2012 October 4

**INADO Update #6**

**iNADO's List of Possible International Standards Commentary for NADOs/RADOs to make to WADA**

This document suggests positions NADOs and RADOs may wish to take in submissions to WADA on this general phase of consultations on the International Standards. Please cut and paste into your own submissions whichever positions you feel comfortable with, or adapt them as you see fit.

**This round of submissions on the International Standards is due no later than October 10, 2012. Submissions must be submitted through WADAConnect (https://connect.wada-ama.org/home.php). For instructions on how to comment, see: http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/The-Code/Code-Review/Consultation-Process/.**

## Prohibited List

- Make the process of the changes and adoption of the List more concise and more transparent, by
  - upgrading the List Expert Group to a Committee of its own, rather than a subcommittee)
  - clarifying the decision process from the draft to the adoption of the List
  - eliminating or at least minimising last-minute changes to the draft List
  - sharing scientific date regarding substances included on the (draft) Prohibited List and the Monitoring Program, and
  - clarifying the process of including substances and methods in the List.

- Clarify who can request for substances being included into the Monitoring Program.

## International Standard for Testing (IST)

- The IST should place more emphasis on conducting smart testing.

- The proportionality approach to High Priority Athlete Pools should be further emphasized and described in more detail in the IST and specific guidelines.

- More emphasis should be placed on conducting risk analysis in order to evaluate in which sports (i) out-of-competition tests and (ii) whereabouts were necessary.

- Required analysis for testing needs clarification.
  - WADA requires "full" menu analysis but "full" menu doesn't mean the ICT menu set by WADA. Also in the draft of new code, it says "available analysis", and the rationale for "available analysis" should be explicit.

- Clarify responsibilities for testing and result management.
  - Whenever the Testing Authority and the Result Management Authority are different, whose procedure applies for the testing?

- 3.1 : the definition of ADO is not clear. Can a National Federation be a Testing Authority? With Result Management Authority? How about regional federation, such as Asian Federation, European Federation? By reading the definition, NFs and regional federations would not be considered as ADOs, but in reality, some of regional federations contact NADOs claiming to be Testing Authorities.
- 3.1/3.2: there is no definition of Result Management Authority. This definition should be written. Within the definition, the role of Results Management Authority should be made clear. And if the Testing Authority is different from Results Management Authority, if there are differences between them, who decides which organisation's rules to follow? (for example, for additional samples or follow-up investigations)

- Article 3.2 refers to the definition of "Chaperone", a definition which limits a Chaperone's role to activities outside of the Doping Control Station. We recommend that this definition be amended to make clear that a Chaperone's duties can include observing Athletes who are present in the Doping Control Station. This would help Doping Control Station Managers and Doping Control Officers, for example in relation to ensuring that Athletes do not consume excessive amounts of fluid while waiting to provide a Sample.

- 5.4.1(d): provides that an Athlete can request that he or she be allowed some dispensation in terms of when he or she must report to a Doping Control Station following notification. It would be helpful to clarify whether attending an ad hoc celebration, team talk or other unplanned activity post Event constitutes a valid reason for delay. Many NADOs believe that there needs to be greater flexibility for Doping Control Personnel in this regard. As long as the Athlete is appropriately and discretely chaperoned, we do not see any significant risk in an Athlete participating in an ad hoc post-Competition. These situations often arise after major finals or other important matches, and Athletes will frequently feel frustrated, dismayed and confused at being denied an opportunity to share in the celebration of sporting success with their teammates. Doping Control Personnel are placed in challenging positions by having to insist on Athletes no attend celebrations following notification. More importantly, these situations diminish Athlete respect for the anti-doping process. If anti-doping is about protecting the rights of clean athletes, it is also about the right of athletes to enjoy their celebrations or participate in their commiserations.

- 5.4.1(h): provides that an Athlete should not pass urine while showering before providing a Sample. This is – for obvious reasons - a difficult requirement to police (particularly if the Athlete concerned has been involved in a water sport). As far as we are aware such behaviour would not constitute Tampering (nor should it). Some clarification to the effect that an Athlete may be permitted to shower prior to providing a Sample in exceptional circumstances, subject to the discretion of the Doping Control Personnel, would be sensible.

- 7.3.3: states that an Athlete should avoid excessive Rehydration. As discussed in relation to the definition of Chaperone, it would assist if this Article stated that the DCO and/or the Chaperone can provide the Athlete with an opportunity to hydrate, and monitor that process.

- 7.3.4: provides that an Athlete may leave the Doping Control Station in circumstances mandated by Articles 5.4.5 and 5.4.6 of the IST. Article 5.4.4 should be added to Article 7.3.4, so that it reads "as specified in Clauses 5.4.4, 5.4.5 and 5.4.6". (Clause 5.4.4 providing the basis upon

which a request can be made, with Clauses 5.4.5 and 5.4.6 providing the specifics).

- 8.3.1: provides that ADOs define criteria for sample storage. We recommend that the IST expressly provide that these criteria should include at a minimum, that the location where samples are stored and who is permitted to have access to the Samples be detailed and documented.

- 11: the whereabouts requirements stand alone in the IST. The Group recommended that Article 11 IST would be made into a separate International Standard. This Article currently constitutes over one third of the IST (31 of the 92 pages). Establish a special working group to completely revise and simplify these provisions.

- 11: concerning whereabouts, generally it is necessary to (i) clean up the whereabouts provisions, (ii) make these provisions more accessible and comprehensive, and (iii) to place them in a more logical order.
    - For example, Article 11.3.5(a) comment (ii): omit to declare a regular activity would be considered as filing failure. However, if these regular activities are not specified as within 60min time slot, ADOs have no idea that this information is accurate or not unless we plan test during this time. Therefore, ADOs cannot declare a filing failure for this regular activity, and athletes are not likely to provide too much information because it is not mandatory.

- 11.2.1 and 11.2.2: contain provisions that impact upon Athletes' privacy rights, in that they state that an IF or NADO, as applicable, "shall publish [their RTP] criteria as well as a list of the Athletes meeting those criteria". Some NADOs do not publicly publish either its criteria for inclusion in the RTP, nor details of the Athletes who are part of the RTP. That information is made available to the relevant National Federation, International Federation and WADA, which is as far as a necessary and proportionate sharing of data needs to go. We do not believe that the publication required by Articles 11.2.1 and 11.2.2 of the International Standard for Testing is consistent with the ISPPPI. We suggest that the IST wording be changed in this regard to make it clear that publishing may take place at the discretion of the relevant ADO in a manner that is fair, proportionate and does not infringe national laws.

- 11.1.3: states that an Athlete provide information detailing "where he/she will be living, training and competing". However, this is not reflected in the current functionality of ADAMS. Athletes are able to complete a whereabouts submission without entering all the required information detailed in Clause 11.1.3. It would be helpful if this could be rectified in the next upgrade to ADAMS.

- 11.4.3c: provides that a Doping Control Officer, when seeking to obtain a Sample from an Athlete during that Athlete's "one-hour" slot, must "do what is reasonable" to try and locate the Athlete. Many NADOs provide their Doping Control Officers with a detailed guide as to what it considers "reasonable", and careful scrutiny is made as to the degree to which those steps were complied with before any Missed Test is issued. It would assist WADA's aim of harmonising practice across ADOs if ADO guidelines were collated and made available by WADA to all ADOs, with a view to enhancing best practice.

- 11.7.2 and 11.7.4: IFs should not delegate responsibilities to NFs; it should be to NADOs/RADOs. NFs are not ADOs.

**International Standard for Laboratories (ISL)**

- 2.0: Code Provisions should include Article 2.5, which is the section that deals with "Tampering".

- 4.1.8: says that laboratories should be "operationally independent" from ADOs. While Laboratories can maintain an appropriate degree of operational independence from ADOs, their viability can depend on those ADOs. The relevant Commentary to the ISL should recognise that such practical and/or financial dependence does exist in relation to some Laboratories, but that that dependence of itself does not affect – nor should it be seen to affect – the operational independence of the Laboratory. However, WADA can consider such dependence in its compliance and accreditation review processes.

- 4.4.5: requires a Laboratory to plan for research activities as part of maintaining its accreditation, without there being any defined role for NADOs in this process. We suggest that the ISL be amended to expressly encompass NADOs, and to clarify the monitoring role that WADA has in relation to this research. Requiring Laboratories, when planning their research and development work, to consult with NADOs makes a lot of sense. Laboratories are often financially dependent upon NADOs and NADO budgets, and so the "total annual budget" available to a Laboratory will often depend on the resources that the NADO in turn is in a position to disburse. Coordination regarding how that budget is spent will encompass how it is spent on research, and it makes sense for the ISL to recognise this. Further, it makes equal sense for NADOs to be closely involved with Laboratories in the conduct and reporting of research work.

- 5.2.5: requires a Laboratory to have an AAF "signed off" by two scientists before it is issued. We suggest that the interaction between this provision, and Articles 3.2.1 and 7.1 of the Code, be clarified by WADA. In relation to an AAF made by a Laboratory, Article 7.1 of the Code requires the relevant ADO to conduct a review as to whether there is any apparent departure from the ISL before an Athlete can be notified as to that Finding. However, Article 3.2.1 of the Code provides that WADA-accredited Laboratories are presumed to have conducted sample analysis in accordance with the ISL. Article 3.2.1 therefore suggests that Article 7.1, as far as it relates to the ISL, is superfluous. It would be helpful if the Code and the ISL made clear that the extent of the review (if any) that is required by Article 7.1 and, for example, whether this might be limited to ensuring that Article 5.2.5.1.1 has been complied with.

- 5.2.6.7: requires a Laboratory to report the presence of a Prohibited Substance, but not the concentration. We understand this restriction: in most cases, the fact of Presence will be sufficient, and there is no value in requiring a Laboratory to go any further. However, we suggest that this restriction be relaxed, and that Laboratories have the facility to provide, if requested to do so, approximate concentrations for Prohibited Substances – particularly Specified Substances – found in a Sample. These concentration levels can often be an important part of the evidence in an anti-doping rule violation matter. For example, in cases involving methylhexaneamine, the concentration levels can provide an objective corroboration as to the

absence of any intent to use the substance to unfairly enhance performance. Equally, the concentration levels of non-specified substances can disprove an athlete's bogus story that a substance was used inadvertently as part of a supplement or medication. (We have case studies that illustrate both points made: in one case, the availability of approximate concentration data saved an athlete from what would otherwise have been a two year sanction.) We do not suggest that such data be made available as a matter of course. However, it should be available – at approximate levels – on request.

- 5.4.4.1.1: Laboratories are not obliged to report concentrations for a non-threshold prohibited substance. Yet often knowing the threshold is important under 10.4 or 10.5 in assessing the athlete's evidence about intent or how the substance entered his/her system. The Article should include a provision that a lab report on the concentration when requested by the ADO as part of the results management process.

- 6: includes a number of provisions relating to the receipt, analysis and reporting of results concerning blood samples that appear to apply to all blood Samples collected by an Anti-Doping organisation, including those collected in connection with the Athlete Blood Passport Program (ABP). It would be helpful if the ISL clarified the position vis-a-vis such Samples, and the extent to which Article 6 of the ISL is intended to apply to ABP Samples. When a blood Sample is collected for analysis as against the Prohibited List, a B Sample is collected from the Athlete at the same time. However, when a blood Sample is collected for analysis as part of a Blood Passport profile, no B Sample is required to be taken. (Practice in this regard varies: some ADOs take only one such Sample from an Athlete, whereas others will take two, but the second is not a B Sample as such, but rather, a "spare" Sample in the event that a Laboratory wishes to re-analyse a Sample). Article 6 does not draw any distinction between the two collection scenarios. What we would like to see is a clear distinction within Article 6 as to the protocols to be followed in respect of "analytical" blood Sample collections (where a B Sample is required) and "passport" blood Sample collections (where a B Sample is not required). This will add clarity and integrity to the process (and emphasis that analytical Samples should not be used for passport purposes).

- More sharing of information via (preferably) ADAMS (such as Mission Order (starting from planning phase) and results, etc.)
    - Even though it is written in IST 4.3.7, not many ADOs are sharing testing plan including companies such as IDTM, PWC and so on. In order to avoid duplication of tests, it is much easier to share starting from making a mission order in ADAMS. Or maybe the concept of "coordinated Testing Activity" is not clear and needs definition.

- Requests from WADA regarding (i) documentation or (ii) the retesting of samples would be properly communicated to the laboratory, and that WADA provided the reasons for such requests to the laboratory.

- Laboratory reports on unusual findings were relevant with respect to article 2.5 (tampering) and target testing.

- Increasing the involvement of laboratories in consultation of International Standards, Technical Documents and Guidelines.

**International Standard for Therapeutic Use Exemptions (ISTUE)**

- The current common practice at the national level of allowing retroactive TUEs for national level athletes, who were not included in the NADO RTP, should be included in the ISTUE.

- 4.1b: provides that a TUE may only be granted if the use of the relevant substance or method would produce no additional performance enhancement. It is difficult to determine that the use of a particular substance or method would produce "no" additional enhancement of performance. TUECs will generally operate on the basis that they will grant a TUE if it is "highly unlikely" that a substance or method would cause an additional enhancement of performance. We suggest that Article 4.1b be amended accordingly.

  Article 4.1b also provides that TUEs should not be granted for a prohibited substance or method that increases "low-normal" levels of an endogenous hormone. This is an illustration of how the first part of Article 4.1b should be applied in this situation rather than constituting a separate ground. The last line of Article 4.1b should be deleted and the text added to the relevant WADA medical information documents.

  Incidentally, there is currently no guidance in the WADA TUE guidelines document (version 6.0) regarding whether there is scope for TUECs to take into account an applicant's sport when determining if a treatment request fulfils 4.1b. It would be helpful if such guidance was provided to avoid inconsistent approaches occurring between different TUEC review panels.

- 4.1d: provides that a TUE cannot be granted in circumstances where the need for the TUE arises in connection with the use of a substance or method, which in turn is being used as a result of using another substance or method, for which the Athlete did not have a TUE. In our experience, this ground is redundant: TUECs grant or reject applications in accordance with three criteria (Article 4.1a-c).

- 4.3: provides that a TUE will not be granted retroactively unless it is required in connection with emergency medical treatment, or in some other exceptional circumstance. Many NADOs have specified a community of athletes who are required to obtain a TUE in advance of using a prohibited substance or method, and others who are only required to obtain a TUE following Doping Control. This specification is in accordance with ISTUE Article 7.2b. Article 4.3 is not consistent with Article 7.2b, and we recommend that it is amended by the addition of an additional criterion: "The athlete is not required by his or her National Anti-Doping Organisation to obtain a TUE in advance of Doping Control."

- 4.3b: states that an application can be considered for retroactive approval in exceptional circumstances. The WADA TUE guidelines document outlines some useful examples of such circumstances. However, no guidance exists regarding whether 4.3b can be applied to an athlete if they fail to obtain a TUE in advance of Doping Control but have never received anti-doping education (for example, an athlete competing for the first time at a level in sport where drug testing is occurring). There is no guidance to clarify whether ADO can use their discretion in such circumstances and review the application retrospectively. We are in favour of having this discretion since an athlete would still need to fulfil the criteria outlined in Article 4.1.

- Comment to Article 4.3: suggests that retroactive TUE applications are "uncommon" and "infrequent". The experience of many NADOs is different: for example, nearly half of all applications received by one major NADO in 2011 were for emergency treatments, treatments of acute medical conditions or applications submitted due to imminent competition. We suggest that this comment is deleted.

- 6.1: establishes the requirements as to the composition of a TUEC. But the Article does not state whether a TUEC can grant a TUE if the review panel fail to reach a unanimous decision (for example, two panel members approve, one rejects). However, requiring a unanimous decision may not be appropriate for all ADOs whose TUEC panels comprise more than three members. We recommend that a TUEC, regardless of the size of the panel, should grant a TUE if the number of TUEC members agreeing to do so is a significant majority of that panel (for example, three members out of a four member panel, or four members out of a five member panel).

  The Article also requires that at least one TUEC member shall have specific experience with the care and treatment of athletes with impairments when reviewing applications made by athletes who intend competing in sports for athletes with an impairment. While having a physician with such experience is desirable, we recommend that it should not be a mandatory requirement, if an expert with in-depth knowledge of the specific medical sector pertaining to the application is a member of the review panel. We recommend that the words "or has specific experience in relation to the Athlete's relevant impairment or impairments" be added to Article 6.1.

- 6.3: details the role of the WADA TUEC. We suggest, given that Article 6 is primarily concerned with the constitution of ADO TUECs, that Article 6.3 be combined with Article 10.0 to create a new Article. This Article could usefully explain the composition and role of the WADA TUEC.

- 7: requires IFs and NADOs to make it clear when athletes are required to apply for TUEs. However, it is not clear as to the responsibilities of Major Event Organisers. On occasion, Major Event Organisers require that participating athletes obtain a TUE prior to the event. If the athletes do not fall within the "pools" established by IFs and/or NADOs pursuant to Article 7, and the relevant Major Event Organisers do not provide a facility whereby such athletes can obtain a TUE via the Major Event Organisers, this can cause problems. We suggest Article 7 be amended so that it is clear that TUE responsibilities for athletes who do not fall within the "pools" established in accordance with either Article 7.2b (or Article 8.1) should be the responsibility of the Major Event Organiser.

- 8.8: requires athletes to disclose their TUE history when applying for a TUE. We do not believe that this is necessary, or indeed always helpful – primarily because there is no guarantee that the information provided will be accurate and/or complete. We suggest that the requirement be deleted from Article 8.

- 8.13: requires that TUECs should make their decisions within thirty days of receipt of all relevant documentation. We believe that this timeframe is too long. The target of some NADOs is much shorter, for example within seven days. We suggest that this should be the norm, with appropriate provision for a longer time being authorised in unusual or complex cases.

**International Standard for the Protection of Privacy and Personal Information (ISPPPI)**

- Bring the retention times mentioned in the various International Standards (especially the ISL) in line with the (annex to the) ISPPPI.

- The ISPPPI should clarify that whereabouts information can be used for purposes other than "planning, coordinating or conducting Testing" where such use is required as evidence in connection with a possible ADRV. Article 14.3 of the Code expressly restricts the use of whereabouts information to "exclusively for purposes of planning, coordinating or conducting Testing". This is an important provision. Whereabouts information is not obtained so that ADOs can monitor the movements of Athletes. It is obtained to facilitate the provision of Samples from Athletes, usually Out-of-Competition. However, in certain cases whereabouts information can also be relevant to possible ADRVs: most obviously, a whereabouts violation matter. But also in connection with a violation where the evidence stems from the Athlete Biological Passport (for example, an Athlete may claim that data obtained as part of the Athlete Biological Passport is consistent with his training at high-altitude altitude: whereabouts information provided by the Athlete might be used by an ADO to rebut that claim, if the information suggested that the Athlete was not at a high-altitude location at the relevant time). It would be strange if, in such a case, an Athlete could use his whereabouts information as evidence (because it is his personal data) but an ADO could not. We note that a corresponding amendment may be needed to Article 14.3 of the Code.

- 5.3 (a): restricts the extent to which an ADO can process data supplied to it in connection with an application for a TUE. It appears that this information can only be used by an ADO for this purpose. We agree with this in principle: the use of such sensitive data by ADOs should be managed in a responsible, proportionate and fair manner. Article 5.3 (a) suggests that such information cannot be used for testing, or in results management proceedings. This can be, in certain cases, an unnecessarily restrictive provision. For example, if an athlete applied for a TUE for a steroid, an ADO might be concerned to ensure that that athlete (assuming the application was declined) was not using the steroid thereafter. The ISPPPI might helpfully clarify how data furnished in relation to a TUE application can be used by an ADO for "non-TUE" purposes. We suggest that words to the effect "save that such information may be used for other purposes by the ADO where such use is fair, proportionate and does not infringe national laws".

- 6: provides a large amount of detail as to how consent is to be provided by a Participant in the context of anti-doping work. This Article must inevitably read in light of the anticipated changes to European data privacy regulation, and in particular the regulations that will be placed around the extent to which consent will be a viable basis for processing data in the context of anti-doping work. We recommend that the ISPPPI be amended in light of these anticipated developments, with additional provision made as to the means by which data might be processed without the consent of the Participant.

- 7.2 (supplemented by 7.3): requires that where personal information is received from a person other than the individual to whom it relates, the ADO must "as soon as possible and without delay" notify the individual of the information unless that information has already been provided to the individual. There is no apparent exception in the ISPPPI to this notice requirement. These mirror, to an extent, the notification requirements present in data privacy

legislation. However, Article 7.2 is rather more restrictive than some national data privacy legislation, which exempts or a data controller (in certain circumstances) from these notification requirements, relaxes those requirements. The wording in Article 7.2 is problematic in that if information is received by a third party such as law enforcement, it requires that the individual be notified as soon as possible. This could alert a Participant to the fact that they are being investigated, which is not always helpful. The ISPPPI could clarify how data furnished by a third party in relation to an individual might be retained without notifying that individual. We suggest that words to the effect "save that such information may be retained without notification by the ADO where such use is fair, proportionate and does not infringe national laws".

- 8.3: permits the disclosure of personal information to third parties other than ADOs where that disclosure is necessary to assist law enforcement or governmental authorities. We agree that this accords with data privacy legislation. We do however have an operational concern over the specific wording in the Article. It states that the disclosure is only permitted "provided that the Personal Information requested is directly relevant" (emphasis added). We believe that having to wait for a specific request for information from a law enforcement agency before sharing relevant information is not practical or conducive to opening up two-way gateways between ADOs and law enforcement. We would suggest that where the ADO determines the information held would assist the law enforcement agencies operations, or help the ADO itself to further build a case on an athlete/support personnel, the ISPPPI should provide that the information can be sent immediately.

- Information stored on ADAMS: NADOs are able to manage their own records (electronic and hard-copy), and in particular destroy them when retention is no longer necessary (such destruction is indeed required by data privacy legislation). However, information that is stored on ADAMS cannot be deleted by an ADO after it has been entered. Some NADOs would welcome a dialogue with WADA as to how best to manage the deletion of information held on ADAMS, in circumstances where WADA does not automatically become aware that retention is no longer necessary.