INTERNATIONAL STANDARD FOR LABORATORIES (ISL) Consultation - Consultation to all WADA stakeholders

Showing: **All (178 Comments)**

PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS (6)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

Other Suggestions:

The UCI would support the adoption of a more reader- and user-friendly numbering system for the ISL articles.

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

The proposed review constitutes a major change on the current version of the ISL, WADA should consider an additional round of comments and also reduce to the minimum changes that need to be made now.

Remaining changes should be aligned with ongoing discussions relating to the Code Revision and also to the work of the governance working group. Anticipating some changes, could oblige some countries to change legal frameworks to answer to ISL changes and later change again those frameworks in order to reply to new Code requirements.

A reasonable period of time should be granted for entities to adapt to new requirements if they imply changes on the legal and regulatory framework of the institutions hosting anti-doping labs.

Polish Centre for Accreditation SUBMITTED
kamila skrzypczak-zbiciak, coordinator (Poland)
Other - Other (ex. Media, University, etc.)

1.

the number of the standard *ISO/IEC 17025* should be written without a hyphen (not *ISO/IEC-17025*)

International Paralympic Committee SUBMITTED
James Sclater, Director (Germany)
Other - Other (ex. Media, University, etc.)

General- There should be more transparency around what substance/metabolites each of the WADA-accredited laboratories is required to include in their methods. There is some concern that depending on what laboratory a sample arrives at, there could be different substance/metabolites in their menu.

It would be beneficial if labs reported more information regarding substances found, that do not produce an AAF. These could be threshold substances that are in lower concentrations or substances that cannot be confirmed.

SADoCoL SUBMITTED
Hanno du Preez, Operations Manager (South Africa)
Other - WADA-accredited Laboratories

PART ONE: INTRODUCTION, *CODE* PROVISIONS AND DEFINITIONS

Section 1 - Introduction, Scope and References

1.2.1 Technical Documents

Subject to the above, the analysis of *Samples* or the review of analytical data may occur based on a newly approved Technical Document immediately upon its approval.

Does this apply to EQAS results as well? If yes, please indicate this.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

This submission is provided on behalf of the World Association of Anti-Doping Scientists (WAADS).

During the previous consolation phase a number of issues were raised by the laboratories through WAADS. Some of the issues raised have been address in the revised version presented in this consultation phase. One of the main issues raised was the penalty points systems which was not addressed in the review process from the last consultation phase.

In order to have a effective anti-doping testing program all the stakeholders need to trust each other. It should be clarified that the laboratories provide analytical services to support WADA and related stakeholders to fulfil obligations according to the Code.

The laboratories shall be independent entities providing evidence for ADRV. The laboratories shall not be compared to cheating athletes, excluding cases of corruption, when it comes to sanctions for a laboratory, that is, a performance evaluation of a laboratory should first be a basis for improvement and not a sanction. Only when a laboratory has demonstrated that it is not capable of fulfilling the standard or corrective actions are not satisfactory, then the application of a point scale should be considered or a risk based assessment. Sanction shall not be immediately and automatically.

As it stand now the laboratories have many scenarios with no realistic chance of improvement without a sanction by WADA.

This is in clear contrast to the basic standard for analytical testing, ISO 17025.

This process of sanction being the only solution will create miss trust rather than open sharing of information between laboratories as well as between WADA. The greatest can be achieved by working together with common aims and understanding where help is required.

The laboratories aim to provide the anti-doping testing services as set out by the standards but continues improvement is always required and through WADA's support rather than sanctioning better outcomes will be achieved. A sanction, that is, suspension or revocation, should be a last resort because there is a fundamental issue which can not be address through a corrective action in a timely manner. If a laboratory has had a problem and the completed corrective action has been reviewed and accepted by the Laboratory Expert Group, the laboratory can not face a sanction 12 months after the fact through accumulation of points when the issue/s has been corrected.

In this consolation WAADS proposes a system in which a reviewed and accepted CAR will accumulate less points but we also encourage more timely action to be taken if there is a issue which can not be addressed by a laboratory in the short team irrespective of accumulated points. This will be more in standing with ISO 17025 and provide a system which will foster greater confidence in the anti-doping movement.

Section 1 - Introduction, Scope and References

1.1 The ISL and the World Anti-Doping Program (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

paragraph 3: 'as much as possible, harmonization in Analytical Testing from all Laboratories' **Recommendation:** This wording implies that the laboratories will use the same procedures but actually as per previous ISL we 'harmonized results and reporting from all Laboratories'

1.2 WADA Laboratory Standards

1.2.1 Technical Documents (4)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

Article 1.2.1 (5th bullet point):

We understand the reasons for this (all labs should be applying the most up to date methods where possible), however it can result in inequalities for athletes where one laboratory is already meeting the new requirements and others are not (e.g. the implementation of the adjustment for specific gravity). To avoid this situation in the future, it could be a good idea to provide some way that all laboratories and RMAs can be aware of which other laboratories have implemented the new TD and when.

cadf SUBMITTED
francesca rossi, director (switzerland)
Sport - IF – Summer Olympic

*Implementation of the requirements detailed in a Technical Document may occur prior to the effective date for implementation specified in the Technical Document, and shall occur no later than the effective date**3**;*

Comment: We understand the reasons for this (all labs should be applying the most up to date methods where possible), however it can result in inequalities for athletes where one lab is already meeting the new requirements and others are not (e.g. the famous implementation of the adjustment for specific gravity). To avoid this situation in the future, it could be a good idea to provide some way that all laboratories and RMAs can be aware of which other laboratories have implemented the new TD and when.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

• Subject to the above, the analysis of Samples or the review of analytical data my occur based on a newly approved Technical Document immediately upon its approval.

Recommendation: Does this apply to EQAS results as well? If yes, please indicate this.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

- 3rd dot point - typographical error

Once approved, a Technical Document~~s~~

- Note 3

Although fairly obvious 'SOP' should be defined in section 3.2

- 7th dot point, 2nd line

change' imply' to 'implies'

- 8th dot point, 2nd line

Change 'my' to 'may'

1.2.2 Technical Letters (2)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

The testing authorities should always be provided with the technical letters as these contain potentially important information for the results management phase. We would therefore suggest removing the "Or".

cadf SUBMITTED
francesca rossi, director (switzerland)
Sport - IF – Summer Olympic

Technical Letters are approved by the WADA Laboratory Expert Group (LabEG) and become effective immediately, unless otherwise specified by WADA4. Technical Letters are provided to Laboratories and/or Testing Authorities and are not published on WADA's website;

Comment: The testing authorities should always be provided with the technical letters as these contain potentially important information for the results management phase. We would therefore suggest removing the "Or"

1.4 Laboratory Accreditation Framework (3)

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

Pending the Work of the Governance Work Group, A definition of the modus operandi of the LabEG should be presented. The LabEG should be constituted by experts and should be able to operate independently from other bodies and departments of WADA. A proportional representation could be defined, for example with a 9 persons group, 2 nominated by WAADS, 2 nominated by Governments, 2 nominated by Sport institutions and 2 and a chair co-opted by the already appointed members.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

In this section 'Other terms are used in the ISL and other *WADA* Laboratory standards as follows:'

Recommendation: define 'Shall' also in relationship to use in a Guideline.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

In the paragraph starting, 'in order to.....' It states that Accreditation bodies are required to use various documents including Technical Letters as reference documents but accreditation bodies do not have access to these. either change the wording or give accreditation bodies access to the letters.

Section 2- Code Provisions (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

2.1.3 Excepting those substances for which a quantitative threshold is specifically identified in the Prohibited List, the presence of **any quantity** of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample shall constitute an anti-doping rule violation.

2.1.4 As an **exception** to the general rule of Article 2.1, the Prohibited List or International Standards may establish special criteria for the evaluation of Prohibited Substances that can also be produced **endogenously**.

Recommendation: 2.1.3 and 2.1.4 cover exception for threshold and endogenous substances, is it possible to add something related to the many other substances which are not reported at any quantity because of reporting limits set by WADA or that there is not enough scientific knowledge of metabolism to report findings. Maybe just including an additional section 'Exception those substances for which additional instructions are documented in TD, TL, TN or Guideline.'

Section 3 - Terms and Definitions

3.1 Code defined terms (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

- In the definition of Athlete,the following sentence needs revision:

However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any Athlete over whom an Anti-Doping Organization has authority who competes below the international or national level, then the Consequences set forth in the Code (except Article 14.3.2) must be applied.

I suggest the following:
However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any Athlete, who competes below the international or national level, over whom an Anti-Doping Organization has authority then the Consequences set forth in the Code (except Article 14.3.2) must be applied.

- In the comment under the Athlete definition, the following senstence does not make sense. I can't suggest a change but a sentence should not start with 'But'

But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2).

3.2 ISL Defined Terms (3)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

The UCI believes it should be clarified whether there is any difference between the terms “further analysis” and “re-analysis”. If there is no difference, then only one of these terms should be used in the ISL and WADA Code for consistency and to avoid any confusion. If the terms refer to something different, a definition of re-analysis should be provided.

Regarding the wording of the definition of further analysis, it may also be useful to clarify what is meant exactly by “and previously reported”

It is also suggested to add a definition for “Reporting Limit”.

cadf SUBMITTED
francesca rossi, director (switzerland)
Sport - IF – Summer Olympic

Further Analysis

Any analysis of a Sample already subjected to Analytical Testing and previously reported. Further Analysis can be performed through the application of any Analytical Method and for any Prohibited Substance(s) or Prohibited Method(s), except those Prohibited Substance(s) or Prohibited Method(s) for which the Athlete has previously been notified of an asserted Anti-Doping Rule Violation based on an Adverse Analytical Finding established in the concerned Sample.

[Notwithstanding the above, if a Laboratory applies an Analytical Testing Procedure during Further Analysis, which confirms the presence in the Sample of a Prohibited Substance, its Marker(s) or Metabolite(s), or of Marker(s) of the Use of a Prohibited Method, for which an Adverse Analytical Finding had been previously reported and asserted as an Anti-Doping Rule Violation, the Laboratory shall report the finding according to the obtained analytical results. The previously asserted Anti-Doping Rule Violation shall then be taken into consideration during the results management process].

Comment:

It should be clarified whether there is any difference between the terms “further analysis” and “re-analysis”. If there is no difference, then only one of these terms should be used in the ISL and WADA Code for consistency and to avoid any confusion. If the terms refer to something different, a definition of re-analysis should be provided.

Regarding the wording of the definition of further analysis, it may also be useful to clarify what is meant exactly by “and previously reported”

It is also suggest to add a definition for “Reporting Limit”

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

- For Analytical Testing Procedure, there is no such thing as an 'ISO/IEC 17025 accredited procedure'. The wording should be based on the wording you use in section 5 for note 29, eg. 'a method included in the Laboratory's ISO/IEC-17025 scope of accreditation'
- For Fitness-for-purpose, '-15189' should have the prefix ISO, ie. ISO-15189 as it is not a joint ISO/IEC document.
- For flexible Scope of Accreditation, it is suggested that you remove the word national as, for example NATA is not the national AB of Thailand, Japan or Qatar but we assess their WADA labs.
- As mentioned in section 1.2, a definition for 'SOP' would be useful for completeness unless it in included the first time it is used, ie. standard operating operating procedure (SOP).

PART TWO:LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

One of the frustrations with the ISL is the imposition of additional requirements on Laboratories with little consideration to the cost implications of meeting those additional requirements. While the need for increased precision and capability to identify modern doping practices grows, this should to be balanced against the limited resources of those who pay for these laboratory services.

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

-

2.1– Should be updated to reflect proposed changed to Code

SADoCoL SUBMITTED
Hanno du Preez, Operations Manager (South Africa)
Other - WADA-accredited Laboratories

Section 2 - *Code* Provisions

2.1.3

Excepting those substances for which a quantitative threshold is specifically identified in the *Prohibited List*, the presence of any quantity of a *Prohibited Substance* or its *Metabolites* or *Markers* in an *Athlete's Sample* shall constitute an anti-doping rule violation.

"*Presence of any quantity*"… The code is a higher level document than a TD. According to the code the only exceptions is threshold substances and endogenous substances. How does this fit in with Section 4: Reporting of non-Threshold substances TD MRPL?

Is the use of 'any' in this paragraph correct? It seems to be contradictory to reporting limits / criteria specified in Technical Documents.

Section 4 - Process and Requirements for WADA Laboratory Accreditation (3)

ministère chargé des sports, direction des sports SUBMITTED
Michel LAFON, Chef de bureau (France)
Public Authorities - Government

The modifications of this standard should enter into force in 2019. This leaves little time to organise the administrative and operational independence between the laboratory and the ADO when it's not already the case, such as in France. So an additionnal time should be allowed (one year ?) to implement this requirement, regarding operationnal difficulties to ensure this separation.

SADoCoL SUBMITTED
Hanno du Preez, Operations Manager (South Africa)
Other - WADA-accredited Laboratories

Section 4 - Process and Requirements for *WADA* Laboratory Accreditation

It is recommended that the annual accreditation fess is published, including deliverables for the fee.

It is recommended to stipulate minimum requirements for suspended or revoked laboratories to ensure a minimum level of continued monitoring.

· E.g. The laboratory should at all costs continue with the WADA EQAS rounds, unless affected by the specific suspension or revocation criteria.

· Research activities should continue, unless affected by the specific suspension or revocation criteria.

· The laboratory should continue with its in-house training initiatives.

· Etc.

4.1.3.2

The candidate laboratory shall also submit a business plan, which shall include market considerations (clients, number of *Samples*, maintenance costs, etc.), facility, instrumental, staffing and training needs, and shall guarantee the long-term provision of adequate financial and human resources to the Laboratory.

Add a section (4.1.3.3) to ensure a declaration by the laboratory to affirm their independence. In the light of recent events, it is surprising that such explicit requirement is not stipulated in the ISL.

e.g. The candidate laboratory shall submit a statement with its application, which states their independence from any other entities as specified in Articles 4.1.6. and 4.4.3 of the ISL.

4.3.1.7

In order for a probationary laboratory to be considered for *WADA* accreditation, it shall have validated and incorporated into its ISO/IEC-17025 scope of accreditation all mandatory analytical methods, as determined by *WADA*.

List of mandatory analytical methods must be published annually for e.g. as a Technical Letter and send to all labs.

4.3.2

4.3.2 (par 2) Once all accreditation requirements have been satisfactorily met, the LabEG will submit its recommendation to grant *WADA* accreditation to the *WADA* Executive Committee

Timelines for the process of approval by the Exco should be indicated.

4.6.4.1 Suspension of Accreditation

4.6.4.1.1 In accordance with the procedure detailed in ISL Article 7.3, the Chairman of the *WADA* Executive Committee may suspend a Laboratory's *WADA* accreditation if *WADA* identifies any non-compliance with the ISL and/or Technical Documents and/or Technical Letters based on the Laboratory's performance during the EQAS or during routine Analytical Testing

Use a flow chart or risk chart to stipulate criteria for suspension or revocation that would be applied consistently and within clear guidelines and timelines for all laboratories. An example of such chart was provided under Annex B, as a basis, and can be extended to accommodate more scenarios. This will also be in line with the ISO/IEC 17025 Standard to identify and mitigate risk, which will be clear an unambiguous.

Section 4.6.4.1.2

Failure to appoint a permanent Laboratory Director or other senior management positions (*e.g.* Quality Control Manager) within a reasonable timeframe;

Keep consistent with terminology. WADA often refers randomly to Quality Managers, Quality Assurance Managers and Quality Control Managers, irrespective of the true and actual functions performed by these different functions!!!!

Section 4.8.1

Satisfactory participation in the *WADA* EQAS or similar *WADA*-approved quality assurance program for analysis of blood variables;

This is not in line with TD BAR and the harmonization of ABP results amongst WADA Labs through the Sysmex XN1000 and CSCQ EQAS scheme for ABP. The protocol for other available EQAS schemes such as Thistle EQA (clinical labs) differs from the protocol currently followed for CSCQ. E.g. CSCQ sample is analyzed 7 times compared to the single analysis for Thistle. Thistle EQA is designed for closed mode while CSCQ is run in open mode due to the sample container. Routine and EQAS samples must be run in the same manner.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: A annual accreditation fees should be published, including deliverables for the fee.
Recommendation: Stipulate minimum requirements for suspended or revoked laboratories to ensure a minimum level of continued monitoring.
Example:

- The laboratory should continue with the WADA EQAS rounds, unless affected by the specific suspension or revocation criteria.
- Research activities should continue, unless affected by the specific suspension or revocation criteria.

- The laboratory should continue with its in-house training initiatives.
- etc.

4.1 Applying for a WADA Laboratory Accreditation

4.1.2 Submitting Initial Application Form (2)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

We thought the connection between laboratory accreditation and the operation of the country's NADO has been previously severed. These amendments appear to be an attempt to establish that link again.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Section 4.1.2 or 4.1.3

Recommendation: In these early stages it should be included that the laboratory shall be required to submit a statement with its application, which states their independence from any other entities as specified in Articles 4.1.6. and 4.4.3 of the ISL.

4.1.6 Laboratory Independence (2)

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

Laboratories might either be public or private. Public Laboratories are always in some way dependent of "political organisations" namely the state and its budget. The current definition could lead to a bias interpretation of operational independence, so it should be improved. A good example of definition can be found on the recent Council of Europe recommendation on the operational independence of NADOS.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

The phrase '.....the laboratory’s competence, impartiality, judgment or operational integrity....' which comes from 4.1.5 d in the 2005 version of ISO/IEC 17025 is not in the 2017 version of ISO/IEC-17025. You should therefore consider other wording and might like to look at clause 8.5 of the current ISO/IEC 17025 for such wording.

4.1.7 Compliance with the Code of Ethics (ISL Annex A) (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

How does a laboratory director scrutinise "past" ethics compliance. Australia questions the need for the phrase "past and present" in this Article.

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)

NADO - NADO

4.1.7 – Further detail on what level of scrutiny is expected is required. The scrutiny of staff's past compliance with the code of ethics could be a difficult, even unachieveable, task depending on the level of scrutiny expected. .

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

'All laboratory employees shall be scrutinized by the laboratory Director for present and past compliance with the Code of Ethics.' is it possible to have a footnote to explain what this would entails, in particular how to assess past compliance.

4.3 Obtaining WADA Accreditation (1)

Organizacion Nacional Antidopaje de Uruguay SUBMITTED
José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

Review the accreditation criteria of each laboratory and understand the needs of the region. The financing must be fulfilled by the NADOs of the region

4.3.1 WADA Accreditation Assessment (2)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

4.3.1.2 Can IRMS can be done within this time frame?

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.3.1.7 In order for a probationary laboratory to be considered for WADA accreditation, it shall have validated and incorporated into its ISO/IEC-17025 scope of accreditation all mandatory analytical methods, as determined by WADA.

Recommendation: The addition of following 'A list of mandatory analytical methods shall be published annually by WADA and provided to all laboratories.' This could be in form of a TL and sent to all candidate, probationary and accredited laboratories.

4.3.2 WADA Recommendation for Accreditation (2)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

4.3.2.2 This amendment raises the question as to who pays for the second opinion. The request for a second opinion may also be seen as undermining the integrity and effectiveness of the accreditation process - WADA does not trust the results of a newly accredited laboratory. .

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.3.2 (par 2) Once all accreditation requirements have been satisfactorily met, the LabEG will submit its recommendation to grant *WADA* accreditation to the *WADA* Executive Committee for approval.

Recommendation: A timeline for the approval process by the Exco should be indicated ie is a out of session vote possible? or only during meetings which happen 3 times per year.

4.4 Maintaining WADA Accreditation (1)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

One of the issues for laboratories is when a technical document or requirement is issued by WADA but the information which is required to do the implementation is not provided until a week before the effective date or even after the effective date of implementation.

Some of the delays are caused by ADAMS not being ready to accept the information. The burden on the laboratories to jump instantaneously meet WADA's requirements is huge. This may not be something to address in the ISL but it undermines the effective operation of the ISL.

4.4.1 Maintaining ISO/IEC 17025 Accreditation

4.4.1.1 Flexible Scope of Accreditation (2)

Institute of Biochemistry, German Sport University Cologne SUBMITTED
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

4.4.1.1.2....In such cases.....the Laboratory ~~shall~~ should successfully participate in an inter-laboratory collaborative study or WADA organized.....

Rationale: Some laboratories have implemented new methods, which are validated, published and ISO accredited, but which are not yet implemented in other laboratories. Therefore inter-laboratory studies are not possible.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.4.1.1.2....In such cases.....the Laboratory ~~shall~~ should successfully participate in an inter-laboratory collaborative study or WADA organized.....
Rationale: Some laboratories have implemented new methods, which are validated, published and ISO accredited, but which are not yet implemented in other laboratories. Therefore inter-laboratory studies are not possible.

4.4.3 Laboratory Independence (4)

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

Se previous comment.
The way this is currently formulated it could seem that the laboratory could not be a public entity, since

those have always administrative links with "political organisations".
Also the definition is not feasible since public laboratories will have to abide to national and sometimes European legislation in terms of budget definition, resources procurement and staff recruitment.

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

"L'AFLD souscrit à cette évolution du standard. La séparation organique d'un laboratoire indépendant actuellement juridiquement intégré à la même structure qu'une ONAD impliquera cependant la création d'une nouvelle entité, un transfert de patrimoine et des contrats passés pour les achats réalisés, une reprise des personnels après concertation et modification de leur contrat de travail, la définition de modalités de financement et la séparation physique des systèmes d'information. Pour cela, des mesures législatives et réglementaires devront intervenir.

En conséquence, l'AFLD propose que l' entrée en vigueur de ces nouvelles exigences soit différée de 12 mois. L'AFLD souligne pour ce qui la concerne que le dernier audit conduit par l'AMA a confirmé la qualité des analyses realisées par le laboratoire de Paris ainsi que la réalité de l'indépendance opérationnelle dont ce dernier bénéficie, conformément au standard actuel. Aussi, le délai demandé ne portera pas un préjudice disproportionné à la crédibilité et la fiabilité du système antidopage international."

AFLD - Département des analyses SUBMITTED
Mathieu Duez, Quality Manager (France)
Other - WADA-accredited Laboratories

Will the laboratory have enough time to comply with this new requirement?

If the laboratory independancy requires legal reforms from the host country and cannot be applicable immediately, WADA shall be informed. A maximal 18 months delay can be granted to the laboratory but the laboratory will have to regularly inform WADA of the progress on the matter until independancy is obtained.

We consider that the Laboratory and the French NADO would need at least 12 months after the document has been released to be compliant because of the significant changes that need to be done.

Currently we are operationally independent of our NADO with an independent budget but still administratively attached to it. A period of compliance is absolutely necessary to allow this separation in good conditions due to the legal constraints of our country :

- to have a new legal status for the new administrative structure that will be created (independent or attached to a bigger structure),

- to amend the French sports code

- to implement a new budget and its financing,

- to implement a sustainable organization,

- to renegotiate contracts with laboratory staff, suppliers, etc ...

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

- 4.4.1.1.4 there appears to be double underlining under 'of a method or procedure'

- It seems strange to repeat the same wording for an accredited lab as was used for an applicant lab. It is suggested to changfe the wording to 'the Laboratory shall maintain administrative and operational independence.....'

- As per 4.1.6

The phrase'.....the laboratory's competence, impartiality, judgment or operational integrity....' which comes from 4.1.5 d in the 2005 version of ISO/IEC 17025 is not in the 2017 version of ISO/IEC-17025. You should therefore consider other wording and might like to look at clause 8.5 of the current ISO/IEC 17025 for such wording.

4.4.4 Documenting Compliance with the WADA Laboratory Code of Ethics (ISL Annex A) (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.4.4.1 The Laboratory shall annually provide to WADA a letter of compliance with the provisions of the Code of Ethics, signed by the Laboratory Director. All staff employed at the Laboratory, permanent or temporary, shall also read and sign the Code of Ethics as part of their personnel file on a yearly basis. The Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics.

Recommendation: the review of Code of Ethics by all staff annually seems excessive. Review during induction to laboratory and further review at each revision should be sufficient.

4.4.5 Documenting Implemented Research and Development Activities (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.4.5.2 '...implementing with minor adjustments...'**Recommendation:** definition for what would constitute a 'minor adjustment'

4.4.8 Providing Renewed Letter(s) of Support (2)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

-

4.4.8 – The letter of support from an ADO to a Lab is not a contractual agreement with the Lab and so should not bind an ADO to using that Laboratory.

4.4.10 Publication of Fee Schedule (1)

NMI - ASDTL SUBMITTED

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

To assist Testing Authorities in developing Test Distribution Plans in relation to the use of different Sample analysis menus for various sports or sport disciplines, Laboratories shall report into ADAMS an up-to-date price list for each type of analytical method or service that is public to the Anti-Doping Organizations.

Recommendation: 'shall' changed too should. Laboratories shall not be obliged to cast their financial issues, readable for everyone. Laboratories can choose to publish price list but shall not be completed to.

4.4.11 Participating in WADA/Accreditation Body Re-assessments and Surveillance Assessments (1)

Polish Centre for Accreditation SUBMITTED
kamila skrzypczak-zbiciak, coordinator (Poland)
Other - Other (ex. Media, University, etc.)

1. point 4.4.11 *Participating in WADA/Accreditation Body Re-assessments and Surveillance Assessments*

- title of these point concerns “surveillance assessments”, but according the new standard ISO ISO/IEC 17011:2017 *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies:* term “surveillance” was deleted and replaced by an approach based on “continuous assessment during the accreditation cycle”

- in the content of this point (4.4.11 ISL) we find information only about requirements for reassessment, which is inconsistent with the title of this point

4.5 Removal of Samples (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

The provisions allowing WADA to direct the re-analysis of samples for the purposes of Laboratory quality assessment should also require WADA to notify the relevant anti-doping organisations (ADO - eg the Australian Sports Anti-Doping Authority). The ADO ought to be involved in the process as the negative samples may still be of significant interest in terms of long-term storage and potential re-analysis. The use of some sample volume for quality reassurance would decrease the ADOs capacity for future re-analysis hence it is recommended that ADOs be notified of WADAs intent to use samples for this purpose and be given the opportunity to request that certain samples be excluded from this use.

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)

NADO - NADO

The provisions allowing WADA to direct the re-analysis of Samples for the purposes of Laboratory quality assessment should also require WADA to notify the Testing/Results Management Authority. We recommend that the TA/RMA be involved in the process as the negative samples may still be of significant interest to the TA/RMA for the purpose of long-term storage and potential re-analysis. The laboratory may not be yet aware of this. The use of some sample volume for quality reassurance would decrease the TA/RMAs capacity for future re-analysis hence we recommend that the TA/RMA be notified of WADAs intent to use samples for this purpose and be given the opportunity to request that certain samples be excluded from this use.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

In addition, *WADA* may also direct, at its expense, the re-analysis of *Samples* for purposes of Laboratory quality assessment, including the implementation of a system of exchange of *Samples***9** reported as Negative Findings between Laboratories. In this regard, *WADA* may direct re-analysis of more *Samples* from one Laboratory and less from another Laboratory, according to the criteria established in ISL Article 6.2.1.3.

Recommendation: In this section there are a few concerns

1. Laboratory quality assessment implies that the exchange of these samples could result in the gaining of EQAS points - is that the case?The program should only be developed in order to educate and improve laboratories not to penalise. 2. The possibility of exchanging different numbers of samples could lead to a laboratory feeling targeted, in particular, if false negative involves EQAS points. Clearly a laboratory which has 1000 samples removed and reanalysed has a higher chance of finding a problem than another laboratory who only has 10 samples removed. It should be clear that all laboratories should be equally assess in a 12 month cycle.

4.6 WADA Monitoring of Accreditation Status

4.6.4 Loss of WADA Accreditation (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

for note 10, revise the wording 'such capacity' to 'such a capacity'

4.6.4.1 Suspension of Accreditation (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.6.4.1.1 In accordance with the procedure detailed in ISL Article 7.3, the Chairman of the *WADA* Executive Committee may suspend a Laboratory's *WADA* accreditation if *WADA* identifies any non-compliance with the ISL and/or Technical Documents and/or Technical Letters based on the Laboratory's performance during the EQAS or during routine Analytical Testing

Recommendation: Suspension as the result of "any non-compliance with the ISL and/or technical documents." This is far to general. It shall be restricted to serious non-compliances and these shall be defined. A non-compliance is always a starting point for improvement.

Recommendation: Use a flow chart or risk chart to stipulate criteria for suspension or revocation that would be applied consistently and within clear guidelines and timelines for all laboratories. An example of such chart was sent to WADA directly as could not be included in WADA connect, as a basis, and can be extended to accommodate more scenarios. This will also be in line with the ISO/IEC 17025 Standard to identify and mitigate risk, which will be clear and unambiguous.

4.6.4.1.2 ... Non-compliances with the ISL include, but are not limited to:

Recommendation: change to **'**Non-compliances with the ISL are defined as:'

4.6.4.1.2 • Laboratory staff and/or management issues, including but not limited to:

- Major changes in senior Laboratory management positions (e.g. Laboratory Director, Quality Control Manager) without proper and timely notification to WADA;

Recommendation: Historically only a change of Laboratory Director was notified to WADA. A limited list must be provided in the ISL in relation to which positions must be notified to WADA not only examples as that is open to interpretation.

4.6.4.1.2• Laboratory staff and/or management issues, including but not limited to:

- Failure to appoint a permanent Laboratory Director or other senior management positions (e.g. Quality Control Manager) within a reasonable timeframe;

Recommendation: Consistent terminology in relation to Quality Managers, Quality Assurance Managers and Quality Control Managers as these seem to be randomly referred to irrespective of the true and actual functions performed by these different roles.

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

4.6.4.1.1 "...may suspend a Laoboratory's WADA accreditation if WADA identifies any non-complience...."
Comment: Suspension of Accreditation - a very serious reaction for the affected laboratory - should be reflected by the seriousness of the non-complience.

Suggestion: A graded penalty system, with defined reactions, timeframes and necessary actions. A "reaction system" moving from less serious non-compliences where the reaction is a CAR (and no suspension), through preliminary and partial suspension (e.g. single method/analyte) with CAR, to partial immediate suspension of increasing time (depending of the seriousness) - to revocation for the most serious and non-corrected/repeated con-compliences.
This would also be in line with the new ISO 17025:2017, chapter 7.10 Nonconforming Work of ISO 17025:2017, where actions in response to a nonconformance “are based upon the risk levels established by the laboratory”.
4.6.4.1.2Comment: Please define the list of senior staff for which changes needs to be notified WADA. The use of "e.g in the brackets "...(e.g. Laboratory Director, Quality Control Manager)...", leaves this paragraph open for different interpretations and hence, different ways of complying.
Comment: We believe it should be sufficient to notify WADA about change of Laboratory Director, and when the Laboratory Director is fairly new; also a change of the Deputy Director.

4.6.4.2 Revocation of Accreditation (1)

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

Revocation of accreditation should only follow well identified Code and ISL non-compliance. On the current proposal WADA is increasing the penalization points system to a point were minor non-conformities that do not affect the reliability of results could lead to a laboratory suspension or revocation, departing from the need of proportionality.

4.6.4.3 Provisional Suspensions (1)

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

Better definitions of clerical/administrative errors and technical or methodological errors should be better defined. It is not sufficient to say that ones are the contrary of the others

4.6.4.3.1 Mandatory Provisional Suspension (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

The conditions on mandatory Provisional Suspension are very harsh when taken into consideration that WADA can decide send more EQAS samples to one laboratory than another and that the points scale in the draft ISL version 10 is a lot harsher.

4.6.5 Consequences of Suspended or Revoked Accreditation

4.6.5.1 Suspension (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.6.5.1.4 If the reason for the Laboratory Suspension was related to the reporting of false Adverse Analytical Finding(s), all ongoing analyses in the suspended Laboratory shall cease immediately.In addition, the Laboratory shall transfer11 the following Samples (“A” and “B” Samples) in the Laboratory’s custody to another Laboratory for the performance of the “A” and, if needed, the “B” Confirmation Procedures, unless otherwise instructed by WADA:• Samples, which had been previously reported as an Adverse Analytical Finding for the same class of Prohibited Substances or Prohibited Methods when applying the same Confirmation Procedure;
Recommendation: A time limit such as 3 months must be included

4.6.5.2 Revocation (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

in 4.6.5.2.1 should the word 'transfer' have a superscript of 11 like the other instances of 'transfer' or 'transferred'

4.8 Criteria for Approval of non-WADA Accredited laboratories for the Athlete Biological Passport (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.8 Criteria for Approval of non-WADA Accredited laboratories for the Athlete Biological Passport
Recommendation: Using the terminology of non-WADA Accredited laboratories and WADA-approved makes it difficult to follow. Remove the use of non-WADA Accredited laboratories
Suggestion: 4.8 Criteria for Accreditation of WADA-approved laboratories for the Athlete Biological Passport

Section 5 - Application of ISO/IEC-17025 to the Analysis of Samples (2)

International Paralympic Committee SUBMITTED
James Sclater, Director (Germany)
Other - Other (ex. Media, University, etc.)

The IPC supports the merging of Sections 5 and 6.

SADoCoL SUBMITTED
Hanno du Preez, Operations Manager (South Africa)
Other - WADA-accredited Laboratories

5.2 Structural and Resource Requirements

5.2.2.1

Every *Person* employed by, or under contract with, the Laboratory shall have an accessible personnel file, which shall contain copies of his/her curriculum vitae or qualification form, a job description, records of completed and ongoing training and records of authorization to perform their defined duties.

This is in direct contradiction to the latest ISO 17025 Standard.

A personnel file is no longer an ISO/IEC 17025 requirement, however, it is up to the laboratory to determine how they want to define and implement it.

Furthermore, the 17025 standard does not require records of authorisation per employee in personnel files to perform their defined duties. Again, it is up to the lab to determine how they want to implement it. In fact, it could be done in a governing document, such as a Quality Manual and SOPs!! Also, the lab could declare a staff member competent through an annual Performance and Development program, which is part of the entire system of authorization and which ensures continues monitoring of performance for allowing staff members to continue with their assigned work.

The ISO standard also does not specify the use of Job Descriptions anymore!!!! Again, the lab should show how they apply the requirement into their systems.

WADA cannot be in direct conflict with the ISO 17025 Standard.

e.g. The laboratory shall have procedures and records for Every *Person* employed by, or under contract with, the Laboratory, shall have an accessible personnel file, covering records related to a curriculum vitae, or qualification form certificate, a job description or similar document giving direction on the required tasks, roles and responsibilities, records of completed and ongoing training, competency records and authorization to perform their defined duties.

Furthermore, a CV is a reflection of qualification and not clear evidence of qualification from an institution. Therefore, it should rather be required to also have a copy of a qualification certificate.

5.2.3.5.5

"*be backed up on a regular basis, e.g. weekly*"

If back-ups is done on a weekly basis, the risk of losing data increases if something happens mid-week. It would be advantageous to back-up data more frequently.

5.2.2.4

All Laboratory personnel shall sign the *WADA* Laboratory Code of Ethics on a yearly basis and the signed documents shall be kept as part of their personnel file. The Laboratory shall maintain appropriate confidentiality of personal information.

Again, the 17025 standard does not prescribe a specific system for maintaining such documents and can be done as deemed fit by the laboratory as long as it can be evidenced that it is available and part of a system or process at the lab. How the lab does it, is up to them!!

e.g. All Laboratory personnel shall sign the *WADA* Laboratory Code of Ethics on a yearly basis and the signed documents shall be kept by the laboratory.

5.2.2.6 Laboratory Quality Manager

The Laboratory shall have a single staff member appointed as the Laboratory Quality Manager in accordance with the requirements of ISO/IEC-17025. The Quality Manager shall have responsibility and authority to implement and ensure compliance with the Quality Management System. The Quality Manager shall remain independent from routine Laboratory analytical activities.

The 17025 standard no longer specifies the use of the term Quality Manager. It is up to the laboratory how they want to define the essential functions, their roles and responsibilities.

If WADA requires this, then do not refer to the 17025 standard. Instead, change the wording to suffice for the requirement in the ISL!!!

e.g. The Laboratory shall have a single appointed staff member (e.g. Quality Manager, or however named) who is responsible for managing and monitoring the Quality Management System of the laboratory in accordance with the requirements of the ISO/IEC 17025 Standard, which includes, but is not limited to the design, implementation, maintaining and improvement of the Quality Management System. The Quality Manager shall have the responsibility and authority to implement and ensure compliance with the Quality Management System. The Quality Manager shall remain independent from routine Laboratory analytical activities.

5.2.2.6

The Laboratory Quality Manager qualifications shall include:

At least Bachelor's Degree in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical sciences;

Be careful to stipulate a Bachelor's Degree, because this is not termed the same by all countries. Instead add the following:

At least Bachelor's (or similar) Degree in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical sciences;

5.2.3.2

5.2.3.2.3 Security of the Facility, Equipment and Systems

Two (2) main levels of access shall be considered in the Quality Manual or threat assessment plan:

The ISO 17025 standard no longer specifies the use of a Quality Manual.

Two (2) main levels of access shall be defined in Laboratory formal written procedures or threat assessment plan:

5.3.1.5.2

"… *seven (7) calendar days that a Sample with noted…"*

Include the sections relevant to TA/RMAs as an annex to the ISTI similar to TD BAR and TD EAAS in the ABP Guidelines.

5.3.2.1.3.5

This must be included in the ISTI as the lab will not necessarily know if there is a challenge or dispute in cases where B-sample analysis was waivered.

5.3.2.2.1.2

· If, after completion of analyses on the cellular components of whole blood, the *Sample* is centrifuged to obtain the plasma fraction for additional analyses (*e.g.* Erythropoiesis Stimulating Agents), then this plasma *Sample* shall be stored according to ISL Article 5.3.2.2.1.

If analysis of this plasma is requested, should it be regarded as an "A" sample? If an AAF is reported for this sample (e.g. EPO) and a "B" Sample analysis is requested, what is to be done…?

5.3.4.4

· This section is ambiguous and lend itself to different interpretations by laboratories and assessors.

· This section must rather be a frame work and more details regarding on how the validations must be conducted, and results interpreted should be in a TD, Guideline or Technical Note. There must be harmonization between laboratories to circumvent the different interpretations.

· Will this section be implemented retrospectively or only from the effective date forward?

· Literature:

1. FDA-Bioanalytical Method Validation Guidance for industry. May 2018.

2. European Medicines Agency. Guideline on bioanalytical method validation.

3. EURACHEM. Fitness for Purpose of Analytical Methods. 2014.

Validation of qualitative analytical methods. E Trullols, I Ruisánchez, FX Ruis. Trends in Analytical Chemistry, 2004, 23 p137-145.

Please note that in all accepted international guidelines, the validation of affinity binding assay (e.g. immunoassays) are different to that of LC-based assays: there are other criteria applicable and some criteria for LC-based assays are not applicable to affinity binding assays, or are accessed differently, such as carry-over…

5.3.4.1.4

"*adulteration and manipulation*"

Please include reference to the TD EAAS

5.3.4.4.1

Validation of Analytical Testing Procedures for Non-Threshold Substances

Qualitative or semi-quantitative analysis of substances. Currently this section covers chromatographic, ligand binding/affinity assays, biomarkers etc. which do not necessarily have the same parameters or acceptance criteria

"*adequate number of representative samples…"*

Please define adequate number of samples or provide an applicable amount

According to literature the minimum number is 6, but in TD DL it is 10. Specify a specific number.

"*recovery"*

Recovery is a quantitative measurement and therefore the applicability thereof to ITP analysis of non-threshold substances is not clear. If the S/N ratio at LOD is adequate (3/1), the relevance of recovery is not apparent

This is a quantitative parameter and not a qualitative parameter

Robustness of an analytical procedure is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters. E.g. mobile phase composition, injection volume, column temperature. Sample condition is not a method parameter.

Variations in analytical conditions can therefore also include different analysts, more than one validation batch or instruments.

Matrix variations also affects the selectivity of the method. Rather include it in selectivity or matrix interference which is a subheading of selectivity according to literature.

5.3.4.4.1.1

"The Laboratory shall develop, as part of the validation process, acceptable standard solutions for identification of Non-Threshold Substances using Reference Materials. In the absence of suitable" Reference Materials, Reference Collections may be used;

This is a general comment applicable to any validation procedure. Suggestion move to point 5.3.4.4 Also include the number of samples and batches to be used for validation.

List the validation parameters separately. Selectivity and absence of matrix interferences may be interpreted as either one or two parameters according to literature.

Matrix interferences must be clarified as there is different opinions, e.g. different matrices or comparison of a blank matrix spiked after extraction with pure reference standard.

Robustness, add definition as for CP.

Recovery is a quantitative validation parameter.

According to literature the only parameters necessary for qualitative analysis to be validated is selectivity and LOD. Other additional parameters may be validated.

Reference Collection

This bullet has to do with identification capability. Suggest it is moved to IC

5.3.4.4.1.2 Validation of Confirmation Procedures

Matrix interferences: The Confirmation Procedure should avoid interference in the detection of *Prohibited Substances* or their *Metabolite*(s) or *Marker(*s) by other components of the *Sample* matrix;

Please define an adequate number as it can be anything from 1 to 10. Preferably the same number of samples must be used for all the parameters. The ISTD should also be included in the validation.

Please specify what WADA wants under Matrix Interference.

e.g.

Also referred to as Matrix Effects and which can lead to enhancement or suppression in an analytical method. Matrix Interference or Effects is calculated for example:

ME% = 100 * extract/standard

Extract represents the peak area of the analyte when diluted with matrix extract and standard represents the peak area of analyte in the absence of matrix. The concentration of the analyte in both samples should be the same. A value close to 100 indicates the absence of matrix influence, while a value less than 100 indicates suppression and larger than 100, indicates matrix enhancement.

OR, similar formula:

ME% = 100 * extract/standard - 100

Negative values indicates suppression, while positive values signifies matrix enhancement. A value of 0 indicates the absence of matrix interference or effect.

“Identification Capability

This does not make sense since all these criteria have already been covered during the selectivity assessment: if a method is selective for a certain compound, it can only be so if it has the capability to specifically identify that compound. So by proving Selectivity, Identification Capability has already been proven…

As for non-threshold substances. This does not make sense since all these criteria have already been covered during the selectivity assessment: if a method is selective for a certain compound, it can only be so if it has the capability to specifically identify that compound. So by proving Selectivity, Identification Capability has already been proven…

5.3.4.1.4

Further guidance on assessing tampering or adulteration is provided in TD EAAS.

5.3.4.4.2

Validation of Analytical testing procedures for Threshold substances

ITP methods include threshold substances so this section is unnecessary

5.3.4.4.2.5

Validation of Confirmation Procedures for Threshold Substances

This section and the corresponding section on Method Development and Validation in TD DL needs to correspond with each other.

Footnote: Further guidance is provided in TD DL

Number of batches for repetition must be specified. Min of 3 batches is normally required.

Footnote:

5.3.4.5.1

Mandatory analytical Procedures

List to be published by WADA

5.3.4.5.3.8

As commented above, ITP of threshold substances is included in the total ITP, therefore the reference standards for threshold compounds should be included in the ITP at the threshold concentration so that the

decision to perform the quantitative CP for threshold compounds, can be made upon assessment of the ITP data.

5.3.4.5.4.6.3

Footnote: For further information refer to the Guideline on TUE Enquiries.

*TUE***[1], [2]**.

Will the TUE Guideline be updated to reflect this? If there is an agreement between the TA/RMA and the lab for PAAFs, how will this be recorded in ADAMS?

5.3.4.5.4.6.9

The IRMS example given here, is for steroid profile parameters which are not regarded as Threshold Substances. The only endogenous Threshold Substances according to TD DL is hCG and hGH

5.3.4.5.4.7

This point and the following one must be included in the ISTI, so that it can be included in their rules.

5.3.4.5.4.7.10

“presence…”

This state that the sample is resealed in the presence of the athlete, while in the Guideline for Conducting and Reporting Subcontracted Analysis footnote 1, the B-sample is resealed by the athlete/representative/independent witness.

5.3.4.5.4.7.11

The selection of a closed vessel in which the aliquot will be transferred, should also be allowed so that there is no evidence that there is tampering by the Lab during the aliquoting process.

5.3.4.5.5.6

However, Further Analysis shall not be applied to substances or methods, which are no longer prohibited at the time of Further Analysis.

5.3.5.2.6.2

“A” Sample test Report

Align this section with sections 5.3.4.5.4.6.6 - 10

5.4.3.2

QC charts

This needs to be established across **all** methods (ITP and CP) and not only for threshold substances (ITP and CP). Site Visit CAR.

5.4.3.3.2

iQAS sample

What is a sufficient number of samples? Regular basis e.g. bi-monthly

How does WADA ensure that ALL labs do iQAS. There are some labs (well respected ones, whom indicate they do not have time for “unnecessary” confirmations. If a lab such as us dare to make this comment we will be reprimanded seriously.

5.4.11.2

Ensuring Responsiveness to WADA

This should be a reciprocal process, and WADA should also commit to give feedback regarding responses from Lab. For instance, there should feedback when Corrective Action Reports have been committed and accepted. At the moment, responses are only given when CAR are “unacceptable”.

5.4.11.3

Responsiveness

Responsiveness is not a one way street. TAs/RMAs and WADA must also be responsive in return. Is responsiveness towards laboratories included in the ISTI?

5.3.5.2.6.1

in *ADAMS***[3]**

This should not be a footnote, but a paragraph under this section…

[1] In principle, the enquiry by Laboratories about the existence of an approved *TUE* for a Beta-2 Agonist may be applied not only to those Beta-2 Agonists which are prohibited under any condition, but also to those which are considered Threshold Substances and are permitted only by inhalation up to a maximum dose (*e.g.* salbutamol, formoterol and salmeterol). In such cases, the Laboratory may enquire about the existence of an approved TUE for the use of a prohibited route of administration or a supra-therapeutic inhalation dose.

[2] However, unless there is a prior agreement between the Testing Authority and the Laboratory, contacting the Testing Authority in such cases does not constitute an absolute requirement for the Laboratory. Indeed, the Laboratory may proceed to confirm the Presumptive Adverse Analytical Finding for Amfetamine, Methylphenidate, Beta-2 Agonists, Glucocorticoids or a declared *Prohibited Substance* or *Prohibited Method* and report the finding in *ADAMS* according to the confirmation results obtained. In such cases, the existence or not of an approved TUE shall be taken into consideration during the results management process.

[3] The Laboratory is not required to provide any additional Test Report, either in hard copy or digital format, to that submitted in *ADAMS* (except as described in ISL Articles 5.3.5.2.6.7 and 5.3.5.2.6.11). All *Code*-compliant Testing Authorities shall be able to access the Test Reports of their *Samples* in *ADAMS*. The Laboratory should record the *ADAMS* Test Report as part of the *Sample*’s documentation.

5.2 Structural and Resource Requirements

5.2.2 Laboratory Personnel

5.2.2.1 (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.2.2.1 Every Person employed by, or under contract with, the Laboratory shall have an accessible personnel file, which shall contain copies of his/her curriculum vitae or qualification form, a job description, records of completed and ongoing training and records of authorization to perform their defined duties.

Recommendation: This is in direct contradiction to the latest ISO 17025 Standard.
A personnel file is no longer an ISO/IEC 17025 requirement, however, it is up to the laboratory to determine how they want to define and implement it.

Furthermore, the 17025 standard does not require records of authorisation per employee in personnel files to perform their defined duties. Again, it is up to the lab to determine how they want to implement it. In fact, it could be done in a governing document, such as a Quality Manual and SOPs! Also, the lab could declare a staff member competent through an annual Performance and

Development program, which is part of the entire system of authorization and which ensures continues monitoring of performance for allowing staff members to continue with their assigned work.

The ISO standard also does not specify the use of Job Descriptions anymore! Again, the lab should show how they apply the requirement into their systems.

WADA cannot be in direct conflict with the ISO 17025 Standard.

Example: The laboratory shall have procedures and records for Every *Person* employed by, or under contract with, the Laboratory, shall have an accessible personnel file, covering records related to a curriculum vitae, or qualification certificate, a job description or similar document giving direction on the required tasks, roles and responsibilities, records of completed and ongoing training, competency records and authorization to perform their defined duties.

Furthermore, a CV is a reflection of qualification and not clear evidence of qualification from an institution. Therefore, it should rather be required to also have a copy of a qualification certificate.

5.2.2.4 (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.2.2.4 All Laboratory personnel shall sign the WADA Laboratory Code of Ethics on a yearly basis and the signed documents shall be kept ~~as part of their personnel file. The Laboratory shall maintain appropriate confidentiality of personal information.~~

Recommendation: The 17025 standard does not prescribe a specific system for maintaining such documents and can be done as deemed fit by the laboratory as long as it can be evidenced that it is available and part of a system or process at the lab. How the lab does it, is up to them.
Suggestion: All Laboratory personnel shall sign the WADA Laboratory Code of Ethics on a yearly basis and the signed documents shall be kept by the laboratory.
Suggestion: In relation to 'The Laboratory shall maintain appropriate confidentiality of personal information.' should this be a separate section as it is not clear how it only relates to the Code of Ethics.

5.2.2.5 Laboratory Director (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.2.2.6 Laboratory Quality Manager (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

5.2.2.6 The appointment and training of a single staff member as a quality manager and expecting them to be independent of routine laboratory analytical activities imposes a significant financial impost on the laboratory. These are likely to be costs that are passed onto sporting organisations and NADOs,

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

The Laboratory shall have a single staff member appointed as the Laboratory Quality Manager in accordance with the requirements of ISO/IEC-17025. The Quality Manager shall have responsibility and authority to implement and ensure compliance with the Quality Management System. The Quality Manager shall remain independent from routine Laboratory analytical activities.

Recommendation: The 17025 standard no longer specifies the use of the term Quality Manager. It is up to the laboratory how they want to define the essential functions, their roles and responsibilities. If WADA requires this, then do not refer to the 17025 standard. Instead, change the wording to suffice for the requirement in the ISL.
Example:The Laboratory shall have a single appointed staff member (e.g. Quality Manager, or however named) who is responsible for managing and monitoring the Quality Management System of the laboratory in accordance with the requirements of the ISO/IEC 17025 Standard, which includes, but is not limited to the design, implementation, maintaining and improvement of the Quality Management System. The Quality Manager shall have the responsibility and authority to implement and ensure compliance with the Quality Management System.
Recommendation: remove 'The Quality Manager shall remain independent from routine Laboratory analytical activities.' This may not be possible depending on the organisational structure of the laboratory or the host organisation and depends how the laboratory has defined the job description. In some host organisation certain aspects of the Quality Management system are provided by the host organisation which means internally to the laboratory a full time role may not be feasible and that the Laboratory Quality Manager may need to take on task which could be seen as routine Laboratory analytical activities.

The Laboratory Quality Manager qualifications shall include:

- At least Bachelor’s Degree in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical sciences;

Recommendation: Be careful to stipulate a Bachelor’s Degree, because this is not termed the same by all countries. Instead add the following:
At least Bachelor’s (or similar) Degree in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical sciences.

Consideration: Review term 'Bachelor’s Degree' in ISL and replace with Bachelor’s (or similar) Degree

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

It should be up to the laboratory director to decide whether the QM also has other tasks - e.g. analytical - in the lab.

The person filling the QM-position should be allowed to have two different roles/wear two different hats, though not at the same time. And it should be the responsibility of the laboratory director to find a person with suitable personal characteristics (in addition to qualifications) for this position.

5.2.3 Laboratory facility and Environmental Conditions

5.2.3.2 Security of the Facility, Equipment and Systems (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)

Other - WADA-accredited Laboratories

5.2.3.2.3 Two (2) main levels of access shall be considered in the Quality Manual or threat assessment plan:

Recommendation: The ISO 17025 standard no longer specifies the use of a Quality Manual. Replace with 'Two (2) main levels of access shall be defined in Laboratory formal written procedures or threat assessment plan:'

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

5.2.3.2.7

Comment regarding Limited access to stored samples for analytical personell: this can work for samples in long-term storage, but during the analysis process this would be a highly ineffecient and impractical way to work for many laboratories.

Security (inside controlled zones) can still be achieved by:

- All freezers where original bottles are stored (prior to long-term storage) shall be within monitored and access-controlled areas.

- Analytical personell (not in charge of sample reception, aliqouting and storage activities) should not access stored samples alone, but always be accompanied by another staff member when handling original sample bottles in/out of freezers, and this should be documented.

5.2.3.4 Relocation of Laboratory Facilities (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

For the 3rd dot point, at NATA we do not continue accreditation when we inspect a facility after a relocation, we just send a letter saying that the re-location is to our satisfaction either straight after the visit or after the lab has addressed any issues we identify. we only continue accreditation after a surveillance visit or reassessment.

5.2.3.5 Control of Data and Computer Security (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.2.3.5.6 there are a few instances of this but the word 'document' should be changed to 'record', in that "you document what you do and record what you did".For other examples, i will just comment 'change document to record'

5.2.3.6 Laboratory Equipment (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.2.3.6.6 change 'documented' to 'recorded'

5.3 Process Requirements (1)

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

5.3: Process Requirements"The Laboratory shall maintain paper or electronic Laboratory Internal Chain of Custody procedures for the control of, traceability and accountability for *Samples* and Aliquots from *Sample* receipt through the final disposal of the *Samples* and Aliquots."

Question: With Aliquot - does this mean the initial aliqout from the original container, or does it include the aliquotes prepared for analysis? This is not clear to us.

Comment:

- We disagree with the need for maintaining a record of disposal of the instrument aliquots. There is nothing gained, in our view, with regards to data security or sample integrity by doing this.

Of course, the original Sample needs a full CoC including disposal, and the inital aliquot has a CoC up to the final instrument result.

5.3.1 Reception, Registration and Handling of Samples (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

5.3.1.6 (and other articles: A sample splitting is allowed in ISL but the Code is specific to B sample splitting

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.1.6 In cases when either the “A” or “B” Sample is not suitable for the performance of the analyses (e.g. there is insufficient Sample volume; the Sample container has not been properly sealed and is leaking or has been broken; the Sample’s integrity has been compromised in any way; the Sample is heavily contaminated), the Laboratory, in consultation with the Testing Authority, should consider splitting the other Sample container (“A” or “B”, as applicable), provided that it is still sealed. This process may be applied repeatedly, if necessary.

Recommendation: The ISL here and in other section has A and B sample splitting. The code is explicit about the splitting of the B sample only.

5.3.1.5.2 “… seven (7) calendar days that a Sample with noted…”

Recommendation: Include the sections relevant to TA/RMAs as an annex to the ISTI similar to TD BAR and TD EAAS in the ABP Guidelines.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

- 5.3.1.3 change 'documented' to 'recorded'

- For note 14, change A" to "A"

5.3.2 Storage of Samples (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

In 5.3.2.1.3.1, 3rd paragraph, change "A to "A"

5.3.2.1 Storage of Urine Samples (3)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

Article 5.3.2.1.3.3: The UCI believes it is of utmost importance that the laboratories keep all positive samples until informed otherwise by the Testing Authority, the Results Management Authority or WADA. This would avoid any potential issue that could arise during the results management phase because the positive sample was destroyed due to a misunderstanding. For the sake of clarity, this comment applies to both urine and blood samples.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.2.1.3.5 In cases where both “A” and “B” urine Samples have been reported with an Adverse Analytical Finding and the minimum Sample storage period has expired (see ISL Article 5.3.2.1.3.3), and neither the Testing Authority nor WADA have requested the long-term storage of the Sample for the purpose of Further Analysis, and no challenge, dispute, or longitudinal study is pending or such have been completed, the Laboratory may dispose of the Samples or use them for research or quality assurance/quality improvement purposes (refer to ISL Article 5.3.3.1 below).

Recommendation: This paragraph need to be reconsidered**.** The laboratory would not necessarily know about 'challenge, dispute, or longitudinal study is pending'. The onus must be with Testing Authority or WADA to contact the laboratory to requested the continued storage of the sample.
Additionally: must be included in the ISTI

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

5.3.2.1.3.5As a laboratory, we are very seldom informed about the status of a case; whether it is challenged, pending etc.
It should therefore be the responsibility of the TA/ADO (or WADA), to inform the laboratory that a sample cannot be disposed of after the minimum sample storage time has expired.

5.3.2.2 Storage of Blood Samples (2)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

The UCI believes it is of utmost importance that the laboratories keep all positive samples until informed otherwise by the Testing Authority, the Results Management Authority or WADA. This would avoid any potential issue that could arise during the results management phase because the

positive sample was destroyed due to a misunderstanding.
For the sake of clarity, this comment applies to both urine and blood samples

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Review in consideration of recommendations made for 5.3.2.1.3.5

5.3.2.3 Long-term Storage of Samples (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.2.3.4 change 'documented' to 'recorded'

5.3.4 Sample Analysis (3)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

Article 5.3.4.5.5.8: The UCI believes it should be mandatory to invite the athlete to attend the splitting and resealing procedure of his B sample. The UCI fails to see why it would be mandatory in case of a splitting procedure in accordance with article 5.3.1.6 but not in the case of a splitting procedure on a long-term stored sample. Moreover, this is the only opportunity the athlete has to witness the opening of one of his or her samples – this is important not only for the athlete, but to ensure that the ADO/laboratory cannot be accused of tampering.

Article 5.3.4.5.4.7.5: For the avoidance of any doubt, a Comment to this Article could clarify that a failure to respect the 3-month time limit shall not invalidate an Adverse Analytical Finding unless the athlete can establish that this could reasonably have caused the AAF (as per article 3.2.2 WADC).We would also suggest a cross-reference to article 5.3.4.5.4.7.8 ISL.

Articles 5.3.4.5.4.7.7 and 5.3.4.5.4.7.8: We would suggest the following amendment to article 5.3.4.5.4.7.8

5.3.4.5.4.7.8 The timing of the “B” confirmation analysis may be strictly fixed at short term with no postponement possible, when circumstances so justify. This can notably and without limitation be the case in the context of Testing during or immediately before or after Major Events or when the further postponement of the B sample analysis could significantly increase the risk of sample degradation.

We would also suggest that article 5.3.4.5.4.7.7 ISL cross-references article 5.3.4.5.4.7.8 ISL

Article 5.3.4.5.4.7.19: The outcomes of the internal investigation should also be sent to the Results Management Authority, so it can decide if another ADRV (e.g. Use/Tampering) could potentially be asserted.

With that said, it should be clarified whether this article, in conjunction with the definition of Negative Finding, implies that no ADRV may be pursued (contrary to the WADA Code comment for Use) once a

Negative Finding has been declared:

Article 5.3.4.5.5.1: The UCI would suggest to delete the words “held in long-term storage” so as to clarify any doubt that all samples can be subject to further analysis

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

Article 5.3.4.4.6.3 - Australia sees this as a positive change in terms of improving laboratory efficiency.
Article 5.3.4.5.5.9 This amendment contradicts previous advice received from WADA that testing a sample that has yielded an AAF for another substance has no impact on the final outcome of an ADRV.

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

-

5.3.4.5.4.6.3 – We welcome the extension of the list of substances included at this point as it will remove the need for unnecessary confirmation analyses and hence contribute to improved efficiency. This change will have an impact on the reported %AAFs and hence will need to be noted in future testing figures reports.

5.3.4.1 Sampling and Preparation of Aliquots for Analysis (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.1.4 The Laboratory shall measure the pH and Specific Gravity (SG) of urine Samples during the Initial Testing Procedure and the Confirmation Procedure(s) (“A” and “B” Samples)20. Other tests that may assist in the evaluation of adulteration or manipulation may be performed if deemed necessary by the Laboratory.

Recommendation: for pH and SG measurement for the B sample Confirmation Procedure it should be a 'can' not a 'shall' as the B bottle can have very limited sample volume in which case it would be better to use sample for substance confirmation than pH and SG
Recommendation: include reference to the TD EAAS

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.4.1.3, 2nd paragraph - change 'documented' to 'recorded'

5.3.4.2 Selection of Analytical Methods (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.4.3.1 due to ILAC Resolution GA 20.14, Accreditation Bodies have three years to convert their Reference Materials Producers from ISO Guide 34:2009 to ISO 17034, therefore you could have Reference Materials Producers accredited to ISO Guide 34 until 30 November 2019 but there is no provision in this clause for that.

5.3.4.4 Validation of Analytical Testing Procedures (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

- This section is ambiguous and lend itself to different interpretations by laboratories and assessors.
- This section must rather be a frame work and more details regarding on how the validations must be conducted, and results interpreted should be in a TD, Guideline or Technical Note. There must be harmonization between laboratories to circumvent the different interpretations.
- Will this section be implemented retrospectively or only from the effective date forward?

References:

1. FDA-Bioanalytical Method Validation Guidance for industry. May 2018.

2. European Medicines Agency. Guideline on bioanalytical method validation

3. EURACHEM. Fitness for Purpose of Analytical Methods. 2014

4. Validation of qualitative analytical methods. E Trullols, I Ruisánchez, FX Ruis. Trends in Analytical Chemistry, 2004, 23 p137-145

- Note that in all accepted international guidelines, the validation of affinity binding assay (e.g. immunoassays) are different to that of LC-based assays: there are other criteria applicable and some criteria for LC-based assays are not applicable to affinity binding assays, or are accessed differently, such as carry-over.

5.3.4.4.1 Validation of Analytical Testing Procedures for Non-Threshold Substances (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: Qualitative or semi-quantitative analysis of substances. Currently this section covers chromatographic, ligand binding/affinity assays, biomarkers etc. which do not necessarily have the same parameters or acceptance criteria.

“adequate number of representative samples…”
Recommendation: Please define adequate number of samples or provide an applicable amount. According to literature the minimum number is 6, but in TD DL it is 10. Specify a specific number.
“recovery”

Recommendation: Recovery is a quantitative measurement and therefore the applicability thereof to ITP analysis of non-threshold substances is not clear. If the S/N ratio at LOD is adequate (3/1), the relevance of recovery is not apparent.This is a quantitative parameter and not a qualitative parameter.
"estimate the method recovery and robustness"**Recommendation:**The robustness of a method is not estimated but rather tested to determine what changed have an affect to then ensure these parameters are controlled.

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

Footnote 11, Page 23, last sentence: "If the identification can be achieved, the result, even if below the estimated LOD, is valid and shall be reported."

Comment: Reporting below the LOD should be at the discretion of the laboratory. The sentence could be rephrased to keep it more open, e.g.:
"An established LOD shall not exclude the possibility to report a substance if it's identificationcan be achieved in complience with TD IDCR with a result below the estimated LOD"

5.3.4.4.1.1 Validation of Initial Testing Procedures (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

• The Laboratory shall develop, as part of the validation process, acceptable standard solutions for identification of Non-Threshold Substances using Reference Materials. In the absence of suitable Reference Materials, Reference Collections may be used;

Recommendation: This is a general comment applicable to any validation procedure. Suggestion move to point 5.3.4.4 Also include the number of samples and batches to be used for validation.

Recommendation: List the validation parameters separately.

Selectivity and absence of matrix interferences may be interpreted as either one or two parameters according to literature.

Matrix interferences must be clarified as there is different opinions, e.g. different matrices or comparison of a blank matrix spiked after extraction with pure reference standard.

Robustness, add definition as for CP.

Recovery is a quantitative validation parameter.

According to literature the only parameters necessary for qualitative analysis to be validated is selectivity and LOD. Other additional parameters may be validated.

5.3.4.4.1.2 Validation of Confirmation Procedures (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.4.1.2 '... footnote 23: ...If the identification can be achieved, the result, even if below the estimated LOD, is valid and shall be reported.'
Recommendation: consideration should be given that reporting below the LOD of a method must be at the laboratories discretion. The 'shall' should be 'can'.

- Matrix interferences: The Confirmation Procedure should avoid interference in the detection of *Prohibited Substances* or their *Metabolite*(s) or *Marker(*s) by other components of the *Sample* matrix;

Recommendation: Please define an adequate number as it can be anything from 1 to 10. Preferably the same number of samples must be used for all the parameters. The ISTD should also be included in the validation**.**

Please specify what WADA wants under Matrix Interference.

Example: Also referred to as Matrix Effects and which can lead to enhancement or suppression in an analytical method. Matrix Interference or Effects is calculated for example:

ME% = 100 * extract/standard

Extract represents the peak area of the analyte when diluted with matrix extract and standard represents the peak area of analyte in the absence of matrix. The concentration of the analyte in both samples should be the same. A value close to 100 indicates the absence of matrix influence, while a value less than 100 indicates suppression and larger than 100, indicates matrix enhancement.

OR, similar formula: ME% = 100 * extract/standard - 100

Negative values indicates suppression, while positive values signifies matrix enhancement. A value of 0 indicates the absence of matrix interference or effect.

"Identification Capability"

Recommendation: This does not make sense since all these criteria have already been covered during the selectivity assessment: if a method is selective for a certain compound, it can only be so if it has the capability to specifically identify that compound. So by proving Selectivity, Identification Capability has already been proven…

As for non-threshold substances. This does not make sense since all these criteria have already been covered during the selectivity assessment: if a method is selective for a certain compound, it can only be so if it has the capability to specifically identify that compound. So by proving Selectivity, Identification Capability has already been proven

5.3.4.4.2 Validation of Analytical Testing Procedures for Threshold Substances (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.4.2.1 Validation of Initial Testing Procedures (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: 5.3.4.4.1.1 ITP methods include threshold substances so this section is unnecessary

5.3.4.4.2.2 Validation of Confirmation Procedures (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: This section and the corresponding section on Method Development and Validation in TD DL needs to correspond with each other.

Footnote: Further guidance is provided in TD DL

Number of batches for repetition must be specified. Min of 3 batches is normally required.

5.3.4.5 Application of Analytical Testing Procedures

5.3.4.5.1 (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.1 At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures**29**, as determined by *WADA* in specific Technical Document(s), Technical Letter(s) or Laboratory Guidelines. Laboratories may implement additional methods, provided they are validated and ISO/IEC-17025 accredited, notably for the analysis of particular *Prohibited Substances* or *Prohibited Methods*.

Recommendation: A list of mandatory analytical methods shall be published annually by WADA and provided to all laboratories. This could be in form of a TL and sent to all candidate, probationary and accredited laboratories.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

As mentioned earlier, in the sentence

5.3.4.5.1 'provided they are validated and ISO/IEC-17025 accredited...'
and

There are no such things as accredited methods or procedures so wording similar to that in the note below should be used, eg. 'method included in the laboratory's scope of accreditation....'

5.3.4.5.2 (1)

NATA SUBMITTED

Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

As mentioned earlier, in the sentence

5.3.4.5.2 'Laboratories may apply additional accredited Analytical testing Procedures....' There are no such things as accredited procedures so wording similar to that in the note below should be used, eg. 'proceduresincluded in the laboratory's scope of accreditation....'

5.3.4.5.3 Initial Testing Procedures (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.3.1 change 'documented' to 'recorded'

5.3.4.5.4 Confirmation Procedures

5.3.4.5.4.1 (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

Change 'documented' to 'recorded'

5.3.4.5.4.5 Confirmation Procedure Methods (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

No need for uppercase letters for Binding Assays throughout this clause

5.3.4.5.4.6 "A" Sample Confirmation (3)

Institute of Biochemistry, German Sport University Cologne SUBMITTED
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

5.3.4.5.4.6.3. We welcome the extension of the list of substances e.g. to declared beta-blockers or diuretics. This extension will prevent many unnecessary confirmation analyses.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.4.6.3. We welcome the extension of the list of substances e.g. to declared beta-blockers or diuretics. This extension will prevent many unnecessary confirmation analyses

Recommendation: Update TUE Guideline

5.3.4.5.4.6.9 For endogenous Threshold Substances, *Adverse Analytical Finding* decisions for the "A" *Sample* results may also be based on the application of any Fit-for-Purpose Analytical Testing Procedure that establishes the exogenous origin of the *Prohibited Substance* or its *Metabolite*(s) or *Marker*(s) (*e.g.* GC/C/IRMS).

Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the *Prohibited Substance* or its *Metabolite*(s) or *Marker*(s).

Recommendation: IRMS example given here, is for steroid profile parameters which are not regarded as Threshold Substances. The only endogenous Threshold Substances according to TD DL are hCG and hGH

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.4.6.2 - last sentence - change 'documented' to 'recorded'
5.3.4.5.4.6.3 No need for uppercase letters for Therapeutic Use Exemption.

'Laboratory' is not underlined in 11th sentence
No need for upper case letters in Test Report
5.3.4.5.4.6.4 - last sentence - change 'documented' to 'recorded'

5.3.4.5.4.7 "B" Sample Confirmation (4)

cadf SUBMITTED
francesca rossi, director (switzerland)
Sport - IF – Summer Olympic

For the avoidance of any doubt, a Comment to this Article could clarify that a failure to respect the 3-month time limit shall not invalidate an Adverse Analytical Finding unless the athlete can establish that this could reasonably have caused the AAF (as per article 3.2.2 WADC).

We would also suggest a cross-reference to article 5.3.4.5.4.7.8 ISL

Institute of Biochemistry, German Sport University Cologne SUBMITTED
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

5.3.4.5.4.7.11 The addition of the re-sealing procedure in the SOP is not necessary, because it is sufficiently described in the ISL.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.4.7.3 and 5.3.4.5.4.7.4 included in the ISTI, so that it can be included in their rules.

5.3.4.5.4.7.10 "Presence ..." This states that the sample is resealed in the presence of the athlete, while in the Guideline for Conducting and Reporting Subcontracted Analysis footnote 1, the B-sample is resealed by the athlete/representative/independent witness

5.3.4.5.4.7.11 The addition of the re-sealing procedure in the SOP is not necessary, because it is sufficiently described in the ISL.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.4.7.18 last sentence - change 'documented' to 'recorded'

5.3.4.5.5 Further Analysis (2)

cadf SUBMITTED
francesca rossi, director (switzerland)
Sport - IF – Summer Olympic

CADF believes it should be mandatory to invite the athlete to attend the splitting and resealing procedure of his B sample. The UCI fails to see why it would be mandatory in case of a splitting procedure in accordance with article 5.3.1.6 but not in the case of a splitting procedure on a long-term stored sample. Moreover, this is the only opportunity the athlete has to witness the opening of one of his or her samples – this is important not only for the athlete, but to ensure that the ADO/laboratory cannot be accused of tampering.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.4.5.5.6 Further Analysis includes notably but without limitation the application of newly developed Analytical Testing Procedures and/or the analysis of new target Analytes of *Prohibited Substance*(s) or *Prohibited Method*(s) [*e.g. Metabolite*(s) and/or *Marker*(s)], which were not known or not tested during the initial Analytical Testing of the *Sample*.

Recommendation: Include "Further Analysis shall not be applied to substances or methods, which are no longer prohibited at the time of Further Analysis."

5.3.5 Results Management (1)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

5.3.5.1 Review of Results (2)

Institute of Biochemistry, German Sport University Cologne SUBMITTED
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

5.3.5.1.1 The double check of ITPs ~~shall~~ should be performed from two independenent analysts

Rationale

The mandatory double check of all ITP results is an enormous increase of workload and increases the prize of the analyses. This most probably leads to a reduction of the total number of analyses.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.5.1.1 The double check of ITPs ~~shall~~ should be performed from two independenent analysts
Rationale: The mandatory double check of all ITP results is an enormous increase of workload and increases the price of the analyses. This most probably leads to a reduction of the total number of analyses.

5.3.5.2 Documentation and Reporting (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.3.5.2.3 change 'documented' to 'recorded'

5.3.5.2.6 Test Report

5.3.5.2.6.1 (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Footnote 46: The Laboratory is not required to provide any additional Test Report, either in hard copy or digital format, to that submitted in *ADAMS* (except as described in ISL Articles 5.3.5.2.6.7 and 5.3.5.2.6.11). All *Code*-compliant Testing Authorities shall be able to access the Test Reports of their *Samples* in *ADAMS*. The Laboratory should record the *ADAMS* Test Report as part of the *Sample*'s documentation.

Recommendation: This should not be a footnote, but a paragraph under this section

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

Change 'document' to 'record'

5.3.5.2.6.2 Test Report for Non-Threshold Substances (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

"A" *Sample* Test Report

Recommendation: Align this section with sections 5.3.4.5.4.6.6 - 10

5.3.5.2.6.3 Test Report for Threshold Substances (1)

Union Cycliste Internationale SUBMITTED

Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

It should be clarified here – as it is above – that no quantification should be recorded (e.g. 5.3.4.5.4.7.13.)

5.3.5.2.6.10 (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

The following sentence:
'Information sent by a facsimile is acceptable provided it is verified that the facsimile has been transmitted to the correct facsimile number.'

Should be changed to read something like:
'Information sent by a facsimile is acceptable provided the correct facsimile number is verified prior to transmission and receipt is verified after the facsimile has been transmitted.'

5.3.5.2.7 Laboratory Documentation Package and Certificate of Analysis (2)

Union Cycliste Internationale SUBMITTED
Union Cycliste Internationale Union Cycliste Internationale, Legal Anti-Doping Services (Switzerland)
Sport - IF – Summer Olympic

Even though this already appears in the TD2017LDOC, The UCI would suggest the following addition to this section, to avoid any doubt:

“Laboratories are not required to produce a Laboratory Documentation Package for a Sample in which no Prohibited Substance or Prohibited Method or their Metabolite(s) or Marker(s) was detected”

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.3.5.2.7.2 The Laboratory Documentation Package and/or Certificate of Analysis should be provided by the Laboratory only to the relevant Results Management Authority or WADA upon request and should be provided within ten (10) working days of the request, unless a different deadline is agreed with the Results Management Authority or WADA, respectively.
Recommendation: 15 working day

5.4 Management Requirements

5.4.2 Quality Policy and Objectives (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

The new version of ISO/IEC-17025 does not have a requirement for a quality policy.

5.4.3 Assuring the Quality of Analytical Results

5.4.3.2 (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.4.3.2 Analytical performance shall be monitored by operating quality control schemes appropriate to the type and frequency of Analytical Testing performed by the Laboratory. The range of quality control activities include, but are not limited to:

• Appropriate positive and negative quality control samples (QCs) shall be included in every analytical run both for the Initial Testing Procedure(s) and Confirmation Procedure(s)**48**;

• Appropriate internal standard(s) shall be used for chromatography methods;

• For Threshold Substances, quality control charts (QC-charts) referring to appropriate control limits depending on the Analytical Testing Procedure employed (*e.g.* +/- 2SD; +/- 3SD; +/- *U95%),* shall be regularly used to monitor method performance and inter-batch variability (when applicable).

Recommendation: QC charts need to be established across **all** methods (ITP and CP) and not only for threshold substances (ITP and CP).

5.4.3.3 Internal Quality Assurance Scheme (iQAS) (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

5.4.3.3.2 The iQAS plan shall include the proficiency testing of as many Laboratory procedures as possible, including the submission of a sufficient number of test samples on a regular basis (*e.g.* monthly) and shall incorporate as many categories of *Prohibited Substances* and *Prohibited Methods* as possible.

Recommendation: A minimum number of samples should be provided as an example for ITP and CP.

5.4.3.5 External Audits (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

NATA is happy to accept the use of appropriate external auditors as fulfilling the role of internal auditors and would not expect an additional internal audit.

5.4.7 Control of Non-conformities in Analytical Testing (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.4.7.3 - the new version of ISO/IEC-17025 does not mention preventive actions

5.4.9 Subcontracting of Analysis (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

5.4.9.3 suggest the words 'When subcontracting analysis' be changed to 'When subcontracting' or 'When subcontracting analyses' or 'When subcontracting an analysis'.

5.4.10 Purchasing of Services and Supplies

5.4.10.1 Chemicals and Reagents (1)

Inmetro SUBMITTED
Luciana Almeida, Accreditation Manager (Brazil)
Public Authorities - Government

I would like to suggest the inclusion of a requirement regarding the extension of validity of CRM (Certified Reference Material) used for quantification testing purposes. Would this extension of validity be accepted or not?

5.4.11 Customer Service

5.4.11.1 (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

The new ISO/IEC-17025 no longer specifically mentions 'service to the customer'. See 7.1.7 of 17025 for the current wording in this regard.

5.4.11.2 Ensuring Responsiveness to WADA (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: This should be a reciprocal process, and WADA should also commit to give feedback regarding responses from Lab. For instance, there should feedback when Corrective Action Reports have been committed and accepted. At the moment, responses are only given when CAR are “unacceptable”.

Section 6 - WADA External Quality Assessment Scheme (EQAS)

6.4 Reporting of EQAS results (2)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

It is unclear whether the proposed ban on laboratory contact restricts the ability of a laboratory to get a second expert opinion on a blind sample.

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

6.4 – In some instances, such as a required opinion on an ESA positive, contact between laboratories about EQAS samples may be appropriate. This exemption should be included.

Section 7 - Evaluation of Laboratory EQAS and Routine Analytical Testing Performance (5)

International Paralympic Committee SUBMITTED
James Sclater, Director (Germany)
Other - Other (ex. Media, University, etc.)

The EQAS program should be further strengthened and apply non-compliance issues in a balanced and proportional way, so as to address potential quality and competency issues, however not be overly punitive to laboratories.

Institute of Biochemistry, German Sport University Cologne SUBMITTED
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

In the introduction of chapter 7.0 it should be mentioned that Laboratories only receive EQAS samples from an ISO certified provider of inter laboratory tests.

Rationale:

- In the previous EQAS rounds several shortcomings were detected (contaminations, degradations etc.).

- The WADA labs have to be ISO accredited. Therefore, a laboratory, which provides EQAS samples to these labs has also to be ISO accredited.

- False results of EQAS samples have severe effects on laboratories. The certification of the supplier of the EQAS samples guarantees a higher quality of the EQAS tests and and e.g. a documentation, which allows to justify a sanction of a laboratory.

Footnote 2: Regarding new methods, the successful participation in an inter-laboratory study should not be manadtory to get WADA approval.

Rationale:

Some laboratories have implemented new methods, which are validated, published and ISO accredited but which are not yet implemented in other laboratories. Therefore inter-laboratory studies are not possible.

SADoCoL SUBMITTED
Hanno du Preez, Operations Manager (South Africa)
Other - WADA-accredited Laboratories

7.2 …

EQAS Samples Containing Threshold Substances 7.4[1], [2].

The subjects that are here relegated to a foot note are of major importance since it can influence the accreditation status of a Laboratory. There are many foot notes, throughout the ISL draft, that should be specific paragraphs to give guidance, and not foot notes. Please reduce the foot notes and rather add more paragraphs.

7.2.1

The *WADA Guideline for Corrective Action Investigation and Reporting by Accredited Laboratories 2009* should be updated with this footnote.

Section 7

7.3.1.4.2

Suspension of WADA Accreditation for Technical or Methodological Errors

Unsatisfactory Corrective Action Report

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the Laboratory shall receive twenty (20) penalty points in accordance with the Points Scale Table in ISL

This is ridiculous, considering different approaches and interpretations by different nationalities!!!! Now a lab will be penalised because of different views or opinions!! Also, 20 points is far too much for requesting additional information to a CAR.

How will labs be protected against unrighteous opinions or views when compared to really low standard CARs? It makes sense to apply such measures for absolute absurd and gross neglected CARs, but where a lab really did their utmost to address a CAR and then is penalised because of minor differences in opinions or views, is ridiculous.

There will always be a difference in opinion and therefore and a lab cannot be penalised for this. If after the first review additional information is required and after being submitted, did not suffice a second time for the same CAR

7.3.1.5

Clerical / Administrative Error

10 points are too much.

We are working with people, not robots.

You want to penalise the labs, but how often was it found that WADA made mistakes, but then just casually altered their decisions?

7.3.1.5.2

Suspension for a clerical error is ridiculous, especially where an athlete is not affected.

The point system is really absurd, especially when 10 points are allocated for example for reporting a false negative, while 20 points are allocated for an unsatisfactory CAR.

Consider a better structured evaluation system. Example provided. If WADA wants to impose stronger rules for labs, then WADA needs to apply their rules consistently to all labs in a unified manner, irrespective of incentives that may affect the inconsistent manner in which rules are applied currently. Use a chart that states minimum decision rules. It can be extended to include more criteria.

7.3.3.1

CAR

In general, if a Root Cause Analysis or a CAR is found by WADA/LabEG to be "not satisfactory", an explanation and possible guidance should be given to the Lab to redo the action to the satisfaction of

WADA/LabEG. This can be a very important learning/training experience to the Lab and will be regarded as a positive outcome since all the actions from WADA explained in this Section, have negative consequences and outcomes for the Labs.

7.4

Overall Laboratory Evaluation

The status of a Lab's penalty points should be available to the Lab, for instance on ADAMS or some confidential communication platform. This will assist the Lab to audit its penalty points.

WADA should also indicate if penalty points are "reset" after 12 months, and access to this information will allow the Lab to be aware of its accumulated points.

Type of Penalty

Limitations

Timeframe

Actions

Preliminary Suspension

(constitutes minor corrective active action that has the potential to influence laboratory results)

Analytical work is stopped for the specific method or compound until satisfactory corrective action is implemented.

The Laboratory must continue with WADA EQAS program during suspended period.

Minimum 1-2 weeks, but maximum 4 weeks to perform and implement corrective action.

Submit corrective action for review and approval. Following satisfactory implementation of corrective procedures and upon approval thereof, the laboratory will be able to be re-instated immediately, without further delay.

No site-visit required.

Immediate Suspension

(constitutes serious misconduct, or
a non-compliance, or
athlete results have been impacted by poor laboratory operations, etc.)

Analytical work is stopped for the specific method or compound until satisfactory corrective action is implemented.

The Laboratory must continue with WADA EQAS program during suspended period.

Minimum 1 month, but maximum 3 months to perform and implement corrective action.

Submit corrective action for review and approval. A site-visit is not mandatory, but may be required based upon the severity of the non-conformance.

Minimum 2 months, but maximum 6 months to perform and implement corrective action.

Submit corrective action for review and approval. A site-visit is not mandatory, but may be required based upon the severity of the non-conformance.

Minimum 6 months, but maximum 1 year to perform and implement corrective action.

Submit corrective action for review and approval. A site-visit is mandatory.

Revocation

(constitutes serious misconduct, or non-compliance, or
athlete results have been impacted by poor laboratory operations, or
the laboratory was unable to implement corrective procedures within 1 year. etc.)

Analytical work is stopped for all laboratory activities??? The laboratory may re-apply for re-accreditation of the unaffected analytical work.

Laboratory must / has the option to continue with WADA EQAS program during revocation period???

Minimum 1 year, but maximum 2 years to perform and implement corrective action/s.

Submit corrective action for review and approval. Site visit is mandatory.

An existing WADA laboratory does not need to perform a full re-application process.

Comments on Penalty points system

Labs are told by WADA that they are there to help them and to improve the quality of analytical services. The assessment of laboratory performance as a whole according to this scheme is not conducive to improvement. The standard of WADA labs is of the highest in the analytical world – NO ROOM FOR ERROR!

One mistake in an EQAS round can lead to provisional suspension according to this point scale. This is the start of a vicious cycle, for which we have seen the results in the past few years with many labs getting suspended. The more suspended labs there are, the more pressure on remaining labs, which leads to mistakes and the cycle continues.

What is the aim of **double** penalizing laboratories for the same mistake? Points for unsatisfactory RCAs and CARs? It is suggested that the LabEG conduct a RCA for unsatisfactory RCAs and CARs. May this be the result from lack of feedback to laboratories to what is a satisfactory CAR? Perhaps a lack of training, interpretation and harmonization?

Labs are expected to have training programs according to ISO, National Accreditation bodies provide training so perhaps WADA needs to **RESET** their perspective. **Enable labs** to improve themselves by providing **feedback** and **training** (webinars) on site visit findings, CARs, interpretation mistakes etc. E.g. a workshop on RCAs and CARs with Lab Directors, QMs, LabEG together with external experts.

Request: Add a penalty point section to ADAMS which is eyes only for each lab, so that Directors and QMs can take preventative actions to prevent suspension. If labs are assessed according this point scale they have the right to know their point total.Let’s work together on equal footing not against each other!

Results Evaluation

Non-Conformity

Penalty Points

Actions and Sanctions

***Prohibited Substances* or**

Prohibited Methods

False *Adverse Analytical Finding*

· Unsatisfactory RCA#

§ **Technical or Methodological error**

· Unsatisfactory CAR#

· Satisfactory CAR#

§ **Administrative or Clerical error**

· Unsatisfactory CAR# or *Consequences* for an *Athlete*

2

10

5

5

5

Article 7.3.1

False Negative Finding

· Unsatisfactory CAR# or other False Negative Finding(s)

10

5

Article 7.3.2

Threshold Substances

Unsatisfactory Result[3]

5

Corrective Action Report

Questionable Result 58

2

Internal Investigation

Steroid Profile *Markers*

Unsatisfactory Result

Occurrences**

2

1

Internal Investigation

≥ 3

2

Corrective Action Report

GC-C-IRMS δ13C

Unsatisfactory Result

Occurrences *

1-2

1

Internal Investigation

≥ 3

3

Corrective Action Report

Documentation*

ISL or TD Nonconformity

2

Corrective Action Report

Unsatisfactory CAR#

2

Re-submission of Corrective Action Report

Late Submission of CAR#

1

Per week beyond the applicable deadline

Late reporting of blind or double-blind EQAS results

2

Per week beyond the applicable deadline

Corrective Action Report

Technical Issue

ISL or TD Nonconformity

2

Corrective Action Report

Point Total for single (blind or double-blind**) EQAS round**

≥20

Provisional Suspension until final decision by *WADA*

Point Total for double-blind EQAS for 12 month period**

≥20

Point Total for routine Analytical Testing for 12 month period**

≥20

Point Total (blind and double-blind EQAS and routine Analytical Testing) for 12 month period

≥30

[1] The main criterion applied for the evaluation of EQAS results for the quantification of Threshold Substances is the compatibility of the reported Laboratory result with the assigned value. Therefore, the incorrect reporting of an EQAS sample as a Negative Finding or as an *Adverse Analytical Finding*, as applicable, when the assigned value of the Threshold Substance in the sample is close to the Decision Limit, is not considered as a misreporting of a false finding if the *z*-score for the Laboratory quantitative result is not unsatisfactory.

[2] The *z*–score is calculated according to the following formula:

Where:

is the mean value of the Laboratory's replicate determinations

is the assigned value (reference, nominal or consensus value, as applicable)

is the target standard deviation (*e.g. uc_Max* or robust Reproducibility *sR* of results from all participant Laboratories)

[3] When an unsatisfactory or questionable quantification result leads to the misreporting of the EQAS sample as a false *Adverse Analytical Finding* or as a False Negative Finding, then penalty points will be assigned in accordance with paragraphs 7.3.1 and 7.3.2, respectively.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

In the introduction of chapter 7.0 it should be mentioned that Laboratories only receive EQAS samples from an ISO certified provider of inter laboratory tests.

Rationale:

- In the previous EQAS rounds several shortcomings were detected (contaminations, degradations etc.).
- The WADA labs have to be ISO accredited. Therefore, a laboratory, which provides EQAS samples to these labs has also to be ISO accredited.
- False results of EQAS samples have severe effects on laboratories. The certification of the supplier of the EQAS samples guarantees a higher quality of the EQAS tests and e.g. a documentation, which allows to justify a sanction of a laboratory.

Footnote 2: Regarding new methods, the successful participation in an inter-laboratory study should not be manadtory to get WADA approval.
Rationale: Some laboratories have implemented new methods, which are validated, published and ISO accredited but which are not yet implemented in other laboratories. Therefore inter-laboratory studies are not possible.

WADA shall also apply this Section 7, including the Points System Table in Article 7.4 below, when assessing a Laboratory's routine Analytical Testing operations.

Recommendation: The points scale can not only be applied to routine Analytical Testing. As outlined above even samples which had been specifically prepared by WADA for the purpose of EQAS have failed, to thus then impose the points scale into routine testing will lead not to improvements but further problems.

Recommendation: WAADS propose risk based review of routine Analytical Testing operations with appropriate actions, this is inline with the new ISO17025.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

In 2nd paragraph, change the last mention of 'Laboratory' to 'Laboratory's'

7.1 EQAS Samples Containing Non-Threshold Substances (1)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

7.3.1.4.2 Australia questions why a laboratory would be asked to re-analyse samples if its corrective action report is unsatisfactory.

7.2 EQAS Samples Containing Threshold Substances (3)

Organizacion Nacional Antidopaje de Uruguay SUBMITTED
José Veloso Fernandez, Jefe de control Dopaje (Uruguay)
NADO - NADO

With the glucocorticosteroids the threshold of detection in concentration must be lowered. There are sports that abuse the use of these drugs that have little analgesic and pro recuperator power. Rather, because of the toxic drug that they are sick and do more than cause welfare. This aspect should allow laboratories to work more closely in establishing the true thresholds for even more therapeutic difference in doping

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Footnote Recommendation: The subjects that are here relegated to a foot note are of major importance since it can influence the accreditation status of a Laboratory. There are many foot notes, throughout the ISL draft, that should be specific paragraphs to give guidance, and not foot notes. Please reduce the foot notes and rather add more paragraphs.

7.2.1 Unsatisfactory Quantitative Result (*z*-score > 3 or < -3)

Recommendation: The *WADA Guideline for Corrective Action Investigation and Reporting by Accredited Laboratories 2009* should be updated with this footnote.

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

In Note 55, first dot point, change 'no-conformity' to 'non-conformity'

7.3 Evaluation of Results

7.3.1 False Adverse Analytical Finding Result (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

7.3.1.2 False *Adverse Analytical Finding* during routine Analytical Testing
• If a False Adverse Analytical Finding is reported during routine Analytical Testing and is identified by the Laboratory, the Laboratory shall inform WADA immediately and provide WADA with a satisfactory Root Cause Analysis report explaining the reason(s) for the error within five (5) working days of informing WADA;
Recommendation: five (5) working' should be inline with 7.2.1 and changed to ten (10) working days**Recommendation:** consideration need to be taken in relation to short timelines and what constitutes a 'satisfactory Root Cause Analysis' as the laboratory might only be able to report what reviews it has thus far completed and what further evaluations are in progress as well as provide timelines for expected final CAR which shall include the satisfactory RCA.

7.3.1.4 Technical and/or methodological error

7.3.1.4.1 Provisional Suspension of WADA accreditation for technical or methodological errors (1)

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

▪

7.3.1.4.2 – If a laboratory's corrective action is considered unsatisfactory, it would be premature to ask the laboratory to conduct re-analysis of other samples. This may consume sample volume when the error is yet to be corrected. Re-analysis of samples should only be conducted once the error has been appropriately rectified.

7.3.1.4.2 Suspension of WADA Accreditation for Technical or Methodological Errors (3)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Unsatisfactory Corrective Action Report

• If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the Laboratory shall receive twenty (20) penalty points in accordance with the Points Scale Table in ISL Article 7.4 below;

Recommendation: This is ridiculous, considering different approaches and interpretations by different nationalities!!!! Now a lab will be penalised because of different views or opinions!! Also, 20 points is far too much for requesting additional information to a CAR.

How will labs be protected against unrighteous opinions or views when compared to really low standard CARs? It makes sense to apply such measures for absolute absurd and gross neglected CARs, but where a lab really did their utmost to address a CAR and then is penalised because of minor differences in opinions or views, is ridiculous.

There will always be a difference in opinion and therefore and a lab cannot be penalised for this. If after the first review additional information is required and after being submitted, did not suffice a second time for the same CAR

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

3rd and 7th dot point, change 'document' to 'record'

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

"If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the laboratory shal receive twenty (20) penalty points..."
Comment: This seems highly unreasonable and potentially very unfair.
The laboratory must get the opportunity to improve an initial CAR, add additional information etc. (when requested by the LabEG). As it stands now, even misunderstandings or slight differences in opinions, can suspend a laboratory!

7.3.1.5 Clerical/Administrative Error (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

7.3.1.5 Clerical/Administrative Error

• If the Root Cause Analysis report provided by the Laboratory identifies the error as clerical or administrative, the Laboratory shall receive ten (10) penalty points in accordance with the Points Scale Table in ISL Article 7.4 below.

Recommendation: 10 points are too much. We are working with people, not robots. You want to penalise the labs, but how often was it found that WADA made mistakes, but then just casually altered their decisions?

• The Laboratory shall correct the clerical/administrative error within 24 hours of receiving written notification by WADA and will provide WADA with a satisfactory Corrective Action Report55 within five (5) working days (unless otherwise indicated by WADA) describing the remedial action(s) taken to avoid the recurrence of the particular error and evaluating the impact on routine operations.
Recommendation: '24 hours' should be changed to next working day (similar also in other sections which includes 24 hours)

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

Regarding 10 penalty points for clerical or administriative mistakes:
Comment: This is way too many points. The number of points must reflect the seriousness of the error. See also comment in 4.6.4.1 Suspension of Accreditation, where we recommend a "graded penalty system".
Two examples why we feel strongly about this:
- When reporting EQAS-results in ADAMS, all reporting has to be done manually; we (everybody) know that this potentially creates more mistakes than uploading of csv-files (we are after all, only human).
- When adding data to an already submitted sample (e.g. for the confirmation of endogenous steroids), we cannot "save" and have a look at the data we have entered (e.g. by printing the results page). Because the ITP-results have already been submitted, the CP-results are automatically submitted when we save, leaving us with no possibility to correct a typing mistake.

7.3.1.5.1 Provisional Suspension of WADA accreditation for Clerical or Administrative Errors (1)

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

We repeat our opinion expressed for 7.3.1.5 and 4.6.4.1:
The penalty must reflect the seriousness of the error/non-complience!

7.3.1.5.2 Suspension of WADA Accreditation for Clerical or Administrative Errors (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

There may be circumstances where the inability to provide a corrective action report within a reasonable time frame may be beyond the control of labaoratory eg an ADO's results management process is slow. This requirement may need to take account of these circumstances.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: Suspension for a clerical error is ridiculous, especially where an athlete is not affected.

The point system is really absurd, especially when 10 points are allocated for example for reporting a false negative, while 20 points are allocated for an unsatisfactory CAR.

Consider a better structured evaluation system. Example provided in chart. If WADA wants to impose stronger rules for labs, then WADA needs to apply their rules consistently to all labs in a unified manner, irrespective of incentives that may affect the inconsistent manner in which rules are applied currently. Use a chart that states minimum decision rules. It can be extended to include more criteria.

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

And again:
The penalty must reflect the seriousness of the error/non-complience!
Please, create a graded penalty system, where concequences, time-frames and actions needed reflect the seriousness of the errors.
Such graded penalty system would also ease laboratory risk-assessments, and therefore possibly reduce risk.

7.3.2 False Negative Finding (3)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)

Public Authorities - Government

It is difficult to see why consideration is given to the possibility that faults with the samples may explain the reporting of a false AAF but a similar allowance is not made for the reporting of a false negative finding. This should be revisited.

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

▪

7.3.2 – As per 7.3.1.3, WADA should investigate if the error was caused by the EQAS provider.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Recommendation: In the case of other false negative findings it seems important if the lab had the change to recognize whether or not other false negative findings are involved with the same basis. If it is the same cause that leads to multiple false negative findings, this should be evaluated as one case.

10 additional points for an unsatisfactory CAR is far too much. The lab shall have the chance to improve an already submitted CAR before the conclusion was taken that the case is passed to the DC.

7.3.3 Further EQAS Procedural Evaluations (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

7.3.3.1 If the LabEG considers that a Corrective Action Report is unsatisfactory, two (2) penalty points shall be applied.

Recommendation: In general, if a Root Cause Analysis or a CAR is found by WADA/LabEG to be “not satisfactory”, an explanation and possible guidance should be given to the Lab to redo the action to the satisfaction of WADA/LabEG. This can be a very important learning/training experience to the Lab and will be regarded as a positive outcome since all the actions from WADA explained in this Section, have negative consequences and outcomes for the Labs.

7.4 Overall Laboratory Evaluation (2)

Institute of Biochemistry, German Sport University Cologne SUBMITTED
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

7.4. The suspension of laboratories as sanction should be disestablished and replaced by a sanction system with focus on education and corrective actions.

Rationale

To increase or to keep the capacities of the laboratories , a sensible approach would be to disestablish the suspension of labs as sanction and replace it by a sanction system with focus on education and corrective actions. Suspensions lead to an immediate decrease of capacities and also to a long-term effects by brain drain, financial problems, loss of reputation etc."

7.4. The number of sanction-points after reporting of a false negative sample should be reduced (at least below 5). In case of a satisfactory corrective action by the laboratory no points shall be attributed

Rationale

The current rule of addressing 10 points for a sample, reported falsely negative, in combination of a laboratory provisional suspension after 20 points, i.e. 2 false negatives within a 12 months period, is by no means proportional to the harm upon a laboratory and the complete loss of its reputation after a provisional suspension; not to mention the financial disaster, a laboratory faces after provisional suspension of its accreditation. This holds especially in cases, where the samples reported falsely negative derive from EQAS tests. No concrete harm can be attributed to such a non compliance. The harm to athletes not being caught is an abstract one and not concrete. Even in laboratories with high reputation and high analytical quality adverse analytical findings can be overlooked, simply because of the human factor, like in every other discipline. And the risk is exponentially increased by the total number of samples analyzed per year.

7.4. Before a provisional suspension and especially before publication of a provisional suspension of a laboratory (“google sanction”), the laboratory should have the right of legal processes (hearing, CAS hearing)

Rationale

Every athlete has the right of a direct and fair hearing and be present and heard by the panel. Suspensions of laboratories are issued without the presence of the laboratory director or his / her representative at the time frame of the decision of the panel. Decisions are taken based on the documentation provided. Questions of the panels cannot be directly attributed to the responsible person. The following publication of the suspension on the WADA website destroys the reputation of a laboratory and leads to a loss of its economic basis and is therefore a severe sanction.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

7.4. The suspension of laboratories as sanction should be disestablished and replaced by a sanction system with focus on education and corrective actions.
Rationale: To increase or to keep the capacities of the laboratories, a sensible approach would be to disestablish the suspension of labs as sanction and replace it by a sanction system with focus on education and corrective actions. Suspensions lead to an immediate decrease of capacities and also to a long-term effects by brain drain, financial problems, loss of reputation etc.

7.4. The number of sanction-points after reporting of a false negative sample should be reduced (at least below 5). In case of a satisfactory corrective action by the laboratory no points shall be attributed**Rationale:** The current rule of addressing 10 points for a sample, reported falsely negative, in combination of a laboratory provisional suspension after 20 points, i.e. 2 false negatives within a 12 months period, is by no means proportional to the harm upon a laboratory and the complete loss of its reputation after a provisional suspension; not to mention the financial disaster, a laboratory faces after provisional suspension of its accreditation. This holds especially in cases, where the samples reported falsely negative derive from EQAS tests. No concrete harm can be attributed to such a non compliance.

The harm to athletes not being caught is an abstract one and not concrete. Even in laboratories with high reputation and high analytical quality adverse analytical findings can be overlooked, simply because of the human factor, like in every other discipline. And the risk is exponentially increased by the total number of samples analyzed per year.

7.4. Before a provisional suspension and especially before publication of a provisional suspension of a laboratory (“google sanction”), the laboratory should have the right of legal processes (hearing, CAS hearing)**Rationale:** Every athlete has the right of a direct and fair hearing and be present and heard by the panel. Suspensions of laboratories are issued without the presence of the laboratory director or his / her representative at the time frame of the decision of the panel. Decisions are taken based on the documentation provided. Questions of the panels cannot be directly attributed to the responsible person. The following publication of the suspension on the WADA website destroys the reputation of a laboratory and leads to a loss of its economic basis and is therefore a severe sanction.

7.4 Overall Laboratory Evaluation

Recommendation: The status of a Lab’s penalty points should be available to the Lab, for instance on ADAMS or some confidential communication platform. This will assist the Lab to audit its penalty points.

WADA should also indicate if penalty points are “reset” after 12 months, and access to this information will allow the Lab to be aware of its accumulated points.

7.4.1 *WADA* shall evaluate Laboratory EQAS performance for each EQAS round, as well as Laboratory performance for routine Analytical Testing, and assign penalty points for non-compliances or failures to perform as indicated in the Points Scale Table below.

Recommendation: remove 'as well as Laboratory performance for routine Analytical Testing', it does not form part of the EQAS

Recommendation: in relation to Late reporting of blind and DB samples

- Double blind samples are usually positive for at least one doping agent. Consequently the reporting is done, when the persons in charge in the lab are satisfied with the quality of the analytical data as well as with the chain of custody documentation. This may lead to situations where the analysis takes longer to come to a clear conclusion. I refer to some of the last DB EQAS samples, which have been changed to educational samples by WADA due to their questionable if not unsatisfactory quality (metandienone, CERA, NESP). And there are many other reasons, too, why a results takes time to be reported. E.g. availability of reference material, instrument brake down, timely limited overflow of samples… To get two points for every additional week might be an option for negative samples, but shall not be applied to positive samples.

7.5 Probationary Period and Probationary Laboratory Evaluation

7.5.5 Overall Probationary Laboratory Evaluation (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

7.5.5.4, 2nd paragraph insert an 'a' between 'of' and 'further'

ISL ANNEX A - LABORATORY CODE OF ETHICS (2)

Department of Health - National Integrity of Sport Unit SUBMITTED
Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

The Code of Ethics should include a requirement to report suspicious behaviour

ASADA SUBMITTED
Naomi Speers, Science and Results Manager (Australia)
NADO - NADO

Code of ethics – Consider inclusion of a requirement to report suspicions of laboratory corruption.

2.0 Research (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Laboratories shall participate in research programs provided that the Laboratory Director is satisfied with their *bona fide* nature and the program(s) have received proper ethical (*e.g*. human subjects) approval.
Recommendation: Addition of 'where and if applicable' so it read'Laboratories shall participate in research programs provided that the Laboratory Director is satisfied with their *bona fide* nature and the program(s) have received proper ethical (*e.g*. human subjects) approval, where and if applicable.'

3.0 Analysis (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

3.1 • The Samples have been collected and sealed in appropriate containers according to the International Standard for Testing and Investigations or similar guidelines;
Recommendation: “similar guidelines” should be directly addressed and indicated or removed. This is too ambiguous.

3.1 • The Testing Authority is Code-compliant, as determined by WADA or, if not Code-compliant, it provides the Laboratory with written assurance about the existence of an appropriate results management process in accordance with Code of Ethics Article 3.3.3 below.
Recommendation: WADA shall published list of compliant and non-compliant TA’s and post in ADAMS or the website.
3.2 The letter shall also state that the patient involved is not an Athlete. In case an Athlete is involved, the sample may be accepted for analysis only if a recognized Anti-Doping Organization has collected it and, if appropriate, will follow up on the results if a Prohibited Substance or Prohibited ~~Substance~~ Method is detected.
Question: clinical studies as a follow up to elevated hCG levels to determine an anti-doping rule violation. Where will this fit in?

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

3.2.2 change 'question the integrity of the individual' to 'question the integrity of an individual'
3.3.3 - the first sentence states:
'If the Laboratory accepts Samples from any entity that is not a Testing Authority recognized by the Code.....'
and the last sentence states

'The Laboratory shall provide WADA with a copy of the assurance document received from the Testing Authority'.
If the lab is accepting samples from an entity that is not a Testing authority in the first sentence then how can is receive an assurance document from the Testing Authority in the last sentence? The 2nd mention of Testing authority should be changed to 'entity' or similar.

4.0 Conduct Detrimental to the World Anti-Doping Program (2)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

4.4 Outside of information provided in the context of anti-doping proceedings, no Laboratory employee or consultant shall provide information about a Test Method, which could be used to avoid the detection of doping, to an *Athlete* or *Athlete Support Personnel*.

Recommendation: Agreed that such information will not be provided, but how will this be regulated considering the fact that laboratories are required to perform research or to develop or redevelop methods and, as relevant, to subsequently publish their work?

Therefore, a laboratory will disclose testing methods upon publishing!

If they are not to publish, this is in contradiction to the WADA and hosting institution requirements to perform research and to publish their work.

This section needs rewording!

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

4.6 change the wording 'The Laboratory staff is...' to 'the Laboratory staff member is...' or 'If Laboratory staff are....'

ISL ANNEX B - PROCEDURAL RULES FOR THE DISCIPLINARY COMMITTEE OF THE INTERNATIONAL STANDARD FOR LABORATORIES (2)

Secretaria de Estado da Juventude e Desporto SUBMITTED
Paulo Fontes, Advisor (Portugal)
Public Authorities - Government

Recommendations from the Disciplinary Committee should be of mandatory application.

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

The laboratory shall have the right of a fair hearing in the presence of at least one person representing the lab during the disciplinary panel session.

A written statement of the lab in view of a possible suspension is not enough.

Preferable the laboratory shall have the right for both legal representation and a laboratory expert.

Preamble (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

The structure for suspension and revocation should be reconsidered and better described for clear guidance and decision making.

Where a non-conformance or misconduct is detected, it should be investigated and based upon its severity, actions should be determined accordingly. In other words, the system should be more in line with that followed by the ISO/IEC regulatory bodies.

The severity should fit the suspension period and should be applied consistently to all laboratories. Therefore, an impact / risk chart could provide clear guidance as to the criteria that should be applied in case of potential suspension or revocation. This will also be in line with the Risk Management requirements of the latest ISO/IEC 17025 Standard. The greater the risk, the greater the impact and the period of suspension but when the laboratory is able to fulfil all requirements ie completed CARs then suspension shall be lifted.

PART I - Composition of the Committee (1)

NMI - ASDTL SUBMITTED
Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Article 1 All members of an appointed DC panel shall be independent from WADA and/or the Laboratory concerned. It is clarified that the anti-doping laboratory expert(s) may be member(s) of the WADA Laboratory Expert Group (LabEG), unless the case has been the subject of previous discussion or recommendation by the LabEG.

Recommendation: All members of an appointed DC panel shall be independent from *WADA* and/or the Laboratory concerned, **and exclude members that may benefit from the analysis of samples from the suspended or revoked laboratory**. It is clarified that the anti-doping laboratory expert(s) may be member(s) of the *WADA* Laboratory Expert Group (LabEG), unless the case has been the subject of previous discussion or recommendation by the LabEG.

PART III - Scope of the Committee's Review (1)

NATA SUBMITTED
Mark Worrell, Accreditation Manager (Australia)
Other - WADA-accredited Laboratories

Dot point 6, make the following change'The DC’s decisions, including ~~in regards to~~ the content of its recommendation, shall be by majority.' or

'The DC’s decisions, ~~including~~ in regards to the content of its recommendation, shall be by majority.'