COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Recommendation on standard operating procedures at doping control laboratories [procedures for non-analytical phases] (98/1)

The Monitoring Group of the Anti-Doping Convention, under the terms of Article 11.1.d of the Convention,

Whereas under Article 3 of the Anti-Doping Convention the Parties undertake to co-ordinate the policies and actions of their government departments and other public bodies concerned with combating doping in sport;

Whereas in Article 7 of the Convention the Parties undertake to encourage their sports organisations to harmonise their doping control procedures;

Considering that such standards could also provide a firm basis of confidence upon which to build bilateral and multilateral agreements on all aspects of doping control between organisations, bodies and countries party to the Convention;

Considering that this would also encourage other sports organisations and countries to seek common standards;

Convinced of the need to establish standard operating procedures at the laboratory phase;

Considering that such common operating standards would ensure a fair and equitable system for athletes;

Recalling its Recommendation No. 1/95 of the Monitoring Group of the Anti-Doping Convention to Parties;

Recalling its Recommendation No. 1/97 of the Monitoring Group of the Anti-Doping Convention to Parties;

Having studied the International Olympic Committee's Medical Code and relevant disciplinary procedures adopted within the international sports federations;

Having discussed this Recommendation with international and European sports organisations;

Recommends that Parties to the Anti-Doping Convention include, or where appropriate, strongly urge the national sports bodies concerned to include, in their Anti-Doping Regulations or other appropriate texts, *Standard Operating Procedures at doping control laboratories* based on those appended to the present Recommendation.

Appendix

Background

1. At its 2nd meeting (Paris, 17 - 18 October 1994), the Working Party on Legal Issues considered the question of overturning of positive results. Among the problems identified by the Working Party in connection with this issue were:

- difficulties in the relationships between testing authorities and laboratories;

- incompatibility of sanctions between, for example, national and international federations concerned with the same sport;

- latitude in admitting the defence of inadvertent use;

- problems associated with the chain of custody;

- difficulties in interpreting "borderline" testosterone/epitestosterone ratios.

At the end of its debate, the Working Party expressed agreement with the Secretariat's suggestion that a draft Recommendation should be prepared concerning standard operating procedures subsequent to sample collection.

2. The Working Party on Technical Questions debated the issue at its meeting on 17 November 1994, and added a number of further considerations:

- the absence of internationally agreed rules and procedures in a number of important areas;

- uncertainty as to who should initiate disciplinary proceedings against positive-testing athletes: the country of origin, or the country in which the sample had been taken?;

- equal uncertainty about who takes financial responsibility for the growing costs of such proceedings;

- the absence of an international mechanism of co-operation on the management of test results.

The Working Party considered that the proposed draft Recommendation should not simply take up the anti-doping procedures where Recommendation No. 1/95 left off, but should provide for certain matters before the sampling process, such as agreements as to

the sharing out of responsibilities prior to events.

Objective

3. Recommendation No. 1/95 of the Monitoring Group deals with "Standard Urine Sampling Procedures for Doping Control". Its last operative paragraph is entitled: "7. TRANSFER OF SAMPLES TO THE LABORATORY". It is the purpose of this paper to pursue the principles of Recommendation No. 1/95 to the subsequent phases of doping control, from the laboratory to, where relevant, the disciplinary procedures.

4. The purpose of the Monitoring Group in adopting Recommendation No. 1/95 was to provide national anti-doping agencies, national sports bodies and international sports federations with a common set of guidelines on the basis of which they can construct their detailed regulations: the preamble to the Recommendation says that "common operating control procedures would ensure a fair and equitable system for athletes; ... a firm basis [for] agreements for doping control between countries; ... encourage other sports organisations and countries to seek common standards". Based upon the procedures already developed by the International Olympic Committee (IOC), the International Amateur Athletic Federation (IAAF) and several national bodies within the Monitoring Group, the Recommendation provides a basis for the necessary further harmonisation of such procedures. Recommendation No. 1/94 was adopted by IOC Medical Commission (Harmonisation) and distributed to its corresponding partners as a source of inspiration and common guidelines.

5. The objective of this present text is to provide anti-doping organisations with a similar set of standard operating procedures for the subsequent phases of doping control: notably at the laboratory. **It should be stressed that it is not the intention of this text to set down any proposals on the *analytical techniques* used in laboratories for the detection of prohibited substances or methods.** That is a matter for the appropriate specialists. It is also understood that at all stages of operating procedures the analysis will be conducted according to Good Laboratory Practice (GLP). This text confines itself to the procedural aspects while the sample is at the laboratory.

Standard operating procedures at doping control laboratories

[procedures for non analytical phases]

1. Chain of custody from the doping control point to the Laboratory

1.1 There should be a secure and documented chain of custody for the transport of sampling equipment from the despatch of the prepared equipment to the doping control officer and from the doping control officer to the laboratory. If the doping control officer opens the transport container on receipt to check the contents, the sample equipment within must remain sealed. The transport container should be resealed and the code noted. Only authorised personnel may handle specimens to be tested and they shall sign

chain of custody forms to the document when the specimens are in their possession.

1.2 Equipment should be received (by the doping control officer and the athlete) sealed.

1.3 Once the equipment has been used, it should be sealed in a manner distinct from the first sealing system (i.e. by colour/design or other means).

1.4 There should be restricted access to both types of seals. The first seals (from the organisation preparing the kit to the doping control officer) should not be available outside the organisation. A secure method of ordering, delivery and storage of the seals should be implemented, and the organisation should maintain an inventory of issue.

1.5 A copy of the chain of custody form should be sealed inside the kit.

1.6 The chain of custody form should include the following information:

1.6.1 Control code number

1.6.2 Week number/date

1.6.3 Number of samples collected, A and B bottle/container

1.6.4 Competition (event code) or out of competition

1.6.5 Sport/Federation

1.6.6 Outer bag seal number on despatch - sealed by

1.6.7 Outer bag seal number on receipt - received by

1.6.8 Outer bag seal number on return - sealed by

1.6.9 Sampling Kit custody details:

1.6.9.1. seal numbers

1.6.9.2. released by

1.6.9.3. received by

1.6.9.4. purpose

1.6.9.5. date/time

1.6.10 Bottle/container numbers (seal numbers indicate bottle contains urine)

1.7 Despatch form indicating reception by the laboratory.

2. Reception and storage of the sample at the laboratory

2.1 Secure transport and containers

All samples shall be sent to the laboratory by a method of despatch or carrier which is secure and which has been approved by the national [competent] anti-doping organisation.

2.2 Despatch shall take place as soon as reasonably possible after the controls have been completed. An authorised person at the receiving laboratory shall verify the code number, seals, forms, total number of samples and shall sign the chain of custody form and the despatch form indicating receipt.

2.3 The sealed B-sample specimens shall be retained and placed in a properly secure long-term storage (4C° or less) for at least 90 days in the case of a result potentially positive. Within this period a governing body may request the laboratory to retain the specimen for an additional period of time. If no such request is submitted, the specimen may be discarded. However, specific national programmes may have longer storage requirements.

2.4 The B-sample bottles must be kept under locked conditions at all times. Any risk of exposure to sun light or other external factors that could deteriorate the sample must be avoided. Only the head of the laboratory (or a designated delegate) shall have access to the B-specimens.

2.5 The laboratory is responsible for the integrity of samples from the moment when the authorised person has signed the chain of custody and receipt form.

2.6 The laboratory shall use appropriate security measures and facilities to ensure limited and/or controlled access to the samples.

3. Sample Analysis

3.1 The analysis of the A-sample shall be performed as soon as reasonably possible after arrival at the Doping Control Laboratory.

3.2 The samples shall be screened in accordance with the standard analytical techniques and GLP.

3.3 Any declaration of the athlete about any medication or other substance taken in the relevant period prior to the control should be recorded on the Doping Control Form by the athlete or the doping control officer as stated in para. 6.9 of the Recommendation No. 1/95 and transmitted to the laboratory together with samples. If the athlete declines to

make a declaration, this shall be recorded on the Doping Control Form.

3.4 Such information must be treated in the strictest confidence by all who have access to it.

3.5 In addition to the head of laboratory and the laboratory staff, only the head or authorised member of the Anti-Doping Commission/Anti-doping organisation shall be admitted to the laboratory during the A-sample analysis.

3.6. Proper chain of custody controls shall always be enforced during all testing and specimen handling. Only authorised personnel may handle specimens to be tested and they shall sign chain of custody forms to document when specimens are in their possession. Authorised technicians shall sign the chain of custody forms and be responsible for each specimen to be tested.

3.7 If the analysis of the A-sample is positive, the following procedures will be followed.

4. The quorum necessary for the destorage and analysis of the B sample

4.1 The B-sample can be destored and analysed after the responsible officer of the laboratory gives his/her authorisation, in accordance with the timescale agreed with the relevant organisation that authorised the control.

4.2 The destorage and analysis of the B-sample will be performed in the same laboratory having performed the A-sample, in the presence of the representative of the federation, the representative of the sports person with the positive A-sample, the head of the Anti-Doping Commission/Anti-doping organisation and the head of laboratory.

4.3 Before proceeding to the B-sample analysis the witnesses and the head of the laboratory should sign a report that describes the status of the sealing and coding of the B-sample. If the status of the sample is deemed acceptable by the head of the laboratory, the B-sample analysis will proceed.

4.4 A report on the analysis of the B-sample, including a document on the analytical results, will be passed to the responsible authority.

4.5 If the B-sample is positive, the head of laboratory may submit his opinion (in writing and duly signed/sealed) to the Anti-Doping Commission/Anti-doping organisation on whether there may be any mitigating circumstances surrounding the use of a banned substance or method.

5. Description of the form of the report of the analytical phase

5.1 The report shall contain the number of specimens assigned by the submitting authority, the specimen identification number and results of the screening analysis for banned substances and methods. All specimens negative on the initial test or negative on

the confirmatory test shall be reported as negative. Only specimens confirmed positive will be reported positive for a specific banned substance or method. Results may be transmitted by various electronic means (e.g. teleprinters, facsimile or computer). The official report duly signed by the responsible technician and head of laboratory and countersigned by those entitled to be present and with an official stamp shall be sent by mail and sealed. Copies of all analytical results shall be available from the laboratory when requested by an appropriate authority.

5.2 The following reporting format for positive analytical results on sample B shall be used:

5.2.1 Administration

a) Code number

b) Name and date of competition/ out of competition/place of control

c) Name of collecting body

d) Date of receipt of samples at the laboratory

e) Confirmation that the seal of the box was intact

f) Confirmation that the seal of the bottle/container (sampling kit) was intact

5.2.2 Analytical results, for both A-and B-samples

a) pH, density and appearance of the sample, determined in the laboratory

b) Generic name and quantities of the identified substance(s) or methods, the testosterone/epitestosterone ratio, the caffeine concentration according to the thresholds indicated in the current reference list.

The laboratory should also be prepared to supply the following information for the benefit of the athlete involved and the appropriate organisation, delegation or international federation in connection with the identification of the substance(s) or anomalies recorded in 5.2.2 (b) above:

- summary of the analytical procedures performed in the screening and in the identification stages;

- copies of the analytical data relevant to establishing the presence of banned substances or anomalies.

5.3 The report should be sent to:

- The authority that conducted the doping control

- The relevant sports federation or organisation

- The national anti-doping body (if applicable)

6. Procedures guaranteeing the confidentiality of such reports

6.1 The drug-testing laboratory shall perform all work with its own personnel and equipment and within its premises, unless otherwise authorised by the supervising body (National Anti-Doping Commission or other, according to the relevant regulations).

6.2 The report and other relevant data should be protected according to the national or/and international regulations and the general principles of data protection.

6.3 The laboratory should take every step to ensure that only the authorised persons are informed of the result; such authorised persons must not inform unauthorised persons.

7. Minor irregularities

7.1 Minor irregularities, which cannot reasonably be considered to have affected the results of otherwise valid tests, shall have no effect on such results. Minor irregularities do not include the chain of custody of the sample, improper sealing of the container(s) in which the sample is stored, failure to request the signature of the athlete or failure to provide the athlete with an opportunity to be present or be represented at the opening and analysis of the "B" sample.