CORRESPONDENCE MATRIX

NQSA NSQ-100 version 0

NUCLEAR SAFETY AND QUALITY MANAGEMENT SYSTEM – REQUIREMENTS
Model for quality management in design & development,
manufacturing, erection, commissioning and related services

VERSUS

10 CFR 50 Appendix B

NRC Regulations (USA) – Title 10, Code of Federal Regulations
Part 50, Domestic Licensing of Production and Utilization Facilities
Appendix B to Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

CONTENTS

FOREWORD

The objective of this document is to examine each requirement of the "NRC Regulations (USA): Title 10, Code of Federal Regulations Part 50, Domestic Licensing of Production and Utilization Facilities, Appendix B to Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants", and to identify the corresponding criteria, and associated paragraph(s) of the "Nuclear Quality Standard Association (NQSA) document: NSQ-100 (Nuclear Safety and Quality Management System – Requirements)", including comments when relevant.

0. INTRODUCTION

0.1. General – Application of NSQ-100 in the 10 CFR 50 Appx B environment

The purpose of NSQ-100 is to address the quality management in design & development, manufacturing, erection, commissioning, and related services, and its frame is based on ISO 9001:2008.

The purpose of 10 CFR 50 Appendix B is to address Quality Assurance Criteria for Licensees of Nuclear Power Plants and Fuel Reprocessing Plants, and that will be used for guidance in evaluating the adequacy of quality assurance programs in use by other Organizations involved in the design, manufacture, construction, and operation of structures, systems, and components with safety-related functions.

However, in spite of this slight difference of purpose, the Licensee and/or the other Organizations may partially or fully satisfy these 10 CFR 50 Appendix B requirements by referring to and applying NSQ-100 requirements. Comments, when relevant, are identified in the last column of the matrix in *blue coloured characters.*

It can be seen however:

- from the matrix, that Organizations, as qualified to NSQ-100, have the essential ingredients of a management system able to satisfy a customer (Licensee) working in a "10 CFR 50 Appendix B licensing environment".
- that the management system of Organizations, as qualified to NSQ-100, addresses additional, or more detailed international standard criteria, in particular requirements related to:
  - safety culture,
  - graded approach and classification of items and activities,
  - management responsibility (commitment, policies) and management review,
  - planning of product realization (project management, risk management)
  - monitoring and measurement (processes)
  - continual improvement

Note:

Some wording may have slightly different senses or definitions, when used in the two different documents. Therefore, coverage of corresponding requirements may be slightly different too.

0.2. Correspondence Matrix contents

When an NSQ-100 chapter is referred to, it has to be understood as "NSQ-100 requirements for relevant chapter" and "ISO 9001:2008 requirements for the same chapter", those requirements being sometimes clarified in the corresponding chapter and suggested good practices addressed in NSQ-100 Guidelines.

1. CORRESPONDENCE MATRIX

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	Requirements (Abstracts)		
	Introduction		
	The appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of structures, systems, and components	Title of NSQ-100 standard	*NSQ-100 is planned to apply to Organizations involved in the manufacturing and construction phases of the nuclear facility, including commissioning and related services: provisions for operating are not formally addressed*
1.	**Organization**		
	- Responsibility of the applicant for the establishment and execution of the Quality Assurance Program (QAP) - Possible delegation for the establishment and execution of the QAP - Establishment in writing of authority and duties of persons and organizations for activities affecting safety - Authority and organizational freedom, independence from cost and schedule, for persons and organizations performing QA functions, and direct access to the necessary levels of management for those assigned responsibility for QAP execution	4.2.2 Quality Manual 5.5.1 Responsibility and authority 4.1 General Requirements 5.5.2 Management representative	*Satisfactorily addressed* *Note: the "Applicant" is understood as the "Organization" involved in the scope of implementation of NSQ-100 standard*

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	Requirements (Abstracts)		
2.	**Quality Assurance Program**		
	- Establishment of a QAP consistent with the requirements of the Appendix B	4.1 General requirements 4.2.1 General 4.2.2 Quality Manual	
	- Documentation of the QAP (policies, procedures and instructions)	4.2.2 Quality Manual	
	- Identification of the structures, systems & components covered by the QAP	4.1.2 Classification of Items and Activities 4.1.3 Grading the application of quality requirements	*Satisfactorily addressed*
	- Identification of the major organizations and their function, participating in the QAP	5.5.1 Responsibility and authority 5.4.2 Quality management system planning	
	- Controlled conditions for activities affecting quality	4.1.3 Grading the application of quality requirements 7.1 Planning of product realization	*Note: Control of prerequisites is addressed through chapter 7 of NSQ-100*
	- Indoctrination and training of personnel performing activities affecting quality	6.2.2 Competence, qualification, training and awareness	
	- Regular reviews of the status and adequacy of the QAP	5.6 Management review	

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	Requirements (Abstracts)		
3.	**Design Control**		
	- Translation of the regulatory requirements and design basis into specifications, drawings, procedures and instructions	7.3.1 Design and development planning 7;3.3 Design and development outputs 4.2.3 Control of documents	
	- Inclusion of quality standards in design documents and deviations from standards are controlled	7.3.2 Design and development inputs	
	- Measures (selection & review) for suitability of materials, parts, equipments and processes essential for safety–related functions of SSC	7.3.2 Design and development inputs 7.3.3 Design and development outputs	*Satisfactorily addressed*
	- Measures for identification, control and coordination of design interfaces, including procedures for control of documents involving design interfaces	7.3.1 Design and development planning 4.2.3 Control of documents	
	- Measures for design control providing for verifying or checking adequacy of design by people other than those who performed the original design	7.3.1 Design and development planning 7.3.4 Design and development review 7.3.5 Design and development verification	*Note: Items subject to design control measures are not as detailed as in Appendix B*
	- Test program conditions, when performed in lieu of other verifications, to include testing a prototype under the most adverse conditions	7.3.6 Design and development validation 7.3.8 Design and development verification and validation testing	
	- Design control measures for design changes: to include approval by the organization that performed the original design or other designee	7.3.7 Control of design and development changes	
4.	**Procurement Document Control**		
	- Measures for suitable inclusion or reference of regulatory requirements, design bases, and other requirements (necessary to assure adequate quality), in the procurement documents throughout the supply chain - To the extend necessary, requirement for a Quality Assurance Program from contractors and subcontractors .	7.4.2.1 Content of the procurement documents 4.2.2 Quality Manual	*Satisfactorily addressed*

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	Requirements (Abstracts)		
5.	**Instructions, procedures, and Drawings**		
	Documented instructions, procedures , or drawings: - are required, in a type appropriate to circumstances, for prescribing activities affecting quality - shall be implemented - shall include appropriate acceptance criteria	4.1 General requirements 4.2 Documentation requirements	*Satisfactorily addressed*
6.	**Document Control**		
	Measures for control of the issuance of instructions, procedures , and drawings, including changes, that shall include: - review for adequacy and approval for release by authorized personnel - distribution to and use at the location of the activity - review and approval of changes by original organization or other designated responsible one	4.2.3 Control of Documents	*Satisfactorily addressed*
7.	**Control of Purchased Material, Equipment, and Services**		
	- Measures for assurance of conformity of purchased products, including provisions for source evaluation and selection, objective evidence of quality, inspection at source location, and upon delivery - Documentary evidence of conformity of purchased products shall be sufficient ..., and available, and retained at the nuclear power plant or fuel reprocessing plant site prior to installation or use	7.4.1 Purchasing process 7.4.3 Verification of purchased product	*Satisfactorily addressed* *Note: Availability and retention on plant site, of documentary evidence of product conformity, are within the plant owner's responsibility*

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	**Requirements (Abstracts)**		
8.	**Identification and Control of Material, Parts, and Components**		
	Measures for identification and control of materials, parts, and components, including partially fabricated assemblies (designed to prevent the use of defective product)	7.5.3 Identification and traceability 8.3 Control of nonconforming product	*Satisfactorily addressed*
9.	**Control of Special Processes**		
	Measures for control of special processes (welding, heat treating, non-destructive testing…) and accomplishment by qualified personnel using qualified procedures based in accordance with applicable codes and standards…	7.5.2 Validation of processes for production and service provision	*Satisfactorily addressed*
10.	**Inspection**		
	- Program for inspection of activities affecting quality is established and executed by or for the organization, to verify conformance to applicable documented criteria, for each work operation where necessary to assure quality, and performed by individuals who have not performed the activity being inspected	7.5.1 Control of production and service provision 7.5.1.3 Inspection and surveillance activities	
	- In case inspection is impossible or disadvantageous, indirect control by monitoring processing methods Is provided	8.2.4 monitoring and measurement of the product	*Satisfactorily addressed*
	- Both inspection and process monitoring be provided when control is inadequate without both	7.5.2 Validation of processes for production and service provision	
	- If mandatory, inspection hold points are indicated in appropriate documents, requiring applicant's representative for witnessing or inspecting	7.5.1.3 Inspection and surveillance activities 7.4.3 Verification of purchased product (right of access for customer and other parties for verification of conformity of the product)	*Note: Surveillance by applicant (by Hold points) is detailed in the guidelines*

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	Requirements (Abstracts)		
11.	**Test Control**		
	- Establishment and implementation of a test program, based on written procedures which incorporate the requirements and acceptance limits - Test program includes, as appropriate: -> proof tests prior to installation -> preoperational tests -> operational tests - Provisions in test procedure for assuring test prerequisites are met, test instrumentation is available and used, and test is performed under suitable environmental conditions - Documentation and evaluation of test reports	7.3.6 Design and development validation 7.3.8 Design and development verification and validation testing	*Satisfactorily addressed* *Note: Responsibility for the test program may be shared between suppliers and owner, in particular for operational tests*
12.	**Control of Measuring and Test Equipment**		
	Control, calibration, and adjustment at specified periods, of measuring and testing devices (tools, gauges, instruments, etc) shall be controlled and calibrated at specified periods	7.6 Control of monitoring and measuring equipment	*Satisfactorily addressed*
13.	**Handling, Storage and Shipping**		
	Measures established to control the handling, storage, shipping, cleaning and preservation of material and equipment, to prevent damage or deterioration of material and equipment Specification and provisions for special protective environments of particular products, when necessary	7.5.5 Preservation of product 7.5.1.3 Inspection and surveillance activities	*Satisfactorily addressed* *Note: "Special protective Environment" is not explicitly addressed*

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	Requirements (Abstracts)		
14.	**Inspection, Test, and Operating Status**		
	Measures established for (marking or other means), to indicate: - the status of inspections and tests of items - the items which have satisfactorily passed the inspection and tests (precluding inadvertent bypass) - the operating status of structures or components to prevent inadvertent operation	7.5.3 Identification and traceability	*Satisfactorily addressed*
15.	**Nonconforming Materials, Parts, or Components**		
	- Measures to control for nonconforming materials, parts or components to prevent their inadvertent use - Procedures for identification, documentation, segregation, disposition and notification to affected organizations - Review, acceptance, reject, repair of nonconforming items in accordance with documented procedures	8.3 Control of nonconforming product	*Satisfactorily addressed*
16.	**Corrective Action**		
	Measures for prompt identification and correction of conditions adverse to quality and non-conformances Measures for significant condition adverse to quality include: - determination of cause and corrective action taken to preclude repetition - documentation of identification, cause, and corrective action taken, and report to appropriate levels of management	8.3 Control of nonconforming product 8.5 Improvement 8.5.1 Continual improvement 8.5.2 Corrective action 8.5.3 Preventive action 5.6 Management review	*Satisfactorily addressed*

10 CFR 50 Appendix B		NSQ-100 CHAPTER(S)	*Comments*
§	**Requirements (Abstracts)**		
17.	**Quality Assurance Records**		
	- Maintenance of records, that include at least: -> operating logs and results of reviews -> inspection & tests -> audits -> monitoring of work performance -> material analysis - and closely related data such as: -> qualification of personnel -> procedures -> equipment - Inspection and test records identify, as a minimum: the inspector, the type of observation, the results, the acceptability and the action taken in connection to deficiencies - Provisions for identification and retrieval of records and for retention requirements, consistent with applicable regulatory requirements	4.2.4 Control of records 7.2.2 Review of requirements related to the product 7.3 Design and development 7.4 Purchasing 5.6 Management review 7.5 Production and service provision 7.5.1.3 Inspection and surveillance activities 7.6 Control of monitoring and measuring equipment 8.2 Monitoring and measurement 8.2.2 Internal audit 8.3 Control of nonconforming product 8.5 Improvement 4.2.4 Control of records	*Satisfactorily addressed*
18.	**Audits**		
	System for planned and periodic audits, performed to verify compliance with all aspects of the quality assurance program and effectiveness: - in accordance with written procedures or check lists - by appropriately trained personnel, not directly involve in the audited area - documented and reviewed by responsible management - followed-up, including re-audit of deficient areas	8.2.2 Internal Audits 5.6 Management review	*Satisfactorily addressed*