

GNSI QUALITY ASSURANCE PLAN

PROJECT: MANUFACTURING OF U.S. NUCLEAR REGULATORY COMMISSION
LICENSED DRY STORAGE AND TRANSPORT CASKS FOR RADIOACTIVE
MATERIALS (LICENSED PRODUCTS)

REVISION NO. 6

DATE October 29, 1993

SECURITY STATUS NON-PROPRIETARY

PREPARED BY

D. L. Langan 10-28-93
D. L. Langan Date
Director of Quality Assurance

REVIEWED BY

P. L. Paquin 10-29-93
P. L. Paquin Date
General Manager

APPROVED BY

M. J. Cole 29 Oct 93
M. J. Cole Date
President

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November 3, 1993
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- A typical list of QA Program implementing procedures has been added to the CNSI QA Program in response to comment 31. GNSI will request that GNS/GNB incorporate a similar list in the next revision of the GNS/GNB QA Plan.

The following is a summary of key changes included in Revision the GNSI QA Plan

- Section 1.0 was expanded to more clearly address GNSI's Policies, goals and objectives.
- GNSI's retention of overall responsibility for Quality Assurance clearly stated in 1.3.1.
- "Cask Systems" was replaced with "casks" and "Important to Safety" terminology was incorporated throughout the plan.
- Recognition of Gesellschaft für Nuklear-Behälter mbH (GNB), was incorporated.
- The intent of attachment I was clarified to only identify QA Program documents.
- Appendices A (CNSI QA Program) and B (GNS/GNB QA Plan) have been revised, including incorporation of NRC comments.

Please note that the CNSI QA Program (Appendix A to the GNSI QA Plan) is also being submitted under separate cover letter from Chem-Nuclear Systems, Inc. That submittal details the updates and enhancements to the CNSI QA Program.

This revision of the GNSI QA Plan is being implemented as of October 29, 1993. If you have any questions or comments regarding this submittal, please contact me at 803/758-1851.

Sincerely,

GENERAL NUCLEAR SYSTEMS, INC.



David L. Langan
Director of Quality Assurance

DLL/PP/nhs

Enclosure

c: J. Jankovich M. Cole
J. Schneider M. Ryan
J. Spraul P. Paquin



CHEM-NUCLEAR SYSTEMS, INC.

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IN ADDITION TO ALL APPLICABLE CNSI DOCUMENT CONTROL REQUIREMENTS, ANY PROPOSED CHANGE TO QA-AD-001 REQUIRES FORMAL US NRC APPROVAL IN ACCORDANCE WITH 10 CFR 71 OR A SIGNED STATEMENT BY THE DIRECTOR, CNSI QA WHICH JUSTIFIES THAT SUCH APPROVAL IS UNWARRANTED.

REASON FOR CHANGE: Complete revision including incorporation Process Improvement Team recommendations, update to the CNSI organization, clarification of the graded approach, and commercial grade dedication.

PREPARED BY: <i>M.S. Motunabes</i>	DATE: 10-21-93
ALARA REVIEW: <i>M.S. Motunabes</i>	DATE: 10/21/93
ENGINEERING: <i>Patrick D. Quinn</i>	DATE: 10/22/93
SAFETY REVIEW: <i>Michael Flynn</i>	DATE: 10/21/93
QUALITY REVIEW: <i>Larry H. Perry</i>	DATE: 10/21/93
APPROVED BY: <i>Daniel L. L...</i>	DATE: 10/22/93
SRB APPROVAL: <i>Michael Flynn</i>	DATE: 10/25/93

DOCUMENT TITLE

QUALITY ASSURANCE PROGRAM

DOCUMENT NO.

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APPENDIX B

**GESELLSCHAFT FÜR NUKLEAR - SERVICE MBH/
GESELLSCHAFT FÜR NUKLEAR-BEHÄLTER MBH (GNS/GNB)
QUALITY ASSURANCE PLAN
FOR GNSI CASTOR CASKS
LICENSED BY THE
UNITED STATES NUCLEAR REGULATORY COMMISSION
(QAP)**

Should - Denotes a guideline or recommendation.

Special Process - A process whose results are highly dependent on the control of the process or skill of the operators, or both, and for which the specified quality cannot be readily determined by the inspection or test of the product.

Supplier - Any individual or organization or individual who furnishes items or services in accordance with procurement documents. An all-inclusive term used in place of vendor, seller, contractor, subcontractor, fabricator, consultant or their subtier levels.

Surveillance - The act of monitoring, observing or otherwise verifying an item or activity conforms to specified requirements.

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

Traceability - The ability to trace the history, application or location of an item and like items or activities by means of recorded identification.

Use-as-is - A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification - The act of reviewing inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services or documents conform to specified requirements.

Waiver - Documented authorization to depart from specified requirements.

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

Objective Evidence - Any documented statement of fact or other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Procedure - A document that specifies or describes how an activity is to be performed.

Procurement Document - Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchases.

Purchaser - The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.

Qualifications (Personnel) - The characteristics or abilities gained through education, training or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

Qualified Procedures - Approved procedures that have been demonstrated to meet the specified requirements for their intended purpose.

Quality Assurance (QA) - All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service.

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

Receiving - Taking delivery of an item.

Repair - The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirements.

Rework - The process by which an item is made to conform to original requirements by completion or correction.

Right of Access - The right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance or quality assurance audit.

Service - The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, remediation or installation.

Shall - Denotes a requirement.

Design Input - Those criteria, parameters, bases or other design requirements that are the basis for final design.

Design Process - Technical and management processes that commence with identification of design input and that lead to and include issuance of design output documents.

Deviation - A departure from specified requirements.

Documentation - Any written or pictorial information describing defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record.

External Audit - An audit of those portions of another organizations quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Final Design - Approved design output documents and approved changes thereto.

Guideline - A suggested practice that is not mandatory in programs intended to comply with a standard.

Important to Safety - Items and activities necessary to assure that Radioactive Waste is received, handled, packaged, stored, processed, or disposed, without undue risk to the health and safety of the public or the environment. This includes those items identified as Safety Related.

Inspector - A person who performs inspection activities to verify conformance to specified requirements.

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

Internal Audit - An audit of those portions of an organizations quality assurance program retained under its direct control and within its organizational structure.

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 unit.

May - Denotes an option.

Measuring and Test Equipment - devices or systems used to calibrate, measure, gage, test or inspect in order to control or acquire data to verify conformance to specified requirements.

Glossary of Terms

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

Audit - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Certificate of Compliance - A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

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

Characteristic - Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

Commercial Grade Item - An item satisfying (a), (b) and (c) below:

- a. Not subject to design or specification requirements that are unique to nuclear facilities;
- b. Used in applications other than nuclear facilities;
- c. Is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog).

Computer Program - A sequence of instructions suitable for processing by computer. Processing may include the use of an assembler, compiler, interpreter, or translator to prepare the program for execution as well as to execute it.

Conditions Adverse to Quality - An all-inclusive term used in reference to any of the following: failures, malfunctions, 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.

Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.

Design Change - Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

APPENDIX C
GLOSSARY OF TERMS
(4 PAGES)

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CNSO 1002/8-76

LIST OF QA IMPLEMENTING PROCEDURES
(TYPICAL)

<u>NUMBER</u>	<u>TITLE</u>
CN-AD-001	Safety Review Board
CN-AD-002	Document Storage and Control
CN-AD-003	Procedure for Document Preparation
CN-AD-004	Defect Reporting Procedure
CN-AD-005	Incident Reporting Procedure
CN-AD-007	Purchasing Procedure
CN-AD-008	Quality Assurance Records
CN-AD-009	Receipt Inspection
CN-AD-010	Control of Special Processes
CN-AD-011	Control of Measuring and Test Equipment
CN-AD-013	Test Control
CN-AD-015	Nonconforming Item and Corrective Action
CN-AD-018	Inspection Program
CN-AD-023	Certification of Nondestructive Testing Personnel
CN-AD-029	Personnel Training Policy and Implementation Procedure
CN-AD-030	Dedication of Commercial Grade Items
QA-AD-007	Vendor Evaluation Procedure
QA-AD-011	Quality Assurance Audit Procedure
QA-AD-014	CNSI Surveillance Procedure
QA-AD-015	Quality Level (Q-List)

APPENDIX B
QA IMPLEMENTING PROCEDURES
(TYPICAL)
(1 PAGE)

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QA-AD-001

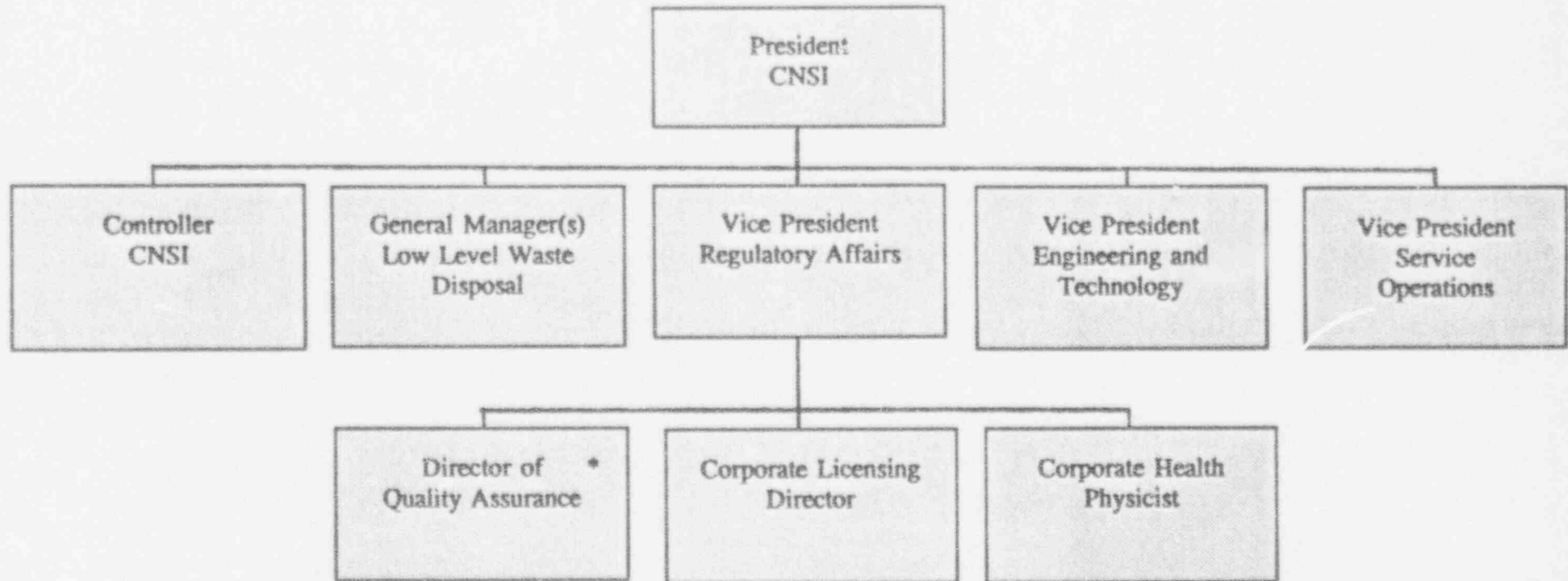
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CNSI ORGANIZATION



*The Director of Quality Assurance has unencumbered access to the President of CNSI for Matters of Quality.

APPENDIX A
CNSI ORGANIZATION
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18.3 Audit Reports

- 18.3.1 A verbal presentation of the findings, conclusions and recommendations of the audit shall be made to management personnel affected by the audit.
- 18.3.2 A written report containing the findings and recommendations (if any) presented in the verbal report is prepared and distributed to the responsible divisions and appropriate management.
- 18.3.3 Audits shall include an assessment of the effectiveness of the Quality Assurance Program implementation.

18.4 Audit Follow-Up

- 18.4.1 The originator of an audit report or a designated alternate is required to follow an open finding until action is taken to correct the deficiency. Follow-up actions are taken to verify corrective actions are implemented and effective.
- 18.4.2 Responsible management personnel shall evaluate each audit report item and correct deficiencies as promptly as possible after they are identified.

interface control drawings, copies of material test reports, tabulation of materials for "as built" configuration, nondestructive examination reports, including examination results, and Nonconformance reports.

17.4 Non-permanent Records

All non-permanent records required to verify compliance with the applicable codes and the vendor's or subcontractor's Quality Assurance Program shall be maintained until project completion, unless otherwise stipulated.

17.5 Record Storage Facilities

Record storage facilities shall be constructed, located and/or secured to prevent destruction of records by fire, flood, theft, and deterioration. As an alternative duplicate sets of documentation may be maintained in separate locations.

18.0 AUDITS

Planned audits shall be performed to provide comprehensive, independent verification and evaluation of the CNSI or vendor activity being audited. The audit scope shall encompass evaluation of quality system practices and/or procedures and the effectiveness of their implementation, monitoring of operations and activities, and a review of pertinent documents and their control and maintenance. Checklists or procedure shall be used when conducting an audit.

18.1 Audit Schedule

Internal audits shall normally be conducted once every 12 months. However, unscheduled audits may be performed more frequently in specific areas, if deemed necessary by Quality Assurance and/or when the need is indicated by the existence of chronic problems. Vendor audits, when required, shall be conducted at least once every 36 months.

18.2 Audit Personnel

Audits shall be performed by CNSI personnel with no direct line responsibility for the function audited. The audit personnel shall have the required level of technical capability to accomplish the audit functions. Representatives from various CNSI departments may be called upon for technical advice or assistance.

17.0 QUALITY ASSURANCE RECORDS

17.1 Maintenance and Access to Records

The record system maintained by Chem-Nuclear Systems, Inc. includes the retention of those design, fabrication, inspection and surveillance records essential to demonstrate product quality for important to Safety items and activities. It provides for the identification of materials and their corresponding manufacturing, installation, test and inspection records and certificates. Operating records maintained will include inspection, test and audit results. Records are maintained according to established procedures, are identifiable, and are readily retrievable.

17.2 Contents of Record Files

17.2.1 It is the policy of CNSI that adequate records be maintained for important to Safety component and material inspections and tests. Inspection and test records shall contain the following, as applicable:

17.2.1.1 A description of the type of observation;

17.2.1.2 Evidence of completing and verifying a manufacturing, inspection or test operation;

17.2.1.3 The date and results of the inspection or test;

17.2.1.4 Information related to conditions adverse to quality;

17.2.1.5 Inspector or data recorder identification;

17.2.1.6 Evidence as to the acceptability of the results;

17.2.1.7 Identification of the procedure(s) and revision(s) used.

17.2.2 Records shall also be maintained of vendor and subcontractor quality assurance reviews, surveillances and audits, and documents pertaining to CNSI internal quality assurance audits. The files shall also contain procedures and specifications written for a specific project.

17.3 Lifetime Records

Lifetime file records shall include, as a minimum: design specifications, stress reports or stress calculations, "as built" and

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15.5 Assessment of Nonconformances

Nonconformance reports shall be analyzed periodically to show quality trends, and the results reported to CNSI management for review and assessment.

16.0 CORRECTIVE ACTION

- 16.1 Conditions adverse to quality (e.g., nonconformances, failures, malfunctions, deficiencies, deviations, defective materials, etc.) shall be evaluated to determine the need for corrective action in accordance with established procedures.
- 16.2 Corrective action shall be promptly initiated when it is determined that a condition adverse to quality exists.
- 16.3 The corrective action shall include the following for significant conditions adverse to quality:
- 16.3.1 Investigation of discrepancy;
 - 16.3.2 Determination of cause;
 - 16.3.3 Corrective action to be taken;
 - 16.3.4 Action to preclude recurrence.
- 16.4 The appropriate departments shall be assigned the responsibility for corrective actions. Corrective action includes, but is not limited to, procurement or manufacturing operations, design, construction and operation. The results of corrective actions shall be documented. Quality Assurance shall verify proper implementation of corrective action. Effectiveness of corrective actions shall be tracked to identify trends adverse to quality. Significant conditions adverse to quality, the cause of such conditions, and the corrective action taken shall be reported to cognizant levels of CNSI management for review and assessment.
- 16.5 When corrective action requests affect a CNSI vendor, the vendor shall be required to provide the following information:
- 16.5.1 A description of factors contributing to the deficiency;
 - 16.5.2 A description of corrective actions taken. Action to prevent recurrence of the discrepancy in future production shall be identified for significant conditions adverse to quality.

15.1 Internal Nonconformances

CNSI Important to Safety materials, parts and components which are determined to be discrepant shall be identified, reported, and, when feasible, physically separated from acceptable items. The method of identification shall clearly describe the nature of the defect. Nonconformance reports shall be forwarded to the designated department(s) for disposition. A holding area with controlled access shall be provided when necessary for material and/or component segregation. Nonconformance reports shall indicate the nature and extent of the discrepancy and the disposition.

15.2 Vendor Nonconformance Control

Vendors providing Important to Safety items shall promptly notify CNSI of deviations from the procurement requirements, such as deviations from the required codes or approved drawings. A nonconformance notice shall be initiated by the subcontractor in accordance with the vendor's quality assurance program. After detection of the deviation, further fabrication shall not be performed until the nonconformance has been resolved in accordance with the vendor's program and procurement documents. The vendor shall supply records of nonconformance reports disposition "accept as is" or "repair" as required by the procurement documents. These reports shall be made part of the inspection records and forwarded with the hardware to CNSI for review and assessment.

15.3 Verification of Rework or Repair Acceptability

Acceptability of rework or repair of Important to Safety materials, parts, components, systems and structures shall be verified by reinspection and/or retesting the item to the original criteria, or by a method which is at least equal to the original inspection and testing method. Inspection, testing, rework and repair records shall be documented and filed in CNSI quality records files.

15.4 Nonconformance Disposition

The individuals or groups identified on nonconformance reports shall have the responsibility for disposition of nonconforming items. CNSI Quality Assurance is responsible for concurring with and verifying implementation of the disposition of nonconformances. Technical justification shall be provided by qualified personnel for the acceptability of nonconforming items dispositioned as repair or use-as-is. Nonconformances to design requirements dispositioned use-as-is or repair are subject to design control measures commensurate with those applied to the original design.

not proceed without the concurrence of Quality Assurance because of witnessing, examination or testing requirements.

14.4 Check Lists of Examinations, Tests and Inspections

Prepared check lists shall include the document number and revision to which the examination, inspection or test shall be performed. The check list shall have space provided for recording results of examination, test or inspection and for witness signatures, initials or stamp and date for activities witnessed.

14.5 Examination of Process Status

Measures shall be established to indicate during receiving, fabrication and equipment operation the status of examinations and tests performed on items, systems and components that are Important to Safety. These measures shall provide identifications of those items which conform to examination and test requirements and those that do not conform.

14.6 Inspection Status

14.6.1 CNSI inspection stamps, initials or signatures shall be applied to documentation for Important to Safety materials, items, systems and components to indicate the inspection status and to provide traceability to the individual performing the inspection.

14.6.2 A tag indicating the inspection status shall normally be applied directly to the item which has been examined.

14.7 Control of Inspection Stamps

Inspection stamps shall be serialized for traceability to the individual inspector. Quality Assurance shall control and issue inspection stamps, as required, to authorized personnel. Stamps removed from service because of loss, employee termination, etc., shall be retired.

15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

Procedures for control of nonconforming materials, parts or components that are Important to Safety ensure that such materials are adequately identified and segregated from acceptable materials, if feasible, to preclude their inadvertent use.

13.2 Procedures and instructions shall be used for storage, preservation and packaging of shipment to protect the products from damage, loss, deterioration or substitution.

13.3 Transport Casks

13.3.1 Transport cask handling and operation shall conform to the written handling and operating procedure for each licensed cask.

13.3.2 Prior to the shipment of a transport cask, conditions of the NRC's Certificate of Compliance (specifications, tests, inspections) shall be satisfied. Required shipping papers shall be prepared and shall accompany the shipment.

13.3.3 Established safety restrictions concerning handling, storage and shipping shall be included in the handling and operating procedures for transport casks.

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 Equipment Status

14.1.1 The inspection, test and operating status of Important to Safety items shall be known at all times during manufacturing and operation.

14.1.2 Operating procedures shall include reporting requirements which establish the equipment status at key events (after unloading, prior to shipment, etc.).

14.1.3 Equipment status will be maintained by operating personnel who are responsible for inspection, test and operating activities.

14.2 Establishment of Examinations and Tests

In-process and final examinations and tests shall be established to ensure conformance with documented instructions, procedures, drawings, rules and regulations.

14.3 Hold Points

The procurement documents, drawings, quality plans and transportation and operating procedures shall establish any required mandatory hold points which shall be reflected in the fabrication or operation schedule. Hold points shall be designated points in the fabrication or operation schedule beyond which the operations shall

impractical, the label or tag may be placed on the M&TE container. The status file shall be maintained for all calibrated equipment.

12.1.3 Measuring and test equipment shall be transported, stored, and calibrated in an environment which will not adversely affect its accuracy. M&TE may be issued to and retained between calibrations by those requiring its use. Each user has the responsibility to ascertain, prior to use, that the measuring and test equipment calibration date has not expired and that damage or rework has not taken place since the last calibration.

12.2 Measuring and Test Equipment at Subcontractors

Measuring and test equipment used by subcontractors and vendors engaged in fabricating and furnishing materials, parts and components, that are Important to Safety, to CNSI shall be controlled commensurate with the requirements of this section.

12.3 Inspection Validity

M&TE and reference standards found to be out of calibration or which have not been properly maintained or calibrated, or which have been subjected to possible damage, shall be identified as non-conforming and removed from service until corrective measures have been taken. When M&TE is found to be out of tolerance, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.

12.4 Records are maintained to demonstrate conformance to M&TE requirements and to identify the calibration status of each device. These records are filed to provide ready retrievability and contain sufficient information for traceability to the individual piece of equipment to which it applies. Calibration records shall also contain the identification of the persons and company performing the calibration, calibration data including the test equipment used, calibration interval, date of the last calibration, when the next calibration is due, and any limitations on equipment use.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 Measures used to control packaging, shipping, storage and handling of components and material to prevent damage or deterioration shall be documented to reflect contractual and CNSI specified requirements.

11.2 Test Records

11.2.1 Records of tests performed shall be prepared, showing the applicable drawing or procedure revision, identification of test performed, date, test data and other essential test information.

11.2.2 The test record shall be signed by the individual performing the test and any test witness, if so required. Test records shall be retained.

11.3 Test Control for Procured Items

Test control requirements are imposed on vendors by procurement documents. They identify the tests to be performed and stipulate that vendors' test procedures be submitted for approval. Tests are conducted by groups within the vendor's organization, and test control systems are monitored during Quality Assurance surveillance, evaluation, or audit. Records of tests are reviewed for acceptability.

11.4 Modifications, Repairs and Replacements

Modifications, repairs and replacements shall be tested in accordance with the original design and test requirements or acceptable alternatives approved in the same manner as the original.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Measuring and test equipment with the necessary range and accuracy shall be provided to qualified personnel for the inspection, test and acceptance of material, parts, components and systems. Equipment accuracy shall be ensured by calibration traceable to national standards or a documented alternate basis for calibration.

12.1 CNSI's Equipment Calibration and Control

12.1.1 Inspection and test equipment shall be subjected to maintenance and calibration at periodic intervals, prior to use, or immediately after use by qualified personnel or subcontractors. Frequency of calibration shall be based on the equipment type, historical experience and operational requirements.

12.1.2 Each item of measuring and test equipment (M&TE) shall be serialized for record and identification purposes. A label or tag is attached to the M&TE indicating the due date for the next calibration and the initials or signature of the calibrator. If placing the label or tag on the M&TE is

the requirements and acceptance limits specified by the applicable design documents.

11.1 Test Procedures

11.1.1 Test procedures and instructions prepared by the responsible CNSI department are reviewed in accordance with standards, procedures or instructions to ensure inclusion of the following quality assurance requirements, as applicable:

11.1.1.1 Requirements and acceptance limits as contained in the applicable design documents;

11.1.1.2 Detailed instructions for performing the test;

11.1.1.3 Test prerequisites, including, but not limited to the following:

- Calibrated instrumentation;
- Adequate and appropriate equipment;
- Trained, qualified, and as appropriate, licensed and/or certified personnel;
- Preparation, condition and completeness of the item to be tested;
- Suitable and, if required, controlled environmental conditions.

11.1.1.4 Mandatory inspection hold points for witness by responsible individual;

11.1.1.5 Acceptance and rejection criteria;

11.1.1.6 Method for documenting or recording test data and results;

11.1.1.7 Designation of the individual(s) or group(s) responsible for evaluating and making decisions based on test results.

11.1.2 Test procedures shall be subject to document control as outlined in this program. They shall be maintained current by revisions issued upon changes in specifications, documentation, drawings or contracts.

10.4 Inspection Controls

10.4.1 Inspection procedures and instructions are written documents which provide the following information:

- 10.4.1.1 Identification of characteristics and/or activities to be inspected;
- 10.4.1.2 Identification of the individual or group responsible for performing the inspection;
- 10.4.1.3 Acceptance and rejection criteria;
- 10.4.1.4 A description of the inspection method;
- 10.4.1.5 Recorded evidence of completing and verifying a manufacturing, inspection, or test operation;
- 10.4.1.6 Recording inspector or data recorder, the inspection date, and the results of the inspection operation.

10.4.2 Inspection procedures and/or instructions are used in conjunction with the applicable specifications or drawings when inspection operations are performed.

10.5 Vendor Inspection

CNSI identifies inspection requirements in procurement documents issued to subcontractors and vendors for important to safety items or services. The subcontractors and vendors are responsible for inspection of their products, and CNSI Quality Assurance verifies their controls to assure adequacy of inspection. Vendor documents (procedures, instructions, drawings, etc.) are required to recognize those CNSI notification or hold points specified by procurement documents.

10.6 Indirect Control

In the event that direct inspection is not possible, indirect control of the inspection process shall be provided by monitoring processing methods, equipment and personnel where applicable.

11.0 TEST CONTROL

A test control program established at CNSI for Important to Safety items and services assures that required testing is identified and performed in accordance with written test procedures or instructions, which incorporate

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9.1 Personnel Certification

Personnel responsible for performance, inspection and control of special processes and operations which require special skills, and have an effect upon quality of Important to Safety items, shall be certified. Personnel for these processes or operations shall be trained and qualified in accordance with the codes and/or standards applicable to the process. The period of effectiveness for all certifications shall be specified and each individual shall be re-certified at the end of such period as required by applicable standards. Inspection results and quality audits shall be used as indicators of the need for additional training and recertification of fabrication, installation and inspection personnel without regard for established re-certification periods. A record of the names of certified personnel, their skills and certification periods shall be maintained on file for review at the facility performing special processes.

9.2 Subcontractor Control

Special processes performed by CNSI's subcontractors and vendors shall be specified in procurement documents.

9.3 Procedures

Special process procedures and instructions shall be reviewed and approved to ensure their adequacy. Special Process procedures shall include the method, qualification requirements, equipment and associated control parameters.

10.0 INSPECTION

10.1 The established inspection program at CNSI verifies the conformance of quality related activities with the applicable requirements. The verification is performed in accordance with written procedures, instructions or drawings. Personnel performing the inspections are independent from the individuals performing the activity being inspected.

10.2 Equipment modifications, repairs and replacement are inspected in accordance with the original design and inspection requirements unless an approved alternative exists. Provisions for mandatory inspection hold point identification requiring witnessing by the inspector are incorporated in the appropriate documents, such as procurement specifications, test procedures, etc.

10.3 The inspection program also provides for identification and documentation of deficiencies discovered during inspection.

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8.1.3 Items not suitable for individual marking, shall be individually tagged, placed in an identified container, or otherwise segregated.

8.1.4 The storage area shall contain only items which have been inspected and accepted. Surveillance shall be maintained over the storage areas to assure that materials subject to certification control or age limit requirements are properly segregated, dated and controlled. This surveillance shall also include checking for conformance to proper standards of packaging and storage of all components, materials, parts and assemblies.

8.2 Bulk Raw Material

8.2.1 Following the acceptance of bulk raw materials, a tag showing the purchase order, the material identification, mill heat number or heat code (if applicable) and the date of receipt shall accompany the material.

8.2.2 If during fabrication all identification has been removed from the part of the material being used, the remnant shall be marked before being returned to stock.

8.2.3 Material marking shall not be affected by contact incident to normal handling, exposure to the elements, shipment or storage. All markings shall offer ready readability and prompt identification of the material. Physical marking of material shall be accomplished in a manner which will not adversely affect the machining, forming or fabrication of the material.

8.3 Identification

Identification requirements shall be determined during generation of specifications and design drawings. Identification of materials and parts for Important to Safety systems or components shall be traceable to the appropriate documentation, such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports and physical and chemical mill test reports.

9.0 CONTROL OF SPECIAL PROCESSES

Fabrication, installation and inspection processes which have an effect upon the quality of Important to Safety items or services shall be controlled by process procedures.

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7.4 Receiving Inspection

Receipt inspections shall be performed for purchased items that are important to safety (including spare or replacement parts) to ensure that:

- 7.4.1 Items are properly identified and correspond to the receiving documentation;
- 7.4.2 Inspection records or certificates of conformance attesting to the acceptance of items are available;
- 7.4.3 Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.

7.5 Vendor Evaluation and Audit

A documented evaluation is required annually for vendors maintained on the Approved Vendors List. Vendor audits, when required, shall be conducted at least once every 36 months in accordance with the audit section of this document.

7.6 Vendor Performance Trending

The results of vendor audits, evaluations, surveillances, receipt inspections, and shop inspections are tracked and trended to assure any trends adverse to quality are identified and corrected.

8.0 IDENTIFICATION AND CONTROL OF COMPONENTS AND MATERIALS

The identification and control as described herein shall apply to Important to Safety components, production materials, bulk raw materials, parts and assemblies at all stages of fabrication and installation from receipt of components and material to completion of the system or component.

8.1 Components and Materials

- 8.1.1 The inspection status of items shall be accomplished by marking, tagging or stamping components or materials at the appropriate stages of fabrication or installation.
- 8.1.2 Identification of items shall be accomplished by a method that will provide legible identification without adverse effect on its life and utility.

7.3 Vendor Surveillance

7.3.1 CNSI Quality Assurance is responsible for conducting and documenting vendor surveillance activities. Surveillance activities may include:

7.3.1.1 Witnessing test, inspections, nondestructive examinations and various special process operations;

7.3.1.2 Monitoring heat treatment, welding, cleaning, preserving, and packaging activities;

7.3.1.3 Verifying vendor conformance with established procedures such as:

- Use of CNSI accepted drawings and procedures;
- Use of accepted product and process quality planning;
- Document change control;
- Material identification and traceability control;
- Control and calibration of measuring equipment;
- Control of major repair welding.

7.3.1.4 Reviewing completed product quality documentation and/or checklists prior to release of equipment for shipment.

7.3.2 The documentation package for purchased items is reviewed prior to release of the items for use. This documentation includes material test reports, inspection and test reports, NDE reports and applicable code data reports.

7.3.3 The frequency and extent of surveillances are consistent with the complexity and quantity of the item or service being furnished.

and quality performance, and include any or all of the following as appropriate:

7.1.1.1 Historical performance data, particularly in product quality and delivery;

7.1.1.2 Review and comment on vendor's quality assurance program;

7.1.1.3 Source audits or surveillances to verify vendor's quality assurance program implementation, as required;

7.1.1.4 Source qualification programs.

7.1.2 Vendor evaluation considerations include the elements of the Nuclear Regulatory Commission's and other regulatory agency Quality Assurance Criteria to the extent these criteria are applicable to the items or services being procured.

7.2 Procurement Requirements

Requirements to be met by the vendor are detailed in the procurement documents which may include procurement specifications. Procurement specifications detail the aspects of vendor quality assurance such as inspection reports, provisions for inspection, equipment calibration prior to use, and provisions for inspection after component repair. The procurement specification may also require the successful bidder to submit the following for CNSI's review:

7.2.1 Special process procedures for performing welding, heat treatment, and nondestructive examination;

7.2.2 Recommended inspection point program;

7.2.3 Appropriate documentation as required by applicable codes, standards and procurement documents;

7.2.4 Notices of nonconformances and their disposition;

7.2.5 Test procedures in accordance with applicable codes and standards.

- 6.3.3 Procedures and their changes are distributed on a formal basis and are of standard format.
- 6.3.4 Drawings and/or documents sent to a customer or subcontractor are accompanied by a document transmittal letter showing the drawing and/or document number, revision and date of transmittal. Transmittals are tracked to assure receipt acknowledgement.
- 6.3.5 Purchase orders for manufacturing projects are amended to indicate the effect of engineering changes. On completed projects, as-built drawings and documents are maintained in the project file.

6.4 Document Availability

Documents shall be available prior to commencement of work at the locations where activities governed by the document are to be performed.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

CNSI procurement controls establish measures to ensure that procured items and services for important to safety applications are clearly and adequately specified in procurement documents. Important to Safety Items and services are supplied by vendors and subcontractors who are capable of producing items and furnishing services which conform to procurement document requirements. These procurement methods are controlled by procedures for vendor evaluation, review of procurement requirements and surveillance of vendor's facility.

Commercial Grade Items may be procured and dedicated for important to safety application. Engineering and Technology 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 Commercial Grade Items. Quality Assurance shall concur with the method of dedication.

7.1 Vendor Evaluation

- 7.1.1 CNSI Engineering, Procurement, and Quality Assurance personnel participate, as appropriate, in evaluation of procurement sources. Recommendations of procurement sources are based on these evaluations. Results of vendor evaluations performed prior to contract award are documented and retained. The evaluations cover review of capabilities and facilities for technical, manufacturing

6.0 DOCUMENT CONTROL

CNSI implementing procedures control drawings, specifications, procedures, instructions and their respective changes.

6.1 Document Types Controlled

Controlled Documents include, but are not limited to, procedures, plans, design drawings, specifications, and manufacturing, inspection, and test instructions.

6.2 Document Review

6.2.1 Design drawings and specifications are developed by Engineering and Technology. They are reviewed and approved by trained and qualified personnel for adequacy and compliance with applicable quality standards and/or contractual requirements. The review assures the availability of all information required to conform with design requirements. The review process is the same for document changes.

6.2.2 Procedures and instructions, including changes, are prepared, reviewed and approved by trained and qualified personnel. New procedures are also approved by the CNSI Safety Review Board to assure safety and health issues have been appropriately addressed.

6.3 Document Control

6.3.1 Execution of an effective document control system requires the following:

6.3.1.1 Each document shall have an identifying number and a complete descriptive title.

6.3.1.2 Each document shall have means for identifying the revision status and the effective date of each revision.

6.3.2 The number of copies made and issued of a document is controlled by a document distribution list maintained in the document file. Obsolete documents are removed from work locations or identified as obsolete to preclude their use in important to safety activities. History copies of obsolete procedures are maintained in the document files.

4.3.6 Inspection, witness and hold points as applicable.

4.4 The individual authorized to control and release purchase orders prepares the Purchase Order, incorporating all applicable information referenced in the preceding paragraph. One copy of all Purchase Orders is maintained in a control file.

4.5 Procurement documents for spare or replacement parts shall be subject to the same controls that are applied to the original equipment. Changes and revisions to procurement documents are subject to the same review process as original documents.

4.6 Original and revised procurement documents shall be clearly annotated to indicate the completion of the aforementioned review and approval sequence.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 Important to safety activities are prescribed by documented instructions, procedures or drawings of a type appropriate to the circumstances. They include quantitative and/or qualitative acceptance criteria for determination that the prescribed activities have been satisfactorily performed. The activities are accomplished in accordance with the instructions, procedures or drawings.

5.2 Procedures and instructions are prepared by the cognizant department. All instructions and procedures are maintained current with a documented method of revision. Instructions, procedures and drawings are readily available to personnel at locations requiring their use.

5.3 Procedure owners are designated by the SRB and are responsible for revision initial approval, approval and implementation of the procedures assigned. Procedures, instructions and drawings are prepared, reviewed and approved in accordance with established procedures by cognizant department personnel. Personnel responsible for preparation, review and approval of plans, procedures, instructions and drawings used to control important to safety activities are trained to assure incorporation of appropriate quality and regulatory requirements.

5.4 The CNSI Safety Review Board reviews and approves new procedures, assuring safety and health issues are appropriately addressed.

- the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

3.9 Computer programs are placed under configuration control to assure that changes are documented and approved by authorized personnel prior to their use. Where changes to previously verified computer programs are made, verification shall be required for the change.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 The procurement of items or services for Important to Safety applications is accomplished with a procurement document. Only Purchasing is authorized to release Purchase Orders, and is responsible for conforming with established procurement and record keeping procedures. The sequence of events leading to Purchase Order issuance, and the associated record keeping activities are detailed in CNSI procedures.

4.2 It is the CNSI policy that procurement documents, except for administrative supplies, are reviewed by the cognizant manager/supervisor. When the manager/supervisor or designee determines that the procurement is for important to Safety items or services, appropriate Quality Assurance requirements are included in the procurement documents.

4.3 Important to Safety procurement documents include the following items as applicable:

4.3.1 The applicable 10CFR Part 50, Appendix B and 10CFR71, Subpart H, 10CFR72, Subpart G requirements which must be addressed;

4.3.2 The design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, tests and inspection requirements, and special process instructions;

4.3.3 The documentation to be prepared, maintained, and submitted to the purchaser for review and approval;

4.3.4 The records to be retained, controlled, and maintained by the vendor, and those delivered to the purchaser prior to use or installation of the materials or components;

4.3.5 The procuring agency's right of access to vendor's facilities and records for source inspection and audit;

- 3.3.4 The Checker reviews the drawings for technical accuracy and checks the design to ensure that the equipment can and will perform the functions for which it was designed.
- 3.3.5 The Project Manager reviews the design and confirms that the total design package meets all regulatory requirements and is ready for release and fabrication.
- 3.4 The Design Control Program provides for design reviews to ensure that design characteristics can be controlled, inspected, and tested, and that inspection and test criteria are identified. Formal design reviews may include the Cognizant Engineer, the Lead Designer, and any other individuals or groups involved in the development of the design. Design reviews may be called at any time a problem is identified. Records are kept of these design reviews, and measures are taken to ensure that design errors are corrected and not repeated. Design controls also extend to other individuals or groups in interfacing design organizations.
- 3.5 Items and processes are controlled as outlined in Section 7.0 of this document. The procurement documents specify all design base requirements including the applicable regulatory requirements, material and component requirements, drawings, specifications, codes and industry standards, test and inspection criteria, and special process instructions. All items are reviewed for suitability prior to selection.
- 3.6 Changes to final designs, field changes and modifications are justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the items are still valid. Changes are approved by the same groups or organizations responsible for review and approval of original design documents.
- 3.7 CNSI design control procedures ensure that only current copies of design output documents are used.
- 3.8 Computer programs (whether generated, transferred to, or purchased) used to calculate or develop quality related data shall be subject to documented verifications or validations. Computer programs may be used for design analysis without individual verification of the program for each application provided:
- the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

2.4 Quality Assurance Program Distribution

Measures to control the distribution of the Quality Assurance Program and revisions thereto are described in Section 6 of this document.

2.5 CNSI Implementing Procedures

This program incorporates the 18 criteria addressed in 10CFR71, Subpart H; 10CFR72, Subpart G and 10CFR50, Appendix B. Implementation of this program is accomplished through written approved procedures.

3.0 DESIGN CONTROL

3.1 The Design Control Program at CNSI ensures that design characteristics are controlled, inspected, and tested; that designs developed by the CNSI Engineering Department meet applicable regulatory requirements; and that design activities are carried out in a planned, controlled, and orderly manner.

3.2 A comprehensive system of established procedures and instructions is used for developing and implementing design projects, as well as controlling design documents (drawings) and design document distribution.

3.3 CNSI Engineering and Technology is responsible for the selection and control of design parameters and for the development of design documents. Their responsibilities are summarized below:

3.3.1 The Cognizant Engineer is responsible for the initial interpretation of design requirements and for confirming that applicable regulatory requirements are correctly translated into specifications, drawings, procedures, and instructions.

3.3.2 The Lead Designer coordinates with the Cognizant Engineer and serves as a liaison between drafting, the Cognizant Engineer, and Quality Assurance. The Lead Designer also supervises drafting and confirms that design specifications are properly referenced on drawings and other design documents.

3.3.3 The Draftsman produces accurate and precise drawings that conform to the design specifications and that properly list or reference those specifications.

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- 2.2.2 CNSI personnel performing Important to Safety activities are trained in the principles and techniques of the activity being performed;
- 2.2.3 The scope, objective and the method of implementing indoctrination and training are documented;
- 2.2.4 Proficiency of personnel performing Important to Safety activities shall be monitored and documented on a periodic basis.

2.3 Quality Assurance Policies, Goals and Objectives

2.3.1 It is the policy of CNSI that all activities which are governed by the Code of Federal Regulations, licenses, Certificates of Compliance, or other regulatory requirements, be conducted in accordance with written, approved procedures or instructions which incorporate the regulatory requirements in a manner which is easily understood by the user. Important to Safety activities shall be performed with specified equipment under suitable environmental conditions and prerequisites shall be satisfied prior to inspection, operation or testing. Adherence to the procedure requirements is mandatory for all CNSI activities. New procedures affecting health and safety are required to be submitted to the Safety Review Board for approval prior to implementation.

Appendix B provides a typical list of procedures that govern the implementation of this program. Appendix B is current at the time of issuance of this program. Updates to procedures do not require revision of Appendix B. Appendix B will be updated at the next revision of the Quality Assurance Program.

- 2.3.2 The CNSI Quality Assurance Program to provides the controls necessary to achieve an effective Quality Assurance Program for activities which are important to safety. This is achieved through the use of procedures and instructions.
- 2.3.3 Differences of opinion between QA personnel and other CNSI departments shall be resolved by the Director of Quality Assurance.

Activities within the scope of this program include waste and water processing equipment design, fabrication and operation; design, fabrication, maintenance and operation of storage, disposal and transport containers; waste transportation services; and low-level radioactive waste disposal site development and operation. The requirements of this program are applied to an extent commensurate with the item or activities importance to safety.

CNSI uses the graded approach to establish three quality levels. Quality Level I consists of those critical important to safety items and services in which a defect or failure could result directly in a condition adverse to health and safety. Quality Level II consists of important to safety items and services whose failure could indirectly result in a condition adverse to health and safety. Quality level III applies to commercial grade items. Quality level III items may be dedicated for use in an important to safety application.

2.1 Management

The President of CNSI has the responsibility to ensure effective implementation, assess the scope and status, and determine the effectiveness of the QA Program. Programmatically these functions are accomplished through the use of audits, field investigations (audits, inspections or surveillances), customer/user service reports, and internal reporting procedures. This program is reviewed annually to assure conformance with current practices and requirements.

The CNSI Safety Review Board reviews the conduct of CNSI business where matters of safety are involved and to assure compliance with applicable regulatory requirements, procedures, policies, licenses, permits and certificates. The Safety Review Board is chaired by the Vice President, Regulatory Affairs. Safety Review Board membership consists of CNSI management personnel providing expertise in engineering, operations, quality assurance, safety, ALARA, and other areas. Members are designated by the Safety Review Board Chairman.

2.2 Personnel Qualifications

Personnel assigned to perform quality functions are indoctrinated in accordance with ANSI N45.2.6, NRC Regulatory Guide 1.58, ANSI N45.2.12 and other applicable documents. Indoctrination and training is established such that:

- 2.2.1 CNSI personnel responsible for performing Important to Safety activities are instructed as to the purpose, scope and implementation of instructions and procedures;

- assure that measures of control are applied until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

1.3.2 Position descriptions for the Director of Quality Assurance and Quality Assurance personnel include prerequisite experience and/or required training. Qualifications for the Director of Quality Assurance include:

- A Bachelor's degree in a technical field or equivalent experience;
- At least ten years experience in quality assurance, engineering or manufacturing;
- A working knowledge of applicable quality-related codes, standards, and regulatory requirements;
- The ability to prescribe, apply and assess compliance with the applicable requirements.

1.4 Organizations other than CNSI may be delegated the tasks of establishment and execution of a QA program, however, the responsibility for CNSI activities that are important to safety is retained by CNSI. The Director of QA, upon notification of need for further direction or resolution of QA problems, has the authority to communicate, or direct communications, with any contractor doing business with CNSI.

Where more than one organization is involved in the execution of activities covered by this program, the responsibility and authority of each organization is clearly established. Internal and external interfaces between organizations are documented in project specific plans or implementing procedures.

2.0 QUALITY ASSURANCE PROGRAM

The Quality Assurance Program is comprised of those planned and systematic actions necessary to assure adequate confidence that CNSI activities that are important to Safety will be conducted in a satisfactory manner and that Important to Safety equipment and material will perform satisfactorily in service. Important to Safety items and activities are those necessary to assure that radioactive waste is received, handled, packaged, stored, processed, or disposed, without undue risk to the health and safety of the public or the environment.

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effectiveness of systems and processes in meeting regulatory requirements and ensures the health and safety of the public and CNSI employees.

- Licensing is responsible for ensuring compliance with applicable federal and state licensing requirements. This department interfaces with licensing agencies and provides them with technical information and requested support information.
- Health Physics ensures radiation safety, as well as compliance with radiation control regulations. Health Physics also has specific responsibilities for the review of radiation control programs and their implementation.

1.2 CNSI's organizational structures and responsibility assignments are such that quality is achieved and maintained by those who have been assigned responsibility for performing work, and quality achievement is verified by persons or organizations not directly responsible for performing the work.

1.3 The Director of Quality Assurance has the overall responsibility for assuring effective establishment and maintenance of the QA program. The Director of Quality Assurance is supported by a staff of quality assurance personnel.

1.3.1 The Director of Quality Assurance reports to the Vice President, Regulatory Affairs and has unencumbered access to the President of CNSI for matters of quality. The Vice President, Regulatory Affairs reports to the President of CNSI. QA personnel are provided sufficient authority, responsibility, access to all work areas and records, and the organizational freedom to function effectively without hinderance or reservation to:

- identify quality problems, stop unsatisfactory work, and control further processing, delivery or installation on nonconforming items;
- initiate, recommend and approve solutions through corporate channels;
- verify implementation of solutions; and

1.0 ORGANIZATION

1.1 The President of Chem-Nuclear Systems, Inc. (CNSI) is responsible for the overall establishment and effectiveness of the QA Program. The President may delegate activities to others, but retains overall responsibility for the QA Program and its implementation. The CNSI Organization is shown in Appendix A. The following is a summary of key organizational responsibilities.

- 1.1.1 Low-Level Waste Disposal Services - Provide disposal services to generators of Low-Level Radioactive Waste in strict accordance with licenses granted by state agencies and the United States Nuclear Regulatory Commission (USNRC).
- 1.1.2 Service Operations - Provides transportation and waste processing services to generators of Low-Level Radioactive Waste. Waste processing services include water processing, waste solidification and dewatering, fuel pool cleanup and volume reduction and repackaging services.
- 1.1.3 Engineering and Technology - Provides design, development, construction and test engineering for CNSI activities. Engineering provides support for waste and water processing equipment; storage, disposal and transport containers; development of project specific equipment, and technical activities associated with low-level radioactive waste disposal sites.
- 1.1.4 Controller - Provides financial and administrative support including procurement of goods and services for operations throughout the company.
- 1.1.5 Regulatory Affairs - Provides regulatory compliance oversight to assure that CNSI's activities comply with regulatory, permit and license requirements. Regulatory Affairs provides interface with regulatory agencies to ensure safe operations that comply fully with federal, state, and local regulations. In addition, the Regulatory Affairs Division works closely with customers to ensure that the waste shipped to disposal facilities meet packaging, transport, and disposal requirements. Regulatory Affairs includes the following functional areas:
- Quality Assurance is responsible for the overall direction and management of the corporate QA Program. Within CNSI, Quality Assurance is a management tool that evaluates the

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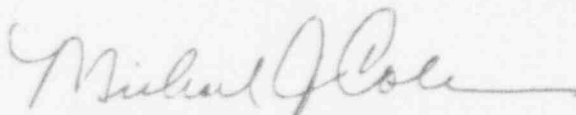
POLICY STATEMENT ON QUALITY ASSURANCE

Chem-Nuclear Systems, Inc., (CNSI) requires activities governed by regulations, licenses, certificates of compliance, or other quality/safety commitments to be conducted in accordance with the CNSI Quality Assurance (QA) Program. CNSI's QA program is implemented through procedures, instructions and drawings. Adherence to this policy, the CNSI QA Program and the implementing procedures, instructions and drawings is mandatory for all CNSI employees and subcontracted organizations.

CNSI's Quality Assurance (QA) program complies with the requirements of ASME NQA-1; ASME Boiler and Pressure Vessel Code, Section VIII; ANSI N45.2; 10 CFR 50, Appendix B; 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; NUREG 1293; and Mil-Q-9858A. The CNSI QA Program and implementing documents provide the controls and responsibilities that assure compliance with these codes and standards.

The Director of Quality Assurance has been delegated the responsibility and authority to develop and maintain the CNSI QA Program and to verify effective implementation.

The objective of the CNSI QA program is to achieve reliable quality for activities that affect health and safety and assure full compliance with regulatory and customer requirements. This program provides assurance that the performance objectives and technical requirements will be met. The effective implementation of these measures has my full and unconditional support.



Michael J. Cole, President
Chem-Nuclear Systems, Inc.

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