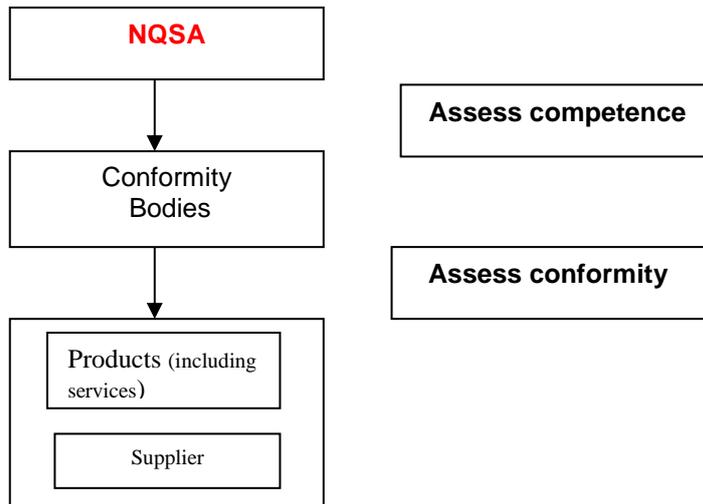


ABSTRACT

This document specifies the general requirements, based on NF EN ISO/CEI 17011, and the system allowing NQSA to qualify a Certification Body (CB) in order to be authorized to deliver NSQ-100 certificate. It also defined the procedures set in place by NQSA for granting, monitoring, extending, suspending and withdrawal the CB qualification.



SUMMARY

- Qualification process for CB
- Responsibilities of NQSA and CB
- Requirements for CB and Candidates for NSQ-100 certification

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1 QUALIFICATION PROCESS FOR CERTIFICATION BODIES:

1.1 Requirements for Certification Bodies:

Each CERTIFICATION BODY (CB) has to make a written application to NQSA. The “application form for CERTIFICATION BODY” and all documents associated are joined to this demand. Uncompleted application won't be taken into account.

A NQSA board decision (only industrial members) is needed to begin the qualification process of the CB.

1.1.1 Criteria to approve the application of the CERTIFICATION BODY

To get an approval from the NQSA board (only industrial members), these criteria must be respected by the CERTIFICATION BODY :

- A permanent structure (legal entity),
- A valid accreditation ISO 17021 within its scope ISO 9001 and AS/EN9100 or TS 16949
- A minimum number of auditors qualified in the field of nuclear industry (EA code 11)
- An international organization
- An experience within nuclear activities (perform ISO 9001 assessment)
- The ability of the CERTIFICATION BODY to develop specific procedures and tools to enable it to carry out granting, maintaining, extending, reducing, suspending and withdrawing NSQ-100 certification

1.1.2 Preparation for assessment

After Board approval on the application, the NQSA Certification Committee will appoint an assessment team consisting of a lead assessor and, when needed, a suitable number of assessors. When selecting the assessment team belonging to a NQSA member (only industrial members), NQSA Certification Committee will ensure that the assessors (lead and others) have:

- Appropriate knowledge of Certification System
- Auditing experience.

NQSA Certification Committee will ensure that the team members act in an impartial and non-discriminatory manner. In particular, the assessment team will inform NQSA, prior to the assessment, about existing, former or envisaged link or competitive position between themselves or their organization and the CB to be assessed.

NQSA Certification Committee will inform the CB of the names of the members of the assessment team and the organization they belong to. CB can object to the appointment of any particular assessor. In case of a disagreement between the CB and NQSA, the NQSA Impartiality Committee will be in charge to investigate the request and will advise the CB of the final decision.

NQSA Certification Committee will decide on the assessment duration based on number of NSQ-100 auditors (a minimum is 2 days).

The costs of the NQSA assessment and surveillance actions will be charged to the CB.

The task of the assessment team is to review the CB's documents and to conduct the on-site assessment of the main or head office.

The assessment of the conformity services of the CB will be conducted at least at the premises of the CB from which the key activities are performed and, where relevant, will perform witnessing at other selected locations where CB operates, to gather objective evidence that in the applicable scope the CB is competent and conforms to this procedure.

NQSA Certification Committee will agree, together with the CB and the assigned assessment team, to the date and schedule for the assessment.

The language used for the assessment is English or another language mutually agreed (NQSA Certification Committee, CB, assessment team).

1.1.3 Document and record review

The assessment team will review the following documents to evaluate the CB system for conformity with this procedure prior to proceed of the on-site assessment:

- Application form and relevant associated documents, including the quality manual and procedures of the main applicant's qualification of auditors
- The CB procedures and relevant associated documents and records to perform NSQ-100 certification.

The results of this review are communicated to the CB.

If the review is satisfactory, the admissibility is pronounced, the initial on-site assessment can then be scheduled, normally within six months after the end of this review.

The assessment team may decide not to proceed with an on-site assessment based on the nonconformities found during this review. In such case, the nonconformities will be reported in writing to the CB. The closure by the lead assessor is needed prior the on-site assessment. If after one year, the actions plan is not satisfactory, the qualification file is closed by NQSA Certification Committee.

1.1.4 On-site assessment

The lead assessor prepares the on-site assessment by sending an audit plan to NSQA Certification Committee and to the CB.

The assessment team will mainly check that all relevant information and evidence gathered during the documents and records review are well implemented.

The on-site assessment will be conducted in according with Guidelines NF EN ISO 19011 and must include:

- Reviewing the adequacy and compliance with the requirements
- Verifying the application of these procedures;
- Reviewing the adequacy of the CB organization to provide the services subject to its application;
- Assessing the performance of the control staff and auditors of the CB to perform NSQ-100 certification within Nuclear supplier organization.

When the assessment team cannot reach a conclusion about a finding, the team will refer back to the NQSA Technical Manager.

1.1.5 Assessment report

A meeting will take place between the assessment team and the CB prior to leaving the site. At the meeting, the assessment team will provide a written report on its finding obtained from the audit (see 1.1.4).

Then, a written report on the outcome of the assessment will be brought to the attention of the CB within a period not exceeding one month. This assessment report will contain comments on competence and conformity, and will identify non conformities, if any, to be resolved in order to conform to all of the requirements for qualification.

The CB will respond to the assessment report by describing the specific action taken or planned to be taken, within 6 months, to resolve any identified nonconformities.

The report official language is English. Translation can be agreed during the agreement's step.

NQSA Certification Committee will ensure that the responses of the CB to resolve nonconformities are reviewed to see if the actions appear to be sufficient and effective. If the CB responses are found not to be sufficient, further information and evidence will be requested. NQSA Certification Committee may decide to carry out a follow-up assessment to verify effective implementation of corrective actions.

1.1.6 Decision-making and granting NQSA qualification

The information provided to NQSA board (only industrial members) will include the following documents:

- A valid accreditation ISO 17021 within its scope ISO 9001 and AS/EN9100 or TS 16949
- The number of auditors qualified in the field of nuclear industry (EA code 11)

- A document certifying the experience within nuclear activities (for example : perform assessment ISO 9001)
- The assessment report :
 - Non major non conformity on the ISO 17021 requirement and the requirements present in the document and related document
 - Lead assessor positive recommendations.
- The list of auditor qualified to perform NSQ-100 certification
- The agreement signed between NQSA and CB mentioning in particular the proper use of the NQSA marks.
- any other relevant information or event ;

The qualification is decided by the NQSA board (only industrial members) based on the information above. NQSA will provide a qualification certificate to the CB. This qualification certificate will identify :

- the NQSA references and logo
- the name and address of the headquarter of the CB
- all premises from which the NSQ-100 certification are performed and which are covered by this qualification.
- the qualification number of the CB
- the effective date of granting of qualification and the expiry date
- the signature of the NQSA Chairman.

The qualification certificate will be installed on NQSA website. The information will be maintained during the validity of the qualification. In case of withdrawal of the qualification, the information related to the CB will be erased from the website and a NQSA letter will be sent to the organization certified NSQ-100 by this CB.

The qualification will be delivered for 5 years. A surveillance on-site assessment will be performed no later than 12 months from the date of initial qualification.

1.1.7 Appeals

The CB has the opportunity to appeal any decision of NQSA affecting the status or scope of qualification. The NQSA Impartiality Committee will be in charge to investigate the appeal, will decide on the validity of the appeal and will advise the CB of the final decision.

1.1.8 Reassessment and surveillance

Reassessment is similar to an initial assessment (see 1.1.2).

Surveillance on-site assessments are less comprehensive than reassessments.

The Surveillance on-site assessment will be carried out according to 3 devices:

- Check of audit reports
- On-site oversight as an observer
- Audit of the procedures and the tools developed by the certification body.

Reassessment will take place at intervals not exceeding 5 years.

NQSA will carry out a yearly surveillance on-site to monitor the continued fulfillment by the qualified CB of the requirement for qualification.

When, during surveillance or reassessment, nonconformities are identified, the assessment team will specified in accordance with the Certification Committee the time limits for corrective actions to be implemented.

NQSA may conduct extraordinary assessments as a result of complaints or significant changes (see 2.1).

1.1.9 Extending qualification

In response to an application for an extension of scope of a CB qualification, NQSA Certification Committee will analyze this request in order to determine whether or not an on-site assessment needs to be carried out.

1.1.10 Suspending, withdrawing or reducing qualification

In case of inconvenient issuance of a NSQ-100 certificate the CB will lose its qualification (French Safety Nuclear Authority advice).

NQSA may suspend, withdraw or reduce all or part of qualification when a CB has persistently failed to meet the requirements of qualification.

This NQSA board decision will be sent to the CB with acknowledgment of receipt.

The decision can be based on:

- the loss of the ISO 17021 within its scope ISO 9001 and AS/EN9100 or TS 16949
- the loss of sufficient number of auditor qualification
- the improper use of NQSA marks.
- a client's or NQSA's significant claim ;

A notification is sent to the CB with the decision of the board, and in case of a reassessment a new qualification certificate is joined to the notification.

The CB will keep the same qualification number but will have an updated certificate.

The CB also has the ability to voluntarily reduce their scope of agreement, or withdraw completely.

1.1.11 Records on CBs

NQSA Certification Committee will keep the following records on CBs to ensure confidentiality :

- Relevant correspondence,
- Assessment records and reports
- Records of Board and Certification Committee deliberations and decisions
- Copies of NQSA qualification certificates.

1.1.12 Annual activity report

Each CB will send to the NQSA Certification Committee an annual activity report specifying in particular:

- Follow-up of the auditors qualification
- Appeal request management

2 RESPONSIBILITIES OF NQSA AND CB

An agreement is signed between the CERTIFICATION BODY and NQSA.

2.1 Obligations of the CB

The agreement will define the duties, liability and confidential aspect.

By signing this agreement with NSQA, the CB will commit to :

- Fulfil continually this procedure in order to maintain its qualification,
- Authorize to NQSA representatives to provide access to all its premises, personnel files, documents and records as necessary for the assessment and maintenance of the qualification
- Communicate, prior to the assessment, the documentation required for the preparation of the assessment;
- Arrange towards its customers, NSQ-100 certified holders or candidates through a contract or by any other equivalent means in order to impose, where appropriate and upon request, the presence of NQSA assessors during an on-site assessment. A non-compliance of this NSQA requirement may be a case of suspension (see 1.1.10).
- Pay all costs related to NQSA assessments, whatever conclusions they lead, as well as annual fees,

- Not use its qualification in such a manner as to prejudice the reputation of NSQA and not make any statement relating to the NSQ-100 certification that the NQSA could reasonably be regarded as misleading
- Ensure compliance with the rules of use of the NQSA logo and symbol.
- Inform NQSA, without delay, of any significant change relevant to its qualification, in any aspect of its status or operation relating to:
 - o Its legal, commercial, ownership or organizational status,
 - o The organization, top management and key personnel,
 - o Main policies,
 - o Resources and premises,
 - o Scope of ISO 17021 accreditation, and
 - o Other such matters that may affect the ability to fulfill this requirements for qualification.
- Recognized ISO 9001 certificates issued under the control of the IAF. This recognition is subject to review and approval of last audit ISO 9001 report.

2.2 Obligations of NQSA:

2.2.1 Confidentiality

All CB information collected by NQSA and/or assessment team for a NQSA qualification starting with the submission of its application are considered and treated as confidential.

The following information will be installed on the NQSA website :

- Name and address of the CB
- Date of granting qualification and expiry dates
- Scope of qualification.

As the qualification connected with an activity related to the regulation, the CB will be informed by NQSA of the administration query to waive confidentiality.

2.2.2 Complaints

Nuclear field customers, suppliers or CBs have the opportunity to complain by referring to the qualification granted by NQSA.

Written complaint shall be addressed to the NQSA General Secretary.

The Impartiality Committee will be informed of the complaints and actions undertaken.

2.2.3 Information

NSQA informs each CB who have signed an agreement of any significant modification of the qualification requirements.

A notification will be sent with the requirement details and the delays to integrate these within the CB's organization.

2.2.4 Nuclear safety authorities surveillance

The association NSQA or its representatives offer to authorities all reasonable cooperation required, including:

- Access to all its premises, personnel, documents and records covered by the request and useful for the conduct of their surveillance;
- Communication, prior to the surveillance, of the documentation required for the preparation

3 REQUIREMENTS FOR CERTIFICATION BODY AND CANDIDATES FOR NSQ-100 CERTIFICATION:

3.1 General principle :

The general principle is, of course, to fulfill the NQSA requirements specified within this procedure. However, NQSA may accept exemption but these must be documented, controlled and validated by NQSA.

Basic principles :

- In case of being unable to respect the requirements for the qualifications of auditors and for the assessment process of a nuclear supplier, an exemption with a supported request must have been granted by NQSA before the implementation of the work. Should the opposite occur, the CB's qualification can be questioned.
- The CB will manage a list of qualified auditors. This list must be sent to NQSA as well as the updates. The evidence of the qualification of the auditor will be kept by the CB and checked during the NQSA surveillance.
- CB will have to develop specific procedures and tools to enable it to carry out granting, maintaining, extending, reducing, suspending and withdrawing NSQ-100 certification.

3.2 Management system:

The CB organization implements a management system based on the general requirements of ISO 17021 and ISO 9001. NQSA requirements for NSQ-100 certification will be formalized through a specific procedure.

The above documentation shall be available in English.

3.3 Specific requirement for NSQ-100 certification:

The organization defines a coordinator to manage the international NSQ-100 certification scheme to:

- Ensure that in all locations within the CB qualification scope have implemented a system based on the general requirement of ISO 17021 following the accreditation requirement of their country and NQSA requirements for NSQ-100 certification.
- Ensure that the NSQ-100 auditors' competences are followed and maintained. Records shall be maintained in the main office. It is recommended to keep a copy of the files in the local office too.
- Ensure that inspections and audits are performed on a regular basis to ensure the respect of the certification process and the NQSA requirements for NSQ-100 certification.

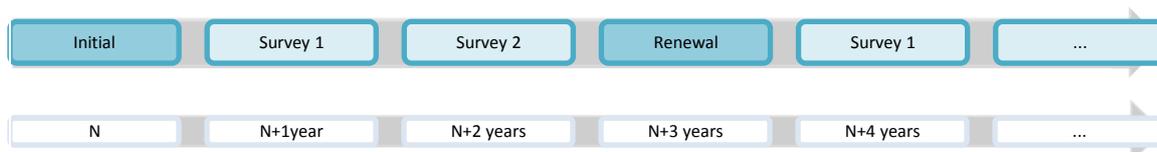
3.4 Lead auditors/auditors qualification:

Auditor qualifications are specified in the NQSA procedure: "NSQ-100 auditors qualification procedure"

3.5 NSQ-100 certification scheme

An audit cycle of 3 years with an annual surveillance

The NSQ-100 certification scheme is based upon ISO 9001 and shall be coordinated to ISO 9001 certification cycle.



The certification cycle begins with the issuance of the first NSQ-100 certificate.

Note: Surveillance on-site audits could be scheduled (for example, at 6-monthly basis) as per agreed with client at application stage.

Surveillance audits or desk audit need to be done after one year +/- 2 months after the last day of the initial audit.

The surveillance audit can be replaced by a desk audit (documentary review – see 3.1.8) in case of a very small organization (less than 5 employees). This exemption needs a NQSA acceptance. For NSQ-100 certification renewal, the audit needs to be done at least 3 month before the end of the certificate validity.

3.6 Case of transfer:

A transfer of certification occurs when a client certified by another CB chooses to switch to a new CB. Certification transfer can be realized in the middle of a cycle, if the certification process is in a good shape (no major nonconformities pending). The NSQ-100 certificate remains valid without modifying the expiry date. Certifications under suspension or withdrawal or having open major nonconformities are not eligible for this transfer process and shall be considered as new certifications, requiring a full system audit. The NSQ-100 certification transfer is allowed only between the CB under agreement with NQSA.

3.7 Renewal :

Certificate will be renewed on 3-yearly basis and is performed under the condition of initial certification. This renewal shall include the review of the previous audit results.

3.8 Serious Incidents

In case of serious incident in a NSQ-100 certified organization an unscheduled audit may be authorized and/or the next scheduled audit may be brought forward. The rescheduling of the renew audit need to be authorized by NQSA.

3.9 Multiple sites certification

No sampling audit is allowed for multiple sites organization. Each site will be audited during the initial and renewal audit, and once in the two years of surveillance.

3.10 Duration of audit for NSQ-100 certification:

The duration of an audit that integrates ISO 9001 and NSQ-100 requirements shall be defined in accordance with the IAF Guidance for ISO 9001 certification as a minimum. In addition, the on-site audit time for NSQ-100 certification shall be defined according to the following table, also depending on organization size :

Additional Auditor-days	Total Number of person working in the scope of NSQ-100 certification within the organization		
	5-100	101-1000	Over 1000
Initial or renewal assessment	+1.5	+2	+3
Annual Surveillance	+1	+1.5	+2

The CB can increase this additional audit time in case of multiple activities with high complexity.

3.11 Desk audit (documentary review):

All certified organization will submit to the CB the following information for a documentary audit of surveillance:

- Nuclear field sales volume and object of contract realized during the year of surveillance
- Quality management review
- Number of claims, details and actions undertaken to solve the claims and correctives actions realized to ensure the absence of recurrences
- Major change in the organization and action undertaken to prevent non conformities do to this change.

- Results of internal audits and inspections and actions undertake to solve non conformities and correctives action undertake.
- Quality objectives and indicators.

The result of the documentary audit can lead to an on-site surveillance audit.

Documentary audit shall not exceed 0.5 auditor day.

3.12 Audit team :

- 2 qualified auditors if the duration of the audit is over 5 days
- At least, one auditor of the initial audit team for the surveillance assessment (see general principle in case of impossibility to respect this item)

3.13 Requirements for reporting:

- General principles :
 - The statement of conformity of a regulatory requirement must be supported with examined convincing elements and mentioned in the report and/or kept in the auditor file.
 - The principles used during an ISO audit 9001 will be implemented (2 nonconformity levels (major, minor), corrective action plan, nonconformity form issued at the end of the audit and signed by the client, closure of nonconformity,...)

3.14 Nonconformity

- Major nonconformity : an action plan need to be drafted under a month and send to the CB with a deadline of 3 months max for each action. On the initiative of the CB, an additional on-site assessment or an examination of evidences could be performed. In all cases, the closure of the major nonconformity is essential to deliver or renew a NSQ-100 certificate.
- Minor nonconformity : an action plan need to be drafted under a month and send to the CB but without freezing the issuance or the renewal of the certificate.

The nonconformity level is set by the auditor during the audit debriefing.

The assessment process including the audit questionnaire or equivalent and the audit report must be described in a specific procedure which is one of the requirements to be drafted by CB and approved by NQSA.

3.15 Audit report

CB's form defined in the assessment process procedure will be used.

The report official language is English. Translation can be included in the contract.

Issuance of the report must be done one month maximum after the end of the audit.

The auditor checklist shall be integrated to the annex of the report.

The customer may request NSQ-100 certification audit report to the supplier. The CB shall introduce in their condition of services and requirement for certification an obligation to the supplier to submit the report to customer and prospect in case of a query.

3.16 NSQ-100 Certificate

The NSQ-100 certificate will be notified formally by the CB and will contain:

- The scope of the certificate (rating of activities): activities involved in the scope (design or/and manufacturing and services)
- The name of the organization
- The address of the main office
- List of the certified site and their addresses
- The date of this certification
- A NQSA chronologic number and a version indexation
- The expiry date
- The signature of CB certification manager
- NQSA Logo
- CB Logo

The certificate will mention the common reserve of certification and at least that this certificate is issued by the CB under its General Conditions of Certification available on their website. The CB draw the attention to clauses limiting liability, indemnification and jurisdiction set out in the CB Terms of Service. The authenticity of this document can be verified on NQSA web site. Unauthorized modification, alteration or falsification of the content or form of this document is unlawful and offenders are liable for all penalties imposed by law.

The NSQ-100 certification number with the expiry date, the scope of activities as well as the status of the certificate (valid, suspended, removed) will be installed on the NQSA website.

The certificate number will be assigned by NQSA.

For each certificate, NQSA will define a fee, paid by CB, for recording and publishing it on NQSA website.

3.17 Definition of the services condition:

This condition shall include the requirement of submission of the report by the certificated body in case of request by any nuclear field customer or prospect.

This condition shall include that the withdraw of ISO 9001 certification of the supplier will lead to a complete NSQ-100 and ISO 9001 audit on site with the 3 month of the withdraw.

The CB shall inform NQSA in 5 open days after their certificate decision of any change in the supplier certification status.

The supplier will have to inform its customers in case of suspension or withdrawal of its NSQ-100 certificate.