AORC Guidelines for Controlling the Application Of Screening Limits

INTRODUCTION

1. The International Horseracing Federation of Horseracing Authorities defines an International Screening Limit (ISL) as "*the urine or plasma concentration adopted for the screening of a specified therapeutic prohibited substance; it is derived from administration studies followed by a risk analysis consisting of two components: a risk assessment (evaluation of the effect of the substance and factors related to its control) and a risk management (decision step for harmonisation). ISLs are harmonised detection limits agreed following input by international consensus and are conveyed by instruction from racing authorities to their laboratories… Quantification is not required.*" [1].

2. This document provides a set of minimum criteria and recommendations for implementation of a Screening Limit (SL). These guidelines are to assist racing chemists and their laboratories, whose responsibility it is to ensure the quality and integrity of the data is defensible and fit for the intended purpose. Furthermore, laboratories should document their own minimum criteria for considering that a SL has been exceeded in a particular sample.

ANALYTICAL REQUIREMENTS

3. Racing authorities operate in a wide variety of legal environments and have differing views on the type and level of service that their laboratory should be able to provide to them. Consequently, the laboratory should consult the racing authority on the analytical approach for implementing the SL.

4. The analytical approach for implementing the SL should be documented by the racing authority or the laboratory and, as a minimum, should state the acceptable protocol for the following areas:

a. The stage of the analytical process at which the specified SL is to be implemented. The recommendation is the initial screening stage, but it may also be implemented at the confirmatory stage or at both of these stages.

b. The basis upon which the laboratory would consider whether or not the concentration of the specified substance in a sample may have exceeded the SL. As a minimum, the laboratory should use the response of EITHER an external calibrator spiked at the SL, OR an internal isotope-labelled calibrator spiked at the SL, to identify samples in which the SL may have been exceeded.

c. The laboratory may, at its own discretion, adopt more stringent analytical methodology or even add supplementary analyses to increase the confidence that the level of a specified substance in a sample exceeds the SL. However, the use of more stringent methodology is not mandatory unless the racing authority requires it.

d. The laboratory should establish the manner in which the SL is to be applied when evaluating the analytical data. In particular, the laboratory should document whether a margin should be applied to the applicable "cutoff" response to reduce the risk of reporting a prohibited substance which is below its SL to the racing authority.

METHOD VALIDATION

5. A method can be considered to be sufficiently reliable if it meets the desired performance level and is *fit for the intended use* according to the requirements of ISO/IEC 17025. In the case of a prohibited substance with an applicable SL, the procedures adopted should take into account that the substance is prohibited at any level and that the intention is simply to exclude samples with concentrations of the substance not exceeding the SL from further analysis.

6. The laboratory should ensure that its methods and processes are consistent with the racing authority's requirement.

REPORTING PARAMETERS

7. Sample(s) considered to contain a prohibited substance in excess of the SL shall be subjected to qualitative confirmatory analysis and, if the resulting data meets the laboratory's criteria for qualitative identification, the qualitative presence of the prohibited substance is reported (using whatever statement is applicable in the jurisdiction).

REFERENCES

1. International Federation of Horseracing Authorities, *International Screening Limits - Definition and Recommendations for their Application in the Control of Therapeutic Substances*, http://www.ifhaonline.org/default.asp?section=IABRW&area=1

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