

PROJECT REVIEW

“Harmonisation of uncertainty calculations of the quantitative doping control analytical procedures.”

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Uncertainty is an important analytical and legal issue for reporting WADA Prohibited List threshold substances. Threshold substances require quantitative analysis to compare analytical signal and concentration of the substance of interest in the athlete' sample to the threshold value. The importance of the uncertainty parameter in reporting an adverse analytical finding of a threshold substance is the fact that the uncertainty value is used as an, among others, additional protection for the athlete from a highly improbable false positive report. On the other hand, a high value of uncertainty can guide to false negative results. For that reason, uncertainty has been found in the middle of court evidence arguments. Consequently, a correct and harmonized calculation of uncertainty is required not only for legal reasons but also to reveal probable analytical drawbacks.

More specifically, the current project proposes:

1. To evaluate uncertainty estimation for isotope ratio mass spectrometry and hematological analyzers technologies, where pour literature has been published so far.
2. To survey within the WADA Accredited Doping Control Laboratories various ways for uncertainty estimation of the quantitative procedures.
3. To incorporate uncertainty specifications from the under preparation WADA technical document on uncertainty
4. To develop a software tool for uncertainty evaluation, specific for the WADA Accredited Doping Control Laboratories based on the 1-3 above paragraphs
5. To distribute a first version of the software tool to WADA Accredited Doping Control Laboratories to perform a first evaluation.
6. To collect evaluation points, apply a second software version and distribute the software to the WADA Accredited Doping Control Laboratories.

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Results and Conclusion;

Uncertainty is an important analytical gauge for the quality of the analytical data that are produced from a quantitative procedure. Uncertainty estimation is based mainly on validation data for the ISO 17025 accredited analytical methodologies. Moreover, uncertainty is added or subtracted to the concentration of the, according to the WADA List, threshold substances found in doping control urine or blood samples in order to decide to report for an adverse analytical finding or not, i.e. uncertainty is a major decision parameter.

According to the International Standard for Laboratories, measurement uncertainty reporting for the prohibited substances required quantification is mandatory and WADA Accredited Laboratories are obliged to comply with this specification.

WADA will bring into force by September 1st, 2010, the technical document TD2010DL entitled “DECISION LIMITS FOR THE CONFIRMATORY QUANTIFICATION OF THRESHOLD SUBSTANCES”, where a full description of the uncertainty estimation scheme is included.

Facilitating and harmonising the way that Accredited Doping Control Laboratories estimate uncertainty to their quantitative methodologies will add one more ring in the WADA lab network chain. The project has concentrated information for the various ways of uncertainty estimation within the WADA Accredited Laboratories, the WADA Technical Document and from literature sources and it has provided with a friendly software tool called MUADS for this purpose.