THE JOURNEY TO A CERTIFIED EQUIPMENT QUALIFICATION LABORATORY – WESTINGHOUSE APPROACH AND LESSONS LEARNED

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ABSTRACT

Equipment Qualification is required to provide documented evidence that safety-related equipment in Nuclear Power Plants can perform its function(s) during and/or after specified normal, abnormal and accident conditions. Equipment Qualification is normally performed by laboratories specialized in this domain. During recent years, some national nuclear authorities have begun to focus on the qualifications of such Equipment Qualification laboratories. This has for example in Finland led to the fact that the nuclear authority has requirements on the testing organization to be certified to applicable standards (e.g. EN ISO/IEC 17025).

Westinghouse believes that requirements for certified test methods and resources will become more common in the future. Therefore, Westinghouse began in 2012 a journey to certify its Equipment Qualification laboratory in Västerås (Sweden) to comply with requirements in SS-EN ISO/IEC 17025:2005 and the regulations from the Swedish board for accreditation, SWEDAC. This paper describes the general approach and the lessons learned from this process.

1. Introduction

Quality of materials and components used in nuclear power plants must fulfill high standards. Classification of systems and components relative to their importance for nuclear safety is used to define safety classes, i.e. SC1 (the strictest one), SC2, etc. for which detailed requirements on materials, manufacturing etc. are defined. In addition to safety classes there are classifications defining functionality e.g the electric equipment classes 1E, 2E, and 3E, where components classified as 1E have the highest electrical safety function. To assure that a material or a component fulfill the requirements of its intended function a qualification has to be performed. In a given location of a nuclear power plant a material or a component may be exposed to a range of environmental conditions that are typically described by pressure, temperature, humidity, as well as radiation and vibration levels. Qualification implies assuring that the material or component can withstand the environment and maintain its intended function at all plant conditions, and throughout its intended lifetime.

As nuclear power plant gets older, materials and components age and their function may degrade. Ageing management plans are used to monitor, service, and if necessary replace components [1.]. Systematic ageing management requires addressing both physical ageing of systems, structures and components (SSCs) and obsolescence of SSCs, i.e. their becoming out of date in comparison with current knowledge, standards and regulations, and technology. Installation of a replacement component requires a type conformity assessment. In cases of obsolescence an alternative, new component may be needed. Any of these actions requires methods, laboratory equipment and personnel resources that are trained and knowledgeable of the materials and components properties, and how to measure and assess these.

Suitability analysis, [2.], of a component or a material may include assessing:

- functional features and performance
- reliability
- endurance of environmental conditions
- electro technical dimensioning and protection
- operation of the component in case of disturbances or transients
- the applicability of the standards used in design and manufacture of the component
- testability and maintainability
- service life

The number of parameters and the methods used to assess suitability and to qualify a material or a component for a nuclear power plant is generally large. As an example the equipment qualification laboratory at Westinghouse Electric Sweden facilities maintains resources to asses over 40 different test methods.

Along with the growing need to replace ageing materials and components has followed an awareness of the importance to use certified laboratories and resources for qualification. Certification of an equipment qualification laboratory implies except for the general company level ISO-certifications such as ISO-9001 and ISO 14001, specific certification, by an accredited body or inspection organization. In Europe this is controlled by ISO/IEC 17025. This paper presents experience from accreditation according to ISO/IEC 17025.

2. Standards for accreditation

Accreditation according to ISO/IEC 17025 implies that test methods and procedures used in the qualification for the certificate shall be described in such detail that they can be assured to be repeatable. The method of accreditation shall cover the test methods listed in the certificate and be performed according to ISO/IEC 17011.

A number of supporting documents which provide conformity in methods and procedures are provided:

- EA-4/02:1999 – Expression of the Uncertainty of Measurements in Calibration (including supplement 1 to EA-4/02) from EA, the European Accreditation association
- GUM: Guide to the Expression of Uncertainty in Measurement (BIPM)
- ISO 17043

The implementation of the procedures in these documents helps to demonstrate that the customers can confide in the accuracy and repeatability of the measurement results. The challenges are mainly to assess the measurement uncertainty and to find suitable proficiency testing program that will cover the entire test method and thus ensuring that the method maintain high standard according to ISO 17043 and compared to other laboratories. It is possible to discover that some instruments are not sufficiently reliable and therefore have to be excluded from the accreditation or in worst case discarded. To keep track of instrument reliability it is important to only perform calibration in accredited laboratories.

3. Components of an accreditation plan

To succeed with the accreditation it is necessary to establish an accreditation plan. The plan shall at a minimum define the mandatory parts of the accreditation. This is not limited to definition of the intended methods covered by the certificate but must also include organizational issues, company quality system and the involvement of the company quality organization, facility adjustments, as well as audit preparations. Hence it is clear that a larger part of the company must be involved in the accreditation effort than may initially be

envisaged. The accreditation plan serves also as a basis for schedule and resource planning.

In section 4, the general process of becoming an accredited laboratory is presented in a flowchart in **Error! Reference source not found.**.

3.1 Identification of test methods

As mentioned above the complete list of methods and parameters that are measured by equipment qualification laboratories can be long. If the laboratory has no previous experience of accreditation it may be wise to base the accreditation on a prioritized list of methods, naturally those of most importance for the service provided to utilities by the laboratory. One requirement on an accredited laboratory is to keep an updated record of accredited methods. The list of methods developed for the accreditation plan naturally forms the basis for this mandatory record.

Type inspection and type conformity assessment to qualify a material or a component is, where possible, done relative to an applied standard. Hence for each certified method the standard/standards to be fulfilled must be determined and the implications of the demands of the standards on laboratory layout, laboratory equipment, and personnel training etc. determined. A suitable list format can be structured as in Table 1 below.

Aspect #	Aspect	Documentation of aspect	Application of aspect	Applied standards	Range of accreditation
1					
2					
etc.					

Table 1. Suitable format of a list of test methods for the accreditation plan.

It is recommended to carefully develop the list of methods for which the accreditation certificate is intended, specifically the standards to be applied, which is clearly influenced by the needs of the customer basis of the laboratory. The standards referenced must also be assembled, kept updated and be available in the laboratory.

3.2 Requirements on facilities

The methods of the intended certificate typically refer to standards with specific environmental requirements on the workstations in the laboratory. Also some instruments can require certain environmental conditions to ensure the measurement quality and uncertainty. There can be requirements on air quality, humidity and temperature control, static electricity, electromagnetic field disturbances etc.. Generally these are requirements that calls for careful attention in terms of performance of ventilation systems, heating systems, and on building construction including surface materials etc.. Properly mapping the requirements is absolutely necessary before a decision to start the accreditation is made.

A detailed planning of workstations layout, documented with drawings providing details on location of measurement equipment used, lighting, power supplies, ventilation systems items, gas and compressed air supplies, and even furniture, needs to be prepared before submitting the accreditation application.

3.3 Management and support organization

To achieve accreditation the organizational responsibilities must be clearly defined. The key roles that must be available and for which identified resources shall be assigned are:

- The organizational body which makes decisions on policy and allocates resources must be described. This will normally be the board of directors or an equivalent body with financial control.

- The quality organization must be defined and a quality manager assigned.
- The technical management structure has to be specified. This must make clear who is responsible for technical management and the scope of their responsibilities. For example, if different technical areas have different managers, this needs to be specified and their range of responsibilities clearly defined. It is generally expected that in any specific laboratory there will be a distinct laboratory manager, but in larger organizations with several technically distinct laboratories there may be several laboratory managers with specific technical briefs and with no overall defined technical manager.
- There should be provision for deputies for all key posts, especially those of quality manager and laboratory manager, so that their functions can still be discharged in their absence.

The management structure shall be documented and available at the time application for the certificate is submitted. It is therefore wise to early on prepare the organization and the assigned representatives of their roles and expectations since this will be reviewed by the accreditation body.

3.4 Impact on personnel training

Certified methods and procedures used by the accredited laboratory shall be described in such detail that they can be assured to be repeatable. This implies also that personnel performing work in the laboratory must be properly trained in the methods and procedures. A competence record shall be available and maintained that lists each personnel's formal qualifications, previous experience and date of recruitment. These qualifications will be verified by inspection of educational and/or training certificates or equivalent evidence. The verification can be done by the personnel department or the laboratory management, but the record should include a declaration, signed by an appropriate person, of the evidence seen. This could be a personnel manager, the laboratory manager or the quality manager.

To maintain accreditation personnel must be provided continuous training on any changes in methods and procedures. A record of regular re-assessment of the personnel's competence shall thereby be maintained. The accredited laboratory shall also assure that sufficient working time is allocated to tasks such that the certified quality of the services performed can be achieved.

3.5 Equipment register and log

In order to comply with ISO 17025 the accredited laboratory shall maintain records of installation, maintenance, calibration and checks carried out on instruments and other equipment; this should be in the form of an individual equipment log for each major item of equipment, or composite logs for smaller items, such as balances, thermometers, glassware, etc..

3.6 Records of operation

ISO 17025 requires that the accredited laboratory maintains all original observations, raw data, calculations and derived data in the form of work sheets, notebooks, instrument output, etc. These must be dated and should all be traceable to the person who made the observation or measurement and to the equipment used. The laboratory shall also maintain:

- Copies of all reports issued
- Records of all audits and reviews of the quality system, including records of corrective and preventive actions taken.
- Records of all customer complaints and response to non-conforming work, and details of follow-up and any corrective action taken.
- Records of suppliers and sub-contractors.

4. Steps in an accreditation plan

Establishing the accreditation plan is a necessary step in order to be able to plan the work properly before embarking on the journey. There are many steps, such as facility adjustments, workstation interferences, documentation interfaces etc. that should be paid attention to early on in order to progress in an efficient manner. The flowchart in Figure **1** outlines the accreditation steps carried out by Westinghouse Electric Sweden AB and their interdependencies.

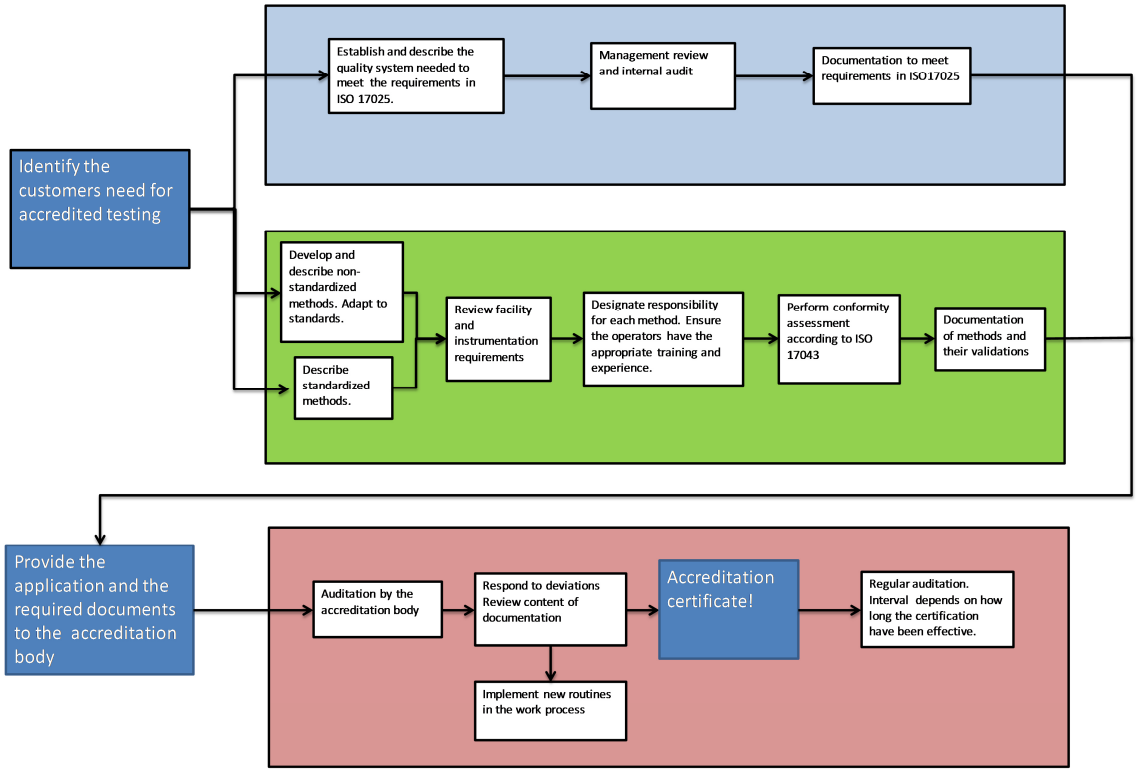

Figure 1, Flowchart of the accreditation process

When accreditation is well incorporated in the laboratory an application for a flexible accreditation can be done. If a flexible accreditation is granted, the laboratory can make

changes to its accreditation, for example include additional activities in the scope, without first receiving approval from the accreditation body. The changes are then followed up during the next audit.

5. Maintaining accreditation

The accreditation plan shall include an analysis of the requirements that exists in order for the laboratory to maintain its certificate. Once the certificate has been obtained regular audit will be needed, the interval depends on how long the certification have been effective. In addition every four year a renewed assessment of the laboratory will be made. The regular audit is performed by the body issuing the certificate and will examine changes in conditions that can have an impact on the laboratory's ability to fulfill requirements. This includes:

- Organizational changes including key management personnel
- Company ownership structure and financial stability
- Relocations of parts of or the whole operations to new facilities
- Status of major equipment

The cost of regular audits should be estimated since it will affect laboratory overhead.

6. Summary of lessons learned

Along the journey to become a certified Equipment Qualification laboratory Westinghouse have gained many new experiences. Every small step in each method has been reviewed and standardized to ensure the quality of the testing, every time. The laboratory has started to participate in proficiency programs to be able to see rating compared to other laboratories. The personnel have gained an increased consciousness about measurement uncertainty, environmental impact on results and the importance of repeatability. All personnel are more aware of organization and policies of the company in general and the laboratory in particular.

7. References

[1.] IAEA Safety Reports Series No. 82, Ageing Management for Nuclear Power Plants: International Generic Ageing Lessons Learned (IGALL), IAEA, Vienna (2015)

[2.] Radiation and Nuclear Safety Authority (STUK). YVL Guide E7. Electrical and I&C equipment of a nuclear facility.