ROADMAP TO BECOMING A NUCLEAR QUALIFIED SUPPLIER

Prepared for:

Organization of Canadian Nuclear Industries

Comprised of:

Guideline No: 1

Guideline for the Development and Implementation of a Nuclear Management System that meets the Canadian Requirements for the Provision of Items and Services to the Canadian Nuclear Industry

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AND

Guideline No: 2

Guideline for the Development and Implementation of a Quality Assurance Program that meets the Canadian Requirement for the Nuclear Pressure Boundary

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Pamphlet No: 1

Guidelines for the Development and Implementation of a Nuclear Quality System that meets the Canadian Requirements for the Provision of Items and Services to the Canadian Nuclear Industry

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INTRODUCTION

This pamphlet provides for the steps and associated activities for a non-nuclear supplier to become qualified to supply items and services to the Canadian nuclear industry. Pamphlet No, 2 provides the Guidelines for the Development and Implementation of a Quality Assurance Program that meets the Canadian Requirement for the Nuclear Pressure Boundary. It is not unusual for a supplier pursuing nuclear pressure boundary qualification to also be required to implement a quality system as described in this Pamphlet No. 1.

Being qualified means a nuclear customer has accepted an implemented Quality Assurance Program (CSA N299 QA Program) or Management System (CSA N286 Management System), both referred to as a Nuclear Management System (NMS) unless stated individually. The nuclear customer (herein after referred to as customer) can be a nuclear utility, or one of the many qualified nuclear suppliers referred to as Tier 1 suppliers. It is also very common to supply items and services to customers who are Tier 2 or Tier 3 nuclear suppliers, dependent on the item or service being provided. Regardless, all are referred to as customers.

The process of obtaining qualification to provide items and services to the nuclear industry is quite different than in non-nuclear industries, and requires significant effort to be successful. There is a level of attention to detail that often proves to be a “tripping point” for companies and their personnel. Implementing an NMS also requires “a culture change” from the way activities are performed in the non-nuclear industry. There is some commonality with providing items and services to a regulated industry such as oil and gas, aerospace, military etc., but for those providing basic commercial products the effort will be significant, even if operating under an existing ISO 9001 Quality Management System (QMS) or similar.

Successful qualification results from a clear vision, hard work, a budget and schedule, a dedicated internal resource to drive the project and, above all, total commitment by Senior Management and their visible involvement. A clear vision of what and why implementing the new QA Management System is important to the success of the company, and important for employees to understand why they are going to have to commit their time to it.

The discussion on qualification in this pamphlet addresses the implementation of one or a combination of the following nuclear quality standards:

- CSA N299-16, Quality assurance program requirements for the supply of items and services for nuclear power plants, category 1, 2, 3 or 4.

  The N299 series of standards pre-grades requirements into one of the 4 Categories, with Category 1 being the highest. The category level required to be implemented is established by the customer, the supplier then grades the Category level of the items and services it intends to procure for its products.

- CSA N286-12, Management system requirements for nuclear facilities.

  This standard permits the supplier to grade requirements based on the scope of work and acceptable to the customer.

- CSA N286.7-16, Quality assurance of analytical, scientific, and design computer software.

  This standard will be called up by the customer when designs performed by the supplier are related to nuclear plant life-cycle systems, components or structures (commonly referred to as SSCs).

This pamphlet does not address technical evaluations and qualifications of an item or service, which is the sole responsibility of the supplier and customer.

Qualification to provide Pressure Boundary items and services is addressed in Pamphlet No. 2

STEPS TO QUALIFICATION

The NMS qualification journey is comprised of the following 8 Steps.

1. Need and Timeline – what NMS and when is it required by
2. Current quality system status – certified or not certified
3. Resourcing and budget
4. Nuclear Quality System development - documentation
5. Role out and implementation – start work
6. Independent Internal audit – verification of compliance prior to customer evaluation
7. Customer qualification audit – customer or their representative
8. Successful qualification – Supplier is added to the customer ASL

STEP 1 - Need and Timeline

a) What is the need for a nuclear quality system?

The need can be either customer driven based on a certainty of work upon successful qualification; or is self-identified as part of the company's strategic business planning.

b) What nuclear quality system is required?

There are two scenarios to establishing which NMS is required; the customer who is driving the qualification will determine the NMS requirements, or by the supplier talking with the nuclear utilities and/or other potential customers within the supply chain to see what would be most appropriate. In addition, the recommendations of a supply chain nuclear quality consultant can be sought.

Another consideration is to decide if the NMS is to be stand-alone for nuclear items and services or is to be integrated into an existing quality program or QMS for commercial products. If the nuclear work will only be a small percentage (<40%) of the business, then controlling it with a separate NMS from the commercial program is recommended. By integrating with a current commercial quality system, the controls will be elevated to a level not required for the commercial work, thus increasing costs. A current program can be leveraged by the NMS referencing existing quality system documentation when controls in the existing documents meet nuclear requirements.

Additionally, if operating within a corporate multi site non-nuclear quality program, how will the stand-alone requirements of the NMS be permitted and/or integrated with the corporate program.

c) What is the timeline?

Typically, a customer driven need for qualification will result in a shorter timeline than planning implementation for possible future work. In the second scenario, the timeline for implementation is often established with customers who may have an interest in using the services of a new supplier but are not ready to commit to issuing a PO. The timing of a qualification audit from a potential customer is very difficult to establish as the customer will not be motivated to spend the time to audit and qualify if they are not planning to release a PO.

It is not unreasonable to expect on average to spend 8 to 18 months developing and implementing the required NMS. Eight months is typical when a supplier has a reasonable existing quality system. Obviously there are various degrees of existing programs and systems that will influence these average timelines, as will the scope of the NMS to be implemented.

Another consideration is the ability to provide personnel with the time required to develop and implement the NMS. Many companies secure the help of outside consultants to develop the required documentation, however, supplier personnel still require time to help map current processes and responsibilities, and reviewing the documents prepared by the outside consultant.

STEP 2: Current Quality System Status

Establishing the status of any current quality program or quality management system documentation against the requirements of the required NMS (gap analysis) is important

in helping establish the scope of work required in moving forward. This is achieved by populating a Requirements Compliance Matrix (RCM) for the required NMS standard. The RCM is a spreadsheet identifying all clauses and sub-clauses of the NMS in one column, populating another column with references to where in the current quality manual (if there is one) that the requirement may be covered at a high level, populating another column with procedure references (if there are any) where the details may be covered, in whole, or in part. Another column is then populated with any additional details that are required when a requirement is partially addressed by current documentation.

If it is recognized up front that a current system is likely lacking most of the requirements, then doing, or continuing to do, the gap analysis is not recommended. A lot of time will be spent documenting the obvious, time which is much better spent developing the NMS documents. The RCM will then be used to identify where in the new documentation each of the requirements are covered as the documents are being developed.

For any supplier currently providing nuclear items and services to USA and/or international customers under an NQA-1 / 10CFR50 App B program, the requirements for acceptance of that program should be discussed directly with the customer.

STEP 3: Resource and Budget

Developing and implementing an NMS is no different than executing any other project and as such should be managed that way. A clearly defined schedule of activities and internal program deliverables, and resources and budget to enable the work required should all be part of planning the NMS. The major milestones are represented by the Steps identified in this Pamphlet, however, there are many subtasks that should be planned and tracked so as to keep development and implementation on-track.

There are two key resources, a champion to drive the program (typically the QA Manger) and the process owners who will be providing input and reviewing the developed documentation.

The senior manager must also be prepared to budget some time to ensuring the project is well received by those who will be affected by the program, and to continue to push the importance of success.

STEP 4: Nuclear Quality System Development

Obtain a copy of the Quality Standard(s) to which compliance is required and prepare a requirements compliance matrix (RQA) if one was not prepared during STEP 2.

NMS Documentation:

The NMS is established as a hierarchy of an ordered set of documents – a Manual, procedures, instructions and specifications that contain the appropriate information for directing and determining that prescribed activities are satisfactorily accomplished and

ensuring the implementation of the required NMS. The documentation is established in three distinct levels that integrate the policies, procedures, and working documents. Tier one is the QA Manual, Tier 2 are the Procedures that implement manual requirements, and Tier 3 are the Instructions, Standards, Department Procedures, and forms.

The manual is the top tier (Tier 1) document which defines the scope of items or services covered by the program, and provides an overview of the NMS describing the requirements (the "what"). The manual also provides a roadmap to the implementing procedures that describe the processes. The degree of content is related to the quality standard required, and scope and complexity of the item or service. It is important the manual does not duplicate the detailed information in the implementing procedures, this not required and will help prevent conflicting information between the manual and procedures – especially as changes occur.

> *Note: CSA N299.4 does not require a QA Manual; however, it does require a document that outlines the business, facilities, and the items and services covered by the NMS, therefore, for simplicities sake, this Pamphlet will also refer to the N299.4 document as a QA Manual. Similarly, procedures are not required but descriptions of the processes and requirements are, so these will be referred to as procedures in this Pamphlet*.

Implementing procedures are Tier 2 documents that implement the requirements (the "how", "when" "where") as well as responsibilities and interfaces (the "who"). In some cases, standards and program documents may be created to describe requirements, expected behaviours and supporting programs. Tier 2 documents refer to Tier 3 documents, when applicable.

Tier 3 documents consist of Functional/Department/Plant processes/work instructions, forms and checklists etc. to support implementation of the manual and procedures and to control work required of a nuclear project. The forms when populated will become quality records.

> *Note: NMS documentation may be newly developed and/or be existing documents updated to meet requirements*.

The NMS may also utilize other business processes such as IT systems, Health, Safety and Environment, HR and Financial practices, Project Management modules etc. that are not specifically designated as Tier 3 documents, but may serve and be referenced as Tier 3 documents to support nuclear projects.

An organization is established to address the various required NMS Roles (not positions or titles) as the manual and procedures are developed. Names will be assigned to the management and process owner roles for the purpose executing the reviews and subsequent implementation of the NMS documents as early in the process as possible.

> *Note: One person may perform more than one Role, and in some cases several roles - this is particularly true in smaller organizations. Caution shall be taken to ensure a person does not verify their own work.*

As the NMS is developed it is important to establish roles for verification activity. It must be clearly stated that those performing verification shall be independent of the work being verified. In manufacturing this is typically achieved by inspectors functionally

reporting to a management representative who is independent of the work being verified. In design organizations, this is achieved by the design verification processes assuring verifiers are sufficiently independent of the design to be verified.

Change control to ensure documents reflect current requirements and practices is key to ensuring NMS compliance.

The NMS documentation shall be reviewed annually to ensure its ongoing relevance to the business and compliance with changes to codes and standards.

Independent Documentation Assessment

If the NMS documentation was prepared by the supplier's own personnel, it is recommended that a consultant experienced in the NMS being developed verifies that the documents adequately and correctly reflect the requirements and the intent of the QA standard. Once this is complete the documents are processed through document control for roll out and implementation.

Customer Phase A Qualification

When the customer establishes a 2 Phase approach to qualification where Phase A is the acceptance of the supplier's NMS documentation, the supplier will submit the QA Manual, Procedures and other documents for review and comment. Once documentation is accepted, the customer will qualify the supplier on the condition of a successful on-site implementation audit (Phase B) performed shortly after work begins. The customer then issues a PO to permit the start of work enabling objective evidence to be developed in support of the Phase B implementation audit.

STEP 5: Roll-Out and Implementation

Roll-Out and Training

Roll-out refers to the introduction of employees to an NMS document they will be using to control their work. The roll out does not introducing employees to technical requirements.

Roll out also includes training personnel in the processing requirements of the NMS documentation and, when identified by Management, qualified to a process. Training typically parallels implementation as the need to execute work begins.

All personnel who will be executing nuclear work are provided quality indoctrination in the NMS and other general topics. The goal is to ensure people are aware the NMS and their role within it. For CSA N299 Category 1, 2 and 3, and CSA N286, the indoctrination includes awareness of safety culture.

It is not necessary to have everyone trained and qualified in preparing for the customer qualification audit. Typically, only a small group performing immediate nuclear work in preparation of a customer audit will require training and qualification. This cuts down on the time required to prepare for an audit and ensures others who receive the training and

who will not be executing work right away, do not forget the training when they do come to use it.

Implementation

Implementation of the program is initially designed to generate objective evidence of compliance with NMS requirements that can be presented during the customer qualification audit. Implementation can take one of two paths.

1. PHASE B implementation audit of the two-phase qualification approach triggered by a customer's acceptance of the NMS documentation and issuing of a PO to begin work in PHASE A. The work is executed in accordance with NMS documentation and objective evidence generated that will be used by the customer when performing their PHASE B implementation audit to complete the qualification process.

2. The second approach is to prepare a demonstration sample that will exercise all elements of the NMS prior to the customer audit. This can be done for design services as well as manufactured items and materials. The demonstration sample can be a dummy project that has no value after the customer audit, or by processing a commercial order as if it were nuclear. The second of these options is less costly as a portion of the cost is recovered by its sale to the commercial customer. Either way the goal is to produce objective evidence that can demonstrate work was processed in accordance with NMS requirements.

Following completion of an agreed scope of work related to the PHASE B implementation audit; or completion of a demonstration sample, Quality ensures all records/documentation are available and that they accurately reflect compliance to NMS requirements. Quality then declares readiness for an internal audit to be performed prior to the customer qualification audit. CSA N286, and N299.1 and .2, require an internal audit, but N299.3 and .4 doo not; however, it is strongly recommended that an independent internal audit still be performed to prepare for the customer audit.

STEP 6: Independent Internal Audit

Internal Lead Auditor

The internal audit must be performed by a qualified Lead Auditor who has not been involved in the work to be audited, including implementation of the NMS documentation. The Lead Auditor is qualified in accordance with the Supplier's Lead Auditor qualification requirements which typically requires performing 3 or more audits under the direction of a qualified Lead Auditor. Unfortunately, most suppliers will not have someone available with the required qualification at this early stage of implementing the new program, as such, it is normal to secure the services of a qualified Lead Auditor who can perform the audit and mentor a supplier representative as part of achieving the internal Lead Auditor qualification.

Internal Audit

The internal audit needs to be scheduled enough time ahead of the planned customer qualification audit to ensure deficiencies can be corrected and closed.

The internal audit is designed to ensure activities are being performed in accordance with the supplier's detailed NMS documentation requirements, and not just the higher-level applicable CSA standard requirements. It is important to note that the NMS documentation was previously confirmed as meeting the CSA Standard requirements when developing the program in STEP 4, the internal audit now makes sure people are executing work in accordance with the NMS documentation requirements.

It is important to coach personnel to respond openly with the Lead Auditor and to self declare any known deficiencies or errors with the NMS documents their work is controlled by. The internal audit is the opportunity to identify and correct deficiencies helping to ensure a successful customer audit.

Deficiencies identified during the internal audit are reported, processed, and cleared in accordance with the supplier's Corrective Action process.

STEP 7: Customer Qualification Audit

The purpose of the audit is to enable the customer to evaluate the adequacy of the NMS documentation in covering the scope of the activities in the program, that the requirements of the governing quality Standard(s) has been addressed, and that the program as set out in the NMS documentation has been effectively implemented.

The customer qualification audit can be performed in one of three ways:

1. If the customer is a nuclear utility, the utility can either perform the audit themselves or have it performed by the Candu Procurement Audit Committee (CANPAC).

   A supplier cannot use another supplier's successful CANPAC or nuclear utility audit to qualify the supplier for addition to their approved supplier list, the supplier must perform its own qualification of their suppliers.

2. The customer performs their own audit.
3. The customer (non-nuclear utility) can contract the Candu Industry Assessment Committee (CANIAC) to perform the audit on their behalf. This will enable a sharing of the audit with other CANIAC members, under contractual arrangements.

The nuclear customer audit is a detailed evaluation of the NMS against the requirements of the applicable quality standard. Only work performed under the NMS is audited.

Following he audit, an exit meeting will be held with the supplier's management, including Executive/ senior management as this demonstrates support for the program. The Lead Auditor will review the results of the audit and provide a general summary of the implementation effectiveness of the NMS, and the likelihood of the supplier being recommended for qualification once any corrective actions are resolved.

Supplier actively pursues processing and customer issued corrective actions, and obtaining closure from the customer.

STEP 8: Customer Qualification

The final step in the process is receiving the qualification letter from the customer. The letter identifies the scope of the qualification, any restrictions deemed necessary by the customer to address program gaps or to mange risk, a requirement that the supplier notify the customer of any changes to the NMS that the customer based their qualification on, and the qualification expiry date – normally there years from the date of the audit.

References

1. **CSA N299-16,** Quality assurance program requirements for the supply of items and services for nuclear power plants
2. **CSA N286-12,** Management system requirements for nuclear facilities
3. **CSA N286.7-16,** Quality assurance of analytical, scientific, and design computer software

Pamphlet No: 2

Guidelines for the Development and Implementation of a Quality Assurance Program that meets the Canadian Requirement for the Nuclear Pressure Boundary

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Introduction

Nobody wants to be introduced to the adventure of developing their company into an exciting new field by reading warnings and statements that cast a shadow. Yet, experience shows that companies embarking on this journey of qualification most times underestimate the effort required. it would be negligent if this pamphlet did not say up front what is to be expected if the goal is to be achieved.

The process of successfully obtaining a Certificate of Authorization for construction of pressure boundary equipment is a different experience in the nuclear industry to obtaining one in the non-nuclear industry. There is a level of attention to detail that often proves to be a “tripping point” for companies and their personnel. The best way to describe it, is to call it “a culture change” from the way activities are performed in the nonnuclear pressure boundary industry.

The time elapsed from the start of the project to the actual survey by the accrediting organization can run from 9 months to a 1½ years. The time required depends on the scope of the Certificate, the ability of the company to develop the culture change, the support of management to make the necessary changes and to provide the budget and time to develop new and adapt old procedures including the necessary indoctrination and training of staff.

The Theory/Concept

Our discussion on Quality Assurance in this work is associated/limited to the control of activities associated with design and construction of pressure boundary equipment. In Canada our pressure boundary design and construction are controlled by the CSA Standard N285.0[1]. This standard is called up in the utilities licensee and the associated Licensees’ Condition Handbook (LCH). Therefore, it is a legal requirement that the utility meet the requirements of N285.0.

The Canadian approach to the integrity of the pressure boundary in the nuclear equipment has been to adopt the requirements of Section III[2] of the ASME Boiler and Pressure Vessel Code through reference in N285.0. CSA N285.0 is the upper tier in a series of standards that were developed to accommodate the different reactor concept in Canada i.e., CANDU as opposed to

PWR/BWR designs in the USA, and of course the regulatory requirements in Canada. Well over 90% of the technical requirements of Section III have been adopted by direct reference in CSA N285.0 to Section III.

Th Canadian provincial regulatory authorities have adopted the technical requirements of the ASME Boiler and Pressure Vessel Code (BPVC) for several decades. The methodology is to develop a Canadian standard and reference the applicable Section appropriate to the product covered by the BPVC. For the commercial (non-nuclear) component the CSA Standard B51[3] has been developed. When the nuclear industry was started the same model was used. In this case it was the N285 series of standards.

Quality Assurance Requirements in Canada: Clause 10 of N285.0 addresses the quality assurance requirements for the design and construction of nuclear pressure boundary. Effectively Clause 10 requires the quality assurance program (QAP) for construction of pressure boundary equipment to be equivalent to the requirements of NCA-4000 of Section III. N285.0 specifically states that the equipment does not require stamping. Therefore, the program can be equivalent to NCA-4000 together with any additional requirements of N285.0 but will not be surveyed by an ASME Team.

In Canada, although the QAP for pressure boundary effectively mirrors the ASME program, the role of ASME in accreditation is performed by TSSA in Ontario and similar organizations in the other Provinces (Régie du bâtiment in Quebec, ABSA in Alberta, Inspection Services in New Brunswick). This accreditation process is recognized by the Regulator in Canada, CNSC.

Section III Approach: The QAP requirements for Section III are contained in Article NCA-4000 in Subsection NCA; specifically, paragraph NCA-4134. There are 18 sub-paragraphs that reference the 18 Requirements of Part 1 of the ASME Standard NQA-1 “Quality Assurance Program for Nuclear Facilities”. Because NCA-4134 addresses the requirements for Section III, for many of the elements there are additional requirements, and these are identified in in each sub-paragraph.

IMPORTANT to NOTE: Section III is very clear that the QAP in Section III is focused on ensuring that the requirements of the Code are met in the construction of the components in the nuclear pressure boundary. The definition of Quality Assurance Program in the NCA-9000 Glossary is given below.

> “**Quality Assurance Program:** As used in this Section (means Section III), quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that all items designed and constructed are in accordance with the rules of this Section.”

N285.0 has adopted this same approach.

The Process[4]

There are four phases in the process of becoming accredited to produce pressure boundary items for the nuclear pressure boundary: Preparation, Application, Assessment and Certification.

Preparation

Applicants should decide and/or prepare the following before applying for a certification:

- Go to the applicable website to review the information provided by the certification bodies e.g., TSSA, http://www.TSSA.org, or ASME, http://www.asme.org.
- Decide on the scope of work that will be considered in the certification process.
- Obtain the required standards.
- Form a contract with an Authorized Inspection Agency for inspection services, in Ontario TSSA, in New Brunswick Inspection Services, in Quebec Régie du bâtiment, in Alberta ABSA).
- Develop the quality manual (a written description of the quality program) and the associated procedures and forms,
- Indoctrinate and train personnel who will implement the quality program
- Prepare a demonstration item – Refer to Appendix B
- Perform an internal audit of the objective evidence generated in executing the demonstration item, as applicable to the scope of the demonstration item, and of the QA Program support activities, such as initiating a made-up NCR, and CAR (if a CAR is not issues as a result of the internal audit).

2. Application

The information with respect to making an application are usually on the websites. In Ontario the TSSA website http://tssa.org contains information under the Boilers and Pressure Vessels. A similar page is available on the ASME website http://asme.org under conformity assessment. The process for making an application falls under roughly the following headings.

- Complete and submit the Certificate of Authorization application form.
- Include the required deposit fee (as shown on the application form)
- Include a copy of your company-approved Quality Assurance Program Manual (QAM).
- All applicable supporting documentation such as the agreement between the company and an AIA

3. Assessment

The next step in the process is the assessment by the regulator of the applicant's program. The purpose of the assessment is to determine that the program proposed by the applicant has been fully implemented and conforms to the requirements of the Standard/Code. As pointed out above in the definition of Quality Assurance for the pressure boundary, the goal is to ensure "that all items designed and constructed are in accordance with the rules of this Section (Section III and in the case of Canada N285.0)"

- The assessment takes the form of a survey that includes a detailed review of the QAM with its associated documentation, implementing procedures and checklists, and includes a detailed evaluation of a demonstration item that has been constructed to the requirements of N285.0 in accordance with the applicant's QAP.

This will require an internal audit of the objective evidence generated in executing the demonstration item, as applicable to the scope of the demonstration item, and of the QA Program support activities, such as initiating a made up NCR, and CAR (if a CAR is not issues as a result of the internal audit).

A survey is very similar to an audit. Section III defines the survey as an evaluation of the whole program, while defining an audit as a limited evaluation of an aspect of the program. Although an audit, could be expanded to include the whole program.

Detail on the nature and content of a Survey are given in Appendix A and for the Demonstration Item in Appendix B.

4. Certification

A Certificate will be granted only after the applicant successfully demonstrates the adequacy and effective implementation of their quality program. In Ontario the Survey Team reports the results to the Chief Inspector who will review the results of the assessment and if acceptable will issue the Certificates of Authorization.

Certificates are valid for three years. A renewal application and applicable fees must be submitted at least three months prior the certificate expiration date to begin the certificate renewal process.

In ASME the survey reports are reviewed by the ASME Committee on Nuclear Certification (CNC). The CNC is composed of subject-matter experts who are stakeholders in the nuclear industry, including manufacturers and regulators. After the CNC reviews the report submitted by the Survey Team, they will either authorize the issuance of the Certificate or request additional action by the applicant.

5. Additional Information

Depending on the item being manufactured, the nuclear applicant may also require a Quality Assurance program that meets the requirements one of the programs/categories of the CSA N299 Series[5]. While these programs have a lot in common there may be additional information required to meet the requirements of the N299 category.

It is recommended that the additional requirements are included in a supplement to QAM of the pressure boundary program. There should also be a statement at the start of the supplement pointing out that the requirements for the N299 program are not part of the pressure boundary program and therefore are not covered by the approval signature of the nuclear inspector supervisor, who is required to approve the QAM for the pressure boundary. The guidelines for the development and implementation of the N299 Series program is given in Pamphlet No: 1 of this OCNI document.

In Appendix C, an N285.0 checklist is provided for information. This checklist is available from the TSSA website. It provides a list of the requirements that the TSSA surveys expect to be covered as appropriate by your Quality Assurance Manual. The link has been provided.

In Appendix D a list of 24 steps in the process of Certification has been provided curtesy of WAG QA Services Canada Inc.

In Appendix E, Guidelines for Nuclear Certificates of Authorization, Nuclear Scopes, Limitations, and Implementation Guide provides detailed information on the expectations of TSSA. The link has been provided.

6. References

4. **CSA Standard N285.0-17/N285.6 Series-17** General requirements for pressure-retaining systems and components in CANDU nuclear power plants/Material Standards for reactor components for CANDU nuclear power plants

5. **ASME BPVC Section III, Division 1: Subsection** NCA General Requirements for Division 1 and Division 2.

6. **CSA Standard B51:19** Boiler, pressure vessel, and piping code.

7. **ASME Nuclear Certification Handbook -** Applicant information handbook: REV. 2 NUC-FRM-19, 01/30/18.

8. **CSA Standard N299-16 Series** Quality assurance program requirements for the supply of items and services for nuclear power plants.

Appendix A

The Survey

Purpose

The purpose of the survey is to evaluate the adequacy of the applicant's quality manual to cover the scope of the activities in the companies' program, that the requirements of the governing Standards have been addressed, and that the program as set out in the manual has been effectively implemented.

The Survey consists of five segments as follows:

a. Manual Review:

The review of the program will be performed on the first day of the Survey by the Survey Team which includes the Inspector's Supervisor and the Inspector. This review will normally be held in a location remote from the applicant's facility. The review of the manual may extend on subsequent days at the applicant's facility as necessary. Pre-Survey questionnaires and manual checklists which are part of the application process will be used by the Survey Team at this time.

The Quality Program Manual programmatic controls mandated by NCA-4000 to be included in the manual are defined by the terms what, who, where, when, and how. These are defined as follows:

What: The Manual identifies the activities that affect quality in the supply of product (items/services).

Who: The Manual identifies the individual by title within the organization, at any level, that is responsible for performing the activity? This includes activities which are being delegated; the title of the delegate is to be identified.

Where: The Manual identifies the location(s) at which the activity is performed or indicates if the activity is being subcontracted to an approved supplier/vendor.

When: The Manual indicates the point of time the activity is required to be performed.

How: The QA Manual identifies the technique (planning & accomplishment) used to achieve quality, e.g., drawings, procedures, work instructions, forms, travelers and/or tags.

b. Entrance Meeting / Facility Tour:

This will be held on the second day. The entrance meeting will provide the Applicant and the Survey Team an opportunity to: introduce themselves, review the Certificates and Scopes applied for, and to establish the Survey agenda. During the entrance meeting the applicants should identify the specific personnel who will interface with the various team members to fully support a timely, effective, and efficient Survey. The survey team attempts to determine whether executive/senior management fully support the program. It is well known that unless this support from the top management is needed to ensure continued successful implementation of the program. During this meeting the Applicant may give a presentation of the company, products, personnel, etc.

c. Implementation:

The Applicant is expected to demonstrate the implementation of the Program on Code work, demonstration item(s), or a combination thereof. If any deficiencies are discovered during the Survey, they will be immediately identified to the Applicant to provide them an opportunity to correct them prior to the conclusion of the Survey.

d. Team Closed Meeting:

This meeting will be held at the Applicant's facilities prior to the exit meeting. This meeting will be attended only by the Survey Team and observers authorized by ASME. During this meeting the Survey Team will review the results of the Survey and vote on the recommendation that the team will present to the Chief Inspector of TSSA or in the case of ASME the Committee on Nuclear Certification (CNC).

e. Exit Meeting:

This meeting will be held with the Applicant's management and will review the results of the Survey. Executive/ senior management should attend the exit meeting as this demonstrates support for implementation of the program. If there were any finding issued, they will be reviewed, and the Applicant will be advised of their status. The Survey Team's recommendation to the TSSA management will be made known. The Applicant will be able to ask any questions relative or pertinent to the Survey. At the conclusion of the exit meeting the Survey is officially ended.

Appendix B

The Demonstration Item

Purpose of the Demonstration Item

The purpose of the demonstration is to allow the Applicant to provide evidence of their knowledge of requirements for each Certificate and scope being requested. All elements of the ASME Section III Program must be described in the Quality Assurance Manual or Quality System Manual and shall be demonstrated.

This means, for component manufacturers or fabricators (N-Type Certificate applicants as defined in Section III), the demonstration shall cover all the NCA-4134 requirements addressing all applicable elements of the program, including NCA-3800 and NCA-3900 as applicable. If the Applicant has no design responsibility, demonstration for design control need only establish how the applicant receives and controls customer supplied design documents. The N285.0 checklist, Appendix A of this pamphlet, illustrates how the N285,0 program has adopted NCA-4134 with any additional requirements of N285.0.

It is important to understand the role that the demonstration item fulfills in the implementation process. This role is highlighted in the point listed below. The Manual must be the Manual presently in use. For component manufactures and fabricators, (N-Type Certificate Applicants), the company's approved manual must be accepted by the Applicant's Authorized (Nuclear) Inspector's Supervisor.

1. If the Applicant proposes changes to the Manual is response to an issue raised by the Survey Team, copies of the proposed changes shall be provided for review by the Survey Team. The Applicant will be expected to demonstrate the proposed changes during the implementation portion of the Survey.

2. When the quality manual addresses multiple codes, standards, or regulatory requirements, the manual shall indicate those portions which are not applicable for the implementation of the ASME Section III Code requirements.

3. An Applicant's Quality Assurance Manual not based solely on N285.0 (NCA-4134) is acceptable only if it also includes all the controls necessary to establish compliance with N285.0 (NCA-4134) requirements. This also applies to applicants Quality System program for materials.

4. For forms exhibited in the Quality Assurance Manual or Quality System Manual, the Survey Team will find it beneficial to have the completed example forms provided for their review at the time of the Manual Review.

5. The Applicant will be required to demonstrate the implementation of their Program for each Certificate applied for. The unique features of each Certificate scope shall be

demonstrated. It is not necessary to repeat processes, when multiple certificates are called up in the application.

6. When using suppliers of subcontracted services (NCA-3125) or approved suppliers (NCA-3855), such as NDE, design activities, auditing, etc., the supplier's qualification procedure and records as required by shall be made available for review by the Survey Team at the location of the Survey.

7. All demonstrations shall be to the most restrictive Code Class to be included in the scope of the Certificate and as identified in the application. For example, applicants applying for Class 1, 2 & 3 shall provide a demonstration to the Survey Team that is based on Class 1 Code requirements.

8. Demonstrations shall not be planned to exclude any type of Code activity. Some examples of this type of activity are:

    a. An applicant using a thin-walled vessel demonstration item that takes advantage of the exemption that does not require demonstration of fracture toughness. In this case the applicant will be required to provide another demonstration item to implement fracture toughness requirements for thicker walled items, unless thick-walled items are excluded from the scope of the program.

    b. For applicants wanting to make use of the requirement for utilization of unqualified source material must demonstrate certification of material, qualification of material organizations, and approval and control of suppliers, unless excluded in the Quality Assurance Manual.

    c. For Certificate Holders with design in their scope utilizing subcontracted suppliers for design activities, these applicants shall demonstrate the requirements of NQA-1 Requirement 3 Paragraph 500, Design Verification. This demonstration activity cannot be subcontracted.

    d. For applicants Material Organization in the certificate scope, NCA-3851.2 activities shall be demonstrated, unless excluded in the Quality System Manual or Quality Assurance Manual. If in 1, 2, 3 or 4 above an activity is excluded, the exclusion statement shall include provisions to require the Certificate Holder to notify the certification body if they desire to remove this exemption from their program.

Appendix C

TSSA Checklist for N285.0 Certificate of Authorization

TSSA has a checklist that is available on their website. It details the various requirements that need to be addressed in the Quality Assurance Manual. They use this checklist in the survey to determine that the quality assurance program of the company covers the requirements of the CSA N285.0/N285.6 Standard for the activities to be undertaken by the company. These activities will be identified in the Scope of the Certificate of Authorization.

The link for this webpage is:

Manufacturers-of-Nuclear-Items.pdf (tssa.org)

Appendix D

Typical Steps in the Certificate of Authorization Process

Nos	NQS Documentation	Nos	Demonstration Sample	Nos	Internal and AIA Audits
1	QAM: Prepare & Internal Review	10	Obtain Manufacturing Design Drawing	19	Perform PB Internal Audit of the demonstration sample
2	QAM: Final Draft & Submit to AIA for review	11	Obtain Manufacturing Design	20	Process Corrective Actions
3	QAM: Update with AIA feedback	12	Purchase material from QSC supplier	21	AIA Audit
4	QAM: Final & Internal Approval	13	Purchase unqualified source Material	22	Process Corrective Actions from survey
5	QAM: Submit to AIA	14	Upgrade unqualified source material	23	AIA Verification of CARs
6	QPs: Prepare	15	Manufacture demonstration sample	24	Award of C of A
7	QPs: Internal Review	16	Subcontract welding and associated NDE, or perform in-house		
8	QPs: Final Versions & Approval	17	Receive with partial data sheet if subcontracted, or prepare partial data sheet if in-house		
9	NQS documentation roll-out, and Indoctrination & training	18	Final inspection, prepare History Docket and Records		

Appendix E

Guidelines for Nuclear Certificates of Authorization, Nuclear Scopes, Limitations, and Implementation Guide

TSSA has provided detailed information on their scope statements, listed the limitations, and provided comprehensive guidance on their expectations.

The link for this webpage is:

TSSA Guidelines for Implementation.pdf