

71-0231



GENERAL NUCLEAR SYSTEMS, INC.

A Chem-Nuclear Company

November 3, 1993
RA-0738-93

Robert Baer
Chief - Source Containment and Devices Branch
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

- References:
- (1) Docket No. 72-1000 (CASTOR V/21 TSAR)
 - (2) Project No. M-50 (CASTOR X/28-33 TSAR)
 - (3) Docket No. 99901025 (GNSI QATR)
 - (4) Docket No. 71-0231 (CNSI QA Plan)

Subject: Revision 6 of the General Nuclear Systems, Inc. Quality Assurance Plan

Dear Mr. Baer:

Revision 6 to the General Nuclear Systems, Inc. (GNSI) Quality Assurance (QA) Plan, attached, is submitted for your review and approval pursuant to 10 CFR 50.55, Paragraph (f), 10 CFR 71.101, Paragraph (f), and 10 CFR 72.140, Paragraph (d).

In response to your request for additional information relative to Revision 4 of the GNSI QA Plan, GNSI committed to make certain revisions to the GNSI QA Plan, the CNSI QA Program (appendix A of the GNSI QA Plan) and the GNS QA Plan (Appendix B of the GNSI QA Plan). Revision 5 of the GNSI QA Plan, issued on October 5, and was an interim revision incorporating NRC comments to Appendix B (GNS/GNB QA Plan).

Revision 6 of the GNSI QA Plan, incorporates the changes committed to in response to your request as well as a general update to the CNSI QA Program. This document supersedes the previous QA Plan for the CASTOR V/21 TSAR (Ref. 1) for GNSI and the CASTOR X/28-33 TSAR (Ref. 2)(submitted to Mr. L. C. Rouse, USNRC, on March 4, 1985). Please note the following changes and clarifications to our previous response to NRC comments, based on telephone conversations with Mr. J. Schneider.

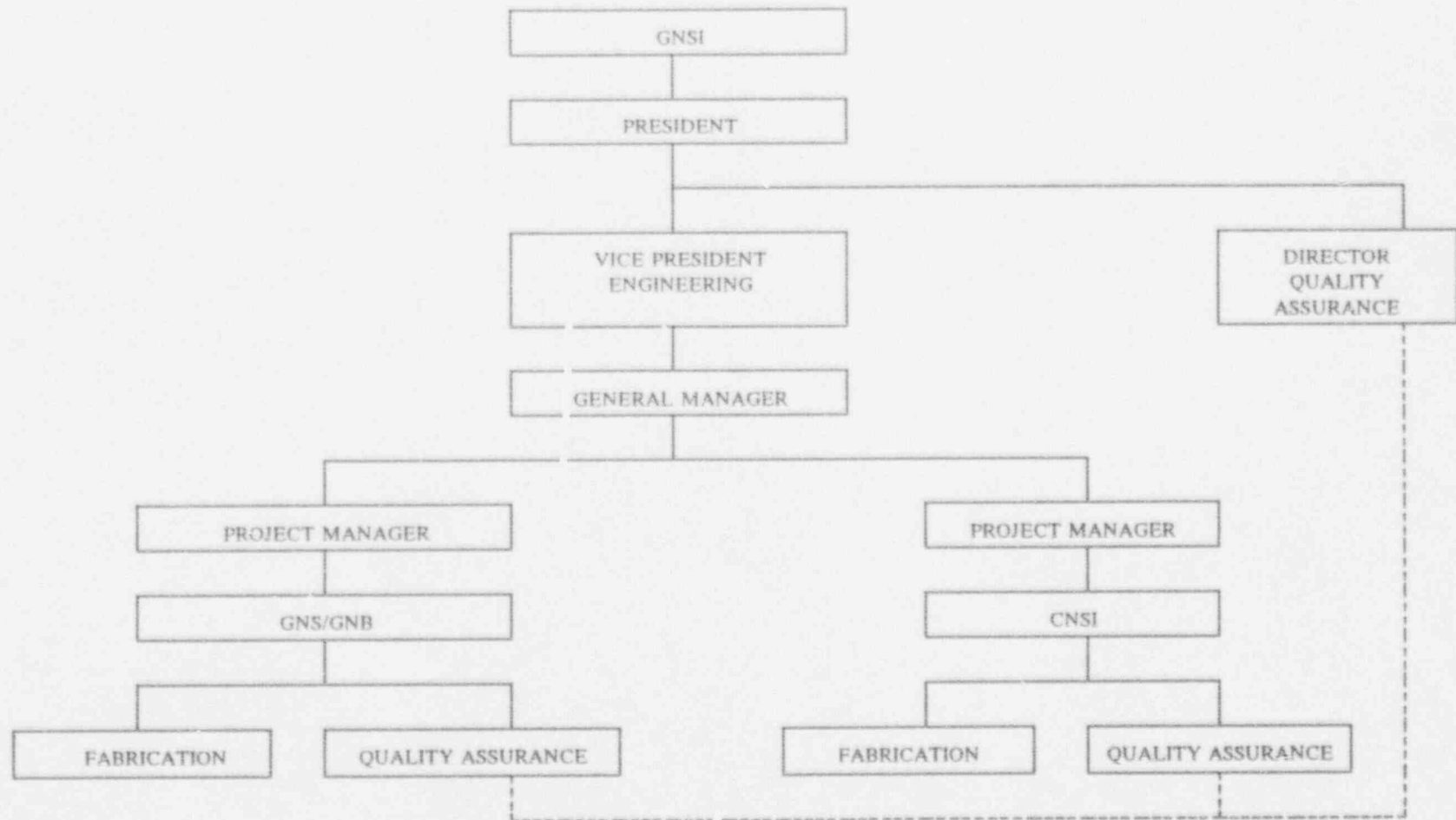
- In response to the general comments of the request for additional information, a specific statement that GNSI retains overall responsibility for the QA Program was added to section 1.3.1. This combined with the expanded introduction and the organization as depicted in Figures 1 and 2 of the GNSI QA Plan clearly show that GNSI retains overall responsibility for the QA Plan.
- The previous response to comment 6 stated that a graded approach discussion would be added to the GNS/GNB QA Plan. The graded approach is not currently being implemented by GNS/GNB. The graded approach may be incorporated in a later revision.
- An expanded discussion of Safety Review Board membership is included in the CNSI QA Program in response to comment 16.

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FIGURE 2
ORGANIZATIONAL CHART

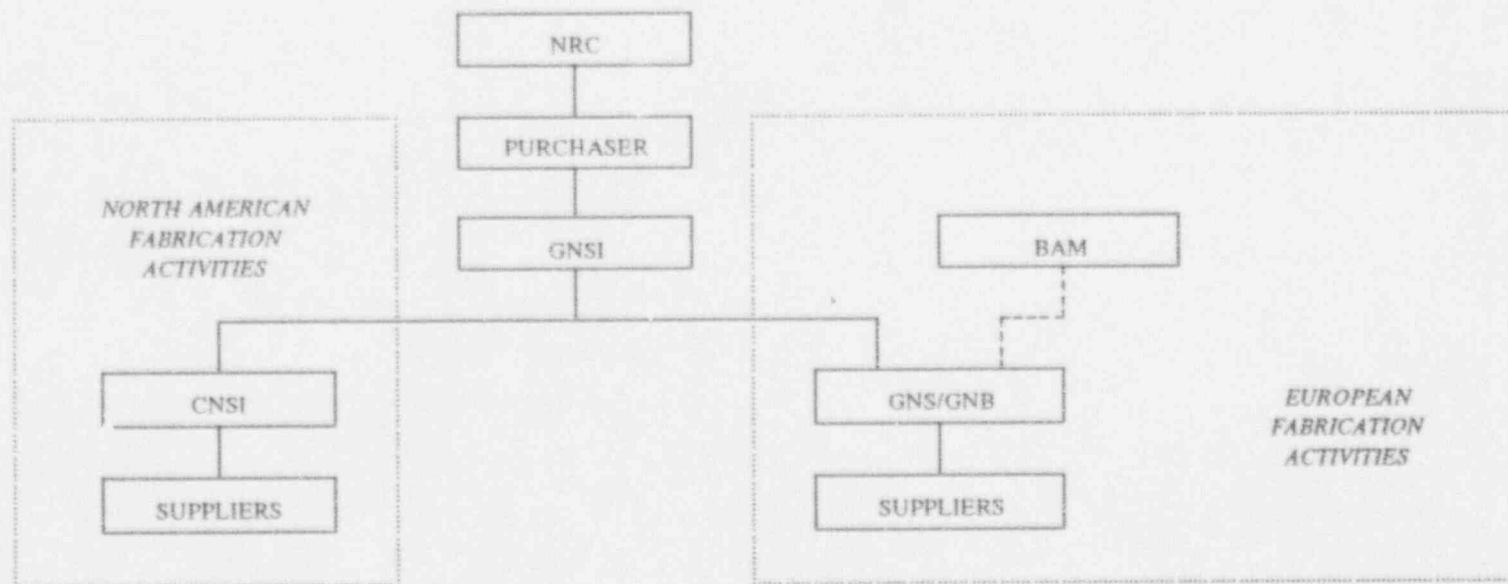


APPENDIX A

CHEM-NUCLEAR SYSTEMS, INC (CNSI)

QUALITY ASSURANCE PROGRAM

FIGURE 1
ORGANIZATIONAL RELATIONSHIPS



ATTACHMENT II

TYPICAL WITNESS AND HOLD POINTS

Activity	Item	*GNS/GNB Document Used
Ultrasonic Examination	Cask Body	PV 10
	Trunnions	PV 12
	Primary Lid (P)	PV 11
	Secondary Lid (S)	PV 11
	P and S Bolts	PV 13
	Trunnion Bolts	PV 13
Identification (Stamping and re-stamping during cutting/machining) of materials and test specimens and Examination of Mechanical Properties including Spectroscopic and Boron content Examination of Radionox Plates for Fuel Basket.	Cask Body	WB 02 or BS 04
	Trunnions	WB 12 or BS 06
	Radionox Plates for Fuel Baskets	BS 05
	Primary Lid	WB 20 or BS 06
	Secondary Lid	WB 20 or BS 06
	P & S Bolts	WB 14 or BS 06
	Trunnion Bolts	WB 13 or BS 07
Dimensional Examination and Final Identification check.	Cask Body	A500.11-02/3
	Trunnions	C 500.11-12
	Primary Lid	A 500.11-20
	Secondary Lid	A 500.11-55/2
	P & S Bolts	MUN 601.11/2
	Trunnion Bolts	MUN 601.11/2
Surface Cracks Examination	Cask Body	PV 20
	Trunnions	PV 22
	Primary Lid	PV 21
	Secondary Lid	PV 21
	P & S Bolts	PV 23 or PV 26
	Trunnion Bolts	PV 23 or PV 26
Leak Test	Completed Cask (Primary and Secondary Lids & Penetrations)	PV 32

* Procedures, Drawings, Material Specifications, etc.

ATTACHMENT I

MATRIX OF QUALITY ASSURANCE REQUIREMENTS

QUALITY CRITERIA	10 CFR 50 APPENDIX B & 10 CFR 72 SUBPART G	10 CFR 71 SUBPART H	ANSI ASME NQA-1-1989
Organization	I	71.103	BR-1 S-1S-1
Quality Assurance Program	II	71.105	BR-2 S-2S-1,2,3
Design Control	III	71.107	BR-3 S-3S-1
Procurement Document Control	IV	71.109	BR-4 S-4S-1
Instructions, Procedures, & Drawings	V	71.111	BR-5
Document Control	VI	71.113	BR-6 S-6S-1
Control of Purchased Material, Equipment, & Services	VII	71.115	BR-7 S-7S-1
Identification & Control of Materials, Parts, & Components	VIII	71.117	BR-8 S-8S-1
Control of Special Processes	IX	71.119	BR-9 S-9S-1
Inspection	X	71.121	BR-10 S-10S-1
Test Control	XI	71.123	BR-11 S-11S-1
Control of Measuring & Test Equipment	XII	71.125	BR-12 S-12S-1
Handling, Storage, & Shipping	XIII	71.127	BR-13 S-13S-1
Inspection, Test, & Operating Status	XIV	71.129	BR-14
Non-Conforming Materials, Parts, or Components	XV	71.131	BR-15 S-15S-1
Corrective Action	XVI	71.133	BR-16
Quality Assurance Records	XVII	71.135	BR-17 S-17S-1
Audits	XVIII	71.137	BR-18 S-18S-1

- o Personnel Reviewing/Approving FPP's (does not include BAM/TÜV Personnel)
- o Leak Testing
- o Welding
- o Painting
- o NDE/Visual
- 6. Certificates of Calibration
 - o UT Equipment
 - o MT Equipment
 - o Leak Test Equipment
 - o Measuring Equipment
 - o Painting (Film Thickness Gauge)
- 7. Approved Vendors List
- 8. Engineering and Fabrication Drawings
- 9. Purchase Orders (Materials)

8.4.2 The following Records, generated by GNSI, CNSI, or CNSI's suppliers, shall be retained by GNSI as QA Records in accordance with the CNSI QA Program.

1. Certificates of Conformance/Compliance
2. Index to the QA Records
3. As-Built Drawings
4. Visual and Dimensional Examination Reports
5. Certified Material Test Reports (CMTR), Physical and Chemical
6. Welding Procedures and Qualification Records
7. Heat Treatment Procedures and Reports
8. Non-Destructive Examination Procedures and Reports
9. Repair Procedures and Repair Records
10. Test Procedures and Reports
11. Nonconformances and Corrective Actions
12. Qualification Records for Inspection, Test (NDE), and Audit Personnel
13. Calibration Records
14. Audit Records (GNSI, CNSI)
15. Fabrication and Material Specifications
16. Topical Safety Analysis Report
17. Approved Vendors List
18. Parts Lists
19. Purchase Orders (GNS/GNB and CNSI)
20. Repair Records
21. Design Verification (Shielding/Poison)

8.5 Corrections to QA Records shall be annotated with initials (or stamp) and date by the individual(s) authorized to make the correction.

9.0 CONCLUSION

The quality assurance requirements specified in this QA Plan will provide adequate confidence that manufacturing activities conform to US NRC regulations.

8.4.1 The QA Records listed below are to be submitted to GNSI by GNS/GNB for European Fabricated Casks, and shall be retained as lifetime records:

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

1. Fabrication and Test Sequence Plans (FPP)
2. Dimensional Examination (Gauging) Reports
3. Nondestructive Examination Reports (PT, MT, UT, Visual)
4. Heat Treatment Records
5. Material Test Reports and Certifications
 - o Chemical
 - o Mechanical (Tensile, Elongation, Fracture Toughness, NDTT)
 - o Weld Rod, Wire and Flux
 - o Shielding Materials
 - o Poison Materials
 - o Expendables Contacting Stainless Steel (not applicable if approved cleaning program is implemented)
6. Test Reports
 - o Painting (Film Thickness, Porosity Test)
 - o Leak Test
7. Pressure Switch Functional Test (Calibration)
8. Repair Records
9. Supplier Nonconformance Reports/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)
 - o Internal
 - o Supplier
2. Procedures
 - o NDE (UT, PT, MT, Visual/Dimensional)
 - o Leak Test
 - o Handling, Storage, Packaging and Shipping
 - o Cleaning, Surface Preparation and Painting
 - o Shielding Design Verification
 - o Poison Design Verification
 - o Welding and Weld Qualification
 - o Repair
3. Fabrication and Material Specifications
4. Parts Lists
5. Statements of Personnel Qualification:
 - o Audit Personnel

specifications. The Certificate of Conformance will be a part of the Final Documentation/Quality Assurance Record.

- 6.3 Enforcement - BAM, acting as the Competent Authority in Germany, will inform the USNRC in writing of any information which could result in enforcement action under the German Federal Law for Transport of Dangerous Goods.

7.0 NON-COMPLIANCES AND DEFECTS (10 CFR PART 21)

- 7.1 GNSI and its suppliers shall comply with the requirements of 10 CFR Part 21 and shall advise the NRC immediately of any non-compliance or defects. Any person employed by GNSI and its suppliers obtaining information which reasonably indicates that a product or activity or basic component supplied by them fails to comply with the Atomic Energy Act of 1954 as amended, or any applicable rule, regulation, order, or license of the NRC relating to substantial safety hazards, or contains defects which would create a substantial safety hazard as defined by regulations which the NRC shall promulgate, shall immediately notify their management of such failure or defect for proper evaluation and reporting to the NRC in accordance with 10 CFR Part 21.
- 7.2 The GNSI General Manager shall be the responsible official for reporting non-compliances or defects to the NRC.

8.0 QUALITY ASSURANCE RECORDS

- 8.1 Records providing documentary evidence of the quality of the item and activities affecting quality shall be maintained throughout the life of the item by GNSI. GNSI may delegate the maintenance of Quality Assurance Records to the Purchaser provided that delegation is documented and approved by both organizations.
- 8.2 Quality Assurance Records will be submitted by suppliers to GNSI for proper distribution and maintenance.
 - 8.2.1 The General Manager shall be responsible for the distribution of Quality Assurance Records.
 - 8.2.2 The Director of Quality Assurance is responsible for the maintenance of Quality Assurance Records.
- 8.3 Quality Assurance Records shall be made available by GNSI and its suppliers to NRC, BAM, Purchasers, their designated agents, experts, and consultants.
- 8.4 The QA Records identified below, generated by GNS/GNB, CNSI, or their suppliers, shall be retained by GNSI.

6.1.1. Inspection Planning - Inspection planning is to assure that the stipulations of the authorization for manufacturing are maintained by means of suitable fabrication and inspection plans. The plans should be documented using BAM Standard Form, Fertigungs - u. Prüffolgeplan (FPP - Fabrication and Test Plan) and shall be reviewed by BAM or their agent prior to use. The review will be based upon the latest revision of drawings and specifications as stated in the US NRC approved Cask Safety Analysis Report as well as any specifications required by the GNS/GNB procurement documents. The BAM shall assign their Witness and Hold Points in the FPP. The following information must be included or referenced in this plan:

- . Specification of work and inspection in the form of work and test instructions, including qualitative and quantitative acceptance criteria.
- . Specification of data to be maintained in the form of technical drawings, material specification, procedures, instructions, etc.
- . Person(s) responsible for performing, witnessing, or certifying the activity.
- . Type of verification and documentation required.

6.1.2. In-Process Inspection - In-Process Inspections must be performed in accordance with the requirements stipulated in the FPP. Inspections shall be determined by the importance of the item or feature influenced by the manufacturing process. Test results must be verified against procedures, drawings, applicable European specifications, and recorded in the FPP. The activities shown in Attachment II are typical Witness and Hold Points that may be inspected, witnessed, and verified by BAM or their agent during the manufacturing process.

6.1.3. Final Inspection - After manufacturing, each completed item which is important to safety will be inspected prior to final acceptance and use. This inspection may be performed by BAM or their agent. Part of the final inspection shall be verification of documents as to completeness and accuracy.

6.2 Certificate of Conformance - After final inspection, documentation review, and evaluation of test results, BAM will issue a Certificate of Conformance. This Certificate will confirm that the material, parts, or completed component or cask system was manufactured in accordance with the requirements of the FPP. The Certificate of Conformance shall list all deviations to the drawings or European

- B. Quality Assurance Program
- C. Design Control
- D. Procurement Document Control
- E. Instructions, Procedures, and Drawings
- F. Document Control
- G. Control of Purchased Material, Equipment, and Services
- H. Identification and control of Materials, Parts, and Components
- I. Control of Special Processes
- J. Inspection
- K. Test Control
- L. Control of Measuring and Test Equipment
- M. Handling, Storage, and Shipping
- N. Inspection, Test, and Operating Status
- O. Nonconforming Materials, Parts, or Components
- P. Corrective Action
- Q. Quality Assurance Records
- R. Audits

5.4.3 GNSI, USNRC, and Purchasers may, at their discretion, audit CNSI suppliers of subcontract services and items.

6.0 BUNDESANSTALT FÜR MATERIALPRUFUNG (BAM)

Due to the unique nature of fabricating USNRC licensed spent fuel storage and shipping components in Europe, GNSI enhances its overview through additional independent activities to assure quality. GNSI, through GNS/GNB, employs the services of the BAM to assure that manufacturing activities performed in Europe conform to the requirements of this QA Plan. BAM provides assurance that manufacturing activities in Europe conform to the requirements of the US NRC approved design and GNS/GNB Quality Assurance Program. To provide this assurance, BAM or their agent performs the following activities:

6.1 Inspections - The following inspection activities are performed:

- D. Procurement Document Control
- E. Instructions, Procedures, and Drawings
- F. Document Control
- G. Control of Purchased Material, Equipment, and Services
- H. Identification and control of Materials, Parts, and Components
- I. Control of Special Processes
- J. Inspection
- K. Test Control
- L. Control of Measuring and Test Equipment
- M. Handling, Storage, and Shipping
- N. Inspection, Test, and Operating Status
- O. Nonconforming Materials, Parts, or Components
- P. Corrective Action
- Q. Quality Assurance Records
- R. Audits

5.3.3 GNSI, BAM, USNRC, and Purchasers may, at their discretion, audit GNS/GNB suppliers of subcontract services and items.

5.4 CHEM-NUCLEAR SYSTEMS, INC. (CNSI), USA

5.4.1 CNSI is responsible for activities performed in North America and shall perform all work in accordance with their established Quality Assurance Program (Appendix A).

5.4.2 CNSI is responsible for selecting, qualifying, and auditing their suppliers of subcontracted services and items. Suppliers must have an established and documented Quality Assurance System that satisfies the applicable requirements of References 3.1 C, D, and E, and is consistent with the requirements of the CNSI Quality Assurance Program. CNSI Suppliers' established Quality Assurance System shall include the following criteria as applicable:

- A. Organization

- B. Perform internal quality assurance audits of GNS/GNB and CNSI annually. Internal audits shall be performed by personnel not directly responsible for the activity being audited.
- C. Establish and execute, at their discretion, surveillance points, witness points, and hold points during the manufacturing process of Dry Storage and Transportation Casks. Surveillance, hold and witness points will be established by review of manufacturing plans or other work controlling documents and shall be communicated to the supplier in writing.
- D. Review all fabrication drawings prepared for or by GNS/GNB to assure conformance with the requirements of the USNRC approved design and purchaser specifications.
- E. Assure initiation of nonconformance reports for any deviations to Purchaser's specificatio. s.
- F. Review and concur with dispositions of nonconformance reports prior to forwarding to Purchaser.
- G. Perform review of Quality Assurance records associated with the manufacturing of Dry Storage and Transportation Casks.
- H. Issue Certificates of Conformance.
- I. Maintain record copies of lifetime records.

5.2 GESELLSCHAFT FÜR NUKLEAR - SERVICE MBH/GESELLSCHAFT FÜR NUKLEAR-BEHÄLTER MBH (GNS/GNB), GERMANY

- 5.3.1 All cask activities performed by GNS/GNB for GNSI shall be in accordance with their established Quality Assurance Plan (Appendix B).
- 5.3.2 GNS/GNB is responsible for selecting, qualifying, and auditing their suppliers of subcontracted services and items. Suppliers must have an established and documented Quality Assurance System that satisfies the applicable requirements of References 3.1 C, D and E, and is consistent with the requirements of the GNS/GNB Quality Assurance Plan. GNS/GNB Suppliers' established Quality Assurance System shall include the following criteria as applicable:
 - A. Organization
 - B. Quality Assurance Program
 - C. Design Control

issuance shall be recorded and maintained by the Director of QA:

- A. Purchaser
- B. GNS/GNB
- C. BAM
- D. USNRC
- E. CNSI

4.5 CHANGES TO QA Plan

4.5.1 Changes to this QA Plan may be initiated by the General Manager, Project Manager, Director of QA, or Purchasers. Changes that do not reduce the commitments in the previous QA Plan revision shall be submitted to the NRC by GNSI at least annually. QA Plan changes that reduce previous commitments shall be submitted to the NRC and NRC approval received prior to implementation. The Director of QA shall evaluate the QA Plan changes and determine whether the change is a reduction in commitment.

4.5.2 Approved QA Plan changes shall be controlled and distributed in the same manner as described in Paragraph 4.4.5.

5.0 QUALITY ASSURANCE

5.1 PURCHASER

5.1.1 The purchaser has the authority to perform, at their discretion, Inspections, Surveillance, and other Verification Programs (Witness Points and Hold Points) to assure quality.

5.1.2 The purchaser has the authority to review documentation and Quality Assurance Records supplied by GNSI prior to final acceptance.

5.2 GENERAL NUCLEAR SYSTEMS, INC. (GNSI)

5.2.1 GNSI has primary responsibility for providing Quality Assurance overview of the activities addressed in the QA Plan through audits, surveillances and reviews. The Quality Assurance overview will be conducted by CNSI Personnel in accordance with the CNSI Quality Assurance Program (Appendix A).

5.2.2 GNSI will perform the following quality assurance activities:

- A. Review and accept the GNS/GNB Quality Assurance Plan applicable to the USNRC Licensed Casks for GNSI.

4.0 GENERAL REQUIREMENTS AND PREREQUISITES

- 4.1 This QA Plan describes all quality assurance functions to be implemented to provide adequate confidence that manufacturing is performed in accordance with the applicable Code of Federal Regulations, technical codes, and engineering standards.
- 4.2 The basic responsibility for compliance and quality assurance rests with GNSI and its suppliers. The management of all organizations involved shall foster a quality assurance and compliance awareness throughout their respective organization. It is therefore essential that every individual in their organization be aware of and trained in their duties and responsibilities within their Quality Assurance program and this QA Plan at all stages of procurement, fabrication, handling, shipping, storage, cleaning, inspection, testing, documentation, and certification.
- 4.3 GNSI and its suppliers shall operate in accordance with this QA Plan, Purchaser's Procurement Documents, and applicable licensing requirements.
- 4.4 ADMINISTRATION AND DISTRIBUTION OF QA Plan
 - 4.4.1 GNSI is responsible for the administration of this QA Plan. GNSI shall cooperate with Purchasers, NRC, BAM, their designated agents, consultants, and representatives in the execution of the overall project. Project relationships are established and shown in Figure 1 - Organizational Relationships.
 - 4.4.2 A General Manager has been designated by GNSI who is responsible for ensuring the effective implementation of this QA Plan.
 - 4.4.3 A Project Manager has been designated by GNSI for the project who will be responsible for coordinating the project and acts as liaison between GNSI, CNSI, GNS, Purchasers, and other organizations.
 - 4.4.4 A Director of Quality Assurance has been designated by GNSI who is responsible for ensuring effective implementation of the quality assurance requirements imposed on GNSI and its suppliers.
 - 4.4.5 The NRC QA Plan Acceptance Letter, master copy, and all previous revisions of the QA Plan and QA Topical Report shall be maintained and controlled by GNSI. Controlled copies with assigned control numbers of the QA Plan will be issued to the following, as a minimum, and their

2.23 TESTING

An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

2.24 VERIFICATION

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

3.0 REFERENCED DOCUMENTS

3.1 CODE OF FEDERAL REGULATIONS AND GUIDES

- A. Title 10, Part 2 (10 CFR 2) Appendix C
- B. Title 10, Part 21 (10 CFR 21)
- C. Title 10, Part 50 (10 CFR 50) Appendix B
- D. Title 10, Part 71 (10 CFR 71) Subpart H
- E. Title 10, Part 72 (10 CFR 72) Subpart G
- F. Regulatory Guide 7.10
- G. Regulatory Guide 1.28

3.2 TECHNICAL CODES AND STANDARDS

- 3.2.1 American National Standard Institute/American Society of Mechanical Engineers ANSI/ASME NQA-1-1989 Quality Assurance Requirements for Nuclear Power Plants.
- 3.2.2 Standards of Deutsches Institut für Normung e.V. (German Institute of Standardization) DIN - Applicable Technical Standards which are specified in the Topical Safety Analysis Report or any licensing documents reviewed and approved by the NRC for a particular design.
- 3.2.3 Applicable ANSI, ASTM, and ASME standards as specified in Topical Safety Analysis Report.
- 3.2.4 Applicable alternate standards to those specified in the Topical Safety Analysis Report or any licensing documents reviewed and approved by the NRC may be used if evaluated to show that such standards are equivalent standards. This evaluation shall be documented and maintained as a record.

3.3 MATRIX OF QUALITY ASSURANCE REQUIREMENTS

- 3.3.1 Matrix of Quality Assurance Requirements (Attachment I) is developed to show the main elements of Quality Assurance Programs and the relationships between

quality of an item or activity, based on observations, measurements, or tests which can be verified.

2.15 PROCEDURE

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

2.16 PURCHASER

A responsible organization, party, or person authorized by the US NRC to use the GNSI Dry Storage and Transport Casks.

2.17 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.

2.18 QUALITY ASSURANCE OVERVIEW

The combination of QA audits, surveillances, inspections and document reviews that provide assurance of compliance with established requirements.

2.19 QUALITY ASSURANCE RECORD

A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

2.20 REVIEW

Examine in detail. Reviewing of documents shall require signing or stamping and dating by the authorized reviewer, either on the document(s) or on records traceable to the document(s).

2.21 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 sub-tier levels.

2.22 SURVEILLANCE

The act of monitoring or observing to verify whether a manufacturing step or activity conforms to prescribed requirements.

2.6 CONDITION ADVERSE TO QUALITY

An all-inclusive term used in reference to any of the following: failures, malfunctions, deviations, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

2.7 CORRECTIVE ACTION

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

2.8 DEVIATION

A departure from specified requirements.

2.9 DOCUMENT

Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this QA Plan.

2.10 INSPECTOR

A qualified and authorized person who performs inspection activities to verify conformance to specific requirements.

2.11 INSPECTION

Examination or measurement to verify whether an item or activity conforms to specified requirements.

2.12 ITEM

An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or units.

2.13 NONCONFORMANCE

A deficiency in characteristic, documentation, or procedure which renders the quality of an item or activity unacceptable or indeterminate.

2.14 OBJECTIVE EVIDENCE

Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the

manufacturing activities in Europe as described in Section 6.0 of this QA Plan.

1.3.5 In addition to the activities performed by BAM for manufacturing by GNS, GNSI will assure that manufacturing activities conform to the requirements of the US NRC approved design and this QA Plan. Specific GNSI activities are described in Section 5.2

1.3.6 The US NRC regulates and has the authority to inspect activities that are important to safety to assure that the US regulations are being complied with and this QA Plan is properly implemented.

1.3.7 Other specific interface control and responsibilities of organizations shown in the Functional Organization Chart (Figure 2) are defined and documented in the various sections of this QA Plan.

2.0 GLOSSARY OF TERMS

2.1 ACCEPTANCE CRITERIA

Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

2.2 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 materials or items.

2.3 CERTIFICATE OF CONFORMANCE

A document signed by an authorized individual certifying the degree to which items or services meet specified requirements.

2.4 CERTIFICATION

The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

2.5 COMPETENT AUTHORITY

Any national authority designated to inspect and enforce the applicable regulations.

appropriate quality assurance program is established and of verifying that activities affecting quality have been correctly performed.

1.2.2 This QA Plan is applicable to all items and activities which are "important to safety" per 10 CFR 71 and 10 CFR 72. These items and activities shall be specified in Safety Analysis Reports or any licensing documents reviewed and approved by the US NRC.

1.2.3 This QA Plan is not applicable for repair, maintenance, and modification of Dry Storage and Transport Casks after they have been accepted by the Purchaser.

1.3 RESPONSIBILITY

1.3.1 General Nuclear Systems, Inc. (GNSI) is responsible for meeting the requirements of this QA Plan. GNSI retains overall responsibility for the QA Program. The requirements of this QA Plan shall be implemented in accordance with CNSI or GNS written approved procedures, instructions and drawings.

The following GNSI positions are fulfilled by Chem-Nuclear Systems, Inc. personnel:

- ° President
- ° Vice President Engineering
- ° General Manager
- ° Project Manager
- ° Director of Quality Assurance

GNSI shall provide quality assurance overview of activities covered by this QA Plan. This overview shall be performed by CNSI personnel in accordance with the CNSI Quality Assurance Program. GNSI shall be responsible for being the liaison with regulatory agencies, purchasers, and other organizations involved in the manufacture of Dry Storage and Transport Casks. Figure 1 shows the GNSI, CNSI, GNS, and other key relationships.

1.3.2 GNSI has delegated to GNS/GNB, in Germany, the responsibility for activities in Europe. GNS/GNB shall perform all work in accordance with this QA Plan.

1.3.3 GNSI has delegated to CNSI, in Columbia, South Carolina, the responsibility for activities performed in North America. CNSI shall perform all work in accordance with this QA Plan. CNSI is also responsible for record retention and document distribution for GNSI.

1.3.4 The Bundesanstalt für Materialforschung und-prüfung (BAM) or their agents monitor GNS and GNS supplier

GNSI QUALITY ASSURANCE PLAN (QAP)

1.0 INTRODUCTION

General Nuclear Systems, Inc. (GNSI) is a joint venture company formed by Chem-Nuclear Systems, Inc. (CNSI) of Columbia, South Carolina and Gesellschaft für Nuklear-Service mbH of Hannover, Germany/Gesellschaft für Nuklear-Behälter mbH of Essen, Germany (GNS/GNB). The organization is based in Columbia, South Carolina and is involved in the supply of casks for the shipment and storage of nuclear material and in the management of high level wastes.

It is the GNSI's Policy that activities governed by regulations and licenses be conducted in accordance with the GNSI Quality Assurance Plan. This plan is implemented through procedures, instructions and drawings. Adherence to the GNSI's QA Plan and the implementing procedures is mandatory. The Director of Quality Assurance has been delegated the responsibility and authority to develop and maintain the GNSI QA Plan and to verify effective implementation.

The Objective of the GNSI QA Plan is to achieve reliable quality for activities that affect health and safety and assure full compliance with regulatory and customer requirements. This plan provides assurance that the performance and technical requirements will be met. The effective implementation of these measures has the full and unconditional support of the President of GNSI.

1.1 SCOPE

- 1.1.1 This Quality Assurance Plan provides general requirements and guidance for the establishment and execution of the Quality Assurance Program for manufacturing US NRC licensed Dry Storage and Transport Casks for radioactive materials. Items and activities which are important to safety shall meet the requirements of 10 CFR 71 and 10 CFR 72. Those items and activities designated as "important to safety" in this QA Plan shall also mean "safety related" when applied to the 10 CFR 50 requirements. The requirements and guidance pertain to activities including procuring, fabricating, handling, shipping, storing, cleaning, inspecting, and testing which affect the quality of nuclear items that are important to safety.

1.2 APPLICABILITY

- 1.2.1 The requirements of this QA Plan apply to all activities that affect the quality of important to safety items for US NRC licensed Dry Storage and Transport Casks for radioactive materials (licensed products). Activities include performing the functions of attaining quality objectives and the functions of assuring that an

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