QUALITY ASSURANCE PROGRAM

FOR

NEUTRON PRODUCTS, INCORPORATED

REVISION 3

JUNE 24, 1980

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Quality Assurance

6/26/80

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President

I. Introduction

Neutron Products, Inc. (NPI) was established in 1959 to commercially produce radioisotopes. Activities of the company have grown to include the production of radioactive sources for medical and industrial applications, the sterilization of hospital supplies and the radiation processing of chemicals to change their chemical and physical properties.

NPI has, and will continue, to provide quality products and services to its customers. Efforts to improve the safety of company personnel, the public, the local environment, and when possible, the users of NPI products will continue and are closely coupled to the company's Quality Assurance Program.

NPI operates under the regulatory scope of the Nuclear Regulatory Commission (NRC), the Food and Drug Administration (FDA), the Department of Transportation (DOT), and the State of Maryland. In the interest of public and occupational health and safety, regulations have been established with respect to quality assurance.

Execution of the Quality Assurance Program presented in this document, *which* has been written to comply with all appropriate regulations and is part of a continuing effort to provide high quality services at reasonable costs to *our* customers, *is the sole responsibility of NPI.*

II. Company Organization

A company organization chart is indicated in Figure 1. Mr. J. A. Ransohoff, President of the company, is responsible for overall management and operation. Mr. M. M. Turkanis is the Vice President directly responsible for cobalt-60 production, marketing, and distribution. Mr. D. G. Woodard is the Vice President directly responsible for the radiation processing and radiation testing operations of the company.

Mr. C. Smedira is the Quality Assurance Manager. As such, he will be responsible for the company's QA program. The QA Manager has the authority to stop any company operation which he has reason to believe is proceeding in an unsatisfactory fashion. The QA Manager reports directly to the President and *has the authority to identify problems, to initiate, recommend, or provide solutions, and to verify the implementation of solutions.*

The Quality Assurance Manager must have a sufficiently broad education and experience to be able to interpret the requirements of all regulatory agencies to all aspects of the company's operations.

The QA organization reviews and concurs with inspection plans, test, calibration, and special process procedures; drawings and specifications; and changes thereto.

Because of the relatively small size of the company, some personnel, among them the QA Manager, have been assigned multiple responsibilities. The specific QA/QC functions which are to be performed by the NPI QA organization are listed in Section V of this document.

Corporate finance and administration occur under the direction of the Corporate Treasurer and Secretary, respectively. The Corporate Secretary also manages the company's Laminar Flow Technology activities.

From time to time, special projects are undertaken under the direct supervision of the President of the company. When this happens, a senior technical manager, as opposed to one of the corporate officers or the QA Manager, will be given the responsibility to execute the project.

The President and the QA Manager shall confer at the initiation of any such project to determine an appropriate QA approach for the project.

Personnel assignments and responsibilities are presented in more detail in each of the specific quality control programs presented in Section V.

The President of NPI will, at least once each year, communicate to all representative organizations and individuals that the requirements of the QA program and procedures are mandatory and that he has charged the QA Manager with the responsibility to implement and enforce these requirements. The President of the company shall be responsible for the resolution of all disputes involving quality arising from a difference of opinion between the QA Manager and other line management in the company. Line management at NPI shall be responsible for establishing an indoctrination and training program such that:

1. Personnel responsible for performing quality related activities are instructed as to the purpose, scope, and implementation of the QA program, instructions, and procedures.

2. Personnel performing quality affecting activities are trained and qualified in the principle 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.

III. Company Operations

This section presents a listing and brief description of the present and anticipated products and services of NPI.

1. Cobalt-60 Irradiation Sources

The company is engaged in the business of selling cobalt-60 sources for teletherapy, intercavity, and industrial applications. Toward this end, company activities include cobalt-59 target design, procurement, transportation, and irradiation, as well as cobalt-60 transportation, processing, encapsulation, delivery, installation, maintenance, and replacement.

2. Maintenance of Teletherapy Units

The company is engaged in the business of repairing and reconditioning cobalt-60 teletherapy units currently in use.

3. Radiation Processing

The company uses cobalt-60 irradiators to process materials to achieve desired biological, chemical, and physical properties *and in conjunction with a chemical mix plant, to produce a* group of polymeric products largely based on *acrylamide*. Irradiators are also used for testing to determine the effect of radiation on chemical and physical properties of substances and to determine the performance of equipment used in radiation environments during normal and off-normal conditions.

4. Laminar Flow Testing

The company provides inspection, testing, and routine maintenance services for horizontal and vertical laminar flow hoods used in hospitals, pharmacies, and in other clean room applications.

5. Product Marketing

The company markets the following products of other manufacturers:

Block and Wedge Holder - This attachment to teletherapy units allows finer collimation of the radiation beams during therapy.

NEUTRON PRODUCTS, INC.

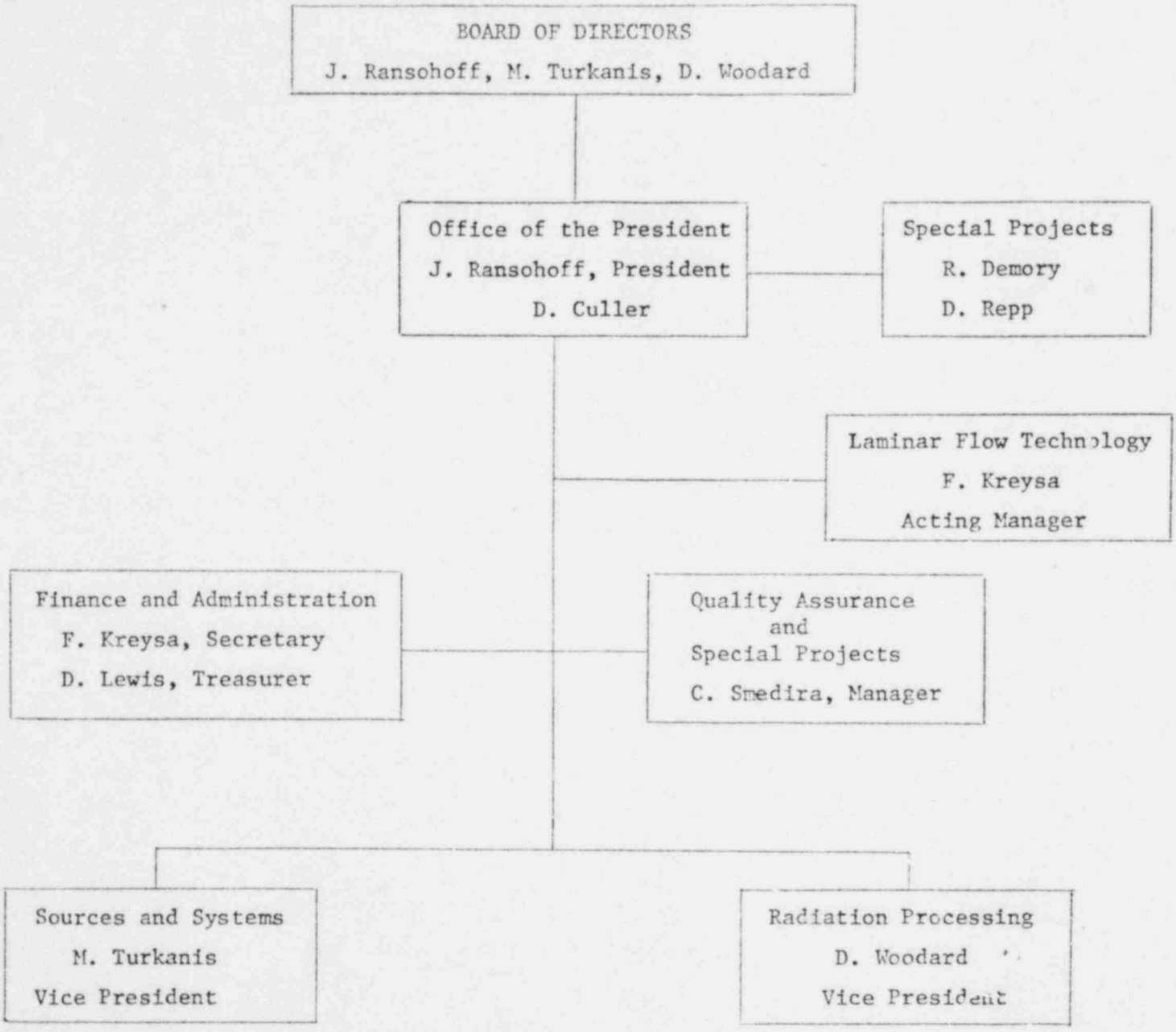

Figure 1

Radiation Detectors - The company sells the Primalert-10 Radiation Level Monitor and the optional Primalarm remote signal unit.

Simulators - The company plans to market a new radiation therapy simulator, a device used in the localization of tumors and for planning radiation treatments.

IV. General Quality Assurance Approach

10 CFR 50, Appendix B, and 10 CFR 71, Appendix E, provides 18 guidelines for establishing and implementing a quality assurance program for some types of nuclear activities. 21 CFR 5 provides nine guidelines for the establishment of "Good Manufacturing Practices" for medical devices. The NPI Quality Assurance Program is committed to complying with these 27 guidelines (not all of which are different). This QA plan represents NPI's application of these guidelines to company activities. The formal QA approach presented in this document consists of the following key elements:

Planning - what to do to provide quality

Judgement - to determine what should be verified and/or documented

Execution - of the plans established

Documentation - of the execution and verifications

Inspecting and Auditing - to see if activities are performed and documented correctly

At NPI the line organization has the responsibility for the planning, judgement, execution, and documentation activities. The QA Manager participates and concurs in these activities and has the responsibility for auditing tasks. In view of NPI's size, maximum use of line individuals has been made. Line individuals will be qualified to check, verify, test, and inspect independent actions of other line individuals. The QA Manager will continue to assess the effectiveness of the overall program and be responsible for program change, indoctrination and training, monitoring, and coordination.

Because of the diverse nature of the various operations of the company, separate subplans for quality assurance have been generated for each operation. The intent of each of these subplans follows from Section I of this document, the organization in each of these subplans follows from Section II, and the basic approach is consistent with the general intention of this section.

NPI management will assess the scope, status, implementation, and effectiveness of the QA program to assure that the program is adequate and complies with all applicable regulations, at least two times a year. The QA Manager will continue to assess the effectiveness of the overall program and be responsible for program change, indoctrination and training, monitoring, and coordination.

Each subplan follows this outline:

Scope

1. Organization
2. Quality Assurance Definitions
3. Buildings
4. Equipment
5. Design Control
6. Procurement Document Control
7. Instructions, Procedures, and Drawings
8. Document Control
9. Control of Purchased Material, Equipment, and Services
10. Identification and Control of Materials, Parts, and Components
11. Special Processes
12. Inspection
13. Test Control
14. Control of Measuring and Test E[illegible]nt
15. Handling, Storage, Distributing, Shipping, and Installation
16. Evaluation, Inspection, Test, and Operating Status
17. Nonconforming Materials, Parts, and Components
18. Corrective Action
19. Packaging and Labeling

Where a particular section is not appropriate to a specific subplan, it is so stated.

V. Special Quality Assurance Programs

The specific subplans which are contained in this section are:

1. Cobalt-60 Irradiation Sources

   1.1 Reactor Target Assemblies
   1.2 Radioactive Source Inventory Control
   1.3 Radioactive Source Fabrication
   1.4 Radioactive Materials Transportation
   1.5 Radioactive Source Transfer

2. Teletherapy Unit Reconditioning

3. Radiation Processing

   3.1 Dose Control Irradiations
   3.2 Physical and Chemical Properties Irradiations
   3.3 Polyacrylamide Production
   3.4 Other Irradiations

4. Laminar Flow Testing

5. Product Marketing

1.1 Reactor Target Assemblies

1.1.1 Organization

Design, fabrication, transportation, and irradiation of cobalt-60 reactor targets is the responsibility of the Vice President for Sources and Systems. He will be assisted by other company personnel as appropriate.

A definite distribution of responsibilities between NPI, other contractors, and the reactor operator will be established for each contract and the procedures, specifications, and criteria of a contractor which shall be approved by NPI will be documented in the contract agreement.

1.1.2 Definitions

Reactor target assemblies - completed rods, herein called targets, ready for loading into a reactor.

Capsule - a sealed stainless steel tube containing cobalt-59 material. This tube is contained inside the target assembly.

Quality - a quality target is one which has the purity and integrity of composition to withstand the necessary handling, irradiation, and transportation without the release of cobalt to any reactor system or the environment and perform its intended neutron absorbing function within the reactor.

1.1.3 Buildings

Targets and target components will be fabricated and handled in NPI existing buildings and in other facilities. Adequate space shall be provided to facilitate cleaning, prevent mixups, and assure the orderly handling of incoming material, rejected material, material in the fabrication process, and testing and measuring equipment. Adequate lighting, ventilation, and temperature and humidity control shall be provided. Airborne contamination shall be monitored and kept within appropriate limits. Inspections of the building condition shall be periodically performed and the results of these inspections shall be recorded. The NPI and contractor quality assurance organizations shall be responsible for the performance and documentation of these inspections in their respective facilities. No less than two inspections per year will be performed. The line organization shall be responsible for cleaning the buildings. Adequate sanitary facilities will be provided.

1.1.4 Equipment

Nondisposable equipment used in the manufacturing process of target components and assemblies shall be cleanable and, if necessary, adjustable. Equipment shall be stored in such a manner to reduce contamination by dust or dirt or radioactivity. Equipment will be clean when used. Equipment which requires periodic adjustment shall have allowable tolerances posted where the equipment is stored or used.

Materials used in the manufacturing process and not desired in the final product will be removed and such removal shall be documented.

1.1.5 Design Control

The Vice President for Sources and Systems shall establish and implement methods for controlling design activities to assure that applicable design criteria, codes, standards, practices, and requirements for targets are defined and correctly translated into specifications, drawings, procedures, and instructions. He shall also establish and implement a method for coordinating and interfacing with other organizations, contractors and the reactor operator to assure compliance with these requirements. A design review to assure that the design meets the design criteria shall be conducted. Representatives of other organizations (such as the reactor operator) may participate in this review. Only parts, materials, and processes which have been proven to be acceptable for targets will be used. Specifications, drawings, instructions, and other engineering documents which may be necessary to describe the design, materials, fabrication, installation, testing, inspection, packaging, shipping and storage requirements of the targets will be prepared at NPI and at other contractor organizations. A specific definition of responsibilities for all documentation shall be made.

A method shall be established to define and control design interfaces between NPI and the reactor operator. Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design.

1.1.6 Procurement Document Control

Vendors supplying target material and/or capsule material shall comply with NPI Specifications, P-2, Specifications, Procedures, and Quality Control Plan for Tube Type Cobalt Targets, and P-3 Specifications, Procedures, and Quality Control Plan for Clad Wire Type Cobalt Targets.

1.1.7 Instructions, Procedures, and Drawings

All instructions, procedures, and drawings necessary to assure quality in the fabrication of targets and capsules will be listed in NPI Specification P-6, Quality Control Plan and Outline of Fabrication Procedures for Cobalt Target Rod Assembly and in the approved specifications of a contractor as appropriate. Periodically, audits shall be conducted to check for conformance.

1.1.8 Document Control

Instructions, procedures, drawings, and specifications shall be issued by the *Vice President for Sources and Systems* and by contractors, as appropriate. These documents shall be submitted to the *QA Manager* for approval. Changes to any of these documents shall also require his approval.

1.1.9 Control of Purchased Material, Equipment, and Services

Independent materials testing and examination of each and every target and capsule shall be performed and the results documented.

1.1.10 Identification and Control of Materials, Parts, and Components

The *Vice President for Sources and Systems* shall establish a control area in which all targets and capsules are stored and labeled. Access to this area shall be limited. Vendors supplying target and/or capsule materials shall comply with NPI Specifications P-2 and P-3.

1.1.11 Special Processes

Any individual performing a welding, heat treating, or nondestructive examination of target components or a forming or melting operation of the components shall be certified by the *appropriate designee of the Vice President for Sources and Systems* or by the contractor's organization. Nondestructive examination of target components shall be in conformance to NPI Specifications Q-4, X-Ray Inspection (Hollow), Q-5, X-Ray Inspection (Solid), Q-6, Helium Mass Spectrography Inspection, and Q-7, Dypenetrant Inspection, or those of a contractor approved by NPI.

1.1.12 Inspection

Contractor inspection requirements for targets and capsules shall be in accordance with NPI Specifications P-2 and P-3.

Per odically, NPI personnel will witness these inspections. Inspections to be performed by NPI personnel will periodically be witnessed by the Quality Assurance Manager or his designee.

1.1.13 Test Control

Helium leak testing of assembled targets and capsules shall be in accordance with NPI Specification Q-6 or by a NPI contractor procedure approved by NPI.

1.1.14 Control of Measuring and Test Equipment

Equipment used to examine targets and capsules shall be controlled, calibrated, adjusted, and maintained. Calibrations shall be recorded. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which a calibration should be performed.

1.1.15 Handling, Storage, Distributing, Shipping, and Installation

Targets and component materials shall be handled and stored in accordance with NPI Procedures R 2003, General Procedure for In-Pool Source Operations, NR 2005, Procedure for Decanning Cobalt-60 Sources from Zircaloy Tubes, and NR 2008, Procedure for Placing and Unloading Casks in Main Storage Pool.

Target installation in a reactor shall be in accordance with the appropriate technical specifications of the reactor operator.

1.1.16 Evaluation, Inspection, Test, and Operating Status

Target operating status shall be ascertained by the reactor operator via flux level indicators, flowmeters, and thermocouples. Acceptable flux and temperature levels for each target shall be specified prior to irradiation.

Upon receipt of the irradiated target, NPI personnel shall ascertain the condition of the target in accordance with Section 1.2 of this plan.

1.1.17 Nonconforming Parts

Incoming target or capsule material identified as nonconforming to any NPI specification shall be tagged accordingly.

Nonconforming material shall be stored physically apart from acceptable material and a list of nonconforming items shall be prepared by the *Vice President for Sources and Systems* or by contractors and provided on a weekly basis to the *Quality Assurance Manager*. The *Vice President for Sources and Systems* shall make recommendations for appropriate disposition for nonconforming materials. The approval of the *QA Manager* is required for any disposition of nonconforming material. Such disposition shall be documented.

1.1.18 Corrective Action

The *Vice President for Sources and Systems* shall document the cause for nonconformance of any items so labeled. He shall also document recommendations for suggested corrective actions.

1.1.19 Packaging and Labeling

All targets and capsules shall be uniquely labeled.

1.2 Radioactive Source Inventory Control

1.2.1 Organization

The responsibility for the characterization and maintenance of all radioactive source material inventory has been delegated to the Vice President for Sources and Systems. Under the Vice President, the responsible individual is the Section Manager for Source Production, Mr. J. Corun. Mr. Corun will be assisted by other company personnel as appropriate.

1.2.2 Definitions

Inventory quality control program - one which (1) continually and accurately records the identity, location, and activity of all individual source material; (2) is conducted in compliance with the NPI Radiation Protection Program; and, (3) does not result in releases of radioactive cobalt to the local environment.

Target sources - cobalt-60 sources contained in target rod assemblies.

Teletherapy sources - singly or doubly encapsulated cobalt-60 teletherapy slugs. Teletherapy sources acquired from customers or other suppliers may contain cobalt-60 pellets.

Teletherapy slugs - cobalt-60 sources prepared by a melting process.

Industrial sources - doubly encapsulated rods and/or springs of solid cobalt-60.

Rod sources - singly encapsulated cobalt-60 rods.

Spring sources - singly encapsulated cobalt-60 springs.

Check sources - cobalt-60 or cesium-137 sources used for calibration or checking of radiation monitors.

1.2.3 Buildings

Inventory control facilities shall have adequate space and storage equipment to prevent mixups and to assure the accurate handling of all incoming cobalt-60 sources, regardless of form, and to enable the operator to unload and store all incoming shipments. Space shall also be adequate for equipment to assure the quality of source activity calibrations.

1.2.4 Equipment

Nondisposable equipment used in the handling and calibrating process shall be cleanable and, if necessary, adjustable. Equipment shall be stored in such a manner to reduce contamination by dust or dirt. Equipment will be clean when used. Equipment which requires periodic adjustment shall have allowable tolerances posted where the equipment is stored.

1.2.5 Design Control

Not applicable

1.2.6 Procurement Document Control

Not applicable

1.2.7 Instructions, Procedures, and Drawings

After target rod sources have been removed from an incoming shipping cask and documented as to their position in the pool storage tank, they shall be calibrated. After calibration, the target rods shall

be cut open and the contained individual rod and spring sources shall be removed and documented as to their holder and holder positions. The sources shall be calibrated on an individual basis and then returned to their holders. The holders shall be placed in the pool storage tank and their positions documented.

1.2.8 Document Control

For each target or source calibrated, a calibration trace shall be generated. This trace shall contain information as to target number, source number, source type, date of calibration, activity, date of activity, and source holder number and position. After areas have been run on these traces and activities calculated, the traces shall be stored in notebooks by holder numbers. Changes to these traces can be made only at the direction of the persons originating the traces. After sources have been sold, the traces for that source shall be removed from the inventory file, identified as to encapsulated source number, and placed in the customer's file.

1.2.9 Control of Purchased Material, Equipment, and Services

Not applicable

1.2.10 Identification and Control of Materials, Parts, and Components

As each rod is removed from the shipping cask, its identifying number shall be documented and the position in the pool storage tank noted.

1.2.11 Special Processes

Each individual source shall be calibrated and the results documented. All rod and spring sources shall be calibrated by the underwater pool calibrator or by the hot cell calibrator (in both of these the source is passed under a shielded collimated detector and the output reading plotted; the readings are compared to a known standard to determine curie activity). Teletherapy sources shall be rated by direct output dose rate by measurement in the hot cell.

1.2.12 Inspection

periodic inspections shall be conducted to assure that the pool operator can locate a particular source. The source shall be pulled from the holder and calibrated and the resulting trace shall be compared with the trace already existing for that source. A record of such inspections shall be maintained by the Quality Assurance Manager.

1.2.13 Test Control

Not applicable

1.2.14 Control of Measuring and Test Equipment

The industrial source calibrators shall be periodically tested by measurement of standard industrial sources. The dose rate meter shall be periodically tested by measurement of a standard teletherapy source. The calibrator and planimeter shall be tested periodically.

Records of such testing and the results shall be kept.

1.2.15 Handling, Storage, Distributing, Shipping, and Installation

All incoming target rods shall be handled in accordance with NPI Procedures NR 2001, Procedure for Loading and Removal of Radioactive Shipping Containers from the Main Storage Pool; R 2007, Calibration by Area Method; R 5002, Opening Hot Cell Door After Processing Single and Double Encapsulated Cobalt-60; R 5004, Transfer of Sources Between Hot Cell and Canal Tanks; R 5005, Loading of Encapsulated Sources in Transfer and Shipping Containers from Hot Cell; and, NR 5007, Processing Exposed Cobalt-60.

The rods shall be stored in the main storage pool. Rod and spring sources and industrial sources shall be stored in the main storage pool. Teletherapy sources shall be stored in canals.

1.2.16 Evaluation, Inspection, Test, and Operating Status

Once a quarter the Vice President for Sources and Systems and the QA Manager shall spot review the source inventory log records. Pool operating temperatures shall be inspected by the Source Production Manager or appointee at least once a day and a graph of pool temperature as a function of time shall be provided on a weekly basis to the Vice President for Sources and Systems.

1.2.17 Nonconforming Parts

Encapsulated sources which fail leak tests or are damaged or otherwise defective shall be stored separately from all others and held for disposal.

1.2.18 Corrective Action

Each nonconforming source will be evaluated on a case-by-case basis to decide if salvage or disposal is warranted.

1.2.19 Packaging and Labeling

All sources shall be uniquely labeled.

1.3 Source Fabrication

1.3.1 Organization

Source design and fabrication and equipment and facilities for fabrication, testing, and calibration is the overall responsibility of the Vice President for Sources and Systems. He has delegated this responsibility to the Section Manager for Source Production.

1.3.2 Definitions

Quality source fabrication - the process of transforming irradiated cobalt-60 target material into calibrated, encapsulated sources for specific end use, in accordance with NPI Radiation Protection and Radioactive Respiratory Protection Programs and in accordance with all applicable Federal and state regulations.

Teletherapy sources - sources designed specifically for use in medical teletherapy units.

Industrial sources - sources designed specifically for industrial use.

Other sources - sources designed for use other than above.

Hot cell - the shielded enclosure in which the majority of source fabrication operations are performed.

Pool - a pool of dimeneralized water used for storage of cobalt-60 sources and for certain fabrication operations.

1.3.3 Buildings

Sources are fabricated and handled in a hot cell and pool until transferred to a shipping cask. Both cell and pool shall have adequate space for operations and storage of all sources including as received, in work, and finished product. Adequate lighting, ventilation, and temperature control shall be provided to assure the safety of operations, containment of contamination, and integrity of the product.

1.3.4 Equipment

All equipment used in the fabrication process and unique building services shall be designed, maintained, and operated to provide safe and functional working conditions, to minimize the spread of radioactive contamination, and to provide a high degree of reliability and reproducible accuracy as required.

1.3.5 Design Control

Not applicable

1.3.6 Procurement Document Control

Vendors supplying source encapsulation materials shall supply manufacturer's test reports and certifications for these materials. This control shall be the responsibility of the Source Production Section Manager and periodically checked by the Quality Assurance Manager or appointee in accordance with NPI Specification P-4, Procedure for Encapsulation of Teletherapy Sources.

1.3.7 Instructions, Procedures, and Drawings

All instructions, procedures, and drawings required to fabricate sources will be provided in NPI Specification M-1, Specification for Seamless Stainless Steel Tubing for Encapsulation of Radioactive Sources and Specification P-4.

1.3.8 Document Control

Documents relating to source fabrication shall be maintained by the Source Production Section Manager. These shall have the approval of the Vice President of Sources and Systems.

1.3.9 Control of Purchased Material, Equipment, and Services

The Source Production Section Manager will initiate and approve all purchases and maintain records of the source inventory.

1.3.10 Identification and Control of Materials, Parts, and Components

The Source Production Section Manager shall establish a control area where all encapsulation materials are stored and identified.

1.3.11 Special Processes

Fabrication of sources is a special process which will be performed in accordance with NPI Specifications P-2, P-3, and P-4. Changes to these specifications require the approval of the Vice President for Sources and Systems and the Quality Assurance Manager.

1.3.12 Inspection

Inspection of all critical operations will be in accordance with NPI Specification P-1, Specifications, Procedures, and Quality Control for Sealed Cobalt-60 Sources.

1.3.13 Test Control

All sources shall be tested for quality and integrity in accordance with NPI Specification P-1.

1.3.14 Control of Measuring and Test Equipment

Equipment for calibrating and measuring shall be in accordance with NPI Procedure R 2007.

1.3.15 Handling and Storage

Source handling and storage shall be in accordance with NPI Procedure R 2003.

1.3.16 Evaluation, Inspection, Test, and Operating Status

Not applicable

1.3.17 Nonconforming Materials

All nonconforming source encapsulation materials shall be disposed of by physical removal from encapsulation material storage and "written off" the inventory records. All sources encapsulated or otherwise in-work found to be nonconforming shall be set aside in a segregated area for disposal and so documented.

1.3.18 Corrective Action

Nonconforming encapsulated sources will be reviewed by the Vice President of Sources and Systems for a determination regarding disposal or salvage on a case-by-case basis.

1.3.19 Packaging and Labeling

All finished teletherapy sources shall be uniquely identifiable. Packaging for shipment shall be in accordance with Section 1.4 of this document.

1.4 *Radioactive Materials Transportation*

1.4.1 *Organization*

Design, fabrication, and maintenance of radioactive material shipping containers and transportation of radioactive shipments is the responsibility of the Vice President for Sources and Systems. He shall be assisted by other company personnel as appropriate.

1.4.2 *Definitions*

Quality packaging - the loading of radioactive materials in an NPI or other organization's shipping container for shipment in conformance with applicable regulatory requirements, and completion of the documentation of this activity in accordance with the requirements of this section.

Off site location - a location other than Dickerson at which a radioactive shipment controlled by NPI may originate.

Quality transportation - the safe and efficient carrying of radioactive materials from one site to another in accordance with applicable requirements and the completion of documentation of this activity.

Radioactive materials shipping container - herein called container, is one complying with the applicable regulations of the DOT and NRC.

1.4.3 *Buildings*

Buildings in which shipping containers are stored or handled shall have adequate space for cleaning, maintaining, and orderly handling of incoming and outgoing shipments. Airborne contamination shall be minimized and monitored in facilities which have encapsulated radioactive materials. Inspections of the building conditions shall be performed periodically and the results recorded.

1.4.4 Equipment

Equipment used in handling and vehicles used for transporting containers shall be stored in such a manner as to maintain an adequate condition for use. Shipping containers, overpacks, special handling equipment, instruments, and tools will be maintained by the Teletherapy Services Section Manager. Equipment needed to perform quality related activities shall be specified prior to use, as shall the environmental conditions under which the equipment is to be operated.

1.4.5 Design Control

The Vice President for Sources and Systems is responsible for the design of containers and handling equipment. When additional transportation equipment design is required, he shall establish procedures to assure that applicable design criteria, standards, practices, and regulatory requirements are defined and translated into specifications, drawings, procedures, and instructions. He shall establish and implement a method for coordinating with other organizations and contractors. A design review shall be conducted to assure that (1) the design meets the design criteria; (2) design characteristics can be controlled, inspected, and tested; and, (3) inspection and test criteria are identified. The individual responsible for the design review shall be other than the original designer and the designer's immediate supervisor. Design and specification changes shall be subject to the same design controls and approvals that were applicable to the original design. For each design activity for a transportation package, specific organizational responsibilities shall be established.

1.4.6 Procurement Document Control

Vendors or contractors supplying shipping containers, handling equipment, and parts shall comply with NPI Specification E-1, Equipment Specification for a Lead Shielded Shipping Cask or other appropriate specification. Control of procurement documents shall be the responsibility of the Vice President for Sources and Systems. He shall be responsible to (1) prepare as appropriate, procedures or instructions that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of permanent documents; (2) identify in all appropriate procurement documents, the applicable 10 CFR Part 71, Appendix E requirements which must be complied with and described in the supplier's QA program; (3) require 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; and that they specify 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 NPI for review and approval; (4) specify those records to be retained, controlled, and maintained by the supplier, and those delivered to NPI prior to use or installation of the hardware; and, (5) require NPI's right of access to supplier's facilities and records for inspection and audit.

Changes and revisions to procurement documents shall have at least the same review and approval as the original document.

1.4.7 Instructions, Procedures, and Drawings

See Section 1.4.8. Periodic audits to check for conformance to these documents will be conducted by the QA Manager or his designee.

1.4.8 Document Control

Instructions, procedures, drawings, and specifications for containers, container handling, packaging and shipping are listed in and shall comply with NPI QC Procedure 1001. Responsibilities for the initiation, review, approval, and issuance of these documents are specified in this procedure and no changes to these documents shall be made without the approval of the same people who initially approved these documents. Approved changes in instructions, procedures, drawings, and other documents shall be made prior to the implementation of such changes. The QA Manager shall be responsible for assuring that the sequence of actions required by Procedure 1001 for the preparation and review of required documentation is followed.

Appropriate documents shall be available at all work locations prior to commencement of work. The Vice President for Sources and Systems shall have and maintain a master list which identifies the current revision number of instructions, procedures, specifications, drawings, and procurement documents.

1.4.9 Control of Purchased Material, Equipment, and Services

The Vice President for Sources and Systems shall have an evaluation done of all suppliers to assess their capability to provide acceptable

quality services and products. This evaluation shall be based on 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. All supplier evaluations shall be documented and filed. When required, NPI surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components shall be performed to assure conformance to the purchase order requirements. All suppliers shall be required to furnish the following records as a minimum to the purchase:

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."

Receiving inspection of the supplier-furnished material, equipment, and services shall be performed to assure:

1. The material, components, 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 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.

1.4.10 Identification and Control of Materials, Parts, and Components

The Vice President for Sources and Systems shall be responsible for the proper identification and control of materials, parts, and components associated with the fabrication of radioactive shipping containers.

1.4.11 Special Processes

Loading and unloading containers for radioactive shipments are special processes. These shall be performed in accordance with NPI QC Program 1003, Package Loading Procedure for Radioactive Materials and QC Program 1004, Package Unloading Procedure for Radioactive Materials.

1.4.12 Inspection

Inspection of all quality conformance activities shall be performed under the responsibility of the QA Manager in accordance with QC Procedure QC 1006. Inspection personnel will be independent from those performing these activities. These inspectors shall be qualified in accordance with the company's training program and when other qualifications and certifications are required they shall be kept current.

Modifications, repairs, and replacements for shipping casks shall be inspected in accordance with the original design and inspection requirements, or acceptable alternatives.

Operating and QC procedures will identify, where applicable, mandatory inspection hold points for witness by an inspector.

1.4.13 Test Control

The Vice President of Sources and Systems shall be responsible for shipping cask test control. A test procedure for demonstrating that shipping casks will perform satisfactorily in service is established and documented. This procedure is a checklist performed in accordance with QC Procedure 1006. Any modifications, repairs, or replacements to shipping casks shall be tested in accordance with the original design and test requirements or acceptable alternatives.

Test results are documented, evaluated, and their acceptability determined by the Section Manager responsible for the radiation shipment.

1.4.14 Control of Measuring and Test Equipment

All measuring and test instruments shall be calibrated at specific intervals to assure accuracy for intended purposes. Calibration test data for these instruments shall be identifiable and traceable.

Whenever test equipment is found to be out of calibration, previous tests will be investigated for validity and so documented.

Where applicable, as in the case of radiation measuring instruments, the basis for calibration will be traceable to nationally recognized standards.

1.4.15 Handling, Storage, and Shipping

All operations concerning handling, storage, and shipping of radioactive shipping casks shall be in accordance with NPI QC Procedure 1005, Handling, Storage, and Shipping Procedure for Radioactive Materials. Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established in this procedure. These are accomplished by trained, specifically designated qualified individuals in accordance with the above procedure.

All conditions of NRC package approval and U. S. DOT shipping requirements shall be satisfied prior to any shipment. All necessary shipping papers shall be properly prepared. Departure and arrival time and destination of each package shall be established and monitored to a degree consistent with safe transportation of the package.

1.4.16 Evaluation, Inspection, Test, and Operating Status

Inspection, testing, and operating status of all shipping packages and components shall be in accordance with NPI QC Procedure 1006, Inspection, Test, and Operating Status Procedure for Radioactive Materials.

Identification, test, and operating status of all packages and components shall be known by all affected sections.

Application and removal of inspection tag markings, and shipping or other labels shall be controlled in accordance with QC Procedure 1006. By-passing of required inspections, tests, and other critical operations, requires the prior approval of the Vice President for Sources and the QA Manager.

The status of nonconforming, inoperative, or malfunctioning packages or components shall be clearly identified to prevent inadvertent use.

1.4.17 Nonconforming Parts

Any nonconforming parts will be so identified and segregated for disposal or removal from the container or shipping areas. Nonconforming materials, parts, components, and services shall be controlled in accordance with NPI QC Procedures 1005 and 1006 which require the identification, documentation, segregation of nonconforming items and the notification of affected individuals. Designations of individuals responsible for the review and disposition of the materials are made in these procedures.

Documentation shall identify the nonconforming item, state its inspection requirements, describe the nonconformance, and identify final disposition. Signature approval of the Vice President for Sources and Systems is required for final disposition.

Acceptability of rework or repair shall be verified by reinspection and retesting, as required, and as originally inspected or by an equal method.

1.4.18 Corrective Action

The QA Manager shall conduct an evaluation, in conjunction with the Vice President for Sources and Systems, of any conditions determined to be adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective materials and equipment) to determine the need for corrective action.

Repair or replacement of nonconforming parts or the correction of other deficiencies shall be recommended by the Source Production Section Manager, the Manager for Utilization, Facilities, and Equipment, or the Health Physics Technician, and must be approved by the Vice President for Sources and Systems.

To the extent possible, corrective actions shall attempt to preclude recurrence of the adverse condition.

Followup reviews shall be conducted by the QA Manager to verify the proper implementation of corrective actions and to close out the corrective action documentation.

1.4.19 Packaging and Labeling

All NPI radioactive shipments shall be packaged and labeled in accordance with NPI QC Program 1003.

1.5 Radioactive Source Transfer

1.5.1 Organization

The Vice President for Sources and Systems has the overall responsibility for radioactive source transfers.

The loading and unloading of radioactive shipping containers and the preparation for shipment at NPI is the responsibility of the Source Production Section Manager. Loading, unloading, and preparation for shipment offsite is the responsibility of the Teletherapy Services Section Manager who is also responsible for installation of sources into teletherapy units.

Design and fabrication of source adapters which are installed in a teletherapy unit is the responsibility of the Source Production Section Manager. Design and fabrication of container insert holders and adapters which are part of the transfer operation are the responsibility of the Utilization, Facilities, and Equipment Manager.

1.5.2 Definitions

Radioactive source transfer - the field operation involving the transfer of sources between shipping containers and teletherapy units, unloading units, transferring sources into and out of an operating unit and transferring sources from one operating unit to another, including teletherapy unit checkout, servicing, and maintenance.

Teletherapy unit - a machine using cobalt-60 at a distance for radiation therapy.

Quality radioactive source transfers - transfers made in accordance with the procedures referenced herein.

1.5.3 Buildings

Not applicable

1.5.4 Equipment

Shipping containers, overpacks, special handling equipment, instruments, and tools will be maintained by the Teletherapy Services Section Manager. Vehicle maintenance will be the responsibility of the user.

1.5.5 Design Control

Not applicable

1.5.6 Procurement Document Control

The Teletherapy Services Section Manager shall be responsible for assuring that necessary requirements are specified in all procurement documents associated with equipment or services in support of any radioactive source transfer operation.

1.5.7 Instructions, Procedures, and Drawings

These will be prepared, maintained, and listed in NPI Specification P-9, Procedures for Source Transfer, Maintenance, and Service Associated with Teletherapy Devices, and approved by the Vice President for Sources and Systems.

1.5.8 Document Control

Instructions, procedures, drawings, specifications, and shipping and transfer documents shall be maintained by the Teletherapy Services Section Manager. These documents and changes or revisions to them shall be approved by the Vice President for Sources and Systems.

1.5.9 Control of Purchased Material, Equipment, and Services

Control of purchased material, equipment, and services for source adapters installed in a teletherapy unit shall be the responsibility of the Source Production Section Manager. Control for parts used in transfer of sources shall be the responsibility of the Teletherapy Services Section Manager.

1.5.10 Identification and Control of Materials, Parts, and Components

The Teletherapy Services Section Manager shall be responsible for all materials, parts, and components used in making equipment for radioactive source transfers.

1.5.11 Special Processes

Source replacement in the field is a special process and shall be performed only by trained and licensed personnel.

1.5.12 Inspection

Routine inspection of containers, equipment, instruments, tools, and parts shall be conducted by the Teletherapy Services Section Manager. Transportation vehicles shall be inspected by the Quality Assurance Manager or his designee.

1.5.13 Test Control

Not applicable

1.5.14 Control of Measuring and Test Equipment

The Teletherapy Services Section Manager shall be responsible for the maintenance and calibration of radiation monitoring instruments used in the field.

1.5.15 Handling, Storage, Distribution, Shipping, and Installation

Handling, storage, and shipping of transfer equipment is the responsibility of the Teletherapy Services Section Manager.

1.5.16 Evaluation, Inspection, Test, and Operating Status

Teletherapy units serviced by NPI personnel shall be checked for operating condition in accordance with NPI Specification P-9.

1.5.17 Nonconforming Parts

Any nonconforming parts will be segregated and identified for disposition.

1.5.18 Corrective Action

In the event that either customer or NPI personnel have reason to believe that some corrective action associated with an NPI performed radiation source transfer is necessary, the Teletherapy Services Section Manager shall make appropriate recommendations for the approval of the Vice President for Sources and Systems and the QA Manager.

1.5.19 Packaging and Labeling

All parts will be packaged and labeled for identification. The shipping container shall be labeled in accordance with regulatory requirements.

2.1 Teletherapy Unit Reconditioning

2.1.1 Organization

Reconditioning of teletherapy units is the overall responsibility of the Vice President for Sources and Systems. The Teletherapy Services Section Manager is responsible for accomplishment of this work.

2.1.2 Definitions

Teletherapy unit - a machine using cobalt-60 at a distance for radiation therapy

Quality teletherapy unit reconditioning - the repair, replacement, refurbishing, shipping, installation, and testing required to produce reusable units or components, in compliance with ANSI "Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment," N449-1974.

2.1.3 Buildings

The buildings in which teletherapy units and components are reconditioned shall have adequate working space, with appropriate lighting and ventilation systems to afford good shop conditions. Safe and proper handling equipment shall be provided. Well lighted bench space shall be provided for reconditioning of electrical control and other small subassemblies.

Buildings of contractors' shall also comply with the above conditions.

General building conditions shall be periodically inspected by the Vice President for Sources and Systems and independently by the QA Manager.

2.1.4 Equipment

Reconditioning and installation equipment and tools shall be maintained by the Teletherapy Services Section Manager. Responsibility for the maintenance of vehicles shall be with the Teletherapy Services Section Manager.

Equipment purchased for replacement items shall be the responsibility of the Teletherapy Services Section Manager.

2.1.5 Design Control

Not applicable

2.1.6 Procurement Document Control

Documentation of procurements for materials or components for reconditioning teletherapy units shall be the responsibility of the Teletherapy Services Section Manager.

2.1.7 Instructions, Procedures, and Drawings

All instructions, procedures, and drawings required for reconditioning, shipping, and installation shall be in accordance with NPI Procedure R 5010. Periodically audits will be conducted to check for conformance.

2.1.8 Document Control

All documents relating to reconditioning, instructions, procedures, drawings, and specifications shall be controlled by the Teletherapy Services Section Manager and shall have the approval of the Vice President for Sources and Systems. Changes to these documents shall require his approval.

2.1.9 Control of Purchased Material, Equipment, and Services

The Teletherapy Services Section Manager shall be responsible for procurement of purchased material, equipment, and services.

2.1.10 Identification and Control of Materials, Parts, and Components

The Teletherapy Services Section Manager shall establish and maintain a clean area in which parts for reconditioning teletherapy machines are stored and labeled.

2.1.11 Special Processes

Installation of a source into a reconditioned teletherapy unit is a special process which is covered by Section 1.5 of this document.

2.1.12 Inspection

Routine inspection of parts and components shall be done by the Teletherapy Services Section Manager or his appointee. A complete inspection of finished units or components before shipping and after installation shall be in accordance with NPI Procedure R 5010.

2.1.13 Test Control

NPI Procedure R 5010 establishes the steps necessary to assure that an installed unit has not suffered damage in transport.

2.1.14 Control of Measuring and Test Equipment

Meters used to check radiation leakage from teletherapy units shall be periodically calibrated. Calibration shall be recorded. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which a calibration should be performed.

2.1.15 Handling, Storage, Distribution, Shipping, and Installation

All operations concerning the handling, storage, distribution, shipping, and installation shall be in accordance with NPI Procedure R 5010. Conformance is the responsibility of the Teletherapy Services Section Manager.

2.1.16 Evaluation, Inspection, Test, and Operating Status

The evaluation, inspection, test, and operating status shall be in accordance with NPI Procedure R 5010.

2.1.17 Nonconforming Parts

Parts from existing teletherapy units and/or purchased parts found to be nonconforming will be so identified and segregated for disposal or removal.

2.1.18 Corrective Action

If a reconditioned teletherapy unit is suspected of needing corrective action by NPI or customer personnel, the Teletherapy Services Section Manager shall recommend an appropriate course of action to

the Vice President for Sources and Systems and the QA Manager. The Vice President for Sources and Systems shall make the determination of appropriate corrective action.

2.1.19 Packaging and Labeling

Reconditioned teletherapy units shall be packaged for transit and transported by truck. A reconditioned unit shall be appropriately labeled.

3.1 Dose Control Irradiations

3.1.1 Organization

The Vice President for Radiation Processing Services, Mr. D. G. Woodard, has the responsibility for all activities required to perform dose control irradiations. The responsibility for assuring compliance with the customer's specifications and schedules has been delegated to the Microbiological Control Products Manager, Ms. G. Barrett. The responsibility for conducting the irradiation has been delegated to the Irradiations Section Manager, Mr. M. W. Harmon. Mr. Harmon is responsible for the day-to-day operations of the irradiators and is also responsible for assuring that qualified operators are available to run these machines.

3.1.2 Definitions

Quality - A quality dose control irradiation is one which was conducted in accordance with the requirements of this section and which delivered a dose (from cobalt-60) to a product in the range specified on the purchase order received from the customer.

Irradiators - There are two irradiators at the company's Dickerson facility. The first irradiator is called Dickerson I, the second is called Dickerson II. Both use cobalt-60 as their radiation sources.

3.1.3 Buildings

For any operation or processing campaign, sufficient space shall be provided to facilitate adequate cleaning, prevent mixups, and to assure the orderly handling of incoming material, rejected material, material in the irradiation process, and testing and measuring equipment. Adequate space to perform dosimetry measurements will be provided as will sufficient lighting, ventilation, and temperature control. Airborne contamination shall be kept within

acceptable industrial standards. Inspections of the building condition shall be periodically performed and the results of these inspections shall be recorded. The NPI quality assurance organization shall be responsible for the performance and documentation of these inspections. No less than two inspections per year will be performed. The line organization shall be responsible for cleaning the process areas. Sanitary facilities will be provided.

3.1.4 Equipment

Nondisposable equipment used for handling, irradiation, and shipping shall be cleanable and, if necessary, adjustable. Equipment shall be stored in such a manner to reduce contamination by dust or dirt or the accummulation of chemicals. Equipment will be clean when used. Equipment which requires periodic adjustment shall have allowable tolerances posted where the equipment is stored or used.

3.1.5 Design Control

Not applicable

3.1.6 Procurement Document Control

Not applicable

3.1.7 Instructions, Procedures, and Drawings

NPI Procedures R 6001, General Procedure for Package Irradiator Operations, R 6002, Procedure for Package Irradiator Operator Qualifications, R 6003, Procedure for Routine Package Irradiator Maintenance, and R 7003, General Procedure for Dickerson II Irradiator Operations and Instructions for Specific Products shall be used for all irradiations.

3.1.8 Document Control

Instructions, procedures, drawings, and specifications shall be issued by the Microbiological Control Product Manager or by the Irradiations Section Manager. These documents shall have the approval of the Vice President for Radiation Processing Services. Changes to any of these documents shall also require his approval.

3.1.9 Control of Purchased Material, Equipment, and Services

Control of materials, equipment, and services shall be the responsibility of the Irradiations Section Manager.

3.1.10 Identification and Control of Materials, Parts, and Components

Materials, parts, and components required for irradiation, except cobalt-60, shall be stored and identified by the Irradiations Section Manager.

3.1.11 Special Processes

Not applicable

3.1.12 Inspection

Product dosimetry shall be the principal means of inspection. Dosimetry shall be performed in accordance with Irradiator Operating Instructions, Processing Dosimetry. Products determined to be nonconforming to the customer's specifications shall be tagged accordingly and stored physically separate from acceptable material. The *Microbiological Control Product* Manager shall document all nonconformances and bring them to the attention of the Vice President of Radiation Processing Services and the QA Manager within 24 hours.

3.1.13 Test Control

Not applicable

3.1.14 Control of Measuring and Test Equipment

Dosimetry equipment will be used to ascertain uniformity and/or levels of radiation doses. This equipment will, at a minimum, consist of an optical density reader and a thickness gauge. These items will be examined to determine if periodic calibration is required. Calibration will be performed per NPI Instruction, Calibration of Far West Dosimeters.

Periodic calibrations shall be recorded. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which a calibration should be perform'.

3.1.15 Handling, Storage, Distributing, and Shipping

For each product handled by NPI, a specific instructi n is prepared which documents the company's methods for controlling customer products during handling, storage, and shipping.

3.1.16 Evaluation, Inspection, Test and Operating Status

Operation of the irradiators shall be in accordance with NPI Procedures NPI R 6001 and R 7003.

3.1.17 Nonconforming Materials, Parts, and Components

Not applicable

3.1.18 Corrective Action

In the event that dosimetry reveals that a product has not received the required dose, this fact shall be documented and reported to the Vice President for Radiation Processing Services and the QA Manager. The Irradiations Section Manager shall determine and document the cause of the problem. Upon obtaining the approval of the Vice President for Radiation Processing Services, he shall reirradiate or return the product as appropriate.

3.1.19 Packaging and Labeling

Incoming and irradiated products shall be labeled in accordance with specific instructions.

3.2 Physical and Chemical Properties Irradiations

3.2.1 Organization

See Section 3.1.1.

The Polymer Modification Product Manager, Mr. J. Tang, has the responsibility for assuring compliance with the customer's specifications and schedules. He supervises the laboratory work necessary to determine required doses and to ascertain the quality of the product.

3.2.2 Definitions

Quality - a quality physical or chemical property irradiation is one which was conducted in accordance with the requirements of this section and which results in a product which has achieved the physical and chemical properties specified on the purchase order received from the customer.

Irradiators - See Section 3.1.2

3.2.3 Buildings

See Section 3.1.3.

Appropriate laboratory space shall be provided for product sampling and testing.

3.2.4 Equipment

See Section 3.1.4.

3.2.5 Design Control

Not applicable

3.2.6 Procurement Document Control

Not applicable

3.2.7 Instructions, Procedures, and Drawings

See Section 3.1.7.

Specific instructions shall be written for the necessary laboratory support and product testing activities.

3.2.8 Document Control

Instructions, procedures, drawings, and specifications shall be issued by the Irradiations Section Manager for activities associated with running the irradiators and by the *Polymer Modification Product* Manager for laboratory support activities. These documents shall have the approval of the Vice President for Radiation Processing Services and by the Quality Assurance Manager.

Changes to any of these documents shall also require their approval.

3.2.9 Control of Purchased Material, Equipment, and Services

See Section 3.1.9.

3.2.10 Identification and Control of Materials, Parts, and Components

See Section 3.1.10.

3.2.11 Special Processes

Not applicable

3.2.12 Inspection

Properties testing shall be the principal means of inspection. Testing shall be performed in compliance with written instructions.

Dosimetry shall be performed in accordance with Irradiator Operating Instructions, Processing Dosimetry. Products determined to be nonconforming to the customer's specifications shall be tagged accordingly and stored physically separate from acceptable material. The *Polymer Modification Product* Manager shall document all nonconformances and bring them to the attention of the Irradiations Section Manager and the Vice President for Radiation Processing Services within 24 hours.

3.2.13 Test Control

See Section 3.2.12.

3.2.14 Control of Measuring and Test Equipment

Laboratory equipment necessary for sampling and testing of products shall be available and the *Polymer Modification Product* Manager shall determine if periodic adjustments or calibrations are required. Laboratory equipment which requires periodic adjustment shall have allowable tolerances posted where the equipment is used.

Periodic calibrations shall be recorded. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which a calibration should be performed.

3.2.15 Handling, Storage, Distributing, and Shipping

See Section 3.1.15.

3.2.16 Evaluation, Inspection, Test, and Operating Status

See Section 3.1.16.

3.2.17 Nonconforming Materials, Parts, and Components

Not applicable

3.2.18 Corrective Action

The *Polymer Modification Product* Manager and the Irradiations Section Manager shall recommend in writing to the Vice President for Radiation Processing Services and the QA Manager:

- an appropriate disposition for nonconforming products; and,

- the likely cause of the nonconformance.

The Vice President for Radiation Processing Services shall make the determination of the final disposition.

3.2.19 Packaging and Labeling

Incoming and irradiated products shall be packaged and labeled in accordance with specific instructions.

3.3 *Polyacrylamide Production*

3.3.1 *Organization*

The Vice President for Radiation Processing Services, Mr. D. G. Woodard, has the responsibility for all activities required for the production of polyacrylamide. The responsibility for assuring compliance with the customer's specifications and schedules has been delegated to the Polymerization Plant Section Manager, Mr. D. Deore. The responsibility for conducting the irradiations has been delegated to the Irradiations Section Manager, Mr. M. W. Harmon. Mr. Harmon is responsible for the day-to-day operations of the irradiators and is also responsible for assuring that qualified operators are available to run these machines.

3.3.2 *Definitions*

Quality - A quality polyacrylamide product is one which was produced in accordance with the requirements of this section and which throughout its progression from a monomer to a polymer has the physical and chemical properties specified by the customer, Hercules.

Irradiators - See Section 3.1.2.

3.3.3 *Buildings*

See Section 3.1.3.

The acrylic acid building shall be maintained in such a fashion as to preclude entry by unauthorized personnel and the public. Its explosion relief and prevention features shall be maintained by appropriate personnel under the direction of the Polymerization Plant Section Manager. The condition of this building and the tank room and their supporting heating and cooling systems, shall be inspected by the Quality Assurance Manager or his designee at least twice a year and such inspections documented.

3.3.4 Equipment

See Section 3.1.4.

Maintenance of the tanks, process lines, heating, ventilating, and cooling systems, and control devices for the acrylic acid building and the tank room is the responsibility of the Polymerization Plant Section Manager.

3.3.5 Design Control

Not applicable

3.3.6 Procurement Document Control

Supplier certifications of make up chemicals shall be retained for at least two years.

3.3.7 Instructions, Procedures, and Drawings

See Section 3.2.7.

3.3.8 Document Control

Instructions, procedures, drawings, and specifications shall be issued by the Irradiations Section Manager for activities associated with running the irradiators and by the Polymerization Plant Section Manager for chemical processing and laboratory support activities. These documents shall have the approval of the Vice President for Radiation Processing Services and by the Quality Assurance Manager.

Changes to any of these documents shall also require their approval.

3.3.9 Control of Purchased Material, Equipment, and Services

Control of purchased material, equipment, and services is the responsibility of the Polymerization Plant Section Manager.

All incoming shipments of acrylic acid and acrylamide shall be tested for conformance to Hercules' specifications.

3.3.10 Identification and Control of Materials, Parts, and Components

See Section 3.1.10.

3.3.11 Special Processes

Not applicable

3.3.12 Inspection

Inspections and evaluations of finished product shall be performed in accordance with Hercules' specifications.

3.3.13 Test Control

Testing and control of tests of finished products shall be performed in accordance with Hercules' specifications.

3.3.14 Control of Measuring and Test Equipment

Laboratory equipment necessary for sampling and testing of products shall be available and the Special Irradiations Section Manager shall determine if periodic adjustments or calibrations are required. Laboratory equipment which requires periodic adjusiment shall have allowable tolerances posted where the equipment is used.

Periodic calibrations shall be recorded. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which a calibration shall be performed.

3.3.15 Handling, Storage, Distributing, and Shipping

See Section 3.1.15.

3.3.16 Evaluation, Inspection, Test, and Operating Status

See Section 3.1.16.

3.3.17 Nonconforming Materials, Parts, and Components

Not applicable

3.3.18 Corrective Action

The Polymerization Plant Section Manager and the Irradiations Section Manager shall recommend in writing to the Vice President for Radiation Processing Services and the QA Manager:

- *an appropriate disposition for nonconforming products; and,*
- *the likely cause of the nonconformance.*

The Vice President for Radiation Processing Services shall make the determination of the final disposition.

3.3.19 Packaging and Labeling

Not applicable

3.4 Other Irradiations

3.4.1 Organization

The Vice President for Radiation Processing Services has the overall responsibility for all irradiations conducted at NPI's facilities. He has delegated the responsibility for the day-to-day operations of the irradiators to the Irradiations Section Manager and the responsibility for laboratory support activities and special irradiations to the *Special Irradiations and Laboratories* Section Manager.

3.4.2 Definitions

Quality - A quality irradiation is one which was conducted in accordance with the requirements of this section and which subjects a product to the environmental or testing conditions specified in accordance with NPI Procedure R 2013, Special Irradiations, and whose history has been documented in accordance with this procedure.

Irradiations - See Section 3.1.2.

3.4.3 Buildings

See Section 3.2.3.

3.4.4 Equipment

See Section 3.2.4. Equipment requirements for any special irradiation shall be specified in accordance with NPI Procedure R 2013.

3.4.5 Design Control

The *Special Irradiations* Section Manager or other designee specified per NPI Procedure R 2013, will assure that special irradiations or tests are designed in accordance with the previously specified requirements. He shall also establish and implement a method for coordinating and interfacing with customers or other organizations as may be necessary. A design review to assure that the proposed test or irradiation meets the established requirements will be conducted. Representatives of other organizations (such as a customer) may participate in this review.

A method shall be established to define and control interfaces between NPI and other organizations. Design changes, including procedural changes, shall be subject to control measures commensurate with those applied to the original design.

3.4.6 Procurement Document Control

Customer supplied material shall be in accordance with NPI Procedure R 2013.

3.4.7 Instructions, Procedures, and Drawings

All instructions, procedures, and drawings necessary to specify tests and assure quality of subsequent irradiation shall be prepared in accordance with NPI Procedure R 2013. Periodically audits shall be conducted to check for conformance and the results recorded.

3.4.8 Document Control

Instructions, procedures, drawings, and specifications shall be issued by the Section Manager for *Special Irradiations* or by another section manager specified by the Vice President for Radiation Processing Services. These documents shall have the approval of the Vice President for Radiation Processing Services. Changes to any of these documents shall also require his approval.

3.4.9 Control of Purchased Material, Equipment, and Services

Responsibility for control of material, equipment, and services shall be specified in accordance with NPI Procedure R 2013.

3.4.10 Identification and Control of Materials, Parts, and Components

Materials, parts, and components required for irradiation, except cobalt-60, shall be stored and identified by the section manager designated by the Vice President for Radiation Processing Services.

3.4.11 Special Processes

Since all of the processes designated under this Section 3.3 are in essence special processes, this section is not applicable.

3.4.12 Inspection

Product dosimetry and properties testing as appropriate shall be performed. Products determined to be nonconforming to the previously set specifications shall be tagged accordingly and stored physically separate from the acceptable material. The responsible section manager shall document all nonconformances and bring them to the attention of the Vice President for Radiation Processing Services and the QA Manager within 24 hours.

3.4.13 Test Control

Not applicable

3.4.14 Control of Measuring and Test Equipment

See Section 3.2.14.

3.4.15 Handling, Storage, Distributing, Shipping, and Installation

Additional instructions or requirements for handling, storage, and shipping may be specified in accordance with NPI Procedure R 2013.

3.4.16 Evaluation, Inspection, Test, and Operating Status

Operation of irradiators shall be in accordance with NPI Procedures R 6001 and R 7003. Additional operational procedures may be required in accordance with NPI Procedure R 2013.

3.4.17 Nonconforming Materials, Parts, and Components

Not applicable

3.4.18 Corrective Action

In the event that dosimetry or physical and/or chemical properties testing reveals that a product has not received the required dose

or other specified environmental condition, this fact shall be documented and reported to the Vice President for Radiation Processing Services and the QA Manager. The responsible section manager shall recommend to them in writing:

- an appropriate disposition for nonconforming products; and,

- the likely cause of the nonconformance.

The Vice President for Radiation Processing Services shall make the determination of the final disposition.

3.4.19 Packaging and Labeling

Incoming and irradiated products shall be packaged and labeled in accordance with specific instructions.

4.1 Laminar Flow Testing

4.1.1 Organization

The *Corporate Secretary* is responsible for NPI laminar flow testing activities. *He* will be assisted by other company personnel as appropriate.

4.1.2 Definitions

Laminar air flow - For the purpose of this document, laminar air flow is defined as air flow in which the entire body of air within a confined area essentially moves with uniform velocity along parallel flow lines.

Quality laminar flow testing program - one which accurately examines laminar flow equipment for compliance with the manufacturer's specifications and the appropriate criteria of Federal Standard No. 209B.

4.1.3 Buildings

Not applicable

4.1.4 Equipment

Nondisposable equipment used in the examination and testing program shall be cleanable and, if necessary, adjustable. Equipment shall be stored in such a manner to reduce contamination by dust or dirt. Equipment will be clean when used. Equipment which requires periodic adjustment shall have allowable tolerances posted within the equipment storage boxes.

The *Corporate Secretary* shall prepare and keep current calibration procedures for all equipment which requires periodic calibration. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which a calibration should be performed.

4.1.5 Design Control

Not applicable

4.1.6 Procurement Document Control

Not applicable

4.1.7 Instructions, Procedures, and Drawings

NPI personnel shall conduct all laminar flow testing work in accordance with NPI Procedure 10001, Standard Procedure for In-Place Integrity Inspection and Testing of Horizontal and Vertical Laminar Flow Hoods.

Audits *will* be conducted to check for conformance.

4.1.8 Document Control

All instructions, procedures, and specifications for the laminar flow testing program *and changes of same* shall be issued by the *Corporate Secretary*. These documents shall have the approval of the Quality Assurance Manager.

4.1.9 Control of Purchased Material, Equipment, and Services

A qualitative and, whenever possible, quantative evaluation of installed HEPA filter performance shall be made on the Field Service Inspection Report. The *Corporate Secretary or his designee* shall examine these reports once every calendar quarter to determine if purchased HEPA filters have been in compliance with NPI procurement specifications.

4.1.10 Identification and Control of Materials, Parts, and Components

Materials and parts used in the laminar flow testing program shall be stored either in the service vehicles or in a reserved separate area of the facility.

4.1.11 Special Processes

Not applicable

4.1.12 Inspection

NPI Procedure 10001 lists all inspections required for the laminar flow testing program.

4.1.13 Test Control

NPI Procedure 10001 lists all tests required for the laminar flow testing program.

4.1.14 Control of Measuring and Test Equipment

See Section 4.1.4.

4.1.15 Handling, Storage, Distributing, Shipping, and Installation

Equipment and replacement parts are stored and transported by vans. Maintenance of the van is the responsibility of the *Corporate Secretary*.

4.1.16 Evaluation, Inspection, Test, and Operating Status

For each unit serviced, the NPI Field Service Inspection Report shall be completed. The original shall be given to the customer and one copy shall be kept in NPI company files.

4.1.17 Nonconforming Parts

Incoming material identified as nonconforming to any NPI specification shall be tagged accordingly. Nonconforming material shall be stored physically separate from acceptable material and appropriately disposed of by the *Corporate Secretary*.

4.1.18 Corrective Action

When a nonconforming item is disposed of, the *Corporate Secretary* will document this disposition and the reasons

therefore in a note to the laminar flow files, with a copy to the QA Manager.

4.1.19 Packaging and Labeling

A NPI Inspection and Testing Sticker shall be placed, when appropriate, on all units serviced by the Laminar Flow Technology Section. Documentation of what, if any, sticker was affixed to a customer's unit shall be made on the Field Service Inspection Report.

5.1 Product Marketing

5.1.1 Organization

The President of Neutron Products, Inc. is responsible for marketing of all NPI products. He may be assisted by other company personnel as appropriate.

5.1.2 Definitions

Quality product marketing - the completion of all activities necessary to sell and deliver a product that conforms to all stated specifications.

5.1.3 Buildings

Buildings used for the fabrication and handling of NPI marketed products shall have sufficient space to facilitate adequate cleaning, prevent mixups, and to assure the orderly handling of incoming material, rejected material, material in the fabrication process, and testing and measuring equipment. Appropriate lighting, ventilation, and temperature and humidity control shall be provided. Inspection of the building condition shall be periodically performed and the results of these inspections shall be recorded. The NPI and manufacturers' QA organizations shall be responsible for the performance and documentation of these inspections in their respective facilities. No less than two inspections per year will be performed. Sanitary facilities will be provided.

5.1.4 Equipment

Nondisposable equipment used in the manufacturing process of NPI marketed products shall be cleanable and, if necessary, adjustable.

Equipment shall be stored in such a manner to reduce contamination by dust or dirt. Equipment will be clean when used. Equipment which requires periodic adjustment shall have allowable tolerances posted where the equipment is stored or used.

Materials used in the manufacturing process and not desired in the final product will be removed and such removal documented. Measuring equipment will be examined to determine if periodic calibration is required. Product calibration shall be recorded. Each calibration record shall show the name of the person who performed the calibration, the date on which it was done, and the next date on which the calibration should be performed.

5.1.5 Design Control

For any product which NPI markets there shall be a specific distributorship agreement written in which the specifications of the product to be marketed are clearly and completely delineated. Any changes to this specification or distribution shall require the approval of the QA Manager.

5.1.6 Procurement Document Control

The manufacturer shall have definite specifications for all purchased material. The distributorship agreement between the manufacturer and NPI shall state which, if any, of these specifications will require NPI's approval. In all circumstances, NPI will have the right of inspection to check for compliance with these specifications.

5.1.7 Instructions, Procedures, and Drawings

All instructions, procedures, and drawings necessary to assure quality in the fabrication of a product to be marketed by NPI will be listed in the manufacturers' specifications. NPI shall have access to these specifications and shall be allowed to conduct periodic audits to check for conformance.

5.1.8 Document Control

The manufacturer shall assure that all instructions, procedures, drawings, and specifications are controlled by a sufficiently high level of management and shall warrant that changes to any of these documents will not occur without the same level of management approval.

5.1.9 Control of Purchased Material, Equipment, and Services

The manufacturer shall inform NPI of all testing and examination activities which he conducts to ascertain the condition of purchased material, equipment, and services.

5.1.10 Identification and Control of Materials, Parts, and Components

The manufacturer shall establish control areas in which all materials, parts, components, and completed products are stored and labeled. NPI shall have the right to insp for conformance to this method.

5.1.11 Special Processes

Special manufacturing processes such as welding, heat treating, or nondestructive examination of manufactured components or parts shall be certified by a suitably high level of manufacturer's management. NPI shall be given the specifications to which these special processes have been performed.

5.1.12 Inspection

Manufacturer's inspection methods shall be provided to NPI. NPI personnel may witness these inspections.

5.1.13 Test Control

The manufacturer shall specify to NPI the way in which the products are tested to assure suitability for application. NPI personnel may witness these tests.

5.1.14 Control of Measuring and Test Equipment

Equipment used to examine components and products shall be controlled, calibrated, adjusted, and maintained in accordance with written procedures. NPI personnel may check for conformance.

5.1.15 Handling, Storage, Distribution, Shipping, and Installation

Handling, storage, distribution, shipping, and installation shall be in accordance with the distributorship agreement between the manufacturer and NPI.

5.1.16 Evaluation, Inspection, Test, and Operating Status

NPI shall monitor, as appropriate, performance of all products distributed by NPI. A performance record for all products marketed by

NPI shall be made at least once per year and appropriate corrective action initiated. Products which in the judgement of the President of NPI have had unacceptable performance will either be dropped from further marketing or actions taken to improve the product quality.

5.1.17 Nonconforming Parts

The manufacturer shall identify and tag parts which do not conform to written specifications. Nonconforming material shall be stored physically separate from acceptable material and a list of nonconforming items shall be prepared. The disposition of nonconforming material shall require the approval of the manufacturer's QA organization.

5.1.18 Corrective Action

The manufacturer shall try to determine the cause for recurring nonconformances. He shall document actions taken to correct such problems. This information shall be available to NPI upon request.

5.1.19 Packaging and Labeling

All products shall be packaged and labeled in accordance with the distributorship agreement between NPI and the customer.

VI. Records

NPI line organizations and the QA Manager shall maintain records in accordance with the specific QA subplans presented in Section V. These records shall be retrievable, identifiable, and available to company management as evidence of the workings of the QA program.

Provisions have been established to control the distribution of the following documents and revisions thereto:

1. The NPI Quality Assurance Program
2. NRC Cask Use Certificates
3. Road Use Certificates

The following documents are also maintained:

1. Procurement Documents
2. Procedures
3. Instructions
4. Drawings
5. Specifications
6. Design Review Reports
7. Contract Agreements
8. Installations

9. Dosimetry Records
10. Health Physics Records
11. Radioactive Respiratory Protection Program
12. NPI's Program for Radiation Protection of Employee Exposures
13. Truck Driver's Logs (Form MCS-59)
14. Vehicle Inspection and Maintenance Records
15. Annual Review of Drivers' Driving Record
16. Daily Reports of Vehicle's Condition
17. Reports of Accidents (Forms MCS 50-T and MCS 50-B)
18. Radioactive Shipment Record
19. Personnel Qualification Approval and Certification Records
20. Shipping Package Maintenance Schedule and Authorization
21. Shipping Package Modification Authorization
22. Medical Device Description for Reconditioned Teletherapy Units
23. Device Master and History Records for Sources
24. Customer Complaint Files
25. Calibration Records
26. Inspection and Test Records

    These records shall contain the following where applicable:

    a. A description of the type of observation.
    b. Evidence of completing and verifying a manufacturing, inspection, or test operation.
    c. The date and results of the inspection or test.
    d. Information related to conditions adverse to quality.
    e. Inspector or data recorder identification.
    f. Evidence as to the acceptability of the results.

27. Component Control and Nonconformance Records

    These documents shall include records of the acceptance or rejection of all components used in target and source manufacture, records of the disposition of all obsolete, rejected, or deteriorated components, records of the removal of unwanted materials from manufacturing, and records of nondestructive examination and other test results.

28. Equipment/Maintenance Records

    These records shall include a description of the piece of equipment used or in operation, along with any modifications or adjustments, and shall document the performance and necessary maintenance schedules.

29. Driver Qualification Record

    Records required to be maintained pursuant to Federal Motor Carrier Safety Regulation 391.51. This file shall include:

- The medical examiner's certificate of the driver's physical qualification to drive a motor vehicle or a legible photographic copy of the certificate;

- A letter granting waiver of a physical disqualification, if a waiver was issued;

- The memorandum on the annual review of the driver's driving record;

- The list or certificate relating to violations of motor vehicle laws and ordinances;

- Any other matter which relates to the driver's qualifications or ability to drive a motor vehicle safely;

- The driver's application for employment;

- The responses of state agencies and past employers to inquiries concerning the driver's driving record and employment;

- The certificate of driver's road test issued to the driver or a copy of the license or certificate which NPI accepted as equivalent to the driver's road test;

- The questions asked, the answers the driver gave, and the certificate of written examination issued to him, or a copy of a certificate which NPI accepted as equivalent to a written examination; and,

- The driver's name, his social security number, and the identification number, type, and issuing state of his motor vehicle operator's license.

30. Device Distribution Records

Adequate distribution records for critical devices shall include, or make reference to, the location of: the name and address of the consignee, the name and quantity of devices, the date shipped, and the control number used.

31. Corrective Action Reports

32. QA Audit Reports

The above records shall be maintained at specific locations in the NPI facilities and shall be reasonably accessible, many on a proprietary basis, to government employees designated to perform inspections.

All shipping package design related records shall be maintained for the life of the shipping package; irradiator operations charts, irradiator logs, and irradiation worksheets which document dose control irradiations shall be maintained for at least five years; and all other records are maintained at least two years.

VII. Audits

Audits of the Quality Assurance Program will be dependent on the significance of the activity being audited. Audits shall include

an evaluation of the shipping and manufacturing practices and/or procedures, and shall be concerned with the safety and effectiveness of their implementation. Audits shall be planned and include the monitoring of operations and activities, review of pertinent documents and their control and maintenance. Audit procedures will be established prior to conducting an audit and shall stress the safety aspects of the package or device.

Audits shall be performed at least twice a year with spot checks as deemed necessary by the QA Manager. Those areas having a higher safety significance, as well as those areas in which undesirable problems habitually are found, shall be audited more frequently.

Audits shall be performed by persons who do not have responsibility for the area being audited, and who possess the ability to evaluate adequately the functions under investigation.

The results of these audits shall be *documented and* maintained by the QA Manager and reported to the President along with any suggestions of recommendations for improvement. *Subsequently, the President shall direct line management to take whatever corrective actions he decides is necessary.*

In the event that deficient areas are located, they shall be re-audited on a timely basis to verify implementation of corrective actions.