National Nuclear Regulator

Position Paper

No	Title	Rev.
PP-0012	MANUFACTURING OF COMPONENTS FOR NUCLEAR INSTALLATIONS	0

Approved: Mr. O Phillips **Date:**

Senior Manager: Standards, Authorisation, Review and Assessment

Signature:

APPROVAL RECORD

	Name	Designation	Signature	Date
Prepared By	P Bester	Special Nuclear Projects Coordinator		
Reviewed by:	T Pather	Manager: NTWP		
	T Hill	Manager: NPP		
	P Mkhabela	Functional Coordinator: Design Safety		
	A Singh	Functional Coordinator: Operational Safety		
	U Coetzee	Chief Inspector: NPP		
		Legal Advisor		
	M Europa	Principal Specialist		
Recommended for Approval By	W Leotwane	Senior Manager: CAE		

Please note: The original, signed document is retained by the Record Management.

REVISION HISTORY

Rev No.	Date Approved	Nature of Revision	Prepared by

TABLE OF CONTENTS

1 INTRODUCTION

The manufacturing of components important to safety of nuclear installations involves various parties, organisations, processes, documents and requires regulatory oversight. Interventions carried out in a procurement process for components important to nuclear and radiation safety (hereafter referred to as nuclear safety) may be identified by the applicant, designer, independent inspector (if the code or standard requires the involvement of an independent inspector) and the National Nuclear Regulator (NNR).

The fundamental safety objective as per the IAEA Fundamental Safety Principles is "*to protect people and the environment from the harmful effects of ionizing radiation"*. This is accomplished for nuclear installations by:

I. preventing accidents in nuclear installations with high confidence;
II. ensuring that, for all accidents taken into account in the design of the plant, radiological consequences, if any, would be minor; and
III. ensuring that the likelihood of a severe accident with serious radiological consequences is extremely low.

Accident prevention is the first priority and is achieved through the use of reliable components and procedures in a nuclear installation operated by personnel that are committed to a strong safety culture. The primary means of achieving safety is the prevention of accidents and this is achieved through:

a) Conservative design
b) High quality in **manufacturing**, construction and operation of the plant
c) Quality assurance of the design intent
d) Fostering a positive safety culture of individuals involved in activities that have an impact on safety of the plant

In terms of the application of the Defence-In-Depth principle in the design, construction and operation of a Nuclear Installation the aim of the first level of defence is to prevent deviations from normal operation, and to prevent system failures. This leads to the requirement that the plant be soundly and conservatively designed, constructed, maintained and operated in accordance with appropriate quality levels and engineering practices, such as the application of redundancy, independence and diversity. To meet this objective, careful attention is paid to the selection of appropriate design codes and materials, and to the control of manufacturing of components and plant construction.

The authorisation process requires amongst others that a safety assessment need to be developed by the applicant that will demonstrate the safety of the nuclear installation taking into consideration the relevant regulatory standards, requirements and criteria. The safety assessment has to be assessed by the NNR before an authorisation for construction can be granted.

The claimed characteristics of the components in the design are the basis of the construction and operational safety assessment. The NNR is therefore mandated to exercise regulatory control related to safety over the manufacturing of components. The

applicant/authorisation holder is responsible for nuclear safety and therefore has to ensure through various processes that the quality of components is verified to be commensurate to their level of safety significance. The various manufacturing oversight activities therefore have to ensure that the characteristics of the component being manufactured are consistent with the material and design specifications.

2 PURPOSE

The purpose of this document is to:

I. Define and outline the process to be followed to commence with the manufacturing of components of a nuclear installation in advance of a nuclear installation licence (NIL) for construction and/or operation,
II. Specify the NNR requirements and deliverables associated with the authorisation process,
III. Define the pre-requisites for the manufacture of components important to nuclear safety,
IV. Define actions in event on of non-compliance to the NNR requirements.

3 SCOPE

The document covers the manufacture of components important to nuclear safety and is applicable to applicants of new nuclear installation licenses.

Existing holders of a NIL wishing to manufacture new or modified components important to nuclear safety have to comply with the relevant conditions in their respective NIL relating to manufacturing and modification of the nuclear installation. These conditions should include the conditions, as referred to in 6.1.3 (iii), or equivalent. The prerequisites and conditions defined in sections 6.2, 6.3 and 6.4 of this position paper can be equally applied to existing holders of a NIL for the manufacturing of new or modified components important to nuclear safety and should be used as guidance where appropriate.

4 TERMS, DEFINITIONS AND ABBREVIATIONS

4.1 Terms & Definitions

In this document any word or expression to which a meaning has been assigned in the NNRA [1] or SSRP [2] shall have the meaning so assigned.

Term, Definition	Explanation
Authorised Inspection Authority	An organisation that is empowered by the local authority or regulatory body to provide inspection personnel and services as required by the regulations, standards or codes.
Certification	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Term, Definition	Explanation
Component	A component is a discrete element of a system and includes parts and pieces. Examples of components are wires, transistors, integrated circuits, motors, relays, solenoids, pipes, fittings, pumps, tanks and valves.
Conformity Assessment	Conformity assessment is any activity to determine, directly or indirectly, that a process, component, or service meets relevant standards and fulfils relevant requirements.
Construction	Those actions required to assemble components, parts and appurtenances to functional units at site. Those actions may include forming, machining, assembling, welding, brazing, heat treating, examination, testing, inspection, and certification of manufactured components as well as activities associated with civil works such as driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations and erection of civil structures. Construction in the context of Section 5 of the NNR Act does not include design and manufacturing of components.
Configuration	The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing installation.
Design Specifications	Documents providing the complete basis for manufacturing and construction of a component. Design specifications are part of the procurement documents and specify the required characteristics of a component.
Equipment	An all-inclusive term used in place of any of the following: appurtenances, assemblies, components, instrumentation and control devices (including software), supporting structures, subassemblies, subsystems
Fundamental Safety Functions	The Fundamental Safety Functions to be ensured for a nuclear installation will be one or more of the following three considerations: - Reactivity Control - Heat Removal - Confinement of Radioactivity The FSF are provided by single or combinations of the Safety Functions and should be determined from a hazard analysis.
Important to nuclear safety	Provide or support safety functions to ensure nuclear safety in terms of the Fundamental Safety Functions. Products important to nuclear safety are safety classified as level 1 or level 2 in accordance with RD-0034.
Inspection	Examination, measurement, testing or gauging to verify whether an item or activity conforms to specified requirements
Integrated Management System	A single coherent management system in which all the organisational processes are integrated to enable the organisation’s goals, strategies, plans and objectives to be achieved.
Intelligent Customer	The capability of the organisation to have a clear understanding and knowledge of the component or service being supplied

Term, Definition	Explanation
Item	An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, sub-assembly, subsystem, system, or unit.
Licensing document(s)	Documents to be submitted to the NNR in support of licence application, or variations to the licence, or modifications of operating nuclear installations.
Manufacturing	Those actions required to manufacture source material, components, parts and appurtenances. These actions may include forming, machining, assembling, welding, brazing, heat treating, examination, testing, inspection, and certification.
Measuring And Test Equipment	Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements.
Non-Conformance	a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.
Procurement Documents	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 components to be purchased. Procurement documents include Design Specifications.
Product	A product is the result of a material or non-material process and includes components and services.
Quality Plan	document specifying which qualified procedures and associated resources will be applied by whom and when to a specific project, component, process or contract.
Resources	‘Resources’ includes personnel, infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources.
Repair	Action on a non-conforming product to make it acceptable for its intended use.
Safety Classification System	A grading system that classifies SSC commensurate with their importance to nuclear safety.
Safety Culture	Characteristics and attitudes of organisations and individuals which ensure that, as an overriding priority, nuclear safety issues receive the attention warranted by their significance.
Safety Functions	Specific SSC functions that must be accomplished for nuclear safety at SSC level to support the achievement of a Fundamental Safety Function.
SANS 347	Standard Specification for categorization and conformity assessment criteria for all pressure equipment, SANS 347, published by the South African Bureau of Standards.
SANS 10227	Standard Specification for the criteria for the operation of inspection authorities performing inspection in terms of the Pressure Equipment Regulations, SANS 10227, published by the South African Bureau of Standards.

Term, Definition	Explanation
SANS/ISO 17020	Standard Specification for general criteria for the operation of various types of bodies performing inspection, SANS 17020, published by the South African Bureau of Standards.
(Approved) Supplier	Organisation or person that provides a component or a service. This definition also covers sub-suppliers. “Supplier” includes in principle designers and/or architect engineers. An approved supplier has been evaluated and approved by the licensee in accordance with the requirements of RD-0034 and with the licensee requirements.
Structure	Structures are the passive elements; buildings, vessels, shielding, etc.
System	A system comprises several *components*, assembled in such a way as to perform a specific function.
Testing	An element of verification for the determination of the capability of an item or SSC to meet specified requirements by subjecting the item / SSC to a set of physical, chemical, environmental, accidental or operating conditions.

4.2 Abbreviations

Abbreviation	Explanation
AIA	Authorised Inspection Authority
DoL	Department of Labour
NDE	Non-Destructive Examination
NIL	Nuclear Installation Licence
PER	Pressure Equipment Regulations
PIE	Postulated Initiating Events
QA	Quality Assurance
SANAS	South African National Accreditation System
SSRP	Regulations in terms of section 36, read with section 47 of the NNR Act no. 47 of 1999 on Safety Standards and Regulatory Practises
SSC	Structures, System and Components

5 REGULATORY FRAMEWORK

The Department of Labour (DoL) has the responsibility to regulate occupational safety under the Occupational Health and Safety Act. DoL also regulate pressurized systems and equipment both in nuclear and other conventional applications through the registration of boilers and pressure vessels, approval and regulation of approved inspection authorities, and enforcement of the regulations. There is an overlap between the roles of the NNR and the DoL as regards to regulatory oversight over any nuclear installation's design, construction, commissioning and operation in particular as it relates to pressurized systems.

Implementation of the regulatory oversight on manufacturing of component calls therefore for cooperation of the NNR with other stakeholders in regulating the manufacturing activities. Modalities for the cooperation include the establishment of cooperative agreements and advising on relevant national standards.

5.1 National Nuclear Regulator Act

In terms of the National Nuclear Regulator Act (NNR Act) [1], no person may site, construct, operate, decontaminate or decommission a nuclear installation, except under the authority of a nuclear installation licence (NIL), granted by the NNR. Any person wishing to site, construct, operate, decontaminate or decommission a nuclear installation may apply in the prescribed format to the Chief Executive Officer of the NNR for a nuclear installation licence and must furnish such information as the NNR Board requires.

Section 5 (b)(i) of the NNR Act provides that the NNR, amongst others, exercise regulatory control related to safety over the siting, design, **manufacturing,** construction, operation, decontamination, decommissioning and closure of nuclear installations, through the granting of nuclear authorizations. For this purpose the safety assessment submitted in support of the application must cover the design, siting, construction, *manufacture of component parts*, operation and decommissioning stages. The NNR assessment and inspection processes cover the design, siting, construction and manufacturing aspects as well as operation and decommissioning.

The NNR is therefore mandated to perform regulatory control over the manufacturing of components of the nuclear installation. To this end, the manufacturing of components important to nuclear safety shall not commence prior to obtaining a relevant nuclear authorisation from the NNR for applicants of new nuclear installation licenses.

5.2 Occupational Health and Safety Act (Act No. 85 of 1993)

The Occupational Health and Safety Act (OHSA) [3] provide requirements for inter alia the protection of the health and safety of persons in connection with the use of plant and machinery against hazards to health and safety arising out of or in connection with the activities of persons at work.

Section 43 of the OHS Act allows the Minister to make regulations including regulations regarding the planning, layout, construction, use, alteration, repair, maintenance or

demolition of buildings and the design, manufacture, construction, installation, operation, use, handling, alteration, repair, maintenance or conveyance of plant and machinery. This section also provides for the preventive and protective measures for major hazard installations with a view to the protection of employees and the public against the risk of major incidents.

Section 44 of the OHS Act allows for the incorporation of health and safety standards in regulations. This section is especially relevant, as it specifies the design codes and standards that may be used for components that may be used in electrical, mechanical or pressurized systems.

5.2.1 Pressure Equipment Regulations (GNR.734 of 15 July 2009)

The Pressure Equipment Regulations (PER) provides mandatory requirements for the design, **manufacture,** operation, repair, modification, maintenance and testing of pressure equipment where the design pressure of the equipment is equal to or greater than 50kPa. While there are a number of exclusions from the scope of application, the PER is applicable to nuclear pressurised equipment.

The PER specifies the **duties of manufacturers**, importers and suppliers, users and AIA and invokes the application of SANS 347 [5] in terms of categorisation and conformity assessment of pressurised equipment and the requirements of an applicable health and safety standard.

Pressurised equipment is categorised into hazard categories based on the fluid characteristics and the product of the design pressure and nominal diameter for piping or volume for steam generators and vessels. Both the PER and SANS 347 require the intervention of an AIA in the assessment of adequacy of pressurised equipment both during manufacturing and operation of the equipment.

The OHS Act defines AIA as an inspection authority approved by the Chief Inspector (DoL). The duties of the AIA for pressurised equipment have therefore to be approved by the Chief Inspector. The approval of the AIA is subject to:

I. Accreditation of AIA by SANAS in terms of ISO 17020 and SANS 10227
II. Accreditation of foreign Inspection Bodies by International Accreditation Forum (IAF) under certain conditions

The PER also requires that a certificate of manufacture be issued with a verification signature by the AIA stating compliance with PER. The importer and suppliers are required to assume the liability of the manufacturer in terms of PER.

5.2.2 SANS 347: Categorisation and Conformity Assessments

SANS 347: Categorisation and Conformity Assessments is based on the European Directive 97/23/EC also known as the Pressure Equipment Directive (PED). Changes have been made to accommodate specific requirements in the vessels under pressure regulations, renamed as the Pressure Equipment Regulations in the Occupational Health and Safety Act, 1993 (Act No. 85. of 1993). SANS 347 specifies the criteria to be used for

the categorization and conformity assessment of pressurised equipment (metallic and non-metallic) for use by but not limited to the manufacturer, users, certification bodies and AIAs.

I. Article 1. Paragraph 3.8 of the PED provides the following exclusion from the scope of the Directive: items specifically designed for nuclear use, failure of which may cause an emission of radioactivity. SANS 347 does not have a similar exclusion. This explicitly means that all pressurised equipment for nuclear use falls within the scope of its requirements.
II. SANS 347 does not however in its current form consider the particular risks and consequences posed by pressurised equipment in nuclear service.

To promote consistency in the Regulatory Framework as it relates to nuclear pressure equipment adjustments will need to be made to SANS 347 to include considerations for pressurised equipment used in nuclear service in order to ensure consistency with national requirements. An alternative is that a similar exclusion to the one in the PED needs to be included into SANS 347. This would allow a supplementary document to be drafted specifically for equipment in nuclear service.

Note: It is the NNR position that any pressure equipment intended to be used in nuclear industry shall conform to the highest level of conformity assessment requirements for the conventional pressure equipment as given in chapter-5 of SANS 347 along with the additional NNR requirements.

5.2.3 SANS 10227: Standard Specification for the criteria for the operation of inspection authorities performing inspection in terms of the Pressure Equipment Regulations

The criteria for organisations/entities performing inspection in terms of the PER are contained in SANS 17020 and SANS 10227. These criteria include the applicable administrative requirements, requirements on independence, impartiality, integrity, quality systems and confidentiality. SANS 17020 is a European standard that has been adopted for use in South Africa. It is supplemented by SANS 10227 that provides the specific accreditation criteria to meet the South African Regulatory requirements that include the approval process (of inspection authorities), the scope of activity, and the qualification requirements of personnel.

It is recognised that nuclear pressure equipment has to satisfy the existing South African regulations for pressurised equipment and that AIAs are accredited by SANAS to perform the respective assessments in accordance with the requirements of SANS 17020 and SANS 10227. The NNR agreed with DoL/SANAS as part of the PBMR licensing process an interim approach for accreditation of nuclear AIA and required amongst others compliance to the following additional requirements[1]:

I. Employ Nuclear Inspectors and at least one Nuclear Inspector Supervisor who are qualified according to ASME QAI-1:2003. This requires that Nuclear Inspectors and

[1] This agreement is relevant to the use of the ASME code only. Should any other code eg RCCM be used, the oversight process needs to follow the rules or equivalent rules of the code of choice.

Nuclear Inspector Supervisors hold the appropriate US National Board Commissions and satisfy relevant requirements of QAI-1:2003 for Inspectors and Nuclear Inspector Supervisors respectively. Documentation of satisfactory completion of these requirements has to be maintained by the AIA for NNR review.

II. Implement and maintain a documented Quality Program which satisfies the requirements ASME QAI-1:2003 as detailed in Appendix 2 of P-0694-C.

III. Perform the duties as required in ASME QAI-1:2003 and specified in Appendix 2 of P-0694-C

IV. The Inspector Supervisor plays an important role in the ASME system of inspection, ensuring the continuous competency of the Inspectors assigned to him by regular audits and other means. It is therefore required that the Inspection Agency employs both Inspectors and Inspector Supervisors.

5.3 Cooperative Agreement between NNR and DoL

The DoL has the responsibility to regulate occupational safety under the Occupational Health and Safety Act. DoL also regulate pressurized systems and equipment both in nuclear and other conventional applications through the registration of boilers and pressure vessels, approval and regulation of approved inspection authorities, and enforcement of the regulations. In accordance with the provisions of section 6 of the NNR Act, the NNR has entered into co-operative governance agreement with the DoL. The purpose of the agreement is to:

I. Ensure the effective monitoring and control of nuclear hazards;
II. Co-ordinate and minimize the duplication and procedures for the exercise of such functions; and
III. Promote consistency in the exercise of such functions.

The NNR further collaborate with the South African National Accreditation System (SANAS) on the application of standards set out in a health and safety standards incorporated in SANS 347 specifically relating to the requirements on nuclear inspection authorities and inspectors as well as on manufacturers. SANAS is the government endorsed national accreditation body. Through its accreditation process it provides formal independent third party recognition of an authoritative body's competence to carry out specific tasks within the regulatory domain. The criteria for bodies performing inspection in terms of the PER are contained in SANS 17020 and SANS 10227. Once a certificate of accreditation is achieved, approval may be conferred by the Chief Inspector to operate as an approved body if no additional requirements have been set. The NNR will perform oversight of accreditations and certifications by SANAS of the:

a) Qualification programs and records for nuclear inspectors
b) Certification processes for AIA and manufacturers
c) Certification / approval records of AIA and manufacturers

The NNR will also perform an assessment of compliance with RD-0034 requirements relating to the operator (owner) and supplier of pressure equipment as part of its compliance assurance process.

6 AUTHORISATION TO MANUFACTURE

The NNR acknowledges that certain components require long procurement and manufacturing times, so-called Long Lead time Items, and that the need may arise to start manufacturing prior to the assessment and acceptance of the safety case for construction by the NNR. Any applicant wishing to start with manufacturing of components prior to review and acceptance of the safety case has to apply for an Authorisation to Manufacture and must make provisions in the schedule for regulatory oversight and assessment prior to the start of manufacturing. It has to be noted that the subsequent assessment of the safety assessment may conclude that the chosen code or standard, material and/or design specifications are inappropriate for whatever reason.

6.1 Nature of the Application

Any applicant wishing to construct a nuclear installation and seeking to engage the NNR on the manufacturing of components for the nuclear installation in advance of the issuance of the construction licence being issued may apply to the CEO of the NNR for a nuclear authorisation to manufacture components of the nuclear installation.

6.1.1 Application of Section 21 of the NNR Act

The application of section 21 of the NNR Act is not applicable to applications of this nature.

6.1.2 Authorisation Fees

The NNR will recover costs incurred as a result of the manufacturing oversight process in the initial financial year on an hourly basis consistent with the Notice issued in terms of Section 28 of the NNR Act as may be amended from time to time. Authorization fees for subsequent financial years will be gazetted in the Notice on Fees for Nuclear Authorizations in accordance with the normal process.

The NNR will also recover all operational costs on a monthly basis incurred as a result of the process. Operational costs may include, but are not limited to, services rendered by consultants, holding of meetings (consultants or bilateral partners) and workshops, participation at audits, international conferences, procurement activities, development of NNR assessment tools, and relevant NNR capacity building initiatives.

6.1.3 Process and deliverables

i. Applicants for construction of a nuclear installation wishing to manufacture components of a nuclear installation in advance of the construction license being issued, have to submit a written application to the CEO of the NNR for a Nuclear Authorisation for the manufacturing of components
ii. On the basis of the review of the application and subsequent audit /inspection, the NNR may issue an authorisation with terms and conditions as deemed necessary.
iii. The conditions of authorization should be of a general nature (ie not component specific), for example requiring compliance to the relevant NNR requirements or standards such as the Quality and Safety Management Requirements for Nuclear Installations (RD-0034) that details the requirements of the NNR for quality and safety management systems for licensees, applicants of the nuclear installation

license, as well as for designers and suppliers involved in the design, *manufacturing*, construction and commissioning, operation, modification, and decommissioning of nuclear installations in South Africa under the NNR Act. The construction license will supersede the authorization for manufacturing by including the above conditions for manufacturing as required.

6.2 Pre-condition for authorisation to manufacture

In terms of the South African legislation and the NNR Act, any person wishing to site, construct, operate, decontaminate or decommission a nuclear installation may apply in the prescribed format to the NNR Chief Executive Officer for a nuclear installation licence and must furnish such information as the NNR Board requires.

An application for construction of the nuclear installation has to be in place and being processed by the NNR as a pre-condition for issuance of an authorization to manufacture components.

The regulatory process requires the applicant to establish and to comply with several requirements on Quality and Safety Management [8] before design, manufacturing, testing and commissioning of components important to nuclear safety can be initiated.

As part of the overall NNR requirements the applicant has to have in place a Quality and Safety Management system complying with the requirements of RD-0034 supported by various processes such as its supplier qualification and procurement processes before manufacturing can proceed. The NNR will assess the adequacy of the respective processes for manufacturing and verify the implementation thereof as part of its authorization process and before issuance of an authorization to manufacture.

6.2.1 Documents to be provided for authorization to manufacture

I. Quality and safety management documentation as required
II. Procurement process documents
III. Supplier qualification and control process documents
IV. Classification (safety, quality, seismic and environmental) process documents
V. Basic design information[2], including safety features and barriers, of the nuclear installation
VI. Site parameters postulated for the design, and an analysis and evaluation of the component design in terms of those site parameters
VII. Codes and standards process documentation
VIII. List of applicable codes and standards
IX. Detailed list of components to be manufactured, their safety classification and applicable codes and standards.
X. Detailed design of the components, or outline design specifications if design is to be performed by manufacturer.
XI. Justification of compatibility and interfaces of the components with the installation.
XII. Details of the applicants' technical resources, qualification and experience.

[2] The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations

XIII. Plan for Manufacture (at earliest availability)
XIV. Inspection and Test Plan (at earliest availability)
XV. Training and retraining requirements of the organization for the personnel engaged in manufacturing of components important to nuclear safety along with training facilities available.

6.3 Supplier and Component Qualification

As part of the safety classification process all component have to be allocated to quality classes. These quality classes are based on the safety classification of the SSC, which indicates the required level of confidence in the functioning and behaviour of the components.

The definition of the required quality assurance measures takes into account, the operational and functional requirements and nature of the components. The allocation of components to the safety and quality classes must follow a systematic approach and has to be agreed by the NNR.

The applicant must have oversight over all activities that have the potential to impact nuclear safety and all organizations in the supply chain have to maintain intelligent customer capability. The applicant will have to ensure that all suppliers of components and services implement systems and processes ensuring compliance to the NNR requirements.

6.3.1 Supplier Qualification

RD-0034 requires amongst many others that all suppliers of components important to nuclear safety involved in design, manufacturing, construction, operation and decommissioning has to be registered in an up to date list (database) of approved suppliers. These suppliers have to be categorised considering the importance of the component to nuclear safety to allow for the identification of applicable requirements. The scope and extent of supplier qualification depends on the classification of the components to be manufactured consistent with the implementation of a graded approach. Management system, and process audits where appropriate, should be performed on the suppliers as part of the supplier qualification process and to maintain intelligent customer capability.

6.3.2 Component Qualification

General requirements for the monitoring and measurement programme to be fulfilled by the applicant and its suppliers are provided in RD-0034, paragraph 11.1 “Monitoring and Measurement”. This requires an audit and/or inspection plan or quality plan to be developed and submitted to the NNR. These plans should define the hold and witness points during the manufacturing and construction processes for important to safety components. It is the aim of the NNR to observe the quality and safety characteristics of the component at specific points during the manufacturing and construction process to ensure that these characteristics (assumed in the safety assessment) are fulfilled.

6.4 Pre-conditions for manufacturing

The issues to be addressed and assessed before manufacturing should commence, other than compliance with management system and process compliance, are summarized below:

I. Safety Assessment: The applicant and the main constructor /designer as his designee have to develop a Safety Assessment that defines the design and the safety concept of the nuclear installation. The Safety Assessment further has to demonstrate that the specific component will meet its design intent under all conditions and that the design and performance criteria are met.

II. Safety and Quality Classification: The Safety Assessment defines those components that are needed to ensure that the Fundamental Safety Functions for the nuclear installation are not compromised considering the deterministic design principles such as defence in depth, ALARA and single failure criteria. For indication of the individual importance of components in terms of these criteria, a Safety Classification system has to be implemented, reflecting the consequences of component failures in terms of the specific safety functions of the nuclear installations. In addition, quality classes should be assigned commensurate with the required quality and reliability targets for the specific components.

III. Design Envelope and Load Classes: For definition of the design envelope of the nuclear installation a comprehensive evaluation of the operational states and the consequences of the Postulated Initiating Events (PIE) have to be performed to specify all operational and accidental loads and to define the design requirements for the entire life cycle of the SSC. As a basis for the design process and code application load classes need to be defined.

IV. Material Selection: Taking the design envelope and the environmental conditions into account, appropriate materials have to be selected for the SSC. Proven materials covered by standards and codes should be preferred. Potential gaps between the qualification conditions of proven materials and the nuclear installation design envelope and the environmental conditions need to be demonstrated by an appropriate Test and Qualification Programme.

V. Selection of Codes and Standards: The applicant has to specify the codes and standards for the design and manufacturing process of the SSC. The selected codes and standards have to be justified considering the design envelope and the safety and quality classification. The selected codes and standards for important to safety SSC need acceptance by the regulator.

VI. Design Specification: Provides the mechanism by which the applicant integrates its suppliers with the authorisation process and becomes the principal document governing the design and manufacturing of components. A copy of the design specification has to be available before manufacturing begins and should include amongst others the function and boundary of the component, material requirements including test to be performed, environmental conditions, component classification, code editions and code cases, and load combinations.

6.4.1 Documentation to be provided prior to manufacturing

Following the issuance of an authorisation to manufacture, the following documents[3] for the specific components have to be submitted to NNR and found to be acceptable before manufacturing[4] of that component may commence:

1. **Safety Evaluation documents**
   - I. Performance requirements and design basis
   - II. The bases, with technical justification upon which the performance requirements have been established,
   - III. The evaluations required to show that safety functions will be accomplished.

2. **Design input documents**
   - I. Design specifications
   - II. Loading catalogue
   - III. Interface documents
   - IV. Material selection report
   - V. Code justification

3. **Design documents**
   - I. Design reports
   - II. Design drawings

4. **Overall manufacturing documents**
   - I. Welding list
   - II. Quality Control Plan,
   - III. Purchase (basic design and sizing) documents and drawings
   - IV. Purchase Order and Specification

5. **Manufacturing documents of sub-supplier/s**
   - I. Manufacturing Plan
   - II. Test (NDE) procedures
   - III. Drawings

6. **Manufacturing documents of supplier**

   - I. Manufacturing sequence and schedule,
   - II. Quality Plan,
   - III. Inspection and Test Plan
   - IV. Inspection and Test procedures,
   - V. Drawings

[3] The list of documents to be provided is based on the manufacturing of typical metallic components for nuclear installations. Similar or equivalent types of documents should be provided for non-metallic, electrical and other types of components

[4] Manufacture includes those actions required to procure source materials such as forgings, plates, etc.

7 REGULATORY OVERSIGHT

The NNR Regulatory oversight during the manufacturing process involves inspections and audits on the relevant processes at the license applicant as well as its suppliers of components and services. To strengthen and optimise its regulatory oversight the NNR may also integrate (as appropriate) its inspections and audits with those of the Regulatory Authorities of the countries in which the manufacturing process is taking place.

7.1 Prior to manufacturing

The NNR will assess the adequacy of the applicants' Quality and Safety Management system supported by various processes for manufacturing as part of its compliance assurance process against the requirements of RD-0034 before issuance of an authorization to manufacture and will verify compliance to the processes on a routine basis.

7.2 Supplier Qualification

The NNR will assess, and observe where necessary, the implementation of the applicants' supplier qualification process. The NNR reserves the right to perform its own audits on suppliers if it deems it necessary. The following conditions will apply when the NNR observes audits by the applicant or its suppliers:

- The NNR is not a member of the audit team but an independent observer.
- The NNR can introduce questions for consideration during audits in advance of the audits to avoid an active role during the audit.
- The NNR will maintain independent audit records and an independent audit report.

7.3 During Manufacturing

The NNR hold and witness points during manufacturing and construction will be based on the safety classification of the SSC and the quality classification of the components. For this purpose, an inspection sequence plan or quality plan has to be developed and submitted to the NNR sufficiently in advance of these activities to allow for proper planning and interventions where necessary.

The NNR may send inspector(s) to the site of the manufacturer to perform inspections and surveillances as part of its regulatory oversight during manufacturing. The NNR inspector(s) will have the right of access to any place where licensed parts of a nuclear installation as contemplated in the licence application are present or being manufactured as well as to the relevant documents, records and persons.

Applicants should also submit manufacturer's quality and technical documents as specified in paragraph 6.4.1 supporting the procurement and manufacturing processes well in advance of the planned activities.

The NNR may adjust its participation where the codes and standards to be applied to the SSC and the implemented QA system, implements redundancies in the measurement system, such as independent inspectors, and where the effectiveness of the processes and interventions have been demonstrated.

7.4 Review of final manufacturing reports

An end of manufacturing (or assembling if appropriate) report has to be provided for components important to safety that should include as a minimum:

i. Final design report,
ii. Compliance certificate,
iii. Inspection and test results,
iv. Non-conformance reports,
v. Procurement records,
vi. Storage, transport, installation and test instructions,
vii. Operation and maintenance manuals,
viii. Operating conditions and limits, and
ix. As-built drawings.

8 REGULATORY ENFORCEMENTS

Compliance with the NNR requirements shall be ensured. In case of non-compliance, manufacturing shall be suspended and manufacturing process corrected before the manufacturing is resumed. The applicant has to inform the NNR of all non-compliances to requirements and agreed processes.

9 REFERENCES

[1] “Act No. 47 of 1999: National Nuclear Regulator Act, 1999”, published in Republic of South Africa Government Gazette, Vol. 414, No. 20760, 23. December 1999.

[2] Regulations in Terms Of Section 36, Read With Section 47 Of The National Nuclear Regulator Act, 1999 (Act No. 47 Of 1999), On Safety Standards And Regulatory Practices (Published in Government Gazette 28755 April 2006)

[3] Occupational Health and Safety Act, Act No. 85 of 1993

[4] Pressure Equipment Regulations, Regulations in terms of Section 43 of the OHSA, 2009

[5] SANS 347, Categorisation and conformity assessment criteria for all pressure equipment, 2007

[6] SANS 10227, Criteria for the operation of inspection authorities performing inspections in terms of the Pressure Equipment Regulations, 2007

[7] SANS/ISO 17020, Standard Specification for general criteria for the operation of various types of bodies performing inspection

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