Du Pont Merck Pharmaceutical Company

Quality Assurance Program
for Radioactive Material Packages

331 Treble Cove Road
North Billerica, Massachusetts
01862

Contact: Distribution Operations

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Revised 12/90

1.0 Introduction and Scope

1.1 Effective on January 1, 1991 the facilities located at 331 Treble Cove Road, North Billerica Massachusetts will be owned and operated by the Du Pont Merck Pharmaceutical Company. The majority of the operations on site will consist of the manufacture and distribution of radiopharmaceuticals and radioactive sources for a broad spectrum of user applications. The Du Pont company will continue to operate three businesses on site involving the manufacture of radioactively labeled research products and radioimmunoassay products. These radioactive materials from both companies are predominantly shipped in small quantities as Type A packages. However, the radioactive raw material for the manufacturing operations may be shipped to our site in Type B quantities and, on occasion, a Type B quantity is shipped out to a customer.

1.2 The Du Pont Merck Pharmaceutical Company as well as the Du Pont company policy requires that all activities which are governed by: the Code of Federal Regulations; licenses; certifications of compliance; letters of approval; or other regulatory requirements, be conducted in accordance with written, approved procedures which incorporate the regulatory requirements in a manner which is easily understood by the user. Quality-related activities shall be performed with specified equipment and under suitable environmental conditions. Adherence to the procedure requirements is mandatory for all employees. All procedures required to assure health and safety must be submitted to the Transportation Safety Committee for approval prior to implementation.

1.3 This Quality Assurance Program describes the primary policies and procedures to be used at the Billerica site by the Du Pont Merck Pharmaceutical Company the Du Pont Company to control safety-related functions involved in the purchasing, handling, shipping, storing, and inspection of Type B packaging for radioactive material.

All Type B containers are purchased or leased from a qualified manufacturer or supplier of Type B containers. The Du Pont Merck Pharmaceutical and the Du Pont operations at the Billerica Site do not design, fabricate, or modify Type B containers. The Quality Assurance criteria for these functions are delegated to the container manufacturer.

1.4 The Billerica Site management of Du Pont Merck Pharmaceutical Company has approved, and requires adherence to, the policies, procedures, and objectives of this program. It will be the responsibility of the management of the Du Pont Merck Pharmaceutical Company to ensure the Du Pont operations in Billerica adhere to the policies, procedures and objectives of the program.

1.5 Revisions or additions to this program will be made as necessary to conform to the current regulatory requirements. Such revisions will be incorporated and cited on the revision page of this program document.

Copies of this Quality Assurance Program are available to regulatory agencies, as required, and issued to each operative unit identified in the program. Assigned copies of this procedure will have controlled distribution and documented revision.

2.0 Organization and Responsibility

2.1 The administration of this Quality Assurance organization within the Billerica Site is vested in the site's Transportation Safety Committee (TSC), the members of which represent the controlling levels of management for each of the operative program areas, including the Du Pont operations. The TSC members manage the following functions affected by this program:

a. Compliance with the Department of Transportation hazardous materials regulations;
b. Quality control;
c. Distribution and transportation.

The functions of the TSC are directed by the Quality Assurance Program Manager, within the scope of this program. The Quality Assurance Program Manager is directed by the Manager of Safety and Environmental Affairs.

This reporting route was selected specifically to allow the Quality Assurance Program Manager sufficient authority to implement and direct the Billerica Site's Quality Assurance Program to assure conformance to quality requirements and to function independent of undue influence and responsibilities for schedules and costs (see figure 1-1).

2.1.1. In order to assure effective implementation, assess the scope and status, and determine the effectiveness of the Quality Assurance Program, the Manager of Safety and Environmental Affairs (a member of site senior management) is granted broad authority to execute these functions through the use of internal audits, site investigations, customer/user service reports, and internal reporting procedures.

2.1.2 The D.O.T. Compliance Officer is responsible for ensuring compliance with the Department of Transportation hazardous materials regulations and is a member of the TSC.

2.1.3 The Area Supervisor, Safety and Environmental Affairs, or qualified designee, is responsible for implementing all program elements relating to the purchased or leased Type B containers utilized for radiological waste shipments.

2.1.4 The specific Operations Management representative is responsible for implementing all program elements relating to purchased or leased Type B containers utilized for product shipments for their own operations.

2.1.5 The Operations Manager of Distribution, or qualified designee, is responsible for compliance with the Department of Transportation hazardous material safety regulations, and for assuring that all Quality Assurance controls are performed prior to shipping and/or transporting Type B containers.

2.1.6. Any of the above listed individuals, or their designee, will be a member of the TSC and may be assigned committee chairperson.

2.2 The TSC has the authority, specified in written procedures, to perform the following functions effectively;

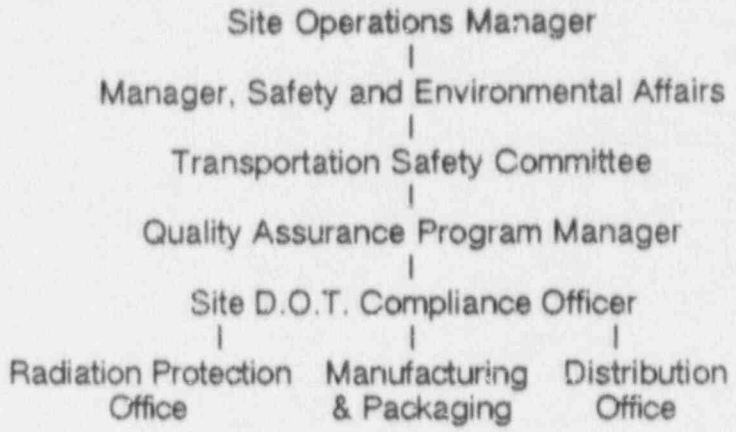
a. identify quality problems, specify corrective actions, and control the disposition of non-conforming material

b. recommend and/or approve corrective actions through proper channels

c. verify implementation of corrective actions

2.3 Position descriptions of the Quality Assurance Program Manager and all Quality Assurance personnel include prerequisite experience and/or required training, which assures competence to perform the assigned duties.

Figure 1-1



3.0 Quality Assurance Program

The Quality Assurance Program is comprised of those planned and systematic actions necessary to assure adequate confidence that all activities are conducted in a satisfactory manner and that all equipment and materials will perform satisfactorily in service. The intent of this program is to insure that all activities are conducted in a manner with the degree of reliability on which safety and performance of these activities were evaluated. The Quality Assurance Program applies to the purchase, use, handling, storage, and shipping of Type B containers.

3.1 Procedures cross-referenced to the 18 Criteria of 10 CFR 71, Appendix E

Key:

I.	Organization
II.	Quality Assurance
III.	Design Control
IV.	Procurement Document Control
V.	Instructions, Procedures, and Drawings
VI.	Document Control
VII.	Control; Purchased Materials, Equipment, Services
VIII.	Identification and Control of Materials
IX.	Control of Special Processes
X.	Inspection
XI.	Test Control
XII.	Control of Measuring and Test Equipment
XIII.	Handling, Storage, and Shipping
XiV.	Inspection, Test, and Operating Status
XV.	Non-conforming Materials, Parts, or Components
XVI.	Corrective Action
XVII.	Quality Assurance Records
XVIII.	Audits

Procedure #	Title	Criteria Addressed
TSC-1	Quality Assurance Program	I - XVIII
TSC-1/QA-4	Procurement Document Control	IV
TSC-1 /QA-5	Instruments, Procedures, Drawings	V
TSC-1/QA-6	Document Control	VI
TSC-1/QA-7	Control of Purchased Material	VII
TSC-1/QA-8	Identification and Control of Materials	VIII
TSC-1/QA-9	Inspections	X
TSC-1/QA-10	Handling, Storage, and Shipping	XIII
TSC-1/QA-11	Nonconforming Materials	XV
TSC-1/QA-12	Corrective Action	XVI
TSC-1/QA-13	Quality Assurance Records	XVII
TSC-1/QA-14	Audits	XVIII

4.0 Procurement Document Control

The procurement of Type B containers is accomplished with a written Purchase Order. Purchase order forms are controlled and in the possession of a limited number of individuals. Only these individuals are authorized to release Purchase Orders, and are responsible for conforming with established procurement and record-keeping procedures.

The Du Pont Merck Pharmaceutical Company Billerica site policy, including the Du Pont operations, requires the review of procurement documents by the responsible operation or site manager. When the operation or site manager (or delegate) determines that the procurement action is governed by an applicable standard, specification, code, regulation, license, or Certificate of Compliance, the procurement document is submitted to Quality Assurance for review and approval.

The Quality Assurance reviewer examines the procurement document to ensure that complete information is provided to identify:

a. The applicable 10 CFR Part 50, Appendix B and 10 CFR 71 Appendix E requirements which must be addressed;

b. The technical requirements, including the applicable regulatory requirements, identification requirements, specifications, codes, and industrial standards;

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

d. The procuring agency's right of access to supplier's records for inspection and audit;

e. Quality requirements, which must be correctly stated, inspectable and controllable, with adequate acceptance and rejection criteria.

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

Original and revised procurement documents must be clearly annotated to indicate the completion of the aforementioned review and approval sequence. Record copies must be maintained in accordance with document control procedures in effect at time of preparation.

5.0 Instructions, Procedures, and Drawings

Activities affecting quality are prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstance.

The purpose of the instructions, procedures, or drawings, is to provide and communicate standards for quality determination and are directed at maintaining an overall quality program.

Procedures and instructions are prepared by the cognizant site operation. 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.

The Billerica Site Quality Assurance organization will review instructions, procedures, or drawings to insure that adequate quantitative and qualitative acceptance criteria are present.

6.0 Document Control

The Billerica Site written procedures, procedure control specifications, instructions, and their respective changes, are required to insure adequacy.

6.1 Document-types Control

The control includes all documents and their changes affecting the quality program. These documents include, but are not limited to, specifications, procurement documents, Quality Assurance manuals, and inspections. The control system provides adequate and timely distribution of all documents to recipients listed on a document distribution list, and prompt removal of all obsolete documentation from defined document control centers.

6.2 Document Review

All safety related documents, including the documents applicable to the Du Pont operations on site, are reviewed and approved by the Du Pont Merck Pharmaceutical Company Billerica Site Quality Assurance organization.

6.3 Document Control

Execution of an effective control system requires the following:

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

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

The number of document copies made and issued is controlled by a document distribution list maintained in the document file. The removal of obsolete documents, procedures, details, forms, etc. is accomplished immediately when such material is made obsolete by new or revised documents. Obsolete documents are destroyed except for a history copy maintained in the document file. Procedures and their changes are distributed on a formal basis and are of standard format. In case of emergency, however, approved handwritten procedures or mark-up changes, can be considered satisfactory as long as they are converted to the standard form and become official within 30 days.

6.4 Document Change Control

All proposed changes are reviewed by Quality Assurance prior to approval to determine the effect of the change and the resultant changes.

6.5 Document Availability

Documents will be available, prior to commencement of work, at the location where activities involving them are to be performed.

7.0 Control of Purchased Material

The procurement control methods uses established measures to assure that procured items are clearly and adequately specified in procurement documents and supplied by vendors who are capable of producing items which consist of procedures or instructions, include provisions for vendor evaluation and review of procurement requirements.

7.1 Supplier Evaluation

Billerica Site Quality Assurance personnel participate in evaluation of procurement sources. Recommendation of procurement sources is based on these evaluations. Results of supplier evaluations performed prior to contract award are documented and filed. The evaluations cover review of capabilities and include the following:

a. Historical performance data, particularly in product quality and delivery;

b. Review and comment on supplier's Quality Assurance program.

The evaluation considerations include the elements of the NRC Quality Assurance Criteria delegated to the supplier to the extent these criteria are applicable to the container being purchased or leased.

7.2 Receiving Inspection

Receipt inspections are performed on leased or purchased items to insure that:

a. Material is properly identified and corresponds to the receiving documentation.

b. Material is inspected and judged acceptable in accordance with specified requirements prior to use;

c. Inspection records attesting to the acceptance of material are available and are filed with the Site D.O.T. Compliance Officer;

d. Items accepted and released are identified as to their inspection status prior to forwarding them to controlled storage areas or releasing them for use.

7.3 Supplier Audit

Measures used for auditing suppliers are described in the Audit section of this document.

8.0 Identification and Control of Purchased Containers

The identification and control described herein applies to all purchased Type B containers from the time of receipt of the containers.

The inspection status of all containers must be evident at all times. This will be accomplished by marking, tagging, or stamping.

Identification of containers with an identifying number must be accomplished with a method that will provide legible identification as permanent as the normal life expectancy of the item marked, without adverse effect on its life and utility.

Containers not suitable for individual marking must be individually tagged.

The storage area will contain only those containers which have been inspected and accepted.

9.0 Inspection

The established inspection program at the Billerica Site verifies the performance of quality related activities within the applicable requirements. The verification is performed in accordance with written inspection procedures. The inspection program also provides for identification and documentation of deficiencies discovered during inspection and the required corrective action.

9.1 Inspection Procedures

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

a. Identification of activities to be inspected;

b. Identification of the individual's responsibilities for performing the inspection;

c. Acceptance and rejection criteria;

d. A description of the inspection method;

e. Recording evidence of completing and verifying an operation;

f. Recording inspector or data recorder and the results of the inspection operation.

Inspection procedures and/or instructions are maintained current by established document control measures.

10.0 Handling, Storage, and Shipping

Quality Assurance requirements for Type B packaging, handling, storage, and shipping must be documented.

Prior to the shipment and/or transportation of a container, all conditions of the Quality Assurance Program must be satisfied, the shipment is properly described, and the container properly marked and labeled according to the applicable regulations of the Department of Transportation.

11.0 Nonconforming Materials

Procedures for control of nonconforming material assure that such materials are identified and segregated from acceptable materials to preclude their inadvertent use.

11.1 Nonconformance Disposition

The Quality Assurance personnel have the responsibility and the authority for the disposition of nonconforming items.

11.2 Assessment of Nonconformance

Nonconformance instances must be analyzed periodically to show quality trends of a manufacturer or supplier. Instances of nonconformance must be documented and retained within the procurement documents.

12.0 Corrective Action

Du Pont Merck Pharmaceutical, and Du Pont, Quality Assurance personnel at the Billerica Site must evaluate conditions adverse to the quality standards to determine the need for corrective action. Corrective action must be promptly initiated when it is determined that the condition is due to an assignable cause and is repetitive in nature.

The corrective action procedure is divided into five steps:

a. Investigate the condition;

b. Determine the cause;

c. Define the corrective action;

d. Implement the corrective action;

e. Evaluate the corrective action.

Specific individuals from appropriate site organizations must be assigned the responsibility of accomplishing each of the phases. The results of each phase must be documented and become part of the corrective action. Quality Assurance must review records to verify proper implementation of corrective action. The corrective action documentation must not be closed out until results of the corrective action have been evaluated and approved by Quality Assurance.

13.0 Quality Assurance Records

13.1 Maintenance and Access to Records

The records system maintained at the Billerica Site includes the retention of the procurement, inspection, and nonconformance records essential to demonstrate container quality. All records are maintained according to established procedures and will be identifiable and retrievable.

13.2 Contents of Record Files

It is the policy of the Quality Assurance organization to maintain adequate records of all procurement, nonconformance, and inspection. Inspection must contain the following where applicable:

a. A description of the type of observation;

b. Evidence of completing and verifying the inspection operation;

c. The date and results of the inspection;

d. Information relating to conditions adverse to quality;

e. Inspector or data recorder identification;

f. Evidence as to the acceptability of the results;

g. Identification of the procedure(s) used.

Records must also be maintained of the supplier's Quality Assurance programs and documents pertaining to the Billerica Site's internal Quality Assurance audits. File of personnel qualifications and training must also be maintained.

14.0 Audits

Planned audits must be performed to provide comprehensive, independent verification and evaluation of the Billerica Site's Quality Assurance Program and that the supplier has an NRC approved Quality Assurance Program. The audit scope must encompass an 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 maintenance and control. Audit checklists must be established prior to conducting an audit.

14.1 Audit Schedule

Internal audits must be conducted routinely once every twelve months. However, unscheduled audits may be performed more frequently in specific areas, when the need is indicated by the existence of chronic problems. All audits must be performed on a random, unannounced basis to ensure optimum effectiveness and a prompt disclosure of deficiencies.

14.2 Audit personnel

Audits must be performed by the Manager, Safety and Environmental Affairs (or designee) and an additional site operations representative with no direct line responsibility for the function audited. The operations' representative must have the required level of technical capability to accomplish the audit functions satisfactorily and to conform to the requirements.

14.3 Audit Reports

A verbal presentation of the findings and conclusions of the audit is made to the Transportation Safety Committee. Recommendations for quality related improvement are presented as well. A written report containing the findings and recommendations reviewed in the verbal report is prepared and distributed to the responsible management personnel affected by the audit findings. Audits must include an assessment as to how well the Quality Assurance Program meets regulatory or other requirements.

14.4 Follow-Up

The originator of an audit report or a designated alternate is required to follow an open item until action is taken to satisfy an audit action item. Records of actions taken to achieve resolution are maintained. Follow-up actions are taken to verify corrective action is effective. Responsible Quality Assurance personnel must evaluate each audit report item and correct deficiencies as promptly as possible after they are revealed.

TYPE B CONTAINER SHIPPING INSPECTION

Name: _____ Bldg. : _____
Date: _____ Time: _____

Customer Name: _____
Address: _____
City, State, ZIP Code _____
P.O. #/NENC# _____ Container Serial # _____
Weight _____ lbs. _____ Kg NRC Certification # _____

External Wipe Survey (MUST BE LESS THAN 2200 dpm/100cm^2)
Top _____ Bottom _____ Side _____

Surface Radiation (MUST BE LESS THAN 200 mR/hr)
Top _____ Bottom _____ Side _____

Transport Index (MUST BE LESS THAN 10 mR/hr.)
Top _____ Bottom _____ Side _____

Physical Appearance
Note any damage : _____

OPERATOR _____ INSPECTOR _____

SHIPPING INFORMATION

- Proper Shipping Name
( ) Radioactive Material, N.O.S UN 2982
( ) Radioactive Material, L.S.A., N.O.S. UN 2912
( ) Radioactive Material, Empty Packages, UN2908
( ) Radioactive Material, Articles, Manufactured from Depleted Uranium, UN2909

- ADDITIONAL ENTRIES REQUIRED

  - Name or symbol of each radionuclides _____
  - Total activity in GBq _____
  - Physical State (solid, liquid, gas) _____
  - Chemical Form : (circle one)

    Laboratory Waste — Calibration Source
    Container Shielding — Radiopharmaceuticals
    Inorganic Salt — Other _____
  - Labels Applied _____
  - TI (Y II or Y III) _____
  - Dimensions (metric) _____ X _____ X _____
  - Type of Aircraft

    ( ) Passenger
    ( ) Cargo Only — Labels Affixed _____

- OTHER REQUIREMENTS

  ( ) Security Seal Affixed
  ( ) Opening Instructions Affixed
  ( ) Non Applicable Labels Removed

OPERATOR _____ INSPECTOR _____

DISTRIBUTION DEPARTMENT

ADMINISTRATION :

Carrier _____ AWB/BOL# _____
Ship Date _____ Admin. Preparer _____
( ) Attach Copy of Airway Bill/Bill of Lading

SYSTEMS :

Carrier Contact _____
Proof of Delivery : Date _____ Time _____
Signature _____

Systems _____ Date _____

TYPE B CONTAINER RECEIVING INSPECTION

Date:_____ Time:_____

Shipper Name:_____ _____
Address:_____
City, State, Zip Code:_____
P.O#/NENC#_____ Container Serial #_____
Waybill#_____ NRC Certification#_____
Carrier_____ Expiration Date_____
External Wipe Survey (MUST BE LESS THAN 22,000 dpm/100cm^2)
Top_____ Bottom_____ Side_____

Surface Radiation: (MUST BE LESS THAN 200 mR/hr)
Top_____ Bottom_____ Side_____

Transport Index (MUST BE LESS THAN 10 mR/hr)
Top_____ Bottom_____ Side_____

Physical Appearance:
Note any Damage:_____
Security seal Intact (Y/N)_____

Check documents to assure information corresponds to container

Item:	Shipping Documents	Container
Isotope (Nuclides)	_____	_____
Quantity	_____	_____
Physical Form	_____	_____
Label Type	_____	_____
TI	_____	_____
Proper Shipping Name	_____	_____
Handling Labels	_____	_____
Other	_____	_____

Report any discrepancies to your immediate supervisor

Operator:_____ Witness:_____

Container released to:_____

Bldg#_____ Lab#_____ Time_____ By_____

Container Received by:_____

Bldg#_____ Lab#_____ Time_____

Opening Inspection: (attach vendor drawing & opening instructions)

Security seal removed (Y/N)_____
Outer Container Bolt(s) Removed (Y/N)_____ No. of Bolts_____
Inner Container Bolts Removed (Y/N)_____ No. of Bolts_____
Inner (2R) container present (Y/N)_____
Indicate No. of turns required to open 2R container_____
Primary container intact (Y/N)_____
Comments_____
_____

Empty Container Storage Location_____

Operator_____ Witness_____

REASSEMBLE CONTAINER:

Primary container removed (Y/N)_____
Inner (2R) container present (Y/N)_____
Indicate No. of turns required to close 2R container_____
Inner Container Bolts Secured (Y/N)_____ No. of Bolts_____
Outer Container Bolt(s) Secured (Y/N)_____ No. of Bolts_____
Security Seal Affixed (Y/N)_____

Operator_____ Witness_____

Forward this form to;
TSC Chairman, Bionuclides Packaging,
Bldg. 250-1/Billerica