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QUALITY ASSURANCE PLAN FOR GNSI CASTOR CASKS LICENSED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION (QAP)

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REVISION PAGE

Revision Status	Date	Author/ Signature	Explanation	Section/ Page
00	05.02.93	Web	First Edition	N/A
01	04.10.93	Web	Add information to address NRC comments, extention of the GNS/GNB QA Plan to Suppliers and the dedication of commercial grade items.	Miscellaneous

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INTRODUCTION

The GNS/GNB Quality Assurance System described by this Plan is established to meet the applicable requirements of the following regulations, engineering codes, and standards:

1) DIN ISO 9001 (EN 29001) Qualittssicherungssysteme. Modell zur Darlegung der Qualittssicherung in Design/Entwicklung, Produktion, Montage und Kundendienst

2) KTA 1401 - General Requirements for Quality Assurance

3) American National Standard Institute and American Society of Mechanical Engineers quality assurance program Requirements for Nuclear Power Plants (ANSI/ASME NQA-1 - 1989)

4) Title 10, Part 50 (10 CFR 50) Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants

5) Title 10, Part 71 (10 CFR 71) Subpart H - Quality Assurance Requirements for Packaging of Radioactive Material for Transport and Transportation of Radioactive Material under certain Conditions

6) Title 10, Part 72 (10 CFR 72) Subpart G - Quality Assurance Requirements for an Independent Spent Fuel Storage Installation (ISFI)

7) Title 10, Part 21, (10 CFR 21) Reporting of Defects and Nonconformances

Implementation of this Quality Assurance System is accomplished through this Quality Assurance Plan and approved written procedures.

STATEMENT OF AUTHORITY AND POLICY

It is the policy of GNS and GNB to perform all work in strict accordance with contract requirements and guidelines set forth by law. The Quality Assurance Department shall assure that the established quality assurance system as described in this plan is properly implemented and followed for the duration of all GNSI contracts for USNRC Licensed Casks by all personnel of GNS and GNB.

The authority and responsibility for the management of the GNS/GNB Quality Assurance (QA) System has been delegated to the Quality Assurance Manager. The Quality Assurance Manager has direct access to the higher management and shall have sufficient authority and organizational freedom to assure effective implementation of the quality assurance system requirements. The Quality Assurance Manager is also authorized to sign off Certificates of Conformance and Compliance.

All personnel involved in nuclear construction activities important to safety for CASTOR casks fabricated for GNSI must operate in accordance with this Plan. All personnel performing quality assurance functions shall have sufficient authority, access to work areas, and organizational freedom to:

identify quality problems

initiate, recommend, or provide solutions to quality problems through designated channels

verify implementation of solutions, and

assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

The management shall review and resolve any nonconformance or corrective action as needed that cannot be resolved by the quality assurance personnel.

Any personnel obtaining information which reasonably indicates that a product or activity of basic component supplied by GNS/GNB fails to comply with the United States of America (US) Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Nuclear Regulatory Commission (NRC) relating to substantial safety hazard, or contains a defect which would create a substantial safety hazard as defined by 10 CFR 21 shall immediately notify the management or the Quality Assurance Manager of such failure or such defect, for proper evaluation and reporting to the NRC in accordance with 10 CFR 21 or to the Customer/Owner in order for them to report the failure or defect to the NRC.

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SECTION 1.0 ORGANIZATION

1.1 SCOPE

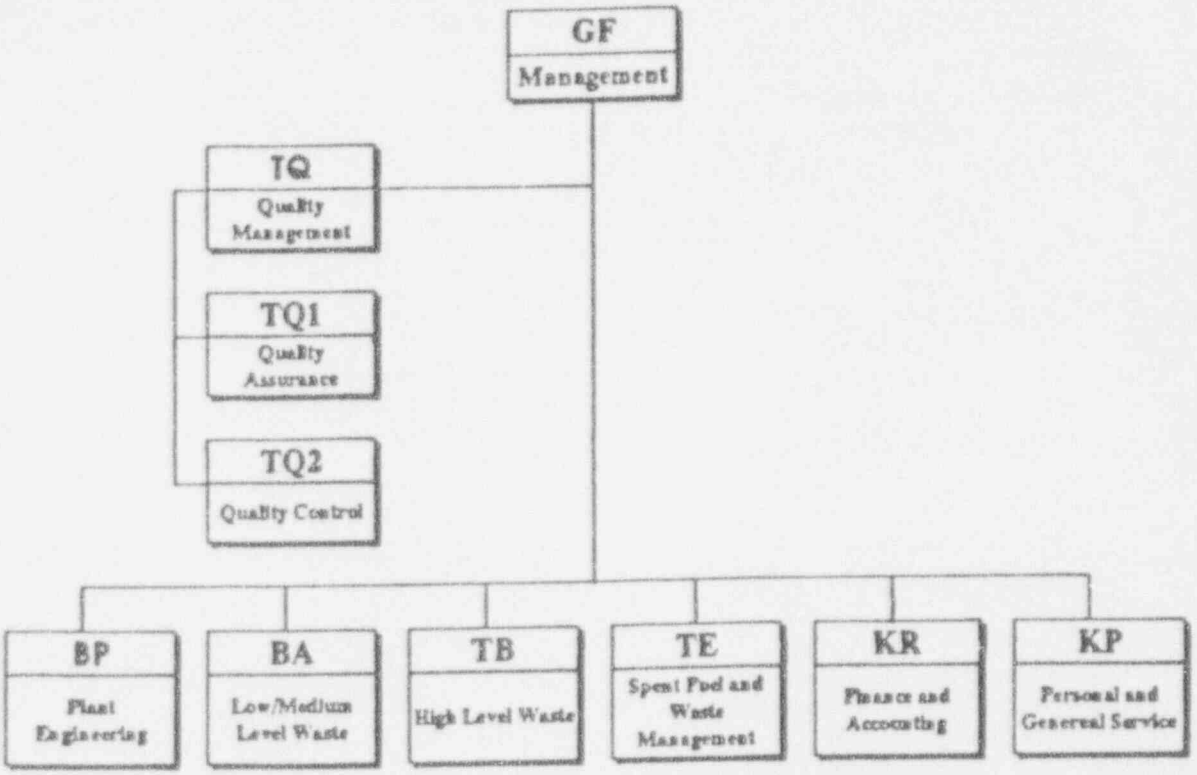
1.1.1 The GNS and GNB Functional Organization Charts are shown in Figure 1 of this section. Based on the Functional Chart, the organizational structure, levels of authority, and lines of communication for activities affecting quality are clearly established and delineated.

1.1.2 The authority and responsibility is vested with the QA organization to assure that the program is correctly and effectively executed and verified, and to assure a direct access to management at a level where appropriate action can be affected.

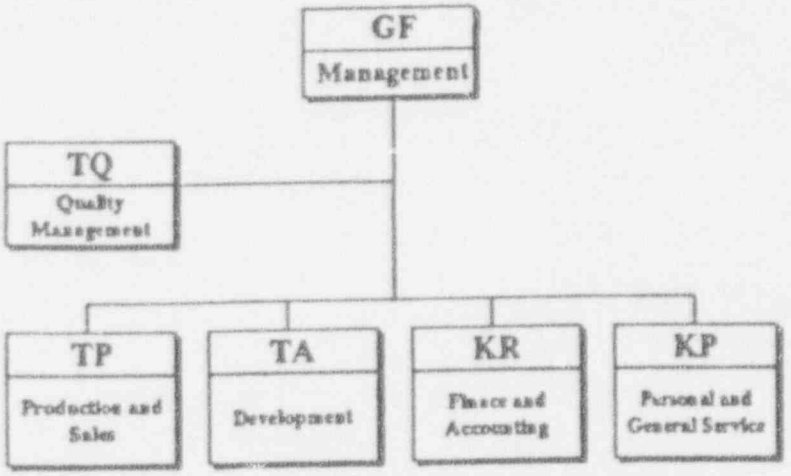
1.1.3 All Quality Assurance Department personnel shall have authority and organizational freedom, including sufficient independence from cost and schedule considerations to assure that all items are constructed in accordance with specification and contract requirements.

Figure 1 Organization Charts of GNS and GNB

Organization Chart GNS



Organization Chart GNB



1.2 DESCRIPTION OF DEPARTMENTS AND FUNCTIONS

The organization charts of GNS and GNB are given in Figure 1. The following description is limited to the main departments involved in the execution of this QAP.

1.2.1 Management GNS-GF, GNB-GF

The management bears the overall responsibility for the company and formulates, in this capacity, quality policies. It will implement the quality system and carries out reviews at regular intervals to ensure its continuing suitability and effectiveness.

1.2.2 Quality Management GNS/GNB-TQ

One particular feature of the quality policy shared by GNS and GNB is the focusing of the quality system of both companies in one department.

The quality management department (GNS/GNB-TQ) ensures the introduction and maintaining of the required quality in the planning, production, use, sale, maintenance and disposal of GNS and GNB products.

GNS/GNB-TQ deals systematically with two areas of work:

GNS/GNB-TQ1 - Quality assurance -
complies, looks after and controls the quality system of GNS and GNB. This includes the compilation, review and looking after of the quality assurance manual and the relevant, also applicable, procedures and instructions. These rule implementation of all quality assurance measures. The performance of audits and evaluation of suppliers, together with the relevant reports, the quality assurance documentation, the control of inspection, measuring and test equipment and the running of a central standards office are specialized to deal with the requirements of nuclear waste management industry.

GNS/GNB-TQ2 - Quality control -
carries out, within the framework of clearly defined quality assurance programs, preliminary, production, commissioning and repeat tests as well as administering the test equipment, all in agreement with the respective persons in charge of assignments and projects.

There are adequate means and well-trained staff to carry out quality assurance and quality control. Another area of quality management is the inspection and continuous follow-up of routines and their results.

The staff of the quality management department are independent of those responsible for the carrying out of the work to be inspected.

In addition, there is an obligation for all managerial staff mentioned in this manual to report immediately to the head of the quality management department and to the managing directors in case of fundamental incidents, in order to meet quality requirements.

Fundamental incidents are, for example, the following:

- recognizable deviation concerning adherence to the quality system,
- refusal of acceptance by customers, authorities or experts,
- complaints from customers, authorities or experts,
- recognizable quality system deviations by suppliers in carrying out projects.

The quality management department is then set the special task of evaluating the reports, propose corrective action and supervise their implementation. In serious cases, the quality management department may be obliged to cut short, in agreement with the managing directors, the carrying out of projects of handling of orders.

The managing directors of GNS and GNB have awarded the head of the quality management department unlimited authority and the responsibility of ensuring and supervising adherence to the quality assurance measures. Within this area, he has the authority to issue directives.

1.2.3 High-Level Waste (GNS-TB)

The main functions of the department GNS-TB are the handling and the transport of spent fuel, waste containing high active and other nuclear fuel, and the disposition of systems. Furthermore GNS-TB is responsible for the coordination of activities concerning licensing procedures of GNS/GNB and its subsidiary companies.

The department is split in two sections:

- GNS-TBH: Project Management and Transports,
- GNS-TBG: Licensing.

1.2.4 Production and Sales (GNB-TP)

Casks for the transport and storage of high-level radioactive waste are being manufactured by suppliers by order of GNS and GNB. Such orders are managed in the form of projects with extensive specifications:

- time schedules and cost plans,
- compilation of design and fabrication documents,
- compilation of the technical parameters for the invitation of bids and the placing of orders,
- follow-up of orders (schedules, deviations, corrections),
- guarantee of the necessary inspections, tests, and approval,
- production planning and the compilation and inspection of production documents,
- acquisition of production and installation capacities,
- control of the production steps and final inspection,
- production documentation.

The sales section (GNB-TP) analyses and registers requirements of purchasers and potential purchasers and guarantees the translation into offers meeting quality and requirements standards.

The department adheres strictly to the market conditions and the capacity planning of GNS and GNB in formulating contractual agreements.

The sales department is responsible for the entire management of orders, from acquisition and customer services to the follow-up of orders (schedules, deviations, corrections).

1.2.5 Development (GNB-TA)

The department GNB-TA is responsible for:

- the development and fabrication of transport and storage casks, handling, transport and storage equipment for fuel assemblies and high-level active residues,

- project definition, the compilation of design parameters and of the concept including licensing documents, a safety analysis report and the license in accordance with Road Traffic Legislation,
- the performance of burn-up, shielding and criticality calculations, thermal and mechanical calculations, compilation, acquisition and maintenance of program software,
- documentation,
- cask design and specifications.

1.2.6 Finance and Accounting (GNS-KR, GNB-KR)

The finance and accounting department is, like all the other technical and non-technical departments, subject to the requirements of quality management. The work includes:

- invoicing including the business administration of projects and the reports system,
- financing,
- business planning,
- the solution of business and tax-related questions,
- the ensuring of a consistent purchasing routine,
- the coordination and control of purchasing activities of goods and services for GNS/GNB and its subsidiaries.

1.2.7 Personnel and General Services (GNS-KP, GNB-KP)

The scope of responsibility of the personnel department has essentially been designed to meet quality requirements:

- personnel planning with permanent analysis of potential and improvement of the staff structure,
- personnel deployment and service,
- development of personnel including performance and potential evaluation,
- junior staff planning, training measures.

SECTION 2.0 QUALITY ASSURANCE PROGRAM

2.1 SCOPE

2.1.1 This program is implemented through this plan and approved written procedures, instructions and drawings.

2.1.2 The Quality Assurance Program as described in this Plan is established to:

A. Include consideration of the technical aspects of the activities affecting quality.

B. Provide control over activities affecting quality to an extent consistent with their importance.

C. Provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions shall include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that the prerequisites for given activity have been established.

D. Provide for any special controls, processes, test equipment, tools, and skills to attain required quality and for necessary verification of quality such as by inspection or test.

E. Provide indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

F. Assure management personnel implementing the program, or portions thereof, assess regularly the adequacy of the program and assure its effective implementation.

2.2 RESPONSIBILITIES

2.2.1 GNS/GNB performs the functions of contracting with and furnishing materials to suppliers for which GNS/GNB retains overall responsibility. GNS/GNB accepts overall responsibility for the construction of items and services important to safety for which manufacturing and provision is subcontracted to GNS/GNB approved suppliers.

2.3 CONTROL AND DISTRIBUTION OF THE QUALITY ASSURANCE PLAN

2.3.1 The master copy of this Quality Assurance Plan and all previous revisions shall be maintained and controlled by the Quality Assurance Manager. Issues of controlled copies have assigned control numbers and their issuance is recorded on the distribution list maintained by the Quality Assurance Manager. This list reflects the assignment of the QAP, the date issued, and the date acknowledged. Controlled copies of the QAP shall be distributed only to GNS/GNB personnel, suppliers, and the customer when required. Transmittal letters and written confirmations shall be used for issuance for controlled QAP.

2.3.2 Non-controlled QAPs may be issued by the Quality Assurance Manager and shall be current when assigned, but will not be maintained or audited. A "QAP Distribution List" shall be kept for information purposes on the issuance of non-controlled QAPs.

2.4 REVISIONS TO THE QUALITY ASSURANCE PLAN

2.4.1 All QAP revisions shall be reviewed and approved in the same manner as the original issue.

2.4.2 The revision page shall show the appropriate section revision level and date of revision. All revised sections shall be issued with the revised Table of Contents and cover page indicating Management approval of the Quality Assurance Manager. The QAP revision level shall be that shown on the revision page and cover page.

2.4.3 Approved revisions shall be distributed to controlled QAP holders using the transmittal letter. The letter contains instructions to insert revised sections into the plan and is to be acknowledged. If this acknowledgement has not been received, the Quality Assurance Manager shall perform a follow-up and corrective action may result. Records of distribution and acknowledgements shall be maintained by the Quality Assurance Manager on the QAP Distribution List.

2.5 INSTRUCTION, TRAINING, AND QUALIFICATION OF PERSONNEL

2.5.1 Instruction, training, and qualification of personnel shall be established to assure that suitable proficiency is achieved and maintained. GNS/GNB shall provide instruction, training, and qualification of personnel. All personnel performing activities that affect quality or are important to safety shall be properly trained and qualified prior to their performance of such activities.

2.5.2 The Quality Assurance Manager shall be responsible for carrying out the objective to the extent necessary to assure that all phases of implementation of the QAP are used for continued compliance to contract requirements. Qualification for the position of Quality Assurance Manager shall be as follows:

A. A bachelor's degree in a technical field or equivalent.

B. At least six years of experience in engineering or manufacturing.

C. A working knowledge of applicable quality-related codes and regulatory requirements.

D. The ability to prescribe, apply, and assess compliance with the applicable requirements.

E. Effective in oral presentation and written communications.

2.5.3 All employees whose duties will affect quality assurance functions within the scope of this QAP shall be indoctrinated to the extent necessary by their respective Manager and/or Supervisor to assure full understanding as to the importance of this program.

2.5.4 Seminars and training courses offered by schools, professional organizations, suppliers, and other educational institutes, may be utilized to train personnel to assure continued competence in their performance of duties.

2.5.5 Additional instruction and training shall be provided when:

A. The QAP is extensively revised.

B. Employees change their area of responsibility.

C. New employees are hired.

2.5.6 Written records documenting meetings, indoctrination, and training described in this section shall be prepared by the responsible Department and kept by the GNS/GNB-KP or GNS/GNB-TQ. These records shall contain the following information as a minimum.

A. Date

B. Subject

C. Attendees

D. Instructor/Trainer

2.5.7 QA auditing personnel shall be appointed and qualified by the QA Manager on the basis of their education, prior training, and background of work experience. If necessary, additional courses of instruction or training shall be performed to ensure a level of competence to evaluate the object presented for audits.

2.5.8 All personnel performing special processes such as welding, nondestructive examination, heat treating, shall be qualified and trained by GNS, GNB, or their suppliers in accordance with specified requirements. Training and qualification records shall include test results and shall be kept in the GNS/GNB QA files or in the files of concerned suppliers.

2.6 MANAGEMENT ASSESSMENTS

2.6.1 The Quality Assurance Manager shall schedule a meeting at least yearly to review the adequacy of the QAP. The meeting, at which the overall effectiveness of the QAP will be discussed, shall be attended by the Quality Assurance Manager and the Management of GNB-TP and GNB-TA as a minimum. The discussion and results of the meeting shall be documented.

SECTION 3.0 DESIGN CONTROL

3.1 SCOPE

3.1.1 This section describes methods and procedures to be used:

- to accurately translate requirements of the purchase order and design specification into drawings, design reports, instruction, and procedures to be used for construction;
- to assure that all required quality standards are included in design documents;
- translation of requirements to design documents are verified by persons other than those who designed the item; changes to design documents are controlled in exactly the same manner as the original document was prepared.

3.2 DEFINITION, INITIATION, AND COORDINATION OF ACTIVITIES

3.2.1 Production and sales (GNB-TP) shall define and establish in writing what activities are to be carried out by the several technical areas and what documents are to be prepared. Design (GNB-TA) shall be responsible to see that the persons and offices involved have all the applicable design bases, regulatory requirements, limits, quality standards, and other contract requirements, during the performance of their work.

3.3 REVIEW OF PURCHASE ORDER AND DESIGN SPECIFICATION

3.3.1 The purchase order and design specification shall be reviewed for adequacy with respect to technical, quality, and regulatory requirements.

3.3.2 The Production and Sales (GNB-TP) shall be responsible for having the purchase order and design specification reviewed for technical requirements. The Quality Assurance (GNS/GNB-TQ) shall be responsible for the review of these documents for quality assurance requirements.

The review shall be documented on the "Checking of Customer's Order Documents" and returned to GNB-TP.

3.3.3 The Engineering Development and Design (GNB-TA) shall be responsible for the selection of suitable materials, parts, equipment, and processes to be used for items important to safety. (GNB-TA) shall also assure that material, parts, and equipment which are standard, commercial (off the shelf), or which have been previously approved for a different application are reviewed and justified for suitability prior to selection or use.

3.3.4 GNB-TA shall inform the external bodies about conflicts or ambiguities of the Design Specification with respect to the applicable codes and contract found during the review of the specification and contract documents.

3.4 REVIEW OF PURCHASE CHANGE ORDER AND DESIGN SPECIFICATION REVISIONS

3.4.1 All design change orders and revisions to the design specifications shall be reviewed for scope, technical, certification, and Quality Assurance in the same manner as the original issue. Reviews shall be documented on the "Checking of Customer's Order Documents".

3.5 DEVELOPMENT OF DESIGN DOCUMENTS

3.5.1 All design documents shall be developed in accordance with the requirements defined by the purchase order, design specification, and revisions thereof. Design documents shall include required quality standards or reference appropriate quantitative and qualitative acceptance criteria for determining that the items have been satisfactorily accomplished.

3.5.2 Design documents shall be developed and approved by GNB-TA as follows:

A. Applicable design inputs such as design bases, performance requirements, regulatory requirements, codes, and standards specified shall be identified in the Design Document. Appropriate quality standards shall be identified.

B. Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analysis and verify the adequacy of the results.

Calculations shall be identifiable by subject (including part, structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.

C. Documentation of design analyses shall include, as applicable, the following:

- Definition of the objective of the analysis;
- Definition of design inputs and their sources;
- Results of literature searches or other applicable background data;
- Identification of assumptions and indication of those that must be verified as the design proceeds;
- Identification of computer calculations affecting safety or quality of the product, including computer type, code or programming, inputs, outputs, and code or program validation;
- Review and approval.

3.6 INDEPENDENT REVIEW (CHECKING) OF DESIGN DOCUMENTS

3.6.1 An independent review of the design documents shall be performed. The individual or group not responsible for the development of the original design shall be responsible for reviewing the documents for conformance with the design Specification, and applicable code. This independent review shall be documented e.g. in the "Document Routing Slip Form" by the reviewer's sign-off.

3.7 CUSTOMER APPROVAL OF DESIGN DOCUMENTS

3.7.1 After the development and internal approval of design documents and revisions thereof, GNB-TA through GNB-TP shall submit the documents to the external bodies for approval, when required by the contract.

3.8 REVISIONS TO DESIGN DOCUMENTS

3.8.1 No design documents shall be revised without prior authorization of GNB-TA. This authorization is defined as an approved "Change Notice". All approved and completed "Change Notice" forms shall be kept at the GNB-TP office after revision of design documents. Each revision shall be made readily distinguishable on the documents.

3.8.2 Revisions to design documents shall require the same approval, independent review, and certification cycle as the original issue.

3.9 DISTRIBUTION OF DESIGN DOCUMENTS

3.9.1 All design documents shall be distributed and controlled in accordance with Section 6.0 DOCUMENT CONTROL.

SECTION 4.0 PROCUREMENT DOCUMENT CONTROL

4.1 SCOPE

4.1.1 This section describes procurement of items, parts, and services and the manner in which suppliers are qualified by GNS/GNB. The manner in which purchases are made is described and the responsibilities for each activity delineated.

4.2 SELECTION AND QUALIFICATION OF SUPPLIERS

4.2.1 Suppliers are selected, and if required, qualified by means of an on-site survey by a qualified quality assurance auditor using a checklist developed and controlled by GNS/GNB-TQ for assurance that they have an acceptable quality assurance program or procedure consistent with the applicable requirements and provisions for maintaining the program (according to the list of sets of regulations in the chapter "Introduction" of this manual). Suppliers maybe approved to perform work under the GNS/GNB QA Plan, provided the necessary interface controls and source verifications are established in the work controlling documents (e.g., purchase orders, FPPs, etc.). GNS/GNB-TQ shall evaluate the acceptability of the supplier from the documented Survey Report and when accepted, place the supplier on the "List of Approved Manufacturers and Vendors".

Source Surveillance or inspection may be used to extend GNS/GNB's QA Plan to a non-qualified supplier. The source surveillance or inspection presence at the suppliers facility extends the GNS/GNB QA Plan, including the provisions of 10 CFR 21, over activities surveilled or inspected by GNS/GNB TQ. Suppliers covered under this provision will be added to the "List of Approved Manufacturers and Vendors" with the necessary interface controls and source verifications established in the work controlling documents (e.g. Purchase Orders, FPPs, Inspection and Surveillance Plan, etc.).

4.2.2 All material, items, and services procured as important to safety shall be procured from suppliers listed on the "List of Approved Manufacturers and Vendors".

4.2.3 Materials, items, and services may be procured as commercial products and dedicated as important to safety. Development (GNB-TA) shall identify the critical characteristics and the

method(s) (e.g., special tests and inspections, commercial supplier survey, source verification, and/or acceptable supplier/item performance record) to be used to dedicate the materials, items or services. Quality Assurance (GNS/GNB-TQ) shall concur with the method of dedication.

4.2.4 Suppliers of products procured as important to safety shall be audited at least once every three (3) years during the interval in which the material or service is being controlled. Special audits may be performed when an area or activity of the supplier is suspected to be deficient or inadequate. A documented assessment of each supplier's quality performance shall be completed every year in which that supplier is not audited.

This audit shall be performed in accordance with Section 18.0 AUDITS.

4.2.5 The "List of Approved Manufacturers and Vendors" shall be maintained by GNS/GNB-TQ and distributed to GNS/GNB-KR and GNB-TP. The List shall be updated and redistributed any time a supplier is added or deleted by GNS/GNB-TQ.

4.3 PURCHASING PROCEDURE

4.3.1 GNB-TP shall be responsible for the preparation of purchase requisitions. The purchase requisition shall specify technical and quality requirements and be prepared to include drawings, specifications, and instructions that describe the item, parts, or services to be furnished.

4.3.2 The purchase requisition shall state the scope of work to be furnished and shall contain the following information as applicable:

A. Project name

B. Quantity and description of each item

C. Codes and standards applicable to contract

D. Material requirements and additional requirements including those not referenced in material specification

E. Examination, testing, and inspection requirements

F. Submittal record and documentation requirements

G. Necessary design drawings to applicable revisions

H. Requirements for submittal of process procedures

I. Special handling, storage, or shipping requirements

J. Provisions for audit and inspection, right of access by the GNS/GNB and its external bodies it requested

K. Submittal of Construction Plan, when required

L. Whether the item is "important to safety"

M. Whether 10 CFR Part 21 applies

N. Requirements for reporting nonconformances with recommended dispositions of "repair", "use-as-is", or "scrap" (when materials have been furnished by GNS/GNB).

4.3.3 Upon completion of a quality related purchase requisition, Quality Assurance (GNS/GNB-TQ) shall review the requisition. This review shall determine that quality requirements are correctly stated, inspectable and controllable, and that acceptance and rejection criteria are adequate. Approval shall be documented by sign-off on the purchase requisition prior to issue.

4.3.4 After review by (GNS/GNB-TQ), the Purchasing (GNS/GNB-KR) shall prepare the purchase order. The purchase order shall contain all information supplied on the (GNS/GNB-TQ) approved purchase requisition.

4.3.5 The purchase order shall be reviewed by (GNB-TP) and shall be approved by authorized personnel prior to issue by Purchasing (GNS/GNB-KR).

4.4 CHANGES AND REVISIONS TO PURCHASE DOCUMENTS

4.4.1 Changes and revisions to purchase documents shall be handled in the same manner as the original issue.

4.5 FOLLOW-UP DELIVERIES

4.5.1 Inquiries and purchase order for follow-up deliveries according to approved documents may be performed without any new test run by the processing department.

SECTION 5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 SCOPE

5.1.1 This section describes the manner in which instructions, procedures, and drawings are prepared, reviewed, and accepted or approved by GNS/GNB and external bodies. Instructions, procedures, and drawings shall include or reference appropriate quantitative and qualitative acceptance criteria for determining that the prescribed activities have been satisfactorily accomplished.

5.2 DRAWINGS

5.2.1 Drawings are developed and approved in accordance with Section 3.0 DESIGN CONTROL.

5.3 PROCESS AND TEST PROCEDURES AND INSTRUCTIONS

5.3.1 GNB-TA shall be responsible for the preparation and qualification (if necessary) of all required process and test procedures and instructions.

A. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying of checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse conditions.

B. Design control measures shall be applied to items such as the following: criticality analysis, stress, thermal, and accident analysis; compatibility of materials; accessibility for maintenance and repair; and the delineation of acceptance criteria for inspections and test.

5.3.2 All procedures and instructions after preparation shall be reviewed and approved by GNB-TA, GNB-TP, and GNS/GNB-TQ. NDE procedures shall be reviewed and approved by a qualified Level III NDE personnel.

5.3.3 GNS/GNB suppliers may also prepare all necessary procedures and instructions which shall be submitted to GNS/GNB for acceptance. NDE procedures shall be approved by a supplier or GNS/GNB qualified Level III NDE personnel. The GNB-TA, GNB-TP, and GNS/GNB-TQ shall be responsible for the review of suppliers' procedures and instructions.

5.3.4 Procedures and instructions approved by GNS/GNB shall be submitted to the customer through GNB-TP, if required by the contract.

5.3.5 Any revision to procedures and instructions shall be reviewed and approved in the same manner as the original issue.

Process procedures and instructions may include:

A. Welding procedure specifications including procedure qualification records

B. Nondestructive examination (NDE) procedures

C. Heat treatment procedures

D. Bending and forming procedures

E. Repair procedures

F. All other procedures for special process such as cleaning, sandblasting, painting, packaging, and shipping

5.3.6 Test procedures shall include, as applicable:

A. Final inspection (e.g. Pressure Test)

B. Performance Test

C. Leak Test

D. Instrumentation Test

E. All other test procedures required under the contract

5.4 INTERNAL OPERATING PROCEDURES (IOP)

5.4.1 Internal Operating Procedures, when required, shall be prepared, checked, approved, and issued, provided they do not negate any requirements of this manual.

5.4.2 All internal operating procedures or instructions shall be reviewed by the department issuing the procedure and GNS/GNB-TQ.

5.5 DISTRIBUTION AND CONTROL OF INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.5.1 All instructions, procedures, and drawings shall be distributed and controlled in accordance with Section 6.0 DOCUMENT CONTROL.

5.6 FABRICATION AND QUALITY CONTROL PLANS

5.6.1 GNB-TP or suppliers shall prepare a fabrication and quality control plan prior to manufacturing of the item. The fabrication and test sequence plan (Fertigungs und Prüffolgeplan, FPP) shall be reviewed by GNS/GNB-TQ prior to use. GNS/GNB-TQ shall also assign required witness points and hold points on the plan during the review.

SECTION 6.0 DOCUMENT CONTROL

6.1 SCOPE

6.1.1 This section describes the issuance, approval, distribution, retention, and maintenance of drawings, reports, procedures, and QA related documents applicable to the construction of items and services important to safety. All documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed.

6.2 LIST OF DOCUMENTS

6.2.1 For each contract, GNB-TP prepares a "List of Documents" which enumerates all technical and quality documents applicable to a contract. The "List of Documents" shall state the title, identification number, and revision level. The "List of Documents" shall also include distribution status of documents and approval status by customer.

6.2.2 The "List of Documents" shall be prepared after a contract or order is accepted by GNB-TP. At this time, the order or contract include the customer supplied documents on which the contract will be based. The customer supplied documents are specifications, drawings, and other related requirements.

6.2.3 After completion and checking of the documents required for a contract in accordance with Section 3.0 DESIGN, GNB-TP will include the "Checking of Customer's Order Documents" into the "List of Documents".

6.2.4 When documents included in the "List of Documents" are revised, the "List of Documents" shall be revised to reflect the status of documents. The revised "List of Documents" shall indicate the new date of issue and new revision level.

6.2.5 GNB-TP shall distribute the "List of Documents" and all revisions thereof to GNB-TA and GNS/GNB-TQ.

6.3 STORAGE AND DISTRIBUTION

6.3.1 GNB-TP shall receive and keep customer supplied documents and shall distribute copies of the documents to GNB-TA if required, and GNS/GNB-TQ.

6.3.2 All master copies of documents prepared by GNS and GNB shall be kept by the department which prepares and revises the documents until the completion of the contract. The department which prepares and revises the documents shall assure that approved changes are included in documents before implementing the changes and that documents are available where work is to be done before the work is initiated. The office which prepares and revises the document shall also be responsible for internal distribution of documents. GNB-TP shall be responsible for transmittal of GNS/GNB documents to the customer.

6.3.3 Documents shall be released by GNS/GNB to external offices by GNB-TP. The documents shall be properly stamped and transmitted. One of the following stamps shall be used.

A. For Information Only

B. Released for Quotation

C. Released for Construction

6.3.4 After termination of the contract, all original documents shall be collected and properly stored by GNB-TP. Lifetime records will be sent to GNSI for retention.

6.4 OBSOLETE DOCUMENTS

6.4.1 Obsolete documents distributed to personnel and suppliers shall be destroyed or marked "VOID".

SECTION 7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 SCOPE

7.1.1 Control of purchased material, items, and services to assure conformance with specified requirements shall be accomplished by GNS/GNB-TQ or by the GNS/GNB supplier. GNS/GNB selection and qualification of suppliers shall be in accordance with Subsection 4.2 of this Quality Assurance Plan. GNS/GNB shall review the documentary evidence that material and equipment conform to the procurement requirements. The GNS/GNB supplier shall implement this control in accordance with his quality assurance program which has been evaluated and accepted by GNS/GNB, or in accordance with the GNS/GNB QA Plan.

7.2 RESPONSIBILITIES

7.2.1 GNS/GNB-TQ shall verify that control of purchased material, equipment, and services to assure conformance with specified requirements are performed in accordance with the supplier's quality assurance program.

7.2.2 GNS/GNB may procure materials in accordance with Section 4.0 PROCUREMENT DOCUMENT CONTROL which are shipped directly to the supplier's facilities from the material supplier. GNS/GNB will provide an unpriced copy of the purchase order and referenced documents to the supplier for his use in receiving inspection and acceptance of the purchased item.

SECTION 8.0 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS

8.1 SCOPE

8.1.1 Identification and control of material, parts, and components to assure that only correct and accepted items are used or installed, shall be accomplished by the GNS/GNB supplier. The GNS/GNB supplier shall implement the required identification and control in accordance with his quality assurance program which has been accepted by GNS/GNB.

Identification requirements shall be determined during generation of specifications and design drawings. Identification of materials and parts for safety-related systems or components shall

be traceable to the appropriate documentation, such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and certified material test reports.

8.2 RESPONSIBILITIES

8.2.1 GNS/GNB-TQ shall verify that identification and control of material, parts, and components to assure that only correct and accepted items are used or installed, are performed in accordance with the supplier's quality assurance program.

SECTION 9.0 CONTROL OF SPECIAL PROCESSES

9.1 SCOPE

9.1.1 Special processes that control quality such as those used in welding and heat treating shall be performed by the supplier's qualified personnel, using qualified procedures.

9.1.2 Special processes that verify quality such as those used in nondestructive examination (NDE) shall be performed by GNS/GNB or the supplier's qualified personnel using approved procedures.

9.2 PROCEDURES

9.2.1 All procedures and instructions used in controlling special processes shall be prepared, approved, and controlled in accordance with Section 5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS and Section 6.0 DOCUMENT CONTROL.

9.3 PERSONNEL QUALIFICATION

9.3.1 All personnel performing special processes shall be qualified and trained by GNS/GNB or the supplier in accordance with specified requirements.

A. NDE personnel shall be qualified in accordance with German Association for Nondestructive Testing (DZGfP or customer accepted equivalent) and/or American Society of Nondestructive Testing (ASNT) recommended practice SNT-TC-1A.

B. Welders shall be qualified in accordance with German Welding Code and Standards (DIN), American Society of Mechanical Engineers (ASME) Pressure and Vessels Code Section IX, or American Welding Society (AWS) Welding Code AWS D1.1 or customer accepted equivalent.

9.4 RESPONSIBILITIES

9.4.1 GNS/GNB-TQ shall verify that the control of special processes is performed in accordance with the GNS/GNB or the supplier's quality assurance program and procedures.

SECTION 10.0 INSPECTION

10.1 SCOPE

10.1.1 This section describes the method used by GNS/GNB to assure and verify compliance by the supplier with his quality assurance program, contract specifications, purchase orders, and

drawings. Inspection of construction by the GNS/GNB in no way relieves the supplier of his responsibilities for compliance with the above documents.

10.1.2 If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.

10.2 RESPONSIBILITIES

10.2.1 GNS/GNB-TQ shall be responsible for planning and establishing the quality assurance interface with the supplier.

10.2.2 The supplier through his approved quality assurance program shall be responsible for the execution of all inspections that are required by the contract specifications, purchase orders, and drawings. Inspection methods to be employed and characteristics to be inspected shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

10.2.3 GNS/GNB retains the responsibility for the completed item through construction surveillance, inspection, and the witness/hold point program described below.

10.3 WITNESS/HOLD POINT PROGRAM

10.3.1 The supplier shall be required, by the purchase order, to submit a fabrication and test sequence plan to GNS/GNB. The GNS/GNB-TQ shall determine witness/hold points for GNS/GNB. A copy of the fabrication and test sequence plan shall be kept in the GNB-TP for coordinating purposes. When required, the GNB-TP shall submit the plan to the customer for his review and assignment of customer witness/hold points.

10.3.2 The fabrication and quality control plan with GNS/GNB assigned hold and/or witness points shall be transmitted to the supplier for incorporation into his planning. The GNS/GNB customer's hold and/or witness points shall also be incorporated when required.

10.3.3 Hold points designated by the GNS/GNB may be waived only by written consent of GNS/GNB-TQ.

10.4 CONSTRUCTION SURVEILLANCE

10.4.1 The GNS/GNB-TQ shall be responsible for surveillance of construction to assure compliance with the supplier's quality assurance program and purchase order requirements. The Quality Assurance Manager shall assign qualified personnel to perform the surveillance activity.

10.4.2 In-process and final inspection shall be documented by the designated person conducting the inspection by stamping or signing the appropriate space in the fabrication and test sequence plan.

SECTION 11.0 TEST CONTROL

11.1 SCOPE

11.1.1 This section describes the test required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service.

11.2 RESPONSIBILITIES

11.2.1 GNS/GNB shall be responsible for specifying the tests required by the Design Specification to be performed on items and components.

11.2.2 GNS/GNB shall supervise all these tests being performed.

11.2.3 When required by the Contract, the Customer or his representative shall be offered the opportunity to witness all the required tests.

11.3 TEST METHODS, PROCEDURES, AND EVALUATIONS

11.3.1 All tests such as structural integrity test, leak test, functional test, instrumentation test, etc., shall be performed by qualified personnel in accordance with applicable test procedures prepared and approved in accordance with Section 5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS.

Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

11.3.2 All measuring and test equipment to be used for testing shall be properly maintained and calibrated in accordance with the supplier's quality assurance program.

11.3.3 All testing shall be conducted by the supplier and shall be supervised by a representative of GNS/GNB designated by GNS/GNB-TQ. Results of test shall be documented and shall be evaluated by GNS/GNB, and when required, by customer for acceptance.

11.3.4 All inspection and test records shall contain the following information as applicable:

A. A description of the type of observation

B. The data and results of the inspection or test

C. Information related to conditions adverse to quality

D. Inspector or data recorder identification

E. Evidence as to the acceptability of the results

SECTION 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 SCOPE

12.1.1 Control of measuring and test equipment to maintain accuracy within necessary limits shall be accomplished by GNS/GNB suppliers. GNS/GNB selection and qualification of suppliers shall be in accordance with Subsection 4.2 of this QAP. The GNS/GNB supplier shall implement his control of measuring and test equipment in accordance with his quality assurance program which has been accepted by GNS/GNB.

12.1.2 GNS/GNB's own measuring and testing devices are, if not standardized elsewhere, calibrated at least once within a period of two years and checked and documented by GNS/GNB-TQ.

12.1.3 Any measuring and test equipment found to be out-of-calibration shall be taken out of use until it is recalibrated. A documented evaluation shall be performed of the validity of previous inspection or test results using any equipment found to be out-of-calibration.

12.2 RESPONSIBILITIES

12.2.1 GNS/GNB-TQ shall verify that control of measuring and testing equipment is performed in accordance with the supplier's quality assurance program.

SECTION 13.0 HANDLING, STORAGE, AND SHIPPING

13.1 SCOPE

13.1.1 Control of handling, storage, cleaning, packaging, shipping, and preservation to prevent damage or loss and minimize deterioration of an item shall be accomplished by GNS/GNB or their suppliers. The supplier shall implement his control in accordance with his quality assurance program which has been accepted by GNS/GNB. The handling, storage, packaging, shipping, and preservation of an item or equipment by the supplier shall be performed in accordance with procedures approved by GNS/GNB and when required by contract, approved by the customer.

13.2 PROCEDURES

13.2.1 GNS/GNB or the supplier shall be required to reference special handling, storage, cleaning, preservation, or protection procedures, including packaging and packing procedures, on the fabrication and quality control plan.

13.2.2 Handling, storage, cleaning, packaging, shipping, and preservation procedures shall be reviewed and accepted by GNS/GNB-TQ and customer, when required for compliance with design specification and the purchase order.

13.3 RESPONSIBILITIES

13.3.1 GNS/GNB-TQ shall verify that the handling, storage, and shipping procedures include, as required: any special environments, examination, test of special handling tools and equipment, marking provisions which are adequate to identify the items shipped, and precautions necessary for their preservation during shipment, and a permanent type of marking or identification when outdoor storage is a possibility.

13.3.2 In the case of GNS/GNB's own transport operation, the GNS/GNB Transport Department (GNS-TBH) is responsible for measures provided for in Sections 13.1, .2, and .3 and is also subject to the QA check.

SECTION 14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 SCOPE

14.1.1 Inspection, test, and operating status shall be accomplished by GNS/GNB and suppliers. GNS/GNB selection and qualification of suppliers shall be in accordance with Subsection 4.2 of this QAP. The supplier shall control his inspection, test, and operating status in accordance with his quality assurance program which has been accepted by GNS/GNB.

14.2 RESPONSIBILITIES

14.2.1 GNS/GNB-TQ shall verify that inspection, test, and operating status are controlled and performed in accordance with the supplier's quality assurance program. The status of inspection and test shall be identified either on the item or in documentation traceable to the item where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and test are not inadvertently installed, used, or operated. The status shall be maintained through indicators such as tags, markings, shop travelers, stamps, inspection, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified.

SECTION 15.0 CONTROL OF NONCONFORMING ITEMS

15.1 SCOPE

15.1.1 This section describes how items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. The control shall include identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and notification of organizations affected. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

15.2 RESPONSIBILITIES

15.2.1 Any employee of GNS/GNB shall be required to report nonconformance detected during the performance of his duties.

15.2.2 All suppliers shall be required to report nonconformances in accordance with the terms of the purchase order and his quality assurance program.

15.2.3 GNS/GNB-TQ shall be responsible for the control of all nonconformances and shall report nonconformances to the external bodies, e.g., the customer, as required by the contract through GNB-TP.

15.2.4 GNS/GNB-TQ shall maintain the records of all nonconformances. GNS/GNB-TQ shall periodically analyze nonconformances to determine quality trends and shall provide the results to the appropriate management.

15.3 INTERNAL NONCONFORMANCES (GNS/GNB)

15.3.1 All nonconformances identified by GNS/GNB shall be documented in a report by GNS/GNB-TQ. The report shall include the following information as a minimum:

A. Project

B. Manufacturer, GNS/GNB order no.

C. Item Identification

D. Report Number

E. Date

F. Description of Nonconformances

G. Disposition (repair, rework, use-as-is, or scrap)

H. Cause of Nonconformance

I. Corrective Action to preclude recurrence

15.3.2 The responsible department shall review the reported nonconformance and shall recommend a disposition with justification. He shall then forward the report to GNS/GNB-TQ. GNS/GNB-TQ, GNB-TP, and GNB-TA shall review the nonconformance report for approval and authorization of disposition. When required by contract, GNS/GNB-TQ shall submit nonconformance reports to external bodies, e.g., the customer, for approval through GNB-TP prior to authorization of disposition.

15.4 GNS/GNB SUPPLIER NONCONFORMANCES

15.4.1 Nonconformances discovered by suppliers shall be dispositioned in accordance with the supplier's quality assurance program and purchase order.

15.4.2 When the supplier proposes a disposition of "repair" or "rework", he shall submit the nonconformance report to GNS/GNB-TQ for approval through GNS/GNB-TQ, GNB-TP, and GNB-TA.

15.4.3 Upon receipt of the supplier's nonconformance report, GNS/GNB-TQ shall initiate an internal report and identify the supplier's nonconformance. GNS/GNB-TQ shall process the report in the manner described in Subsection 15.3. The supplier's nonconformance report can be attached to the GNS/GNB report or used in complete form as a substitute for a GNS/GNB report (e.g., in the case of minor faults).

15.4.4 After approval of the disposition by GNS/GNB-TQ, GNB-TP, GNB-TA and the customer, a copy of the supplier's and/or GNS/GNB's report shall be sent to the supplier for authorization to proceed or replace the nonconforming item.

SECTION 16.0 CORRECTIVE ACTION

16.1 SCOPE

16.1.1 This section describes how conditions adverse to quality are identified and corrected as soon as practical.

16.2 PROCEDURE

16.2.1 Corrective action shall be required for all reported nonconformances and audit findings.

16.2.2 GNS/GNB-TQ shall be responsible to initiate a corrective action request to the appropriate organization. The GNS/GNB-TQ corrective action request shall include the following as applicable:

A. Person or organization responsible for providing corrective action

B. Violated documents

C. Description of the discrepancy including reference documents as applicable

D. Date when the response is required

GNB-TP shall be responsible to provide the following:

A. Action to correct the deficient condition

B. Action to be taken to prevent recurrence

C. Date when corrective action is completed or will be completed

16.2.3 The person or organization responsible for nonconformances or audit findings shall determine the cause of the condition adverse to quality and shall take corrective action to preclude recurrence.

16.2.4 GNS/GNB-TQ shall review the proposed corrective action and if acceptable shall authorize its implementation by signing the corrective action request.

16.2.5 Follow-up action to verify corrective action implementation by GNS/GNB-TQ shall be performed by one of two methods:

A. The appropriate organization will submit documentary evidence, as required, to verify completion of the indicated corrective action; or

B. The indicated corrective action will be verified by GNS/GNB-TQ after the scheduled implementation date or during the next scheduled audit. This verification shall be documented on the corrective action request.

16.2.6 Corrective action records shall be maintained and distributed to GNB-TP and other cognizant GNS/GNB departments by GNS/GNB-TQ.

SECTION 17.0 QUALITY ASSURANCE RECORDS

17.1 SCOPE

17.1.1 This section describes how quality assurance records that furnish documentary evidence of quality are specified, prepared, and maintained as required by the contract. Records shall be legible, identifiable, retrievable, and protected against damage, deterioration, and loss.

1.2 Storage of permanent (lifetime) records shall be the responsibility of GNS/GNB or GNSI respectively, or external bodies unless special contract arrangements are agreed upon at the time the contract is issued.

17.2 STORAGE FACILITY

17.2.1 All records pertaining to quality generated by GNS/GNB shall be properly stored, controlled, and maintained in accordance with the applicable sections of the QAP at GNS/GNB facilities.

17.2.2 All quality assurance records generated by GNS/GNB suppliers shall be properly stored, controlled, and maintained in accordance with their quality assurance program accepted by GNS/GNB at their respective facilities.

17.3 DOCUMENTATION

17.3.1 GNS/GNB-TQ shall be responsible for having all quality related documents generated by GNS/GNB and submitted by suppliers reviewed for compliance with the contract requirements.

17.3.2 Test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

17.3.3 The following documents applicable to casks fabricated for GNSI shall be submitted to GNSI for retention as lifetime QA records:

A. Records to be provided to the customer and submitted to GNSI for retention upon cask delivery:

1. Fabrication and Test Sequence Plans (FPPs)
2. Dimensional Examination (Gauging) Reports
3. Nondestructive Examination Reports (PT, MT, UT, Visual)
4. Heat Treatment Records
5. Material Test Reports and Certifications
   - Chemical
   - Mechanical (Tensile, Elongation, Fracture Toughness, NDTT)
   - Weld Rod, Wire and Flux
   - Shielding Materials
   - Poison Materials
   - Expendables Contacting Stainless Steel (not applicable if approved cleaning program is implemented)
6. Test Reports
   - Painting (Film Thickness, Porosity Test)
   - Leak Test
7. Pressure Switch Functional Test (Calibration)
8. Repair Records
9. Supplier Nonconformance [illegible]/Internal Deviation Reports
10. GNS/GNB Certificate of Conformance
11. BAM Certificate of Conformance
12. Design Verifications (Shielding, Poison)
13. As-Built Drawings

B. Records to be submitted to GNSI for retention upon cask delivery:

1. Audit Records (GNS/GNB)
   - Internal
   - Supplier
2. Procedures
   - NDE (UT, PT, MT, Visual/Dimensional)
   - Leak Test
   - Handling, Storage, Packaging and Shipping
   - Cleaning, Surface Preparation and Painting
   - Shielding Design Verification
   - Poison Design Verification
   - Welding and Weld Qualification
   - Repair
3. Fabrication and Material Specifications

4. Parts Lists
5. Statements of Personnel Qualification
   - Audit Personnel
   - Personnel Reviewing/Approving FPPs (does not include BAM/TÜV Personnel)
   - Leak Testing
   - Welding
   - Painting
   - NDE/Visual
6. Certificates of Calibration
   - UT Equipment
   - MT Equipment
   - Leak Test Equipment
   - Measuring Equipment
   - Painting (Film Thickness Gauge)
7. Approved Suppliers List
8. Engineering and Fabrication Drawings
9. Purchase Orders (Materials)

SECTION 18.0 AUDITS

18.1 SCOPE

18.1.1 This section describes how quality assurance audits are planned, scheduled, and performed to verify compliance with all aspects of GNS/GNB and suppliers' quality assurance programs, and to determine their effectiveness.

18.2 AUDIT PLANNING

18.2.1 Audits shall be conducted as planned by GNS/GNB-TQ. GNS/GNB QAP implementation shall be audited on a yearly basis. Suppliers' quality assurance programs shall be audited at least once within three years during the interval in which material or services are being controlled. A documented assessment of each supplier's quality performance shall be completed every year in which that supplier is not audited.

18.2.2 Audits shall be performed in accordance with written procedures or checklist by personnel trained and qualified by GNS/GNB-TQ and who do not have direct responsibility for performing the activities being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.2.3 A Lead Auditor shall be appointed when the audit team is composed of two or more auditors. The Lead Auditor's responsibilities include orientation of the audit team, coordinating the audit process, establishing the pace of the audit, assuring communications within the team and with the organization being audited, participation in the audit performance, and coordinating the preparation and issuance of reports. The audit team members, under the supervision of the Lead Auditor, shall perform the audit in accordance with Subsection 18.3.3.

18.2.4 Organizations to be audited shall be notified prior to the audit. The notification shall include information as to the scope and schedule of the audit. Special audits may be performed when an area or activity is suspected to be deficient or ineffective.

18.3 AUDIT PROCEDURES

18.3.1 Audit Checklist - Audits shall be conducted using a checklist prepared by the Auditor and approved by the Quality Assurance Manager except the checklist for GNS/GNB-TQ, which shall be reviewed and approved by the management.

18.3.2 Entrance Meeting - A brief meeting prior to the audit shall be conducted with the cognizant management of the organization being audited. The purpose of the meeting is to outline the scope of the audit, present the audit plan, introduction of attendees, discuss audit sequence, and establish channels of communication as required.

18.3.3 Audit Performance - Objective evidence shall be examined by auditor(s) to verify compliance with the quality assurance program and contract requirements.

Selected elements of the quality assurance program shall be audited to the depth necessary to determine whether or not they are being implemented effectively.

When a nonconformance or program deficiency is found or identified as a result of an audit, further investigation shall be conducted by the audited organization in order to identify the cause and effect of the nonconformance, and to determine the extent of the corrective action required.

Nonconformances or program deficiencies shall be acknowledged by a member of the audited organization.

Conditions requiring immediate corrective action shall be reported at once to management of the audited organization.

Specific attention shall be given to corrective action on program deficiencies identified during previous audits.

18.3.4 Exit Meeting - At the conclusion of the audit, an exit meeting shall be held with the cognizant management of the audited organization to present and reach agreement on the audit results.

18.4 AUDIT RESULTS

18.4.1 The auditor shall prepare an audit report in which the audit results and findings are documented. The report will be submitted to the Quality Assurance Manager for evaluation.

18.4.2 Corrective action shall be required for all reported deficiencies in accordance with Section 16.0 CORRECTIVE ACTION.

18.4.3 Any nonconformance or corrective action that cannot be concluded by GNS/GNB-TQ and the organization being audited shall be resolved by the management.

18.4.4 Audit records shall be maintained by GNS/GNB-TQ. GNS/GNB-TQ shall analyze audit data and reports to determine quality trends and the effectiveness of the QAP.

18.5 MANAGEMENT REVIEW

18.5.1 Copies of audit reports shall be distributed to cognizant organization and GNS/GNB management by GNS/GNB-TQ.

18.5.2 Audit data and reports, including identified trends adverse to quality, shall be reviewed with the management by GNS/GNB-TQ. This review shall be performed during the annual management review and assessment of the adequacy and effectiveness of the established quality assurance program as described in Section 2.0 QUALITY ASSURANCE PROGRAM.

GLOSSARY

1. ACCEPT: Agree to or concur with. As used herein, acceptance requires signing.

2. APPROVAL: Official permission. As used herein, approval requires signing.

3. AS-BUILT-DRAWINGS: Drawings reflecting as constructed conditions and has been reconciled with the design report.

4. AUDIT: A documented activity performed in accordance with written procedure or checklist to verify, by examination and evaluation of objective evidence, that selected elements of the quality program have been developed, documented, and implemented in accordance with specified requirements. An audit does not include surveillance or inspection for the purpose of process control or acceptance of material or items.

5. CERTIFICATE OF CALIBRATION: Written statement attesting to the calibration of equipment based on review of supporting documentation.

6. COMMERCIAL PRODUCT: An item that complies with all three of the following criteria:

   a. not exclusively designed or specified for the nuclear industry or GNS/GNB;
   b. also used outside the nuclear industry and not only by GNS/GNB; and
   c. is ordered from the manufacturer or the supplier on the basis of industry standards (e.g., DIN, European standards, etc.) or specifications given by the manufacturer in product descriptions (e.g., a catalog).

7. CORRECTIVE ACTION: Action undertaken to identify the cause of a deficiency, discrepancy, or nonconformity, to correct a condition adverse to quality and prevent recurrence.

8. DESIGN DOCUMENTS: These documents include design specifications, design calculations, design drawings, and design reports.

9. DESIGN REPORT: Design document which includes, if appropriate, stress analysis or calculations or both to show that allowable limits are not exceeded for the loading specified in the design specification. Drawings used for design and construction must be identified in the design report.

10. DISCREPANCY REPORT: A written document used to report and resolve nonconformities or deviations from contract requirements.

11. DISPOSITION: An action taken to resolve a nonconformance.

12. DRAWINGS: Design drawings used for fabrication of an item. Design drawings are documents prepared by GNS/GNB, or others, in accordance with the design specification which depict the dimensional and material requirements of the item.

13. EXTERNAL BODIES: Customers, authorities, experts, inspectors.

14. GNB: Gesellschaft für Nuklear-Behälter mbH, Germany
    GNS: Gesellschaft für Nuklear-Service mbH, Germany

15. HOLD POINT: Hold points at which witnessing is required by GNS/GNB and/or customer shall be indicated in the fabrication and test sequence plan. Work shall not proceed beyond mandatory witness/hold points without the consent of GNS/GNB and customer as appropriate.

16. ITEM: Any product material and structures, systems and components important to safety for technical installations.

17. NONCONFORMITY: A deficiency in characteristic, documentation, or procedures which renders the quality of an item of activity unacceptable or indeterminate.

18. PROCEDURE: A step-by-step instruction for carrying out processes, inspection, control, examination, and test.

19. QUALITY ASSURANCE (QA): All those planned and systematic actions necessary to provide adequate confidence that all items designed and constructed are in accordance with the design specification and contract requirements. Quality assurance includes quality control.

20. QUALITY CONTROL (QC): The examination of the physical characteristics of a material or item to establish conformance to the acceptance standards associated with those examinations.

21. REPAIR: An activity to attempt to restore a nonconforming item or material to an acceptance condition although it does not meet the original requirements.

22. REV.: Revision

23. REVIEW: Examine in detail. Reviewing of documents shall always require signing or stamping and dating by the authorized reviewer, either on the document(s) or on records traceable to the document(s). When review is performed it is for acceptance or approval.

24. REWORK: An activity undertaken with a previously used process or technique on the item to attempt to restore that item to the original condition and design requirement.

25. SCRAP: Nonconforming items which are unfit to be used as is, repaired, reworked, or returned to the supplier shall be identified as scrap and segregated from conforming material.

26. SIGNING AND SIGN-OFF: When used herein, means signing, initialing, or stamping and always with the date.

27. STATEMENT OF PERSONNEL QUALIFICATION: Written statement attesting to the qualification of personnel based on review of supporting documentation.

28. SUPPLIER: Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and subtier levels.

29. SURVEY: A documented evaluation of an organization's ability to perform activities as verified by a determination of the adequacy of the organization's quality program and by a review of the implementation of that program at the location of the work.

30. USE-AS-IS: A disposition to accept a deviation from the original requirement without repair.

31. VERIFICATION: An act of confirming, substantiating, or assuring that an activity or condition has been satisfactorily performed or created in compliance with specified requirements. As used herein, verification required signing or sign-off.

32. WITNESS POINT: An operation which is to be witnessed by external bodies or GNS/GNB personnel. Adequate notification shall be provided to the assignor but if he is not present to witness the operation, work shall continue.