PDR

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 01 1979

FCTR:RHO
71-0009

Isomedix, Incorporated
ATTN: Mr. George R. Dietz
P.O. Box 177
Parsippany, NJ 07054

Gentlemen:

This refers to your application dated May 26, 1978 requesting approval of your Quality Assurance (QA) program as meeting the QA program requirements of 10 CFR §71.51.

Additional information is required to satisfy the requirements of Appendix E to 10 CFR Part 71. To assist you in preparing this information, we have enclosed the acceptance criteria the staff uses to evaluate a licensee's QA program for transportation packages for normal/special form radioactive material. We note that your application does not address design control. In order to build packages to DOT specifications, it is necessary to include design in your QA program because these specifications do not include specific fabrication drawings.

Please revise your QA program description to address the enclosed criteria and submit seven copies of the revised program within 30 days following receipt of this letter. If you have any questions regarding this request, please contact Jack Spraul at (301) 492-7741.

Sincerely,

Charles E. MacDonald, Chief
Transportation Branch
Division of Fuel Cycle and
Material Safety, NMSS

Enclosure:
Acceptance Criteria

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10 CFR 71 - APPENDIX E

ACCEPTANCE CRITERIA - TRANSPORTATION PACKAGES

FOR NORMAL/SPECIAL FORM RADIOACTIVE MATERIAL

I. Organization

1. Provide a statement that the responsibility for the QA program is retained and exercised by the applicant.

2. Identify and describe the QA/QC functions performed by the applicant's QA organization or delegated to other organizations providing controls to assure appropriate elements of Appendix E will be implemented.

3. Provide a current organizational chart that identifies the organizational elements which function under the control of the QA program.

4. Identify and describe the responsibilities of each job function shown on the organization chart.

5. Describe the duties and qualifications of the individual who retains overall authority and responsibility for the QA program.

6. Provide a statement that designated QA individuals have the responsibility and authority, delineated in writing, to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material.

II. Quality Assurance Program

1. Provide a statement that management (i.e., above or outside the QA organization) regularly assesses the scope, status, implementation, and effectiveness of the QA program to assure that the program is adequate and complies with 10 CFR Part 71, Appendix E criteria.

2. Provide a statement that provisions are established to control the distribution of the QA manuals and revisions thereto.

3. Provide a statement that provisions are established for communicating to all responsible organizations and individuals that quality policies, QA manuals, and procedures are mandatory requirements which must be implemented and enforced.

4. Identify the safety-related systems, structures and components controlled by the QA program.

5. Provide a statement that provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA/QC personnel and other department (engineering, procurement, manufacturing, etc.) personnel.

6. Provide a statement that 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 manuals, instructions, and procedures.

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

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

   (4) Proficiency of personnel performing quality-affecting activities is maintained by retraining, reexamining, and/or recertifying.

7. Provide a statement that 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. Provide a statement that measures are established to carry out design activities in a planned, controlled, and orderly manner.

2. Provide a statement that measures are established to correctly translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions.

3. Provide a statement that quality standards are specified in the design documents, and deviations and changes from these quality standards are controlled.

4. Provide a statement that designs are reviewed to assure that (1) design characteristics can be controlled, inspected and tested and (2) inspection and test criteria are identified.

5. Provide a statement that proper selection and accomplishment of design verification or checking processes such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under design conditions should be used.

6. Provide a statement that individuals or groups responsible for design verification are other than the original designer and the designer's immediate supervisor.

7. Provide a statement that design and specification changes are subject to the same design controls and approvals that were applicable to the original design unless the licensee designates another qualified responsible organization.

8. Provide a statement that the positions or groups responsible for design reviews and other design verification activities and their authority and responsibility are identified and controlled by written procedures.

IV. Procurement Document Control

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

2. Provide a statement that procurement documents identify the applicable 10 CFR Part 71, Appendix E requirements which must be complied with and described in the supplier's QA program.

3. Provide a statement that procurement documents contain or reference the design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions.

4. Provide a statement that procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedures qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to the purchaser for review and approval.

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

6. Provide a statement that procurement documents contain the procuring agency's right of access to supplier's facilities and records for source inspection and audit.

7. Provide a statement that changes and revisions to procurement documents are subject to at least the same review and approval as the original document.

V. Instructions, Procedures, and Drawings

1. Provide a statement that activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

2. Provide a statement that 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. Provide a statement that 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. Provide a statement that 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. Provide a statement that changes to documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations delegated by the applicant.

3. Provide a statement that approved changes are included in instructions, procedures drawings, and other documents prior to implementation of the change.

4. Provide a statement that documents are available at the location where the activity will be performed prior to commencing the work.

5. Provide a statement that a master list, or equivalent, 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. Provide a statement that qualified personnel evaluate the supplier's capability to provide acceptable quality services and products.

2. Provide a statement that 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. Provide a statement that the results of supplier evaluations are documented and filed.

4. Provide a statement that 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. Provide a statement that 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. Provide a statement that 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, equipments, 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 material 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. Provide a statement that procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

2. Provide a statement that 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. Provide a statement that identification of materials and parts important to the function of safety-related systems and components can be traced to the apropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

4. Provide a statement that the location and the method of identification do not affect the fit, function, or quality of the item being identified.

5. Provide a statement that 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. Provide a statement that special processes such as welding, heat treating, nondestructive testing, and cleaning are procedurally controlled.

2. Provide a statement that procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.

3. Provide a statement that qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

X. Inspection

1. Provide a statement that 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. Provide a statement that inspection personnel are independent from the individuals performing the activity being inspected.

3. Provide a statement that inspectors are qualified in accordance with applicable codes, standards, and company training programs; and their qualifications and certifications are kept current.

4. Provide a statement that modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

5. Provide a statement that provisions are established that identify mandatory inspection hold points for witness by an inspector.

XI. Test Control

1. Provide a statement that 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. Provide a statement that modifications, repairs, and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

3. Provide a statement that test results are documented, evaluated, and their acceptability determined by a qualified, responsible individual or group.

XII. Control of Measuring and Test Equipment

1. Provide a statement that 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. Provide a statement that measuring and test equipment is identified and traceable to the calibration test data.

3. Provide a statement that 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. Provide a statement that 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. Provide a statement that 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. Provide a statement that 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. Provide a statement that all necessary shipping papers will be prepared, as required.

4. Provide a statement that 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. Provide a statement that identification of the inspection, test, and operating status of packages and components is known by affected organizations.

2. Provide a statement that the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps are procedurally controlled.

3. Provide a statement that bypassing of required inspections, tests, and other critical operations is procedurally controlled.

4. Provide a statement that the status of nonconforming, inoperative, or malfunctioning packages or components is identified to prevent inadvertent use.

XV. Nonconforming Material, Parts, or Components

1. Provide a statement that the identification, documentation, segregation, review disposition, and notification to affected organizations of nonconforming materials, parts, components, or services are procedurally controlled.

2. Provide a statement that 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. Provide a statement that nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned.

4. Provide a statement that 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. Provide a statement that 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. Provide a statement that corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

3. Provide a statement that 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. Provide a statement that sufficient records are maintained to provide documentary evidence of the quality and safety of items and the activities

affecting quality and safety.

2. Provide a statement that 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. Provide a statement that records are identifiable and retrievable.

4. Provide a statement that a list of the required records and their storage locations will be maintained.

5. Provide a statement that 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. Provide a statement that 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. Provide a statement that 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. Provide a statement that audit results are documented and then reviewed with management having responsibility in the area audited.

3. Provide a statement that responsible management takes the necessary action to correct the deficiencies revealed by the audit.

4. Provide a statement that deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.

5. Provide a statement that audits of the QA program are performed at least annually based on safety significance of the activity being audited.