADO shall appoint one DCO as the senior DCO who shall have overall responsibility for the conduct of testing at that session.

2.3.3 When appointing DCOs to be responsible for managing the conduct of sample collection sessions, the ADO shall not appoint a DCO who has an interest in the outcome of the collection or testing of a sample from any athlete who might provide a sample at that session. For the purpose of this standard, a DCO is deemed to have an interest in the collection or testing of a sample if he/she is involved in the administration of the sport or sport organisation for which testing is being conducted, or is related to or involved in the personal affairs of any athlete who might provide a sample at that session.

2.3.4 DCOs may personally perform any of the functions for conducting testing, or they may direct a chaperone to perform specified functions which fall within the scope of the chaperone's authorised duties.

2.3.5 Only DCOs and chaperones who have an accreditation recognised by the ADO shall be authorised by the ADO to carry out sample collection procedures.

2.3.6 The ADO shall establish criteria and specifications for sample collection equipment and documentation and use only sample collection equipment and documentation which meet the defined criteria and specifications.

2.3.7 The ADO shall define criteria for the designated doping control station where a sample is collected. The DCO must endeavour to use a venue for the sample collection that is in accordance with these criteria.

2.3.8 The athlete is entitled to have a representative present during the sample collection session. The ADO shall establish criteria for who may be authorised to be present at the sample collection session.

2.3.9 The DCO must ensure that the athlete has no opportunity for sample manipulation by observing the athlete from the time of arrival at the designated doping control station until provision of the sample.

2.3.10 The DCO must ensure that the athlete is offered a choice of sample collection equipment and also must provide the athlete with the opportunity to hydrate.

2.3.11 The DCO must ensure that the athlete is advised of the requirements of the sample collection procedures at the time of notification and throughout the sample collection session.

2.3.12 The DCO or chaperone shall witness the actual provision of the sample by the athlete and confirm the witnessing in writing. The person who witnesses the actual provision of the sample shall be the same gender as the athlete providing the sample.

2.3.13 The DCO shall declare a sample invalid if he/she has doubts about its origin or authenticity. The DCO shall document the reasons for invalidating the sample.

2.3.14 The DCO must ensure that the Doping Control Form includes a record of all details relating to the identity of the sample, medications taken by the athlete being tested, and persons present during the sample collection session. The Doping Control Form shall be signed by the athlete and the DCO and, if present, the athlete's representative. Copies of the Doping Control Form must be distributed to the relevant parties at the end of the sample collection session.

2.3.15 The DCO shall ensure that all samples collected during a sample collection session are securely stored from the time they are collected until the completion of the sample collection session.

2.3.16 The DCO must complete a report on the collection procedure, recording the order of events, times, persons present and detailing any irregularities in procedures.

2.3.17 All samples collected and the necessary documentation shall be securely stored and sealed in the transport bag(s) by the DCO at the completion of the sample collection session. A copy of the security number(s) shall also be sealed within the transport bag(s).

2.4 Handling of Samples

Policy Statement

The objectives for the handling of samples are to ensure that the samples are in proper condition for the laboratory to do the necessary analysis, to trace where the samples are and who is

responsible for their security at any given time, and to document all critical steps in the handling process in a proper and secure manner.

The scope of the sample handling activities starts following the sealing of the transport bag(s) containing the collected samples and the necessary documentation, and ends with the laboratory's confirmation of receipt of the samples.

The main activities are:

- Arranging for the secure transport of samples and doping control documentation to the laboratory and ADO respectively;
- transporting the samples and documentation;
- confirming receipt of the samples at the laboratory.

The ADO has the overall responsibility for the administration of a secure and reliable system to transport, store, trace and document the location of the samples.

Standards

2.4.1 When the seal on a transport bag is broken while in the care of the DCO, the DCO shall ensure that the transport bag is resealed in accordance with the requirements set out in standard 2.3.17 above and document the resealing. The DCO shall record the security number of the transport bag and provide this number to the ADO in writing.

2.4.2 When the seal is broken in transit while not in the care of the DCO, the ADO shall require the responsible person or organisation to ensure and verify the secure chain of custody of the bag.

2.4.3 The DCO shall sign the required documentation and send it in a secure manner to the ADO as soon as practicable after completing the sample collection session and if possible no later than the next working day.

2.4.4 The ADO shall monitor the reports and other sample collection documentation provided by DCOs to ensure that the collection procedures and related documentation have been properly completed.

2.4.5 The samples shall be dispatched to the laboratory by a transport supplier approved and contracted by the ADO as soon as practicable after completing the sample collection session. If practicable, the DCO shall send the samples directly to the laboratory immediately after completing the sample collection session.

2.4.6 The samples shall be transported in a transport bag in a manner that ensures the integrity of the samples for analysis.

2.4.7 During the period that the DCO is responsible for the samples, they shall be stored in a secure area where the DCO has control over who has access to the area at all times, and all reasonable efforts shall be made to keep the samples cool.

2.4.8 The ADO shall ensure that:

- the transport supplier has a system that allows confirmation of the location of the transport bag at any time;
- the DCO provides written confirmation of the transfer of the samples to the transport supplier for delivery to the laboratory;
- the laboratory provides written confirmation of having received the samples.

2.5 Sample Analysis

Policy Statement
The objective of sample analysis is to provide an accurate and valid test result.

The scope of sample analysis begins with the receipt of the samples by the laboratory and ends with the provision of all required laboratory results and reports to the NADO.

The main activities are: proper intra-laboratory chain of custody, inspections and preparations of samples, sample analyses and provision of results and reports.

Responsibility for sample analysis rests with the laboratory.

Standards
2.5.1 Laboratories shall be fully accredited by the IOC and also certified by an independent internationally recognised accreditation body.

2.5.2 The samples shall be analysed using good laboratory practices in accordance with recognised IOC standards and those of an independent internationally recognised accreditation body.

2.5.3 The laboratory shall be contracted by the ADO and other relevant authorities as appropriate. The contract with the laboratory will include:

- financial terms and conditions
- classes of substances for which each sample will be analysed
- timelines and procedures for provision of results, reports and advice
- purposes for which samples may be used
- criteria under which the laboratory will reject a sample for analysis.

2.5.4 The reference for banned substances and practices shall be defined in accordance with standards 3.1.1.5 and 3.1.1.6 under section 3.1.1 Laws and Regulations.

2.5.5 A proper intra-laboratory chain of custody and proper security practices must be ensured by the laboratory.

2.5.6 All samples collected under the auspices of the ADO will remain the exclusive property of the ADO.

2.5.7 All «A» samples shall be analysed and the results reported in confidence to the ADO, and other relevant authorities as appropriate, as soon as possible but no later than 10 working days following the receipt of the samples by the laboratory.

2.5.8 In the event that an «A» sample analysis indicates the presence of a substance classified as prohibited or restricted, the designated signatory of the laboratory will provide a confidential report with supporting analytical data to the ADO and**,** as appropriate, other relevant authorities.
2.5.9 The laboratory shall provide a written report to the ADO in the event that the «A» sample will not be analysed because it does not meet the laboratory specifications for sample analysis.

2.5.10 In the event that the «A» sample is problematic as to volume, suitability or content, the designated signatory of the laboratory will provide a confidential written report to the ADO and, as appropriate, other relevant authorities.

2.5.11 In the event that a «B» sample confirmation analysis is required, it will be conducted in accordance with section 2.6 Results Management.

2.6 Results Management

Policy Statement
The objectives of results management are to process laboratory results and failures to comply with doping control requirements in a manner that is fair to the athlete, and to provide an accurate and fair determination of a reportable doping infraction to the athlete, relevant sport organisation and, as appropriate, relevant disciplinary body.

The scope of results management starts with the receipt of a laboratory result or a failure to comply report, and ends with the notification of a determination of a reportable doping infraction to the athlete, relevant sport organisation and, as appropriate, relevant disciplinary body.

The main activities include the receipt of test results and failure to comply reports, gathering and assessment of relevant information, determining the validity of a test result or the validity of a failure to comply report, and notification of the determination.

The ADO or relevant authority has the primary responsibility for results management.

Standards

2.6.1 The ADO, or other relevant authorities as appropriate, shall establish a system for reaching a determination on a reportable doping infraction based on a test result from the laboratory or a failure to comply report.

2.6.2 All results from the laboratory and all failure to comply reports from DCOs shall be sent in confidence to the designated official of the ADO and, if appropriate, other relevant authority.

2.6.3 In the event of a laboratory report indicating the possibility of a doping infraction or a failure to comply report from a DCO, the ADO or other appropriate relevant authority may request that a further sample be obtained.

2.6.4 The ADO or relevant authority shall be able to suspend an athlete from competition after the «A» or «B» sample analysis if the result indicates a possible doping infraction.

2.6.5 Should the «B» sample result not confirm the «A» sample result, the athlete may immediately return to competition. In such cases, the ADO or relevant authority shall have the option to review the matter further.

2.6.6 The athlete may waive his/her rights to the «B» sample analysis in writing, thereby accepting the «A» sample finding as conclusive evidence of a positive test result.

2.6.7 If a «B» sample is required, it shall be analysed as soon as possible but no later than 5 working days after notification of the athlete. This period may be extended by mutual agreement between the athlete and the ADO or relevant authority as appropriate**.**

2.6.8 The athlete has the right to attend the identification, opening and analysis of the «B» sample, and to appoint a representative. Where that does not occur, a surrogate for the athlete's representative may be appointed by the ADO or relevant authority.

2.6.9 Prior to reaching a determination, the ADO or relevant authority shall provide the athlete with the option to present evidence, in writing, that may require the ADO to invalidate the test result or that demonstrates reasonable cause for failure to comply. If the athlete intends to present evidence, he/she must indicate this intention in writing to the ADO or relevant authority within 5 working days of notification.

2.6.10 In the case of a reported failure to comply, the burden of establishing a reasonable cause will rest with the athlete.

2.6.11 The ADO or relevant authority shall assess the results and/or reports and other relevant information, and determine whether or not a reportable doping infraction has occurred. The determination of a reportable doping infraction together with information and deadlines for appeal opportunities will be provided in confidence to the athlete, relevant sport organisation and, as appropriate, relevant disciplinary body.

2.6.12 The athlete and relevant sport organisation shall be entitled to receive written confirmation of all test results and failure to comply reports.

2.6.13 Where the ADO conducts sample collection at international events, the ADO shall receive copies of doping control forms and test results from the laboratory that analyses the samples and also from the relevant international sports organisations.

2.7 Disciplinary Procedures, Sanctions and Appeals

Policy Statement
The objectives of disciplinary procedures, sanctions and appeals are to ensure that the athlete's right to natural justice is respected and upheld, and that appropriate sanctions are imposed, as necessary.

The scope for these objectives starts with the ADO notifying the relevant disciplinary body of a reportable doping infraction, and ends when the disciplinary body determines whether a doping infraction has occurred and, if it has, what sanction is applied. If an appeal is lodged, the scope ends with reporting the result of the appeal.

The main activities are considering the evidence, making a decision, imposing an appropriate sanction as required, and if an appeal is lodged, the provision of an appeal system.

The disciplinary body is responsible for conducting an independent hearing process, considering the evidence, making decisions and imposing appropriate sanctions as required. The ADO and/or relevant sport organisation is responsible for providing an independent appeal system.

Standards
2.7.1 The athlete shall be informed of the reportable doping infraction and be provided with relevant documentation on the reportable infraction.

2.7.2 The athlete shall have the opportunity to present any information to the disciplinary body, either in writing or in person. The athlete can be represented at the hearing of the disciplinary body.

2.7.3 The disciplinary body shall make a decision as to whether or not a doping infraction has occurred after consideration of all of the evidence presented.

2.7.4 Following the decision that a doping infraction has occurred, appropriate sanctions shall be imposed that as a minimum are consistent with the current IOC Medical Code.

2.7.5 The ADO shall be advised of the decisions made by the disciplinary body and/or the relevant sport organisation.

2.7.6 The ADO and/or the relevant sport organisation shall apply and monitor the imposition of sanctions, and shall ensure that the sanctions are applied across sports.

2.7.7 All disciplinary body decisions confirming that a doping infraction has occurred shall be publicly disclosed by the relevant sport organisation.

2.7.8 The athlete and the relevant sport organisation shall have the right to appeal a decision or a sanction, and have the appeal heard by an appeals tribunal that is independent of the disciplinary body.

3.0 Frame Conditions for Anti-Doping Organisations

National Anti-Doping Organisations (NADO)

3.1.1 Laws and Regulations

Policy Statement
The objective is to have internationally consistent anti-doping sport policies, laws and/or regulations that ensure the authority of the national sport governing bodies to require athletes to undergo doping tests and to sanction athletes who violate the doping regulations. The anti-doping sport policies, laws and regulations shall protect the athletes' rights. Based on these principles, and for international consistency, the national anti-doping sport policies, laws and regulations shall specify the list of banned substances and practices, the doping control procedures and the sanctions for doping infractions.

The national anti-doping sport policies, laws and/or regulations shall include all necessary legal and/or regulatory aspects, from the authority of the national sport governing bodies to the description of the appeal system.

The main activities are approval and enforcement of the anti-doping sport policies, laws and/or regulations, approval and enforcement of the sanctions, development of the doping control procedures, the process of defining lists of banned substances and practices, and management of the doping control process.

A national organisation independent of national sport organisations, and with full integrity in the anti-doping field, shall have responsibility for ensuring the enforcement of the anti-doping sport policies, laws and/or regulations.

Standards
3.1.1.1 There shall be a set of complementary anti-doping sport policies, laws and/or regulations that apply to all sport governing bodies.

3.1.1.2 The anti-doping sport policies, laws and/or regulations shall describe the authority of the national sport governing body to require doping controls and to impose sanctions on athletes who violate the anti-doping regulations.

3.1.1.3 The national anti-doping authorities shall have the right to require athletes to undergo doping controls at any time and place, without prior notice.

3.1.1.4 The sport policies, laws and/or regulations shall define what constitutes a doping infraction.

3.1.1.5 Each year, the national anti-doping organisation shall specify in a schedule which substances and doping practices are banned.

3.1.1.6 The schedule of banned substances and doping practices shall be based on the International Olympic Committee (IOC) list of prohibited substances and doping infractions. The schedule shall also define:

- which substances, at a minimum, the national anti-doping organisation shall test athletes for when conducting «in competition» testing;
- which substances, at a minimum, the national anti-doping organisation shall test athletes for when conducting «out of competition» testing;
- which substances, at a minimum, the national anti-doping organisation shall test athletes for when conducting tests on behalf of international sport organisations.

3.1.1.7 The national anti-doping authorities shall establish a system to ensure that the list of banned substances and practices is distributed to all national level athletes each year. This list shall be available to all registered athletes.

3.1.1.8 The national sport policies, laws and/or regulations shall define who has the authority and responsibility for enforcing the anti-doping regulations. The national anti-doping authority shall be independent of the national sport organisations and have full integrity in the anti-doping field.

3.1.1.9 The national sport policies, laws and/or regulations shall define the national anti-doping authorities' responsibilities pertaining to anti-doping regulations, sanctions, doping control procedures and the list of banned substances and practices.

3.1.1.10 The national sport policies, laws and/or regulations shall define that, within the national anti-doping structure, the disciplinary body shall be independent of the executive/prosecuting authority.

3.1.2 Organisational Responsibilities and Authorities

Policy Statement
The objective is to have an independent national anti-doping organisation (NADO) that has the necessary authority and responsibility for planning, co-ordinating, implementing, monitoring and advocating improvements in the doping control process. The government, the NADO and the national sport organisations (NSOs) shall have clearly defined areas of responsibility. The NADO shall ensure that the NSOs fulfill their defined responsibilities. The national anti-doping structure shall represent a well-defined distinction between the legislative, the executive and the disciplinary authorities.

The main activities for reaching the objectives are as follows:

- ensure that the NSOs and the government understand the need for an independent anti-doping organisation, and thereby accept this as an organisational model
- act to bring about changes, if necessary, to the national and international sport policies, laws and/or regulations
- define and make the necessary resources available
- the NADO together with the NSOs need to define the NSOs responsibilities and tasks
- ensure that there is a mechanism to sanction NSOs that do not fulfill their responsibilities.

The NADO is responsible for initiating and co-ordinating the main activities and for achieving the described objectives.

Standards

3.1.2.1 There shall be one NADO that has the necessary authority and responsibility for planning, co-ordinating and monitoring the doping control process.

3.1.2.2 The NADO shall have the necessary authority and responsibility to advocate changes to sport policies, laws and/or regulations. In particular, the NADO shall advocate, in co-operation with other NADOs, that:

- changes be made to the IOC list of prohibited substances and doping practices in areas where the IOC list is identified as inadequate or deficient;
- changes be made to the sanctions specified in the IOC or international sport organisation's rules where those sanctions are identified as being inappropriate or inconsistent;
- sport disciplinary bodies seek expert medical and scientific advice when they convene hearings to determine whether doping infractions have occurred and, if they have occurred, what might be appropriate sanctions.

3.1.2.3 Within the national anti-doping structure there shall be a formal and organisational distinction between the executive/prosecuting authorities and the disciplinary body.

3.1.2.4 To ensure that the doping control process is carried out in accordance with the overall objective of being effective in prevention, deterrence and detection of athletes who dope, the NSO shall endorse the present national anti-doping policy and comply with the tasks and responsibilities as defined for the NSO. These tasks and responsibilities shall include:

- updating specified information on athletes and events and providing this information to the NADO;
- informing the athletes about the list of banned substances and practices;
- assisting with the sample collection session;
- assisting with investigating the circumstances surrounding doping infractions;
- informing the NADO about possible use of banned substances and practices;
- implementing and monitoring sanctions.

3.1.2.5 The NADO shall secure the necessary resources to fulfill its objectives and responsibilities.

3.1.3 Plans

Policy Statement
The objective is to develop long-term strategic plans and annual operational plans to continuously improve the efficiency and the harmonisation of different anti-doping systems.

The national long-term strategic plans and annual operational plans and reports shall outline the objectives and activities relating to the critical success factors for achieving drug-free sport: doping control, research, education, and international advocacy and co-operation.

The NADO is responsible for the development of long-term strategic plans and annual operational plans.

Standards
3.1.3.1 The national long-term strategic plans shall outline at least the following four main programmes: doping control, research, information and education, and international advocacy and co-operation.

3.1.3.2 Annual national short-term plans shall be developed to be consistent with long-term strategic plans, and they shall identify necessary resources to achieve the NADO's mandate.

3.1.3.3 The NADO shall develop a system to report on progress regarding the long-term strategic plans and the annual operational plans.

3.1.3.4 The NADO's planning for doping control shall be consistent with quality management principles.

3.1.3.5 The NADO, in co-operation with other NADOs and other research institutions, shall support appropriate scientific and sociological research to improve the effectiveness of the anti-doping programme.

3.1.3.6 The NADO shall develop, implement and review information and education programmes for specific target groups.

3.1.3.7 To further international co-operation, the NADOs shall prepare and exchange reports on the outcome of their respective long-term strategic plans and annual operational plans.

3.1.4 Resource Management

Policy statement
The objective is to acquire and manage resources in an effective, efficient and accountable manner that enables the NADO's goals to be achieved.

Resource management starts with establishing the operational plans and ends with providing feedback on the use of resources as part of the planning cycle.

The main activities are:

- determine the resources required to implement the plans;
- acquire sufficient and appropriate resources;
- plan, monitor, evaluate and modify how resources are used;
- document resource management activities.

The NADO has the overall responsibility for ensuring that resources are managed appropriately and in a manner that fulfills the defined objectives and responsibilities.

Standards

3.1.4.1 The NADO shall identify and acquire the resources necessary to implement the operational plans including:

- sample collection staff and accreditation of doping control officers (DCOs) and chaperones;
- administrative staff to provide support for doping control activities;
- sample collection equipment;
- support services including courier services, laboratory services, legal services;
- corporate operations required for doping control activities;
- information technology;
- resources for international advocacy and co-operation.

3.1.4.2 The NADO shall prepare and document an annual budget for required resources based on accurate costing information.

3.1.4.3 The NADO shall maintain and periodically review ongoing records for the use of human, financial, equipment and service resources.

3.1.4.4 The NADO shall conduct and document an annual evaluation of the efficiency and effectiveness of allocation of resources against the annual operational plan.

3.1.4.5 The NADO shall negotiate and document agreements to secure required resources.

3.1.4.6 The NADO shall document job descriptions or duty statements and follow specified selection criteria and recruitment guidelines for hiring staff.

3.1.5 Sample Collection Personnel

Policy statement
The objective is to have sample collection personnel who have adequate qualifications to conduct sample collection sessions.

The scope of this objective starts with the development of selection criteria for sample collection personnel, and ends with the formal authorisation of doping control officer status.

The main activities are: development of selection criteria, recruitment, training, authorisation and accreditation, continuous monitoring of performance and reaccreditation of the sample collection personnel.

The NADO has the overall responsibility for recruitment, initial and ongoing training, authorisation and accreditation, monitoring and reaccreditation of sample collection personnel.

Standards
3.1.5.1 The NADO shall establish selection criteria for sample collection personnel positions.

3.1.5.2 A recruitment system shall be implemented according to the doping control programme's geographical and human resource needs.

3.1.5.3 The NADO shall establish a training programme consistent with the IOC requirements for certification of DCOs. The training programme shall include practical experience in various types of «in competition» and «out of competition» testing.

3.1.5.4 The NADO shall establish a training programme for the authorisation of chaperones.

3.1.5.5 The NADO shall continuously appraise the performance of sample collection personnel, and provide them with written and verbal feedback on performance.

3.1.5.6 The NADO shall provide the DCOs with an identifiable accreditation (identity card) with a period of validity of not more than two years.

3.1.5.7 The NADO shall establish a reaccreditation programme for DCOs and a reauthorization programme for chaperones. These programmes shall include upgrade training.

3.1.5.8 DCOs and chaperones shall be of adult age.

3.1.5.9 The NADO shall establish a code of conduct for DCOs and chaperones which shall be signed by the DCOs and chaperones. Breach of the code of conduct or procedural irregularities will be reviewed by the NADO, and may result in removal of accreditation or authorisation.

The NADO shall recognise DCOs currently accredited according to these standards.

3.2 International Sport Organisations

(To be developed by international sport organisations)

3.3 International Event Organisers

(To be developed by international event organisers)

4.0 Policies and Standards for Applying ISO 9002 to Doping Control

4.1 Policy Statement

The objective is to manage the doping control process by introducing quality management principles and by developing quality systems at the national or organisational level in compliance with ISO 9002.

Through the implementation of quality systems for doping control which satisfy the requirements in the IADA Standard for Doping Control, the doping control procedures and practices will be consistent, secure and reliable in all phases of the process.

Through the development and implementation of consistent, secure and reliable doping control procedures and practices:

- the athlete's right to fair and drug-free competition will be protected;
- world-wide confidence in sport will be enhanced;
- the doping control process will be effective in prevention, deterrence and detection of athletes who dope, both at the national and international levels;
- the doping control practices based on the quality systems for doping control will positively influence the international sports community and world-wide doping control procedures and practices.

The key customer in the doping control process is the athlete.

Through information exchange and promotion, the IADA members will encourage other countries and international organisations to implement quality systems for their doping control practices.

4.2 Standards for Quality Management in Doping Control

4.2.1 Anti-doping organisations (ADOs) shall develop quality systems for doping control in accordance with the ISO 9002 standard. The quality systems shall ensure the effective implementation of the international Policies and Standards for the Doping Control Process. The quality systems shall be certified according to ISO 9002 by an accredited certifying agency.

4.2.2 The ADO shall interpret and adopt the requirements in the ISO 9002 standard in a manner that is appropriate for the doping control process. All ISO 9002 requirements are applicable to doping control except 4.19 Servicing.

4.2.3 The participating countries or organisations in the IADA Quality Concept shall annually maintain, review and, as appropriate**,** improve the Policies and Standards for the Doping Control Process in order to represent world best practices for doping control.

The management of the ADO shall state management responsibilities for the development, implementation and maintenance of the quality systems, and allocate necessary resources to conduct quality systems activities.

4.2.5 The ADO shall develop a Quality Policy for Doping Control which states the goals and objectives related to quality management in the doping control process.

4.2.6 The ADO shall develop a Quality Manual that conveys accurately, completely and concisely the quality policy and the quality objectives. The Quality Manual shall describe the structure of the quality systems and include or refer to documented quality systems procedures.

The ADO shall develop and establish procedures and quality system documentation according to the ISO 9002 requirements.

4.2.8 The ADOs participating in the IADA Quality Concept shall develop and institute a designated number of international procedures and quality system documents to control activities that directly involve the athlete. Each ADO must adopt and use these international procedures in their doping control activities.

The IADA shall establish and maintain a master list of international quality system documentation.

4.2.10 The ADOs shall review and audit the quality systems through internal audits according to the ISO 9002 standard.

4.2.11 The ADOs participating in the IADA Quality Concept shall establish a system at the international level that ensures international harmonisation and improvement of the IADA Standard for Doping Control and the quality systems. The system shall be based on reported non-conformities and preventive and corrective actions in the quality systems.

4.2.12 The ADO shall define and document a training programme for management and DCOs on quality management and ISO 9002.

4.2.13 The ADOs participating in the IADA Quality Concept shall develop and review guidelines on how NADOs, international sport organisations and international event organisers should implement quality systems for doping control.

A list of definitions of the most common phrases used in the doping control process and in quality management shall be produced and reviewed. The reference for quality management terminology shall be ISO 8402.

5.0 Common International Quality Documentation

Developing and practising common international quality documentation for doping control activities that directly affect the athlete, will lead to consistent and harmonised doping control practices at national level.

Within the IADA Quality Concept it is decided to have common international procedures with related work instructions for:

- Athlete notification;
- Conducting the sample collection session;
- Handling of samples.

It is also decided to have recommended specifications for purchasing of the following services:

- Sample collection equipment;
- Laboratory services;
- Transport services.

Doping control practices shall be implemented that fully comply with the international procedures in order to ensure that the athletes faces the same doping control practices

In order to maintain and improve the common international quality documentation it is decided to have international quality control documentation for:

- Changing and controlling the IADA Standard for Doping Control;
- Producing quality documents;
- Changing international quality documents;
- Controlling international quality documents.

The specific procedures with related work instructions and the recommended specifications are enclosed the IADA Standard for Doping Control as appendixes.

6.0 Definitions

ADO	Anti-doping organisation
Anti-Doping Organisation	A national anti-doping organisation or an anti-doping organisation as part of an international sport organisation or an anti-doping organisation as part of an international sport event organisation.
Appeal	A component of procedural fairness whereby an athlete or sport or the NADO may apply to a recognised authority for the review, reversal or confirmation of a decision ruling.
Appeal System	A system of natural justice that provides opportunity for an athlete or other party such as an NSO or ADO to appeal a decision by a disciplinary body.
Athlete	See «registered athlete».
Athlete Pool	A pool or listing of athletes from various sports who are subject to doping control.
Chain of Custody	Procedures designed to maintain control and accountability of the urine or blood samples from the point of collection, through the departure of the samples from the doping control station to the delivery and receipt of samples at the designated laboratory, and within the designated laboratory through an intra-laboratory system of control and accountability
Chaperone.	An authorised official responsible for notifying the athlete selected for testing and for accompanying and monitoring the athlete until registered at the doping control station, and for witnessing and verifying the provision of the sample
Competition Testing	Testing that takes place at a sporting competition or event immediately following the completion of the competition or a race or event that forms part of the competition.
Conformity	Fulfillment of specified requirements.
Contractor	Supplier in a contractual situation.
DCO.	Doping control officer
Determination	The review of a laboratory finding, failure to comply report or other information, to decide whether or not a possible doping violation has occurred.
Designated Doping Control Station	A venue selected for carrying out the sample collection session that meets the criteria defined by the ADO as required in quality standard 2.3.7.
Disciplinary Body	The bodies responsible for administration of justice pertaining to drug-free sport.
Doping Control Officer	Trained and certified official responsible for the management of the doping controls and doping control station.
Doping Control Process	The doping control process is defined as the development of policies and plans to conduct doping controls, the selection and notification of athletes to be tested, the preparation for and conduct of the sample collection session, handling of samples, laboratory analysis of samples, results management, sanctioning of athletes, the appeal system and related investigations, and the overall management of the doping control process.
Doping Control Station	See «designated doping control station».
Doping Infraction	The use of banned substances or practices by an athlete.
Drug Control Station	See «designated doping control station».
Failure to Comply	A refusal or failure by an athlete to follow proper doping control procedures
High, Medium or Low Risk Sport	Sports that are categorised into high, medium and low probability of using banned substances or methods, based on established criteria specified in quality standard 2.2.8 for effective allocations of athlete testing
IADA	International Anti-Doping Arrangement.

IF	International sport federation.
Inspection	Activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.
International Sport Federation	The international governing body for a sport.
IOC	International Olympic Committee.
ISDC	International Standard for Doping Control.
ISO	International Organisation for Standardisation
NADO	National anti-doping organisation.
National Anti-Doping Organisation	An independent national organisation responsible for leading, co-ordinating and administering a comprehensive drug-free sport programme in their country that includes doping control, education, research and advocacy.
National Sport Organisation	National organisations responsible for the governance and administration of each sport within a country.
Non-conformity	Non-fulfillment of specified requirements.
No-Notice Testing	Testing which takes place immediately after notification with no advance warning to the athlete (in and out of competition).
NSGB	National sport governing body.
NSO	National sport organisation
Operational Plan	A more specific statement of how the organisation or programme intends to achieve its goals, typically involving the allocation and management of resources toward a certain end. Such a plan normally defines the necessary steps, timelines and resources needed to attain specific objectives or outcomes within a designated period (ie., usually 12 months).
Out of Competition Testing	Testing which takes place outside of competition situations.
Policy Areas	Issues or activities for which an overall position or rationale is required, embracing general goals and acceptable procedures with which to address such issues or undertake such activities.
Policy Standard	Defines the specific activities or practices that will enable the achievement of the defined objectives of the relevant IADA Standard for Doping Control policy statements.
Policy Statement	Describes the ideal situation for doping control in a policy area of the IADA Standard for Doping Control manual by defining the objectives, scope, activities and responsibilities of that policy area.
Positive Result	A positive laboratory test result identifying the presence of a prohibited substance or the use of a prohibited doping method following analysis of a urine or blood sample.
Priority Sport	Sports that have been identified for more frequent athlete testing based on the interests of sport and the public interest.
Procedure	Specified way to perform an activity.
Prosecuting Authority	The body empowered and responsible for upholding the application of rules and regulations (ie., NSO, IF, NADO).
Purchaser	Customer in a contractual situation.
Quality	The total effect of the features of a process, product or service on its performance, or the customer's perception of that performance. It is not just a feature of the finished product or service, but involves a focus on internal processes and outputs.

Quality Assurance	A term used to describe all the procedures an organisation needs to carry out in order to give it, and its customers, confidence that a quality process or function is being adequately performed and that, as a result, its products or services will meet customers' requirements.
Quality Audit	Independent and internal systematic examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Quality Auditor	Person qualified to perform quality audits.
Quality Control	Operational techniques and activities that are used to monitor and ensure that prescribed standards are met.
Quality Improvement	Actions taken throughout the organisation to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organisation and its customers.
Quality Management	The overall management functions that determine the quality policy, objectives, responsibilities, and implementation plans including quality planning, quality control, quality assurance and quality improvement within the quality system.
Quality Manual	A document setting out an organisation's quality policies, procedures and practices. The document contains policy statements, details of authorities and responsibilities, and describes the organisation and the systems within the organisation for ensuring quality.
Quality Objectives	Objectives that clearly link to the quality policy, but are intended to operate within a shorter time framework.
Quality Planning	Activities that establish the objectives and requirements for quality and for the application of quality system elements.
Quality Policy	The overall intentions and directions of an organisation with regard to quality as formally expressed by top management.
Quality System	The organisational structure, responsibilities, procedures, processes and resources that are established to ensure the quality of products and services.
Random Selection	Athlete selections through a random process. Selection may be «weighted» for high risk sports, disciplines or positions within a given sport.
Record	Document which furnishes objective evidence of activities performed or results achieved.
Registered Athlete	An athlete who is a member of or participates in the activities of an international sport federation, a national sport organisation or a regional sport governing body in a country, or a national sports league or club affiliated with a national sport organisation or regional sport governing body in a country.
Relevant Authority	An authority other than a national anti-doping organisation (eg., an international sport federation or national sport organisation), that may be responsible for functions including doping control, results management, the conduct of disciplinary procedures and appeals, and the imposition of sanctions.
Sample Collection Staff	Individuals who are authorised to assist with or conduct the sample collection process in the doping control station.
Sample Collection Station	See «designated doping control station».
Short-Notice Testing	Testing that takes place, where possible, within 24 hours of the athlete being notified of his/her selection for doping control.

Strategic Plan	A document which specifically defines the rationale and purpose of an organisation or programme, its mission, vision, goals and objectives for a specified period (usually 3 to 5 years), and the means by which it will achieve and evaluate its work
Subcontractor	An organisation or individual that provides a product to the supplier.
Target Athlete	Athletes who due to the «risk» status of their sport, their recent performances, or other specific factors, may be subject to «target testing».
Target Testing	Selection of athletes for doping control where specific athletes or groups of athletes in the athlete pool are deliberately selected for testing at a specified time.
Test Distribution Plan	A plan that identifies the distribution of competition and out-of-competition (short and no-notice) tests across sports over a 12 month time period. The tests are allocated to sports: (i) based on an assessment of established criteria (eg., a sport's testing history, perceived benefits of drug use for athletes in a sport, etc.) for effective allocation of athlete testing as specified in quality standard 2.2.8; and (ii) at key times in a sport's competition cycle (eg., 2 to 3 months prior to major national or international events, etc.).
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Appendix

A. Quality control documentation

IADA100 Procedure for changing and controlling the IADA Standard for Doping Control

IADA101 Procedure for producing quality system documents
- **IADA101.1** Template for producing quality system documents
- **IADA101.2** Template for producing quality system documents: guidelines

IADA102 Procedure for changing international quality documents

IADA103 Procedure for controlling international quality documents

B. International procedures

IADA200 Procedure for athlete notification: no notice testing

IADA201 Procedure for athlete notification: short notice testing

IADA202 Procedure for conducting the sample collection session: chaperoned in waiting room
- **IADA202.1** Work instructions for conducting the sample collection session: chaperoning when athlete temporarily leaves waiting area

IADA203 Procedure for conduction the sample collection session: collection of urine sample
- **IADA203.1** Guidelines for conducting the sample collection session: laboratory volume and quality requirements for samples
- **IADA203.2** Work instructions for conducting the sample collection session: insufficient sample
- **IADA203.3** Work instructions for conducting the sample collection session: checking that the sample is fit for analysis

IADA204 Procedure for conducting the sample collection session: security/post test administration

IADA205 Procedure for conducting the sample collection session: processing possible failures to comply

IADA206 Procedure for handling of samples

C. Recommended specifications

IADA300 Recommended specifications for purchasing sample collection equipment

IADA301 Recommended specifications for purchasing laboratory services

IADA302 Recommended specifications for purchasing transport services

Objective

The objective of the procedure is to secure the process of changing and controlling the IADA Standard for Doping Control in such a way that all participating organisations in countries that are members of the IADA have equal opportunities to influence and approve changes in the IADA Standard for Doping Control, and that the valid version of the IADA Standard for Doping Control is available and easily accessible at any time.

Scope

The scope of the activity is the review, revision, approval, production and distribution of the approved, revised IADA Standard for Doping Control and the removal of the parts of the IADA Standard for Doping Control that are invalid as a result of the approved revision.

The activity starts with the first initiative to review the IADA Standard for Doping Control, and ends with the distribution of the revised, approved version, and if necessary, with changes to the participating organisations' quality documentation and removal of the parts of the IADA Standard for Doping Control that are invalid as a result of the approved revision.

Responsibility

Each participating organisation is responsible for making proposals to improve the IADA Standard for Doping Control.

The IADA Secretariat (or another body designated by the IADA Steering Group) is responsible for reviewing the proposals and developing a new draft version of the IADA Standard for Doping Control.

The IADA Steering Group (or designated body) is responsible for approving the IADA Standard for Doping Control.

The IADA Secretariat (or designated body) is responsible for producing and distributing the revised version of the IADA Standard for Doping Control, while the IADA Secretariat (or designated body) and the Organisation Project Co-ordinator (OPC) are responsible for removal of the parts in the IADA Standard for Doping Control that are invalid as a result of the approved revision.

Actions

1. The IADA Standard for Doping Control shall be reviewed and, if needed, revised annually. Under certain circumstances (determined by the IADA Steering Group or designated body), participating organisations may revise the IADA Standard for Doping Control at any time if two-thirds of the participating organisations request such a revision.

2. The IADA Secretariat (or designated body) shall be responsible for producing a plan for reviewing the IADA Standard for Doping Control.

3. All participating organisations should actively monitor, identify and document potential improvements and related changes to the existing IADA Standard for Doping Control.

4. Proposals for changes shall be sent by participating organisations to the IADA Secretariat (or designated body) no later than 3 months prior to the upcoming IADA Steering Group (or designated body's) meeting.

5. The IADA Secretariat (or designated body) shall analyse the documented submissions and present areas for improvement or proposals to change the IADA Standard for Doping Control for consideration by the participating organisations and the IADA Steering Group.

6. The IADA Secretariat (or designated body) shall be responsible for co-ordinating the proposals and developing a draft revised version of the IADA Standard for Doping Control.

7. The IADA Secretariat (or designated body) shall be responsible for distributing the draft revised IADA Standard for Doping Control to the participating organisations 5 weeks prior to the IADA Steering Group (or designated body's) meeting. All incoming proposals shall be compiled by the IADA Secretariat (or designated body) and presented at the IADA Steering Group (or designated body's) meeting as an enclosure to the draft revised version of the IADA Standard for Doping Control.

8. The IADA Secretariat (or designated body) shall be responsible for documenting the proposed changes in the IADA Standard for Doping Control by putting the changes in italics in the original text.

9. Proposals for changes will be discussed and finally approved in the IADA Steering Group (or designated body's) meeting according to the principle of consensus.

10. The IADA Secretariat (or designated body) shall be responsible for producing a new approved version of the IADA Standard for Doping Control and for distributing this to the OPCs no later than 5 weeks after the IADA Steering Group (or designated body's) meeting.

11. The OPC shall confirm in writing to the IADA Secretariat (or designated body) that the new approved IADA Standard for Doping Control has been received and that the parts in the IADA Standard for Doping Control that are invalid as a result of the approved revision have been removed.

12. The IADA Standard for Doping Control is effective from a date set at the IADA Steering Group (or designated body's) meeting, taking into account the need for adjustments at the national and organisational levels.

13. Each participating organisation must implement the revisions incorporated into the new version of the IADA Standard for Doping Control in their organisation quality documentation within the date set at the IADA Steering Group (or designated body's) meeting and confirm this in writing to the IADA Secretariat (or designated body).

14. The outdated version of the IADA Standard for Doping Control must be filed by the IADA Secretariat (or designated body) according to a filing system.

Records

Document presenting incoming proposals
Plan for reviewing the IADA Standard for Doping Control
Written confirmations concerning the receipt and implementation of the new approved version of the IADA Standard for Doping Control

References and appendices

References
ISO 9002 - 4.5 Document and data control

Objective

The objective of the procedure is to ensure that the documentation in the IADA Quality Concept is consistent and harmonised at the international, national and organisational levels by using a common process for producing the documentation.

Scope

The scope of the procedure is the production of international, national and organisational quality system documentation to be included in the IADA Quality Concept.

The procedure starts with deciding that a new international, national or organisational quality system document is needed and ends prior to the approval of the quality system document.

The quality system documentation relevant to this procedure consists of:

- Procedures which generally describe how to perform an activity and define the objective, scope, responsibility and critical actions of the activity
- Work instructions which describe in more detail how to perform an activity and are included in the quality system documentation when the performance and sequence of sub-activities are essential to the outcome of the main activity
- Checklists which list specific actions to be performed in order to more precisely control the activity
- Other documentation such as plans, lists, specifications, etc.

The description of the common process and actions for producing quality system documentation is limited in scope and has been designed to secure and control the process of producing procedures, being more complex in structure than other types of quality documentation. Ensuring the consistency and harmonisation of other types of quality documentation is not as critical and may be secured through discussion at IADA Quality Concept meetings and other means of communication amongst the organisations developing the documentation.

Responsibility

The IADA Steering Group (or a body designated by the IADA Steering Group) and the Anti-Doping Organisation (ADO) have responsibility for initiating and producing quality system documentation.

The IADA Steering Group (or designated body) will decide what quality system documentation should be produced at the international level as common documentation, while the ADO will decide what quality system documentation should be produced at the national or organisational level in accordance with the requirements in the IADA Standard for Doping Control and ISO 9002.

The IADA Steering Group (or designated body) and the ADO are responsible for the production of the quality system documentation agreed to at the international level.

Actions

1. Preparation and planning

1.1 Organise a small working group of 3 to 5 people with competencies, experience and skills relevant to the actual policy area and the specific activity being documented.

- Start by giving an overall briefing on the IADA Quality Concept and the task of developing quality system documentation such as plans, procedures, work instructions, checklists, specifications and criteria.
- Designate one person to produce a draft procedure for discussion and review by an appropriate review group. The following activities are to be co-ordinated by the designated person.

1.2 Study relevant documents. The working group should have access to and study documents such as:

- the IADA Standard for Doping Control (ISDC)
- the relevant policy statements and standards in the ISDC
- existing national/organisational procedures and practices
- relevant regulations, procedures and plans in other IADA countries
- the IOC Medical Code and documentation from the IOC Medical Commission
- relevant documentation from the Council of Europe
- Quality Assurance course material from the 1995 ISO workshop in Oslo
- Quality System Documentation course material from the 1996 ISO workshop in Paris.

Extract items from these documents that could be of importance for developing the procedure or should be integrated into the procedure.

1.3 Identify specific problem areas within the activity. Look for problem indicators such as complaints, non-conformities, reports, etc.

1.4 Discuss the need for quality system documentation within the specific policy area.

- Check to see whether the policy statements and standards that are defined in the ISDC require quality control of the activity.
- The main criterion for producing a specific procedure should be that the activity is of vital importance to the quality of the doping control process. If the activity is one where problems occur often or the consequences of non-conformities are critical or substantial, the activity needs to be improved and controlled through the use of a procedure.
- Discuss these criteria with the members of the working group to determine whether quality system documentation is needed for the activity. After deciding that there is a need for quality system documentation, decide what type of documentation is needed.

1.5 Check to see if there are any ISO 9002 requirements for documented procedures for the activity, as the quality system must be in compliance with ISO 9002.

1.6 Make a plan. If the decision is to produce a procedure, a plan must be established defining roles and responsibilities, how the procedure is going to be produced, required resources and timeframes.

2. Brainstorming Session

2.1 Organise a brainstorming session around the following questions:

- What should be the objective of the actual activity? Try to focus on what you ideally want to achieve within the policy area.
- What is the scope of the activity or process involved? Define the scope in terms of the purpose or essential sub-activities of the activity, as well as in terms of when the activity starts and when it ends.
- Who is responsible for reaching the defined objectives and executing the sub-activities? Who should be responsible for controlling, maintaining and improving the procedure?
- What actions are necessary to ensure that the defined activity, including critical sub-activities, are performed in accordance with the policy statement and standards in the ISDC as well as ISO 9002 requirements?

3. Review and integrate the ideas from brainstorming session

3.1 Review and organise the ideas from the brainstorming session.

3.2 Using the chart below, have the working group discuss and decide on the key words for the four main sections of the procedure: objective, scope, responsibility and actions.

Objective:	
Scope:	
Responsibility:	
Actions:	

3.3 Clarify the need for other types of supporting quality documentation such as work instructions, check lists, etc.

4. Produce and finalise the procedure

4.1 Use the prescribed template for procedures, including the template for procedures that include guidelines, to ensure consistency and harmonisation with other IADA Quality Concept documentation. (See the attached appendices: IADA101.1 Template and IADA101.2 Template.)

4.2 Based on the key words in the chart, formulate proposals for the various elements in the procedure. Determine the records required to document the actions and outcomes of the procedure and also the references and appendices needed as supporting documentation for the procedure.

4.3 Discuss the draft procedure with the review group and submit the draft for comments from other people in the organisation or other people in the doping control field in order to improve and finalise the procedure.

4.4 If other supporting quality documents are needed, produce them using relevant parts of this procedure.

Records

Approved quality system documents, produced in accordance with the IADA101 Procedure for producing quality system documents

Reference and appendices

References

IADA Standard for Doping Control, version 2.0
ISO 9002 - 4.2 Quality System

Appendices

IADA101.1 Template for producing quality documents
IADA101.2 Template for producing quality documents: guidelines

IADA Quality Concept for Doping Control	**Document: IADA101.1** **Page: 1 of 1**
Content: **Template for producing quality documents**	**Version: 2.0** **Date: Oct 30-1998**
Developed by: IADA Project Management Team Signature:	Approved by: IADA Steering Group Signature:

IADA Quality Concept for Doping Control (10 point bold italic)	**Document: [#]** **Page: [#] of [#]** (10 point bold)
Content: (10 point unbold) **Procedure for [title]** (14 point bold) **[:subtitle, if any]** (12 point bold)	**Version: [#]** **Date: Mth dd-yyyy** (10 point bold)
Developed by: Signature: *(Note: this signature box* (10 point unbold) *appears on all page headers)*	Approved by: IADA Steering Group Signature: [Chair] *(Note: this signature box* (10 point unbold) *appears on all page headers)*

Objective (14 point bold italic)
[text] (12 point unbold)

Scope (14 point bold italic)
[text] (12 point unbold)

Responsibility (14 point bold italic)
[text] (12 point unbold)

Actions (14 point bold italic)
1. [text] (12 point unbold)

2. [text] (12 point unbold)

etc.

Records (14 point bold italic)
[list] (12 point unbold)

References and appendices (14 point bold italic)
<u>References</u> (12 point underlined unbold)
[list] (12 point unbold)

<u>Appendices</u> (12 point underlined unbold)
[list] (12 point unbold)

Template for procedures

A procedure in the IADA Quality System for Doping Control should be designed and structured as follows:

Objective

Define the objective for the activity covered by the procedure and what the procedure controls or secures within the activity. The objective should express what you ideally want to achieve through the procedure.

Scope

It is necessary to define the scope of the activity, including the critical sub-activities that the procedure should cover. To ensure an efficient flow between the different activities it is necessary to define when the activity starts and when it ends. By doing this it will clearly be stated what is within and what is outside of the activity covered by the procedure.

In addition, it will often be necessary to specify required resources, equipment and relevant areas of application for the scope of the procedure and the activity to be clear.

Responsibility

According to ISO it is important to define authority and responsibility within the quality system for both the operations and management of the doping control process. The procedure should identify which position or group is responsible for achieving the defined objectives and for executing the sub-activities. It is also important to clarify who is responsible for controlling, maintaining and improving the procedure. This is normally specified in this section of the procedure.

Actions

It is necessary to define the actions needed to control activities, including critical sub-activities, in order to ensure that the activities comply with the relevant policy statement and standards in the IADA Standard for Doping Control (ISDC). Defining what to control and specifying how to achieve control are perhaps the most important elements in a procedure.

Still it is important to remember that a procedure is intended to be a general description of how to carry out the activity. A work instruction is a more detailed description and will be a supplement to a specific procedure if necessary.

Records

A vital part of the quality system is to document that the activity has been performed in accordance with the quality system documentation and also to document the result of the activity, if required. These records may be different types of documentation to be found in files such as signed checklists, phone logs, minutes, plans, reports, etc.

References and appendices

It is important to identify and list relevant reference documents in the quality system or other relevant doping control documents, and to append quality system documentation such as check-lists, criteria, specifications, work instructions, etc. that are to be used when carrying out the procedure.

Objective

The objective of the procedure is to secure the process of changing international quality documents within the IADA Quality Concept in such a way that all participating organisations will have equal opportunities to influence and approve changes in the international quality documents.

Scope

The scope of the procedure is the review, improvement and revision of international quality documents.

The activity starts with the first initiative to review an international quality document and ends with a draft revised version of the international quality document prior to its approval.

Quality documents relevant to this procedure are procedures, work instructions, check lists, specifications, plans etc.

Changing the IADA Standard for Doping Control is controlled by a specific procedure (IADA100 Procedure for changing and controlling the IADA Standard for Doping Control).

Responsibility

Each organisation is responsible for making proposals to improve the international quality documents.

The IADA Secretariat (or another body designated by the IADA Steering Group) is responsible for establishing a system for changing the international quality documents.

The IADA Secretariat (or designated body) is responsible for conducting the activities prescribed in the system for changing the international quality documents (such as reviewing the proposals and developing new draft versions of the international quality documents).

Actions

1. The international quality documents shall be reviewed and, if needed, revised each year. Under certain circumstances (determined by the IADA Steering Group, or designated body), participating organisations may revise the international quality documents at any time during the year, if two-thirds of the participating organisations request such a revision.

2. The IADA Secretariat (or designated body) shall be responsible for producing a plan for reviewing the international quality documents each year.

3. All organisations should actively monitor, identify and document potential improvements and related changes to the existing international quality documents.

4. Each organisation shall present areas for improvement or proposals to change the international quality documents for consideration by the other participating organisations and the IADA Steering Group.

5. Proposals for revisions to the international quality documents shall be sent by the participating organisations to the IADA Secretariat (or designated body) no later than 3 months prior to the upcoming IADA Steering Group (or designated body's) meeting.

6. The IADA Secretariat (or designated body) shall be responsible for co-ordinating the proposals and producing draft revised versions of the international quality documents.

7. A draft version of the revised international quality documents shall be distributed to the participating countries 5 weeks prior to the IADA Steering Group (or designated body's) meeting. All incoming proposals from the participating countries shall be compiled by the IADA Secretariat (or designated body) and presented at the IADA Steering Group (or designated body's) meeting as an enclosure to the draft revised versions of the international quality documents.

8. The IADA Secretariat (or designated body) shall be responsible for documenting the proposed changes to the international quality documents by putting the changes in italics in the original text.

Records

Document presenting incoming proposals
Plan for reviewing the international quality documents
Draft revised versions of international quality documents

References and appendices

References
IADA Standard for Doping Control - version 2.0
ISO 9002 - 4.5 Document and data control

Objective

The objective of the procedure is to secure control over the international quality documents within the IADA Quality Concept so that all relevant and appropriate documents are available and easily accessible in an approved and valid version for personnel who require these documents in their work

Scope

The scope of the procedure is the approval, distribution and filing of valid versions of documents and the removal of invalid and/or obsolete documents.

The activity starts with approving a quality document and ends with the removal of invalid and/or obsolete documents.

Quality documents relevant to this procedure are procedures, work instructions, check lists, specifications, plans etc.

Control of the IADA Standard for Doping Control is secured through a specific procedure (IADA100 Procedure for changing and controlling the IADA Standard for Doping Control).

Responsibility

The IADA Secretariat (or another body designated by the IADA Steering Group) is responsible for:

- establishing a system to control the approval, issue, distribution and filing of international quality documents and the removal of invalid and/or obsolete documents
- conducting the activities within the system for controlling the international quality documents.

The IADA Steering Group (or another body designated by the IADA Steering Group) is responsible for approving international quality documents.

Actions

1. International quality documents shall be approved by the IADA Steering Group (or designated body) annually in a regular meeting using the principle of consensus.

2. The IADA Secretariat (or designated body) shall be responsible for producing a master documentation list that shows the international quality documents that are valid at any time, and the list shall be adjusted and updated whenever new international quality documents have been produced and approved.

3. The IADA Secretariat (or designated body) shall be responsible for producing a distribution list for the different categories of international quality documents.

4. The IADA Secretariat (or designated body) shall be responsible for documenting the changes in the new quality document by putting the changes in italics in the original text.

5. The IADA Secretariat (or designated body) shall be responsible for finalising the approved and valid versions of the international quality documents and distributing these no later than 5 weeks after the IADA Steering Group (or designated body's) meeting.

6. The Organisation Project Co-ordinator (OPC) shall confirm in writing to the IADA Secretariat (or designated body) that the new international quality documents have been received and incorporated into their organisational quality documentation and the outdated versions have been removed.

7. If a new international document represents a substantial change or is of vital importance for the doping control process, the IADA Secretariat (or designated body) shall be responsible for initiating relevant information activities before implementation of the requirements prescribed in the new document.

8. The new international quality documents shall be effective from a date set at the IADA Steering Group (or designated body's) meeting, taking into account the need for adjustments at the organisational level.

9. Each participating organisation shall incorporate the new international quality document into their quality documentation by the date set at the IADA Steering Group (or designated body's) meeting.

10. Outdated versions of international quality documents must be filed by the IADA Secretariat (or designated body) according to a filing system.

Records

Master documentation list
Distribution list
Written confirmations from OPCs concerning the receipt and incorporation of new approved international quality documents, and removal of outdated versions

References and appendices

References
IADA Standard for Doping Control, version 2.0
ISO 9002 - 4.5 Document and data control

Objective

To inform the selected athlete of his/her selection for testing, responsibilities and rights and to ensure the integrity of the process from the time of notification until the athlete checks in at the designated doping control station.

Scope

Starts from the time the DCO initiates the notification of the selected athlete. Ends when the athlete registers at the designated doping control station and the sample collection procedure is initiated or when the athlete's failure to comply is brought to the attention of the responsible person or authority.

Responsibility

1. The DCO has the primary responsibility for ensuring proper notification of the athlete. The responsibility for carrying out elements of the notification so specified within the procedure may be delegated to a chaperone.

2. The DCO/chaperone has the responsibility to continually observe the notified athlete throughout the notification process.

Actions

1. In preparing to notify the athlete the DCO shall ensure the following items are in place:
   - appropriate authorisation from the ADO
   - identification card for the DCO/chaperone
   - Notification Form confirming selection criteria.

2. Where the DCO is not to be the chaperone, he/she shall ensure that information regarding athlete selection is communicated to the chaperone in a confidential manner and shall provide the chaperone with the Notification Form naming the selected athlete and/or selection criteria.

3. The DCO/chaperone shall establish the location of the selected athlete and plan the approach and timing to ensure proper notification, taking into consideration the specific circumstances of the sport/competition and the situation in question.

4. The DCO/chaperone shall identify him/herself to the athlete using his/her ADO identification card and confirm the athlete's identity by an approved method. Failure to confirm the identity of the athlete shall be noted on the Notification Form.

5. The DCO/chaperone shall notify the athlete of his/her selection for testing and requirement to provide a urine sample, without prior notice, and shall inform the athlete of his/her rights and responsibilities regarding doping control. These shall include:
   - the requirement to remain within sight of the designated chaperone or DCO at all times until the completion of the sample collection procedure

- the right to have a representative.

6. The DCO/chaperone shall ask the athlete if he/she has understood his/her rights and responsibilities and then to sign the Notification Form, a copy of which shall be provided to the athlete by the responsible person.

7. In the event that the athlete refuses to accept notification, the DCO/chaperone shall inform the athlete of possible consequences. The DCO/chaperone shall make all reasonable efforts to persuade the athlete to comply but if the athlete continues to refuse, the chaperone (if not the DCO) must immediately report all relevant facts to the DCO. The DCO will then institute the procedure for investigating and processing a possible failure to comply (IADA205 Procedure for possible failures to comply).

8. The DCO/chaperone shall inform the athlete of his/her requirement to report to the doping control station as soon as practicably possible. For competition testing the DCO/chaperone shall require the athlete to report as soon as practicably possible but within sixty minutes or as specified by the International Federation rules.

9. From the time of notification the DCO/chaperone shall observe/escort the athlete at all times until he/she has checked in at the doping control station, or he/she is relieved of the responsibility by another DCO/chaperone.

10. The DCO/chaperone shall consider requests to delay the reporting time to enable the athlete to complete one or more of the following:
    - locate a representative
    - media commitments
    - warm down, including obtaining clothing and refreshments
    - medal ceremony
    - participate in further events
    - receive treatment for injuries
    - or other reasons considered acceptable to the DCO.

11. The DCO/chaperone shall record the reasons for any delay in the reporting time in the manner specified by the ADO.

12. If a DCO/chaperone observes any unusual behaviour by an athlete while keeping that athlete under observation, the circumstances shall be noted and, in the case of a chaperone, reported to the DCO. The DCO will then institute the procedure for investigating and processing a possible failure to comply.

Records

Notification Form
Failure to Comply Report
DCO Report Form

References and appendices

References

ADO authorisation

DCO/chaperone accreditation and identification card

Rights and responsibilities checklist

List of approved identification methods

IADA205 Procedure for possible failures to comply

Objective

To inform the selected athlete of his/her selection for testing, and responsibilities and rights and ensure that he/she checks in at the designated doping control station, at the designated time which shall be no more than twenty four (24) hours from notification.

Scope

Begins with the authorisation of the DCO or other person to notify the selected athlete and ends when the athlete checks in at the designated doping control station , or when the athlete's failure to comply is brought to the attention of the responsible person or authority.

Responsibility

1. The ADO has responsibility to properly notify the athlete by the appropriate means. This responsibility may be delegated to the DCO or other authorised person under specified circumstances.

2. The DCO or chaperone authorised by the DCO has responsibility to meet the athlete at the designated doping control station and complete the notification procedure.

Actions

1. The ADO will authorise a DCO/chaperone to notify the selected athlete.

2. The DCO/chaperone will notify the selected athlete by approved means as set out in Protocol for Notification.

3. The ADO and/or DCO/chaperone, as appropriate, shall follow the system established by the ADO for logging athlete notification attempt(s) and outcome(s) and, where required, report possible failures to comply.

4. If the athlete does not report to the doping control station at the time required the DCO will then institute the procedure for investigating and processing a possible failure to comply.

5. When the athlete arrives at the designated doping control station, the DCO or chaperone shall identify him/herself to the athlete, using his/her ADO identification card and confirm the athlete's identity by an approved method. Failure to confirm the identity of the athlete shall be noted on the Notification Form.

6. The DCO/chaperone shall complete the notification process and shall inform the athlete of his/her rights and responsibilities. These shall include:
   - the requirement to remain within sight of the designated chaperone or DCO at all times until the completion of the sample collection procedure
   - the right to have a representative.

7. The DCO/chaperone shall ask the athlete if he/she has understood his/her rights and responsibilities and then to sign the Notification Form a copy of which shall be provided to the athlete by the responsible person.

8. The DCO/Chaperone shall then check in the athlete.

9. In the event that the athlete refuses to accept notification, the DCO/chaperone shall inform the athlete of the possible consequences. The DCO/chaperone shall make all reasonable efforts to persuade the athlete to comply but if the athlete continues to refuse, the chaperone (if not the DCO) must immediately report all relevant facts to the DCO. The DCO will then institute the procedure for investigating and processing a possible failure to comply.

10. The DCO will then institute the procedure for investigating and processing a possible failure to comply.

Records

Short notice notification attempts log
Notification Form
Failure to Comply Report
DCO Report Form

References and appendices

References
Protocol for Notification
Pre-notification checklist
DCO/chaperone accreditation and identity card
System for logging notification attempts
Rights and responsibilities checklist
List of approved identification methods
IADA205 Procedure for possible failures to comply

Objective

The objective is to ensure that the athlete is under observation from the time of arrival at the doping control station until the athlete is able to provide a sample.

Scope

The scope starts from the time the athlete arrives at the doping control station and ends when the athlete leaves the waiting area to provide a sample.

Responsibility

The chaperone(s) is responsible for ensuring each athlete who arrives at the doping control station is under observation until the athlete is able to provide a sample.

Actions

1. Upon arrival at the doping control station, the athlete and the athlete's representative (if present) will be checked-in by an ADO official.

2. One or more chaperones shall keep all athletes in the doping control station waiting area under observation from the time the first athlete arrives and until the last athlete leaves the waiting area to provide a sample (except as noted in #4 below).

3. The athlete is given the opportunity to hydrate.

4. Where an athlete who has arrived at the doping control station wishes to temporarily leave the doping control station and has the approval of the DCO to do so (see IADA202.1 Work Instructions), a chaperone shall accompany and observe the athlete until the athlete returns to the doping control station.

5. If a chaperone observes any unusual behaviour by an athlete while keeping that athlete under observation, the chaperone shall report that fact to the DCO as soon as practicable. The DCO will then follow the procedure for investigating and processing possible failures to comply (see IADA205 Procedure).

Records

Notification Form

References and appendices

References

DCO Manual

IADA205 Procedure for processing possible failures to comply

Appendix

IADA202.1 Work instructions for chaperoning when athlete temporarily leaves waiting area

Work Instructions

1. The athlete can only leave the doping control station under appropriate observation by a chaperone and with the approval of the DCO. The DCO will consider any reasonable request by the athlete to leave the doping control station until the athlete is able to provide a sample. Examples of athlete requests the DCO should consider include:
   - to attend a victory ceremony
   - to attend media commitments
   - to compete in further events
   - to perform a warm down
   - to obtain necessary medical treatment
   - to attend to personal hygiene activities
   - or other reasons considered necessary by the DCO.

2. If the DCO gives approval for the athlete to leave the doping control station, the DCO should agree with the athlete on those conditions that shall be met for the athlete to return to the doping control station.

3. The gender of the chaperone who observes the athlete when the athlete is temporarily away from the doping control station does not have to be of the same gender as the athlete unless the athlete is engaged in personal hygiene activities.

Records

DCO Report Form

References and appendices

References

DCO Manual

IADA202 Procedure for chaperoning in waiting area

IADA205 Procedure for processing possible failures to comply

Objective

The objective is to ensure that each athlete's urine sample is: (1) of a quality and quantity that meets laboratory guidelines; (2) clearly identified; (3) securely sealed in the athlete's presence; and (4) accurately documented.

Scope

The procedure begins when the athlete indicates he/she is ready to provide a urine sample and the chaperone and DCO are ready to collect the sample. The process ends when the athlete's sample is sealed and associated documentation is completed.

Responsibility

The DCO has the responsibility for:

- confirming the identity of the athlete who has been notified of his/her selection for doping control
- ensuring the athlete is informed of his/her rights and responsibilities
- ensuring that each urine sample is properly collected, identified and sealed in the athlete's presence
- ensuring that all samples dispatched meet laboratory guidelines.

The DCO/chaperone has the responsibility for:

- directly witnessing the passing of the urine sample to reduce the likelihood that the athlete is able to manipulate the sample.

Actions

1. When the athlete indicates he/she is ready to provide a urine sample, the DCO shall ensure that the athlete is informed about his/her rights and responsibilities and the sample collection process.

2. The athlete shall select a sealed collection container with which he/she is satisfied. If the athlete is not satisfied with a container, he/she shall select another container. If the athlete is not satisfied with any containers and no other containers are available, this should be noted on the Doping Control Form and the DCO shall instruct the athlete to proceed with the test. However, if the DCO agrees with the reasons put forward by the athlete that all available containers do not meet specifications, the DCO shall terminate the test and this should be noted in the DCO Report Form.

3. The athlete shall retain control of the collection container and any sample provided until the sample is sealed. A DCO and/or chaperone shall handle the collection vessel only if authorised to do so by the athlete.

4. The chaperone and athlete shall proceed to the toilet area to collect a sample.

5. The chaperone who is to witness the passing of the sample shall be of the same gender as the athlete providing the sample.
   - For athletes who are at or over the legal age of consent, only the athlete and chaperone are permitted in the toilet area.
   - When collecting a sample from an athlete who is under the legal age of consent, the athlete and athlete's representative shall have the right to request the athlete's representative also be present in the toilet area during the passing of the sample.
   - The athlete's consent is required before the athlete's representative is permitted to be present in the toilet area.
   - If the athlete gives consent, the athlete's representative can be present in the toilet area but will not witness the passing of the sample. The presence of the athlete's representative in the toilet area shall be noted on the Doping Control Form.

6. The chaperone shall directly witness the passing of the sample by the athlete.

7. Once the athlete has completed passing the sample, the athlete and chaperone shall immediately return to the DCO who will oversee the process of sealing the sample.

8. The chaperone who witnessed the passing of the sample shall sign the Doping Control Form to verify the sample was passed by the athlete.

9. The DCO shall ensure that the volume of the urine sample satisfies laboratory requirements for analysis in full view of the athlete (see IADA203.1 Guidelines).

10. Where the volume of urine is insufficient, a partial sample collection procedure shall be conducted (see IADA203.2 Work Instructions).

11. Where there is sufficient urine, the athlete shall select a urine kit with which he/she is satisfied and in which the sample will be sealed. If the athlete is not satisfied with the urine kit, he/she shall select another kit until satisfied. If the athlete is not satisfied with any urine kits and no others are available, this should be noted on the Doping Control Form and the DCO shall instruct the athlete to proceed with the test. However, if the DCO agrees with the reasons put forward by the athlete that all available urine kits do not meet specifications, the DCO shall terminate the test and this should be noted on the DCO Report Form.

12. Once a urine kit has been selected, the DCO and athlete shall check the urine kit to determine that it is suitable (e.g. kit numbers match, kit not damaged, etc.). If after this inspection the kit is considered unsuitable by the DCO, the athlete shall be asked to select another kit (i.e. repeat action #11). If no additional kits are available, the DCO shall terminate the test and no sample shall be secured.

13. The athlete shall open the kit, pour at least the prescribed minimum volumes of urine into the A and B bottles and seal the bottles as directed by the DCO.

14. The DCO shall confirm the sample satisfies laboratory requirements for analysis by testing the residual volume of urine remaining in the collection container (see IADA203.3 Work Instructions).

15. The DCO shall request the athlete to provide information about all medications and other substances used within the last 7 days.

16. The DCO shall complete the Doping Control Form.

17. The DCO, athlete, athlete's representative (if applicable), and any other person where required shall then sign the Doping Control Form to verify the accuracy of the information.

18. The DCO shall provide a copy of the Doping Control Form to the athlete as he/she leaves the doping control station.

19. The DCO shall discard all residual urine.

20. If a chaperone observes any unusual behaviour by an athlete while witnessing the passing of the sample the chaperone shall report that fact to the DCO as soon as practicable. The DCO shall then follow the procedure for investigating and processing possible failures to comply (see IADA205 Procedure).

21. If a chaperone is unable to verify that he/she witnessed the passing of the sample or the chaperone reports observing unusual behaviour by the athlete, the DCO can require the athlete to provide a further sample. If additional samples are collected, all samples collected shall be sent to the laboratory for analysis.

22. If a DCO observes an athlete failing to comply with any direction made by the DCO or chaperone during the sample collection process, the DCO shall follow the procedure for investigating and processing possible failures to comply (see IADA205 Procedure).

Records

Doping Control Form

References and appendices

References

DCO Manual
Rights and responsibilities checklist
IADA205 Procedure for processing possible failures to comply
IADA300 Recommended specifications for purchasing sample collection equipment

Appendices

IADA203.1 Guidelines for meeting laboratory volume and quality requirements for samples
IADA203.2 Work instructions for insufficient sample
IADA203.3 Work instructions for checking that the sample is fit for analysis

Guidelines

1. The volume of urine collected for all samples is dependent on specific gravity readings. The volume of urine required for the following specific gravity ranges is [INSERT contracted laboratory guidelines].

2. The pH reading for all samples shall be between [INSERT contracted laboratory guidelines]. If the reading is outside the pH range, the DCO shall collect a second sample or further samples as specified by the contracted laboratory.

3. Where possible, samples should be stored in cool, preferably refrigerated, areas prior to transport to laboratory.

4. The sample(s) will be sent to the laboratory as soon as possible after completion of the sample collection session to minimise the potential for sample degradation.

5. Any sample received by a laboratory, which analysis reveals cannot be relied upon to produce a definitive analytical result will be reported as “unreliable”.

Records

Doping Control Form

References and appendices

References

DCO Manual
Contracted laboratory guidelines for specific gravity and pH
IADA203 Procedure for collection of urine sample
IADA203.3 Work instructions for checking that the sample is fit for analysis

Work Instructions

1. If there is an insufficient volume of urine in the sample, the DCO shall advise the athlete that the insufficient sample will be secured and a further sample shall be collected to meet the volume requirements.

2. When the athlete is ready to provide a further sample, the DCO instructs the athlete to select a partial sample container with which the athlete is satisfied. The DCO then instructs the athlete to open the partial sample container, pour the insufficient sample into the container and seal it as directed by the DCO.

3. The DCO, chaperone and athlete complete the relevant sections of an Insufficient Sample Form.

4. The athlete shall then return to the waiting area until ready to provide a further sample as required.

5. When the athlete is able to provide an additional sample, procedures for collection of the sample are repeated until sufficient volume of urine is provided (see IADA203 Procedure, Actions #1-10).

6. If following the provision of the additional sample, the DCO indicates a sufficient volume of urine has been provided, the DCO, chaperone and athlete shall complete the Insufficient Sample Form and provide other details specified by the ADO.

7. The DCO shall indicate on the Doping Control Form that an insufficient sample was provided.

8. The DCO shall then direct the athlete to break the seal on the partial sample container containing the previously provided insufficient sample(s), combine and seal the insufficient samples, and then follow the procedure for completing collection of a sample (see IADA203 Procedure, Action #11 onwards).

Records

Insufficient Sample Form
Doping Control Form

References and appendices

References
DCO Manual
IADA203 Procedure for collection of urine sample
IADA205 Procedure for processing possible failures to comply

Work Instructions

1. The DCO shall test the residue of the sample by a method approved by the ADO to determine if the sample meets contracted laboratory guidelines (see IADA203.1 Guidelines).

2. The DCO shall advise the athlete that he/she is required to provide a further sample if the sample is:
   - outside the defined specific gravity range for full and half screen tests (see IADA203.1 Guidelines)
   - outside the defined pH limit for full and half screen tests (see IADA203.1 Guidelines).

3. The athlete shall then return to the waiting area until ready to provide a further sample.

4. When the athlete is able to provide an additional sample, procedures for collection of the sample are repeated until a further sample that meets contracted laboratory guidelines is provided (see IADA203 Procedure, Actions #1 - 14).

5. Once a sample meeting contracted laboratory guidelines has been provided:
   - [INSERT contracted laboratory guidelines for number of samples] samples collected from the athlete shall be retained for analysis
   - the DCO shall discard other samples collected, as appropriate
   - the DCO shall note the pH and specific gravity readings of all samples retained for analysis on the Doping Control Form
   - the DCO and athlete shall continue the procedure for collection of a sample (see IADA203 Procedure, Actions #15 onwards).

6. Documentation shall ensure that the laboratory is aware that all samples belong to a single athlete and the order in which the samples were provided.

Records

Doping Control Form

References and appendices

References

DCO Manual
IADA203 Procedure for collection of urine sample
IADA203.1 Guidelines for meeting laboratory volume and quality requirements for samples
IADA205 Procedure for processing possible failures to comply

Objective

The objective is to ensure that all samples collected at the doping control station and related documentation are securely stored, and post-test administration is accurately completed.

Scope

The procedure begins after the athlete who provided the sample has left the doping control station, and ends with the completion of the administration aspects of the testing session and sealing of the transport bag(s).

Responsibility

The DCO has the responsibility for ensuring all samples are securely stored while the samples are in the doping control station, completing required documentation, and sealing the transport bag(s).

Actions

1. The DCO shall ensure that the sealed sample is securely stored before commencing collection of further samples. Where possible, the sample will be stored in a cool environment.

2. The DCO shall collect and securely store all ADO copies of required documentation relating to each sealed sample that is collected.

3. Actions (1)-(2) are repeated until the final sample is collected.

4. The DCO shall ensure that only authorised personnel have access to sealed samples and transport bags.

5. The DCO shall accurately complete appropriate documentation for each transport bag to ensure the laboratory can verify the contents of the transport bag, and (where required by work instructions) shall provide instructions for the analysis process.

6. The DCO shall compile all documentation relating to the complete sample collection session and confirm that all paperwork has been completed accurately.

7. The DCO shall send laboratory copies of the Doping Control Form and Laboratory Advice Form/Chain of Custody Form to the ADO and/or laboratory in accordance with ADO requirements. These forms shall be placed inside the transport bag containing the relevant samples. Where all documentation is forwarded to the ADO, the ADO shall forward relevant documentation to the laboratory.

8. The DCO shall seal each transport bag at the completion of a testing session. When samples are collected over successive days, transport bags shall be sealed after one session and re-sealed after subsequent sessions. The DCO shall sign the Laboratory

Advice Form/Chain of Custody Form whenever the transport bag is sealed or unsealed.

9. Each transport bag shall contain:
   - the sealed urine kits specified on the Laboratory Advice Form/Chain of Custody Form
   - a laboratory copy of the Doping Control Form for each sample
   - the original copy of the Laboratory Advice Form/Chain of Custody Form.

10. The DCO shall complete a report of the sample collection session.

11. As soon as practicable, the DCO shall send the ADO copies of all Notification Forms, Insufficient Sample Forms (if any), Doping Control Forms, Laboratory Advice Forms/Chain of Custody Forms, Failure to Comply Report Forms (if any), DCO Report, collection session timesheets, and other relevant ADO administrative documentation associated with the collection.

Records

Notification Form
Insufficient Sample Form
Doping Control Form
Failure to Comply Report
ADO collection session timesheets
Laboratory Advice Form/Chain of Custody Form
DCO Report Form

References and appendices

References
DCO Manual

Objective

The objective is to ensure that a DCO completes the appropriate documentation to report any potential failure to comply.

Scope

The procedure begins when a DCO or chaperone notices that an athlete selected to provide a sample is behaving unusually, and ends when the DCO completes appropriate documentation to report any potential failure to comply.

Responsibility

The chaperone is responsible for:

- reporting to the DCO any unusual behaviour by an athlete selected to provide a sample.

The DCO is responsible for:

- reviewing any unusual behaviour by an athlete selected to provide a sample that is observed by the DCO or reported by chaperones to determine if a potential failure to comply has occurred
- completing appropriate documentation to report any potential failure to comply.

Actions

1. A chaperone who:
   - observes any unusual behaviour by an athlete selected to provide a sample
   - observes any unusual behaviour by another person; or
   - receives information from a person that an athlete or other person has engaged in a doping offence

   shall report this fact to the DCO as soon as practicable. The chaperone may advise the relevant athlete of the chaperone's intention to notify the DCO of any unusual behaviour he/she has observed.

2. The DCO shall review any incidents he/she observes of unusual behaviour by an athlete selected to provide a sample, or that is reported to him/her by a chaperone as soon as practicable and before the end of the sample collection session.

3. After reviewing the information available about the unusual behaviour, the DCO shall determine whether to take no further action or to treat the matter as a potential failure to comply.

4. If after reviewing the information available about the unusual behaviour, the DCO does not believe the athlete has failed to comply, the DCO shall make reference to the unusual behaviour in a DCO Report for that sample collection session.

5. If after reviewing the information available about the unusual behaviour, the DCO believes the athlete has failed to comply, the DCO shall, if possible, notify the athlete that

a Failure to Comply Report will be lodged with the ADO and that the ADO will initiate action to ensure appropriate follow-up.

6. If the DCO believes the athlete has failed to comply, the DCO shall complete a Failure to Comply Report, including (where necessary) a written report from the chaperone, and forward it to the ADO with other documentation from the sample collection session.

7. If after a DCO completes a Failure to Comply Report, the athlete referred to in the report subsequently agrees to provide a sample, the DCO's decision of whether or not to collect the sample shall be made in accordance with ADO guidelines.

8. The DCO shall include reference in the DCO Report to any instances of:
   - failure to comply
   - chaperone or DCO observation of unusual behaviour by athletes that did not result in the DCO completing a failure to comply report; and
   - chaperone or DCO observation of unusual behaviour by any other person.

Records

Failure to Comply Report
DCO Report Form

References and appendices

References
DCO Manual
IADA200 Procedure for no notice testing
IADA201 Procedure for short notice testing
IADA202 Procedure for chaperoning in waiting area
IADA203 Procedure for collection of urine sample

Appendix
ADO guidelines for collecting an additional sample from an athlete about whom the DCO has completed a Failure to Comply Report

Objective

The objective is to ensure the safe, secure and timely transportation of:

1. samples and required documentation from the site of collection to the laboratory, and
2. relevant sample collection session documentation from the DCO to the ADO.

Scope

The scope of the procedure commences following the sealing of the transport bag(s) containing the samples and required documentation and ends with the confirmed receipt of the transport bag(s) by the laboratory and relevant sample collection documentation by the ADO.

Responsibility

The ADO:

- has the overall responsibility for the administration of a reliable system to transport, store, trace, and document the location of the samples and sample collection documentation.
- has the responsibility to approve and authorise a transport supplier which meets its requirements and specified standards.

The DCO is responsible for:

- the security of the transport bag(s) until he/she delivers the bag(s) either to the laboratory or to the ADO or to the transport supplier when an approved and contracted transport supplier is used.
- listing and sending the relevant sample collection session documentation to the ADO and the laboratory.

The approved, contracted transport supplier is responsible for:

- transporting the transport bag(s) to the designated destination in compliance with the agreed terms for delivery and handling of the bag(s).

The laboratory is responsible for:

- confirming receipt of the transport bag(s).

Actions

1. If the DCO needs to reseal a transport bag, the DCO shall document the resealing, ensure that the bag is resealed with all of its original contents and the new security number securely stored inside, and provide the new security number to the ADO in writing.

2. The DCO shall arrange for the transport bag(s) to be dispatched to the designated destination as soon as practicable after the completion of the sample collection session.

3. The transport bag(s) shall be sent directly to the laboratory, or if instructed by the ADO, directly to the ADO for forwarding to the laboratory, by either the DCO in person or a person authorised by the ADO, or by an approved and contracted transport supplier.

4. A copy of the Laboratory Advice Form/Chain of Custody Form shall be sent by the DCO or an ADO authorised person to the ADO to record that responsibility for security of the transport bag(s) has been transferred to the laboratory or the ADO or the approved, contracted transport supplier.

5. The DCO shall list and send all necessary sample collection session documentation to the ADO by an approved method as soon as practicable after the completion of the sample collection session.

6. If the seal of a transport bag needs to be broken in transit while not in the care of the DCO, the responsible person or organisation shall provide verification of the secure chain of custody of the bag to the ADO.

7. The laboratory shall confirm the receipt of the transport bag(s) with the ADO by an approved method.

8. If a transport bag(s) and/or the required documentation has not arrived at the estimated time in the respective locations, or the required documentation has not been properly completed, the ADO shall take the necessary steps to resolve the situation including those prescribed in the procedure for handling of non-conformities.

9. At all stages during the transfer and transport of the transport bag(s), all reasonable efforts shall be made to keep the transport bag(s) cool and secure.

Records

Laboratory Advice Form/Chain of Custody Form
DCO Report Form
Doping Control Form

References and appendices

References

ADO/transport supplier contract or agreement
ADO/laboratory contract
ISO 9002 requirements:

- 4.8 Product Information and Traceability
- 4.9 Process Control
- 4.10.4 Final Inspection
- 4.13 Control of Non-Conformities
- 4.15.6 Delivery

Appendix

List of approved transport suppliers

Background to recommended specifications

i. Sports drug testing requires the use of acceptable sample collection equipment which, at a minimum, consists of a vessel for collecting the urine, security containers for sealing urine samples, containers for collecting and securing partial samples, and a container for transporting samples in a secure way. If a range of manufacturers supply the international anti-doping market with equipment that meets minimum set of approved standards, this will ensure continuity, minimise challenges to the integrity or identity of samples. increase athlete confidence and promote cost competitiveness.

ii. Sample collection equipment should meet basic specifications. The intention is to achieve world-wide acceptance of collection systems, both operationally and legally. Standards are also necessary for the secure manufacture, transportation and control of all parts of the equipment system. These basic requirements and standards are set out below.

iii. The documentation necessary to record athlete notifications, rights and responsibilities, sample collection procedures, witness statements and sample identification codes as well as to record the chain of custody of sample containers (i.e. control forms and chain of custody form) should be an integral part of the system to maximise security. A minimum standard for documentation is also required.

iv. An international registration system for the 'corporate logos', the unique identification codes of the various testing organisations (International Federations, National Anti-Doping Organisations) would be essential to ensure the unique identity of samples.

v. The sample collection equipment, documentation and unique registration system for sports drug testing organisations is referred to in this document as sample collection systems.

Recommended Specifications

1. Manufacturers of sample collection equipment

1.1 The manufacturer of the collection system should be independent of the IOC laboratory system, collection agencies and sports federations (although consultation on product design would be acceptable and encouraged).

1.2 The manufacturer's product and/or manufacturing system must be certified under ISO 9000 by a recognised national certification body.

1.3 The equipment's specifications must be clearly stated and must meet the mandatory sections of the equipment specifications set out in this document. The equipment's specifications must not be altered by the manufacturer without the ADO's written agreement. The manufacturer must provide warranties for the equipment's fitness for purpose and condition and hold appropriate indemnity insurance.

1.4 Access to equipment should be restricted to authorised personnel only, this includes employees of the company and controlled distribution to authorised customer personnel. A secure, controlled method for placing orders, as well as for delivering and storing of equipment must be in place. The manufacturer must have an inventory control system to track and account for the manufacture, storage and delivery of equipment, and must retain related records in a secure manner for at least five years.

2. Equipment specifications: general guidelines

2.1 The equipment must be light, strong and compact for ease of packing and transportation, either as individual units or in bulk. The equipment must be simple and easy to use for sample collection personnel, athletes and laboratory personnel, with no unnecessary components.

2.2 There must be a unique identification label system (number, organisation code, and if required, bar code) incorporated into all bottles and containers. The unique identification system must be guaranteed by the manufacturer to ensure no duplicate equipment exists.

2.3 All equipment must have a unique sealing system that is tamper resistant and tamper evident and can be traced directly to the athlete, sample collection personnel and relevant testing organisation.

2.4 The identity of the athlete must not be evident from the equipment itself.

2.5 The equipment must be secure and able to be seen as secure from tampering prior to being opened by the athlete.

2.6 Documentation, whether an integral part of the equipment system or produced separately, must be clear, easy to read and complete, and clearly related to the samples.

2.7 The equipment must include clean, pre-sealed bottles in which the urine samples will be placed and transported. The bottles must be made of non-leaching material.

2.8 Unless the bottles themselves constitute the tamper evident sealing method, the bottles should be placed in a tamper resistant and tamper evident container system for transport to and secure storage at the laboratory.

2.9 The equipment must meet internationally accepted carriage requirements conforming to IATA, EC regulations, and postal, health and safety legislation at the national level covering the originating, transient and recipient countries during transit to the laboratory.

2.10 Generally all equipment should be disposable, although reusable outer containers may be required by some organisations, and have unique identification codes and numbers (and, if required, bar coding) on all bottles, containers and, if appropriate, pre-printed on documentation. The containers may also be used for sealing samples and for transporting them collectively or individually (as pairs of samples) to the laboratory.

2.11 The design and manufacture of the containers must allow the samples to be kept at optimum conditions that maintain the security and integrity of the samples during transport and storage, including storage in freezers.

3. Specific equipment requirements: bottles and containers

3.1 A urine kit must contain two glass specimen bottles with a tamper evident sealing system (which may be achieved by using separate containers for the bottles). The bottle tops must be tightly fitting and made of chemically inert material. The pair of bottles (and containers where used) should be marked with a matching A or B code, six digit number and organisation code suffix or prefix; e.g. A # # # # # # organisation code, B # # # # # # organisation code. The marking must be permanent, tamper resistant and tamper evident.

3.2 Colour coding of the A and B bottles (and containers) is preferred with attention to the avoidance of colours that may be confused by colour blindness. Legibility is important, including the possibility of tactile identification codes for the blind or partially sighted.

3.3 The urine kit should be supplied in a pre-sealed tamper evident package that is ready for use. The package should have an integrity seal on the equipment stating that the equipment is in pristine condition. If the seal is broken the equipment must not be used.

3.4 The glass specimen bottles must be able to hold 100 ml in volume. The bottle labels must show the minimum levels of urine they should contain (for example, A bottle 50 ml, B bottle 25 ml), and a maximum fill level to allow for freezing.

3.5 The neck of the bottle should be at least 10 mm in diameter to allow the urine sample to be poured in with ease and for easy access at the laboratory using pipettes.

3.6 Once the urine samples have been poured into the bottles, the sealing system (for example if using containers) must have tamper resistant and tamper evident security seals with a unique identification system.

3.7 The sealing system for equipment that has been used should be distinct from the original presentation sealing method, either by colour or design, to demonstrate that the urine kit has been used.

4. Specific equipment requirements: sample collection containers
   4.1 Sample collection containers are required to collect and hold the urine as the athlete urinates. These must meet the same standards of security and integrity as the bottles.

   4.2 Sample collection containers must be supplied individually in a pre-sealed, tamper-evident package made of chemically inert material and guaranteed to be in pristine condition.

   4.3 The containers must be able to hold at least 200 ml and they should have an easy-to-read volume measurement of up to 200 ml in 10 ml increments.

   4.4 To avoid accidental spillage, a closure system for the sample collection container should be available. This closure system might also be used as a sealing system if the sample collection container is used to collect and securely hold partial samples. If so this must meet the same standards as the bottles. The interface of the sample collection container with a partial sample system will determine whether a unique identifying code is required.

5. Specific equipment requirements: partial sample containers
   5.1 When a partial sample is provided, it must be sealed in a way that ensures it has a unique identifying code. This may be achieved by using the urine kit bottles (and containers) and a separate and distinct sealing system or by using the collection container or a separate container. The unique identifying code should distinguish this as a partial sample, e.g. P # # # # # # organisation code suffix or prefix. This code will also be recorded on related documentation.

   5.2 The sealing system should make the partial sample container tamper evident and tamper resistant.

   5.3 The partial sample container must be able to hold at least 100 ml in volume, with volume graduations (either indicated by label or embossed) at 10 ml increments.

   5.4 The partial sample container must be supplied in a pre-sealed, tamper evident and tamper resistant package made of chemically inert material and guaranteed to be in pristine condition.

6. Specific equipment requirements: transport bag system
   6.1 The transport bag system must be light, yet strong enough to protect samples in transit. The system should allow for the use of re-usable or disposable containers and be capable of holding one pair and/or several pairs of bottles (and containers). The transport bags should have clear labeling that identifies the contents as ‘biological specimens’ in compliance with IATA requirements.

6.2 The sealing system for the transport bag must be tamper resistant, tamper evident and include the unique identification code of the organisation as well as a unique numbering system for sealing the closed container. Self sealing systems are acceptable; however, where a separate sealing system is used, each seal must have a unique number and organisation code. The seal code will also be recorded on related documentation.

6.3 Absorbent material must be included in the bottle container system, and be sufficient to absorb all possible fluids in case of breakage.

6.4 The transportation container will be required to hold the related documents and this may be achieved by a separate secure pocket, area or space in the container for the placement of documents. In addition, the outer surface of the transport container should be able to have an adhesive label attached or a pocket for the courier consignment document.

7. Specific equipment requirements: other sample collection equipment

7.1 To complete the sample collection procedure, additional equipment is required to measure pH and specific gravity, to maintain standards for hygiene and sampling conditions. This includes pH and specific gravity measuring equipment, protective gloves and refrigeration systems. The supply and quality standards of other doping control equipment should meet specifications similar to the basic requirements for the sample collection system.

7.2 The equipment must be light, portable, disposable and meet minimum industry safety standards for contamination and security.

8. Documentation specifications: general guidelines

8.1 Sampling equipment does not stand alone; it requires documentation about the athlete, the collection procedure, the samples and their custody from the point of collection to their arrival at the laboratory. The basic information to be recorded is: athlete selection, athlete notification, the collection process, sample identity, medication declaration, witness signatures, dates and times. The key requirements are clear layout and design, manageable size, a format that is easy to read and complete, multiple carbon copies, and colour coding of pages for easy distribution and security coding. While the number of forms required should be kept to a minimum, it may not be possible to incorporate all information on one form. In such cases it may be possible for organisations to accept separate forms for the various stages of notification, sample collection and failure to comply. Transportation of samples should always be covered by a separate laboratory advice form/chain of custody form.

9. Specific documentation requirements: sample collection form(s)

9.1 Sample collection forms are used to record the athlete's personal data, notification, rights and responsibilities, sample collection information, medications and witness

signatures.

9.2 The athlete notification details to be recorded are:

- athlete's given name and surname
- date of birth
- sport/event
- country/team
- identification/accreditation number
- notification date and time
- notification order, statement of rights and consequences of refusal
- reporting time and date
- signature of sample collection official confirming notification was given
- signature of athlete confirming notification was received.

9.3 The test details to be recorded are:

- the time the athlete reported for test
- sex of athlete
- total volume of urine collected
- unique test code number
- partial sample volume(s) and seal number(s) with confirming signature
- bottle (and container) code numbers
- pH reading
- specific gravity reading
- declaration of medications and other substances taken by athlete in preceding 7 days, dosage, time/date
- temperature of sample (if taken)
- comments of athlete and/or Doping Control Official
- confirmation that sample collection was witnessed or that athlete refused to comply with request to provide sample
- signature of sample collection official to certify witnessing the provision of the sample and that the correct procedures were followed
- signature of athlete
- signature of accompanying official, if present*
- signature of International Federation representative, if present*
- signature of IOC representative, if present.*

[* to record the presence of these individuals in case of a challenge to the collection procedures which they observed]

9.4 A consistent colour scheme should be used for sample collection documentation to facilitate distribution of copies to relevant parties. Copies are required as follows:

- athlete notification and final copies (unless separate forms are used)
- laboratory copy (excluding athlete details)

- IOC/IF/sport organisation/sample collection organisation copies (individual copies for all relevant organisations).

9.5 The following colour scheme is suggested:
- red for notification to athlete
- green for final copy to athlete
- yellow copy for laboratory
- blue copy for organisation commissioning the test
- red copy for IOC/IF
- black copy for national sport federation.

9.6 Copies must be clearly labeled and version controlled (e.g. page 1 of 6, version number).

10. Chain of custody documentation specifications: general guidelines

10.1 There should be a secure, controlled and documented chain of custody for the transfer of samples from the dispatch of prepared equipment to the Doping Control Official. If the Doping Control Official opens the transport container to check the contents, the sample equipment within must remain sealed. A 'signature required' system is necessary to confirm ownership of the samples at all stages of transportation detailing who released the transport container (e.g. name, organisation, date and time) and who received custody of the samples (e.g. name of courier company with identification number of courier employee who has custody of the samples). The chain of custody system must be able to be used with a transport supplier who operates a computerised tracking system with transfer records.

10.2 All information relating to the sealing of collected samples and transfer of the sealed samples from the collection site to the laboratory must be recorded on the chain of custody form. This form should provide a contemporaneous record of the sample transport process, covering the placement of sealed containers in the custody of the Doping Control Official, sealing within a transport container, transfer to the laboratory and receipt by the laboratory. It should be adaptable to use in conjunction with a bonded courier system that has its own audit trail of custody which should be available on request.

10.3 The laboratory advice form/chain of custody form should be page controlled and version controlled. A copy of the laboratory advice form/chain of custody form should be sealed inside the transport bag.

11. Chain of custody documentation specifications: specific requirements

11.1 The chain of custody form should be a colour-coded, multiple carbon copy form that is used to record the following information:
- unique test code number

- week number/date
- number of samples enclosed in the transport bag
- list of A and B code (and seal) numbers enclosed in the transport bag
- type of test e.g. competition (including collection venue if appropriate) or out-of-competition test
- sport/federation
- outer transport bag seal number on dispatch from the sample collection site, signature of sealing official (Doping Control Official or IOC/IF representative)
- custody details such as transport bag seal number
- released by (name and signature)
- received by (name and signature)
- purpose of transfer of custody
- date/time of transfer
- customs declaration encouraging the customs authorities to contact the relevant authority before breaking the seals, in which case secure sealing procedures can be maintained by negotiation or witnessing.

11.2 Copies of the form are required as follows:

- laboratory: yellow copy which is to be placed inside the transport container before it is sealed
- sample collection organisation: red copy which should be attached to the courier company's receipt
- IOC/IF/sport organisation copies: black copy including original copy.

12. Invitation to manufacturers

12.1 Manufacturers are invited to indicate the additional features offered by their product, including a full and detailed description and specifications and in particular:

- robustness of all equipment (compression, pull, shear and twist resistance of all sections)
- standards of cleanliness of containers and bottles
- contaminants from materials including glass
- relevant standards applied during design and manufacture.

Recommended specifications

1. The laboratory must have IOC accreditation.

2. The laboratory should have ISO Guide 25 certification for analysis of biological specimens.

3. The contract for laboratory services shall specify that the ADO owns the samples collected under the ADO's jurisdiction.

4. The laboratory shall provide the ADO with written acknowledgement of receipt of transport bags and their contents as soon as practicable after delivery of the bags. The written acknowledgement shall include the following information:
   - courier company name and address
   - waybill number(s)
   - date when the laboratory received the samples
   - client/organisation name
   - client reference number
   - name of doping control officer in charge of collecting the samples
   - country where the samples were collected
   - identification of event/competition or out-of-competition testing for which samples were collected
   - total number of samples received
   - transportation bag/container code number(s)
   - signature of the laboratory official who prepared the written acknowledgement.

5. The laboratory shall report sample analysis results to the ADO within specified timelines, but no later than 10 working days after receiving the samples (unless other arrangements have been agreed to by the ADO).

6. The laboratory shall confirm and conduct the specified types of sample analysis in compliance with the ADO's instructions.

7. The laboratory shall establish and maintain a system for detecting and reporting non-conformities in the sample analysis process.

8. The laboratory shall require formal and independent investigations of identified false positive and false negative analysis results.

9. The laboratory shall be prepared to defend their analysis results at athlete appeals, hearings, in court, etc.

10. The contract for laboratory services shall specify timelines for providing laboratory expert advice/recommendations to the ADO regarding analytical reports.

11. The contract for laboratory services shall include analyses of "control" samples provided to the laboratory by the ADO.

12. The contract for laboratory services shall include the provision of expert advice, requested reports and presentations on specialised subjects (e.g. advice on specified banned substances, detection methods, research, etc.).

13. The laboratory shall provide the ADO with its documented procedures for:
    - confirming receipt of the samples
    - reporting results of analyses that are negative
    - reporting results of analyses that are positive
    - "B" sample confirmation
    - identifying irregularities with respect to equipment, pH and specific gravity readings, chain of custody, and documentation.

14. The laboratory shall submit accurate invoices to the ADO in accordance with the agreed upon financial terms and conditions.

15. The laboratory shall seek approval from the ADO before forwarding any sample or part of a sample to another laboratory for further analysis.

16. The laboratory shall analyse in and out of competition samples according to a list specifying the classes of substances and methods which should be included in the analysis.

17. In all cases where the ADO owns the samples, the laboratory must obtain the ADO's written consent prior to using the samples for any purposes other than those specified in 16 above.

18. The laboratory shall advise the ADO of the criteria under which the laboratory will reject the sample for analysis.

19. If the sample does not meet the criteria for analysis, the laboratory must contact the ADO before taking any further action.

20. The designated signatory of the laboratory shall provide a confidential report to the ADO if the "A" sample analysis indicates the presence of a substance classified as prohibited or restricted and/or on substances that the ADO requested to be analysed.

21. The laboratory shall liaise with the ADO regarding the appropriate date and time for the "B" sample analysis.

22. The laboratory shall not reveal or communicate any information regarding analysis results without prior approval from the ADO (except when IOC regulations require the laboratory to report results to International Federations).

23. The contract for laboratory services must specify the costs for the various types of analyses to be performed by the laboratory.

24. The contract for laboratory services must include a schedule of penalties for failure by the laboratory to achieve contractual obligations.

25. The laboratory must indemnify the ADO against claims and litigation related to laboratory activities.

Recommended specifications

1. An agreement for services to transport doping control samples to the laboratory or ADO can be made with:
   - individuals
   - transport companies.

2. Agreements with individuals:

   2.1 The person responsible for the transport of doping control samples shall be a DCO, a chaperone or other person appointed by the ADO.

   2.2 The transport bag containing samples shall be transported according to the ADO's instructions, which shall include:
   - conditions concerning the means of transportation (e.g. road, rail, air, etc.)
   - conditions for handling and storage of the transport bag during transport (such as temperature, etc.)
   - conditions concerning documentation of the transportation process
   - the timetable for transportation and delivery
   - the delivery address of the laboratory orADO.

   2.3 The transport bag containing samples shall only be handled by authorized persons throughout the transportation process and with security and safety measures that ensure the transport bag is unaccessible to non-authorized persons and cannot be damaged.

   2.4 If possible, the transport bag containing samples shall be kept at a temperature ranging from +4C to +8C at all times during the transportation process. It must not at any time during the transport be subjected to:
   - such a low temperature that there is a risk of the sample freezing
   - such a high temperature that the validity of the sample is threatened.

   2.5 A separate freight document shall be prepared for each transport bag to record the following information sequentially at the corresponding phases of the transportation process:
   - sender information: the transport bag seal number, sender's name and signature, date and time of signature, address where the transport bag is being picked up, delivery address, etc.
   - transfer information: name(s) and signature(s) of person(s) to whom the transport bag is transferred during the transportation process (including initial transfer from sender to the ADO's authorised delivery person), date and time of transfer(s), etc.
   - receiver information: receiver's name and signature (i.e. laboratory or ADO representative), date and time the transport bag was received, etc.

2.6 Every transfer of the transport bag during the transportation process shall be confirmed by a receipt record signed by the person to whom the transport bag is transferred, and the receipt record shall be given to the ADO's authorised delivery person.

2.7 The ADO shall have a system for tracking and establishing the location of each transport bag at any time during the transportation process.

3. Agreements with transport companies:

3.1 The transport company shall have operated in the marketplace for a sufficiently long period of time to enable an evaluation of the quality of its services. The size of the transport company's business during this time shall also be sufficiently large to enable a proper evaluation.

3.2 The offer of the transport company shall contain at least five previous customers as references. When possible, these customers shall have had transportation safety requirements similar to the ADO's requirements.

3.3 The transport company shall agree to transport doping samples (biological material) that are packaged in accordance with the ADO's doping regulations.

3.4 The transportation service shall be 'door-to-door' and/or 'deposit location-to-door' and by means of road, rail or air (or a combination of these transportation modes).

3.5 The transportation service shall be supplied year round, during office hours and/or other hours, and normally without requirements for advance notice (exceptions can be made for nights and public holidays).

3.6 Delivery shall take place within and no later than 24 hours from the time the transport bag is picked up by the transport company.

3.7 The transport bag shall only be handled by authorized personnel throughout the transportation process and with security and safety measures that ensure the transport bag is unaccessible to non-authorized personnel and cannot be damaged.

3.8 If possible, the transport bag containing samples shall be kept at a temperature ranging from +4C to +8C at all times during the transportation process. It must not at any time during the transport be subjected to:

- such a low temperature that there is a risk of the sample freezing
- such a high temperature that the integrity of the sample is threatened.

3.9 The transfer of a transport bag during the transportation process shall be confirmed by a receipt record that is signed by a representative of the transport company and given

to the ADO's representative.

3.10 The transport company shall prepare a separate freight document for each transport bag to record the following information sequentially at the corresponding phases of the transportation process:

- the name and address of the transport company
- the transport bag seal number
- sender information
- receiver information
- date and time when the transport bag was picked up for transport and name of the transport company's delivery person
- date and time of delivery of the transport bag and name of receiving person.

3.11 The transport company shall have a system for tracking and establishing the location of each transport bag at any time during the transportation process.

3.12 The transport company shall be ISO certified, or have an established quality policy and documented work routines, in order to ensure that the quality policy is well understood and applied at all levels in the organization, and to enable implementation of corrective and preventive actions.