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| TITLE | **QMS REQUIREMENTS FOR THE SUPPLY OF QUALITY CLASS 2 PRODUCTS FOR NUCLEAR INSTALLATIONS** | |

## 1 PURPOSE AND SCOPE

1.1 This document prescribes Necsa's general Quality and Safety Management requirements for Suppliers of Quality Class 2 Products to Necsa's nuclear installations. Requirements specific to a particular Product are prescribed in Necsa's Procurement Documents for the Product.

1.2 Quality Class 2 Products (as identified in Necsa's Procurement Documents) are of a high safety and reliability category, and shall be manufactured in accordance with a formal quality system which gives a high degree of confidence that the items conform to specified requirements, and which provides objective evidence of such conformance.

1.3 The purpose of this document is to identify and list the requirements in RD-0034 (Quality and Safety Management Requirements for Nuclear Installations) that apply to Suppliers of Quality Class 2 Products as well as to prescribe additional Necsa requirements. (Note: The Necsa SHEQ System addresses all requirements of RD-0034, including the requirements not prescribed in this document.)

1.4 The requirements prescribed in this document shall be applied to the extent commensurate with the scope of supply specified in Necsa's Procurement Documents.

## 2 REFERENCES

2.1 This document complies with the relevant requirements of:

- RD-0034: Quality and Safety Management Requirements for Nuclear Installations

2.2 The following documents are referenced in this document:

- ASME NQA-1-2004: Quality Assurance Requirements for Nuclear Facility Applications
- ISO 9001:2008: Quality Management Systems – Requirements
- SHEQ-INS-0890: Safety Classification of Structures, Systems and Components

| | NAME | SIGNATURE | DATE |
|---|---|---|---|
| PREPARED | C J H Venter<br>CE: LD | | 2012-07-23 |
| REVIEWED | A L Visagie<br>SM: LD | | 2012-07-24 |
| ACCEPTED | I E Steyn<br>SM: SHEQD | | 27/07/2012 |
| ACCEPTED | L J Shayi<br>GE: NC&S | | 30/07/2012 |
| APPROVED | D G Robertson<br>ACTING CEO pp | | 12/08/02 |
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## 3 REVISION HISTORY

- Revision 0 – 2009/02/29 – First issue (S Venter)
- Revision 1.0 – Document reviewed to list all the RD-0034 requirements that suppliers of QCL-2 SSCs have to conform to. (C J H Venter)

## 4 DEFINITIONS AND ABBREVIATIONS

4.1 Product (ISO 9000): A product is the result of a process. (There are four generic product categories; namely: services, software, hardware and processed materials.)

4.2 Procurement Documents (RD-0034): A set of documents specifying the necessary technical information and data, process and functional requirements, environmental conditions, loads, codes and standards, as well as the QA measures for the Products to be purchased. Procurement Documents include Design Specifications.

4.3 Design Specifications (RD-0034): Documents providing the complete basis for manufacturing and construction of a Product. Design Specifications are part of the Procurement Documents of a Product and specify the required characteristics of a Product.

4.4 Supplier (ASME NQA-1): Any individual or organisation who furnishes items or services (Products) in accordance with Procurement Documents. Supplier is an all-inclusive term used in place of any of the following: vendor, seller, designer, contractor, sub-contractor, manufacturer, fabricator, consultant, and their sub-tier levels.

4.5 Approved Supplier (RD-0034): Organisation or person that provides a Product. This definition also covers sub-suppliers. An Approved Supplier has been evaluated and approved by Necsa in accordance with Necsa's requirements. (Necsa's requirements include the requirements of RD-0034.)

4.6 Quality Plan (RD-0034): A document specifying which qualified procedures and associated resources will be applied by whom and when to a specific project, product, process or contract.

4.7 The following abbreviations are used in this document:

| | |
|---|---|
| QM | Quality Management |
| QMS | Quality Management System |

## 5 QUALITY MANAGEMENT SYSTEM

### 5.1 General Requirements

i) The Supplier's QMS shall be based on ISO 9001:2008 as well as the additional requirements prescribed in this document (SHEQ-INS-0271) which is based on RD-0034. Implementation of the QMS shall be certified as ISO 9001:2008 compliant by an organisation acceptable to both Necsa and the NNR.

ii) For subcomponents or activities provided by sub-suppliers, the Supplier shall ensure that the sub-supplier's QMS is commensurate with the classification of the subcomponent or activity (importance of the subcomponent or activity for the performance of the safety functions of the SSC (see SHEQ-INS-0890)).

iii) The Supplier shall implement requirements (4) to (9) of RD-0034:

*(4) In case important-to-nuclear safety activities are outsourced by the Supplier to other suppliers / sub-suppliers, the delegating organisation must implement oversight measures for these activities to retain intelligent customer capabilities.*

*(5) Where there is collaboration between different organisations involved in the performance of design, manufacturing and/or construction tasks, responsibilities and tasks must be defined and documented. The Supplier must ensure that interfaces between these organisations are clearly specified and described.*

*(6) If the Supplier intends to introduce or accept different QM standards to those specified in this RD, a clear structure or framework must be provided in the QM manual to indicate the intended use of the standards as well as their compliance with the requirements of this RD. In such a case, the QM manual must be submitted to the NNR for acceptance prior to implementation.*

*(7) The Supplier of products important to nuclear safety must develop documents describing its management system. This set of documents must include a management system manual supported by additional documents describing the management policy, priorities, objectives and processes.*

*(8) The organisational structure, functional responsibilities, levels of authority and interactions of departments and persons responsible for managing, performing and assessing work must be described in the QM documentation of the organisation.*

*(9) The organisation must provide a description of the processes and supporting information that reflects how work is prepared, reviewed, carried out, recorded, assessed and improved.*

iv) The Supplier's QMS shall be accepted by Necsa.

## 5.2 Documentation Requirements

The Supplier shall implement requirements (18) to (22) of RD-0034:

(18) *Control measures must be established within the Supplier to ensure that all documents are complete considering relevant requirements before release. All individuals involved in preparing, revising, reviewing or approving documents must be specifically assigned this work, must be competent to carry it out and must be given access to appropriate information on which to base their input or decisions.*

*(19) The Supplier is responsible to ensure that all documents must be unambiguously marked for identification. The identification code must also contain reference to the revision status of the document. Documents of external origin must also be identified and their distribution controlled. The identification code must allow an unambiguous coordination between areas, parts, items etc. and the respective documents throughout the planning, design, procurement, manufacturing, assembly, construction, operation and maintenance phases.*

*(20) The Supplier must ensure that procedures, specifications, instructions or drawings include quantitative and/or qualitative acceptance criteria where appropriate.*

*(21) All organisations involved must be informed of any revisions of procedures, specifications, instructions or drawings without delay. The involved organisations must ensure that the use of incorrect or invalid documents is prevented within their own organisation and that the tasks are performed only in accordance with valid documents.*

*(22) The organisations must ensure that records are retained to furnish evidence of activities affecting quality and safety. These records must be readable, complete, identifiable, classified, stored and easily retrievable. Retention times of records must be defined.*

# 6 MANAGEMENT RESPONSIBILITY

### 6.1 Management Commitment

The Supplier shall implement requirements (30) to (32) of RD-0034:

*(30)* *Senior management must ensure that management systems are established, implemented, assessed and continually improved and must demonstrate its commitment to do so.*

*(31)* *The commitment of senior management of the organisation in terms of safety and quality of the products must be clearly defined and documented and must be communicated to the staff.*

*(32)* *The roles and responsibilities as well as the delegation of authority must be clearly defined within the management system of the organisations.*

### 6.2 Management Priorities, Policy and System Planning

The Supplier shall implement requirements (34) and (35) of RD-0034:

*(34)* *The senior management of the Supplier must ensure that goals, strategies, plans and objectives defined for the management system are achieved. The process must be defined in procedures.*

(35) *The validity and effectiveness of the processes affecting quality and safety of the products must be evaluated periodically by the Supplier.*

### 6.3 Management Responsibility, Authority and Communication

The Supplier shall implement requirements (40) to (45) of RD-0034:

*(40)* *The management structures, responsibilities and accountabilities for management systems must be clearly defined by the senior management of the organisation. The overall responsibility for the management system must rest with a member of the organisation's senior management.*

*(41)* *The authority and responsibilities of the persons and organisational units performing activities affecting quality and/or nuclear safety must be clearly established and defined in writing.*

*(42)* *The QM management functions must be independent from operational and line functions. The persons assigned to be responsible for the management system must be suitably qualified and experienced.*

*(43)* *Persons and/or organisations performing QM functions must be in a position to report to the management at such a level that the required assurance and oversight function is ensured. The persons and organisations performing QM functions must therefore have authority and freedom to identify and correct quality problems or safety relevant aspects and prevent repetition. They must ensure the implementation of corrective and preventive measures and verify the introduction and effectiveness of such measures.*

*(44)* *Guidelines must be defined and documented to ensure effective communication and team support allowing individuals to receive the advice, information and support they require, and to provide the necessary feedback wherever it is required.*

*(45)* *A management review process must be established within the organisation to ensure that an evaluation of the efficiency and effectiveness of the management system with respect to the requirements of this RD is done.*

## 7 RESOURCE MANAGEMENT

The Supplier shall implement requirements (46) and (47) of RD-0034:

*(46)* *The organisation must determine and provide the resources needed to carry out the activities of the organisation, and to establish, implement, assess and continually improve the management system.*

*(47) The organisation must select its personnel and must implement training programmes to ensure and maintain the required levels of qualification and experience. It must be ensured that all staff have the competence to carry out their tasks safely and effectively.*

## 8 PROCESS REALIZATION

### 8.1 Planning and Management of Processes

The Supplier shall implement requirements (52) to (55) of RD-0034:

*(52) All processes needed to achieve the quality and safety goals of the organization must be identified, and their development must be planned, implemented, assessed and continually improved.*

*(53) The interaction of the processes needed to achieve the quality and safety goals of the organization must be described and documented. The interaction between different groups of the organisation involved in a single process needs to be ensured through effective communication and clear assignment of responsibilities.*

*(54) The organisation's management must ensure the effectiveness of the implementation and the control of the processes.*

(55) *For each process a responsible person (process owner) must be determined.*

### 8.2 Licensing-related Processes

The Supplier shall prepare documents which Necsa requires for the nuclear licensing process, as prescribed in Necsa's purchase order. Such documents shall be approved by Necsa.

### 8.3 Design and Development

i) The Supplier shall perform design and development work in accordance with the codes and standards, as well as any specific QA measures, prescribed in Necsa's purchase order.

ii) The Supplier shall implement requirements (66) to (69) of RD-0034:

*(66) Design and development outputs must contain the information necessary for verification and validation to pre-determined requirements and/or design criteria. The Supplier must ensure that the outputs must be reviewed against inputs as part of a design review process to provide objective evidence that the requirements /or design criteria have been met.*

*(67) Validation of the output of the design and development processes must be performed in a controlled manner to ensure that the resulting product is capable of meeting the requirements for the specified use.*

*(68) Design control procedures must be established for verifying or checking the adequacy of design and as a basis for the performance of design reviews.*

*(69) The verification or checking process must be performed by individuals, departments or organizational units other than those who have performed the original design.*

iii) The Supplier's design process shall be accepted by Necsa. Interfaces with Necsa shall be as indicated in Necsa's Procurement Documents.

### 8.4 Procurement

i) The Supplier shall establish a sub-supplier approval process.

ii) The Supplier shall implement requirements (80) to (88) of RD-0034:

*(80) All suppliers of products important to nuclear safety must have a current quality management system appropriate to the scope of supply and must submit a product related QM confirmation issued by a certification or conformity assessment organisation, which is accepted by the NNR and the South African legal framework. The certificate / confirmation*

*must contain a statement of the scope of application, which must be appropriate to the scope of supply, and must be within its stated period of validity. Accreditation must be provided by a relevant organisation where it is required by the selected codes and standards.*

*(81) Suppliers must implement procedures to ensure that product specific requirements and any other requirements affecting the achievement of quality are clearly defined.*

*(82) The Supplier must ensure that the qualification process for sub-suppliers must include an evaluation of their ability to comply with the requirements of this RD (compliance audits) and to perform the required tasks (technical process evaluations and/or audits). The criteria for evaluation of a sub-supplier must be based on product related requirements and, as a minimum, the following aspects must be evaluated:*

- *Technical equipment*
- *Qualification of personnel*
- *Quality management system and Certification*
- *Internal and external surveillance*
- *References and product related experience.*

*(83) It must be ensured that the required reviews, tests and inspections are carried out where procurement documents and / or codes standards require an Authorised Inspection Agency (AIA) or an Independent Inspection company to undertake surveillance during the manufacturing and assembly of SSC or the construction of structures.*

*(84) The Supplier must ensure that procedures are established within its own organisation or at the sub-suppliers to ensure that purchased material, equipment and services, whether purchased directly or through suppliers, conform to the requirements specified in procurement documents. These procedures must include appropriate provisions for source evaluation and selection. Objective evidence of quality must be available covering inspections at the sub-suppliers and their sources for accessory parts and examinations of materials, parts and equipment up to delivery.*

*(85) It must be ensured by the Supplier and its sub-suppliers that materials, parts and equipment must not be used until documentary evidence is available confirming that they conform to the procurement documents.*

*(86) The Supplier and its sub-suppliers must ensure that materials, parts and equipment are inspected before use to identify any damage incurred during transport and to determine whether the delivered products conform to the procurement documents.*

*(87) The Supplier and its sub-suppliers must ensure that documentary evidence is retained confirming that products conform to the design requirements specified in the procurement documents.*

*(88) Procurement documents for material, equipment and services must include or reference the procedures and/or standards required to be applied by the Supplier.*

iii) The Supplier's process to approve sub-suppliers shall be accepted by Necsa.

8.5 **Production and Service Provision**

The Supplier shall implement requirements (95) to (106) of RD-0034:

*(95) Programmes must be established to ensure compliance with relevant requirements during manufacturing, construction and commissioning activities. Procedures must be used in these programmes and must incorporate the requirements and acceptance criteria contained in the applicable design documents and specifications.*

*(96) Special processes including welding, heat treatment, inspection and non-destructive testing must be documented and controlled at supplier level. All special processes must be performed*

*by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications or any other specific requirements or criteria.*

*(97) Procedures must be established for the identification and control of materials, parts, and components, including partly fabricated assemblies of nuclear safety important SSC at supplier level. These procedures must ensure the identification of the items, either on the item or on records traceable to the item, throughout manufacturing, construction, installation and use of the item.*

*(98) The Supplier must ensure that its identification and control procedures and that of its sub-suppliers are designed to prevent the inadvertent use of non-conforming or defective material, parts and/or components.*

*(99) A Supplier must establish a configuration management system to indicate by the use of markings such as stamps, tags, labels, route cards or other suitable means the status of inspections and tests performed upon individual items. Respective procedures must specify the identification of items which have satisfactorily passed required inspections and tests and the release process of those items.*

*(100) A Supplier must establish procedures to control the handling, storage, shipping, cleaning and preservation of materials, components and equipment to prevent damage or deterioration. Surveillance measures must be applied to ensure that the requirements regarding marking, handling, storage, transportation and packaging are met.*

*(101) A Supplier must perform in-process inspections of processed material, items or products for each work step where it is necessary to ensure quality. Where direct inspection of processed material, items or products is impossible or disadvantageous, statistical process control and/or indirect controls must be provided by monitoring processing equipment and personnel.*

*(102) Inspections must be performed at the Supplier during manufacturing and qualification of SSC by qualified organisations and individuals, other than those who performed the activity being inspected.*

*(103) Mandatory hold and/or witness points, beyond which work must not proceed without the consent of Necsa, the NNR or another authority as required by the applied standards and/or design specifications, must be specified in documents. Tests and inspections must be performed at specified hold points during, and at completion of manufacturing, assembly and construction. The production and inspection steps must be coordinated (e.g. by using an inspection sequence plan or quality plan) such that the tests and inspections are performed at a stage when the required quality characteristics can still be verified without restriction. Processes need to be defined for identification of Hold and Witness Points.*

*(104) Qualification and test programmes must be established at the Supplier to ensure the execution of all testing required to demonstrate that SSC will perform their functions satisfactorily. Procedures must be used in the test programme and must incorporate the requirements and acceptance criteria contained in the applicable design documents.*

*(105) Qualification and test procedures of suppliers must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and was used and that the test was performed under testing conditions.*

*(106) The qualification, test and inspection results must be documented, evaluated and accepted by Necsa or another authority as required by the applied standards and/or design specifications to provide assurance that test requirements have been satisfied.*

## 8.6 Control of Monitoring and Measuring Devices

The Supplier shall implement requirements (112) and (113) of RD-0034:

*(112) The Supplier must ensure that procedures are established within its own organisation and at its sub-suppliers to ensure that tools, gauges, instruments and other measuring and testing*

*devices used in activities affecting quality are properly controlled, calibrated and adjusted at specified periods to maintain specified measuring accuracy.*

(113) *The instruction documents relating to the inspection, measuring and testing equipment must specify when, how and by whom the necessary controls and calibrations must be performed, repeated and documented.*

## 9 MEASUREMENT, ANALYSIS AND IMPROVEMENT

### 9.1 Monitoring and Measurement of the Management System

2 The Supplier shall implement requirements (114) to (118) of RD-0034:

*(114) A programme for auditing and inspection of activities affecting quality and safety must be established and executed by the organisation performing the activity to verify conformance to the relevant documented procedures, instructions and drawings.*

*(115) The management system of organisations must be periodically audited to verify compliance with requirements.*

*(116) Senior management and management at all other levels in the organisation must perform self assessments to evaluate the effectiveness of the management system, and to identify areas for improvement.*

*(117) The Supplier will be subjected to audits / assessments in accordance with documented procedures and by appropriately trained personnel who do not have direct responsibilities in the areas being audited.*

*(118) The audit/ assessment results must be documented and reviewed by the management representative of the organisations responsible for the area audited. Follow-up actions, including the re-audit of deficient areas, must be taken as appropriate.*

### 9.2 Control of Non-conforming Product

The Supplier shall implement requirements (124) and (125) of RD-0034:

*(124) Procedures must be established to prevent the use or installation of materials, parts or components, which are not conforming to requirements. These procedures must define the arrangements for identification, documentation, segregation, disposition and notification to affected organisations. The process for notification, release, approval and control of non-conforming products must be clearly documented.*

*(125) Rework and repair actions must be described in documents equivalent to those on which manufacturing of the respective parts was based. These documents must be reviewed and maintained as records in the same manner as the original documents.*

### 9.3 Analysis of Data

The Supplier shall implement requirement (127) of RD-0034:

(127) *The Supplier must ensure that the sources of any data used are traceable and must be validated for the specific application. Documented records must be maintained of the source from which the data is taken and the measures introduced for its validation and verification. Data input must be part of the controlled process defined for QM.*

### 9.4 Improvement

The Supplier shall implement requirements (128) to (132) of RD-0034:

*(128) A continual process for the identification of opportunities for improvement must be implemented by the Supplier and an effective implementation of corrective actions must be ensured. The Supplier must make arrangements to support the feed back process. Work results must be reflected and considered within this enhancement process.*

*(129) Procedures must be established to ensure that conditions adverse to quality, such as failures, deficiencies, defective material, system deviations and equipment non-conformity, are promptly identified and corrected.*

*(130) For significant conditions adverse to quality, the procedures of the Supplier must ensure that the root cause of the condition is determined and that appropriate corrective action is introduced to prevent recurrence.*

*(131) The responsible management representatives of the Supplier must ensure that appropriate corrective actions are identified and introduced. The response to non-conformities must identify the objectives for improvements.*

(132) *The responsible management representatives of the Supplier must clearly define the measures to be adopted to prevent non-conformance of products or unsafe processes.*

## 10 RECORDS

No records are generated by the implementation of this document. Quality records generated by the supplier will be contained in the manufacturing datapacks of the manufactured components.