PUBLICLY AVAILABLE SPECIFICATION

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International protocol for doping control

Protocole international sur le contrôle du dopage

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

ISO/PAS 18873 was prepared by the International Anti-Doping Arrangement (IADA) and was adopted, under a special “fast-track procedure”, by the ISO member bodies.

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.

1.0 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

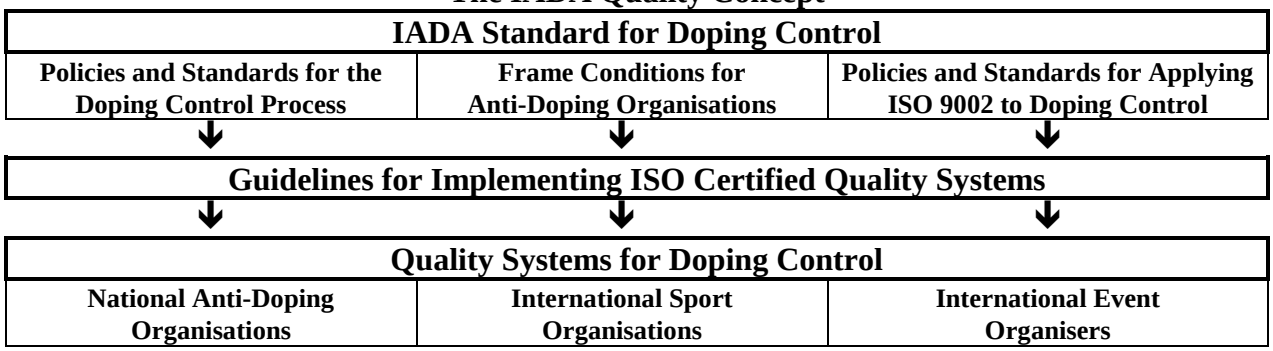
In order to have a certified quality system, the IADA Quality Concept requires quality systems to be in compliance with the standards prescribed in the IADA Standard for Doping Control and the ISO 9002 standard.

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