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THE CHALLENGE OF CIEMAT INTERNAL DOSIMETRY SERVICE FOR ACCREDITATION ACCORDING TO ISO/IEC 17025 STANDARD, FOR *IN VIVO* AND *IN VITRO* MONITORING AND DOSE ASSESSMENT OF INTERNAL EXPOSURES

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The accreditation of an Internal Dosimetry Service (IDS) according to ISO/IEC 17025 Standard is a challenge. The aim of this process is to guarantee the technical competence for the monitoring of radionuclides incorporated in the body and for the evaluation of the associated committed effective dose E(50). This publication describes the main accreditation issues addressed by CIEMAT IDS regarding all the procedures involving good practice in internal dosimetry, focussing in the difficulties to ensure the traceability in the whole process, the appropriate calculation of detection limit of measurement techniques, the validation of methods (monitoring and dose assessments), the description of all the uncertainty sources and the interpretation of monitoring data to evaluate the intake and the committed effective dose.

CIEMAT Internal Dosimetry Service (IDS) has developed and implemented a quality system based on ISO/IEC 17025[1] to ensure compliance with the general requirements of this reference standard. The development of documentary support according to this quality system permitted to standardise the systematic activities performed within the whole body counter and *in vitro* bioassay laboratories as well as the procedures carried out by qualified staff in charge of internal dose assessment. There was no previous experience in the accreditation of other internal dosimetry services in Spain. Then, requirements from the national regulatory body (Nuclear Safety Council, CSN) and national accreditation entity (ENAC) have been considered. The main concerns were to guarantee the traceability in the whole process and to avoid possible charge of interpretation or subjectivity in the methodology of dose assessment due to intakes of radionuclides when calculating from monitoring data. All the related international standards dealing with internal dosimetry were taken into account: ISO 28218[2] 'Performance criteria for radiobioassay', ISO 27048[3] 'Dose Assessment for the monitoring of workers for internal radiation exposure' and ISO 20553[4] 'Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material'. Appropriate and validated commercial software implementing current ICRP biokinetic and dosimetric models was approved as tool for dose assessment. CIEMAT IDS was accredited according to ISO/IEC 17025 in 2012 as demonstration of technical competence for monitoring and dose assessment due to internal exposures, considering the methods described as follows:

- *In vivo* monitoring of (a) gamma emitters in the total body using a FASTSCAN counter or one NaI(Tl) detector inside a shielded room, (b) actinides in the lungs with four LE Ge detectors and (c) radioiodine (^{125}I, ^{131}I) in the thyroid with detection systems mentioned before.
- *In vitro* monitoring of (a) alpha emitters in urine and faeces by alpha spectrometry, (b) beta emitters (^{90}Sr, ^{3}H, ^{32}P, ^{14}C, ^{35}S) in urine by liquid scintillation counting (LSC) and (c) uranium in urine using kinetic phosphorescence analyser (KPA). ICP-SFMS technique is in process of approval and accreditation for the measurement of uranium, thorium and plutonium in urine.
- Evaluation of committed effective dose E(50) from monitoring data, applying ISO standards, ICRP publications and IDEAS guidelines (GL) (EURADOS Report 2013-01)[5].

ACCREDITATION OF CIEMAT *IN VIVO* AND *IN VITRO* RADIOBIOASSAY LABORATORIES AND INTERNAL DOSIMETRY SERVICE ACCORDING TO ISO/IEC 17025

Requirement of traceability in the whole internal dosimetry process in the case of occupational exposures

The assessment of internal exposures is a step-by-step process where the traceability must be ensured since the workplace characterisation and design of individual monitoring programmes to the end (assessment of E(50), recording and reporting). A summary of requirements and procedures is as follows:

(1) Characterisation of the workplace: potential internal exposures must be well identified and documented regarding the radionuclides that can be potentially incorporated, type of radiation, energy and half-life, chemical compounds, particle size and typical amount of activity that is manipulated.
(2) Individual monitoring programmes are established taking into account the biokinetics of the isotopes present in the workplace, the available measurement techniques and the sensitivity (detection limit) of those monitoring methods. The frequency of controls must be established accordingly. As a general approach, the object of a routine monitoring programme is the detection of all intakes resulting in a likely committed effective dose of ≥ 1 mSv y^{-1} (recording level) at the workplace.
(3) Monitoring of workers is carried out using *in vivo* and/or *in vitro* methods. The analysis of spectra permits the identification of radionuclides incorporated in the body and their quantification in terms of the activity retained in the total body or organs M (Bq) for *in vivo* monitoring or excretion rate M (Bq d^{-1}) in the case of *in vitro* monitoring. Results of monitoring should be in accordance with the scenario mentioned before.
(4) The assessment of intake I(Bq) and dose E(50) mSv from monitoring data is done taking into account the time of intake, type of exposure (chronic/acute), incorporation pathway (inhalation/ingestion/wound), absorption type (F, M or S, only in the case of inhalation), aerosol or gas and the particle size (AMAD) if aerosol. Final dose evaluation must be in coherence with the workplace characterisation and the routine or special monitoring programmes previously established.

CIEMAT IDS used ISO/IEC 17025 standard to implement a quality system aimed at improving its ability to consistently produce valid results. ISO/IEC 17025 establishes the following:

- Management requirements—related to the operation and effectiveness of the quality management system within the laboratory.
- Technical requirements—include factors that determine the correctness and reliability of the results obtained by the methods performed in a laboratory.

Main tools and reference publications used by CIEMAT IDS for the implementation of the quality system that guarantee the traceability in the whole internal dosimetry process are presented in the following.

CERTOOL: tool for the implementation of ISO/IEC 17025 quality management system

CERTOOL[6] is a software solution designed by AENOR (national normalisation body in Spain) for the effective management of systems. It is based on the management models defined by the international reference standards, thus facilitating compliance with the requirements established in such standards. It is a powerful, easy-to-use, flexible and adaptable tool to any type of organisation. CIEMAT External and IDS are currently CERTOOL users. All the supporting documents related to the management of laboratories and services are here stored such as the procedures and records associated to accredited methods, qualification of staff, client data, internal and external audits, claims, non-conforming actions and all the evidences that guarantee that ISO/IEC 17025 quality system requirements are fulfilled.

ISO28218 standard on 'Performance criteria for radiobioassay' provides guidance on performance of *in vivo* and *in vitro* laboratories including criteria for the implementation of an appropriate quality assurance programme. Regarding the sensitivity of the monitoring techniques, ISO 28218 presents a methodology that permits the calculation of decision threshold and detection limit according to ISO 11929[7], which was implemented in the gamma spectrometry software of CIEMAT Whole Body Counter (WBC) and validated. Recommendations on quality control (QC) for *in vivo* and *in vitro* monitoring are established on the basis of appropriate levels of accuracy and precision using the relative bias (Br) and repeatability (S_{Br}) as key parameters. The ISO 28218 acceptance criteria generally implemented are as follows:

- Accuracy: range of $(-0.25, +0.50)$ for Br.
- Repeatability: $S_{Br} < 0.4$.

Restricted Br and S_{Br} values were established at CIEMAT *in vivo* and *in vitro* laboratories for some specific cases based on historic data after 20 y of laboratory performance: e.g. a range of $(-0.15, +0.15)$ for Br in the case of QC of *in vivo* detection systems using point sources for checking current calibrations before measurements to individuals, or in the case of *in vitro* systems for QC of LSC checking current annual calibration.

The implementation of ISO 28218 principles for *in vivo* monitoring and *in vitro* radiobioassay and the participation in intercomparison exercises on regular basis (final step of method validation) guarantee the reliability in the identification of radionuclides incorporated in the body and in their quantification in terms of the retained activity M (Bq) and excretion rate M (Bq d^{-1}) in urine and faecal samples.

Suitable individual monitoring programmes are established by CIEMAT IDS based on *ISO 20553 standard 'Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material'*. Recommendations on the choice of monitoring techniques take into account the potential intake scenario and the availability and detection limits of *in vivo* and *in vitro* methods. Regarding frequency of controls, other matters such as human and economic resources

as well as national regulations are also taken into consideration.

The general principles of *ISO 27048 standard on 'Dose assessment for the monitoring of workers for internal radiation exposure'* were essential in the accreditation process to solve the difficulties for including dose assessment in the ISO/IEC 17025 quality system. ISO 27048 methodology refers to a standard step-by-step procedure to calculate intake I(Bq) and committed effective dose E(50) mSv from the monitoring data of internally exposed persons. The object here is to guarantee consistency and reliability in the dose evaluation using actual information of intake scenario. Important matters addressed by ISO 27048 that were implemented by CIEMAT IDS are the analysis of uncertainties using scattering factors (SFs) (same approach as IDEAS GL), the contribution of previous intakes in current monitoring data, the 'maximum likelihood method' for intake assessment and the use of the 'chi-squared' test for checking the 'goodness of fit' of measurement data comparing with the biokinetic model selected according to intake assumptions. All these tools permit to establish a QC in the procedure of intake and dose calculation. In case of complex cases of internal exposures, IDEAS GL complement ISO 27048 (e.g. 'go to an expert' option in the flow chart).

IDEAS guidelines V2 (EURADOS report 2013-01)

IDEAS GL for the estimation of committed doses from incorporation monitoring data establish a philosophy of evaluations of internal exposures in flow charts mainly based on the principles of *Harmonisation* (two assessors should obtain the same dose from a given data set) and *Accuracy* (the 'best' estimate of dose should be obtained).

IDEAS GL use a 'levels of task' scheme to structure the approach to an evaluation of E(50) that was implemented in the CIEMAT IDS:

- Level 0—annual doses <0.1 mSv. No dose evaluation is required.
- Level 1—doses in the range of 0.1–1 mSv. Simple dose evaluation using ICRP reference parameter values is required.
- Level 2—typical doses in the range of 1–6 mSv. Advanced evaluation using additional information as a result of an investigation for a more realistic dose assessment is required.
- Level 3—typical doses >6 mSv. More sophisticated evaluation by an expert is required.

CSN as national regulatory body of radiological protection in Spain establishes a recoding level of effective dose $= 1$ mSv y^{-1} (within a calendar year) and an investigation level also of 1 mSv y^{-1}. Thus, all dose of evaluations resulting in E(50) $>$ 1 mSv must be recorded, evaluated with all the information available regarding the internal exposure occurred at the workplace and investigated. This approach is in agreement with the structure of the levels of IDEAS GL presented above.

Regarding uncertainties, measurements are assumed to be log-normally distributed with a given SF that takes into account Type A and Type B sources of uncertainties. SF_A is calculated from the Type A uncertainty (σ) provided by the laboratory (e.g. uncertainty evaluation and the contributions of all the factors influencing the measurements for actinides determination in excreta by alpha spectrometry are described by Hernandez *et al.*[8]), and SF_B is obtained from the tables of IDEAS GL or ISO 27048 standard.

Validation of methods: participation in intercomparisons for *in vitro* and *in vivo* monitoring of internal emitters (annually)

PROCORAD (www.procorad.org) is a European association of laboratories dealing with *in vitro* measurements of radionuclides in excreta samples. The main aim of the organisation is intercomparisons of samples on a regular basis to promote fruitful scientific and technical exchanges among its members. Laboratories from Europe and outside Europe are regular participants. A scientific meeting is organised each year during the association's general assembly, alternately in France and abroad. A technical report is published each year in French and English. CIEMAT *in vitro* laboratory is a member of PROCORAD since 1998, and it participates in exercises selected from the general programme proposed every year.

CIEMAT Bioassay Laboratory also participates in the *in vitro intercomparison programme* organised by *Bundesamt für Strahlenschutz* (BfS, Germany), as part of the validation process of accredited *in vitro* monitoring methods. All the capabilities of the laboratory are validated and verified at least once within the time required by ISO/IEC 17025 and national regulations (every 4 y maximum) for urine and faecal samples.

Intercomparison exercises of in vivo monitoring of internal emitters are organised by Institut de Radioprotection et de Sûreté Nucléaire (IRSN) in France with the participation of all French whole body counting facilities and other European *in vivo* laboratories. CIEMAT WBC participates annually in all the IRSN exercises of the three alternative programmes of *in vivo* monitoring: (1) gamma emitters in total body, (2) radionuclides deposited in the lungs and (3) radioiodine (^{131}I and ^{125}I) in the thyroid. CIEMAT WBC guarantees the validation of all the calibrations (including phantoms and radioactive sources) associated to accredited *in vivo* methods, for all the available detection systems: FASTSCAN counter, NaI(Tl) detector and LE Ge detectors inside a shielded room.

Computational tools approved to use in the accredited CIEMAT IDS

Commercial software for gamma spectrometry (*in vivo* monitoring) and for the analysis of excreta samples (alpha spectrometry, LSC and KPA) is used at CIEMAT IDS with certification of validation of the manufacturer and internal validation by *in vivo* and *in vitro* bioassay laboratories.

Regarding dose assessment, commercial software for calculation of intake I(Bq) and dose E(50) from monitoring data was validated by the manufacturers and was approved by Nuclear Safety Council (Spanish regulatory body). The codes AIDE (Activity and Internal Dose Estimates, Los Alamos Nat. Lab., USA) and IMBA (Integrated Modules for Bioassay Analysis, www.phe-protectionservices.org.uk/imba, Public Health England, UK) have the capabilities that permit the application of current ICRP recommendations, ISO 27048 methodology and IDEAS GL (V2).

Internal validation of software was also required. Comparison of results of E(50) was carried out using both codes in selected case studies of typical radionuclides associated to CIEMAT IDS monitoring programmes (e.g. reference values from publication *Castellani et al*.[9] were used for validation).

CONCLUSIONS

The main challenges identified in the accreditation process of CIEMAT IDS[10] are as follows:

- To guarantee the traceability in the whole internal dosimetry process from workplace characterisation to dose evaluation, recording and reporting. An important issue is to ensure the traceability of calibration sources. The use of certificate sources is required as well as reference calibration phantoms validated through intercomparisons.
- Appropriate evaluation of the sensitivity of detection was carried out with the implementation of ISO 28218 standard for the calculation of detection limit and decision threshold. This is especially important when designing individual monitoring programmes. ISO 20553 presents appropriate techniques to be selected depending on intake scenarios.
- Uncertainty analysis was an important challenge in the accreditation process of CIEMAT IDS. A detailed study of all the uncertainty sources was carried out, with special attention to *in vitro* monitoring due to radiochemical procedures in the sample treatment. SFs (ISO 27048 and IDEAS GL) were used when calculating intake from monitoring data.
- Regarding the validation of methods, internal validation process is required with a QC programme according to the criteria adopted by ISO 28218. Restricted reference levels for specific QC checks are applied based on historic data. Final validation is achieved with the participation of CIEMAT IDS in intercomparisons on regular basis.
- Dose assessment accreditation was based on the application of current ICRP recommendations, the methodology presented in ISO 27048 standard and IDEAS GL (including QC in the process of calculating intake from monitoring data to check consistency with intake scenario) and the use of suitable (and validated) commercial software.

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