THE WORLD ANTI-DOPING PROGRAM

GUIDELINES FOR
ANTI-DOPING ORGANIZATIONS
DEVELOPING BEST PRACTICE
DOPING CONTROL PROGRAMS

GUIDELINES FOR BODIES OPERATING CERTIFICATION OF QUALITY SYSTEMS FOR DOPING CONTROL PROGRAMS

Supplement to ISO Guide 62

An
International Anti-Doping Arrangement (IADA) – World Anti-Doping Agency (WADA)
Collaboration

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1.0 Purpose

The administration of anti-doping programs is a specialized field. There typically is only one anti-doping organization within each country. Therefore, attaining adequate experience in auditing quality systems for anti-doping programs is a challenge for any certification agency. These Guidelines have been developed to assist certification agencies and anti-doping organizations in identifying key areas and issues that need to be addressed in certifying quality systems for doping control.

This document is a supplement to ISO/IEC Guide 62:1996 (EN 45012) - General requirements for bodies operating assessment and certification/registration of quality systems. The purpose of these Guidelines is to ensure consistency in the certification of quality systems in anti-doping in order to promote worldwide harmonization of doping control programs and associated activities.

2.0 Introduction

In 1996 the International Anti-Doping Arrangement (IADA) introduced the IADA Quality Concept which included the development of the IADA Standard for Doping Control (ISDC) and its appendices of Common International Quality Documentation. In addition to providing a best practice model for doping control programs, the purpose of the ISDC was to encourage harmonization and best practices in all doping control activities. The ISDC and its appendices were recognized by the International Organization for Standardization (ISO) and published as ISO/PAS 18873:1999. The IADA Quality Concept involved the development, implementation and certification of quality systems for doping control in accordance with the requirements of ISO 9002:1994 and the ISO/PAS. The Quality Concept has now evolved to be consistent with the World Anti-Doping Program which was established in 2003 and the more recently updated ISO 9001:2000.

The World Anti-Doping Program (WADP) is administered by the World Anti-Doping Agency (WADA) and includes the World Anti-Doping Code (WADC) and mandatory International Standards. The WADC and mandatory International Standards are anti-doping industry requirements developed by WADA in consultation with anti-doping organizations. The objective of these requirements is to ensure that anti-doping organizations carrying out anti-doping programs and related activities are adhering to a set of minimum requirements collectively recognized as applicable and appropriate for all sports and countries. Models of best practice and Guidelines have also been developed as part of the WADP

WADP Level 1	The World Anti-Doping Code	(mandatory)
WADP Level 2	International Standards	(mandatory)
WADP Level 3	Models of Best Practice/Guidelines	(optional)

IADA and WADA are recommending that anti-doping organizations develop and certify quality systems for their anti-doping programs that are consistent with the requirements of the WADP and the ISO 9001:2000 Quality management systems standard.

IADA and WADA recognize the importance of consistency and reliability in the certification process as a valuable means of ensuring that quality systems are achieving harmonization worldwide.

WADA will identify on its website or by other means of publication those anti-doping organisations which have achieved ISO 9001:2000 certification issued in accordance with the Guidelines for Bodies Operating Certification of Quality Systems for Doping Control Programs.

3.0 Terms and definitions

3.1 For the purpose of these Guidelines, the terms and definitions given in the following documents shall apply:

- The World Anti-Doping Code, the International Standard for Testing, and the International Standard for Therapeutic Use Exemptions
- ISO 9000:2000 Quality management systems - Fundamentals and vocabulary

4.0 Qualification criteria for the certification agency

4.1 The certification agency's accreditation body shall be a member of the International Accreditation Forum (IAF).

4.2 The certification agency shall be in compliance with ISO/IEC Guide 62:1996 (EN 45012). The minimum relevant qualification criteria shall be as defined in ISO/IEC Guide 62:1996 (EN 45012) section 2.2.3.

4.3 The certification agency shall have obtained accreditation for the branch that covers doping control activities as defined by the agency's accreditation body (e.g., NACE Code K 74.3/EAC Code 34 Technical testing and analysis, limited to doping control in sports and related activities).

5.0 Qualification criteria for the audit team

5.1 The audit team shall possess the qualifications defined in ISO/IEC Guide 62:1996 (EN 45012), section 2.2.3.2 and in addition shall have:

- A minimum of 3 years' experience and relevant knowledge related to sport organizations and sport structures.
- A minimum of 2 years' experience and knowledge of doping control sampling, or equivalent (such as similar experience in other sampling processes).

5.2 The certification agency shall determine when it is appropriate to utilize a full audit team during certification and auditing activities based on the issues identified within the audit program. However, a person(s) possessing the sport and doping control experience and knowledge specified in 5.1 shall, as a minimum, be part of the initial certification audit and the re-certification audit every third year.

6.0 Mandatory and optional requirements for certification

6.1 The criteria for the quality system assessment shall be those outlined in ISO/IEC Guide 62:1996 (EN 45012), section 2.1.1.3.

6.2 Certification agencies shall confirm that an anti-doping organization subject to an accredited certification complies with the requirements applicable to doping control programs and related activities in:

- The World Anti-Doping Code
- The International Standard for Testing
- The International Standard for Therapeutic Use Exemptions
- ISO 9001:2000 Quality management systems - Requirements

6.3 Anti-doping organizations may develop quality systems for doping control aimed at achieving a higher level of best practice by complying with the following recommended guidelines in addition to the requirements specified in 6.2:

- World Anti-Doping Program, Level 3 Models of Best Practice and Guidelines
- ISO 9004:2000 Quality management systems - Guidelines for performance improvements (which is recommended to provide further guidance on developing a quality management system for doping control with particular emphasis on management-led improvement and using a quality system as a management tool)
- ISO 19011:2002 Guidelines for quality and/or environmental systems auditing

Compliance with these additional requirements shall be considered by the certification agency as optional for certification purposes.

7.0 Scope of certification

7.1 Section 6 of these Guidelines outlines the applicable mandatory and optional requirements for the audit assessment of the documented quality system.

7.2 The certification agency shall ensure that an anti-doping organization subcontracting any sample collection process is given full access to the subcontracted doping control activities, including access for auditing purposes.

7.3 The sample collection session processes, as defined in the International Standard for Testing, shall be included in the anti-doping organization's certification scope.

8.0 Document review/desktop audit

8.1 The anti-doping organization's documented quality system for doping control shall be reviewed and assessed against the requirements in section 6 of these Guidelines prior to the certification audit, or when significant changes to anti-doping industry standards occur.

9.0 Certification and re-certification audits

9.1 Certification and re-certification audits of the anti-doping organization's quality system for doping control shall be carried out in accordance with the requirements in section 6 of these Guidelines.

9.2 The certification and re-certification audits shall include interviews with relevant management and personnel involved in managing, planning and conducting doping control activities. The certification and re-certification audits also shall include observing the sample collection session processes in the field.

9.3 The certification and re-certification audits shall include auditing a minimum of one out-of-competition and one in-competition sample collection session. Both the sport and the doping control officer shall differ for each of the audited sample collection sessions. The audit team leader shall select the sample collection sessions to be audited.

10.0 Follow-up/surveillance audits

10.1 Following the initial certification/registration, all relevant requirements under section 6 of these Guidelines shall be assessed during the certification period (normally three years).

10.2 Follow-up audits, as required by the certification agency, shall include interviews with management and relevant personnel involved in managing, planning and conducting doping control activities. The follow-up audits also shall include observing the sample collection session processes in the field.

10.3 Follow-up/surveillance audits, as required by the certification agency, shall include auditing a minimum of one out-of-competition and one in-competition sample collection session at least once per year. Both the sport and the doping control officer shall differ for each of the audited sample collection sessions during the certification

period, providing that this is relevant. The audit team leader shall select the sample collection sessions to be audited. Where the anti-doping organization can demonstrate a regular internal audit program that includes auditing a minimum of two on-site sample collection sessions per year, the follow-up audit requirements may be reduced to auditing one sample collection session per year. This decision will be made by the certification audit team leader.

11.0 Confidentiality

11.1 The audit team shall sign a declaration of confidentiality prior to conducting any audits.

11.2 The audit team shall not retain copies of documentation that contain confidential information as identified by the anti-doping organization.

11.3 Records shall be referenced in the audit report or associated documents without disclosing confidential information.

12.0 Certificate

12.1 The certification agency shall define the scope and activities of the certification on the certificate.

12.2 The certificate shall reference compliance to the mandatory requirements applicable to doping control programs and related activities in the following documents:

- ISO 9001:2000 Quality management systems
- Guidelines for Bodies Operating Certification of Quality Systems for Doping Control Programs
- World Anti-Doping Code
- International Standard for Testing
- International Standard for Therapeutic Use Exemptions

Exclusions of mandatory requirements within any of these documents shall be disclosed on the certificate.

12.3 The certification agency can issue an appendix to the certificate referencing compliance to relevant optional requirements in the Level 3 of the WADP based on the scope of the certification.