2027 Code & International Standard Update Process: Third Consultation Phase - International Standard for Laboratories (ISL)

Showing: **All (129 Comments)**

Section 1.0 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

First of all, my sincere thanks for the updated version and for having considered the earlier comments. This is very much appreciated and higly motivating.

General comments:

- Status of the EQAS list is not defined anywhere, it is applied as 2nd level document without formal status nor publication, difficult for implementation (and drifted away from the original context).
- Based on the text (not only in the ISL but in various new TD versions), it is not clear if the status of the DBS will be as a mandatory sample matrix to the laboratories. Please, clarify for efficient planning and transparent discussion.

Reasons for suggested changes

- The laboratory performance is assessed with the EQAS-list and without framework, the process of assigning non-conformities or to evaluate the performance is not fully justified.

Article 1.1.2 (1)

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)

NADO - NADO

General Comments

N/A

Suggested changes to the wording of the Article

Any revision of the TDs, even minor in nature, should be sent for review and approval to the WADA HMRC.

Reasons for suggested changes

Avoids WADA making changes without approval from an expert committee. This also ensures the ability to ask for any clarifications before approval.

Article 1.1.5 (1)

Australian Sports Drug Testing Laboratory SUBMITTED
Vanessa Agon, Laboratory Director (Australia)
Other - WADA-accredited Laboratories

General Comments

If hard copies may be provided during on-site assessments, how does this work for desktop or online assessments?

Section 3.0 (3)

Sport Integrity Australia SUBMITTED
Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

N/A

Suggested changes to the wording of the Article

In respect of the new definition of the term 'Laboratory Chain of Custody (LCOC)', SIA suggests amendments to the definition as follows:

"Information registered by the Laboratory, in accordance with *TD* LCOC requirements, to record, in writing or electronically, the chronological traceability of custody (by authorized Person(s) or upon storage) ~~and actions performed~~ and movement of ~~on~~ the Sample and any Aliquot of the Sample taken for Analytical Testing."

In respect of the definition of the term 'Major Event', SIA considers that the revised definition may be inconsistent with other provisions that imply that a Major Event must be run by an MEO (e.g. ISL Article 6.1.4). Moreover, SIA suggests that WADA consider using a term other than 'Major Event', in that, the term 'Major Event Organization (MEO)' is a defined term within the Code that is also used in the ISL. In SIA's view, this has the capacity to create confusion.

In respect of the definition of the term 'External Quality Assessment Scheme (EQAS)', SIA suggests that WADA provides clarity as to whether the reference to "blood markers" refers to endocrine, haematology, or both.

In respect of the definition of the term 'Independent Witness', SIA suggests a revision the definition as follows:

"A *Person*, invited by the *Testing* Authority (TA), the Laboratory or *WADA* to witness the opening and initial aliquoting of an *Athlete's* "B" sample, or the splitting of an *Athlete's* A or B sample..."

Reasons for suggested changes

'Laboratory Chain of Custody (LCOC)' definition: SIA suggests that a chain of custody does not need to contain actions performed on the sample, except for the creation of a sub-samples/aliquot. SIA's suggested change will cover movement of the sample and the aliquot.

'Major Event' definition: See above.

'EQAS' definition: SIA notes that an ABP blood sample can refer to the haematological and/or endocrine module. The definition of the term 'ABP Laboratory' specifically refers to the Haematological Module.

'Independent Witness' definition: SIA notes that a witness is also required when a sample is split, and so, in SIA's view, the splitting of the A or B sample needs to be included in the definition.

WADA

SUBMITTED

Norbert Baume, ABP Manager (Canda)
WADA - Others

General Comments

3.4 Definition of the Passport Custodian needs to be updated to correspond to the one in IST.

3.5 Consider changing TDEAAS by TDUSP (*Measurement and Reporting of Endogenous Anabolic Androgenic Steroid (EAAS) Markers of the Urinary Steroid Profile*)

Swiss Laboratory for Doping Analyses

SUBMITTED

Tiia Kuuranne, Director (Swizerland)
Other - WADA-accredited Laboratories

General Comments

3.1

Missing terms:

Chain-of-custody

Monitoring program

Further Analysis: Further Analysis occurs when a Laboratory conducts additional analysis on an “A” Sample or a “B” Sample after the final analytical result for that “A” Sample or that “B” Sample has been reported by the Laboratory. Any ~~Sample storage or~~ Further Analysis initiated by an Anti-Doping Organization (ADO) shall be conducted at the expense of the ADO.

Suggested changes to the wording of the Article

TD2021LCOC:

The Laboratory Internal Chain of Custody documentation records the chronological traceability of custody (by authorized Person(s) or upon storage) and the actions performed on the Sample and any Aliquot of the Sample taken for Analytical Testing.

Directly from the WADA webpage:

"The Monitoring Program includes substances that are not on the Prohibited List, but that WADA wishes to monitor in order to detect patterns of misuse in sport. WADA creates the Monitoring Program in consultation with Signatories and governments."

Reasons for suggested changes

- Chain-of-custody should be defined and considered as a mandatory document that the SCA associates to the sample shipment for solid traceability (disappeared after the implementation of paperless systems).

- Monitoring program has an impact on the laboratory processes and reporting, it is defined and controlled by the WADA and involves mandatory elements for laboratories.
- Further analysis: the reference to costs of long-term storage is not correct in here, but is clarified elsewhere (5.3.7.2).

Article 3.2 (1)

Romanian Doping Control Laboratory SUBMITTED

Stan Cristina, Director (Romania)

Other - WADA-accredited Laboratories

General Comments

We would particularly appreciate the recognition of the importance and involvement of Doping Control Laboratories in the fight against doping in sport by including the definition of WADA-accredited Laboratory and their Role and Responsibilities in the Code, given the major importance of Laboratories in proving and deterring doping. Moreover, the scientific foundation of doping control is established, supported and developed by WADA-accredited doping control Laboratories. In the Code, an entire article is dedicated to the activity of Laboratories - article 6 - Analysis of samples.

It would be right that within the definition of the Laboratory its responsibilities should also be included, as established in the definitions for ADO, DTP, NADO, NOC, etc.

The only 30 WADA-accredited Doping Control Laboratories need support and appreciation from WADA and the sports and anti-doping community, given that they are responsible for analyzing all doping control samples collected as part of the anti-doping programs of the over 150 testing authorities worldwide. In practice, the Laboratories ensure the implementation of anti-doping testing programs.

From sample reception, handling, processing, instrumental laboratory analyses to reporting results and compliance with international standards, Laboratories work involves a high level of professionalism and accuracy.

In addition, laboratory personnel must be constantly up-to-date with new, rapidly evolving doping methods and laboratory standards. This constant updating of knowledge requires not only considerable intellectual effort, but also a deep personal involvement in maintaining the highest professional standards. This professional dedication should be appreciated and publicly recognized.

By recognizing their work, not only will the Laboratories' effort and dedication be validated, but the fundamental values of sport will also be supported: fairness, integrity, and respect for human health.

Article 3.5 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

TD APMU missing from the list of relevant TDs

Suggested changes to the wording of the Article

- Please, add the TD APMU

Reasons for suggested changes

- Also those laboratories, which are not providing APMU expertise would benefit from understanding the framework - especially related to requests related to steroid profile confirmation and other further analyses requested upon APMU recommendations.

Section 4.0 (2)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

1. 4.1.4.2.2 Document Compliance with the ISL Code of Ethics

   e) "Upon WADA's request, Laboratories shall provide additional documentation of compliance with the provisions of the ISL Code of Ethics."

   We request that an example of possible "additional documentation of compliance with the provisions of the ISL Code of Ethics" that may be required.

2. 4.2.1.2: Submit Initial Application Form

   - The main change to this Article, in comparison to the first draft, is the increase from 200 to 300 in the number of blood ABP Samples that the National Anti-Doping Organization (NADO) of the Applicant ABP laboratory's host country shall have collected, in compliance with the IST, in the most recent full year

We encourage WADA to increase the minimum number of Samples analysed from 3,000 to e.g. a total of 4,500 for urine, serum Samples and DBS but not to include whole blood Samples in this figure.

We also recommend that these numbers are included in the TD2027IST.

This will help ensure the survival of some of the smaller Laboratories giving them better support from their NADO and experience of a greater number of AAFs. We encourage WADA to consider these smaller Laboratories when reviewing performance, perhaps requiring them to undertake a larger number of internal quality assurance sample analyses.

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

Comment to 4.1.1.2

Many existing laboratories would fail to meet these requirements based on the scope of their national anti-doping programs.

In addition, and probably more relevant for ABP laboratories and Article 4.2, either here or elsewhere, WADA should be responsible for performing a gap analysis on the lack of regional laboratory capacity (based on statistics of testing/ABP testing and information obtained through WADA audits) and proactively search for potential candidates to fill this gap.

This is an obvious problem for the hematological module of the ABP, but it is also relevant for WADA-accredited laboratories due to the introduction of new ABP modules which require collection and transportation of serum samples.

Article 4.1.1 (1)

IDAS Dresden SUBMITTED
Sven Voss, Director (Germany)
Other - WADA-accredited Laboratories

General Comments

Article 4.1.4.2.2:

e) It is recommended to include an example of additional documentation of compliance.

Article 4.1.1.2 (2)

Sport Integrity Australia SUBMITTED
Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

SIA acknowledges and appreciates the exemption added in the comment to Article 4.1.1.2(a), however, we still recommend that the requirement for a specific number of samples collected by a NADO be removed given that Article 4.1.1.3 ensures sufficient samples are collected. SIA notes that in the published 2022 testing figures, there are no countries without a laboratory where that NADO would meet the requirement of collecting 3000 samples. As such, SIA suggests removing the comment to Article 4.1.1.2(a).

Reasons for suggested changes

The comment to Article 4.1.1.2(a) as currently drafted is, in SIA's view, unnecessary, as its subject matter is addressed in Article 4.1.1.3(b). Moreover, SIA's view is that Code Compliance should be a sufficient measure of the NADO's program.

Swiss Laboratory for Doping Analyses SUBMITTED
Tiia Kuuranne, Director (Swizerland)
Other - WADA-accredited Laboratories

General Comments

a) Comment:

Regarding the minimum number of samples, this comment should take into account the consortiums of multiple ADOs/NADOs, who would support and supply the laboratory with samples and stabilise the business plan.

Reasons for suggested changes

- In areas of small ADOs who are willing to collaborate and use the services of the same laboratory, the effort should be acknowledged. For laboratory competence, it does not make a difference if the support is provided by one entity or from a consortium.

Article 4.1.2

Article 4.1.2.5 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

b) A Candidate laboratory shall obtain authorization from WADA to receive sensitive anti-doping information (e.g., methodological or technological information, TNs, or any other non-public information) and/or access to specific, WADA-developed anti-doping tests or materials (e.g., kits, RMs).

Article 4.1.4.2.9 (1)

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

The Testing Authority and other potentially relevant ADOs (e.g. the applicable IF, if a sample is collected by NADO) should also be notified about any new doping substances/methods/practices that are reported by the Laboratories. This is crucial for intelligence purposes and potentially the storage of samples for future analysis.

In addition, 'Sharing of Knowledge Activities' should also include providing training or reports or organizing workshops for interested ADOs on any new developments in anti-doping science. This can only help improve TDP/target testing and – if a new analytical method is expected to be validated in the future – allow for the possibility of collecting samples to be analyzed using the method at later stage (with or without mandatory initial analysis within 20 days of reception as a part of the routine process).

Article 4.1.4.2.10 (2)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

The Laboratory shall report and maintain in ADAMS an up-to-date list of Analytical Testing Procedures and services to assist ADOs in developing TDPs.

Upon request by an ADO, the Laboratory should cooperate by providing other relevant information ~~(e.g., Laboratory analytical capabilities or prices for analytical services) to assist the ADO with their Testing plans.~~

Suggested changes to the wording of the Article

The Laboratory shall report and maintain in ADAMS an up-to-date list of Analytical Testing Procedures and services to assist ADOs in developing TDPs. Upon request by an ADO, the Laboratory should cooperate by providing other relevant information.

Reasons for suggested changes

The second paragraph is redundant.

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

4.1.4.4.2 Document Compliance with the ISL Code of Ethics

"Upon WADA's request, Laboratories shall provide additional documentation of compliance with the provisions of the ISL Code of Ethics."

Suggested changes to the wording of the Article

We request that an example of possible "additional documentation of compliance with the provisions of the ISL Code of Ethics" that may be required

Reasons for suggested changes

To clarify

Article 4.2.1

Article 4.2.1.2 (3)

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

SIA refers to its commentary at Article 4.1.1.2 re: Code Compliance being a sufficient measure of the NADO's program. SIA suggests removing the comment to Article 4.2.1.2(a).

Reasons for suggested changes

See above

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

Also in here, the consortiums of multiple ADOs working together should be considered as sufficient support (e.g. combination of an IF with the NADO).

4.2.2.1

j) A description of how the principles of the ISL Code of Ethics are integrated into the laboratory's Management System as described in Article 4.2.2.2.

Suggested changes to the wording of the Article

4.2.2.1 addition:

and how the process of antidoping samples will be isolated from the clinical samples.

Reasons for suggested changes

Many laboratories aiming at ABP-approved are clinical laboratories and they should be aware of the measures to guarantee the security of antidoping samples at as early stage as possible.

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

We encourage WADA to increase the minimum number of Samples from 3,000 to e.g. 4,500 for urine and serum Samples and not to include DBS or whole blood Samples in this figure.

This will help ensure the survival of some of the smaller Laboratories giving them better support from their NADO and experience of a greater number of AAFs. We assume/encourage WADA to consider these smaller Laboratories when reviewing performance perhaps requiring them to undertake a large number of internal quality assurance sample analyses.

Article 4.2.3.2 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

4.2.3.2 Maintaining ABP Laboratory Status

Indexing of points a) b) c) shall be revised (now d is assigned two times and order is incorrect)

Article 4.3 (2)

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

SIA notes that the definition of the term 'Major Event' is now wider than events that are managed by an MEO. SIA notes that IFs will also host events that are large in scale, such as the World Athletics Championships that are managed by the AIU (and where over 1,000 samples were collected according to AIU).

SIA suggests the inclusion of a requirement to advise WADA of a 'Major Event' in case there is not a broad awareness of all major events.

Moreover, SIA suggests that WADA should consider the effect of multiple events occurring in the one month and resulting in greater than 500 samples being analysed (i.e. is this a 'Major Event'?). If this is the case, the 'Major Event' definition may need to be modified.

SIA suggests laboratories should notify WADA if they are expecting to analyse more tests than what their capacity allows.

Suggested changes to the wording of the Article

SIA proposes that any references to an MEO throughout Article 4.3 should also include other organisation (e.g. IFs).

Article 4.3(a): SIA proposes an addition to this Article as follows:

"A Laboratory shall advise WADA when they become aware that they will providing services for a Major Event"

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)
Other - Other (ex. Media, University, etc.)

General Comments

In the Definitions applicable to the ISL, WADA have introduced a definition of a 'Major Event' which per the wording would be applicable to World Athletics Championships and maybe other World Athletics Series events if the pre-competition testing program is included. Assuming WADA did so knowingly, all provisions and requirements related to Major Events in Article 4.3 ISL apply not only to MEOs but also to the relevant IFs (for example, the need for a written agreement with the Laboratory with respect to analytical testing requirements at least 3 months before the Event in Article 4.3(d)).

Article 4.3.1 (1)

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

SIA suggests that Article 4.3.1.1 Participation in WADA Assessment(s) be moved to Article 4.3 Laboratory Accreditation Requirements for Major Events.

Reasons for suggested changes

In SIA's view, the 15 assessment items from Article 4.3.1.1 are standard requirements for analytical testing services for a 'Major Event' and should apply irrespective of WADA assessment. SIA therefore considers that Article 4.3.1.1 should be moved to Article 4.3.

Article 4.3.1.1 (3)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

4.3.1.1 Participation in *WADA* Assessment(s)

h) "*WADA* will inform the TA/*MEO (*and notify the Laboratory when doing so) of any identified Major Nonconformity (MNC)…"

We recommend that the abbreviation for Major Nonconformity be changed to NC (not MNC) to be consistent with TD2027PERF.

LSI Medience Corporation SUBMITTED

Masato Okano, Director/Dr. (Japan)

Other - WADA-accredited Laboratories

General Comments

C) xiv.

Stress testing shall be required only in cases where fast TAT or the number of samples exceeds the laboratory's routine testing capacity, rather than for all major events.

Suggested changes to the wording of the Article

Stress testing shall only be performed in cases where the laboratory's routine testing capacity is exceeded.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

d) WADA, at its sole discretion and depending on the progress of the Laboratory in preparation for the Major Event, may conduct additional assessments of the Laboratory at the Laboratory's expense, before the scheduled start of Testing for the Major Event.

Suggested changes to the wording of the Article

d) Depending on the progress of the Laboratory in preparation for the Major Event, WADA may conduct additional assessments of the Laboratory, before the scheduled start of Testing for the Major Event.

Reasons for suggested changes

- The number of assessments cannot be completely random/unknown and the laboratory shall have the possibility to anticipate the budget for additional assessments. It could happen that the reason for the supplementary assessment is not the laboratory but simple the changing situation (new methods/technologies or last minute modifications in test distribution plans), which should be not the sole responsibility of the laboratory.

Article 4.3.1.2 (1)

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

SIA suggests that:

Article 4.3.1.2(b) can be removed;

Article 4.3.1.2(a) should be amended to include "...EQAS samples to the Laboratory in preparation for or during a Major *Event*"; and

An option to request EQAS be available to both ADOs and MEOs should be made available within Article 4.3.1.2(b).

Reasons for suggested changes

Article 4.3.1.2(b): SIA considers that it is unnecessarily restrictive to remove WADA's ability to send double blind EQAS during the Major Event. In SIA's view, the capacity to send double blind EQAS during the Major Event should be maintained. SIA also suggests it is an anomaly that MEOs can request EQAS samples be sent but ADOs cannot, hence we have recommended this should be extended to all ADOs.

Section 5.0 (1)

International Cricket Council SUBMITTED

Vanessa Hobkirk, Anti-Doping Manager (United Arab Emirates)

Sport - IF – IOC-Recognized

General Comments

Article 5.3.6.4 (b) - Laboratories must provide an interpretation of results to RMAs when an adverse finding is noted. This should not be optional or 'as deemed necessary' as stated in 5.3.6.4.1 b) iii. The experts of interpretation are likely to reside in the WADA lab and not most RMAs as indicated by 5.3.6.1 d) vii. This is consistent with clinical reporting which may be relevant in such cases.

Article 5.2.2.3 (2)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.2.2.3: Laboratory Responsible(s) for R&D Activities

- The Laboratory shall have a qualified *Person*(s) responsible for R&D activities. The qualifications should include:

  a) A doctoral degree (Ph.D. or equivalent) in one of the natural or life sciences, or a Master degree with a documented ability to oversee research projects and a minimum of ten (10) years' experience in R&D relevant to anti-doping.

  We recommend that the following text is added to the end of this section "e.g. from the fields of forensic toxicology, analytical chemistry or biomedical sciences."

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

Include the R&D responsible person in the general comments before the position descriptions for laboratory personnel.

Specific criteria shall be met by the Laboratory Director, Laboratory Quality Manager, Laboratory Research Manager (or qualified person), and Laboratory Certifying Scientists, as outlined below.

>> or move the requirements for certifying scientists before the person responsible for R&D

>> add "qualified person without research degree but have more than 10 years experience conducting and managing research projects"

Article 5.2.3 (1)

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)
NADO - NADO

General Comments

USADA submits that DBS samples should also be accepted by the laboratory for long-term storage without the need for analysis (and without the need for a concurrent urine sample collection) in cases where the ADO can demonstrate that the DBS sample collection is compatible with a well-designed individualized TDP on specific athletes where the DBS sample could be used in the future for future analysis of substances, help demonstrate in the case of an AAF, the possible window of exposure (e.g. in contamination cases), or other scientifically-valid reasons consistent with published research. Thevis et al. have published a number of papers which clearly demonstrate the benefits of DBS storage without analysis in specific circumstances which could be very useful to athletes and ADOs.

Thevis M, Kuuranne T, Thomas A, Geyer H. Do dried blood spots have the potential to support result management processes in routine sports drug testing?-Part 2: Proactive sampling for follow-up investigations concerning atypical or adverse analytical findings. Drug Test Anal. 2021 Mar;13(3):505-509. doi: 10.1002/dta.3011.

Article 5.2.3.5 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)
Other - WADA-accredited Laboratories

General Comments

~~[Comment to Article 5.2.3.5 c): The data and information management system may also feature process workflow management, Sample and Aliquot LCOC, control of stocks of RMs, etc.]~~

Suggested changes to the wording of the Article

Please, consider removal.

Reasons for suggested changes

Redundant.

Article 5.2.5 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

b) Chemicals, reagents, and kits labelled “Research Only” or “Forensic Use Only”, for example, may be utilized for the purposes of Doping Control provided they are demonstrated to be Fit-for-Purpose by the Laboratory and/or WADA.

What does this mean? How it reads now, the text says that the material is demonstrated to be fit-for-purpose by **both** the laboratory and WADA, or **only by WADA**, but never only by laboratory? Should be reworded.

Suggested changes to the wording of the Article

"... provided they are demonstrated to be Fit-for-Purpose by the Laboratory or authorized to be used by WADA.

Reasons for suggested changes

Laboratory should have the right to demonstrate the applicability, but in certain cases (e.g. CMZ for GH isoforms) the authorization is collectively approved by WADA.

Article 5.2.5.2 (3)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.2.5.2: Reference Collections

- An important modification has been included to this Article, which is that past doping control Samples should not be used as Reference Collections unless there are exceptional circumstances (for example, the worldwide unavailability of Reference Materials) and the Sample is used in accordance with the requirements established in Article 8.2.1. In addition, the identity of the Analyte in the Sample shall have been unequivocally established by comparison to a Reference Material or a well-characterized Reference Collection of known origin.

  We assume that documentation about any RC obtained from “Past Samples” is not required in a Laboratory Documentation Package since it does not appear in the TDLDOC and suggest a specific statement to this effect to avoid possible arguments in a hearing.

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

Concerning the use of "past doping control Samples" that is mentioned here

Suggested changes to the wording of the Article

We assume that documentation about any RC obtained from “Past Samples” is not required in a Laboratory Documentation Package since it does not appear in the TDLDOC and suggest a specific statement to this effect to avoid possible arguments in a hearing

Reasons for suggested changes

To clarify

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

[Comment to Article 5.2.5.2: Under exceptional circumstances (e.g., worldwide unavailability of RM) past Samples may be used as RCs, in accordance with Article 8.2.1, if the identity of the Analyte in the Sample has been unequivocally established by comparison to a RM or a well-characterized RC of known origin.]

Suggested changes to the wording of the Article

[Comment to Article 5.2.5.2: Under exceptional circumstances (e.g., worldwide unavailability of RM) past Samples may be used as RCs, in accordance with Article 8.2.1, if the identity of the Analyte in the Sample has been unequivocally established by comparison to a well-characterized RC of known origin.]

Reasons for suggested changes

It is somewhat contradictory to require identification by comparison to a RM if one justification is its unavailability.

Article 5.2.6 (1)

Romanian Doping Control Laboratory SUBMITTED

Stan Cristina, Director (Romania)

Other - WADA-accredited Laboratories

General Comments

b) i. - In case of subcontracted analysis our laboratory always transfer the entire remaining A sample after ITP, in the A bottle resealed with grey or green cap , thus the subcontrated laboratory has the possibility to repeat the ITP or CP for subcontracted analysis. It is very difficult to secure small quantities of urine.

If the B sample is not splitted (in A and B), it can be transferred with the original seal.

Article 5.3 (3)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.3.1: Reception, Registration and Handling of Samples

- A new requirement has been added for laboratories to identify the Samples with laboratory internal Sample codes, which provide Sample traceability to the collection document or other external chain of custody information.

We recommend that the box in ADAMS for pH be made mandatory for ITP and a mandatory box added for CP to be consistent with ISL or the current box be removed .

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

In SIA's view, clarification is required in Article 5.3.1(d) that this is only intended for samples transferred for LTS purposes and so does not include DBS collected and not immediately analysed.

Suggested changes to the wording of the Article

SIA proposes the below addition to Article 5.3.1(d):

"Each individual Sample (including DBS received for storage) shall be inspected, and identified irregularities recorded (see Article 5.3.2.1)..."

Reasons for suggested changes

SIA suggests our inclusion to ensure clarity that DBS stored for future analysis shall be inspected as different to long-term storage samples which were already inspected by the laboratory who initially analysed the sample. This ensures that DBS samples collected for storage only are inspected for irregularities.

Sport Integrity Commission Te Kahu Raunui SUBMITTED

Jono McGlashan, GM Athlete Services (New Zealand)

NADO - NADO

General Comments

5.3.2.1 Samples with Irregularities

We are concerned that placing the responsibility on the ADO to make this determination could result in potentially suspicious samples being dismissed as damaged and ultimately not analysed.

We have consulted with the Commission's Athletes Commission who are supportive of this submission.

Article 5.3.2 (9)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.3.2: Acceptance of Samples for Analysis

- As an exception, DBS Samples collected with urine Samples during the same Sample Collection Session may be put directly in storage (without an initial analysis), provided that the Testing Authority has requested the laboratory to do so in advance.

- the Athlete's consent for the DBS Sample storage without analysis has been removed from the second draft.

- Furthermore, it has been clarified that when a laboratory combines different Samples, collected from the same Athlete during a single Sample Collection Session, the analytical result obtained for the combined Sample shall be reported independently for each Sample analyzed, while clarifying in the Test Reports that the result was obtained after the analysis of the combined Sample.

To achieve the best use of DBS Samples, it should be permissible to collect them for biobanking without the collection and analysis of a urine Sample. Paragraph 5.3.2 d) implies that a urine Sample must also be collected.

Non-analysed Samples should not count in the statistics for analysed – separate categories for the numbers of DBS Samples both analysed and non-analysed is needed.

Rationale

The collection of DBS and storage without analysis for biobanking reasons is intended to increase the frequency of Sample collections. This enables, in the case of AAFs, conducting further investigations to differentiate between intentional doping and contamination scenarios (one of the main topics at the recent WADA Lausanne symposium). If urine samples, which have to be analysed, have to be collected simultaneously this exceeds the budget of many ADOs.

We also recommend that this be documented in TD2027IST.

Anti-Doping Sweden SUBMITTED

Jenny Schulze, Testing and Science Manager (Sweden)

NADO - NADO

General Comments

ADSE welcomes that as an exception, DBS Samples collected with urine Samples during the same Sample Collection Session may be put directly in storage (without an initial analysis), provided that the Testing Authority has requested the laboratory to do so in advance.

However, to achieve the best use of DBS Samples, it should be permissible to collect them for biobanking without the collection and analysis of a urine Sample. Paragraph 5.3.2 d) implies that a urine Sample must also be collected.

Non-analysed Samples should not count in the statistics for analysed – separate categories for the numbers of DBS Samples both analysed and non-analysed is needed.

Reasons for suggested changes

The collection of DBS and storage without analysis for biobanking reasons is intended to increase the frequency of Sample collections. This enables, in the case of AAFs, conducting further investigations to differentiate between intentional doping and contamination scenarios (one of the main topics at the recent WADA Lausanne symposium). If urine samples, which have to be analysed, have to be collected simultaneously this exceeds the budget of many ADOs.

We also recommend that this be documented in TD2027IST.

Sport Integrity Commission Te Kahu Raunui SUBMITTED

Jono McGlashan, GM Athlete Services (New Zealand)

NADO - NADO

General Comments

5.3.2.2 Sample Splitting Procedure

We query whether there is any potential impact on the steroidal passport data and whether this should be flagged, or a comment made in the ABP system.

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

N/A

Suggested changes to the wording of the Article

Article 5.3.2(d): For clarity, SIA proposes the inclusion of a reference to TD DBS here.

Reasons for suggested changes

Article 5.3.2(d): In SIA's view, the proposed change would reduce duplication and prevent misalignment between the ISL and TD DBS.

Agence française de lutte contre le dopage SUBMITTED

Adeline Molina, General Secretary Deputy (France)

NADO - NADO

General Comments

Un prélèvement DBS, sans prélèvement urinaire associé, doit pouvoir être stocké pour une analyse ultérieure (§5.3.2.d).

Reasons for suggested changes

Un DBS prélevé et stocké permettrait de faire plus de tests et aider à traiter certains cas de AAFs. Par exemple, ces DBS stockés permettraient de différentier le dopage intentionnel du scénario de la contamination.

Ils permettraient également de disposer d'échantillons pour aider au traitement à postériori de certains profils stéroïdiens (esters de stéroïdes).

Enfin, les méthodes d'analyses sur les DBS sont en plein essor et une méthode peut avoir été validée par le laboratoire et par l'AMA mais l'accréditation ISO pas encore obtenue... Il faudrait permettre aux ADOs de disposer de ces méthodes en différé (mettre en attente ces échantillons jusqu'à l'obtention de l'accréditation ISO pour les analyser lorsque les échéances d'accréditation sont proches).

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)
NADO - NADO

General Comments

USADA submits that DBS samples should also be accepted by the laboratory for long-term storage without the need for analysis (and without the need for a concurrent urine sample collection) in cases where the ADO can demonstrate that the DBS sample collection is compatible with a well-designed individualized TDP on specific athletes where the DBS sample could be used in the future for future analysis of substances, help demonstrate in the case of an AAF, the possible window of exposure (e.g. in contamination cases), or other scientifically-valid reasons consistent with published research. Thevis et al. have published a number of papers which clearly demonstrate the benefits of DBS storage without analysis in specific circumstances which could be very useful to athletes and ADOs.

Thevis M, Kuuranne T, Thomas A, Geyer H. Do dried blood spots have the potential to support result management processes in routine sports drug testing?-Part 2: Proactive sampling for follow-up investigations concerning atypical or adverse analytical findings. Drug Test Anal. 2021 Mar;13(3):505-509. doi: 10.1002/dta.3011.

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)
Other - Other (ex. Media, University, etc.)

General Comments

This provision is reasonable for urine samples where issues of sample volume are relatively rare; however, for blood samples, there is a good case for being able to decide on the appropriate analytical menu for a serum sample after the results of the corresponding ABP and urine samples are uploaded to the Athlete's Biological Passport. Further, if it is known that a new analytical method is in the final stages of development, it would be useful to be able to collect and store samples from athletes with a view to analyzing them once the new method is available. There may also be grounds for collecting blood samples from athletes suspected of abusing endogenous compounds (which are not normally detected in the urine e.g., GH, steroid esters), and only have urine samples collected for the purpose of identifying confounding factors/measuring urine steroid profile values, without bearing the cost of the full OOC urine analysis.

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

5.3.2 **Acceptance of *Samples* for Analysis**

To achieve the best use of DBS Samples, it should be permissible to collect them for biobanking without the collection and analysis of a urine Sample. Paragraph 5.3.2 d) implies that a urine Sample must also be collected.

Non analysed Samples should not count in the statistics for analysed – separate categories for the numbers of DBS Samples both analysed and non-analysed is needed.

Reasons for suggested changes

Rationale

The collection of DBS and storage without analysis for biobanking reasons is intended to increase the frequency of Sample collections. This enables, in the case of AAFs, conducting further investigations to differentiate between intentional doping and contamination scenarios (one of the main topics at the recent WADA Lausanne symposium). If urine samples, which have to be analysed, have to be collected simultaneously this exceeds the budget of many ADOs.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

[Comment to Article 5.3.2 d): The stored DBS Sample may not be used for any other purpose than Analytical Testing unless the TA has notified the Laboratory, in writing, that the Sample may be discarded or used for secondary purposes (in accordance with Article 5.3.8).]

Suggested changes to the wording of the Article

Management of DBS samples without initial test requires some clarification.

1) The TA shall inform the laboratory in advance that there is no initial test required.

2) The laboratory shall then report the sample as "Not Analyzed" and keep it stored until six months from reception.

3) If there is no request within six months, TA should then inform the laboratory of long term storage request or of the test menu to apply.

4) If no further instructions are given, the sample shall be free to be discarded or to be anonymized and used for research purposes.

Reasons for suggested changes

It should not be the responsibility of the laboratory to seek instrcutions on the long term storage plan (similarly to any other matrix).

Article 5.3.2.1 (5)

Sport Integrity Commission Te Kahu Raunui SUBMITTED

Toby Cunliffe-Steel, Athlete Commission Chairperson (New Zealand)

NADO - NADO

General Comments

We, the Athlete Commission to New Zealand's NADO, support our NADO's submission on Article 5.3.2.1 Samples with Irregularities

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

Article 5.3.2.1(c)(iii): SIA proposes amendments to this Article as follows:

"In the absence of a timely reply (within seven (7) days) by the TA, the Laboratory ~~shall~~ should report the Sample as "Not Analyzed" in ADAMS. The Laboratory may at its discretion analyse the sample (for example if sample substitution is suspected)."

Reasons for suggested changes

Article 5.3.2.1(c)(iii): SIA suggests including flexibility so that the Lab can perform analysis, for example, where they suspect sample substitution. Without that flexibility the TA could theoretically be complicit in the sample substitution and then fail to respond so that the sample is not analysed.

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)

NADO - NADO

General Comments

Why would damage to transport packaging be considered an irregularity when the actual samples inside are intact and not affected? This potentially opens challenges to the chain of custody which are unnecessary. If the samples are determined to be intact and not damaged or compromised, the status of the transportation package is irrelevant. In our experience, the packaging is

frequently damaged during transport, but the samples remain undamaged. Damage can also be subjective in nature. We recommend removing “Damaged transportation packaging”.

National Anti-Doping Laboratory, Beijing Sport University SUBMITTED

Lisi (Leo) Zhang, Lab Manager (China)

Other - WADA-accredited Laboratories

General Comments

N/A

Suggested changes to the wording of the Article

5.3.2.1 *Samples* with Irregularities

c) Analysis of Samples with Irregularities

ii. Considering the time constraints of blood ABP analyses, it is

recommended that the Laboratory analyzes blood ABP Samples with irregularities ***which does not cause damage to analytical equipment (e.g. obvious clots which may cause clogging of the instrument's capillary components)****, while reporting the noted irregularity(-ies) in the Test Report in ADAMS.*

Reasons for suggested changes

Recommend to add this specific situation of whole blood sample into the above paragraph as example. This does not only affect the sample with irregularity, but could potentially affect/delay the analysis of other samples if the instrument is damaged.

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

- How is the turnaround time captured fairly in ADAMS for labs when they are waiting for response from the TA.
- If no response if received within 7 days, then lab shall report as No analysed BUT if TA/WADA request after it is reported as Not Analysed it is considered a Further analysis. This will be a lot of additional admin work for the lab. What is the ADAMS process for all parties involved in this scenario? How do you report ITP as further analysis is ADAMS?

From the section - *Sample Identification numbers are different between the "A" and the "B" sample containers of the same sample (unless the difference is traceable to the DCF"*

- *With the above irregularity, how will this be reported in ADAMS and how does sample splitting work in this scenario – this becomes very confusing.*

Article 5.3.2.2 (4)

Sport Integrity Commission Te Kahu Raunui SUBMITTED

Toby Cunliffe-Steel, Athlete Commission Chairperson (New Zealand)

NADO - NADO

General Comments

We, the Athlete Commission to New Zealand's NADO, support our NADO's submission on Article 5.3.2.2: Sample Splitting Procedure

LSI Medience Corporation SUBMITTED

Masato Okano, Director/Dr. (Japan)

Other - WADA-accredited Laboratories

General Comments

Comment to Article 5.3.2.2 a) ii)

When the A" or "B" Sample container has not been properly sealed or has been broken, the Laboratory may decide, in consultation with the TA, to perform the ITPs on the affected Sample ("A" or "B", as applicable).

If the result of the analysis is Negative, please specify how the laboratory will report the result.

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

For clarity, change comment (ii) or remove the ambiguity of decisions to perform ITP for samples not sealed correctly to "the Laboratory shall notify and seek authorization from the TA". This will be addressed as an irregularity in ADAMS in the event a doc pack is required at a later stage (AAF sample)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

5.3.2.2. a) iv. The Sample is heavily contaminated.

****

[Comment to Article 5.3.2.2 a) ii.: When the A" or "B" Sample container has not been properly sealed or has been broken, the Laboratory may decide, in consultation with the TA, to perform the ITPs on the affected Sample ("A" or "B", as applicable) and, if the analysis produces a PAAF, proceed to the splitting (in

accordance with the provisions of this Article 5.3.2.2) of the complementary, sealed Sample for the conduct of Analytical Testing, including the repeat of the ITP analyses and the performance of any relevant CP.]

Suggested changes to the wording of the Article

a) iv. By visual inspection, a significant difference is observed between the "A" and "B" Samples and suspected to be due to heavy contamination.

******

[Comment to Article 5.3.2.2 a) ii.: When the integrity of the "A" or “B” Sample container is compromised (e.g. not properly sealed, damaged sealing) the Laboratory may proceed, upon written approval of the TA, to perform the ITPs on the affected Sample. If the analysis produces a PAAF, the Analytical Testing shall be completed by splitting of the adequately sealed Sample, repeating the ITP analyses and performing any relevant CP.]

Reasons for suggested changes

Not typically seen before the analysis and it could be assumed that the urine of same fraction is contaminated in both containers.

*****

To facilitate reading.

Article 5.3.3 (1)

WADA SUBMITTED
Norbert Baume, ABP Manager (Canda)
WADA - Others

General Comments

5.3.3.3 Comment 11 shall be updated to reflect definition of “capillary blood” in IST

Article 5.3.3.2 (3)

USADA SUBMITTED
Allison Wagner, Director of Athlete and International Relations (USA)
NADO - NADO

General Comments

May consider removing the need for single-use disposable tips. COVID demonstrated that supplied can be in short supply and many laboratories devised ways to wash tips to re-use. This can be done safely with specialized equipment and protocols and can save a lot of money.

Suggested changes to the wording of the Article

Footnote 10 to 5.3.2.b)ii “Whole blood is collected in tubes containing an anti-coagulant (e.g., EDTA). Analysis in whole blood means that the collected venous blood is used for analysis as such, without its separation (by centrifugation or other means) into the blood cellular and liquid fractions>” - recommend changing venous to liquid blood.

Reasons for suggested changes

To allow for microcapillary whole blood collections in the future if validated.

WADA SUBMITTED

Norbert Baume, ABP Manager (Canda)

WADA - Others

General Comments

Comment 8: replace “the Steroids (blood) Module” by “the blood Markers of the Steroidal Module” of the ABP

Comment 10: shall be adapted as whole blood now is defined as blood or blood ABP samples in IST…

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

There needs to be a clear procedure established regarding the centrifugation of whole blood samples to give ADOs an opportunity to request additional HBT analyses on the whole blood and/or ESA analysis on a separated plasma based on the uploaded hematological ABP values within, e.g. 2 working days of reporting. There currently seems to be no standardization between laboratories on the matter.

Article 5.3.4 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

The number of subtitles is very high and the document becomes considerably difficult to read. I know that this stage is rather late for a proposal, but I would like to see consideration given to the next chapter layout (without a need to touch the order or content of the chapters):

Suggested changes to the wording of the Article

5.3.4 Analysis of the samples

5.3.4.1 Selection and validation of analytical testing procedures

(chapter to combine current chapters 5.3.4.1 and 5.3.4.2)

5.3.4.2 Initial testing procedures

(current chapter 5.3.4.2.1)

5.3.4.3 Confirmation procedures

(chapter to combine current chapters 5.3.4.2.2 and 5.3.4.2.3)

5.3.4.3.1 Confirmation procedure of "A" Sample (5.3.4.2.4)

5.3.4.3.2 Confirmation procedure of "B" Sample (5.3.4.2.5)

5.3.4.4 Further analyses

5.3.4.5 Alternative biological matrices

Reasons for suggested changes

This would allow for getting rid of one layer of hierarchy, making the text visually easier to read.

Article 5.3.4.2 (6)

Agence française de lutte contre le dopage SUBMITTED

Adeline Molina, General Secretary Deputy (France)
NADO - NADO

General Comments

Il faudrait autoriser les laboratoires à procéder à des analyses hors du champ WADA, et à les reporter, pour information des OADs, dans ADAMS.

Reasons for suggested changes

Le laboratoire devrait pouvoir mettre le résultat en commentaire du résultat ADAMS et transmettre le rapport d'analyse du laboratoire qui a réalisé cette analyse s'il y a eu sous-traitance.

Ex: Ferritine, marqueurs indirects (phtalates)...

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

SIA acknowledges and appreciates the Drafting Team's efforts to remove most of the references to LGs (consistent with feedback previously provided by SIA), however, one reference remains at Article 5.3.4.2(d).

Suggested changes to the wording of the Article

SIA suggests the removal of the reference.

Reasons for suggested changes

See above

WADA SUBMITTED

Norbert Baume, ABP Manager (Canda)

WADA - Others

General Comments

5.3.4.2.1 b) Results from ITPs that are Quantitative Procedures can be included as part of ~~longitudinal studies~~ Athlete's Passport (e.g., Markers of the Steroidal, Endocrine or Hematological Module of the ABP ~~endogenous steroid, endocrine or hematological profiles~~), provided that the method is Fit-for-Purpose.

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

5.3.4.2.5

There should be provision for repeating the 'B' sample Confirmation Procedure in case of a negative Confirmation Procedure result to ensure that it is not a false negative, or at the very least in cases where internal investigation under paragraph iii identifies a departure from proper execution of an analytical method or an issue with any of the reagents/instruments used in the process.

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

Under C sample analysis

> Bottom paragraph "Results from these analyses shall not be reported in ADAMS…" For the ADOs and federations there is a need to conduct analyses outside the WADA analyses. An example is ferritin but there are others. The request from the client is often to put these results in the comment field of the sample for information and upload the certificate from e.g. a hospital doing that type of analyses. This paragraph prevents the labs to do something that the clients want and needs.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

d)

[Comment to Article 5.3.4.2 d): Mandatory Analytical Testing Procedures are those Analytical Methods for which the Laboratory shall have available analytical capacity, in compliance with relevant TDs or TLs, and therefore should have the Analytical Method included in their Scope of ISO/IEC 17025 Accreditation. However, based on an IC or OOC Analytical Testing menu, a mandatory Analytical Testing Procedure is not necessarily applied to all Samples. For some Prohibited Substances or Prohibited Methods, the TA may decide to request their analysis in specific Samples only. These requests shall be detailed in the Sample chain of custody. WADA will maintain the list of mandatory Analytical Testing Procedures in the TD ATP).]

Suggested changes to the wording of the Article

[Comment to Article 5.3.4.2 d): Mandatory Analytical Testing Procedures are those Analytical Methods for which the Laboratory shall have available analytical capacity, in compliance with relevant TDs or TLs, and therefore should have the Analytical Method included in their Scope of ISO/IEC 17025 Accreditation. However, based on an IC or OOC Analytical Testing menu, a mandatory Analytical Testing Procedure is not necessarily applied to all Samples. For some Prohibited Substances or Prohibited Methods, the TA may decide to request their analysis in specific Samples only. These requests shall be detailed in the Sample documentation provided to the Laboratory. WADA will maintain the list of mandatory Analytical Testing Procedures in the TD ATP).]

Reasons for suggested changes

Chain-of-custody documentation is not provided by all Sample Collection Authorities.

Article 5.3.4.2.2 (1)

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)
NADO - NADO

General Comments

Good change and strongly support this.

Article 5.3.4.2.4 (6)

UK Anti-Doping SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)
NADO - NADO

General Comments

Article 5.3.4.2.4 (e) ii - It is proposed that under certain circumstances a Laboratory “may report the presence of a Non-Threshold Substance with MRL in a Sample at an estimated concentration below the MRL as an AAF”. And, in addition, there are other reasons for the reporting, such as consistency with the Athlete’s Doping Control Form declaration of medications, or following justification provided by the Testing Authority, Results Management Authority or WADA.

UKAD has significant concerns related to this new section, and suggests that it is reviewed again and, potentially removed. UKAD’s primary concern is in respect of harmonisation and consistency of application across Laboratories (given the requirement is a “may” rather than a “shall”).

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

Article 5.3.4.2.4: SIA notes that prior Articles of the ISL have changed "TA (or RMA...)" to "relevant ADO". For consistency, SIA suggests continuing with this terminology.

Article 5.3.4.2.4(e)(i): SIA suggests that ATF should be retained in this clause for non-threshold without an MRL.

Article 5.3.4.2.4(e)(ii): SIA suggests including ATF for instances where a TD defines an ATF including diuretics.

Suggested changes to the wording of the Article

See above

Reasons for suggested changes

Article 5.3.4.2.4: For clarity and consistency.

Article 5.3.4.2.4(e)(i): To future proof ISL where other examples may be set in TDs.

Article 5.3.4.2.4(e)(ii): As above.

WADA SUBMITTED

Norbert Baume, ABP Manager (Canda)
WADA - Others

General Comments

N/A

Suggested changes to the wording of the Article

5.3.4.2.4 f) iii) Replace "*For endogenous Threshold Substances, Markers of the "steroid profile"*,…"by *For endogenous Threshold Substances, Markers of the ABP*,…"

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)
Other - WADA-accredited Laboratories

General Comments

The way it is written on the ISL, the reporting of NTS with MRL (below MRL) that is prohibited at all times does not agree with how it is captured in the summary of modifications. If this only applies to ADO request as part of results management, this needs to be clear on the ISL and not separated as two bullet points.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

c) Existence of approved TUE

i.

− hCG (for male Athletes).

Comment: regarding the flexibility to request for the presence of a valid TUE in any case where the athlete declared the use in the DCF, there are still many handwritten DCFs, often in characters/languages unknown to the laboratory.

Suggested changes to the wording of the Article

c) Existence of approved TUE

i.

− hCG.

Reasons for suggested changes

hCG shall not be measured in female samples

Romanian Doping Control Laboratory SUBMITTED

Stan Cristina, Director (Romania)

Other - WADA-accredited Laboratories

General Comments

d) i.

By including the reason that lead to a repeat CP in the LDOC could be used against the laboratory by the athlete's lawyer.

Since the first result is nullified, in defense of the case, maybe would be appropriate for the LDOC to contain only the documentation supporting the AAF result.

The same comment for i) i.

Article 5.3.4.2.5 (5)

UK Anti-Doping SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)

NADO - NADO

General Comments

Article 5.3.4.2.5 b)ii. - We ask WADA to review the timescales applied across various provisions for (i) the notification of the Adverse Analytical Finding to the Athlete, (ii) the provision of the Laboratory Documentation Package, and (iii) the requirement to notify the Laboratory as to whether the “B” Sample analysis will be required. These provisions do not appear to be well-aligned or workable in practice.

The provision of the Laboratory Documentation Pack is included within our notification in accordance with ISRM Article 5.1.2. We therefore envisage an ongoing inherent tension in Laboratories being permitted 15 days to provide the Documentation Pack and Anti-Doping Organisations being required to inform Laboratories within 15 days following the reporting of the “A” Sample as to whether “B” Sample analysis is required. We also do not understand how these provisions sit alongside ISRM Article 5.1.2.2 and the need to provide notification to an Athlete within 20 days of receipt of the Finding.

Article 5.3.4.2.5 e) and f) - We welcome the additional clarifications provided with regards to the attendance of Non-Laboratory Persons, particularly at e)i. with regards to representatives. However, we think it would also be helpful to clarify when the request and approval for observing other steps of the “B” CP need to be sought from, and approved by the Laboratory Director. We also think it would be helpful if this provision clearly set out what an Athlete’s “B” CP rights consist of, e.g. the right to attend the “B” Sample opening, aliquoting and resealing procedures only, subject to any further approval provided at the sole discretion of the Laboratory Director (or designated Person).

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

Article 5.3.4.2.5(j): SIA suggests that this Article should outline the steps that shall be taken where the B sample does not confirm the A sample, including where the B sample identifies an ATF.

Suggested changes to the wording of the Article

See above

Reasons for suggested changes

See above

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)
NADO - NADO

General Comments

(c) Timing of “B” CP

USADA recommends that B-sample analysis is performed as soon as possible once the athlete has been notified of an AAF to avoid the possibility of the athlete intentionally delaying the analysis and the possibility of sample degradation. ADOs should reserve the right to schedule the B-sample

confirmation and proceed with a lab appointed witness if it is determined that the athlete witness availability is not compatible with proceeding with the B-sample confirmation in a timely manner.

(e) Independent Witness

USADA is aware of a specific case where the athlete's scientific expert raised issues with the access they received during the B-sample analysis process which the panel then called into question the validity of the lab analysis. The main concern of the panel included that the athlete representative was not allowed to attend the chromatographic data review stage of the B-sample analysis of the B sample. It appears that the proposed change states that *"The observation by the Athlete and/or their representative of the "B" CP shall not involve the interpretation of the Analytical Data, which is a sole responsibility of the Laboratory."* As long as the athlete and/or the independent witness is provided with the details of the analysis that allows them to come to the same analytical conclusions as the laboratory for the interpretation of the data and the AAF, then this change is supported by USADA. USADA supports scientific transparency of both the analytical processes and the interpretation of data and results reporting to be fair to the athlete. Any interference by the independent witness is obviously not acceptable and USADA supports any analytical or data interpretation concerns raised to be addressed in writing as part of the discovery/case management process and the lab director/staff providing answers as required.

WADA SUBMITTED

Norbert Baume, ABP Manager (Canda)

WADA - Others

General Comments

N/A

Suggested changes to the wording of the Article

5.3.4.2.5 l) ii) Replace "*For endogenous Threshold Substances, Markers of the "steroid profile"*,…"by *For endogenous Threshold Substances, Markers of the ABP*,…"

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

b) ii.

The responsible ADO should inform the Laboratory, in writing, within fifteen (15) days following the reporting of an "A" Sample AAF by the Laboratory, whether the "B" CP shall be conducted (based on the Athlete's request or when the Athlete does not request the "B" Sample analysis or expressly or implicitly waives their right to the analysis of the "B" Sample, but the ADO decides that the "B" CP shall still be performed).

Comment: What if there is no feedback from the ADO?

******

[Comment to Article 5.3.4.2.5 g): In cases when the "B" Sample cannot be used for Analytical Testing, the unopened, sealed "A" Sample may be split (see Article 5.3.2.2). The "B" CPs, if needed, may be performed on an Aliquot taken from the split, resealed "A" Sample fraction that had been designated as the "B" Sample.]

--> The actions have been taken already earlier when selecting the container to analyse. Therefore, these explanations are redudant duplication in the chapter "B" Confirmation Procedure. The text in chapter g) is sufficient and clear (The B sample analysis will be performed on the sample that has been defined as B or B2 upon sample reception).

****

j) iii.

A failure of a “B” CP to confirm the “A” Sample AAF does not necessarily mean that the “A” Sample result is incorrect. This discrepancy between the “A” and “B” Sample results may occur, for example, in cases of substance degradation during “B” Sample storage.]

Suggested changes to the wording of the Article

b) ii.

The responsible ADO should inform the Laboratory, in writing, within fifteen (15) days following the reporting of an “A” Sample AAF by the Laboratory, whether the “B” CP shall be conducted (based on the Athlete’s request or when the Athlete does not request the “B” Sample analysis or expressly or implicitly waives their right to the analysis of the “B” Sample, but the ADO decides that the “B” CP shall still be performed). If the information is not received from the ADO, the Laboratory may dispose the samples according to 5.3.7.1 Table 1.

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~~[Comment to Article 5.3.4.2.5 g): In cases when the “B” Sample cannot be used for Analytical Testing, the unopened, sealed “A” Sample may be split (see Article 5.3.2.2). The “B” CPs, if needed, may be performed on an Aliquot taken from the split, resealed “A” Sample fraction that had been designated as the “B” Sample.]~~

******

j) iii.

~~A failure of a “B” CP to confirm the “A” Sample AAF does not necessarily mean that the “A” Sample result is incorrect. This discrepancy between the “A” and “B” Sample results may occur, for example, in cases of substance degradation during “B” Sample storage.]~~

Reasons for suggested changes

In > 90 % of our AAF cases, we do not hear anything back from the ADOs after reporting.

*****

Removal of Comment to Article 5.3.4.2.5 g)

The actions have been taken already earlier when selecting the container to analyse. Therefore, these explanations are redudant duplication in the chapter "B" Confirmation Procedure. The text in chapter g) is sufficient and clear (The B sample analysis will be performed on the sample that has been defined as B or B2 upon sample reception).

*****

Removal of the latter part of Comment to Article 5.3.4.2.5 j)

I'm in the opinion that a defensive explanation is not too convincing to include in the ISL. The document is aimed at laboratory work and by the description of the chapter iii., laboratory will proceed to the internal investigation, root cause analysis and the associated report. No need to provide an explanation in the ISL.

Article 5.3.4.4 (6)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.3.4.4: Alternative Biological Matrices

A new provision has been added in this Article clarifying that if an analysis is to be conducted on a hair Sample as part of a Results Management process, such an analysis shall be conducted in a WADA-accredited laboratory at the expense of the requestor and after approval by the responsible Results Management Authority or WADA.

b) To avoid unnecessary legal challenges, we recommend removing the requirement for WADA accredited Laboratories and suggest "approved laboratories" similar to those approved for ABP analysis or genetic testing.

WADA can then approve additional non-WADA laboratories with expertise in this field if the laboratory meets the standards required by WADA

Anti-Doping Sweden SUBMITTED

Jenny Schulze, Testing and Science Manager (Sweden)

NADO - NADO

General Comments

A new provision has been added in this Article clarifying that if an analysis is to be conducted on a hair Sample as part of a Results Management process, such an analysis shall be conducted in a WADA-accredited laboratory at the expense of the requestor and after approval by the responsible Results Management Authority or WADA.

Suggested changes to the wording of the Article

To avoid unnecessary legal challenges, we recommend removing the requirement for WADA accredited Laboratories and suggest "approved laboratories" similar to those approved for ABP analysis or genetic testing.

Reasons for suggested changes

WADA can then approve additional non-WADA laboratories with expertise in this field if the laboratory meets the standards required by WADA.

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

Article 5.3.4.4(b) SIA suggests amendments to the Article as follows:

"If an analysis is to be conducted on a hair Sample or other biological matrices as part of a Results Management process, such an analysis shall be conducted in a Laboratory at the expense of the requestor and after approval by the responsible RMA or WADA. Approval from WADA or TA is not required if analysis is conducted not at a WADA Accredited Laboratory."

Reasons for suggested changes

In SIA's view, the amendment proposed above will provide greater clarity that this Article only applies to WADA-accredited laboratories. Moreover, in SIA's view, the suggested addition of "or other biological matrices" future proofs the ISL.

UK Anti-Doping

SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)
NADO - NADO

General Comments

Article 5.3.4.4 - Given the capitalisation of "Laboratory" within this Article, we would welcome confirmation (not necessarily within the ISL itself, but elsewhere as considered appropriate) as to which WADA-accredited Laboratories are capable of conducting analysis on a hair sample. We also seek clarity here as to whether the capitalisation of "Sample" in this Article is intended and correct.

USADA

SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)
NADO - NADO

General Comments

USADA's respectfully disagrees with this newly added requirement. Based on our current understanding, very few WADA-accredited labs can do hair analysis so it would be incredibly limiting to require athletes to exclusively use WADA-accredited labs. In addition, it seems unfair to limit the accused athlete in their choice of offering potentially exculpatory evidence for their defense. Similarly, the bureaucracy and expense created around only allowing a few labs to make the determination whether they will do hair analysis and giving WADA approval rights seems overburdensome, unnecessary and not in the pursuit of justice. One way to incentivize, as opposed to requiring the use of WADA-accredited labs for hair analysis, would be to afford all the normal presumptions that a WADA-accredited lab receives under the ISL to the hair analysis if a WADA-accredited lab is used to perform the analysis, and make it clear that all the presumptions otherwise applicable to a WADA-accredited labs hair analysis is also required by an outside lab's analysis. As much as it may be frustrating to receive hair sample evidence from athletes as part of cases, it may be overly restrictive and open a legal challenge to prevent athletes from presenting any evidence to defend themselves

outside of a WADA-accredited laboratory. It is also up to ADOs to refute that evidence sufficiently in a hearing by challenging the validity of the hair evidence. However, it should be noted that an ADO should always have the right to confirm any athlete evidence through its own independent analysis at a WADA-accredited laboratory.

IDAS Dresden SUBMITTED

Sven Voss, Director (Germany)

Other - WADA-accredited Laboratories

General Comments

b) It is recommended to include the possibility of utilizing WADA approved laboratories instead of limiting the analysis to WADA accredited laboratories only.

Reason: WADA can approve non WADA accredited laboratories to utilize hair analysis labs specialized on the analysis on certain substances if they fulfill WADA requirements.

Article 5.3.4.3 (1)

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

- Reading section e) i) and ii) in the 2027 ISL draft and aligning with the above it says to treat sample as a further analysis (after changing from Not analysed) but section e) i) is saying if ITP only is conducted and a PAAF is detected then we confirm using the B split? Why can't we proceed to CP with the A sample as per normal workflow?
- The term "further analysis" is confusing when no analysis has been conducted in the first place.

Article 5.3.6 (5)

World Rugby SUBMITTED

Ross Blake, Anti-Doping Education Manager (Ireland)

Sport - IF – Summer Olympic

General Comments

Article 5.3.6.4 (c) i: Assuming the two-tier event prioritisation proposed in the current IST draft remains (which we do not believe it should), we consider that improvements are necessary to ADAMS to better accommodate ADO to laboratory expedited analysis requests for Olympic and Paralympic level athletes. A simple change in ADAMS making it possible to state that a sample is related to an Olympic or Paralympic level athlete as part of the Testing Order would avoid unnecessary mistakes at a critical time. This would also allow laboratories to prioritise samples seamlessly with less administrative burden.

Furthermore, if a standard can be set for the Olympics and Paralympics for results to be reported seventy-two (72) hours prior to the Athlete's first competition, we would question why this can not be standardised, and

mandated or achievable for other competitions? A defined maximum time for any fast turnaround stated clearly in the ISL would ensure that IFs are not 'let down' by circumstances where planning for their own World Championships may be derailed by delayed analysis, without consequence for the laboratory. Fixed timescales will greatly facilitate planning on both sides. It must be appreciated that these are not the only two events in the international sporting calendar where the impact of late results reporting will potentially have a significant impact.

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

5.3.6.1 Review of Results,

d) vi. We consider that to require "Compliance of test data with the Analytical Testing Procedure's validation results (e.g. MU)" is too specific and suggest rewording "Compliance of test data with the relevant section(s) of the Analytical Testing Procedure's validation results (e.g. MU)"

UK Anti-Doping SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)

NADO - NADO

General Comments

Article 5.3.6.4 (c) i - UKAD welcomes the inclusion of a non-exhaustive list of valid reasons for "A" Sample analysis to exceed 20 days from receipt.

UKAD considers that it would be beneficial to include the scenario where analysis has to be subcontracted as the required method (e.g. IRMS targeting 19-NA) is not on-scope at the first Laboratory. Also, analysis may be delayed if either the "A" or "B" has been damaged and the TA must offer the Athlete the opportunity to witness the opening and splitting of the intact bottle (ref 5.3.2.2).

UKAD considers that the inclusion of these scenarios would reflect the practical reality for some Samples.

Article 5.3.6.4 (c) iv - UKAD notes that the timeframe for providing a Laboratory Documentation Pack remains unchanged at 15 days from receipt of the request from the RMA or WADA.

UKAD suggests that this timeframe is reduced, for example to 5 days. In UKAD's experience, the current timeframe of 15 days can delay the early stages of the Results Management process – with consequential impact on associated processes, e.g. "B" Sample analysis.

WADA SUBMITTED

Norbert Baume, ABP Manager (Canda)

WADA - Others

General Comments

N/A

Suggested changes to the wording of the Article

5.3.6.4 b) ii) Replace "*If the Laboratory receives a request to conduct additional analyses (e.g., CPs for an atypical or suspicious steroid profile, ERA analysis for a suspicious haematological profile),…"* by "*If the Laboratory receives a request to conduct additional analyses (e.g., confirmation/confirmatory analysis requests for an atypical or suspicious Markers of the ABP, ERA analysis for a suspicious hematological profile),…"*

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

i. Non-Threshold Substances not subject to an MRL

Considering that estimated concentrations for non-threshold substances will most likely be requested in the results management process by either ADO or the Athlete, it seems easier to include them in the original Test Report with appropriate commentary.

ii. Non-Threshold Substances subject to an MRL

The presence of non-threshold substances in estimated concentrations below the MRL should be systematically reported to the Testing Authority to improve their risk assessment/TDP/target testing schemes.

Article 5.3.6.1 (1)

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

under

d) Laboratory Review of AAFs and ATFs

vi. Compliance of test data with the Analytical Testing Procedure's

validation results (e.g., MU).

Suggested changes to the wording of the Article

Remove line vi

Reasons for suggested changes

This criteria is very hard to deal with, as it is written the labs are obliged to review the validation report every time we report a finding. I think this is a criteria very few can do in an effecient way. To be frank, I think very few do it at all. When you have reported a few methylphenidates, you don't wanna go and look.

Moreover, we do have SOPs for this purpose, that states which transitions to use etc. More important to look there. The MU that is specifically mentioned is a living thing that is updated from time to time and I belive that not all have tis information in the validation report. We do have a separte system

Article 5.3.6.4.1 (5)

Council of Europe (CoE)

SUBMITTED

Council of Europe, Sport Convention Division (France)
Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.3.6.4.1: Test Report for Non-Threshold Substances

c) We recommend the addition of wording to require that the estimated concentration is only reported on the A-sample confirmation and should not be included in the LDP.

The estimation is a very approximate estimate based on a non-quantitative method. Such an uncertain value should not be included in an LDP, which contains only precise values.

If an estimate of concentration is also made on the B-sample this is likely to lead to different values between A- and B-sample (because no quantitative methods are used) and can be attacked by the defence weakening a case..

We also recommend that the estimate of concentration is provided after the Athlete has provided an explanation for the AAF to avoid the Athlete using the documented concentration to invent an explanation.

Sport Integrity Australia

SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

SIA acknowledges and appreciates the Drafting Team's efforts to remove most of the references to LGs (consistent with feedback previously provided by SIA), however, one reference remains at Article 5.3.6.4.1.

Suggested changes to the wording of the Article

SIA suggests the removal of the reference to LGs.

SIA also suggests that the comment to Article 5.3.6.4.1(b) should be included within Article 5.3.6.4.1 (rather than as a comment) and the comment to Article 5.3.6.4.1(b) should be moved to Article 5.4.5(c).

Reasons for suggested changes

The comment to Article 5.3.6.4.1(b) will have increasing significance with the increasing occurrence and scrutiny of potential contamination cases and thus this comment should be elevated to be an Article within Article 5.3.6.4.1 (rather than as a comment).

UK Anti-Doping

SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)
NADO - NADO

General Comments

Currently, for AAFs where a NADO is the Testing Authority, the relevant IF (and WADA) is automatically notified of the AAF through ADAMS. However, there is no reciprocal arrangement whereby the relevant NADO is notified of AAFs arising from Samples collected under an IF's Testing Authority.

UKAD proposes that this Article be clear about who is automatically notified of an AAF through ADAMS, and is amended to ensure consistency in respect of the relevant IFs and NADOs.

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

Would the ADO have access to fields for concentrations reported in ADAMS? Why are there options for the way concentrations are reported? i.e. in the comments section in ADAMS.

The 45 days need to consider weekends and public holidays.

How can ADAMS capture realistic reporting times? Situations like Christmas shutdown, easter and other public holidays. Do they expect labs to work on those particular days? TA/SCA/RMA are notified long shutdowns and some are provided with this information in advance.

If WADA starts monitoring lab reporting times, they must capture it fairly

Romanian Doping Control Laboratory SUBMITTED

Stan Cristina, Director (Romania)

Other - WADA-accredited Laboratories

General Comments

5.3.6.4 Reporting Test Results

c) Reporting timelines.

The main objective of the doping control laboratories is to report valid results based on reliable evidentiary data.

Please analyse the possibility to also consider special cases with analytical results that are difficult to interpret. In several cases more time than 45 days was necessary to report the result: ERA cases when it was necessary to subcontract the CP and to repeat the subcontracted CP, which includes the time the TA sends us the agreement for subcontracting and for the transport costs (which they most often do not agree with and we are forced to look for cheaper transporters than those currently used by the laboratory), time to prepare the sample for the shipment, etc.

Maybe it would be useful to clarify what should the laboratory do if the TA does not respond to the information / notification regarding the delay in reporting the results. Is it considered that the TA tacitly accepts the exceeding of the deadline and the reason given? Should the laboratory insist until it receives a response from the TA? How can we subcontract an analysis in a situation where the TA does not send any response to the laboratory's information regarding the delay in reporting the results. Even the subcontracted laboratory may need more than 20 days to report the results, especially for analyses for which there are not many requests and for economic reasons other samples are expected to be received to start a work sequence.

5.3.6.4.1 c) Please clarify how the laboratories should respond to the verbal requests of TA regarding the analytes detected in samples. Laboratories often detect substances out of competition that are prohibited only in competition or detect substances in samples at concentrations that cannot be reported according to the technical documents. There are situations in which TAs argue that they should be informed of these issues so that TAs can test the target athletes. I believe that it should be clearly specified in the ISL what information TAs can request from laboratories and what the consequences are for both TAs and laboratories in the event of information exchange that is not in accordance with the ISL.

Article 5.3.7 (1)

Romanian Doping Control Laboratory SUBMITTED

Stan Cristina, Director (Romania)

Other - WADA-accredited Laboratories

General Comments

5.3.8.2. Secondary use of samples and aliquots for research and quality assurance purposes

It is not clear how to remove all data that can lead to the correlation of a sample with a specific athlete in a situation where it is necessary to keep the athlete's consent for research in the laboratory's records. How can the laboratory subsequently prove that for a specific anonymized sample for research it has the athlete's consent for research?

Samples selected for research or quality assurance are anonymized immediately after the storage date expires, but are used after a longer period. It is necessary to keep certain information about samples, results, especially for those with AAF and ATF results (the initial internal code of the sample appears on the printouts from the equipment).

Article 5.3.7.1 (7)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.3.7.1: Minimum Storage of Samples

the laboratory shall contact and inform the relevant Testing Authority and Results Management Authority (if different) when reaching the applicable minimum storage period before disposing of any Samples with an Adverse Analytical Finding or Atypical Finding.

Change to “In case of samples with an AAF or ATF, the TA/RMA is responsible for requesting extension of storage, if needed, unless there is a different written arrangement with that authority.”

Rationale:

In case of samples with an AAF or ATF, only the TA/RMA knows the status of the results management cases and can request the extension of the storage time.

Anti-Doping Sweden SUBMITTED

Jenny Schulze, Testing and Science Manager (Sweden)

NADO - NADO

General Comments

The laboratory shall contact and inform the relevant Testing Authority and Results Management Authority (if different) when reaching the applicable minimum storage period before disposing of **any Samples with an Adverse Analytical Finding or Atypical Finding.**

Suggested changes to the wording of the Article

Change to “In case of samples with an AAF or ATF, the TA/RMA is responsible for requesting extension of storage, if needed, unless there is a different written arrangement with that authority.”

Reasons for suggested changes

In case of samples with an AAF or ATF, only the TA/RMA knows the status of the results management cases and can request the extension of the storage time.

UK Anti-Doping SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)

NADO - NADO

General Comments

Article 5.3.7.1 (f) - Possible typographical error at footnote 6 to Table 1.

The table specifies a minimum storage time of 6 months for DBS samples that are ‘Not Analysed’, however the footnote states that “The TA shall be responsible for any costs associated with… storage beyond three (3) months.”.

It is suggested that consistency between the table and footnote will avoid confusion.

USADA SUBMITTED

Allison Wagner, Director of Athlete and International Relations (USA)

NADO - NADO

General Comments

5.3.7.1 Table 1 Minimum sample storage periods – remove venous and capillary blood from table and refer to all as “Blood”. It is not necessary to specify the type of blood, and it is overly restrictive for future validation of capillary liquid blood.

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

The minimum period of 3 months appears to be too short in view of the potential need for retroactive analyses based on data from various ABP modules or any collected intelligence. Since the IST prescribes a minimum of 3 OOC tests per year for an athlete included in the RTP, this minimum period should allow for requests for additional analyses on the first sample after the data from the second sample becomes available, and the minimum period therefore should be at least 6 months and preferably 1 year.

IDAS Dresden SUBMITTED

Sven Voss, Director (Germany)

Other - WADA-accredited Laboratories

General Comments

d) It is strongly recommended to move the responsibility for the extension of storage time to the TAs.

LADF SUBMITTED

Magnus Ericsson, Director (France)

Other - WADA-accredited Laboratories

General Comments

The Laboratory **shall** contact and inform the relevant TA and RMA

(if different) when reaching the applicable minimum storage

period before disposing of any Samples reported as an AAF or an

ATF

Suggested changes to the wording of the Article

Have a "should" or remove this, It can not be the responsibility of the lab. It has to be in the clients interest to know about their samples.

Article 5.3.7.2 (1)

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

Sentence to add to the introductory chapter regarding costs of long-term storage.

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To cross-check with the ISDP:

"At the direction of the TA (or RMA, if different) or WADA, or at the Laboratory's own decision and expense (in which case the Laboratory shall inform the TA) any urine or serum/plasma/DBS Sample may be stored in long-term storage (i.e., beyond the minimum storage periods established in Article 5.3.7) for up to ten (10) years after the Sample collection date for the purpose of Further Analysis (see Article 5.3.4.3)."

Suggested changes to the wording of the Article

Any Sample storage initiated by an Anti-Doping Organization (ADO) shall be conducted at the expense of the ADO.

****

Addition:

Ten (10) years is the maximum retention time for Samples.

Reasons for suggested changes

For clarity.

******

The definition in the ISDP is strickt:

"10 years is the maximum retention time for identifiable data and Samples".

Article 5.4.5 (7)

Council of Europe (CoE) SUBMITTED

Council of Europe, Sport Convention Division (France)

Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

Article 5.4.5: Cooperation with Customers and with WADA

The ISL Drafting Team has accepted the following two proposals from stakeholders on the provision of Expert Opinions by Laboratories, which have been added to this Article:

i. The Laboratory may refuse to provide the requested expertise, if it falls outside its competence, knowledge or experience; and

ii. Any expert opinion provided by the laboratory shall be in accordance with ISO/IEC 17025 requirements

5.4.5: Cooperation with Customers and with WADA

We recommend removing the reference to opinions in paragraph ii., since this should be covered by ISO 17025 and hence is tautological

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

Article 5.4.5(c): SIA appreciates, and thanks WADA for, the creation of this specific section on Expert evidence and the additions.

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

The Laboratories should be required to report the specified information to Customers as well as to WADA i.e., any information related to any unusual circumstances or information with regarding Analytical Testing, patterns of irregularities in Samples, or potential Use of new substances.

IDAS Dresden SUBMITTED

Sven Voss, Director (Germany)

Other - WADA-accredited Laboratories

General Comments

c) v. It is recommended to remove this point and directly add what is considered necessay related to ISO 17025, section 7.8.7.

Also: Why refer to ISO when the laboratory anyway needs to follow ISO requirements?

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

For this communication, it will be efficient if there is a general WADA email address the lab can use for this purpose (unless there is already one)

Romanian Doping Control Laboratory SUBMITTED

Stan Cristina, Director (Romania)

Other - WADA-accredited Laboratories

General Comments

5.4.4.

b) This implies that all documents and data to be stored for all urine and whole blood samples for a period of 10 years

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

c) v.

Any expert opinion provided by the Laboratory shall be in accordance with ISO/IEC 17025 requirements.

Suggested changes to the wording of the Article

Any expert opinion provided by the Laboratory shall be in accordance with the Code of Ethics for Laboratories and ABP Laboratories (Chapter 8.5).

Reasons for suggested changes

ISO/IEF 17025 standard is for the laboratory **analyses**, not for expertise. For expertise, especially in those cases where the analysis is not performed by the own laboratory, the expertise does not fall in the scope of 17025. The norm guiding the expertise is ISO/IEF 17020, and it might be better not to mix these things. In my opinion, a reference can be made to ISL Code of ethics, more specicically chapter 8.5 (Duty to Preserve the Integrity of the World Anti-Doping Program and to Avoid any Detrimental Conduct).

Section 6.0

Article 6.1 (2)

Sport Integrity Australia SUBMITTED

Cameron Boland, Assistant Director Anti-Doping Policy (Australia)

NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

SIA suggests removing the reference to “non-WADA staff” from Article 6.1.2.2(a).

Reasons for suggested changes

In SIA's view, a laboratory should retain the ability to object to a WADA staff member. For example, a new WADA staff member may have recently worked in a WADA Lab and therefore may not be suitable for some assessments.

Romanian Doping Control Laboratory SUBMITTED
Stan Cristina, Director (Romania)
Other - WADA-accredited Laboratories

General Comments

c) Please specify how long it takes for the assessment report to be issued by WADA. This information is necessary so that the laboratory can plan its activities and employee rest periods (leaves) according to legal regulations after the assessment. Sufficient time is needed to adequately respond to non-conformities.

Please note that in our country there is a legal obligation to plan vacations at the end of the previous year and to comply with this planning.

Article 6.1.3 (1)

Sport Integrity Australia SUBMITTED
Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

Article 6.1.3(a): SIA appreciates, and thanks WADA for, the addition of the requirement to advise TAs about the movement of samples.

Section 7.0 (2)

Sport Integrity Australia SUBMITTED
Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

See below

Suggested changes to the wording of the Article

SIA suggests adding "IF" alongside "MEO" throughout this Article.

Reasons for suggested changes

In SIA's view, these provisions need to encompass the IF as well as the MEO given the new definition of 'Major Event'.

Swiss Laboratory for Doping Analyses SUBMITTED
Tiia Kuuranne, Director (Swizerland)
Other - WADA-accredited Laboratories

General Comments

Please, consider removal of the term "penalty point" throughout the document when assessing the laboratory performance.

Suggested changes to the wording of the Article

Could be replaced by "assessment score", "assessment point" or "point".

Reasons for suggested changes

The term "penalty" is not compliant with the ISO philosophy of continuous improvement.

Section 8.0

Article 8.3.4 (2)

Sport Integrity Australia SUBMITTED
Cameron Boland, Assistant Director Anti-Doping Policy (Australia)
NADO - NADO

General Comments

SIA notes that the term “Doping Control adjudication” is used within Article 8.3.4 but not elsewhere.

Suggested changes to the wording of the Article

SIA suggests replacing the term “Doping Control adjudication” with the term “Results Management Process”.

Reasons for suggested changes

SIA suggests the replacement of the term “Doping Control adjudication” within Article 8.3.4 to ensure consistency throughout the ISL and Code.

LADF SUBMITTED
Magnus Ericsson, Director (France)
Other - WADA-accredited Laboratories

General Comments

The Laboratory shall not engage in analyzing commercial material or preparations (e.g. dietary or herbal supplements): This is a bit outdated, in fact today more than ever, someone needs to analyze supplements for prohibited substances since the campaigns to prevent the use of these materials have failed, deeply. Moreover, to do that work well, you need to be comprehensive, so in fact our line of labs would be perfect for this. Also, the income from this line of work would help many labs struggling since the number of human samples are not enough.

Suggested changes to the wording of the Article

From our point of view this could be handled in the same way as non-signatories' samples, i.e., not under the WADA accreditation. I propose to add "not under the scope of the WADA accreditation"

Reasons for suggested changes

See above, Moreover, the potential income from this would be appreciated by the labs. and as today, some labs seems to do this anyway.

Other Comments / Suggestions (6)

International Cricket Council SUBMITTED
Vanessa Hobkirk, Anti-Doping Manager (United Arab Emirates)
Sport - IF – IOC-Recognized

General Comments

Labs that can report low levels of a banned substance (even below thresholds) should do so as an advisory/intelligence report - to the RMA/ADO as intelligence that can be used by the ADO to potentially carry out target testing.

VASANOC SUBMITTED
Dave Lolo, CEO (Vanuatu)
NADO - NADO

General Comments

No comments/ suggestions.

RUSADA SUBMITTED
Viktoriya Barinova, Deputy director (Russia)
NADO - NADO

General Comments

Laboratories should inform TA about required IRMS analysis for boldenone/nandrolone and to inform TA about concentration of boldenone/nandrolone in the sample.

We suggest that Testing Authority could ask laboratory to postpone or cancel such IRMS analysis in some cases (and to provide its' motivation). Example: athlete had been tested twice in a short period of time (for example, up to one month), the same substance had been detected in both samples, concentration of substance in the latest sample is lower than in a first one and IRMS analysis for any of these sample had been already initiated.

WADA SUBMITTED

Norbert Baume, ABP Manager (Canda)

WADA - Others

General Comments

Replace blood and blood ABP samples by “whole blood” (refer to IST 4.6.1.3. a)) throughout the whole document. Consider replacing "DBS" by "capillary blood" as well

Reasons for suggested changes

Harmonization with IST

Bird & Bird LLP SUBMITTED

Huw Roberts, Of Counsel (United Kingdom)

Other - Other (ex. Media, University, etc.)

General Comments

Secondary use of Samples and Aliquots for Research and Quality Assurance Purposes

5.3.8.2

There should be provision in this section that the Testing Authority has the right - following completion of all analytical procedures and expiration of the minimum required storage period - to remove samples from a WADA-accredited laboratory and transfer them to a forensic laboratory for the purpose of conducting additional investigations (alternatively, the TA may request the WADA-accredited laboratory to initiate such investigations, if the laboratory has the capacity/interest to do so), provided that it adheres to the provisions of this Article. It seems currently that only the laboratory (and, presumably, WADA) has a capacity to initiate such research.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

Maybe in a future versions, the detailed procedures of sample splitting, B-sample analysis, ITP and CP could be separated from the ISL as independent TDs. Due to high number of details, these paragraphs are cumbersome and difficult to write, read and implement.