Why Accredit ISO/CEI 17025 a Nuclear Waste Management Laboratory? – 15112

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ABSTRACT

When there is no storage, nor repository, available on a site, the entity in charge of nuclear waste management should find outlets in order to evacuate outside the site. Each outlet has his rules and waste acceptance criteria (packaging rules, physical/chemical/radiological criteria for example). Before you are able to evacuate your waste, an acceptance's process (or contract review) takes place. This process scans the entire measures implemented by the site in order to satisfy outlet's criteria. When the acceptance is obtained, shipments could be organized, and the process gets into an observation's phase. During this phase, the outlet could choose to inspect a finished nuclear waste package or to audit regularly the waste management process. In this last case, the outlet rescans the entire documents and implemented measures. This audit lasts from one to several days.
A way to tackle/approach the audit is to acknowledge, by a trusted third party (ie. independent from the outlet), all or part of waste management system, in order to base one's reputation on this organism and win outlet's trust. For this purpose, the entity could choose certification or accreditation. Certification (ISO 9001 as often as not) aims at evaluating a system for managing the quality of one product or service. Accreditation (ISO 17025, for example) provides formal recognition for technical skills within a quality management system (clauses 5 and 4 of the ISO 17025 standard).
In 2006, the LDM laboratory is the first French laboratory accredited, in accordance with ISO 17025 standard, for the characterization by gamma spectrometry on 100L- and 200L- radioactive waste drums (accreditation #1-1712 – scope available on www.cofrac.fr). This accreditation allows the lab:

- to update the quality management system,
- to compile the entire technical file of the gamma-ray assay (description, evaluation of the uncertainties, calibration, proficiency testing programs, measurement procedures, …),
- to pass previous identified constraints on to producers and nuclear waste package production,
- to maintain permanent quality improvement loop,
- to lighten the programs of outlets audits, through the acknowledgement of the technical competence of the laboratory to evaluate by gamma spectrometry the activity contained in our nuclear waste drums.

On the other hand, the lab is re-evaluated periodically to ensure its continued compliance with requirements: within a 12 month's interval for an internal audit, with a 18 month's period for COFRAC (French sole official national accreditation body). Since 2006, the lab is accredited. His accreditation renewed in 2010. A new entire renewal audit is planned in 2015.

INTRODUCTION

In 2003, the LDM was involved in the overhaul of its quality management system, concerning nuclear waste management and activity measurement. One goal is to lighten the outlets' audits, another to update its former system, and the last to find a way to recognized by a third party the quality of the new system and the technical competence. One way to satisfy theses goals is the accreditation.

THE ACCREDITATION OF THE LDM

The French Bruyeres-Le-Chatel (near Paris) and Moronvilliers (near Reims) CEA (Commissariat a

l'Energie Atomique et aux Energies Alternatives – French Alternatives Energies and Atomic Energy Commission) research center are going through a period of dismantling and clean-up. The CEA's Laboratoire Dechets et Mesures (LDM – Nuclear Waste and Measurement Laboratory) is in charge of manage, characterize and evacuate the radioactive waste packages manufactured during the operations. Neither storage, nor repository is available on the site. Evacuate packages need to find either a treatment outlet or a storage outlet, according to the typology of waste :

- Radioactivity : Very Low Level (VLLW), Low and Intermediate Level (LLW/ILW)
- Physical or chemical characteristics: incinerated, compacted, liquid, salt, …
- Packaging: flexible packages, metallic drum, concrete container, tank, …

Each outlet works more or less the same way: it make a service (treatment process, storage site) available to a radioactive waste producer. This service could be use unless you respect some acceptance criteria or rules. The contract review takes the form on an acceptance's process, while every interested party checks that one's requirements are understanding by the other, and vice versa.

Majority of the radioactive waste produced on both sites are evacuated to a storage repository. In France, long term management of all radioactive waste is within the competence of ANDRA (Agence Nationale pour la gestion des Dechets RAdioactifs –French National Radioactive Waste Management Agency). This competence is established by the December 1991 Waste Act (known as Loi Bataille). In its industrial mission, ANDRA put storage sites at radioactive waste producers' disposal. To guaraneee the safety of its sites, and long term protection of the Environment and Mankin, ANDRA set up an acceptance's process of radioactive waste packages which could be sent. This process scans the entire measures implemented by the producer on order to satisfy, for a particular typology of waste, the rules of ANDRA.

This acceptance's process goes through different phases:

- Definition of the project : Explanatory Leaflet Project Approval
- Writing of an Agreement Matrix (list of the criteria to satisfy and the answers of the producer), of a Process Explanatory Leaflet (how the producer manufactured the final package with its wastes), and of Evaluation of Activity Explanatory Leaflet (how the producer will evaluate the radiological activity of the final package)
- Exchanges for documentary updates, technical tests
- Achievement of the acceptance, followed by an observation's phase (see. Figure 1).

This acceptance's process could be repeated as much as there are different packages

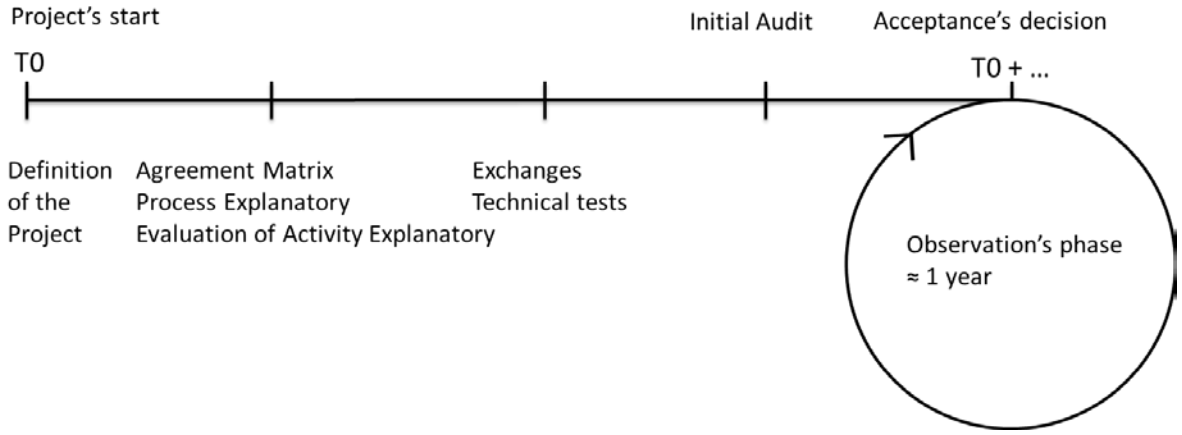

Fig. 1. Acceptance's process

During the observation's phase, the outlet could choose to inspect a finished nuclear waste package or to audit regularly the waste management process. In this last case, the outlet re-scans the entire documents

and implemented measures. This audit lasts from one to several days, according to the numbers of obtained acceptance's cases.

In 2003, the LDM is involved in the overhaul of its quality management system. One goal of this update was to answer, in a more satisfying way, the questioning of the outlets, during the observation's phases. A way to approach the questioning, acknowledgement of all or part of our quality management system and our technical competences, by a trusted third party (i.e. independent from the outlet), could be an answer to this problem, by reinforcing the outlet's trust in our capacities and abilities.
ISO 9001 standard (version 2000, then 2003) evaluate a quality management system for a product or a service. Certification of an entity in accordance with ISO 9001, is the proof of the agreement of this system with this standard. But certification don't rule on technical skills. LDM's certification would just control a par of our system (mastery of nuclear waste management).
But the laboratory would recognized its quality management system as well as its competences in nuclear waste measurements. Accreditation of a laboratory uses specifically developed criteria and proceedings to evaluate technical skills. These criteria are based on ISO 17025 standard – General Requirements for the competence of testing and calibration laboratories (version 1999, then 2005 during our accreditation's procedure). Thus accreditation in accordance with this standard check every factor which could modify testing or calibration, such as:

- skills of staff
- appropriateness and validation of the methods
- traceability to standards, links to calibration standards
- controls of equipments and measures background
- quality and traceability of test results

The laboratory could accredit all or part of its activities, subject to be included in the scope of the ISO 17025 standard. The laboratory gives information regarding its accreditation's perimeter (scope) and all the documents necessary to pre-evaluate. Information given, the organism launches an initial audit to evaluate the entire quality management system and technical services. This evaluation lasts from one to several days, depending on number or complexity of the services. During this audit, there are quality auditors, but above all, technical experts in the evaluated scope. After the audit, one report which contains the entire discussed items (especially items which need a correction or a particular attention) is written. This report is checked by the accreditation's organism (in France, COFRAC is sole official national accreditation body). When the accreditation is obtained, the laboratory is re-evaluate periodically, during a 60 months cycle (see fig. 2)

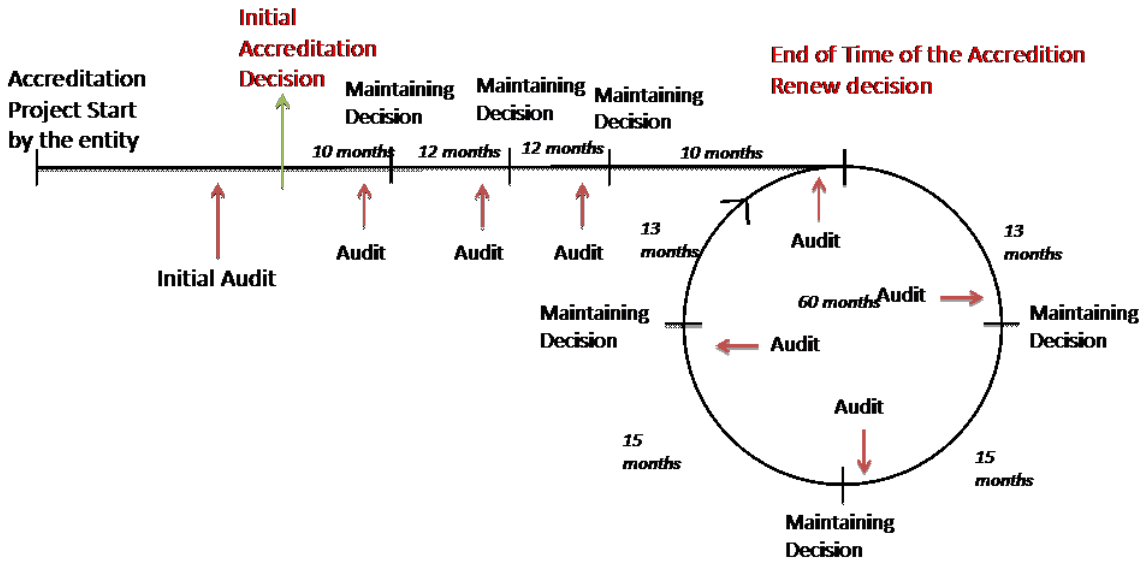

Fig. 2. Accreditation ‘s process

In France, on the contrary of nuclear environment laboratories or medical analysis laboratories, there is no legal obligation for the measurement of nuclear waste packages. The processes chosen by the LDM is voluntary. This voluntarism would accentuate outlets’ trust in the quality of our services. The decided scope is: measurement by gamma spectrometry on 100 L- and 200 L-metallic drums, between 59 keV and 1460 keV.

The choice of this scope was decided in relation to:

- the number of concerned packages (more than 90% of our packages are one of these both categories)
- the way we notify the radiological characteristics (measurement by gamma spectrometry)

Inexperienced in enforcement of a quality management system true to ISO 17025 standard, the LDM is accompanied by a qualified provider. This accompaniment was translated into:

- ISO 17025 standard presentation
- Inventory of the former quality management system and identification of the deficiencies
- Proposal of a progress plan
- Following of enforcement
- Organization of a blank audit
- Taking part in the initial and official audit, as au guest
- Enforcement of corrective acts, after the audit.

Sine qua non condition to make sure that the new quality management system was correctly appropriated by the LDM’s staff (and thus respect one of the criteria of the ISO 17025 standard concerning staff’s competence), the agents of the laboratory written all the documents.

ISO 17025 standard is composed of two main parts:

- clause 4, requirements for quality management
- clause 5, requirements for technical competences

Clause 4 resumes Clauses 4 to 8 of the ISO 9001 standard, such as:

- Mastery of documents (who write, who distribute and how, …)
- Buying, subcontract
- Customer services and claims

- Contract review
- Improvement loop
- Corrective and preventive actions processing
- Internal audits
- Management review

Clause 5 concerns specifically factors which establish the accuracy and reliability of tests:

- human factor
- installations and ambient conditions
- testing or calibration methods
- equipments
- traceability of measurement,
- sampling
- Handling of evaluated objects.

The particularity of the lab is to combine radioactive waste management and measurement of nuclear waste packages. Our daily practices are mainly agreed with the requirements of the ISO 17025 standard. Most of the work consisted of formalizing these practices inside process, procedures, operating handbooks, registrations …

Tough items during the settings of the two clauses are:

- To define who is the client. Contractually, the LDM is the client of the outlets for their storage sites or treatment process. However, the ISO 17025 standard needs to clearly identify the customer of the test report. Thus measurements realized by the LDM are for primary producers. They ask the LDM to manage their waste package, to verify the radiological conformity in accordance with the acceptance criteria. Producers are therefore the customers
- To realize a management review. This is a new requirement in our daily activities
- To define the situation of non-CEA staff. We employ non-CEA people to help us exploiting our installations and achieving measurements. In the sense of the standard, is it subcontract or support staff under contract? The answer could throw back into question the accreditation process. In the first case, subcontract should be clearly identify, not be about the entire scope, and could only be achieved by an accredited entity (therefore, the final report could have the ISO 17025 stamp). However, the second case was kept, in agreement with a COFRAC document, non-CEA staff in our organization scheme haven the same rank as CEA staff.
- To formalize uncertainties calculations. Nuclear waste packages change from one package to an other. It's impossible to have one standard package for each configuration. A more global approach is necessary with reasonable increasing cases. An internal CEA study (based on Monte Carlo simulations) gives us distributions of errors and bias between an ideal 200 L-drum and realistic simulated drums. Even if the results give high uncertainties (near 100% in some cases), there is no problem in accordance with the ISO 17025 standard. The difficulty was to make understand the technical experts, usually regular working on environmental samples with small geometrical dispersion and uncertainties. One consequence of this difficulty is that the report explaining in detail the estimation should be re-written many times after the different audits.
- To validate the test method. ISO 17025 standard requires to use validated methods. Standardized method is an answer to this requirement. Two French standards (NF M 60-302 "High resolution gamma spectrometry activity measurement of waste packages" and N M 60-303 "Recommendations for the calibrating of an activity measurement facility of radioactive waste forms by gamma spectrometry"; these two standards are now combined in ISO 14850 "Waste packages activity measurement") exist to satisfy this ISO 17025 standard criterion.
- To participate proficiency testing programs. Proficiency testing programs for nuclear waste packages are hard to organize. In France, the National Henri Becquerel Laboratory (LNHB,

national metrology laboratory for ionizing radiation) provides every year a test on a sample (15 ml- or 50 ml-resin or liquid) containing βγ emitters. It gives us the opportunity to validate our equipment and the staff competence.

With these elements, the LDM was audited during 1,5 days in 2006. The accreditation decision, with issue of certificate, arrived a few weeks later. This is the first French laboratory accredited for nuclear waste packages measurements.
In 2010, the accreditation was renewed. And in 2015, the LDM will be re-audited and know if its accreditation will be renewed for a 5 years period.

CONCLUSIONS

Accreditation (ISO 17025, for example) provides formal recognition for technical skills within a quality management system (clauses 5 and 4 of the ISO 17025 standard).
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ACKNOWLEDGEMENTS

The laboratory would acknowledge all the staff who take part of the enforcement of the ISO 17025 quality management system and who, every day, contribute to maintain this accreditation. The laboratory also thanks the provider who helps us at the beginning of the project.