INDUSTRIAL NUCLEAR COMPANY
QUALITY ASSURANCE PROGRAM

DESIGN, FABRICATION, ASSEMBLY AND TESTING OF TYPE B SHIPPING CONTAINERS AND SOURCE ASSEMBLIES

REFERENCE: 10CFR71, SUBPART H

QA Manager — Approved/Date 06/09/2022

President/GM — Approved/Date 06/09/2022

REVISION NUMBER	DESCRIPTION	APPROVED BY	EFFECTIVE DATE
15	**Revised RIS 201601 to EPIP L-2020-TOP-0011**	**SJ**	
14	**Added new method of supplier qualification using NEI 14-05A Rev 1 and revised PO reviewers.**	**SJ**	**NA**
13	**Added applicability to source assemblies.**	**SJ**	**5/21/2015**
12	**Added new owner as President/GM; added new position Chief Operating Officer; revised Org Chart, position descriptions;**	**SJ**	**5/5/2014**
11	**Revise Org Chart; Delete VP; Add consultant use; clarified requirements for ITS and commercial POs.**	**FC**	**8/14/2008**
10	**Add QAM Qualification requirements; Add training requirements; Revise Org Chart.**	**EWH**	**11/01/2004**
9	**ADD SPECIAL PROCESS CONTROLS TO SECTION 9.0**	**EWH**	**10/15/98**
8	REFLECT ORGANIZATION CHANGES AND CLARIFY 10CFR71 SUBPART H COMMITMENTS	EWH	5/15/98
7	RE-TYPE DOCUMENT FOR CORRECTIONS AND REVISIONS	EWH	8/31/92
6	RE-TYPE DOCUMENT FOR CORRECTIONS AND ORGANIZATIONAL CHART CHANGE	EWH	8/17/92
5	STATEMENT OF MANAGEMENT POLICY	EWH	7/10/92
4	REVISED TO INCLUDE NRC	WEC	4/17/89
3	COVER SHEET	GL	10/15/88
2	COMPLETE REVISION	GL	7/16/82
1	COMPLETE REVISION	GL	2/15/82
0	ORIGINAL ISSUE	GL	1/13/82

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STATEMENT OF MANAGEMENT POLICY

This Quality Assurance Program was developed to address the requirements of 10 CFR 71, Subpart H as it applies to two INC locations. The implementation of the applicable portions of this program will assure that all work on items important to safety (ITS) comply with this program.

INC-CA is the Corporate Office and designs, manufactures and maintains Type B licensed shipping containers. INC-CA and INC-TX manufacture sealed sources and load licensed shipping containers for transport to licensed users. The location of the two facilities is as follows:

- Industrial Nuclear Company, California (INC-CA)

  14320 Wicks Boulevard
  San Leandro, CA 94577

- Industrial Nuclear Company, Texas (INC-TX)

  300 Highway 146 N
  La Porte, TX 77571

Quality Assurance is recognized as a function affecting all organizational levels and each individual within the organization. It shall be adhered to on all activities requiring a quality assurance program.

The Quality Assurance Manager (QAM) reports directly to the President/General Manager (GM) of INC. The President/GM of INC assigns the responsibility for development, maintenance, control, and implementation of this QA Program to the QAM.

All personnel assigned to operations subject to the requirements of this Program shall be indoctrinated in the requirements, policies and objectives set forth herein. They shall be responsible for executing those policies pertinent to their assignments. Compliance with this QA program is the expectation of the President of INC.

Sameer Jetly DATE 06/08/2022

Sameer Jetly,
President/GM, Industrial Nuclear Company

1.0 ORGANIZATION

1.0.1 Industrial Nuclear Company (INC) as the licensee is solely responsible for the planning and implementation of this quality assurance program.

1.0.2 The President/General Manager (GM) is responsible for the adequacy and effectiveness of the QA Program. The President/GM has assigned the responsibility for development and implementation of all elements of this QA Program to the QA Manager (QAM).

1.0.3 The QAM may delegate some quality functions to outside consultants.

1.0.4 Individuals responsible for performing specific quality functions report to the QAM. These individuals have sufficient independence and organizational freedom to identify quality problems; initiate, recommend or provide solutions; and to verify implementation of solutions. These individuals, by way of organizational structure, shall be provided with freedom from cost and schedule concerns when opposed to safety considerations.

1.0.5 The operating structure of INC is depicted on the Organization Chart included as Attachment 1.0.

1.1 POSITIONS AND RESPONSIBILITIES

1.1.1 President/GM: The President/GM is responsible for the overall operations of INC and is responsible for the adequacy and effectiveness of the QA Program. Responsibilities under the QA Program include issuing the Statement of Management Policy. The President/GM reviews the annual assessment of the adequacy and effectiveness of the QA Program. The President/GM has assigned the responsibility for developing and implementing the QA Program to the QAM. The President/GM approves the QA Program. The President/GM is responsible for the review of deficiencies to determine their significance and reportability under 10CFR Part 21.

1.1.2 Chief Operating Officer: The Chief Operating Officer (COO) reports directly to the President/GM. The COO is responsible for daily operations of INC facilities including sales, purchasing, manufacturing, shipping and receiving with the exception of the QA program responsibility delegated to the QAM.

1.1.3 Radiation Safety Officer: The Radiation Safety Officer (RSO) reports to the President/GM and is responsible for the implementation of the Radiation Safety Program. The RSO is responsible for the calibration of radiation survey meters, which may be used for verification activities under the QA program. The RSO is responsible to report any identified out-of-tolerance conditions of survey meters used under the QA program to the QAM for evaluation.

1.1.4 QAM:

1.1.4.1 Qualification Requirements: The QAM shall have a minimum of one (1) years direct experience in Quality Assurance or Quality Control.

1.1.4.2 The QAM reports directly to the President/GM and has been assigned the responsibility for the development and implementation of all elements of this QA Program. The QAM is responsible to the President/GM for defining policy in the QA Program consistent with applicable codes, standards, and regulations. The QAM has the responsibility, authority and/or organizational freedom to:

a. identify quality problems;
b. initiate, recommend or provide solutions, and verify implementation of solutions;
c. control or stop further processing, delivery, or installation of a nonconforming item until proper dispositioning has occurred;
d. maintain and control the INC QA Program and implementing procedures;
e. review quality procedures to assure correct interpretation of the requirements set forth in this manual;
f. develop training and qualification requirements for personnel;
g. evaluate and qualify suppliers of ITS items and services;
h. review deficiency documents to determine reportability under Part 21;
i. review or perform annual audit(s) of the QA Program;
j. obtain regulatory approval of the QA Program as required.

1.1.5 Engineering Manager: The Engineering Manager (EM) reports to the President/GM and is responsible for the design and qualification of Type B shipping containers. The EM is responsible for the development and review of design documents, including, but not limited to: drawings; specifications; design qualification test plans and procedures; parts classifications; and the determination of critical characteristics. The EM is responsible for the review of nonconforming conditions and the determination of the disposition, review of all design changes, and the review for impact on the qualified design. EM responsibilities may be assumed by a properly trained and approved engineering consultant.

1.1.6 Manufacturing Supervisor: The Manufacturing Supervisor (MS) reports to the COO and is responsible for fabricating Type B shipping containers consistent with the requirements of the QA Program and approved design documents.

1.1.7 Quality Control Inspectors: Quality Control Inspectors (QCIs) report to the QAM and are responsible for performing independent verification activities during receipt, fabrication, and final acceptance of all Type B containers consistent with the requirements of this QA Program. QCIs perform inspections, tests, and source inspections of ITS items and services. QCIs have the responsibility and authority to:

a. identify quality problems;
b. initiate, recommend or provide solutions, and verify implementation of solutions;

c. control or stop further processing, delivery, or installation of a nonconforming item until proper dispositioning has occurred;
d. verify the quality of operations and activities and providing reports as required.

1.1.8 The COO, QAM, EM, RSO, MS, ATL and QCI position responsibilities may be assumed by employees of INC, qualified independent consultants or consultants working directly under INC's quality program. The QAM shall evaluate education, certifications, licenses and experience as applicable to assure consultants are capable of performing the assigned responsibilities. The QAM shall also assure that consultants receive general employee training as specified in Paragraph 2.1.1.

1.2 MANAGEMENT INTERFACE

1.2.1 The President/GM and COO shall be kept informed by the QAM of all quality related matters, including nonconformance reports, corrective action reports, rejected inspections, failed tests, and customer feedback.

2.0 QUALITY ASSURANCE PROGRAM

2.0.1 The President/GM maintains overall responsibility for the development and implementation of this QA Program, including assurance that this QA Program complies in all respects with 10CFR 71 Subpart H. In light of this responsibility, the President/GM exercises final authority over decisions concerning all aspects of the QA Program.

2.0.2 The Quality Assurance Program encompasses the design, fabrication, assembly, testing, and maintenance of radioactive products and establishes INC's quality assurance policy in each of these areas. Those policies shall be implemented by INC's Quality Control Procedures and Radiation Safety Program, which form a part of INC's radioactive material license. They include, but are not limited to:

a. procedures for the design, testing and manufacture of INC products;
b. procedures for verifying that products have been designed and manufactured in accordance with applicable regulatory requirements;
c. procedures for proper use and maintenance of all products.

2.1 Training

2.1.1 All personnel performing activities affecting quality shall receive general employee indoctrination and training in the following areas:

a. 10CFR71, Subpart H;
b. 10CFR Part 21;
c. INC QA Program.

2.1.2 General employee indoctrination and training shall be updated with any revisions of the above documents. This training may consist of classroom or self study and shall be documented.

2.1.3 The training of personnel performing specific quality assurance or quality control functions shall comply with the following:

a. Training shall be performed by personnel with knowledge of the subject matter;
b. The training may consist of self-study and/or on-the-job training;
c. A record of such training shall be maintained and shall include a signed statement by the instructor that the trainee successfully completed the training.
d. Periodic training and/or additional training will be performed as indicated by periodic audits or by corrective action evaluations.
e. A record of such training shall be maintained and shall include a signed statement by the instructor that the trainee successfully completed the training.

2.2 Management Assessment

2.2.1 Annually, the QAM shall conduct an assessment of the adequacy and effectiveness of the QA Program. This assessment shall consist of a review of all INC nonconformance reports, corrective action reports, 10CFR Part 21 reports, internal audit results, customer feedback, and the results of any audits of this QA Program by regulatory agencies or customers issued in the past 12 months.

2.2.2 The results of this assessment shall be issued in a Memorandum to the President/GM and the COO. This Memorandum shall identify the documents reviewed, the results of the review, and contain a statement as to the effectiveness of the QA Program. This Memorandum shall be distributed to the EM, RSO, and MS.

2.3 QA Program and Procedures

2.3.1 INC's QA Program and procedures shall be based on the following considerations concerning the complexity and proposed use of the packages and components:

a. the impact on safety of malfunction or failure of the item;
b. the design and fabrication complexity or uniqueness of the item;
c. the need for special controls and surveillance over processes and equipment;
d. the degree to which functional compliance can be demonstrated by inspection or test; and,
e. the quality history and degree of standardization of the item.

3.0 DESIGN CONTROL

3.0.1 Design control measures shall be applied to items such as radiation shielding, stress, thermal, and accident analyses; compatibility of materials; maintenance and repair; and delineation of acceptance criteria for inspections and tests.

3.0.2 Specifications, drawings, instructions and procedures shall be issued to assure that the package design is identified and controlled.

3.0.3 The EM or engineering consultant shall approve all design documentation to verify the adequacy of the design, which includes confirmation that the licensed package design and regulatory requirements are correctly translated into specifications, drawings, procedures, and instructions.

3.0.4 The QAM shall review all design documentation to verify the inclusion of applicable quality and regulatory requirements.

3.0.5 Written procedures shall be established to assure the adherence to specified standards, requirements and specifications throughout the manufacturing process using appropriate inspections, measurements and tests.

3.0.6 Written procedures shall be established for the selection and review of suitability of materials, parts, equipment and processes that are essential to the safety related function of the materials, parts, and components of the Type B shipping containers. These procedures shall include the determination and documentation of the safety classification of each item, the determination of the items critical characteristics, and appropriate verification methods consistent with the item's importance to safety.

3.0.7 The adequacy of the design of all Type B shipping containers is verified by qualification testing. The qualification testing shall be performed by outside testing agencies. INC shall review and approve all test plans and procedures prior to the performance of the qualification tests. Qualification tests shall use a production or prototype unit tested to the most adverse design conditions. The results of qualification tests shall be reviewed by the EM or engineering consultant to assure that all test prerequisites have been met.

3.0.8 Design changes shall be subjected to design control measures commensurate with those applied to the original design.

3.0.9 Regulatory reviews shall be performed by the Agreement State, the Nuclear Regulatory Commission (NRC) and/or Department of Transportation (DOT) to meet licensing and/or certification requirements.

3.0.10 Changes to the design of the package shall be submitted for approval, as required, to the NRC.

4.0 PROCUREMENT DOCUMENT CONTROL

4.0.1 Procurement documents, such as purchase orders, blanket orders, or contracts shall be prepared, reviewed, approved and controlled for the procurement of ITS items and services.

4.0.2 Procurement documents for ITS purchases shall be issued to suppliers that have been evaluated for the item or service specified. As applicable, procurement documents shall identify the scope of work; quality and technical requirements; special process requirements; documentation requirements; rights of access requirements; requirements for supplier and subsupplier compliance with the applicable portions of 10CFR71, Subpart H; and the applicability of 10CFR Part 21, "Reporting of Defects and Noncompliance". Procurement documents shall require documentation from the supplier that identifies any procurement requirements that will not or cannot be met, including identification of the nonconforming condition and its disposition.

4.0.3 Procurement documents shall be reviewed and approved by the EM and the QAM for prototypes or by QAM for licensed device parts including the selection of the appropriate supplier and inclusion of the appropriate quality and technical requirements.

4.0.4 Revisions to procurement documents require the same review as the original.

4.0.5 Procurement documents shall be issued to the supplier after completion of the required review.

4.0.6 Procurement documents issued to suppliers that have completed a commercial grade survey and are listed on the ASL shall be reviewed by the QAM for inclusion of any conditions specified for that supplier.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.0.1 Activities affecting the quality of Type B shipping containers shall be prescribed by, and accomplished in accordance with, instructions, procedures, and/or drawings of a type appropriate to the circumstance.

5.0.2 Instructions, procedures and drawings shall include appropriate qualitative and quantitative acceptance criteria for determining that the activity has been satisfactorily accomplished.

5.0.3 Instructions, procedures and drawings shall be reviewed for adequacy and accuracy and approved for use by the QAM, President/GM, EM, COO or MS as appropriate.

6.0 DOCUMENT CONTROL

6.0.1 Documents (including changes), such as instructions, procedures and drawings that prescribe activities affecting quality, shall be reviewed for adequacy and approved for release by authorized personnel.

6.0.2 These documents shall be distributed to the location where the activity is taking place.

6.0.3 The QAM is responsible for establishing a method for controlling the distribution of approved documents.

7.0 CONTROL OF PURCHASED MATERIALS, PARTS AND COMPONENTS

7.0.1 The QAM is responsible for the establishment and implementation of measures to assure that purchased materials, equipment and services conform to the procurement documents. These measures shall include provisions for source evaluation and selection, objective evidence of quality furnished by the supplier, inspection at the source, and/or receipt inspection.

7.0.2 INC shall have documented evidence of product conformance prior to the installation or use of ITS materials, equipment and services. INC shall maintain these records for the life of the package to which it applies.

7.0.3 Records shall provide sufficient evidence that the items comply with specified requirements.

7.0.4 INC shall assess the effectiveness of the control of quality by suppliers at intervals consistent with the importance, complexity, and quantity of the product or service. INC may perform this activity or contract it to outside organizations.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.0.1 The identification of ITS materials, parts and components shall be maintained by heat number, part number, serial number, or other appropriate means, either on the item or by records traceable to the item.

8.0.2 ITS materials, parts and components shall be uniquely identified and traceable to their procurement documents and records of acceptance of the items. Nonconforming items shall be tagged and segregated to prevent inadvertent use.

8.0.3 This requirement shall be extended to suppliers performing activities affecting the quality of ITS parts and components by use of a traveler system or other appropriate means. INC shall request and maintain these records as required.

9.0 CONTROL OF SPECIAL PROCESSES

9.0.1 Special processes, such as welding and nondestructive examination, shall be controlled and accomplished by qualified personnel using qualified equipment and procedures in accordance with applicable codes, standards, and specifications.

9.0.2 Welding equipment, procedures and personnel shall be qualified in accordance with the American Society of Mechanical Engineers (ASME) Code, Section IX, latest Edition and Addenda. This function may be performed internally or contracted to outside organizations.

9.0.3 Nondestructive testing personnel (not including visual inspection) shall be qualified in accordance with procedures meeting the requirements of American Society of Nondestructive Testing (ASNT), SNT-TC-1A. This function may be performed internally or contracted to outside organizations. Qualification requirements for personnel performing visual inspection are included in Section 10.0.

9.0.4 ITS special processes that are performed by suppliers shall be controlled by INC under Section 7.0 of this program. Additionally, INC shall review special process procedures for these activities prior to the performance of the special process by the supplier (with the exception of the procurement of NRC licensed products such as the depleted uranium shield).

10.0 INSPECTION

10.0.1 The QAM shall establish measures to assure that ITS items and activities are inspected to verify conformance with instructions, procedures and drawings as applicable.

10.0.2 Any appropriately trained individual may perform inspections. Inspection activities shall be performed by someone other than the person that performed or is responsible for the work activity.

10.0.3 Examinations, measurements, or tests of processed materials or products shall be performed at each step necessary to assure quality.

10.0.4 Indirect process monitoring methods shall be used where direct inspection is not performed. Inspection and process monitoring shall be used when quality control is inadequate without both.

10.0.5 The QAM shall identify appropriate hold and/or witness points in appropriate documentation, such as procurement documents or travelers.

11.0 TEST CONTROL

11.0.1 INC shall develop test procedures that incorporate the requirements of 10CFR71, Subpart H and the requirements and acceptance limits contained in the package approval documentation. This function may be performed internally or contracted to outside organizations.

11.0.2 The test procedures shall be adequate to assure that the package will perform satisfactorily in service. Test procedures shall identify the required test equipment, environmental conditions, test prerequisites, acceptance criteria and documentation requirements. These test procedures shall be approved by the EM and the QAM.

11.0.3 Test results shall be reviewed by the QAM to determine acceptability and that all test prerequisites have been met.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.0.1 Measuring and Test Equipment (M&TE) used in activities affecting the quality of ITS parts or components shall be properly controlled, calibrated, and adjusted at specified frequencies to maintain accuracy within necessary limits.

12.0.2 The QAM shall identify M&TE that is required to be controlled under this program. The QAM shall establish the method used to calibrate M&TE and the frequency.

12.0.3 M&TE shall be uniquely identified. Calibration records shall be traceable to the item. Tests and inspections performed using controlled M&TE shall identify the M&TE used on test or inspection records or on use logs.

12.0.4 Whenever M&TE is determined to be out of calibration, an evaluation for product impact shall be performed in accordance with Section 15.0 of this program.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 Shipping of Radioactive Products

13.1.1 Receipt, preparation and shipment of radioactive products shall be in accordance with the INC radioactive material license.

13.2 Storage and Handling

13.2.1 The QAM shall identify ITS parts and components and establish storage requirements to prevent inadvertent use of incorrect or unacceptable items.

13.2.2 Handling requirements shall be established by the QAM when required to prevent damage to ITS parts or components.

14.0 INSPECTION, TEST AND OPERATING STATUS

14.0.1 The QAM shall develop a system to identify the inspection, test, and operating status of items and components. This system should include the use of suitable marking methods such as tags, stamps, or etching.

14.0.2 The EM and/or MS shall develop travelers to control the fabrication of Type B shipping containers.

14.0.3 The QAM shall identify the required inspections and tests on the travelers. This system shall identify hold or witness points during the fabrication process to prevent by-passing of required inspections and tests.

15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.0.1 The QAM shall develop a procedure for the identification and control of nonconforming items.

15.0.2 The procedure shall provide for the identification, documentation, segregation, disposition, and notification of affected organizations.

15.0.3 Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

16.0 CORRECTIVE ACTION

16.0.1 The QAM is responsible for reviewing conditions adverse to quality, such as deficiencies, nonconformances, deviations, and defective material, to assure identification and correction.

16.0.2 The QAM shall also determine if these conditions are significant conditions adverse to quality. For significant conditions, the cause shall be determined, and corrective actions shall be taken to preclude repetition.

16.0.3 Significant conditions adverse to quality shall be documented and reported to the President/GM and applicable manager/supervisor as a minimum.

17.0 QUALITY ASSURANCE RECORDS

17.0.1 The QAM shall establish a system to identify and maintain sufficient records to document the performance of activities affecting quality. The records shall include instructions, procedures, and drawings as required by Section 5.0 of this QA Program, as well as related records such as personnel, procedure, and equipment qualifications.

17.0.2 The QAM shall establish a records retention program that identifies records to be retained, their retention period, storage location, and assigned responsibility.

17.0.3 These records shall be retained for three years beyond the date when INC last engages in the activities controlled under this QA Program.

17.0.4 Superseded records shall be maintained for three years after they are superseded.

18.0 AUDITS

18.0.1 The QAM shall develop a system of planned and periodic audits. These audits shall verify compliance with all aspects of the QA Program on an annual basis to determine its effectiveness. This function may be performed internally or contracted to outside organizations.

18.0.2 Audits shall be performed using documented procedures and/or checklists, by appropriately trained personnel not having direct responsibility for the area audited.

18.0.3 Audit results shall be documented and reviewed by personnel having responsibility for the area audited.

18.0.4 Follow-up action, including re-audit of deficient areas, shall be taken where indicated.

18.0.5 Suppliers of materials, parts, and components shall be qualified by audit or survey and listed on the Approved Suppliers List based on the results of the audit or survey. Suppliers of testing or calibration services may be qualified by audit, survey or review of third-party certifications as allowed by NRC SER dated November 23, 2020 and identified as EPID L-2020-TOP-0011 and as described in NEI 14-05A, Revision 1 and listed on the Approved Suppliers List for the related certified scope of work.

ATTACHMENT 1.0
ORGANIZATIONAL CHART