

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

Showing: All (62 Comments)

Concept #1 – Further Details of Requirements for WADA Laboratory Accreditation/Approval for the Athlete Biological Passport (ABP) (7)

Council of Europe

Council of Europe, Sport Convention Division (France)

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

SUBMITTED

§1 Robust anti-doping programs in host country of applicant laboratory for WADA accreditation.

Supported

Suggest that the ISL states, for example, “a country wishing to support an anti-doping laboratory for WADA accreditation will be expected to have a well-developed anti-doping program with knowledge and experience of, at least, Test Distribution planning, Sample collection and Results Management”

§2 Review of initial WADA accreditation fee.

Supported

Suggest that the ISL should state what the fees are to cover and that a candidate laboratory will be advised of the cost before initiating the accreditation process.

§3 Candidate Laboratory. Clearer definition of the different stages in the three-year timeline for candidate laboratories

Supported

Suggest including “Candidate and Probationary laboratory” in Chapter 3 of ISL “Definitions and Interpretations”.

§4 Probationary Laboratory. Time limit for probationary laboratories

Supported

§5 Requirement for Laboratories to implement a Research & Development (R&D) Programme

Supported

Essential for laboratory to have a documented research strategy together with a resourcing and information sharing plan (ethics, staff, instrumentation, space, intellectual property, etc.).

§6 Minimum number of annual samples.

Supported

Suggest that numbers should be by matrix, e.g. an ABP blood Sample should carry less weight than a full screen urine analysis.

COCOM

Stephanie Sirjacobs, Legal adviser (Belgium)

NADO - NADO

SUBMITTED

La première mesure a du sens et est à encourager.

Organizacion Nacional Antidopaje de Uruguay

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

SUBMITTED

No comments

Anti-Doping Sweden

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

SUBMITTED

ADSE supports that the requirements are expanded and clarified.

Sport Integrity Australia

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)
NADO - NADO

SUBMITTED

Overall, we support the views of the Drafting Team that additional details are needed to further clarify the requirements associated with the different stages of the accreditation/approval processes.

Our comments in relation to the specific proposals are outlined below.

Robust anti-doping programs in host country of applicant laboratory for WADA accreditation

- We support the principle that a robust national anti-doping program provides a strong foundation for the establishment of a new laboratory and in turn promotes the local anti-doping program. However, we are concerned this may result in a 'chicken and egg' scenario where it is difficult for a country to achieve a robust program in the absence of a 'local' laboratory. A robust program requires the effective collection and analysis of urines, bloods and ABP samples. As some of these processes are time limited, they are dependent on utilising a 'local' laboratory. Where there is not a 'local' laboratory, the required collections and analysis cannot be undertaken, and the country will not be able to demonstrate the program is robust.
- We suggest this problem could be resolved by defining a robust anti-doping program taking into account these limitations by focusing on other criteria, such as the resources the government dedicates.

Review of initial WADA accreditation fee

- We agree with the proposal to consider a clearer definition of the costs needed or involved in the accreditation process prior to WADA accreditation or approval. For transparency, we suggest including information on what the fee covers.

Requirement for Laboratories to implement a Research & Development (R&D) Program

- We agree with this proposal.

Minimum number of annual samples

- We agree in principle with the proposal to make revisions to incorporate the complexity and relevance to perform analyses in different matrices (e.g., blood and dried blood spot (DBS)) as this will increase the robustness of the process.
- However, we would be interested in what the proposed revisions to the current benchmark would be.

Analytical Testing Restrictions (ATR)

- We support the concept of invoking a suspension on the laboratory before revoking the laboratory's accreditation. However, we suggest its application should be selective to the specific Analytical Testing Procedure(s) or the analysis of a particular class(es) of prohibited substances or prohibited method, for which the ATR is issued rather than suspending the whole laboratory operation.

Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand)

NADO - NADO

SUBMITTED

Clearer framework for Research and Development

We support the concept, including a less blunt approach to lab investment into research that can benefit anti-doping.

Minimum number of annual samples

We have no comment on the concept but do note that some laboratories (e.g., Australia) service small remote countries (e.g., New Zealand) that would encounter difficulties with timely blood analysis if that laboratory was unable to meet the benchmark. Accordingly, there should always be some provision for sensible flexibility by WADA in these mandatory requirements.

ABP approval

We support the concept. This ABP approval may assist with the tight timeframes of the Blood Stability Score.

International Testing Agency

International Testing Agency, - (Switzerland)

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

SUBMITTED

Robust anti-doping programs in host country of applicant laboratory for WADA accreditation: If a laboratory gets written letters of support from ADOs and then the laboratory does not receive sufficient number of samples, these ADOs who initially gave their support, but then did not send sufficient number of samples should face consequences (e.g. WADA Approved Laboratory in Panama).

Minimum number of annual samples: The minimum number of annual samples should be re-assessed and the variety of sample types and types of analyses (e.g. EPO, IRMS, hGH...) should also be taken into consideration. Indeed, if a laboratory performs few annual specific type of analyses, then this laboratory cannot be considered as a good laboratory with comprehensive knowledge and expertise.

Concept #2 – WADA-specific Analytical Testing Procedures (4)

Council of Europe

Council of Europe, Sport Convention Division (France)

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

SUBMITTED

Supported

Organizacion Nacional Antidopaje de Uruguay

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

SUBMITTED

No comments

Anti-Doping Sweden

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

SUBMITTED

Supported

Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

SUBMITTED

We support the concept. It is prudent that the lab can prove analysis procedures before applying to WADA for accreditation.

Concept #3 – Monitoring of Accreditation Status : Disciplinary Proceedings (3)**Council of Europe**

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

SUBMITTED

Supported

A meaningful dialogue with WADA Lab EAG and the Laboratory is considered helpful. Suggest adding to ISL a requirement to state which ISL clauses have been violated by the Laboratory.

Organizacion Nacional Antidopaje de Uruguay

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

SUBMITTED

No comments

Anti-Doping Sweden

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

SUBMITTED

Supported. A meaningful dialogue with WADA Lab EAG and the Laboratory is considered helpful. Suggest adding to ISL a requirement to state which ISL clauses have been violated by the Laboratory.

Concept #4 – Secondary Use of Samples : Research and Quality Assurance (11)**Sport NZ**

Jane Mountfort, Principal Policy and Legal Advisor (New Zealand)
Public Authorities - Government

SUBMITTED

This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.

Sport NZ is concerned with the proposal to allow for the use of athlete samples without consent.

The ethical significance of informed consent resides in its role in safeguarding athletes' interests, preserving the confidentiality of personal information, upholding subject autonomy, delineating research and societal interests, and sustaining public trust in researchers and institutions.

Keeping samples in case of undefined future analysis therefore carries a risk of misuse of the sample and data associated with it, which could be disproportionate to the benefit.

Accordingly, Codes of Ethics for research in New Zealand require consent to use personal information for clearly defined research purposes and Ethics Committees that consider applications for humans or human tissue research rarely permit sample storage beyond the defined research purposes.

For these reasons, Sport NZ is concerned that WADA risks losing legitimacy amongst its stakeholders if its ADOs and research partners move to a default position of retaining samples for unspecified future analysis and treating sample use of QA/QI without informed athlete consent.

In reaching this view Sport NZ has taken into account a Māori (indigenous to New Zealand, Aotearoa) perspective including consideration of Tikanga (process and procedures). The proposal to reuse human tissue samples for a secondary test, enabling WADA to stay current with technology, QA and QI purposes, and contributing to the principle of 'equity' without obtaining informed consent, poses breaches and raises ethical concerns for Māori.

Tikanga is a set of customs developed to enable a way a living that protects, provides, and enables a safeguard of practices for the well-being of individuals. Human tissue is sacred ("taonga") meaning that it must be safeguarded under which its use for non-cultural purposes is limited to protect its essence of life ("mauri") and availability for the next generation. Māori therefore require custodians of human tissue to exercise a duty of care to protect its mauri and avoid its misuse, which can affect both the individual in question, their whānau (extended family) and community.

The concept of restricting future access to samples, seeking consent for tissue use in unspecified research, and transferring ownership to the ADO restricts Māori from exercising their right of self-determination over their personal taonga. This is a right protected under te Tiriti o Waitangi (the Treaty of Waitangi), which is part of the constitutional arrangements of New Zealand.

Sport NZ notes that indigenous communities have historically been subject to unethical conduct, inadequate communication, disregard for cultural and spiritual beliefs, and a failure to acknowledge the interests and priorities of Indigenous communities. These factors have created mistrust between researchers and indigenous communities.

We consider that any proposal to override the requirement for informed consent would need to meet a very high threshold of public benefit, supported by compelling evidence, and benefit to the athletes providing the samples. We are not yet satisfied that these benefits are made out.

Moreover, we require evidence supporting the claim that current samples made available for QA/QI/resampling with informed consent are insufficient for the purposes in question. We would also seek engagement on the depth of information proposed to be provided to athletes when their consent to future use is sought.

Finally, Sport NZ seeks that freedom be afforded to NADOs to make culturally appropriate information available on these matters prior to seeking consent.

Council of Europe

Council of Europe, Sport Convention Division (France)

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

SUBMITTED

Supported

COCOM

SUBMITTED

Stephanie Sirjacobs, Legal adviser (Belgium)
NADO - NADO

Ok s'il s'agit bien de conseil et pas d'obligation, mais attention, impact RGPD : nécessité de disposer de l'avis de l'Autorité de protection des données dans de nombreux pays européens.

Organizacion Nacional Antidopaje de Uruguay

SUBMITTED

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

No comments

Anti-Doping Sweden

SUBMITTED

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

Supported

Sport Integrity Australia

SUBMITTED

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)
NADO - NADO

We agree with this proposal.

We note the work of the ISL Drafting Team in this regard, is directly related to the work of the other Drafting Teams that are also tasked with looking at the use of samples and data for research and other activities, and the privacy considerations that arise.

Any amendments will need to be closely considered and properly aligned with policies of seeking consent, personal information, and privacy protection.

Drug Free Sport New Zealand

SUBMITTED

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

We support this concept, so long as athletes are sufficiently consulted and provide informed consent, and anonymity can be ensured when the sample is used for research and quality assurance/improvement.

The Code and ISPPPI should also be reviewed to reflect any changes in the ISL and ensure consistency.

CHINADA

SUBMITTED

MUQING LIU, Coordinator of Legal Affair Department (CHINA)
NADO - NADO

Recognizing the importance of research in the fight against doping, we support the review and update of ISL for the use of doping control samples. The research on prohibited substances and their metabolic patterns is highly important for testing, investigations and results management conducted by ADOs, so it heavily relies on the support of WADA-accredited laboratories. However, certain concerns have been raised by some of these laboratories when ADOs request their involvement in such research activities without explicit authorization under Code Article 19. Therefore, it is suggested that Articles 6.2, 6.3 and 19 in Code and the relevant articles in ISL be amended to encourage and support anti-doping research among ADO and Laboratories.

International Testing Agency

SUBMITTED

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

The Testing Authority should be informed that samples are used for QA/QI activities and ideally which ones.

National Anti-Doping Laboratory, Beijing Sport University

SUBMITTED

Lisi (Leo) Zhang, Lab Manager (China)
Other - WADA-accredited Laboratories

The concept of clarifying more precise requirements and/or effective integration mechanism for R&D activities is very much welcome. But please also take into consideration that a determined percentage of budget allocation (currently 7%) could be quite useful for laboratories during their negotiation with host organizations regarding financial support.

LSI Medience Corporation

SUBMITTED

Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

The use of past AAF or ATF samples collected from athletes as a reference collection in the TDIDCR must be prohibited. A description is required to avoid misunderstanding that it is part of quality assurance.

Concept #5 – Clarification of Further Analysis (8)**Council of Europe**

SUBMITTED

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

Supported

A review of when further analysis is permitted or needed would be of benefit.

Organizacion Nacional Antidopaje de Uruguay

SUBMITTED

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

No comments

Agence française de lutte contre le dopage

SUBMITTED

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

Cette proposition est intéressante mais ses conséquences doivent impérativement être prévues dans les autres documents pertinents de l'AMA pour assurer la cohérence des textes. En matière de gestion des résultats, il est notamment nécessaire, au niveau du standard international voire du Code, de prévoir les règles de cumul des sanctions si un même échantillon peut donner lieu à plusieurs RAA consécutifs alors que la première gestion des résultats peut être achevée.

Anti-Doping Sweden

SUBMITTED

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

Supported

Sport Integrity Australia

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)
NADO - NADO

SUBMITTED

We support this concept but believe greater clarity is required.

We believe the athlete ought to be aware that further analysis is or may be being conducted during the notification/charging. Additionally, we would be interested in how this would work with B samples.

If this further analysis is automatically triggered by initially suspicious results from analyses of samples based on the biological profile, we recommend the financial burden on ADOs be considered.

Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

SUBMITTED

We support this concept given that these samples have been highlighted as suspicious and therefore should attract further justified and consistent analysis.

We propose that the use of this approach be monitored to ensure that it doesn't become a significant and unexpected financial burden for not well resourced Testing Authorities.

UK Anti-Doping

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

SUBMITTED

We support the proposed clarification re: further analysis – however, it would be essential to have a clear demarcation between what is considered “*part of the ongoing analytical testing process*” and at what point (and in what situations) it might become “*Further Analysis*”. For example, would Specific Analysis (e.g. EPO) arising from an APMU recommendation be “*ongoing analysis*” or “*Further Analysis*”?

International Testing Agency

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

SUBMITTED

We support this review and new concept. “Confirmation procedures” should be clearly defined and the types of confirmation procedures should be listed in the ISL.

Concept #6 – Assuring the Validity of Analytical Results (8)

Council of Europe

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

SUBMITTED

Supported

Agreed, subject to the details which are awaited in the next round but the ISO 17025 requirements are sufficient and duplication is undesirable. Additional ideas included in the comments/suggestions section.

Organizacion Nacional Antidopaje de Uruguay

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

SUBMITTED

No comments

Anti-Doping Sweden

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

SUBMITTED

Supported. The ISO 17025 requirements are sufficient, and duplication is undesirable.

Sport Integrity Australia

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)
NADO - NADO

SUBMITTED

We support the ISL Drafting Team to provide an improved description of the quality control procedures to be implemented by laboratories. We support continuous improvement for the purpose of improving the conformity, accuracy, and reliability of analytical methods.

Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

SUBMITTED

We support the concept.

International Testing Agency

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

SUBMITTED

We agree with the review.

National Anti-Doping Laboratory, Beijing Sport University

Lisi (Leo) Zhang, Lab Manager (China)
Other - WADA-accredited Laboratories

SUBMITTED

A dedicated document such as Guideline or Technical Note which describes QC-chart requirements is recommended.

LSI Medience Corporation

Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

SUBMITTED

There is a need to review the prohibited substances and markers that laboratories can query for TUEs during PAAF as described in 5.3.6.2.2. Time and cost of having a confirmation analysis performed by a laboratory and processed by a results management authority even though an athlete holds a TUE should be reduced.

Concept #7 – Update of WADA EQAS (7)**Council of Europe**

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

SUBMITTED

§1 Update ISL Article 6.0 to comply with ISO 17043: 2023 for proficiency testing providers

Strongly supported.

This must not prevent educational samples of new analytes, not available to ISO 17043: 2023 accredited proficiency testing providers, from being circulated to Laboratories. Suggest excluding Educational EQAS from this requirement.

§2 Revise distribution of WADA EQAS modalities (i.e. number of rounds/samples/type of EQAS)

Supported

Suggest increasing educational (double blind) samples and reducing single blind in favour of more double-blind samples.

§3 Introduce a DBS EQAS program into the ISL.

Supported

§4 Review penalty points in the WADA EQAS

Supported

The proposal from the World Association of Anti-Doping Scientists with respect to a revision of the penalty points is supported as well as an improvement approach rather than a penalty approach. More details available from the secretariat (sport.t-do@coe.int), because pictures and tables cannot be inserted here.

Organizacion Nacional Antidopaje de Uruguay

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

SUBMITTED

No comments.

Anti-Doping Sweden

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

SUBMITTED

Supported

Sport Integrity Australia

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)
NADO - NADO

SUBMITTED

We agree with the proposal for the ISL Drafting Team to consider proposing revisions to the distribution of WADA EQAS modalities, and to integrate the introduction of a DBS EQAS program into the ISL.

Additionally, we agree the ISL Drafting Team consider reviewing the allocation of penalty points in the WADA EQAS based on the revised EQAS sample distribution and application of a new Bayesian statistical approach for evaluation of Laboratory EQAS performance.

We also suggest the Drafting Team consider the logistics of different DBS devices and different testing menus across laboratories.

Drug Free Sport New Zealand

SUBMITTED

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

We support the concept, particularly where the process is made more efficient and cost effective.

We note that DBS EQAS samples may be difficult due to the varied analysis and range of devices.

International Testing Agency

SUBMITTED

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

We agree with the proposition.

There are multiple ways to improve the cost efficiency of quality controls samples/material. One of them is to use the same daily/weekly/monthly QC lot and share the data in real time (need to use an IT solution: e.g. [Unity Software Solutions - QCNet](#) | [Bio-Rad](#)) with all labs using the same QC lot. In that way, it is possible to estimate precision, bias, and stability of the quality control samples/material. EQAS samples can then be decreased significantly without any impact on the quality of the laboratory.

LSI Medience Corporation

SUBMITTED

Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

ABP blood parameters (as CSCQ) and ABP urine steroid profile (as standard WADA EQAS) are well-monitored. ABP blood steroid and ABP Endocrine should be considered as well as DBS analysis.

Concept #8 – Laboratory Right of Appeal : Evaluation of Non-Conformities identified during Routine Analysis (5)**Council of Europe**

SUBMITTED

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

Supported

Organizacion Nacional Antidopaje de Uruguay

SUBMITTED

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

Must be fundamental that the Lab needs more space and time to appeals

Anti-Doping Sweden

SUBMITTED

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

Supported

Sport Integrity Australia

SUBMITTED

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)
NADO - NADO

We agree that the ISL Drafting Team consider adding an Article to the ISL that addresses a laboratory's right of appeal against decisions that may lead to the assignment of penalty points if it will further strengthen the process of

laboratory performance evaluation, while maintaining fairness and impartiality.

Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

SUBMITTED

We support the concept.

Other Comments / Suggestions (9)

Council of Europe

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

SUBMITTED

Improvements aimed at reducing the opportunity to challenges by making the following modification to the ISL:

Comment #1 - 5.3.3.2 Sample Splitting Procedure

Requirement on Testing Authority to meet a seven-day deadline. Suggest defining in ISL what action is needed when deadline has been passed.

Comment #2 - 5.3.4 Initial Storage and Sample Aliquoting for Analysis

It is paradoxical to treat urine and blood differently requiring urine to be poured out of the bottle.

Suggest removing this very specific aliquoting requirement from the ISL. Perhaps amend to state more generically that Laboratories shall have procedures to avoid Sample cross-contamination although this is already an ISO 17025 requirement.

Comment #3 - 5.3.8.4 Reporting Test Results

Review and amend ADAMS Test Result print out to be ISO Compliant

Comment #4

The Laboratory should be allowed to downgrade an AAF to an ATF so that additional investigation and possibly further analysis will be undertaken before prosecuting an athlete when the Laboratory finds anomalous or paradoxical results such as an atypical metabolic profile. This will save unnecessary legal costs of cases that may be dismissed because of atypical or paradoxical analytical results.

Comment #5 - Estimate of concentration only with A-Sample

See ISL 5.3.6.2.3 "B" Confirmation Procedure pg 98: *No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) is necessary.* Suggest changing to:

No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) shall be performed.

Comment #6 - Informing Laboratories on TUEs (also requested by the TUE Revision Group)

Add a clause to ISL to ask / require RMAs to advise Laboratories, or allow Laboratories to find this from ADAMS, when they have a Sample from an Athlete with a TUE so that no costly confirmatory analysis is required, i.e. rather than waiting for the Laboratory to ask the RMA. The Laboratory may still be asked / required to provide an estimated concentration from the initial test procedure for the TUE review.

Comment #7 - Substances of Abuse (see also in context of the Code Concept 2)

The WADA Code 2021 deals with Substances of Abuse differently from other Prohibited Substances recognising that these Substances are frequently abused in society outside of the context of sport.

Article 4.2.3, Article 4.2.4 and Article 10.2.4 in particular apply to Substances of Abuse.

A large number of cases involving cocaine under the Substances of Abuse category involve the admission by the Athlete of doses of cocaine of 1 gram or more. These doses, usually taken together with alcohol represents an actual health risk to the Athlete as stated in Article 4.3.1.2 as grounds for making cocaine a Prohibited Substance. "4.3.1.2 Medical or other scientific evidence, pharmacological effect or experience that the Use of the substance or method represents an actual or potential health risk to the Athlete". Furthermore, often these doses are taken sufficiently close to the Competition period that, whilst having been taken Out-of-Competition still result in the Athlete having concentrations of cocaine in their bodies in excess of the 10 ng/mL guideline concentration (Substances of Abuse Under the 2021 World Anti-Doping Code - Guidance Note for Anti-Doping Organizations, 2021-01-11) indicative of In-Competition use.

Cases typically focus on whether the Athlete took the cocaine before 11:59 pm on the day before the Competition or one minute later; this is a situation that often cannot be scientifically decided enabling the Athlete to obtain the reduced sanction available for Substances of Abuse. Concept #2 of the Code Concepts 2027 may address this point sufficiently well and is to be commended if that is the case:

To link the temporal aspect of Article 10.2.4 not to the Code definition of "In-Competition" but rather to an adequate fixed period between ingestion and the actual competition in question (to be defined taking into account the potential doping effect). However, it may be better to consider a maximum concentration rather than a minimum time.

Recommendation

WADA is invited to consider making the guideline on cocaine stronger so that it becomes a rule and to review the World Anti-Doping Code to determine whether any amendment to the articles relating to Substances of Abuse may be needed.

Anti-Doping Sweden

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

SUBMITTED

Comment #1- Estimate of concentrations only with A-samples

See ISL 5.3.6.2.3 "B" Confirmation procedure pg 98: *No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) is necessary.*

Suggest changing to:

No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) shall be performed.

NADA

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

SUBMITTED

NADA Comment With regard to the growing impact of intelligence & investigation, we suggest to allow laboratories to forward any information they have to the RMA with I&I capacities in connection with a sample by giving the topic more room in the ISL.

Under the current ISL there are just few regulations with respect to results which do not automatically lead to an

ATF/AAF:

While Art. 5.3.8.4 (reporting test result) states that the lab should report an irregularity, these irregularities seems to be of a technical nature and are part of TDs. Art. 5.3.6 opens the possibility to add further analysis for non-prohibited substances or methods on request of a RMA or hearing body.

However, it feels that a lot of information (such as substances under threshold (e.g. THC), EPO pictures with room for interpretation and/or missing abbreviating second opinions, IC-only-Substances..) keeps being "stuck" with the labs as the reporting is not mandatory according to any TDs. This information can be used for intelligence reasons and/or smart follow-up testing and may contribute immensely to information which may already be available from other sources.

It seems that the laboratories are unsure if they are allowed to hand out such information. To ensure that ADOS can use ALL AVAILABLE information in its entirety, this should be made clearer and explicitly mentioned in the ISL in connection with the (maybe even in connection with the ISII). The cooperation with the laboratories and their expertise is one of the corner stones in I&I work.

Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand)
NADO - NADO

SUBMITTED

Article 5.3.6.2.3 B Confirmation procedure

We note the requirement that the Testing Authority or Result Management Authority should inform the Laboratory in writing within 15 days following the reporting of an A sample adverse analytical finding by the laboratory that the B Confirmation Procedure shall be conducted.

This requirement should be reconsidered as that timing will not always align with the result management process and the athlete's right to request the B Confirmation Procedure to be undertaken.

CHINADA

MUQING LIU, Coordinator of Legal Affair Department (CHINA)
NADO - NADO

SUBMITTED

On B sample Analysis

An ADRV under Code Article 2.1.2 can be established by any of the following: the presence of a prohibited substance or its metabolites or markers in the athlete's A sample where the athlete waives analysis of the B sample and the B sample is not analyzed; or, where the athlete's B sample is analyzed and the analysis of the athlete's B sample confirms the presence of the prohibited substance or its metabolites or markers found in the athlete's A sample. The question is, if the results of the A sample and the B sample do not match, does it prove that the athlete did not commit an ADRV?

According to Code Article 7.4.5, if a provisional suspension is imposed based on an A sample AAF and a subsequent B sample analysis does not confirm the A sample analysis, then the athlete shall not be subject to any further provisional suspension on account of a violation of Code Article 2.1. We have noted, however, that some athletes have been asserted for ADRVs and imposed periods of ineligibility for cases where the A and B samples do not test the same, such as CAS 2018/A/6069 (André Cardoso v. Union Cycliste Internationale), and the Czech triathlete Vojtech Sommer's positive case for EPO. Considering that there have been a number of cases with inconsistent findings between A and B samples, which have happened to several laboratories in recent years, we suggest that the comment to Code Article 2.1.2 or the International Standard for Results Management clarify how to address these cases.

UK Anti-Doping

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

SUBMITTED

Sample Volume and Long-Term Storage (ISL Article 5.3.8.4)

Upon completion of Sample analysis, we propose that Laboratories are required to state the remaining volume of a Sample when uploading the result in ADAMS and that this should be updated following each additional analysis undertaken. This will assist ADOs in making decisions on which Samples to place in long term storage and/or conduct further analysis on. Having this information within ADAMS would save time and money when making decisions related to storage, further analysis and reanalysis. We understand this will have an impact on Laboratory workload but will be important in the functionality of the Long-Term Storage module of ADAMS which will be further developed to include further analysis requests in the future.

Storage of Samples (ISL Article 5.3.11.1(a))

We propose that the minimum timeframe for Laboratories to store Samples is extended from 3 months (to at least 4 or 5 months). This will facilitate the meaningful assessment by ADOs of Samples for Sample tank storage, in circumstances where ADOs need more data/information to support Sample tank decisions, e.g. notable performance improvements may not be known until the completion of an Athlete's season, at which point, earlier and higher risk Samples may have been discarded. It could also support ABP programmes where retrospective analysis is required on earlier Samples collected from an Athlete and minimise the risk of those Samples having been discarded.

"A" Confirmation Procedure (ISL Article 5.3.6.2.2)

Given that there is frequently expressed concern about the cost of Laboratory analysis, it would be helpful to reduce the amount of unnecessary confirmatory analysis (i.e. where the result aligns with a relevant and valid TUE). It is acknowledged that this could be achieved in a variety of ways. UKAD's preference is that the ISL reverts to provisions at Article 5.3.4.5.4.7.3 of the 2019 ISL – specifically that Laboratories may contact the Testing Authority to enquire whether a TUE exists for any substance declared by the Athlete on the DCF. Where a TUE exists, a review should then be conducted confirming whether the screening concentrations are consistent with the terms of the TUE (and if so, the confirmatory analysis would be cancelled).

International Testing Agency

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

SUBMITTED

- It may be useful for the RMA process and the athletes' understanding in the context of an AAF RM process to split the ISL into two distinct documents: one with the content of the ISL article 5 (analysis, B-sample, etc) and the other which pertains to the accreditation process, EQAS to facilitate the access to this document to athletes and RMA.

- In our experience, laboratories do not report non-conformities in a consistent manner and this creates a lot of confusion when dealing with non-conformities. This should be reviewed and a process similar to the TUE Enquiry Form would greatly streamline the process and foster harmonization.

- It should be mandatory for WADA Accredited Laboratories to provide a list of methods and reference numbers/acronyms to the Testing Authority so there can a better understanding of the type of analyses performed on the samples. Moreover, the laboratory should disclose to the TA the exact list of targeted compounds (parent compound + list of metabolites). This would be useful for intelligence purposes and also greatly inform the TA's decision-making when it comes to further analysis of samples in long term storage.

- WADA should have a reference database for each WADA Accredited Laboratory with the LOQ, LOD for each test method, each targeted compound and updated. The TA should have a right to access this information, upon request, if duly justified.

National Anti-Doping Laboratory, Beijing Sport University

Lisi (Leo) Zhang, Lab Manager (China)
Other - WADA-accredited Laboratories

SUBMITTED

- Considering the nature of DBS samples, it is recommended to revise provision 5.3.6 allowing laboratories not to analyze DBS samples upon reception, but to store the samples for further intel/information (SP results, APMU recommendations) initiating the analysis procedures.
- the timing of “B” Confirmation Procedure is essential especially for those substances known to be unstable. It is recommended to set up a deadline of B confirmation (e.g. 3 months after A sample results reported).

Catalonian Antidoping Laboratory Fundació IMIM

Rosa Ventura, Laboratory Director (Spain)

Other - WADA-accredited Laboratories

SUBMITTED

Point 4.4.2.9. Providing letter(s) of support.

Comment:

WADA knows the number of samples analyzed by each laboratory (Anti-doping Testing Figures). If an accredited laboratory analyzes more than 3.000 samples/year for many years, it should be not necessary to provide letters of support to maintain accreditation. It would be only needed when the number is below 3000 samples/year.

For laboratories in process of accreditation, the situation is different . They need to provide the business plan.

The proposal in this section 4.4.2.9. is to eliminate the need to provide the letters of support if the lab has analyzed more than 3000 samples/year according to Anti-doping Testing Figures.

The propopsed text for the article is as follows:

Letter(s) of support, as described in Article 4.1.3, from *Signatories* shall be provided to *WADA* confirming three (3) years of support when the number of samples analyzed by the laboratory is below 3000 samples/year, according to Anti-doping Testing Figures, or unless otherwise approved by *WADA*.

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

Bram van Houten, Policy adviser, Ministry of Health, Welfare and Sport (Netherlands)
Public Authorities - Government

SUBMITTED

Concept #1 – Further Details of Requirements for WADA Laboratory Accreditation/Approval for the Athlete Biological Passport (ABP)

The number of samples is not a good indicator of a robust anti-doping programme, as it puts smaller nado's and smaller nations at a disadvantage. This requirement should therefore be stricken and rethought.