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CIEMAT EXTERNAL DOSIMETRY SERVICE: ISO/IEC 17025 ACCREDITATION AND 3 Y OF OPERATIONAL EXPERIENCE AS AN ACCREDITED LABORATORY

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In 2008, the CIEMAT Radiation Dosimetry Service decided to implement a quality management system, in accordance with established requirements, in order to achieve ISO/IEC 17025 accreditation. Although the Service comprises the approved individual monitoring services of both external and internal radiation, this paper is specific to the actions taken by the External Dosimetry Service, including personal and environmental dosimetry laboratories, to gain accreditation and the reflections of 3 y of operational experience as an accredited laboratory.

INTRODUCTION

The CIEMAT External Dosimetry Service (EDS) was approved in 1984 by the Spanish regulatory authority, the Nuclear Safety Council (CSN), to perform personal dosimetry using film dosemeters. This approval was extended in 1992 for the use of thermoluminescence dosemeters (TLD).

The EDS started in early seventies to carry out environmental and area dosimetry using its own design of TLD based on lithium fluoride detectors. In contrast to individual monitoring, in Spain, environmental and area dosimetry is not subject to approval and inspection regime.

In 2008, after many years of working on individual and environmental dosimetry and the acknowledgement of the growing trends in Europe, CIEMAT Radiation Dosimetry Service concluded that it was essential to gain accreditation.

For individual monitoring, the approval requirements in Spain are defined in the CSN Safety Guide GS-7.1[1] and include requirements on:

- Personnel and equipment,
- Type testing and calibration,
- Technical procedures.

An initial audit revealed that most of the technical requirements of the ISO/IEC 17025:2005[2] standard were already in place. However, it was also identified that there was a need to implement appropriate management requirements and to document evidence of compliance, in particular for environmental dosimetry.

Consequently, the CIEMAT EDS initiated a long-term programme to review and update its quality assurance system to meet the standard for both management and technical requirements.

The procedures that required most attention for accreditation and the reflections after >3 y of operational experience after accreditation are highlighted in this paper.

MATERIALS AND METHODS

The EDS consist of two laboratories:

(1) LDE[3]: External Dosimetry Laboratory for the determination of the personal dose equivalent, $H_p(10)$ and $H_p(0.07)$, from external exposure by using the Panasonic system:

- Whole-body dosemeter model UD-802.
- Extremity dosemeter model UD-807.
- TLD readers models UD-716 and UD-710.

(2) LDA[4]: Environmental Dosimetry Laboratory for the determination of the ambient dose equivalent, $H^*(10)$, employing:

- Environmental and area dosemeter containing TLD-100 (from Thermo) and GR-200 (from Conqueror Electronics) detectors within CIEMAT designed hanger.
- Thermo TLD readers model 5500.

The service staff is composed of four technicians and four assistants. The dosemeters are provided to ~1000 exposed workers for monthly monitoring and to ~120 environmental and area stations for exposure periods that range from 1 to 3 months. Table 1 shows the distribution of the dosemeters by customers' work sectors.

ACCREDITATION EXPERIENCE

2008:A crucial year

The CIEMAT Radiation Dosimetry Service comprises approved individual monitoring services of both external and internal radiation. With the objective of achieving accreditation, the service management decided in

Table 1. Distribution of dosemeters by customers' work sectors (2015) in both laboratories.

	LDE (%)	LDA (%)
Medicine	24	10
Industry	1	25
Research	32	39
Government	18	—
Waste management	25	26

2008 to implement a quality system[5], based on the standard ISO/IEC 17025, to meet the needs of both internal and EDSs, including their four laboratories: whole-body counter, bioassay laboratory, LDE and LDA. The proposed scope included assessment of $H_p(10)$, $H_p(0.07)$ with whole-body and extremity dosemeters for LDE, assessment of $H^*(10)$ with area dosemeters for LDA and assessment of committed effective dose, E(50), for internal dosimetry. This paper deals only with the EDS, including personal and environmental dosimetry laboratories. Details on the Internal Dosimetry Service accreditation can be found in Reference (6). The synergies between the accreditation processes for both services are explained in Reference (5).

The first step in the accreditation programme was to appoint a quality manager (QM) and a quality group consisting of the QM, the heads of both services and the technicians of all laboratories. The group held progress meetings at least once a month.

The service also contacted other accredited IMSs to learn from their experiences and set up a schedule to achieve accreditation within 3 y.

A new IT tool for the management system (Certool)[7], developed by the Spanish Association for Standardization and Certification (AENOR), was acquired. This software facilitates effective management of the quality system. Its functionality is designed for the management of most of the requirements included in the quality system: staff training, infrastructures and equipment, purchases and suppliers, clients, nonconformities, corrective and preventive actions, external and internal audits and management review. Certool is particularly useful for document and record control, allowing registration of all types of documentation and establishing a document control system for revision, approval and distribution of documents and records. The master list of system documents is automatically updated and its access control system ensures that personnel can only access information they need.

An external auditor was hired to carry out an initial audit of the quality system and to provide recommendations to achieve accreditation in the most efficient manner. The audit revealed that most of the technical requirements of the standard were already in place. However, it was identified that there was a need to implement management control and to demonstrate evidence of compliance. In total, 38 recommendations were made by auditor. These related mainly to document control, equipment, validation, measurement uncertainties and reporting results.

2009–2010: Documentation and implementation

A new edition of Quality Manual and new procedures for management requirements were approved. These included organisation, document control, purchases and suppliers, customers and complaints, nonconformities, corrective and preventive actions and control of records. An in-depth review was carried out of the technical procedures for personal dosimetry, and new versions were approved and issued. For environmental dosimetry, it was necessary to generate new procedures for most of the technical requirements.

According to the CSN GS 7.1[1], the characterisation of the dosimetry system was initially performed according to:

- IEC 61066:1991[8] for whole-body and area dosemeters.
- ISO 12794:2000[9] for extremity dosemeter.

To comply with validation requirements, it was necessary to demonstrate that the initial type testing, carried out for the approval, was still valid after >20 y of operation of the dosimetry service. The analysis of results from calibration, daily quality control and participation in intercomparisons[10] (ICs) during this period were used as evidences.

The criteria adopted by EDS to evaluate the results of participation in inter-laboratory comparisons were those set out in ISO standard 14146[11], commonly known as the 'trumpet curve'.

Detailed estimates of measurement uncertainty were assessed in accordance with the recommendations given in the European Commission's *Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation*[12].

A new dose report layout, including signature and a statement on the estimated measurement uncertainty, was needed to meet the reporting requirements of the standard.

One section that deserved a special mention was the treatment of the records. To pass the quality audits, evidences of all process are required, so it was necessary to generate a big amount of records that must be validated, protected and signed. In particular, the EDS currently deal with >100 records, including both management and technical ones.

In summary, the issues that required more effort in the implementation of the quality system were as follows:

- Design and implement the quality system.
- Elaborate new documentation to comply with management, personnel and training requirements and in-depth revision of all technical procedures.
- Manage and monitor nonconformities, corrective and preventive actions.

- Validate the method and estimate the uncertainty of measurement.
- Meet reporting requirements.
- Control documents and records including programmed periodic revision.
- Generate evidences of validation of the method, the software and the record, including excel files.
- Involve the staff to use Certool to maintain the system and associated documentation.

In order to evaluate the implementation of the quality system, the first internal audit was completed in 2010. It revealed eight nonconformities (Table 2), mostly related to qualification, record and document control, validation and reporting.

EDS worked to implement the necessary actions to correct the detected deviations and to verify the implementation of all aspects included in the quality system, before applying for accreditation.

2011–2012: Application for accreditation. ENAC audit

The second internal audit was conducted in 2011 and showed a marked improvement of the dosimetry system, as only two nonconformities and six minor deviations (Table 2) were found.

At the end of 2011, the CIEMAT Radiation Dosimetry Service applied for accreditation to ENAC and passed the accreditation audit in two phases: technical audit in 2011 and management audit in 2012.

An auditor and a technical expert reviewed the quality system and the dosimetry service performance for 2 d of audit. Only four minor deviations (Table 3) were found. In April 2012, ENAC agreed to grant accreditation to the EDS (Ref. No.: 144/LE1836) in recognition of their technical competence to carry out tests in the area of dosimetry.

AFTER 3 Y OF EXPERIENCE

During the 3 y of EDS experience as an accredited laboratory, a number of advantages and disadvantages have been identified.

The main advantages of being accredited are the systematization of technical and management activities and the ease of proving the reliability of the results to both customers and regulators.

The quality management system facilitates the review, updating and improvement of the laboratory operations.

However, the document system has grown from 8 procedures and 5 technical instructions in 2008 to 23 procedures and >100 records in 2015. Consequently, the effort in document control has grown in the same proportion.

To date, the EDS has successfully passed two ENAC follow-up audits without any significant nonconformities being identified, demonstrating the good performance of the quality system. In addition, the EDS has passed three internal audits and two CSN inspections with satisfactory results.

Table 2. Non-compliances revealed during internal audits.

ISO/IEC 17025 requirement	Classification of deviation: description
First internal audit—2010	
4.3 Document control	NC: Several technical documents are not approved or not controlled
4.13 Control of records	NC: Some records do not include the identity of the responsible personnel
5.2 Personnel	NC: Information about qualification is outdated
5.4.5 Validation of methods	NC: Some validation activities are not documented
5.4.7 Control of data	NC: Some data sheets are not properly validated or protected
5.6 Measurement traceability	NC: No assessment of external calibration certificates
5.9 Quality assurance of test and calibration results	NC: Analysis of the ICs results is not documented
5.10.2 Test reports and calibration certificates	NC: Reports do not include all the information required
Second internal audit—2011	
4.6 Purchasing services and supplies	MD: Some purchases information is not available
4.9 Control of nonconforming testing work	NC: In one case, the procedure to control nonconforming work was not applied
4.13 Control of records	NC: One record in use is not controlled
5.4.6 Estimation of uncertainty of measurement	MD: Uncertainty in assessment of $H^*(10)$ is not available
5.5 Equipment	MD: Some maintenance activities are not recorded
	MD: Some activities of quality control are not recorded
5.9 Quality assurance of test results	MD: In LDA the frequency of participation in ICs does not meet criteria of the accreditation body
5.10.2 Test reports and calibration certificates	MD: The function of the signee is not included

NC, nonconformity; MD, minor deviation.

Table 3. Non-compliances revealed during external audit.

ISO/IEC 17025 requirement	Classification of deviation: description
Accreditation audit—2011–2012	
4.9 Control of nonconforming testing work	MD: The laboratories do not fully apply the procedure to control nonconforming work
5.2 Personnel	MD: Personnel training programme is not fully described
5.4.4 Non-standard methods	MD: In some cases, test procedures are not fully described
5.10 Reporting the results	MD: Reports do not include all the information required

NC, nonconformity; MD, minor deviation.

The necessary corrective actions have been implemented to correct all the minor deviations identified during audits and inspections. ENAC reassessment audit is scheduled for 2016.

CONCLUSIONS

Accreditation is a healthy process for an IMS, which compels it to make an in-depth review of all administrative and technical procedures, the validation of the methods, the control of documents and to pass regular internal and external audits.

During the 3 y of EDS experience as an accredited laboratory, some pros and cons have been identified.

The main advantages of being accredited are the systematization of technical and management activities and the improvement in demonstrating the reliability of the results to both customers and regulators.

The main disadvantage is that the maintenance of the quality system requires time and dedication and the frequency of internal and external audits is sometimes difficult to reconcile with the daily work of a dosimetry service.

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