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

Showing: **All (164 Comments)**

Section 1.0 (3)

Sport Integrity Australia

SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA are seeking clarity, and the drafting team consider whether the changes to article 1.1.4, regarding laboratory guidelines, are intended to be mandatory? If this isn't the case, the drafting should be reworded to make it clear the lab guidelines are not mandatory.

E.g. Article 1.1.4(b)

SIA notes there are a number of provisions throughout the ISL which require compliance with mandatory documents. These documents are listed but also include the Laboratory Guidelines (LG) which are not mandatory.

Suggested changes to the wording of the Article

1.1.4a)i

SIA suggest Article 1.1.4(a)(i) be amended to read: LGs should, where practical, be consulted with WADA stakeholders (including Laboratories).

Anti-Doping Sweden

SUBMITTED

Jenny Schulze, Testing and Science Manager (Sweden)
NADO - NADO

General Comments

ADSE would like to suggest that for every substance on the prohibited list (without current reporting limits) there shall be a reporting limit of one nanogram (1 ng).

Suggested changes to the wording of the Article

Section 1 of the ISL may not be the proper article for this comment, however, we were not sure where else to put this comment, since this change would impact several articles in the ISL as well as Technical Documents.

Reasons for suggested changes

The reason for this is to avoid many situations where there is a high likelihood that the picogram finding of a substance in a sample is unintentional doping and due to contamination, either via skin contact, via intercourse, in the food or in the boxing gloves etc. These situations are extremely difficult for athletes to avoid and subsequently have the burden of proving how it happened. It also requires a lot of resources by the ADO to handle these cases. Resources that would be of much better use in other anti-doping activities. We experience that these cases lead to decreased confidence in the anti-doping system by the athletes and the public, destroyed careers and, in many cases, a negative media attention for the athletes that impacts the quality of their lives for a long time.

We realize that the reason for analysing and reporting substances in the picogram level is to detect the tail end of an excretion curve, which is of course desirable, however, the price for this is too high and it is hurting our mission of clean sport more than the other way around.

Swiss Laboratory for Doping Analyses

SUBMITTED

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

General Comments

This platform was quite complex for provision of detailed feedback (e.g. not all the chapters were indcluded and the recommendations for rewording became not possible to trace).

I have submitted a separate pdf-file to Dr. Osquel Barroso to address the details and remarks. I hope that it could be taken into consideration in the review process. Many thanks.

1.1.1 ABP Laboratory:

Suggested changes to the wording of the Article

* Approved laboratory (with the explanation of limited scope of analysis to support hematological module of the ABP)

Reasons for suggested changes

ABP-laboratory term does not correspond anymore to the prevailing situation as the approved laboratories are performing only hematological profiling and nothing else for other ABP-modules.

Article 1.1.2 (2)

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

General Comments

If the TD increases a DL or MRL, when is this to be implemented? Suggest adding the words “or immediately if reduced”.

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

1.1.2 It is not defined what happens when TD's are time sensitive. Nor is there a definition of time sensitive

Article 1.1.3 (3)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Article 1.1.3 b) ii- SIA expects that the effective date will be nominated will consider the time required to communicate a change and ensure a laboratory can comply.

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

1.1.3 It is not defined what happens when TL's are time sensitive. Nor is there a definition of time sensitive

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

General Comments

1.1.4 LGs and TNs are 3rd level documents and cannot include "shall"s, and the deviations cannot result into non-conformities.

Section 3.0 (5)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

Art. 3.2 Confirmation Procedure (CP) - Definition

Suggest changing “parameter” to “variable” as used elsewhere since parameter is better used to describe the function of an equation, e.g. slope of a regression line.

3.2 [Comment to Laboratory Guidelines: LGs may be later incorporated, partially or in full, in TDs or in the ISL.]

Suggest changing “may be later incorporated,” to read “may be incorporated later,”

Swiss Sport Integrity SUBMITTED

Ernst König, CEO (Switzerland)

NADO - NADO

General Comments

3.2: Defined Terms from the International Standard for Laboratories

- Chain-of-custody - term 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).
- Laboratory Expert Advisory Group (Lab EAG): As this group has a major impact on laboratory assessments, evaluation, and disciplinary processes, a reference should be made to its terms of reference (ToR; available on the WADA website) for transparency.

DoCoLab - UGent SUBMITTED

Peter Van Eenoo, Prof.Dr. / director (Belgium)

Other - WADA-accredited Laboratories

General Comments

Article 3.2, definition of MRPL only refers to TD MRPL, but there are also MRPL in e.g. TDEPO

Norwegian Doping Control Laboratory SUBMITTED

Yvette Dehnes, Laboratory Director (Norway)

Other - WADA-accredited Laboratories

General Comments

3.2 RC

Regarding "a previous doping control sample": do we need some minimum criteria for how a sample from an athlete have become "well-characterized" with regards to an analyte?

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

* Definition of the Laboratory Expert Advisory Group (Lab EAG) should involve the description of the group.

3.2 Additional terms to define:

* Chain of custody (COC)

* Decision limit (DL)

Suggested changes to the wording of the Article

The terms of reference of the Lab EAG are defined and accessible via: tor_lab_eag_jan_2024_final.pdf (wada-ama.org).

Reasons for suggested changes

Reference should be made to the Terms of Reference as the group has a significant role in laboratory assessments, performance evaluation, and disciplinary actions.

Article 3.1 (2)

NADA SUBMITTED
NADA Germany, National Anti Doping Organisation (Deutschland)
NADO - NADO

General Comments

Defintion of MRL: MRLs need more harmonization: Some cases occured in the past where WADA-accredited Laboratories were able to detect substances below the MRLs which led to further problems due to dis-harmonization during the results management process.

Further Analysis / Comment: the last sentence of the Comment should be moved to the definition part as it clearly outlines a mandatory legal consequence.

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA suggest the following revisions to Article 3.1 Defined terms from the 2027 Code that are used in the International Standard for Laboratories:

ADAMS: The Anti-Doping Administration and Management System – SIA suggests this definition be drafted to be consistent with the other definitions/acronyms.

ATF

SIA suggests this definition be expanded as follows: '… prior to the final determination about the finding i.e., the establishing, or not, of an AAF and/or anti-doping rule violation)" This allows for the change of an ATF to an AAF by the Lab as well as a Violation determination by ADO.

Suggested changes to the wording of the Article

Atypical Finding (ATF)

"...prior to the final determination about the finding (i.e., the establishing, or not, of an AAF and/or anti-doping rule violation)"

Reasons for suggested changes

Atypical Finding (ATF)

This addition allows for the change of an ATF to an AAF by the lab as well as a violation determination by ADO

Article 3.5 (2)

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

General Comments

n) TD PERF – Laboratory Performance Evaluation System.p) TD VAL – Method Validation.

When will these documents be drafted?

DoCoLab - UGent
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

SUBMITTED

General Comments

mentioning nominative the TDs here might create issues when a new TD is created and will not be in this ISL...

Article 3.6 (1)

NADA
NADA Germany, National Anti Doping Organisation (Deutschland)
NADO - NADO

SUBMITTED

General Comments

Why is the explanation of Shall/ Should / May and Can only included in the ISL?

This deems to be a general interpretation of key words and expressions and must be inclkuded in the Code defintions.

Section 4.0 (4)

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

SUBMITTED

General Comments

Implement (R&D) and Sharing of Knowledge Activities1. 4.4.2.9 a)

Please define “emerging substances” or change wording.

2. 4.4.2.9 b)

It is recommended that reporting to WADA should be made more specific and suggest “...shall be reported to WADA Science Department within sixty (60) days.”

It also needs to be documented in the ISL that email, with confirmation of receipt, will be accepted as a reporting mechanism.

ONAU
JOSE VELOSO, Antidoping Medical Director (Uruguay)
NADO - NADO

SUBMITTED

General Comments

No comments

DoCoLab - UGent
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

SUBMITTED

General Comments

Article 4.1.2.6: is it 2 years or 3 years. Bullet point a of 4.1.2.6 has a contradiction

Also 4.1.2.8 states 3 years

4.1.2.8: how many times can one reapply? Will it allow continuous candidacy?

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

General Comments

Would the candidate and probational laboratories need to have a right to receive a written decision with justification if the process is suspended or terminated? Right to appeal?

Article 4.1 (1)

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

General Comments

1. Art. 4.1.1.1 Expression of Interest

Suggest changing “advise” to “advice” for consistency as used elsewhere when used as a noun.

2. Art. 4.1.2.5 Analytical Testing Procedures

Suggest defining abbreviations on first use (e.g. PPT as used here).

3. Art. 4.1.3.5 Planning and Implementing R&D and Sharing of Knowledge Activities

4.1.3.5 a) Suggest adding after “analytical method development” “or drug administration studies related to anti-doping”

4. Art. 4.1.3.8 Professional Liability Insurance Coverage

The current requirement for Laboratories to maintain a minimum of two (2) million USD in professional liability insurance coverage annually may no longer be adequate, given the increasing complexity and potential liabilities associated with anti-doping testing. It would be prudent to reassess this threshold in light of recent developments in legal claims, technological advancements, and the expanding scope of laboratory responsibilities. A more dynamic approach could be considered, such as indexing the coverage amount to inflation or establishing a tiered system where higher-risk Laboratories are required to maintain higher coverage. Additionally, the document could benefit from including specific guidance on how often this coverage amount should be reviewed and adjusted to reflect changing conditions in the field of anti-doping science. This would ensure that Laboratories are not underinsured, thereby safeguarding against potential financial and operational risks.

It is strongly recommended that no minimum figure be included in the ISL.

Article 4.1.1.1 (1)

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

General Comments

Suggest changing “advise” to “advice” for consistency as used elsewhere when used as a noun.

Article 4.1.1.2 (4)

Swiss Sport Integrity SUBMITTED
Ernst König, CEO (Switzerland)
NADO - NADO

General Comments

Submit Initial Application Form (related to laboratory accreditation)

- The requirement for support should take into account the consortiums of multiple ADOs/NADOs, who would supply the laboratory with samples and stabilize the business plan.

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA comment to 4.1.1.2 & 4.1.1.3
SIA encourage the drafting team to reconsider a “best practice” approach to assessing a NADO program. SIA is concerned the measures outlined in article 4.1.1.2 are not ‘fit for purpose’. For example, the current assessment is too focused on testing and related matters. Education is recognised as a key component of an anti-doping program and should be included in the assessment of the NADO program. We also note that NADOs are the subject of the comment to Article 4.1.1.2 a), but are unlikely to have visibility of this comment as it is located within the ISL. As such we suggest this comment may be better included or duplicated in the ISCCS.

Additionally, SIA notes that 4.1.1.3 deals with ensuring sufficient samples are committed to being provided by the ADO for the applicant lab. As the NADO is not obliged to send samples to the Lab in their country, the number of NADO samples, therefore, potentially shouldn’t directly impact the lab receiving sufficient samples (3000 and 2500 of those shall be urine samples). Although SIA acknowledge the intent, (i.e. providing enough samples to the lab for validation and sustainability) this obligation may be too burdensome, and this commitment could cause issues for NADO’s or RADO’s where a reasonable portion of their testing is conducted overseas. We suggest this could be a “should” rather than a “shall” or if it remains a “shall” to include wording that allows for exceptional circumstances to occur.

International Testing Agency SUBMITTED
International Testing Agency, - (Switzerland)
Other - Other (ex. Media, University, etc.)

General Comments

Regarding Comment to Article 4.1.1.2 a), we suggest expanding the scope beyond the host country? It is possible for a laboratory located in a smaller country to establish agreements with multiple ADOs from neighboring countries and receive a significantly higher number of samples, potentially exceeding 3,000.

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

General Comments

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

Article 4.1.2 (1)

Swiss Sport Integrity SUBMITTED
Ernst König, CEO (Switzerland)
NADO - NADO

General Comments

4.2.3: ABP Laboratory: the term is outdated as it refers to an approved laboratory, which is authorized to analyze whole blood samples to support hematological module of the Athlete Biological Passport (ABP). The other ABP-modules (steroidal and endocrine) are excluded from their services and a better name could be “Hematological laboratory” or “Approved Laboratory”.

Article 4.1.2.6 (1)

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

Article 4.1.2.6: is it 2 years or 3 years. Bullet point a of 4.1.2.6 has a contradiction

Also 4.1.2.8 states 3 years

Article 4.1.2.8 (1)

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

4.1.2.8: how many times can one reapply? Will it allow continuous candidacy?

Article 4.1.3.3 (1)

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

Bullet b. how does WADA make the ADO's accountable for their letters of support? If not, this is useless

Article 4.1.4 (2)

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

§4.1.4.2.7. thank you!! no more needed for useless letters

§4.1.4.2.8. Increase the number of samples to at least urine 3000

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

General Comments

4.1.2.6 Recommendations are not obligations but elements to consider, and cannot block the approvals or validations of CARs

Article 4.1.4.2 (3)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

1. Art. 4.1.4.2.4 Maintain ISO/IEC 17025 Accreditation

Suggest adding a statement that inclusion of a method under a Laboratory's Flexible Scope of Accreditation will be treated as in subparagraph a)

A Laboratory needs to be able to use its ISO 17025 flexible scope of analysis as an assurance of appropriate validation.

It is understood that when a technical document is specific about the analytes, then only those analytes are covered by WADA accreditation.

Nevertheless, a flexible scope is very important to deal with advances in science and new analytes appearing under an existing category including S0 of the Prohibited List. A WADA accredited Laboratory should be authorized to analyse sports samples for new analytes and by new and improved methods, even if WADA requires no AAF to be issued, but to mandate long term storage of those Samples.

It is recommended that a suitable wording (or a comment) is added to make this clear.

Furthermore, it is recommended that a statement is added to allow a Laboratory to analyse a sample for prohibited substances with non-accredited and non-validated methods should a suspicious result give cause. This must be with the written agreement of the TA. Suspicious Samples, as evidenced by use of the non-accredited and non-validated method, would then be transferred to long-term storage so that they may be re-analysed at a later date when the method is validated and ISO accredited so that an AAF may be issued where appropriate.

2. Art. 4.1.4.2.4 d) ii WADA Specific Analytical Testing Procedures

It is suggested that an official (legally defensible) WADA document is required so that Laboratories can justify that they are following "WADA specific analytical testing procedures", e.g. to their ISO inspectors and/or to deal with legal challenges during hearings. It is suggested adding to TD INDEX.

DoCoLab - UGent SUBMITTED

Peter Van Eenoo, Prof.Dr. / director (Belgium)

Other - WADA-accredited Laboratories

General Comments

4.1.4.2.8: consider increasing to 3500 samples/year (3000 urine minimum). in the 2022 testing figures only Bangkok and Bucharest would fall short (100-150 samples). With the increase we have seen in samples collected world-wide, an increase is surely possible. in all reality less than 10.000 samples is too little to be financially independent and there is considerable risk for undue influence or pressure on the lab. While the number of samples is not a dircet measure of quality, if one does not have a sufficient number of samples to guarantee a stable income, than quality is affected. Similarly, lesser requested methods (e.g. EPO, IRMS, small peptides) need practice in some cases to show proficiency. Not surprsingly, there is an over representation of labs with less than 10000 samples analyzed per year in the labs that were suspended over the last decade.

4.1.4.2.10

Is this really still necessary? Whenever we have a request for sample analysis, the client still asks for the price? Does any ADO even look at this?

National Anti-Doping Laboratory, Beijing Sport University SUBMITTED

Lisi (Leo) Zhang, Lab Manager (China)

Other - WADA-accredited Laboratories

General Comments

The 7% of annual budget for R&D activities is now removed from ISL. It is understood that such requirement might be difficult to "quantify", yet in some cases it has practical value for laboratories to settle their financial arrangement with host organizations.

Suggested changes to the wording of the Article

A [comment] under provision e) of this article would be "good enough":

Comment to Article 4.1.4.2.9 e): It is expected to allocate at least 7% ofthe laboratory's operational annual budget/funding dedicated to Researchand Development activities.

Subsequently, the comment below e)i. is recommended to be revised into [Comment to Article 4.1.4.2.9 e) i.) ...].

Reasons for suggested changes

The proposed "comment" would also allow laboratories to include R&D cost in their analysis service prize, and help the settlement of tax calculation, if applicable.

Article 4.1.4.2.4 (3)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

1. Art. 4.1.4.2.4 Maintain ISO/IEC 17025 Accreditation

Suggest adding a statement that inclusion of a method under a Laboratory's Flexible Scope of Accreditation will be treated as in subparagraph a)

A Laboratory needs to be able to use its ISO 17025 flexible scope of analysis as an assurance of appropriate validation.

It is understood that when a technical document is specific about the analytes, then only those analytes are covered by WADA accreditation.

Nevertheless, a flexible scope is very important to deal with advances in science and new analytes appearing under an existing category including S0 of the Prohibited List. A WADA accredited Laboratory should be authorized to analyse sports samples for new analytes and by new and improved methods, even if WADA requires no AAF to be issued, but to mandate long term storage of those Samples.

It is recommended that a suitable wording (or a comment) is added to make this clear.

Furthermore, it is recommended that a statement is added to allow a Laboratory to analyse a sample for prohibited substances with non-accredited and non-validated methods should a suspicious result give cause. This must be with the written agreement of the TA. Suspicious Samples, as evidenced by use of the non-accredited and non-validated method, would then be transferred to long-term storage so that they may be re-analysed at a later date when the method is validated and ISO accredited so that an AAF may be issued where appropriate.

2. Art. 4.1.4.2.4 d) ii WADA Specific Analytical Testing Procedures

It is suggested that an official (legally defensible) WADA document is required so that Laboratories can justify that they are following "WADA specific analytical testing procedures", e.g. to their ISO inspectors and/or to deal with legal challenges during hearings. It is suggested adding to TD INDEX.

Institute of Biochemistry, German Sport University Cologne SUBMITTED

Hans Geyer, Deputy Head (Germany)

Other - WADA-accredited Laboratories

General Comments

In this paragraph should be included that it is not prohibited for a laboratory to analyse a sample for prohibited substances with non-accredited and non-validated methods. In case of suspicious results, with agreement of the TA, the samples can be transferred to LTS and can be re-analysed with such a method if all requirements of the ISO accreditation and WADA specific analytical testing procedures are fulfilled.

4.1.4.2.4. d ii.

There should be a reference to an **official** WADA document with a definition of WADA specific testing procedures and a list of analytical testing procedures that are included in the category of WADA specific analytical testing procedures

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

General Comments

ii. WADA-specific Analytical Testing Procedures

The order of the process shall be described clearly:

1) Laboratory validates the method.

2) WADA reviews and approves the process.

3) AB assess the method and grants the ISO acceditation

-> the AB should be aware of the framework of the analysis to assess the method correctly for the prevailing WADA rules.

Article 4.1.4.2.9 (8)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Article 4.1.4.2.9S d) ii:

SIA suggests that this point be expanded to include other equivalent experience, ensuring that the qualifications of a qualified *Person*(s) not be limited to a 'Master's or PhD degree in one of the natural or life sciences'.

Suggested changes to the wording of the Article

4.1.4.2.9 d) ii

A Master's or PhD degree, and / or equivalent relevant experience, in one of the natural or life sciences.

Reasons for suggested changes

Reduces the inappropriate prioritisation of degrees over relevant experience, and future-proofs the field given the cost of education and further education.

International Testing Agency SUBMITTED
International Testing Agency, - (Switzerland)
Other - Other (ex. Media, University, etc.)

General Comments

4.1.4.2.10: The existing obligation in this section is often not fully implemented, as the lists are frequently outdated or not harmonized. Enhancing the sharing of information in this area is necessary.

Norwegian Doping Control Laboratory SUBMITTED
Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

General Comments

The points in d) are far too detailed, and regulates too strictly how the laboratory should manage its R&D activites. Different laboratories may, for sound reasons, do this in very different ways.

The requirements (shalls) and recommendations (shoulds) should be more general.

LSI Medience Corporation

SUBMITTED

Masato Okano, Director/Dr. (Japan)

Other - WADA-accredited Laboratories

General Comments

d) i)

Some laboratories have many staff members who perform both routine analysis and research. Laboratories should allow for the establishment of an R&D unit/department **or the appointment of an R&D manager**.

Australian Sports Drug Testing Laboratory

SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

d) If someone already in the position without Masters/PhD but > 10 years experience is this considered suitable?

Suggested changes to the wording of the Article

A Master's or PhD degree in one of the natural or life Sciences. In the absence of a Master's or PhD degree , at least 10 years experience in R&D role in Anti-Doping field.

Reasons for suggested changes

Provide recognition for staff experiences in anti-doping research in lieu of a postgraduate degree

Swiss Laboratory for Doping Analyses

SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

4.1.4.2.9 d i)-v) R&D department:

This is too restricive and nominative. The objective is to ensure that the laboratory participates in the R&D activities, but it is to the laboratory to decide how to establish it internally. Creating a "departement/unit" may create conflicts and confusion to the organisation. The emphasis should be put on a sustainable research strategy and long-term plan, without creating artificial configurations.The ultimate responsibility of the research activities is in the laboratory director.

Suggested changes to the wording of the Article

Consider defining the R&D manager in 5.2 where all the other definitions are made on the laboratory staff qualifications.

Reasons for suggested changes

Creating new structures would create confusion or undermine the independence of the laboratory to manage R&D activities in the best possible way for its process.

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED

Jean-Francois Naud, Professor and Deputy Director (Canada)

Other - WADA-accredited Laboratories

General Comments

What is the qualification needed to be in charge of the R&D section? This should be detailed.

Failure to meet the requirements will result in revocation of the laboratory's accreditation (section 7.1.2.1) What exactly will be required to comply with WADA requirements?

Laboratorio de Control de Dopaje de Madrid SUBMITTED

Gloria Muñoz, Lab Manager (Spain)

Other - WADA-accredited Laboratories

General Comments

d) ii.) Qualifications of reponsible of R&D activities. Actually article refers as “should” and in our opinion that must continue in the final version. Our community is small and we need to have in mind the possibilty to recruit staff with background in researching and the abilty to plan, execute projects and present them in different grants for funding, but maybe they could not have previous knowledge or expertice in Doping Control.

e) iv) I concern about issue that evaluation of Lab EG about R and D activities can conducto to a suspension.

I think the provisions of the ISLD include in this version can help to improve these activities in laboratories. However, to obtain succesful results, not always is going to be so easy. Not only to count with a PhD is going to be a success. it is required some time to build a R and D unit with a relevant PI, able to present projects and be provided with Grants, with a define Research Group with a line of investigation in doping science and a career in research (not only in routinely analysis). So I would like, that the provisions of this specific point would be based mainly in improvement and help and recommendations to improved better than to have a tool to sanction or punish laboratories for not been beind in compliance with this requirements.

I will lead santions only in case of immobilism, because I think that even doing it best, for some laboratories (and include mine here) is not going to be easy to build succesfully this unit in a short time.

Article 4.2

Article 4.2.1

Article 4.2.1.2 (2)

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

See Article above for similar comments to 4.1.1.2.

International Testing Agency SUBMITTED

International Testing Agency, - (Switzerland)

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

General Comments

4.2.1.2 n): It would be beneficial to expand the scope to include the activities of neighboring countries, as in some cases, they can contribute to meeting the minimum required numbers. Additionally, consider establishing a system of accountability for ADOs that support candidacies, in case of any subsequent decline in sample volumes.

4.2.1.2 b. It could be beneficial to consider harmonizing the threshold of 200 samples to that of 300 samples stipulated in arts, 4.2.1.3, 4.2.3.3.

Article 4.3

Article 4.3.1 (1)

International Testing Agency SUBMITTED

International Testing Agency, - (Switzerland)

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

General Comments

4.3.1.1 C) XIV

We suggest to incorporate a more definitive timeline or deadline for the stress test, e.g. at minimum 3 months ahead of the beginning of the Major Event.

4.3.1.1 d) iii.

The outcomes must be shared with the TA/MEO.

4.3.1.1 d) Vii)

Same comment as above – 4.3.1.1.C)

4.3.1.4 The insurance should also cover any potential costs that may arise if the implementation of a contingency (B) plan becomes necessary. In this context, we recommend including a separate provision to address the possibility of accreditation loss and the need for proper planning of a B plan.

Article 4.3.1.1 (1)

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

SIA note there are some clauses with "shall" provisions but which the Lab cannot control. SIA suggest that the drafting consider how these can be applied in practice

Examples:

4.3.1.1 c) ii – Provision of the TDP is important but suggest that the lab cannot control when the MEO provides it.

4.3.1 - "There shall be an arrangement sufficiently ahead of time....." This is not within the Laboratory's control. SIA suggest clarity as to whether the "shall" is applied to the Lab or the MEO.

SIA's experience of the Commonwealth Games in the Gold Coast, the MEO and/or Australian Government decided that the contract with ASDTL would be done via SIA. I.e. SIA had an agreement with the Commonwealth Games for the delivery of the anti-doping project including the use of ASDTL for sample analysis. SIA then had a contract with ASDTL.

SIA suggest there needs to be clarity if this type of contracting is accepted for "an agreement....between the MRO and Laboratory

"sufficiently ahead of time" In our experience with Commonwealth Games was this occurred later than SIA or ASDTL would have considered "sufficiently ahead"

a) 4.3.1 a - "a set of EQAS samples" change to "EQAS samples" so as not to limit WADA to a single set

v) SIA the drafting team provide clarity with regards to what a "dedicated security" is.

4.3.1.3 - see comment above about Lab control of contract being with MEO and timeliness

Section 5.0 (2)

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

See commentary to Article 1.1.4. SIA suggest that the drafting team ensure the wording is clear across the entire ISL, as to whether the guidance in the LG is mandatory. Otherwise, the drafting team needs to ensure there isn't any confusion regarding what the drafting team consider mandatory or

not regarding the LG.

SIA propose the drafting team consider their intent for LGs to be included in 5.4.3 b) against the mandatory compliance of the article. Currently LGs are not mandatory, so to impose a mandatory compliance against them is not in line with their intent and how they are perceived or implemented.

Article 5.4.5 - Cooperation with Customers and with WADA

Article 5.4.5 c) ii

SIA General Comment

SIA does not suggest any changes to this article. However, separate from the Code, SIA acknowledges that WADA could explore expanding the scope of the Athletes' Anti-Doping Ombuds (or similar) to consider including options for athletes to access expert opinion on anti-doping matters as agreed by WADA For example, these identified experts could be former lab directors to assist athletes obtain competent expert advice on complex scientific issues.

Suggested changes to the wording of the Article

5.2.1 ...be compliant with the ISL and its associated Laboratory ~~activities~~normative documents (*TD*s, *TL*s, ~~*LG*s~~). (removed LG)

5.4.3 The control documents that make up the Management System ~~shall~~ should meet the requirements of...

Or

5.4.3 b) The Laboratory shall implement a procedure in its Management System to ensure that the contents of ISL, *TDs*, *TLs* ~~and LGs~~ are incorporated into the Laboratory's SOPs by the applicable effective date and that implementation is completed, recorded, and assessed for compliance

Reasons for suggested changes

5.2.1 LGs are currently not mandatory, so suggest it be removed

5.4.3 LGs are not mandatory so "shall" statement needs to be changes to "should" or remove LGs from 5.4.3 b)

Article 5.4.5 - Cooperation with Customers and with WADA

Article 5.4.5 c) ii

SIA Reasoning

To ensure athletes with varying levels of resourcing can access expert advice which is currently unavailable. This could enhance fairness in the system for athletes and a robust framework supporting quality and assurance.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

5.4.5 Reference to clients should be replaced by "customer" to be in line with the ISO

Reasons for suggested changes

"clients" -> "customers" (as in ISO)

Article 5.2.2.1 (2)

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

SIA suggests this should be drafted more generally to accommodate the principle of full time, being ongoing and for a substantive and reasonable period of time. The role should also not be limited to one person but allow for a shared position.

This provision should also recognise the Lab Director can have other relevant experience, not just limited to the qualifications that are currently listed. (5.2.2.3(c) - Laboratory Certifying Scientists

Suggested changes to the wording of the Article

e) The Laboratory Director should be a full-time appointment. If the Laboratory Director holds other positions, or does not work full-time in the WADA Accredited Laboratory, this ~~they~~ shall not adversely impact the Director's Laboratory responsibilities"

INRS - Centre AFSB (laboratoire de controle du dopage)
SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

Laboratories should have the option of leaving the analyses if the TA does not respond within a reasonable time. We regularly wait a very long time for a response from the TA before making a decision.

"Only unusual conditions shall be recorded" is not precise enough for a normative document.

Article 5.2.2.3 (1)

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

General Comments

c) Bring back the redlined part. This will ensure people with diplomas working in the in anti-doping field with documented experience/knowledge are included.

Article 5.2.3 (1)

DoCoLab - UGent
SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

§5.2.3.1 b) wearing an ID badge for externals is rather silly. the origin goes to ISO9000 environment in the past, where big organizations are present and an external person is not easily identifiable.

The current wording would also indicate that all staff needs to wear a badge, because they are authorized .

Suggested changes to the wording of the Article

remove the clause

Article 5.2.3.1 (2)

Norwegian Doping Control Laboratory
SUBMITTED
Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

General Comments

b) " The Laboratory shall require authorized individuals to carry an identification badge while in the Laboratory facilities"

Suggested changes to the wording of the Article

Remove this point, or add e.g., "when necessary to identify authorized individuals".

Reasons for suggested changes

Most labs are so small that a badge is not necessary: any person not part of staff will be easily identified by everyone within the restricted zones.

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

General Comments

b) wearing an ID badge - Is badge and ID pass the same? please clarify.

Article 5.2.3.4 (1)

Laboratorio de Control de Dopaje de Madrid SUBMITTED
Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

General Comments

I concern about content of TD VAL, we would like to have the oportunity to review joint to this ISL.

In our opinion TDVAL must include general issues (in the same way taht it has been addressed in the ISL) about validation parameters, selectionof methods), but more specific issues about how validation experiments must be done, or how to review acceptance criteria, etc, is better to ketp in TN.

If these issues are addressed in TD we think that maybe some AAF could be difficult to defend,m for example for AAF cases reported previously with a method for a susbtance that was not validated exactly accordingly to TD requirements.

Article 5.2.5 (2)

LSI Medience Corporation SUBMITTED
Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

General Comments

Art. 5.2.5.2 RCs:

b) I do not agree with making routine samples taken from athletes RCs.

Art. 5.3.8.2 is only a simple description of the use after doping tests.

If athlete' samples are to be considered RCs, scientific validity must be demonstrated, such as by being evaluated by multiple laboratories, like EQAS samples.

In the vast majority of cases, it is unclear what drugs or supplements an athlete has taken, so I do not think that doping samples can be RCs.

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? By the laboratory AND WADA, or only by WADA, but never only by laboratory? Should be reworded.

Suggested changes to the wording of the Article

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 or WADA.

Article 5.2.5.1 (5)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

Art. 5.2.5.1b: RM or RC

RM or RC from past doping control samples (which are due for disposal) as RCs, should not be included since this risks promulgating erroneous findings that will greatly damage the confidence in the reliability of the anti-doping system causing long-term harm. It would be better if WADA invested in getting analytes prepared and validated for use by its accredited Laboratories.

However other samples which have been authenticated, such as from EQAS, should be permitted provided suitable checks on sample stability have been conducted.

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Article 5.2.5.2(c)

SIA suggests including a comment to this provision noting that any ‘controlled administration’ must be both legally and ethically authorised through appropriate channels as outlined under Article 8.1.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

5.2.5.2 b) A past Sample used for Quality Assurance in accordance with Article 5.3.8.2.

Suggested changes to the wording of the Article

Remove

Reasons for suggested changes

This is risky as the background of the authentic sample is not known -> not well-characterized for anything else than for the spectrum of assumed target compounds.

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED

Jean-Francois Naud, Professor and Deputy Director (Canada)

Other - WADA-accredited Laboratories

General Comments

How Reference Collections (RCs) should be prolonged? As long as wwe see the substances?

This section should not become too specific, as some people seem to suggest in their comments. We should not restrict whatever the origin of the CR (old EQAS, excretion study, old positive...) everything should remain valid according to the use we make of it of course.

Laboratorio de Control de Dopaje de Madrid SUBMITTED
Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

General Comments

Used of AAF as Reference Collections: it is in discussion the use or not of old AAF samples as "Reference Collections". In one side is the risk of using not controlled urines, and in the other side the dificulty to find reference material of some metabolites or the dificulty to perform controlled studies to achived that metabolites. Maybe, it is needed to explore posibilities of performing adittional analysis on those samples for being used as reference collections, with certain guarantees, and establishes some restrinctions in its use, taking in account that hey have not been obtained in a context of Controlled Study.

Expiration date of RMS: It is indicated that extention of expiration date of RMs is not permitted for RMs used in confirmatory quantifiction of Threshold Substances.

However, expiration date of RMs can be very different for excatly the same product, between companies. For example ephedrine HCl in methanol at 1.000 mg/ml, Lipomed establish 10 years of expiration date, Cerilliant 5 years and LGC reevaluate the product and extend the expiration date.

Even if the product is stable and other has demostrated that it is estable for much time, according to this comment the product must be discard. And sometimes RMs are difficult to obtain due to customs clearence, difficulties of provider to provide....

Expiration date f the compnies can be adjusted due to the comapnie has not develop adittional experiments of stability or due to comercial strategies.

I think, that maybe this must be reconsidered and included specific requirements for extending expiration date.

Article 5.2.6 (2)

International Testing Agency SUBMITTED
International Testing Agency, - (Switzerland)
Other - Other (ex. Media, University, etc.)

General Comments

If external analyses are required by the laboratory, the laboratory must cover the associated costs (shipping + analysis) if the method was listed in the ADAMS in the testing menu.

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

General Comments

Responsibilities shall be clarified for analytical results in subcontracting.

Suggested changes to the wording of the Article

viii) However, the responsibility to defend the result is on the analysing laboratory.

Article 5.3 (6)

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

General Comments

1. Art. 5.3.2. d

It is considered that DBS Samples collected without urine and/or venous blood samples should be permitted since, if not allowed it will greatly impede the use of DBS in the foreseeable future. It is suggested that this restriction be removed and, if WADA is insistent, then add it to TD DBS, which can be more easily modified.

Furthermore, it is considered that the collection of DBS and storage without analyses should be possible to implement a biobank of the athlete with a large number of samples to allow further investigations, e.g. in cases of AAFs with small concentrations to differentiate between doping and contamination scenarios.

Such a biobank would have helped solving many problems with current cases (e.g. cases of Chinese swimmers, Sinner case, Halep case, Banks case, Angermund case etc. and even Vuskovic case). Additionally such a biobank has a deterrent effect.

The DBS samples should not count in the statistics as doping control samples for the athlete but only in total as biobanked material.

It is recommended that the details as to how this is to be implement is detailed in TD DBS, which can be more easily modified than the ISL. The inclusion in TD DBS is important to deal with details such as documenting on ADAMS, recording “not analysed”, separation of DBS from other Samples on WADA and other reporting databases.

Reference:

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.

2. Art. 5.3.2. d

The need for the Athlete's consent should be reconsidered and it is recommended to delete the last part of the phrase:

“…provided that the TA has requested via ADAMS and in advance that the Laboratory put the DBS Samples in storage without initial analysis, and that the Athlete has consented to the collection of the DBS Sample for storage and possible future analysis without first being subject to an Analytical Testing Procedure.”

3. Art. 5.3.3.2 (Venous) Blood Samples

It is suggested to clarify that storage should be at an “indicated temperature” to avoid having to assess the uncertainty of the measurement (of temperature) under ISO 17025 requirements as insisted upon by some ISO accrediting bodies.

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

SUBMITTED

General Comments

There are several instances where the word venous has been inserted before the word blood. Venous blood is currently the default blood matrix and implied in all instances as liquid blood which can either be analyzed as whole blood or as serum or plasma fractions. It is clearly distinguished from dried blood spots which are referred to as DBS, therefore does not need to be explicitly named.

Suggested changes to the wording of the Article

Remove the word “venous” when listed before blood in all instances. Specifically:

5.3.2 d)

5.3.2 e)

5.3.3.2 Title

5.3.7 Table

5.3.7 Comment 4

Reasons for suggested changes

New advancements in blood collection show great promise for the use of microvolumes of capillary liquid blood as a comparable matrix to venous blood. Removing the word venous from the ISL and other international standards allows potential for flexibility to introduce capillary liquid blood collected in smaller volumes than traditional venous draws in the future, pending the necessary required validations without having to go through a lengthy consultation and revision process resulting in unnecessary delays.

Swiss Sport Integrity SUBMITTED

Ernst König, CEO (Switzerland)

NADO - NADO

General Comments

5.3.1: Reception, Registration and Handling of Samples, “e) The Laboratory shall have a system to uniquely identify the Samples and associate each Sample with the collection document or other external chain of custody information.”

Our concern was if the “unique identification” may refer not only to sample code, but also to kit provides (LockCon and Berlinger uses unfortunately the same sample coding and there is a possibility to have the e.g. sample 1234567 from both providers). If the provider information becomes mandatory, this will require additional fields of data management of both SCA and laboratory.

Anti Doping Danmark SUBMITTED

Silje Rubæk, Legal Manager (Danmark)

NADO - NADO

General Comments

There are several instances where the word venous has been inserted before the word blood. Venous blood is currently the default blood matrix and implied in all instances as liquid blood which can either be analyzed as whole blood or as serum or plasma fractions. It is clearly distinguished from dried blood spots which are referred to as DBS, therefore does not need to be explicitly named.

Suggested changes to the wording of the Article

Remove the word “venous” when listed before blood in all instances. Specifically:

5.3.2 d)

5.3.2 e)

5.3.3.2 Title

5.3.7 Table

5.3.7 Comment 4

Reasons for suggested changes

New advancements in blood collection show great promise for the use of capillary liquid blood as a comparable matrix. Removing the word venous from the ISL and other international standards allows potential for flexibility to introduce capillary liquid blood in the future, pending the necessary required validations without having to go through a lengthy consultation process resulting in unnecessary delays.

International Testing Agency SUBMITTED

International Testing Agency, - (Switzerland)

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

General Comments

5.3.1 b) Date and time of sample reception must be recorded in ADAMS, as this is needed for more effective monitoring and analysis.

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

5.3.1. e) The Laboratory shall have a system to uniquely identify the Samples and associate each Sample with the collection document or other external chain of custody information.

Does this refer to a mandatory registration of the kit used for sample collection, as the sample code is not anymore a unique identifier (same codes used by LockCon and Berlinger)?

Suggested changes to the wording of the Article

5.3.1. e) The Laboratory shall have a system to associate each Sample with the collection document or other external chain of custody information.

Article 5.3.2 (11)

International Paralympic Committee SUBMITTED
Phillip Riemann, IPC Anti-Doping Manager (Germany)
Sport - IPC

General Comments

5.3.2 d) Consent of the athlete should not be required to store DBS without an inital analysis. The rationale to collect the consent is not clear to us. Implementing this create additional administrative workload and will most likely stop less well resourced ADOs to collect DBS for this purpose.

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

General Comments

USADA supports the concept of the ability to store DBS samples that are not initially analyzed (5.3.2 d) and agrees this will greatly benefit the results management process, particularly in instances where distinction of OOC and IC use is required. However, we do not agree that consent should be sought from the athlete prior to storage, providing that the stored sample may only be used for future possible routine testing and not for research purposes. Requiring consent from the athlete in advance provides a significant administrative and logistical barrier to implementation of this concept, which is actually designed to benefit the athlete. Finally, it is not possible to provide DCOs an easy explanation to athletes during the sample collection process to obtain their consent for DBS storage without analysis as the reasons for this may vary depending on the athlete, sport risk assessment, test type, etc…

Suggested changes to the wording of the Article

USADA suggests that the wording "…, and that the Athlete has consented to the collection of the DBS Sample for storage and possible future analysis without first being subject to an Analytical Testing Procedure." is removed from the sentence.

Reasons for suggested changes

Requiring consent from the athlete in advance provides a significant administrative and logistical barrier to implementation of this concept, which is actually designed to benefit the athlete. Athletes do not need to consent to sample storage in other instances.

Anti Doping Danmark SUBMITTED
Silje Rubæk, Legal Manager (Danmark)
NADO - NADO

General Comments

ADD supports the concept of the ability to store DBS samples that are not initially analyzed (5.3.2 d) and agrees this will greatly benefit the results management process, particularly in instances where distinction of OOC and IC use is required. However, we do not agree that consent should be sought from the athlete prior to storage, providing that the stored sample may only be used for future possible routine testing and not for research purposes. Requiring consent from the athlete in advance provides a significant administrative and logistical barrier to implementation of this concept, which is actually designed to benefit the athlete.

Suggested changes to the wording of the Article

ADD suggests that the wording "…, and that the Athlete has consented to the collection of the DBS Sample for storage and possible future analysis without first being subject to an Analytical Testing Procedure." Is removed from the sentence.

Reasons for suggested changes

Requiring consent from the athlete in advance provides a significant administrative and logistical barrier to implementation of this concept, which is actually designed to benefit the athlete.

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Article 5.3.2 (d)

SIA is seeking the removal of the reference to 'via ADAMS' as many requests for analysis are submitted by non-ADAMS methods.

Article 5.3.2.2 – *Sample* Splitting Procedure

SIA suggests including the wording "Even if present during the splitting procedure, the Athlete and/or his/her representative has no right to attend the Analytical Testing Procedures to be performed on the first split fraction of the "B" Sample, which shall be deemed as the "A" Sample as per normal A sample procedures " as at 5.

If the B is being split to provide an A and B Sample the Athlete is not entitled to be present for the A analysis.

The inclusion of this wording makes it explicit as to the procedure to be followed.

SIA agrees with the change that allows no DBS analysis to take place where not required, for example where the analysis of an associated blood and/or urine sample can be relied upon.

Suggested changes to the wording of the Article

5.3.2.d) DBS *Samples* collected with urine and/or venous blood *Samples* during the same *Sample* Collection Session, provided that the TA has requested ~~via *ADAMS* and~~ in advance

Anti-Doping Sweden SUBMITTED

Jenny Schulze, Testing and Science Manager (Sweden)

NADO - NADO

General Comments

5.3.2 d)

We consider that DBS Samples collected without urine and/or venous blood samples should be permitted since, if not allowed it will greatly impede the use of DBS in the foreseeable future. We suggest that this restriction be removed.

Furthermore we consider that the collection of DBS and storage without analyses should be possible to implement a **biobank** of the athlete with a large number of samples to allow further investigations, e.g. in cases of AAFs with small concentrations to differentiate between doping and contamination scenarios.

Such a biobank would have helped solving many problems with current cases (e.g. cases of Chinese swimmers, Sinner case, Halep case, Banks case, Angermund case etc. and even Vuskovic case). Additionally such a biobank has a deterrent effect.

The DBS samples should not count in the statistics as doping control samples for the athlete but only in total as **biobanked material.**

Reference:

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.

Suggested changes to the wording of the Article

We recommend that the details as to how this is to be implement is detailed in TD DBS, which can be more easily modified than the ISL. The inclusion in TD DBS is important to deal with details such as documenting on ADAMS, recording "not analysed", separation of DBS from other Samples on WADA and other reporting databases.

International Testing Agency SUBMITTED

International Testing Agency, - (Switzerland)

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

General Comments

5.3.2 d)

We would support extending this principle to other types of samples, while maintaining strict criteria and monitoring mechanisms. This approach would enhance deterrence and enable more efficient use of resources.

5.3.2 e)

We would encourage a broader stakeholder consultation on this.

Institute of Biochemistry, German Sport University Cologne SUBMITTED

Hans Geyer, Deputy Head (Germany)

Other - WADA-accredited Laboratories

General Comments

5.3.2. d

This paragraph should also apply for DBS samples collected without urine and/or venous blood samples.

Reasons for suggested changes

This change of 5.3.2.d allows to increase the frequency of sample collections, without a strong increase of the costs and allows follow up investigations concerning atypical or adverse analytical findings. Additionally, the high number of sample collections has a strongly deterrent effect.

See publication:

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.

Norwegian Doping Control Laboratory SUBMITTED

Yvette Dehnes, Laboratory Director (Norway)

Other - WADA-accredited Laboratories

General Comments

Reg. collection of DBS for storage, under 5.3.2 d):

- when to report "not analyzed"; within the 20 days analysis-limit?

- why should the athlete give consent to such storage? And does this requirement imply that the lab needs to keep track of this?

Surely, this is the responsiblity of the TA/RMA (and that should be made clear in the ISL), and must also be a part of the ISRM.

- Without any further guidance, this could lead to a steadiy increasing amount of DBS-samples beeing stored for an undefined (and very long) time, causing space-issues for the labs.

LSI Medience Corporation SUBMITTED

Masato Okano, Director/Dr. (Japan)

Other - WADA-accredited Laboratories

General Comments

d) How long should DBS samples that are not being analyzed be stored? According to Table 1 in Art. 5.3.7 Storage of Sample, it says three months, but it should be longer than that, right? Please ensure consistency with 5.3.7.

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

a) and b) This has been in the ISL for a while, however, our lab has never experienced combining aliquots and have always wondered how this gets reports in ADAMS. If 2 or 3 samples were combined from the same athlete from the same collection, how does the lab report this? Which bottle number should be used and how are the other bottle numbers dealt with in ADAMS?

e) DBS storage as Not analysed – Fridge or Freezer? For how long? Another thing the lab needs to manage and keep track of.

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

General Comments

b) In cases where the Laboratory receives three (3) or more urine Samples, which are linked to a single Sample Collection Session from the same Athlete according to the DCF(s), the Laboratory shall prioritize the analysis of the first and the subsequent collected Sample with the highest specific gravity (SG), as measured by the Laboratory:

Suggested changes to the wording of the Article

-As registered in the DCF by SCA.

Reasons for suggested changes

"As measured by the laboratory" requires opening the container - also those one that will not be analysed.

Article 5.3.2.1 (7)

Swiss Sport Integrity SUBMITTED
Ernst König, CEO (Switzerland)
NADO - NADO

General Comments

Samples with Irregularities

ii)

- Sample cap and container codes do not match Irregularity only if it does not match with documentation -> the seal and container may have different codes for valid reason, it just needs to be traceable.
- Absence of barcodes on Sample container This obligation sounds too restrictive. Not all the containers have barcodes.

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Article 5.3.2.1

SIA suggests further clarification should be provided to explain how the Laboratory is required to manage, record and liaise with TA on irregularities to ensure the clear and can be practically implemented.

International Testing Agency SUBMITTED
International Testing Agency, - (Switzerland)
Other - Other (ex. Media, University, etc.)

General Comments

This is welcome but we would suggest to continue to refine the language to apply consistently also to blood samples.

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

General Comments

b) Long delivery time. Is it from collection date to lab or actual transit delivery time? What is considered long? What if samples are held up in customs? This is all out of the labs control

Sample exposed to high temperature during transit. How does a lab know this? Only blood samples have temperature logger information to record temp during transit.
c) What happens if TA does not respond in 7 days. How can ADAMS capture to TAT when analysis does not start until information is received. TAT is calculated by the difference of date reported and date received at lab.

Thoughts: there is inconsistency how TA response on the below points. Samples where the lab receives

- a Kit where the A and B are different (due to whatever reason) should be voided. In the event you require B sample analysis, this would be enough to show inconsistencies and confusion.
- Sample cap and container code do not match should be voided. Creates confusion and tracking of differing numbers. What about B sample analysis? There will be no record of the kit (B tube) in ADAMS only commented against the A-Bottle that may cause issues for traceability, records, and legality

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

General Comments

b) Samples exposed to high temperatures

ii)

* Sample cap and container codes do not match

* Absence of barcodes on Sample container

5.3.2.2 Sample Splitting Procedure

iv. The Sample is heavily contaminated.

-> This is not often observed before the analyses.

Suggested changes to the wording of the Article

b) Samples found to have been exposed to high temperatures.

ii)

* Sample cap and container codes do not match with the provided documents.

~~* Absence of barcodes on Sample container~~

Reasons for suggested changes

This is not possible to monitor without loggers and they are not associated in all transports (e.g. all urine samples).

ii)

* The deviation may be explained in sample documentation.

* Barcodes are not always available.

INRS - Centre AFSB (laboratoire de controle du dopage)
SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

Dealing with irregularities is a recurring problem for all laboratories. A lot of time is wasted on case management in general.

Laboratorio de Control de Dopaje de Madrid
SUBMITTED
Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

General Comments

b) ii) Sample with irregulatiries:

Athlete´s identity information in the DCF. Sometimes is not as obvious as the name of the Athlete, but maybe some “real” examples must be indicated as irregularities (presence of signature of the Athlete, for example in the field of Consentiment for Research, some written information as “RECORD”). We find sometimes in the DCF this issues, and we communicate to the TA, to proceed.

- Absence of barcode (OR QR not always there is a BARCODE) on sample container.

is this irregularitie trying to address the case of blood sample in vacutainer withouth identification but inside a sealing container prefectly identified? maybe more calrifications regaring this can be addressed here.

Responsability of lab is communicate TA the iregulariities and TA must providee instructions to proceed. But for the same irregularity every TA proceed with different instructions. Can this be harmornized?

Article 5.3.3 (2)

DoCoLab - UGent
SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

§5.3.3.1 a)The wording here is much better than TDEPO.

Norwegian Doping Control Laboratory
SUBMITTED
Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

General Comments

5.3.3.2 (Venous) Blood Samples

Samples for blood ABP are not aliqouts of the A-sample; they are the A-sample. This should be made clear in the relevant bulletpoints in this paragraph.

Article 5.3.3.2 (4)

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Article 5.3.3.2 a)

As per SIA's general feedback related to LGs, 5.3.3.2 current drafting includes "shall" for LGs which are not mandatory. However, it is noted that *TD*s and *TL*s are mandatory and therefore, the "shall" could remain with the either the article being expanded or a comment to the article that explains that LGs should be followed but are not mandatory.

Suggested changes to the wording of the Article

3.5.3.3.2 a) The Laboratory should ~~shall~~ follow the applicable ~~*Technical Document(s),* Technical Letter(s) or Laboratory Guidelines~~*TDs, TLs* or LGs for handling and storing blood *Samples*.

Reasons for suggested changes

LG's are not mandatory so needs to be a "should" statement rather than a "shall". However, this goes against the principle of TDs and TLs. See general comments to for article 5. section.

DoCoLab - UGent SUBMITTED

Peter Van Eenoo, Prof.Dr. / director (Belgium)

Other - WADA-accredited Laboratories

General Comments

§5.3.3.2. b) the Sysmex does not use disposable tips and can not use these

Suggested changes to the wording of the Article

For blood Samples, the Laboratory shall -except for the measurement of the haematological module of the ABP- obtain Aliquot(s) from the blood Sample container by using single-use disposable pipettes or

pipettes with disposable, non-reusable tips.

Reasons for suggested changes

§5.3.3.2. b) the Sysmex does not use disposable tips and can not use these

Swiss Laboratory for Doping Analyses SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

For blood Samples, the Laboratory shall obtain Aliquot(s) from the blood Sample container.

Suggested changes to the wording of the Article

For blood Samples, the Laboratory shall obtain Aliquot(s) from the blood Sample container, unless required otherwise by the instrumental technique.

Reasons for suggested changes

Not compatible with Sysmex analyses.

Laboratorio de Control de Dopaje de Madrid SUBMITTED

Gloria Muñoz, Lab Manager (Spain)

Other - WADA-accredited Laboratories

General Comments

Related also to 5.3.7.

Storage of Blood Samples.

We have understood that for long-term storage of plasma and serum -70 C was the best temperatura, but if laboratory has enough capability even médium term storege can be done at -70. Unless there is anything that i am not having in mind regarding blood samples storage, maybe this possibility could be also included in the ISL.

Article 5.3.3.3 (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA refers to our introductory comment at 1.1.4 noting that LGs are not mandatory even though they are referred to in clauses requiring compliance.

Article 5.3.4 (2)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA recognises that Further Analysis must include substances on the List at the time of collection, we are seeking to ensure that additional analysis of substances that have since been added to the List can occur. See the list of suggested changes to the wording enclosed including:

- 5.3.4.3 c ii- Remove third dot point about notification to athlete as covered by 5.3.2.2 and potentially in conflict – “shall” vs “should”
- 5.3.4.3- Remove "Further analysis of stored samples shall, as a matter of principle....." to “should”. Further analysis will often be IRMS or ERAs for follow up.

Regarding, article 5.3.4.2(c) – SIA suggest providing clarity as to whether the lab need to report any request for additional analysis into ADAMS.

Furthermore, SIA refers to Concept #5 – Clarification of Further Samples:

The ISL Drafting Team shall consider proposing that certain confirmation procedures (e.g., GC/C/IRMS tests for atypical passport findings related to the steroid profile), which are triggered by initially suspicious results from analyses already performed on samples (e.g., initial testing procedures for the steroid profile), are not considered as further analysis, but as part of the ongoing analytical testing process, even if results for other analyses have already been reported for the sample. This would ensure that if an adverse analytical finding has been reported and the athlete has been charged with an anti-doping rule violation, those confirmation procedures could be performed without requiring the athlete or hearing panel’s consent or approval.

SIA agreed with this proposed approach, as it allows timeliness in RM process. For example, an AAF may be confirmed for a diuretic while IRMS analysis is continuing. Where it is time critical to notify and suspend an *Athlete* (e.g. major event soon) then we suggest that these exceptional circumstances be available to continue IRMS analysis without the *Athlete* or hearing body approval.

[Comment to Article 5.3.4.3 a): does not allow for this.

Suggested changes to the wording of the Article

5.3.4.3 Further Analysis of stored *Samples should* ~~shall~~, as a matter of principle, be aimed at a minimum at detecting all the...

Norwegian Doping Control Laboratory SUBMITTED
Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

General Comments

"For more details on Analytical Testing Procedure validation requirements, refer to the TD VAL."

It is very important that the new TD VAL is similarly general in its description of the requirements, as the current ISL is.

Well validated methods that deviate somewhat from the current TN VAL contents, would otherwise be heavily challenged in court, even though there is no sound scientific reason to do so.

Article 5.3.4.2 (5)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

1. Art. 5.3.4.2 a)

Change “to the analysis” to read “for the analysis”.

2. Art. 5.3.4.2 b)

The reduction of the test menu should also be possible for International-Level Athletes and National-Level Athletes in case of additional investigations in connection with AAFs or ATFs.

It is essential that Laboratories are authorized to undertake additional analytical investigations when called upon to assist with AAFs, ATFs or ATPFs.

Anti Doping Danmark SUBMITTED

Silje Rubæk, Legal Manager (Danmark)

NADO - NADO

General Comments

Art. 5.3.4.2 b)

Comment: The reduction of the test menu should also be possible for International-Level Athletes and National-Level Athletes in case of additional investigations in connection with AAFs or ATFs.

It is essential that Laboratories are authorized to undertake additional analytical investigations when called upon to assist with AAFs, ATFs or ATPFs

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Article 5.3.4.2 d. SIA suggests that the name of the document that sets out the Mandatory Analytical Test Methods be Included. Additionally, suggest that the status of the document is provided i.e. the intent of the document the status is not as a *TD, TL* or LG.

Australian Sports Drug Testing Laboratory SUBMITTED

Vanessa Agon, Laboratory Director (Australia)

Other - WADA-accredited Laboratories

General Comments

c) Do we need to report this into ADAMS what has been requested or this stays out of ADAMS as it is related to further investigation (See section f). Please clarify if the results will need to be reported in ADAMS and without affecting the original finding.

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

There are instances in the IRMS TD or QC neg that are not required (boldenone for example). A superscript 7 should be added to specify “unless otherwise specified in a TD ...

Article 5.3.4.2.2.2 (8)

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

General Comments

Art 5.3.4.2.2.2 c) Existence of approved TUE

It is recommended that the category S4.2 and specifically clomiphene and tamoxifen is added since many cases with these drugs are being encountered under TUE applications and approvals.

Art 5.3.4.2.2.2 c) Existence of approved TUE

The use of routine DBS collection will aid the evaluation of TUE compliance.

Art 5.3.4.2.2.2 c) Existence of approved TUE

also It is recommended that WADA establishes a list of experts, who are able to evaluate the consistency between the laboratory results and the TUE data, for RMAs who have limited expertise/resource.

Art 5.3.4.2.2.2 e)

It is considered that reporting an AAF below the MRL, e.g. when an athlete has declared the use of the Prohibited Substance, should not be permitted as this would defeat the purpose of harmonizing reporting of substances at MRL between the Laboratories.

The better alternative would be to provide a statement as an opinion for the presence of substance below the MRL but not as an AAF.

UK Anti-Doping SUBMITTED
UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)
NADO - NADO

General Comments

5.3.4.2.2.2. (c) - In UKAD’s experience, the list of Prohibited Substances for which the Laboratory may contact the TA (or RMA) to enquire whether an approved TUE exists could be extended.

5.3.4.2.2.2. (e).ii - It is proposed that a Laboratory “may report a Sample containing a Non-Threshold Substance with an estimated concentration below the MRL as an AAF if the Non-Threshold Substance is identified in compliance with the TD IDCR and the TD MRPL 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 TA, RMA or WADA.

UKAD has concerns related to this new section, and suggests that it is reviewed to better ensure consistency of application.

Suggested changes to the wording of the Article

5.3.4.2.2.2. (c) - UKAD would propose that, at a minimum, Clomifene *and Tamoxifen* (prohibited under S4.2 of the 2024 Prohibited List) should be added. Alternatively/additionally, consideration should be given to allowing Laboratories to check for a TUE if the Presumptive AAF corresponds to one or more items included in the Athlete's Doping Control Form declaration of medications.

Reasons for suggested changes

5.3.4.2.2.2. (c) - The reason for the changes suggested above, is that it would reduce unnecessary Confirmation Procedures at the Laboratory, and Results Management activity for the TA/RMA.

5.3.4.2.2.2. (e).ii - Two of UKAD's concerns are as follows: Firstly, in respect of consistency of application across Laboratories (given the requirement is a "*may*" rather than a "*shall*"). Secondly, for substances that are prohibited In-Competition only – whether Laboratories would be in a position of reporting AAFs that relate to Out-of-Competition use (given the Doping Control Form declaration of medications requests substances used over the last 7 days).

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Regarding article 5.3.4.2.2.2 c) i, SIA recommends the Drafting Team consider the addition of oxycodone to the list of substances that Laboratories may contact the TA to inquire about the existence of an approved TUE when there has been a Presumptive Adverse Analytical Finding (PAAF).

Additionally, article 5.3.4.2.2.2 d) iii, we suggest that WADA provide examples for the "valid reasons" the Laboratory must document as justification.

Anti-Doping Sweden SUBMITTED
Jenny Schulze, Testing and Science Manager (Sweden)
NADO - NADO

General Comments

5..25.3.4.2.2.2 c) Recommend adding category S4.2 and specifically clomiphene and tamoxifen
Additional comments:
The use of routine DBS collection will aid the evaluation of TUE compliance.
We also recommend that WADA establishes a list of experts who are able to review TUEs for RMAs who have limited expertise/resource.

kjd
5

Reasons for suggested changes

Many cases with these drugs are being encountered under TUE applications and approvals

Norwegian Doping Control Laboratory SUBMITTED
Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

General Comments

iii):

The TA/RMA may not be in the position/have the competance to make such a desicion.

Rec. to add. e.g., "under the guidance of" - or "following the recommendations by" - the laboratory.

LSI Medience Corporation
SUBMITTED
Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

General Comments

c) Existence of approved TUE

The list of banned substances for which laboratories can query for TUEs should be expanded, which would reduce unnecessary burden on laboratories and results management bodies.

For example, TUEs may be granted for female athletes to use clomiphene or tamoxifen.

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

General Comments

Can report a AAF for NTS below MRL if it passes ion ratio, and they've declared it? Please clarify the reasoning behind this?

INRS - Centre AFSB (laboratoire de controle du dopage)
SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

b) The way it's written, in a multi + case the decision of which molecules to confirm “shall be made in consultation with the TA”. So in each multi + case, the laboratories will have to write to the customer to find out what to confirm. This will create unmanageable situations for the laboratories and make it impossible to deliver results within a reasonable timeframe.

e) It's nonsense to report an MRL result as positive, even if the result is lower than the MRL. Paragraph for NTS with MRL is really dangerous and goes against TDMRPL. A result below the MRL cannot be rendered AAF, otherwise what's the point of the MRL? In the same vein, we wouldn't render a threshold substance as AAF when it's lower than the LD (with the exception of certain threshold substances in the presence of diuretics or masking agents).

f) For endogenous threshold substances, “steroid profile” markers or any other prohibited substance that may be produced endogenously, AAF decisions for sample “A” may also be based on the application of any suitable CP that establishes the exogenous origin of the prohibited substance, its metabolite(s) or marker(s) (e.g. GC/C/IRMS).

This directly contradicts what is stated in the TN WADA specific analytical testing procedures (page 2). A positive IRMS result cannot be reported unless the molecule is already registered in the IRMS TD. I agree with what ISL says, but it's not consistent with existing documents.

Suggested changes to the wording of the Article

- The "shall" shall be replaced by a "should".

Remove the entire part on reporting AAF below the MRL

Article 5.3.4.2.2.3 (8)

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

General Comments

Art 5.3.4.2.2.3 i) i. Repetition of the “B” CP

The subject of last sentence is “The reasons” and implies inclusion always in LDOC rather than only when appropriate. Suggest adding appropriate wording, e.g. “included in the LDOC when CP is repeated”.

Agence française de lutte contre le dopage SUBMITTED
Adeline Molina, General Secretary Deputy (France)
NADO - NADO

General Comments

b) ii

The 15-day deadline to inform the laboratory to conduct or not the CP on the B sample is unrealistic.

The RMA must inform the athlete of the AAF result, and it is the athlete who requests the analysis of the B sample. The delay in contacting the athlete does not allow the laboratory to be informed within 15 days by the RMA.

NADA SUBMITTED
NADA Germany, National Anti Doping Organisation (Deutschland)
NADO - NADO

General Comments

The paragraph is too important to be "hidden" in such a subsequence.

It should recieve its "own" paragraph.

Sport Integrity Commission Te Kahu Raunui SUBMITTED
Jono McGlashan, GM Athlete Services (New Zealand)
NADO - NADO

General Comments

- We support the concept, however, this won't always work in practice.
- Given the B sample analysis is requested by the athlete, there is often a delay due to athlete notification, the athlete getting a lawyer, and initial casework. The RMA may not be able to request the B-sample analysis within the 15 days stated in the ISL.

“This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui.”

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

Why would a member of an NOC of national federation (which is not the TA/R, and hence has nothing to do with the anti-doping work) be allowed to be present during a B-analysis? This is interference . these organisations nolonger can send samples to labs, so they should not get in)-sight in anti-doping results? it also jeopardizes privacy.

Suggested changes to the wording of the Article

§5.3.4.2.2.3 e) remove bullet v

Reasons for suggested changes

Why would a member of an NOC of national federation (which is not the TA/R, and hence has nothing to do with the anti-doping work) be allowed to be present during a B-analysis? This is interference . these organisations nolonger can send samples to labs, so they should not get in)-sight in anti-doping results? it also jeopardizes privacy.

LSI Medience Corporation SUBMITTED
Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

General Comments

There is no mention of remote B sample analysis, which has begun to be attempted during the Covid-19 pandemic.

Does this mean that remote B analysis is not permitted in principle?

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

laboratories must be notified of the opening of pot B in 15 days, at the moment we sometimes wait more than a year for IRMS. We like what is written in the ISL but it should be added what to do when the B pot request comes much later. All these delays are rarely caused by the laboratories. Once again, the pressure should be put on the TA/IF and not on the ISL, which should be a useful document for laboratories.

Laboratorio de Control de Dopaje de Madrid SUBMITTED
Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

General Comments

5.3.4.2.2.3 “B” CP

g) Opening, Aliquoting and Resealing of “B” Sample. I think that include in the acceptance of the Athlete that he/she has been informed about the posibility of attend not only the opening of the sample but also the Analysis, could be interesting to avoid later claims about this point.

i) Repetition of the “B” CP. I am not sure about the repetition on “B” sample CP in a remaining volumen of sample aliquot could be enaough traceable and not generate more later issues.

Article 5.3.4.4 (1)

NADA SUBMITTED
NADA Germany, National Anti Doping Organisation (Deutschland)
NADO - NADO

General Comments

This article is not in line with stakeholder notices e.g. for Clenbuterol.

Therefore it is suggested to add a half-sentence with regard to stakeholder Notices such as Clenbuterol cases.

Suggested changes to the wording of the Article

"..if not supported by WADA in a Guideline or Stakeholder notice otherwise."

Article 5.3.6 (4)

UK Anti-Doping
SUBMITTED
UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)
NADO - NADO

General Comments

5.3.6.4.(c).i. - UKAD notes that the timeframe for reporting an “A” Sample remains unchanged at 20 days from receipt.

5.3.6.4.(c).ii. - 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.

Suggested changes to the wording of the Article

5.3.6.4.(c).i. - UKAD considers that it would be beneficial for this Article to include a bullet point that reflects there may be legitimate reasons why this timeframe might not be achieved, and – in the case of an AAF or ATF – that this does not undermine the finding. For example, the reporting of an AAF may be delayed by necessary validation work, or the provision of a second opinion pursuant to ISL Article 5.3.6.1.c.

5.3.6.4.(c).ii. - UKAD suggests that this timeframe is reduced, for example to 5 days.

Reasons for suggested changes

5.3.6.4.(c).i. - UKAD considers that the inclusion of such wording would be more reflective of the practical reality of sample analysis and reduce the occurrence of inappropriate challenges of the analytical and broader Results Management processes.

5.3.6.4.(c).ii. - 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.

Sport Integrity Australia
SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA requests that 5.3.6.4 b) i be rewritten to allow already commenced/requested analysis to be completed with notification to the athlete that some analysis remains ongoing.

Reasons for suggested changes

SIA feels that if it is time critical to notify and suspend an athlete (e.g. major event upcoming), it should be possible to continue analysis without athlete or hearing body approval. E.g. an AAF may be confirmed for a diuretic while IRMS analysis is continuing.

International Testing Agency
SUBMITTED
International Testing Agency, - (Switzerland)
Other - Other (ex. Media, University, etc.)

General Comments

5.3.6.2 f)ii) the TA should retain the right to obtain a LDOC if necessary, especially considering that a substantial amount of proceedings is closed during the results management process without a hearing.

DoCoLab - UGent
SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

§ 5.3.6.4: Laboratories may have to prioritize the analysis of

Major Event Samples over other Samples.

Suggested changes to the wording of the Article

Agreements may be made with Laboratories to prioritize the analysis of Major Event Samples over other Samples.

Reasons for suggested changes

Prioritizing is not always possible and should be agreed, and should be agreed upon the TA and the lab. The current text is really indicating we are "slaves" that need to do whatever we -as labs are told- by the TA's.

Article 5.3.6.1 (3)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

Art. 5.3.6.1 c) iii. c) Requests for Second Opinions

As written, it is ambiguous which Laboratory Director needs to approve. Suggest adding words such as “by the Laboratory Director of the Laboratory providing the second opinion”.

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Regarding article 5.3.6.1.c.iii, SIA seeks there be clarification as to where the Laboratory Director is and works. SIA suggests it could be where the director works as all the training/approval documentation is with the relevant laboratory and that the Director has best knowledge of the second providers expertise.

Laboratorio de Control de Dopaje de Madrid SUBMITTED

Gloria Muñoz, Lab Manager (Spain)

Other - WADA-accredited Laboratories

General Comments

5.3.6.4.1 Reporting Requirements.

Laboratory shall report the estimated concentrationf for Non-Thresholds Substances subject to MRL. Does it means that must be reported in the Test Report?

Article 5.3.6.4.1.1 (2)

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Article 5.3.6.4.1.1 b)- SIA suggest the drafting team review the clause to ascertain whether the wording can allow the naming of confirmed metabolites (as well as the prohibited substance it is caused by).

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED

Jean-Francois Naud, Professor and Deputy Director (Canada)

Other - WADA-accredited Laboratories

General Comments

For NTS with MRL, the laboratory must report the concentration estimated during the CP of sample A, on request only? If it has to be noted on the test report, then it's basic, isn't it?

It's still an estimate, though. Why should we specify that the value was obtained using a method that has not been validated for quantification? The term “estimate” is sufficient on its own, it seems to me. There's nothing against mentioning it if we're asked to, but not systematically in the results report, not in every report. Should it be a standard feature in the doc packs? No problem.

Article 5.3.7 (12)

Council of Europe SUBMITTED

Council of Europe, Sport Convention Division (France)

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

General Comments

Table 1. Minimum Sample Storage Periods

It is considered that the minimum storage period for urine samples should remain at 3 months. The additional cost of millions of dollars each year is unnecessary. In case the ADO wishes longer storage periods than 3 months then those samples can be transferred into long-term storage.

If the purpose is for the Steroidal Passport ABP, the fact that this has been theoretical and not met in practice over the last 10 years, the >3 million dollars annual additional cost world-wide needs to be justified. Long term storage of specified suspicious Samples would be the more cost-effective solution. The risk of imposing this additional cost of doubling storage time is that the number of samples will be reduced given the cost-restrictions imposed on many NADOs.

UK Anti-Doping SUBMITTED

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)

NADO - NADO

General Comments

UKAD notes the proposed increase in the minimum storage time for negative Urine Samples from three to six months.

Suggested changes to the wording of the Article

UKAD suggests that the storage time reverts to three months (as per the 2021 ISL).

Reasons for suggested changes

UKAD understands that the rationale for the proposed increase is to allow more time for Further Analysis, particularly in response to the Athlete Biological Passport. However, it is anticipated that the proportion of Samples that would benefit from this change will be small, and that the change will lead to an increase in Laboratory costs (which would be passed to the RMA/SCA/TA). The option exists for ADOs to request that Samples be placed into long-term storage (potentially on a short-term basis), in the event they have triggered notifications or recommendations related to the Athlete Biological Passport.

Sport Integrity Australia SUBMITTED

Andrew McCowan, Assistant Director Project Management Office (Australia)

NADO - NADO

General Comments

Article 5.3.7 a) SIA suggest the article and be more explicit with regards to what the storage requirements are and that they need to be in line with the *TDs*. For example, ERAs are required to be stored at-70°C not the-15°C outlined here in Table 1. Minimum *Sample* Storage Periods.

SIA does support the extension for the minimum urine storage from 3 to 6 months. This will support improved follow up of passport abnormalities.

5.3.7.1b, SIA seeks there be clarification i.e. Does this wording "which is under the responsibility of the TA" cover the ITA/IOC storage facility which is utilised for the storage of samples where the ITA aren't the DSP? NADOs currently store samples at this facility, but don't have ownership/responsibility for the storage facility. It is suggested that wording be added to clarify this issue, or by removing "which is under the responsibility of the TA that has ownership of the samples". Additionally, SIA suggests the drafting team consider expanding the article to include "TA shall retain ownership of the samples" to be clear who retains ownership.

International Testing Agency SUBMITTED

International Testing Agency, - (Switzerland)

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

General Comments

Table 1 Minimum Sample Storage: A 3-month storage period for unanalyzed DBS samples seems somewhat short. We recommend extending this timeframe, especially since DBS samples require minimal storage space.

Additionally, the starting point for the time count should be more clearly defined.

Institute of Biochemistry, German Sport University Cologne SUBMITTED

Hans Geyer, Deputy Head (Germany)

Other - WADA-accredited Laboratories

General Comments

5.3.7. table 1

The minimum storage period for urine samples should be 3 months. For a minimum period of 6 months the provision of new storage capacities in the labs is necessary which leads to high costs. In case the ADO wishes longer storage periods than 3 months the samples have to be transferred into long-term storage.

DoCoLab - UGent SUBMITTED

Peter Van Eenoo, Prof.Dr. / director (Belgium)

Other - WADA-accredited Laboratories

General Comments

5.3.7 bullet c now literally means that exactly after the min. period samples need to be destroyed. Most labs destroy on a regular basis, but not on a daily basis.

5.3.7.1: thank you for the change!

Suggested changes to the wording of the Article

5.3.7 c) Samples shall be stored at minimum for the applicable minimum storage periods defined in Table 1 below after reporting all Sample results (“A” and “B”, if applicable) in ADAMS and may be stored for a maximum of ten (10) years after the Sample collection date, unless Sample direct identifiers are removed for secondary use of the Sample(s) (see Article 5.3.8.2).

Norwegian Doping Control Laboratory SUBMITTED

Yvette Dehnes, Laboratory Director (Norway)

Other - WADA-accredited Laboratories

General Comments

Table 1: clear and good.

Storage times a problem, however, due to storage limitations in many laboratories:

- 3 (or perhaps 4), but not 6 months for urine samples

- reconsider -70 for all serum samples stored > 3 months.

Reasons for suggested changes

- Space issues for many laboratories when temp.storage of urine samples increase from 3 to 6 months.

- Also the "-70 or lower" for storage of serum samples > 3 months is now an issue, due to the increasing number of serum samples. These freezers take up a lot of space.

LSI Medience Corporation

SUBMITTED

Masato Okano, Director/Dr. (Japan)

Other - WADA-accredited Laboratories

General Comments

Table 1:

The mandatory urine storage period has been extended to six months.This change will impose costs on analysis laboratories.This should be reconsidered, or it should be made possible to charge storage fees to TAs, etc.

One advantage of DBS samples is that they take up less space, but they have a storage limit of 3 months. DBS may be able to provide longer storage times for analytical laboratories.

Regarding "Not analzed DBS samples", referred to in Art. 5.3.2.d, they are stored for 3 months? Or should it be stored longer?

Swiss Laboratory for Doping Analyses

SUBMITTED

Tiia Kuuranne, Director (Swizerland)

Other - WADA-accredited Laboratories

General Comments

Table 1. Minimum Sample Storage Periods

serum samples: -70□C or less for more than 3 months

5.3.7.2

iii) Transport to external facilities: The laboratory shall reseal the samples only in case if not within the immediate supervision of Laboratory staff member throughout the transfer and if the LTS facility is a part of the accredited area of the laboratory.

Reasons for suggested changes

Knowing that the number of serum samples is continuosly increasing, the storage at deep frozen conditions is probably not manageable in all laboratories. Please, re-consider.

Laboratorio de Control de Dopaje de Madrid

SUBMITTED

Gloria Muñoz, Lab Manager (Spain)

Other - WADA-accredited Laboratories

General Comments

Storage of samples. 6 months for urine. Can this be discussed? Storage capability is limitated, We need to invest room in our facilities and resources (fridges, chambers…) and now for free three moths more.

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

General Comments

5.3.7 Storage of samples. 6 months for urine, too long and not all labs have enough storage
In addition, if samples are stored longer than 6 months it states the lab shall inform the responsible TA. Some lab has a process in place where it disposes by trays, it waits for all the samples in the tray to reach the 6 months before disposal of the whole tray. The lab should not have to contact the TA in this case.

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

6 months is a long period and will maybe be impossible if new infrastructure that cost a lot of money is put in place. It would be interesting to put the pressure on SCA and TA to enter their DCF in ADAMS more rapidly instead of asking labs to keep samples for a longer period of time. Although laboratories are discarding samples in a regular basis (weekly or bi-weekly), it is a nonsense to ask the laboratories to communicate with the TA as soon as samples are kept for a longer period than 6 months.

Article 5.3.8.2 (1)

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

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

A link should be made with section 5.2.5.1 RCs

Section 6.0 (1)

ONAU SUBMITTED
JOSE VELOSO, Antidoping Medical Director (Uruguay)
NADO - NADO

General Comments

IMPORTANT A laboratory may perform repeat or additional analyses on a Sample:—prior to the time that an Athlete is notified by a Results Management Authority (RMA) that the Sample is the basis of an allegation of an anti-doping rule violation, or—

after the case has been finally resolved.

Article 6.1 (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA are seeking clarity as to whether WADA must remove *Samples* for analysis, Further Analysis or QA purposes. As a solution, that this isn't always the case, SIA suggest the inclusion of "and/or" after b) Laboratory and *ABP* Laboratory Assessments.

Suggested changes to the wording of the Article

6.1 *WADA* Laboratory and *ABP* Laboratory Monitoring

WADA shall monitor the compliance and performance of *Laboratories* and *ABP* Laboratories through a series of monitoring and assessment activities, which include but

are not limited to:

a) The *WADA* EQAS Program.

b) Laboratory and *ABP* Laboratory Assessments, and/or

c) Removal of *Samples* for analysis, Further Analysis or Quality Assessment purposes.

Article 6.1.1 (2)

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

General Comments

Where is TD EQAS?

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Article 6.1.1 d) SIA suggest the removal of the word “substantial” as EQAS samples could be used appropriately to substantiate a claim. In this instance, Intelligence shouldn't need to be substantiated (i.e. proven) before it is investigated.

Article 6.1.2 (4)

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

General Comments

6.1.2.1 b) i. “insufficient R&D activities”

It is recommended making this more specific if possible.

Art. 6.1.2.2 Assessment Requirements

Where is TD PERF?

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA suggest that the drafting team consider the removal of the following for clarity:

6.1.2.1 a iv- Remove "imposition". Is it more likely to be for a removal than imposition?

6.1.2.1 b ii- Remove "and the reasons for the assessment". There may be circumstances when it is not appropriate to share the reason, and the removal of the wording doesn't prevent the sharing the reasoning but will ensure there is clarity that it is not a mandatory requirement.

Reasons for suggested changes

SIA suggests there may be circumstances where it is not appropriate to share the reason a laboratory has been assessed and suggests the Drafting Team reword this provision accordingly.

DoCoLab - UGent SUBMITTED
Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

General Comments

It is good to have some more information on WADA assessments. However, for reasons of flexibility, I would also have put these in a TD.

Further:

6.1.2.2. ....WADA shall inform the Laboratory or ABP Laboratory, in advance, of the WADA Assessment Team composition, as well as the invited Accreditation Body observers (if applicable).

Suggested changes to the wording of the Article

6.1.2.2. ....unless deemed necessary, WADA shall inform the Laboratory or ABP Laboratory, in advance, of the WADA Assessment Team composition, as well as the invited Accreditation Body observers (if applicable).

Reasons for suggested changes

This would allow unnanounced visits in case of e.g. fraude at the lab

INRS - Centre AFSB (laboratoire de controle du dopage) SUBMITTED
Jean-Francois Naud, Professor and Deputy Director (Canada)
Other - WADA-accredited Laboratories

General Comments

It would be important for WADA auditors to be forced to undergo auditor training before visiting the labs. IFurthermore, it is unacceptable for NCs to be added outside of what was observed by the auditors during the audit period. Without auditor training, this section should not mention that it is an ISO 17025 assessment.

Article 6.1.3 (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Comment to 6.1.3.a SIA suggest that the drafting team consider including wording that stipulates that WADA shall inform the TA of the movement of *Samples* unless there are exception circumstances. I.e. this would include the investigation of NADOs outlined in article 6.1. This would mean that TA's, as the owners of the *Samples*, should be informed of any movement of Samples.

Article 6.2 (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

See SIA comments regarding LGs in relation to the word "shall". Consider the use of the word "should"

Suggested changes to the wording of the Article

LG's are not mandatory and thus "shall" is not appropriate.

Section 7.0 (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Article 7.5.1- SIA recommend that the drafting team consider including wording that would make clear that a Suspension of a Laboratory be lifted before the end of the 6 months outlined in Part IV Recommendation – *Article A-7*. Additionally, this should be made clear in *Article A-7* that the Suspension is lifted at the time of the decision by the Chair of the WADA Executive Committee to accept the DC's recommendation that the Laboratory shall maintain its WADA accreditation or has WADA has determined the Laboratory has satisfactorily corrected, documented and reported any non-conformance.

Additionally, SIA acknowledge that the process must ensure Laboratories are compliant to maintain the integrity of the anti-doping system, in the same fashion ADOs are. However, we also acknowledge that Laboratories should be an active partner with WADA when agreeing to conditions set out by WADA.

Article 7.1.1

Article 7.1.1.1 (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

Article 7.1.1.1 l), SIA agree that the reporting timelines are critical. However, SIA suggest that the drafting team consider providing examples for what "serious" non-compliances are or define it. Currently, the drafting of article 5.3.6.4 doesn't align with article 7.1.1.1 i) as it stipulates under 5.3.6.4 c) that the reporting of "Ä" *Samples* should occur in ADAMS within twenty (20) days of receipt of the *Sample.* It is noted that the Laboratory are required to inform the TA in writing of any delay in the reporting of the "A" Sample results, including applicable reasons. This could be used to support what "serious" non-compliances are.

Article 7.1.1.2 (1)

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

General Comments

Art. 7.1.1.2 Suspension of Accreditation and ATR

Where is ATR defined; this is the first occurrence. Recommend putting in full on first use (Analytical Testing Restriction).

Article 7.1.2

Article 7.1.2.1 (2)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

7.1.2.1 f & g: SIA suggest that the drafting team review the omission for stipulating how many false AAFs and false negative AAFs are required to be deemed as "repeated". These numbers are stipulated in 7.1.1.1 f).

Additionally, SIA suggest that the drafting team review 7.1.2.1 i) and l) and whether they can be combined.

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

General Comments

7.1.2.1.This whole list should be cross-referenced with the future TD PERF, as soon as it will be ready.

Article 7.2

Article 7.2.3 (1)

International Testing Agency SUBMITTED
International Testing Agency, - (Switzerland)
Other - Other (ex. Media, University, etc.)

General Comments

7.2.3(d)

Consider clarifying who should (or could be asked by WADA to) bear the cost of transferring the samples.

Annex A (1)

Sport Integrity Australia SUBMITTED
Andrew McCowan, Assistant Director Project Management Office (Australia)
NADO - NADO

General Comments

SIA suggests removing reference to Annex C as this no longer exists in the new ISL update.