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Qualification Process – Qualify NDE System

The Qualification Process is a concept describing how qualification of inspection systems is to be performed.

The Licensees apply a comprehensive specification of requirements, PBM2, to meet the requirements given in SSMFS 2008:13. PBM2 has an appendix 1 which together with this document, "Qualify NDE System", constitutes the *Qualification Process*.

This is an English version of the Swedish original and shall be revised accordingly.

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Introduction

The Qualification Scheme (PBM2) [2] forms the Licensees' comprehensive specification of requirements for the implementation of qualification of inspection systems in accordance with the requirements given in SSMFS 2008:13 [1], hereinafter called the regulations. In addition to the regulations, PBM2 is based on the ENIQ's European Methodology document [3].

PBM2 contains definitions of central concepts, directions on work allocation and responsibilities between the parties concerned, a description of how to perform the qualification, and guidelines for the assessment of qualifications. It also includes quality assurance requirements on the qualification body and basic requirements on inspection personnel, -procedures and -equipment to be qualified.

In the capacity as specification of requirements, the contents of PBM2 are focused on what is to be performed. How the qualification activities are to be run in order to take place in an efficient manner, while at the same time produce a technically good result is handled in a qualification process.

In the process description in accordance with the PBM2 appendix 1, the main section "Qualify NDE system" is not described. These activities are instead described in this document. SQC is responsible for ensuring that the document reflects the valid requirements for qualification. Amendments shall be communicated via THAG-ÅK and the valid edition shall always be accessible at the SQC website. This document is based on SQC's instructions, and together with PBM2 it makes up the *Qualification Process*.

Qualification can be divided into two types:

Qualification of inspection systems for in-service inspection, (ISI):

- Qualification of an inspection system for in-service inspection includes the parts; equipment, procedure and personnel. These qualifications can be performed separately or together in a so called system qualification.

Qualification of inspection systems for manufacturing and repair:

- Non-destructive testing in connection with repair, manufacturing and installation which cannot be performed by the use of a well-proven technique shall be qualified to the applicable extent.

1 Plan and Prepare Qualification

This section is described in detail in PBM2, appendix 1.

2 Document NDE System

This section is described in detail in PBM2, appendix 1

3 Qualify NDE System

This document describes the Qualification Body's (SQC's) part in the qualification process, *Qualify NDE System*. The process is given in a flowchart in the generally preferred order of the work flow. The following sections correspond to the numbered activities given in Figure 1. An identical flowchart is given in PBM2 appendix 1, the only difference being that *Qualify NDE System* is inactive and other parts activated.

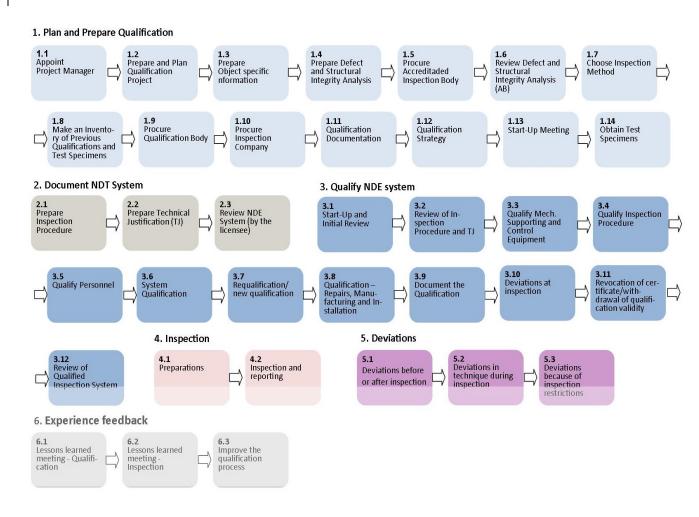


Figure 1 - Flowchart - Qualification process

3.1 Start-Up and Initial Review

3.1.1 Initial review

In this stage, the documents stating the prerequisites of the qualification, the qualification documentation and the Accredited Laboratory's (AL) qualification strategy are reviewed. This review is the basis of the preparation of the qualification procedure. If AL performs the qualification without a direct assignment from the licensee, there is generally only a strategy to be reviewed. This document subsequently replaces the qualification documentation from the licensee and must therefore include the prerequisites of the qualification.

3.1.2 Start-up meeting

See PBM2 appendix 1 section 1.13.

3.1.3 Qualification Procedure

The qualification procedure is the summary document which in short describes all the parts included in a separate qualification, and which states the references to the detailed supporting documents issued by the assigner and filed with SQC. The qualification procedure must at the latest be produced when the review phase begins, in order to provide the opportunity for the licensee and AL to comment on the procedure.

The qualification procedure also describes the requirements for the included qualification stages, procedure-, personnel-, equipment qualification, and where appropriate, system qualification.

3.2 Review of Inspection Procedure and Technical Justification (TJ)

3.2.1 Review of Technical Justification

A TJ, designed in accordance with ENIQ RP 2 [4] interpreted in Enhagen 1[5], is the uniting document in which all theoretical demonstration and reporting of various analyses, that support the chosen inspection method and its application in the inspection procedure, are accounted for. There are several purposes and fields of application of a TJ, such as:

- Present evidence by physical reasoning, mathematical modelling, practical experiments and other sources in order to support the scope of the procedure and justify the chosen inspection method.
- Provide a technical basis in order to identify and justify the inspection system's essential parameters and its acceptable tolerances.
- Justify and present that the chosen equipment can meet the specification of the requirements.

- Justify and present that the test specimens that are produced provide a reasonable simulation of the objects to be inspected. It must also show that the defects in the test specimens are representative in order to enable an assessment of the inspection systems capability.
- Present other facts that prove the inspection system's capability when practical demonstrations are limited.
- Justify that the inspection system gives a good enough result also in relation to the possible defect types that are not included in the test specimen.
- Justify an extension or a change being made to a previously performed qualification.

Taking the above into account, the TJ is reviewed by SQC with respect to the following specific areas/parameters:

- Prerequisites and requirements on the inspection system
- Description of the inspection system
- Influential and important parameters identified, classified and justified in accordance with the intentions given in ENIQ RP 2 [4]
- Physical reasoning
- MTO parameters
- Modelling
- Experimental analyses
- Parametric studies
- Equipment
- Analysis of inspection data
- Measurement uncertainty analysis
- Reporting
- Summary of presented evidence
- Test specimen for practical trials
- Conclusion and recommendations

A TJ shall also be produced for equipment to be qualified independently in relation to a procedure. After completing the review, SQC can make a final decision on the suitability of the suggested test specimens in relation to practical demonstrations.

3.2.2 Review of Inspection Procedure

The SQC review of the inspection procedure includes the structure as well as the technical content. When designing the procedure, ENIQ RP 12 [9] can serve as a guideline.

Before any final assessment on the inspection procedure is made by SQC, it must be reviewed and approved by the licensee with respect to ensuring that it is in agreement with the prerequisites, as well as being internally reviewed and approved within AL.

Inspection procedures must be reviewed and assessed by SQC before the practical demonstration of the procedure. The final review is performed in connection with the practical demonstration of the procedure.

The review of the inspection procedure shall ensure that the following information and elements are included and correctly described:

- What to be implemented.
- How this shall be implemented.
- The intervals within which the result is valid.
- That the inspection volume/area is described.
- That the procedure contains requirements on the personnel's competence for the different working operations during the inspection.
- That the procedure is unambiguous and systematically written and contains all the necessary information required in order to document the inspection correctly. The description of the inspection process in the procedure shall not allow for free interpretation depending on who performs the inspection. Irrespective of whom that follows the procedure, they shall arrive at the same conclusion.
- That the procedure contains information about what kind of inspection object, geometries, material compounds, material and surface structures the procedure is intended for.
- That the procedure contains information about detection targets, defect and damage types and the location of defects, orientation, tilt and skew that the inspection is intended for.
- That the procedure contains information about the tolerances for the result of the inspection. The information refers to positioning and sizing of defects as well as sizing of ligaments.
- That the procedure contains a description of all the components included in the inspection system, including control system and manipulator, cables, inspection equipment, test specimens etc.
- That the procedure contains clear and plain instructions on assembly and check of
 equipment, and that required verifications and system checks are performed as to obtain a
 quality assured inspection.

- That the performance of calibration is sufficiently well described and that the procedure states the calibration specimen and reference reflector to be used. The acceptance requirements for the parameters included in the calibration shall be stated, and there shall be guidelines for measures to be taken if these parameters cannot be met.
- That the approach for data collection is adequately described. That the procedure clearly states the instrument settings, coordinate system, inspection area, reference points and how these are produced.
- That the procedure states which scan pattern, track division, scan speed, probe position and probe assembly to be used.
- That the procedure clearly describes the criteria for check of inspection data quality and checking with respect to the coverage of the inspection volume.
- That the procedure applied for analysing data is sufficiently well described. That the procedure states the equipment settings and the reporting level to be used. It shall also be stated and described how distinctive indication patterns are to be analysed and characterized correctly. It shall also be described which criterions for detection, characterisation, and sizing that are valid.
- It shall be clearly stated how the following parameters are decided
 - Longitudinal or transversal
 - Embedded or surface breaking
 - Volumetric or planar
 - Skew and tilt
- That it with respect to sizing of defects is clearly stated which signal that applies as the basis of the assessment.
- The procedure shall in a clear manner describe how decision-making is to be done, the governing criteria and how the reporting of the inspection is to be performed.

3.3 Qualify Mechanical Supporting and Control Equipment

By automated and semi-automated mechanical supporting and system control equipment are meant such equipment whose task is to carry and support the inspection system's scanning equipment and to control the same within the inspection area in accordance with the predetermined inspection scope .

Qualification of supporting equipment is generally performed by a technical justification of the equipment's function and performance combined with a practical demonstration. The justification of the equipment can be included as a part of the TJ of the inspection system, or consist of a specific TJ only for that particular equipment.

The qualification basis for manipulators/tools for the general procedures AVT01, VT01 and MPT01 shall contain a technical data sheet with object specific parameters and inspection parameters that are inside the frame of the general procedure.

The practical demonstration of equipment is generally performed together with a Factory Acceptance Test (FAT).

A programme for qualification of equipment/FAT is generally produced by AL and reviewed and approved by the licensee and SQC.

The validity of qualified supporting equipment can also be extended to include equivalent objects only supported by technical justification.

3.3.1 Performance of Practical Demonstration - Equipment

SQC shall when supervising a demonstration ensure that the stated requirements/tolerances are met.

It is of great importance that tolerances are stated for all the applications that the equipment is intended for.

Positioning accuracy is the capability of the equipment to move to the coordinates given by the control unit, and that this position corresponds with the actual value, taking into consideration the stated tolerances.

Positioning accuracy is generally divided into two parts, global and local accuracy:

- Global: Corresponds with the positioning accuracy of the system/equipment in a system of co-ordinates, which can be interpreted as the accuracy of the positioning in relation to the zero point.
- Local: The accuracy of the system/equipment's capability to measure a given distance, for example the length of a defect.

By repeatability is meant the performance with respect to positioning, global and/or local is not altered after dismantling and new installation of the equipment, neither at repeated scanning of the stated areas.

Regarding semi-automated equipment without numerical position indication, the requirements refer to the ability to position itself, globally, locally and repeatable in relation to given reference points.

The movements of the equipment shall with respect to flexibility and velocity be adapted to the inspection system.

In addition to the elements checked in relation to tolerances and specific requirements, an assessment shall be performed of the equipment's general suitability for its task in question. As an example, the possibility to identify reference points for positioning and scanning via visual overview of the equipment and the inspection object, can be mentioned. If visual overview is not possible, it shall be possible by some other method to ensure the equipment's positions in relation to reference points and the scanning area.

3.4 Qualify Inspection Procedure

Procedure qualification refers to that the inspection procedure, including a detailed description of the inspection technique and instructions on how to use the technique, is qualified by the use of technical justification and by that it is generally demonstrated in relation to relevant test specimen. This demonstration shall include all the stages in the procedure; calibration, data collection, analysis of data, and reporting.

A qualified procedure can by technical justification be extended as to be applied for another inspection. However, it is the responsibility of the licensee to put forward the arguments that prove such a desired extension. The requirements is assessed from case to case.

In order to implement qualification, the following prerequisites must be met:

- 1. The laboratory must have valid accreditation in the position as third party for in-service inspection in nuclear facilities. The qualification certificate cannot be issued before the accreditation is entirely completed.
- 2. The personnel who are to perform the practical demonstration of the procedure must be certified at level 2 as a minimum, in accordance with SS-EN ISO 9712:2012 or corresponding qualification system.
- 3. All personnel participating in the qualification must adhere to the quality system of the AL in charge.
- 4. Personnel performing the practical demonstration should be individuals who normally perform inspection at the client's.
- 5. The supporting and control equipment described in the procedure must be used for scanning the test specimens used. Should the supporting equipment described in the procedure not be suitable to use at the procedure qualification, such as due to its size, contamination or the like, replacement equipment may be used. A comparison must be performed between the complete supporting and control equipment and the replacement equipment by the customer/AL, demonstrating that the same performance can be obtained with either equipment.

3.4.1 Scope

The scope of a practical demonstration of a procedure and the number of defects to be included is determined by the following factors:

- The analysis of the important variables identified in the TJ.
- The scope taking into account the included stages: detection, characterization, length sizing, height sizing and ligament sizing.
- The geometry of the object.
- The expected orientation, longitudinal and transverse defects.
- Expected damage-/defect types.
- Detection target and anticipated variation of defect size.
- Inspection volume and anticipated location of defects in the same.
- Occurrence of gradient or rotated defects (Tilt and skew).
- The extent of "worst case" defects in the used test specimens.

The total amount of defect population shall be rated as to include all the factors occurring for the object.

The number of defects shall generally be at least 10 in order to result in a reasonable statistical basis.

3.4.2 Performance of practical demonstration - Procedure

The demonstration of the procedure stages calibration, data collection and analysis of data is generally performed as a step by step supervision by SQC at acquisition and analysis of data on the open test specimen. The demonstration shall be considered a practical extension of the review performed in accordance with section 3.2.2 and shall ensure that the procedure is unambiguous and systematically designed and that it includes all the necessary information required to perform an inspection by the use of the procedure in question.

3.4.3 Qualification result

The qualification result is a summary assessment of the qualification prerequisites, the technical justification referred to, and the result of the practical demonstration.

The qualification shall show that inspection in accordance with the stated inspection procedure provides such a result that it can be expected that the requirements imposed are met at inspection performed under actual circumstances.

Regarding analysis/assessment of the qualification result, the following apply:

- The analysis shall include the categories detection, characterization, sizing and where applicable ligament sizing, described in the inspection procedure.
- The analysis is to be performed in relation to the requirements specified in the qualification procedure.

3.4.4 Detection

At procedure qualifications, all defects larger than or of the same size as the detection target shall yield such signals that they can be correctly detected and characterized.

For approved result with respect to detection, the defects must be placed in relation to the actual defect in accordance with the following (the requirement on location of reported defect only serves as making sure that SQC shall be able to regard a defect as detected or not).

- At least 50 % of a longitudinal defect in the X-direction and a transverse defect in the Y-direction shall be placed within the set value of \pm 10 mm in relation to the actual defect location.
- A longitudinal defect shall be placed within ± 10 mm in the Y-direction and a transverse defect shall be placed within ± 10 mm in the X-direction in relation to the actual defect location in order to be considered as detected.

As an aid in the analysis, a rectangle can be drawn with the above given values around the actual defect, as per the below example.

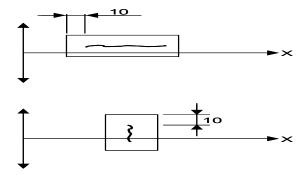


Figure 1 -: Analysis rectangle

The requirement on the number of over-reported defects (so called "False call") shall be taken into account. SQC assigns a value of 20 % of the number of relevant defects included in the analysis, which is to be considered a maximum value for what can be accepted.

3.4.5 Characterization

In order to obtain an approved result with respect to characterization, all defects must be characterized as surface breaking or embedded and where applicable, plane or volumetric.

For surface methods such as MT, PT, ET, VT and A-VT this entails that only a detected defect is reported as surface breaking.

Characterization of surface breaking respectively embedded defects may lead to the requirement/need to resolve a remaining ligament. The ligament is thus the measure of the acceptable inaccuracy that the inspection system applies to distinguish between embedded defects and surface breaking defects. This entails that if the ligament requirement is set at 5 mm, the inspection system must subsequently characterize all defects with a ligament of \geq 5 mm as embedded. Embedded defect with a ligament of \leq 5 mm may thus be characterized as embedded *or* surface breaking. Defects with a ligament of 0 mm must always be characterized as surface breaking.

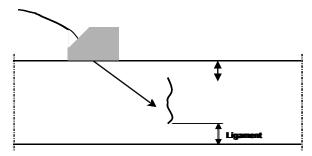


Figure 2 – Ligament.

This uncertainty concerning defects with a ligament of <5 mm is not necessary to add to the measurement uncertainty for height sizing of surface breaking defects since this uncertainty is accounted for separately. If this uncertainty is added, it would result in an incorrect tolerance (too great) of the height sizing of surface breaking defects, since the entire uncertainty contribution is added to the defect end which is entirely separated from the inner surface.

It is sometimes included in the qualification that the inspection system shall measure the remaining ligaments with a certain tolerance, i.e. positioning of a defect end tip. If this is included, the limit of the minimum ligament that the inspection system shall be able to measure must be given. At the practical demonstrations for procedures, the results shall be analysed in relation to a tolerance of 70 % confidence interval and all defects shall be measured within the tolerance interval.

3.4.6 Sizing

The ability to size defects is assessed by that the operator during the demonstration strictly adheres to the procedure and measured values are reported within the tolerances of all the defects included in the qualification.

The requirement on tolerances is generally imposed by the customer and it shall be based on the measurement uncertainty analysis stated and justified by AL.

The following assessment is made by SQC:

- Analyse the difference between the dimension measured by the inspection laboratory and the dimension given in the defect specification.
- It shall be clearly indicated in the inspection procedure the signal which is considered relevant for the defect's end positions (length sizing) and depth position (-s) (height sizing) and that these signals are applied in the analysis.
- In order to obtain approved results with respect to the sizing, all the included defects must be reported within the tolerances.
- The difference between the reported values of height/length and As-built is used to calculate a 70% confidence interval, which also must be within the tolerances in question.

Length sizing and height sizing are assessed separately.

3.4.7 Height sizing

The height of the defects is generally the most important parameter from a damage tolerance perspective. This means that also defects with a length of less than the detection target but which have characteristics of the defect types looked for and with signal levels greater or equal to the reporting level shall still be included in the continuous analysis.

The technique applied for height sizing shall be of the type that measurement takes place on diffracted signals from the fracture tip/tips, alternatively clearly indicates that the signal derives from the fracture tip/tips.

Tolerances of sizing of ligaments shall also be taken into account. The requirements for these shall be understood from the qualification procedure.

3.5 Qualify Personnel

Personnel qualification means that one individual performs an inspection of a test specimen by the use of a qualified inspection procedure. The qualification is generally performed by an assessment of the qualification prerequisites and a practical demonstration. Alternatively, qualification of

inspection personnel, fully or partly, may be performed by a technical justification, i.e. an extension from a previously performed qualification.

The qualification can be divided into the following sub-categories;

- Data collection
- Detection
- Characterization
- Sizing
- Where applicable, ligament sizing.

The qualification may include separate elements or combinations of the same.

3.5.1 Qualification prerequisites

In order to perform a qualification, the following prerequisites must first be verified:

- That the supporting and control system to be used is the same equipment described in the procedure or the same equipment used at the procedure qualification. If the supporting equipment described in the procedure is not suitable to use for personnel qualification, due to its size, contamination etc., a replacement equipment with equivalent performance may be used.
- That suitable test specimens are chosen in accordance with the defect specification in the qualification basis. The defect specification shall contain information of defect types, defect positions, defect orientation, defect tilt, morphologies as well as defect sizes and number of defects.

Personnel can be qualified for one or several categories (this does not apply to methods for which "online" analysis is to be performed). Personnel cannot be qualified for part of a category except for sizing for which length and height sizing may be separated.

Personnel who independently intend to qualify for the categories data collection, detection, characterization and/or sizing must have the following authorization:

- Certified at minimum level 2, in accordance with SS-EN ISO 9712:2012 [7] or corresponding qualification system.
- All personnel who participate in the qualification must adhere to the quality system of the AL in charge.
- Personnel who perform the practical demonstration should be individuals who generally perform inspection at the client.

It is the responsibility of the accredited laboratory to give an account of required training and practice in addition to the above-mentioned certification level.

3.5.2 Scope

Objects and areas for analysis shall contain an adequate selection of given defect types and sizes which makes it possible to make an assessment of the individual's ability to detect, characterize and size the included defects.

The scope of a practical demonstration of personnel in relation to a procedure and the number of defects to be included in such a demonstration is determined by factors identical to the ones taken into account at a procedure demonstration, see paragraph 3.4.1.

Test sets included in the demonstration shall consider the need for defect free areas. This is to test the ability to discriminate. Test sets can be divided into assessment units where both areas with defects and areas without are present. The relation between defect free areas and defect areas shall normally have a total length ratio of 2:1.

Qualification of personnel for the categories detection, characterization and sizing shall always use blind test blocks. Open test blocks can be used if personnel are only qualified for data collection. Open and blind test blocks with their defect simulations shall be designed so that they give equal conditions for qualification and comply with the defect specification in the qualification basis.

MTO parameters identified in the qualification supporting documents, which are of importance to the inspection implementation, shall be taken into account at personnel qualification.

3.5.3 Performance of practical demonstration – Personnel

Data collection:

Demonstration of the personnel's ability to, under the supervision of SQC, perform data collection in accordance with the general requirements given herein fully or partly in accordance with the following:

- By making a comparison between calibrations, scanning and acquired data from procedure and personnel qualification.
- The operator shall demonstrate that they can follow relevant parts of the procedure. The operator shall also produce acceptable calibrations/computer files and assess their quality.

Verification of acquired data can be performed by using it during qualification of a procedure or analyst.

Data analysis:

Demonstration of the operator's ability to in accordance with the qualified procedure with blind defects perform the categories detection, characterization, sizing, and where applicable ligament sizing. Reporting of results is also included in the demonstration. The demonstration may contain elements of step-by-step supervision by SQC.

3.5.4 Qualification results

The following apply with respect to analysis/assessment of qualification results:

- The analysis shall include the categories data collection, detection, characterization and sizing described in the inspection procedure and for which the individual is to be qualified.
- The analysis is to be performed in relation to the requirements specified in the qualification procedure.

3.5.5 Detection

In order to obtain approved results with respect to detection, the defects must be placed in relation to the actual defect in accordance with the following (the requirement on location of the reported defect only serves as a way of enabling SQC to consider a defect as detected or not).

The requirements are identical to the requirements applied for the qualification of procedure, section 3.4.4, with the following exceptions:

- When 10 defects or more are used, at least 80 % of the total number of defects must be detected.
- When less than 10 defects are used, 100 % of the total number of defects must be detected.

It is not acceptable that defects \geq acceptable crack depth (A_{acc}) are not detected.

The requirement on the number of overcalls shall be considered. SQC employs a value of 20% of the total number relevant defects when 10 or more defects are included in the examination. This shall be considered the maximum value for what can be accepted.

When less than 10 defects are included the following applies:

Number of defects	Allowed over reporting
5	0
6	0
7	1
8	1
9	2

Tabell 3.5.5-1 Allowed overcalls.

3.5.6 Characterization

In order to obtain approved results with respect to characterization, it is required that at least 80 % of the detected defects are characterized correctly. When less than 10 defects are used or detected, 100 % of the defects must be correctly characterized. In other respects, the same requirements apply as given for qualification of procedure, section 3.4.5.

3.5.7 Sizing

In order to obtain approved results with respect to sizing of detected defects, the criteria for confidence interval must be met.

Personnel shall be considered qualified for sizing if performed demonstrations prove that data accounted for are within the given tolerances. The requirement on stated tolerances is the same as applied for qualification of inspection procedure, see sections 3.4.6 and 3.4.7, with the difference that all individual defects must not be sized within given tolerances, provided that the confidence interval is maintained.

3.5.8 Extension of a qualification's validity

An operator's qualification may without renewed demonstration be extended to also apply to inspection in accordance with other procedures by the use of a technical justification. These procedures must be based on equivalent equipment, calibration and analysis instructions and be considered imposing the same requirements on the operator's ability with respect to data collection, detection, characterization and sizing.

Such an extension is given limited validity corresponding with the validity period of the qualification referred to.

3.5.9 Requalification

The validity of qualification certificates for personnel are 5 years from the date when the qualification was performed with an approved result. Thereafter a requalification shall be performed if a continued validity of the certificate is desired.

There are two methods available for requalification, alternatively a combination of both:

- Technical justification:

An extension of a certificate by a technical justification may be performed provided that there is an equivalent qualification that can be referred to. This extension is limited in time. The governing factor is the qualification referred to. The extension thus corresponds with the validity period of the qualification referred to.

- Practical demonstration:

Requalification may be performed in the same way as the original practical demonstration.

Requalification of personnel for data collection may also be performed by technical justification, TJ, based on inspections performed in the current 5-year period. One condition is, however, that SQC is provided with signed inspection protocols compiled and verified by the responsible level 3. Calibration shall as a minimum consist of a basic calibration. Such an extension would in this case be valid for 5 years as from the latest inspection date referred to.

3.6 System Qualification

Qualification of inspection systems involves qualifying equipment, procedure and personnel as one unity in relation to blind test specimens. No separate part in this unity can be replaced, which means that neither equipment, operator or procedure can be replaced or altered by no other means than requiring a renewed system qualification.

The qualification of inspection systems is generally performed as an assessment of qualification documentation and a practical demonstration.

3.6.1 Qualification Prerequisites

In order to perform a qualification, applicable conditions in accordance with section 3.5.1 must be complied with. In addition to these requirements, the following apply:

- The supporting and control equipment described in the procedure shall be used for scanning of the test specimen.
- The need for simulation of physical obstacles and other MTO parameters shall be taken into account.
- Technical supporting documents shall be applied to such an extent and detail that they make up a sufficient basis for the intended qualification.
- At least one personnel in each inspection team must have a valid certificate on minimum level 2 in accordance with SS-EN ISO 9712:2012 or corresponding qualification system.
- It is the responsibility of the accredited laboratory to account for required training in addition to the above-mentioned certification level.

Systems can be qualified for one or several categories, such as detection, characterization, or sizing. At characterization, defects shall be characterized as surface breaking or embedded and where appropriate also be characterized as plane or volumetric. Sizing can be performed as length and/or height sizing.

3.6.2 Review of Technical Justification

Review of technical justification, TJ, is performed in accordance with section 3.2.1.

3.6.3 Review of Inspection Procedure

Review of inspection procedure is performed in accordance with section 3.2.2.

3.6.4 Scope

The scope of a practical demonstration and the number and type of defects, and other defect parameters to be included in such a demonstration are determined by the factors in accordance with section 3.4.1.

3.6.5 Perform a practical demonstration – Inspection System

Performed in accordance with the procedure as a demonstration supervised by SQC, of the elements assembly and positioning of supporting equipment, calibration, data collection, data analysis and reporting. The demonstration is generally performed with a fully connected system in an object-similar mock-up in which the blind test specimen is installed. All personnel involved shall participate and perform the tasks they are to be qualified for. The demonstration is to be considered a practical extension of the review performed of Procedure and TJ.

3.6.6 Qualification results

The qualification result is an overall assessment of the qualification prerequisites, the technical justification referred to, and the result from the practical demonstration.

The qualification shall prove that inspection in accordance with the stated inspection procedure leads to such results that it can be expected that the requirements imposed are met during an inspection performed under actual circumstances. Regarding analysis/assessment of the technical justification referred to, the following apply:

- The analysis shall include the categories detection, characterization and sizing, described in the inspection procedure.
- The analysis shall be performed in relation to the requirements specified in the qualification procedure.

3.6.7 Detection

Assessment of the results for detection is based on the same criteria and requirements as applied for personnel qualification, section 3.5.5.

3.6.8 Characterization

Assessment of result for characterization is based on the same criteria and requirements as applied for personnel qualification, section 3.5.6.

3.6.9 Sizing

Assessment of results for sizing is based on the same criteria and requirements as applied for personnel qualification, section 3.5.7.

3.6.10 Mechanical supporting and control equipment

Assessment of the equipment is based on the same criteria and requirements as applied for equipment qualification, section 3.3.1.

3.7 Re-qualification or new qualification

In conjunction with qualification there are two courses of action in the event of a failed result in a qualification:

Re-qualification

Is performed after a failed demonstration or a minor change to a procedure or inspection equipment. When performing re-qualification based on minor changes to procedure/equipment, these changes can only be such that the input data/influential parameters are unchanged, or to the major extent unchanged.

New qualification

Is performed in those cases where the changes of input data/influential parameters are so extensive that the previous qualification cannot be accounted for. For example new inspection conditions, changed inspection technique and changed evaluation criterions.

3.7.1 Procedure:

Re-qualification can become necessary due to a failed demonstration or due to that changes in the inspection procedure have been made.

In case of re-qualification due to a failed procedure demonstration the AL shall show that appropriate measures have been taken in to rectify the shortcomings that lead to the failure. These measures shall at least include a complementary or further developed technique that is technically justified and based on practical investigations.

In case of re-qualification due to minor changes in the inspection procedure these can only be of such nature that the input data/influential parameters are unchanged or for the most part unchanged. When performing re-qualification due to minor changes or failed result the applicable parts of the original qualification procedure are to be followed.

The extent of a re-qualification are decided from case to case depending on what part of the qualification that failed.

In those cases where the changes of input data and/or the influential parameters are so extensive that a previous qualification cannot be accounted for, a new qualification shall be performed. This includes, for example new inspection conditions, changed inspection technique and changed evaluation criterions. A new qualification can the also include other parts of the qualified inspection system. The qualification procedure shall then be revised in order to reflect the new conditions.

3.7.2 Personnel:

Re-qualification of personnel can become necessary due to a failed demonstration.

In case of re-qualification due to a failed result the AL shall show that appropriate measures have been taken in to rectify the shortcomings that lead to the failure. These measures should at least contain a documented training with the actual inspection procedure. The original qualification procedure shall be followed in applicable parts.

Re-qualification of personnel that cannot meet the requirements for one or more parts, can only be performed on one occasion within a period of one year.

A new or complementary qualification for personnel can become necessary if changes in qualification conditions and/or major changes in the inspection procedure have been made. The qualification procedure will be revised to reflect the new conditions.

3.7.3 Equipment:

Re-qualification can become necessary due to a failed demonstration. In case of re-qualification the AL shall show that appropriate measures have been taken to rectify the shortcomings that lead to the failure.

The extent of a re-qualification due to a failed demonstration is decided from case to case depending on what part of the equipment that is failed.

If a qualified equipment is modified in way that affects the equipment's essential parameters it can lead to that the qualified tolerances no longer can be met. In such a case a new or complementary demonstration shall be performed. In case of modification of an equipment the instructions/manuals shall also be revised in accordance with the changes. The qualification procedure is then revised to reflect the changes.

3.7.4 System qualification:

In case of re-qualification due to a failed demonstration the AL shall show that appropriate measures have been taken in to rectify the shortcomings that lead to the failure. The cause of the failure and actions to correct it shall be investigated and documented.

Re-qualification of a system qualification that does not meet the demands for one or several parts can only be performed once in a period of one year.

A new or complimentary qualification shall be performed when parts of the inspection system has been changed such as procedure, personnel or equipment has been changed or altered so that it can no longer be viewed as a qualified system.

In the event of new qualification due to changes in the qualification conditions the qualification procedure is revised in applicable parts and considered as a new qualification.

3.8 Qualification – Repairs, Manufacturing and Installation

Non-destructive testing in connection with repairs, manufacturing and installation which cannot be performed by the use of well-proven techniques shall be qualified to the applicable extent. The conditions for such an assessment are described in PBM2.

3.8.1 Qualification Scope

The licensee shall (together with AL) evaluate and produce supporting documents for the qualification scope and documentation considered applicable for the qualification. SQC reviews the documents and decides on the proposition. A review with respect to the compliance with the requirements stated in SSMFS 2008:13 is generally performed by an accredited inspection body (AB)

Qualification is performed based on the scope and documentation agreed in accordance with section 3.4.1, 3.5.1 or 3.6.1 in this document.

3.8.2 Assessment of Qualification

The combined results of reviews and assessments made of performed parts of the qualification form the basis of the assessment concerning whether or not the qualification meets the set requirements.

3.9 Document the Qualification

3.9.1 Qualification Certificates and Qualification Report

A Qualification Report (KRAP) is issued by SQC after the implementation, and at approved qualification, a certificate is issued for the applicable parts of inspection system; procedure, personnel and equipment.

Qualification documents issued are distributed to the licensee and AL.

3.9.2 Filing of Certificates

SQC administrates and files and all certificates.

3.9.3 Deviations during qualification

Two types of deviations can occur during the performance of qualification.

- At times when it is necessary to deviate from demands a planned non conformity against the management system.
- At times when it afterwards is discovered that a deviation from the management system is made.

If a deviation is issued after an approved qualification (certificate issued) shall this be handled in accordance with 3.11. The customer shall be informed about deviations.

3.9.4 Reporting

When reporting a failed qualification, the information must not contain any suggestions on corrective measures which could lead to SQC's independent role being questioned at a possible requalification.

3.9.5 Final documentation

- SQC administers and files the complete qualification documentation in a qualification file. Depending on the scope of the qualification, the file shall at least include applicable documents such as:
- Qualification documentation (or equivalent)
- Qualification strategy
- Qualification procedure
- Time schedule
- Technical justification
- Inspection procedure
- Technical justification/defect specification for test specimens
- Test specimen drawings including associated documentation
- Fingerprint report and final assessment of test specimens
- FAT/qualification programme for equipment
- Data media from practical demonstrations
- Account of and results from practical demonstrations
- Qualification report
- Certificates
- Documentation and results from "Review of qualified inspection system" (if performed).
- Deviations

3.10 Deviations during inspection

When the AL and/or the licensee discovers that a qualified inspection system cannot be followed during an inspection a deviation shall be issued. In the case of a technical issue not an issue of extent, it shall be handled by SQC.

A deviation report is issued by the AL supported by a technical justification.

SQC reviews the supporting documentation and evaluates the consequence of the change. The SQC administrator will inform on the SQC decision via letter to AL/Licensee. The decision shall contain any demands for corrective actions so that the inspection system can be used in the future without deviations.

If the corrective actions are not accepted or implemented the qualified inspection system is considered no longer approved and will be handled in accordance with Ch. 3.11.

The corrective actions shall be performed at an agreed time. This is in order for an current procedure to be available at the next inspection.

In the event of deviations using general and other mutual procedures SQC shall make an assessment if the deviation has an effect on other licensees. If that is the case other licensees and AL that uses the procedure and other mutual procedures about the deviation and its effect.

3.11 Revocation of certificates / Withdrawal of qualification validity.

If information emerges that makes a qualification questionable it is SQC:s task to investigate and decide on a withdrawal of a qualifications validity. Information can become available to SQC via deviations or similar notification.

Decision about the revocation of a qualification certificate shall be approved by the qualification manager. The decision shall always be preceded by a thorough analysis that clarifies the cause for the revocation and its consequences. Cause and consequences shall always be clarified to AL and the licensee.

Decisions about revocation or changes of the status, temporary or permanent shall be communicated to the affected AL, Licensees and SSM (Swedish Radiation Safety Authority). The licensee informs the AK (accredited inspection body). The decision shall have a copy of the current certificate attached to it.

Withdrawal av certificates can be made for the following reasons e.g.:

- Circumstances where the conditions at the inspection of the actual object does not complies with the conditions that were in effect at the qualification.
- If it shows that the technique cannot manage to detect or correctly asses the defect types that the procedure is qualified for.

- In case of changes to a qualified inspection system that the accepted tolerances from qualification cannot be withheld.
- If it shows that qualified personnel have performed an inspection not consistent with a qualified procedure, and the deviation has not been accepted by SQC.
- Om det framkommer att kvalificerad personal inte provat i enlighet med en kvalificerad procedur, samt att avvikelsen inte accepterats av SQC.

Withdrawal shall always be in writing and be determined by the qualification manager in consultation the responsible administrator. The withdrawal of a qualification certificate can be either temporary or permanent.

In case of a permanent withdrawal it is due to that the investigation has shown such deficiencies that the qualification is considered not valid for the actual inspection object. The qualification report with its certificates are given the status withdrawn.

In case of a temporary withdrawal the procedure, personnel or equipment certificate will be given the status withdrawn during the period of the investigation of the qualifications validity is ongoing. If the investigation shows that the procedure/technique/person is valid for the actual inspection the validity of the certificate is reinstated by issuing a new version.

The certificate validity as withdrawn or reinstated shall be communicated to affected licensee/licensees, AL and the Swedish radiation safety authority (SSM). The licensee informs the AK (accredited inspection body). The decision shall have a copy of the current certificate attached to it.

3.11.1 General procedures with supplementary letter

If in between revisions of a general procedure, circumstances arise that causes a clarification and/or a corrective action that can influence the result of an inspection, this new information shall be communicated via a SQC letter. The procedure is then valid together with this letter until a new revision of the procedure is issued. The corrective action shall be included in the new revision. The SQC letter shall be distributed to all licensees. The licensees are responsible for the distribution to the affected AL.

3.12 Review of Qualified Inspection System

In accordance with SSM2015-5453 [8], an assessment shall be made concerning that conditions of a qualified inspection systems being maintained over time if the testing laboratory holds a national accreditation in accordance with EN ISO/IEC 17025:2018 [8].

This requirement is not applied if the testing laboratory is accredited by Swedac in accordance with chapter 2 section 7 in SSMFS 2008:13 [1] and the validity of the inspection system is thus stated on the qualification certificate.

Regarding foreign AL with a national accreditation in accordance with SS-EN ISO/IEC 17025:2018 [8], the following apply:

- As a substitution for the requirement on Swedac accreditation, a qualification body (QB) shall perform an assessment of the conditions of the qualified inspection system being maintained over time.
- The assessments must not be older than 5 years at the time of the inspection implementation. This is counted as from the qualification date of the procedure or the date when major revisions of the inspection system had been performed. What to be regarded as a major revision is determined by QB.
- QB issues an assessment report after the assessment is completed.
- In the event the assessment has been replaced by a "major revision", it is stated in QB's qualification report

4 Improve the Qualification Process

This section is described in detail in PBM2, appendix 1.

5 References

- [1] The Swedish Radiation Safety Authority's Regulations on Mechanical Components in Nuclear Power Plants, SSMFS 2008:13, ISSN: 2000-0987 (in Swedish)
- [2] PBM2 Qualification Scheme for Qualification of OFP Systems in Sweden
- [3] European Methodology for Qualification of Non-Destructive Testing, Fourth issue. 2019, ENIQ Report nr 31, Technical Area 8 European Network for Inspection & Qualification
- [4] ENIQ Recommended Practice 2 Recommended Contents for Technical Justifications, Issue, 1998, ENIQ report 4, EUR18099.
- [5] Example of a Technical Justification "Enhagen 1", Report 016/06, Issue C
- [6] Non-Destructive Testing Qualification and Certification of OFP Personnel SS-EN ISO 9712:2012
- [7] Decision on Licence Conditions for Swedish Licensees with Requirements on Measures at the Use of Accredited Inspection Laboratories for In-Service Inspection SSM2015-5453 (in Swedish)
- [8] General Requirements for the Competence of Testing and Calibration Laboratories ISO/IEC 17025:2018
- [9] ENIQ Recommended Practice 12 -Strategy and Recommended Contents for Inspection Procedures Issue 1 2019 ENIQ Report No. 63 Technical Area 8, European Network for Inspection & Qualification