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U.S. NUCLEAR REG. COMMISSION MAIL SECTION

ISOMEDIX

REGULATORY OPERATIONS FILE COPY

April 2, 1980

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Mr. Charles E. MacDonald, Chief
Transportation Certification Branch
Division of Fuel Cycle and Material
Safety, NMSS
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. MacDonald:

Per our recent discussion, enclosed are seven copies of our QA Program description regarding fabrication and shipment of 20-WC containers, and Gammacell irradiators.

Very truly yours,

ISOMEDIX, INC.

George R. Dietz
President

GRD:of

Enclosures (7)

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FROM	DATE OF DOCUMENT	DATE RECEIVED	NO:
Isoemdix	4/2/80	4/7/80	15974
	LTR. X MEMO:	REPORT:	OTHER:
TO:	ORIG.: 1 CC: 6	OTHER:	
C.E.Macdonald	ACTION NECESSARY ☐ NO ACTION NECESSARY ☐	CONCURRENCE ☐ COMMENT ☐	DATE ANSWERED: BY:
CLASSIF.: un POST OFFICE REG. NO:	FILE CODE: 71-0009		
DESCRIPTION: (Must Be Unclassified) copies of QA Program description regarding fabrication and shipment of 20-wc containers and Gammacell irradiators.	REFERRED TO	DATE	RECEIVED BY / DATE
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U. S. NUCLEAR REGULATORY COMMISSION

MAIL CONTROL FORM

FORM NRC-326 (1-75)

ISOMEDIX

QA PROGRAM FOR THE PRODUCTION CONTROL AND SHIPMENT OF 20-WC-5 CONTAINERS AND GAMMACELLS

(This Program supersedes any previous QA Programs related to this subject)

APPROVED BY: C. Ronk
General Manager

Louis Cretaldi
QA Manager

George R. Dietz
President

EFFECTIVE DATE: April 15, 1980

DATES OF CHANGES: _____

_____

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GENERAL

Title 10 CFR 71 requires that a QA Program applicable to the construction and shipment of packages related to the shipment of radioactive material be in effect by the using company. This requirement applies to Isomedix in the fabrication of the 20-WC-5 wooden cask, related to the shipment of self-contained sources in Gammacells, and to the Gammacell bodies.

Specifically, Isomedix ships Gammacells containing less than 3,000 curies of cesium-137 (Type B material), utilizing the 20-WC cask. Isomedix is licensed to conduct this activity under License No. 29-15364-01. The 20-WC series cask carries IAEA Certification No. USA/5800/B, and Isomedix is a registered user of the cask.

Isomedix shall retain the responsibility for the following QA Program.

I. Organization

1. The responsibility for the QA Program is retained and exercised by Isomedix, Inc.

2. QA functions performed shall include but not be limited to:

   (1) Periodic design reviews.

   (2) Review of procurement documents for 10 CFR 71 Appendix E control.

   (3) Review of design control procedures.

   (4) Review and concur with inspection plans, calibration and test procedures, drawings and specifications, and changes thereto.

   (5) Review of outside vendor facilities to assure fabrication compliance with specifications.

   (6) Participate in the evaluation of suppliers' capabilities to provide acceptable quality products/services.

   (7) Periodically inspect materials, parts and components to assure that their identification and control is adequate.

   (8) Perform inspections to verify conformance with quality-affecting activities.

(9) Periodically review test instrument calibrations to determine calibration is performed at specified intervals.

(10) Maintain Quality Assurance records.

(11) Maintain Audit records.

3. The current organizational chart is as shown in Figure 1.

4. A responsibility matrix is shown in Figure 2.

5. The duties of the QA manager are to implement and pursue those specific activities outlined in Item 2 above, and to assure general compliance with applicable regulations. His qualifications shall include:

(1) Previous experience in QA related activities.

(2) A working knowledge of applicable regulations.

(3) A background technically sufficient to enable accomplishment of assigned tasks.

6. The designated QA Manager shall have the responsibility and authority to stop unsatisfactory work and to control further processing, delivery or installation of non-conforming material.

II. Quality Assurance Program

1. The President or his designated representative shall periodically assess the scope, status implementation and effectiveness of the QA Program to assure its adequacy and compliance with 10 CFR 71, Appendix E.

2. This QA Manual and subsequent revisions shall be limited in its distribution to the Corporate Office and the Parsippany Plant, unless otherwise authorized by the President.

3. Provisions are established to assure that applicable organizations and individuals are apprised that quality policies, QA manuals and procedures are mandatory requirements which must be implemented and enforced.

4. Safety-related elements controlled by the QA Program include:

(1) Assurance that welds conform to specifications.

(2) Assurance that external dose rates (where applicable) are within specified limits.

(3) Assurance that the final product is adequately packaged for shipment.

5. Disputes between QA and other department personnel shall be resolved by the President or his designated representative.

6. An indoctrination and training program is established such that:

(1) Personnel responsible for performing quality related activities are instructed as to the purpose, scope and implementation of the QA manual, instruction and procedures.

(2) Personnel performing quality-affecting activities are qualified in the principles and techniques of the activities being performed.

(3) The scope, objective and method of implementing the indoctrination and training program are documented.

(4) Proficiency of personnel performing quality-affecting activities is maintained by periodic retraining.

7. Where applicable, quality related activities are performed with specified equipment under suitable environmental conditions, and prerequisites have been satisfied prior to inspection and test.

III. Design Control

1. Measures are established to carry out design activities in a planned, controlled and orderly manner.

2. Measures are established to correctly translate applicable regulatory requirements and design bases into specifications, drawings. written procedures and instructions.

3. Quality standards are specified in the design documents. Deviations and changes are controlled.

4. Designs are reviewed to assure that design characteristics can be controlled, inspected and tested, and inspection and test criteria are identified.

5. Selection and accomplishment of design verification of Gammacell characteristics are accomplished by design reviews. (This paragraph is not applicable to the 20-WC specification container.)

6. Individuals responsible for design verification are other than the original designer or his immediate supervisor.

7. Design and specification changes are subject to the same design controls and approvals applicable to the original design, except where those controls and approvals have become more stringent.

8. Positions responsible for design reviews and verification activities and their authority and responsibility are identified and controlled by written procedures.

IV. Procurement Document Control

1. Procedures are established that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval and control of procurement documents.

2. Procurement documents identify the applicable 10 CFR 71, Appendix E, requirements which must be complied with and described in the QA Program.

3. Procurement documents reference the design basis technical requirments, including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions.

4. Procurement documents identify the documentation to be prepared, maintained and submitted to the purchaser for review and approval.

5. Procurement documents identify those records to be retained, controlled and maintained by the supplier, and those to be delivered to the purchaser prior to use or installation of the hardware.

6. Procurement documents contain the procuring agencies right of access to suppliers' facilities and records for source inspection and audit.

7. Changes and revisions to procurement documents are subject to at least the same review and approval as the original doument.

V. Instructions, Procedures, and Drawings

1. Activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

2. Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, and drawings.

3. The QA organization reviews and concurs with inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes thereto or acceptable alternatives are described.

VI. Document Control

1. The review, approval, and issue of documents and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

2. Changes to documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations as delegated.

3. Approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.

4. Documents are available at the location where the activity will be performed prior to commencing the work.

5. A master list is established to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents.

VII. Control of Purchased Materials, Parts and Components

1. Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products.

2. The evaluation of suppliers is based on one or more of the following:

(1) The supplier's capability to comply with the elements of Appendix E to 10 CFR Part 71 that are applicable to the type of material, equipment, or service being procured.

(2) A review of previous records and performance of suppliers who have provided similar articles of the type being procured.

(3) A survey of the supplier's facilities and QA Program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

3. The results of supplier evaluations are documented and filed.

4. Surveillance, if required, of suppliers during fabrication, inspection, testing, and shipment of materials, equipment and components is planned and performed in accordance with written procedures to assure conformance to the purchase order requirements.

5. The supplier furnishes the following records as a minimum to the purchaser:

(1) Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items.

(2) Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair".

6. Receiving inspection of the supplier-furnished material, equipment, and services is performed to assure:

(1) The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.

(2) Material, components, equipment, and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions, prior to installation or use.

(3) Inspection records or certificates of conformance attesting to the acceptance of materials and components are available prior to installation or use.

(4) Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work.

VIII. Identification and Control of Materials, Parts, and Components

1. Procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

2. The identification and control procedures assure that identification is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

3. Identification of materials and parts important to the function of safety-related systems and components can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

4. The location and the method of identification do not affect the fit, function, or quality of the item being identified.

5. Correct identification of materials, parts, and components is verified and documented prior to release for fabrication, assembling and installation.

IX. Control of Special Processes

1. Special processes such as welding, heat treating, nondestructive testing, and cleaning are procedurally controlled.

2. Procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.

3. Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

X. Inspection

1. An inspection program which verifies conformance of quality-affecting activities with requirements is established, documented, and accomplished in accordance with written and controlled procedures.

2. Inspection personnel are independent from the individuals performing the activity being inspected.

3. Inspectors are qualified in accordance with applicable codes, standards, and company training programs; and their qualifications and certifications are kept current.

4. Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

5. Provisions are established that identify mandatory inspection hold points for witness by an inspector.

XI. Test Control

1. A test program to demonstrate that the item or component will perform satisfactorily in service is established, documented, and accomplished in accordance with written controlled procedures.

2. Modifications, repairs, and replacments are tested in accordance with the original design and testing requirements or acceptable alternatives.

3. Test results are documented, evaluated, and their acceptability determined by a qualified, responsible individual or group.

XII. Control of Measuring and Test Equipment

1. Measuring and test instruments are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

2. Measuring and test equipment is identified and traceable to the calibration test data.

3. Measures are taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

4. Reference and transfer standards are traceable to nationally recognized standards; or, where national standards do not exist, provisions are established to document the basis for calibration.

XIII. Handling, Storage, and Shipping

1. Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by qualified individuals in accordance with predetermined work and inspection instructions.

2. All conditions (operations, tests, inspections, specifications, etc.) of the NRC package approval and the U. S. Department of Transportation shipping requirements are satisfied prior to shipment.

3. All necessary shipping papers will be prepared, as required.

4. Departure, arrival time and destination of a package will be established and monitored to a degree consistent with the safe transportation of the package.

XIV. Inspection, Test and Operating Status

1. Identification of the inspection, test, and operating status of packages and components is known by affected organizations.

2. The application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps are procedurally controlled.

3. Bypassing of required inspections, tests, and other critical operations is procedurally controlled.

4. The status of nonconforming, inoperative or malfunctioning packages or components is identified to prevent inadvertent use.

XV. Nonconforming Material, Parts, or Components

1. The identification, documentation, segregation, review disposition, and notification to affected organizations of nonconforming materials, parts, components, or services are procedurally controlled.

2. Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition.

3. Nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned.

4. Acceptability of rework or repair of materials, parts, components and systems is verified by reinspecting and retesting the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method.

XVI. Corrective Action

1. Evaluation of conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) is conducted to determine the need for corrective action in accordance with established procedures.

2. Corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

3. Follow-up reviews are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

XVII. Quality Assurance Records

1. Sufficient records are maintained to provide documentary evidence of the quality and safety of items and the activities affecting quality and safety.

2. QA records include operating logs; results of reviews, inspections, tests, audits, and material analyses; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

3. Records are identifiable and retrievable.

4. A list of the required records and their storage locations will be maintained.

5. Design related records (e.g., drawings, calculations, etc.) are maintained for the life of the shipping package and all other records are maintained for a minimum of two years.

6. Inspection and test records contain the following where applicable:

   (1) A description of the type of observation.

   (2) Evidence of completing and verifying a manufacturing, inspection, or test operation.

   (3) The date and results of the inspection or test.

   (4) Information related to conditions adverse to quality.

   (5) Inspector or data recorder identification.

   (6) Evidence as to the acceptability of the results.

XVIII. Audits

1. Audits are performed in accordance with preestablished written procedures or check lists and conducted by personnel not having direct responsibilities in the areas being audited.

2. Audit results are documented and then reviewed with management having responsibility in the area audited.

3. Responsible management takes the necessary action to correct the deficiencies revealed by the audit.

4. Deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.

5. Audits of the QA program are performed at least annually based on safety significance of the activity being audited.

FIGURE 1

ISOMEDIX ORGANIZATION

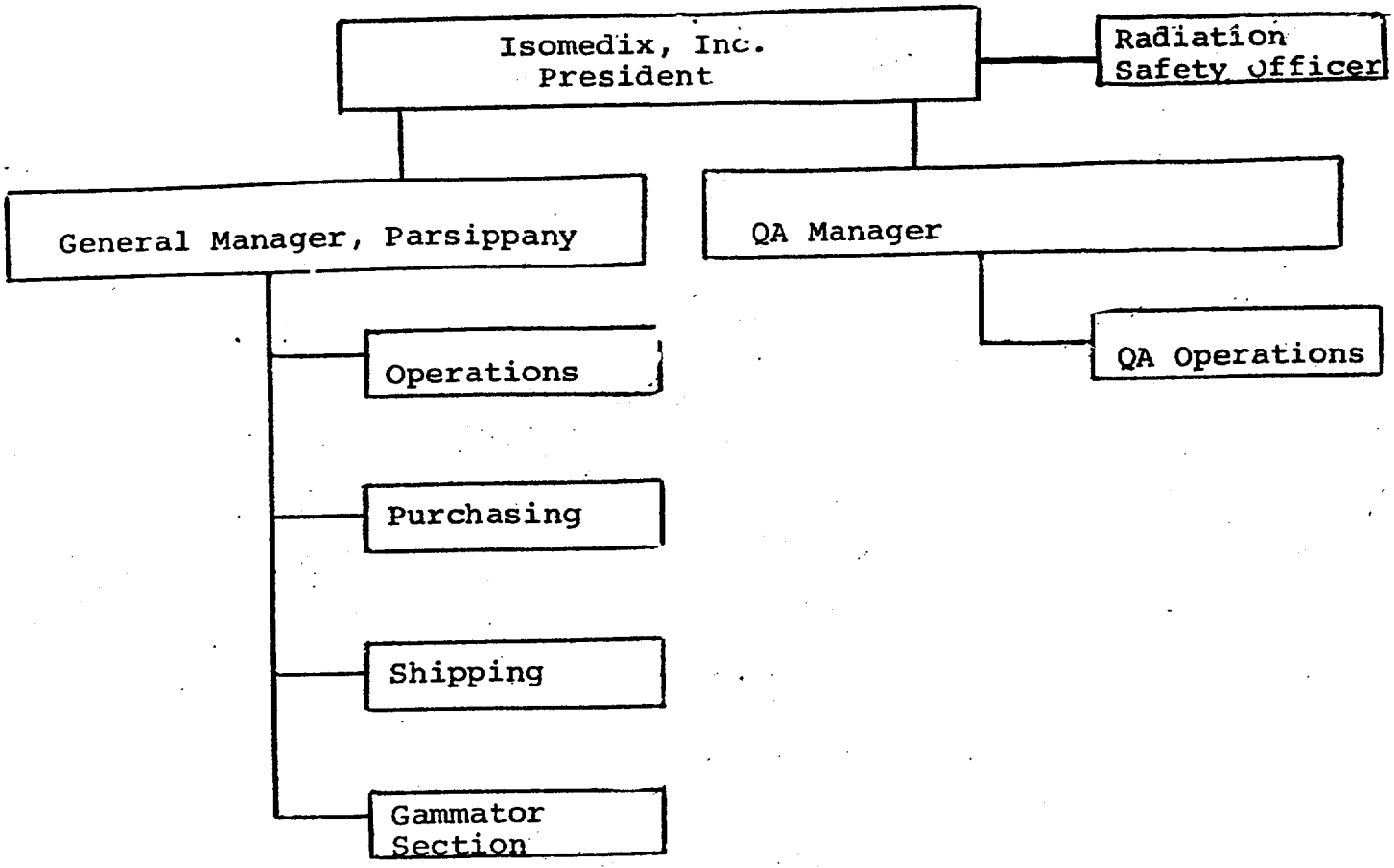

FIGURE 2

RESPONSIBILITY MATRIX

QA FUNCTION	President	General Manager	QA Manager
QA Program	A, C, D	C	A, B
Training		C	A, D, E
Certification	A		A
Testing		A	A, D, E
Document Change	A	A	A, D, E
Shipping		A, D, E	A
Specifications			A, D, E
Audit	A	A	A, D, E

A - Approve
B - Accept
C - Concur
D - Initiate
E - Perform