RADIOACTIVE MATERIAL
PACKAGING QUALITY
ASSURANCE PROGRAM

Union Carbide Corporation
Medical Products Division
Tuxedo, New York

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UNION CARBIDE CORPORATION

MEDICAL PRODUCTS DIVISION

RADIOACTIVE MATERIAL PACKAGING QUALITY ASSURANCE PROGRAM

INTRODUCTION

The Union Carbide Medical Products Division operation at Tuxedo, New York, is currently engaged in the manufacture and development of various radiochemical and radiodiagnostic products for sale on a commercial basis. The majority of shipments of such products consist of discrete packages, each containing only one relatively pure radionuclide, destined for use in the field of nuclear medicine. Four radioisotopes (Mo-99, I-131, I-125, and P-32) contribute by far the largest portion of the shipments at this time. Since most recipients of these products possess limited facilities for the handling of radioactive material, and most shipments travel by means of commercial transport, the packages are designed to be both simple and sturdy, facilitating maintenance and repeated useage of each container.

The radioisotopes are produced in the reactor at the facility and are separated in the adjoining hot cells. Incident to the production and separation of isotopes and other related site activities, both small and large quantity waste shipments must be packaged. These containers must likewise be rugged and sturdy to meet restrictions by the transporter and receiver.

Due to the simple nature of the containers used for packaging, and the routine nature of most shipments, it is felt that the packaging quality assurance program should also be of a simple and straightforward nature. In this manner, it is believed that the interests of safety and package integrity can best be served within the limited scope of activities by the small staff available, while at the same time minimizing confusion and redundant effort.

This Radioactive Material Packaging Quality Assurance Program applies to those packages for which a QA program is required pursuant to 10CFR 71.12. Typical radioactive material packaging performed at the facility includes:

1. Glass and polyethylene bottles of various sizes.

2. Disposable lead shipping containers ranging in wall thickness from 1/8" to 1 3/4" for shipment of Type A quantities of radioactive materials.

3. Sealed metal cans to enclose lead shielded shipping containers for Type A quantities of radioisotopes.

4. Corregated paperboard boxes for Type A shipments.

5. Lead shielded gas cylinders for shipment of radioactive gas at less than atmospheric pressure.

6. Returnable steel clad lead containers for shipment of Type A and Type B quantities of radioactive material.

7. Returnable stainless steel clad depleted uranium containers for shipment of Type B quantities of radioisotopes.

8. Stainless steel Type 2R containers for Type B shipments.

9. Steel clad wooden jackets, Type 20 WC-2, to enclose returnable shipping containers.

10. Spec 17H steel drums for disposal of radioactive waste.

11. Stainless steel clad, lead filled Model B3-1 shipping casks for radioactive waste shipments.

12. Packages approved for large quantity shipments for which the facility is a registered user.

13. Shipment of irradiated MTR fuel elements (shipped pursuant to 10CFR 73.37) and low exposure fissile target material which has been de-gassed and stripped of other fission products (not subject to the requirements of 10CFR 73.37) in packages for which the facility is a registered user.

14. Non-routine shipments package in compliance with existing NRC and DOT regulations (e.g. crated contaminated equipment destined for burial).

1. Organization

The quality assurance organization can best be understood by referring to the organization chart in Figure 1. The responsibilities vested in each position are defined by Figure 2.

Overall responsibility for the packaging quality assurance program will be in the hands of the Business Manager, Radiochemicals. The person holding this position will have an educational background in Science and Engineering with a minimum of three years experience with

the packaging for shipment of radioactive materials under NRC and DOT regulations. Depending on the type of material being packaged (e.g. radiochemicals, spent reactor fuel, or hot cell wastes) there may be numerous set of individuals responsible for the various levels of responsibility of packaging. In a general fashion, each such set is composed of a Level 1, 2, and 3 representative, the levels being defined by the organization chart. Level 1, with the assistance of the Health Physics Supervisor, will be directly responsible for implementation of the program, to include design and procurement criteria, inspection of materials, equipment, and facilities as necessary, and such testing as is required to meet the requirements of 10CFR Part 71, Subpart C. Level 2 will oversee the packaging and shipment of radioactive materials, and will assure that routine inspection of outgoing parcels and returned shipping containers are performed. Level 3 will perform the physical packaging, shipping, and receiving activities.

The Health Physics Supervisor will have the authority to call for any repair, modification, or test of such packages that he deems necessary under 10CFR Part 71, and it will be the responsibility of Level 1 to ensure that such repairs, modifications or tests are promptly carried out, properly executed, and correctly documented. The Nuclear Safeguards Committee will also have the responsibility and authority to provide an effective oversight of all functions involved under this quality assurance program, including the initiation of such actions as may be needed to ensure or improve compliance. This committee meets regularly and as needed at the site to review those activities which have, or may have, an impact on the safe performance of all operations involving radioactive material.

As a service to groups on site who handle radioactive material, the Radiochemicals Group will accept packaged waste material and consolidate it with other wastes shipped from the site. Those individual waste packagers will be required to certify that each container is packaged properly. Health Physics will on a random basis check those containers to assure that proper packaging techniques are being implemented.

Quality Control functions relating to packages of a non-routine or potentially hazardous nature will be directly supervised or performed by individuals possessing specific competence to direct such activities. In most cases, these individuals will be supervisory personnel from the Reactor Operations, Radiochemical Production, or Facilities Engineering groups, with guidance from the Health Physics Department. Through experience and educational background, such people will possess a thorough knowledge and understanding of regulations pertinent to shipment of packages containing radioactive materials and an awareness of any potential hazards associated with a specific type of package.

2. QUALITY ASSURANCE PROGRAM

Since the Business Manager, Radiochemicals, will exercise overall authority regarding the Quality Assurance program, the entire program and any revisions to it must be approved by him, with the concurrence of such other competent managerial positions as he deems appropriate for particular items. The Q.A. program itself will be disseminated and implemented under his approval as an integral part of the facility.

Due to the simple and routine nature of most shipments of radioactive material from this facility, personnel will be qualified to perform basic visual inspection of standard packages through on-the-job training and instruction regarding those sections of the applicable regulations pertinent to this type of shipment. Quality Control functons applicable to non-routine items or activities will be performed by individuals who have demonstrated competence in the area involved, either by virtue of educational background or through acquired experience. Training required for the acquisition of such competence will be directed by Level 1 personnel with the aid of such other qualified individuals as is appropriate or necessary.

All personnel whose work assignment may occasionally require the performance of any packaging Q.A. function will be instructed by the Health Physics Department or Level 1 or 2 personnel to the extent that they may perform basic inspections of packages sufficient to detect obvious flaws. Any personnel assigned to work directly in the packaging area will be further instructed under the direction of Level 1 personnel to the point that they will have a demonstrated working knowledge of applicable regulations and safety criteria sufficient to ensure that no sub-standard package will be released for shipment.

The Q.A. program will be promulgated by management as an integral part of the facility operation procedures. All revisions to the Q.A. program must therefore be reduced to written form and approved by the Business Manager, Radiochemicals, with the concurrence of the Health Physics Supervisor, before any such revision can take effect. A record of these revisions will be maintained on file.

Specific procedures for each type of package will be provided for the use of those personnel preparing such packages for shipment. Means for ensuring that these procedures have been satisfied in each case will be provided, through check-off procedures, tagging, labelling, or logbook entries, as is best applicable to the particular type of package. Engineering procedures and package design provisions will be satisfied by similar means, under the oversight of trained supervisory personnel where appropriate.

Package characteristics which have any significant bearing on the safety of a given shipment will be clearly and specifically delineated through the Q.A. program, and each such item will be subject to particular control through this program. The Q.A. program will provide that all significant safety criteria pertinent to each package are satisfied prior to the shipment of that package.

This Radioactive Material Packaging Quality Assurance Program will be included as a discrete section of the Procedures Manual, along with all official revisions. Distribution of this manual and revisions are controlled by the issuance to each the following:

Business Manager, Radiochemicals

Secretary, Nuclear Safeguards Committee

Manager, Nuclear Operation

Reactor Supervisor (2 copies)

Supervisor, Radiochemical Production

Health Physics Supervisor

Site Library

Senior Development Scientist

As a specifically designated portion of the official operating procedures, this packaging Q.A. program and all policies and procedures described in it, are mandatory requirements which must be followed and implemented by all personnel involved. Such adherence to all provisions will be enforced in all cases by the Business Manager, Radiochemicals.

Any dispute involving the quality of packaging arising from differences of opinion between persons exercising QA/QC responsibility and any other group shall be resolved first by the Health Physics Supervisor. If such a decision is not deemed satisfactory by either party, questions may be escalated to the Business Manager, Radiochemicals, acting in concurrence with the Manager of Health, Safety, and Environmental Affairs. If further resolution is required, the Nuclear Safeguards Committee will provide a final and binding decision.

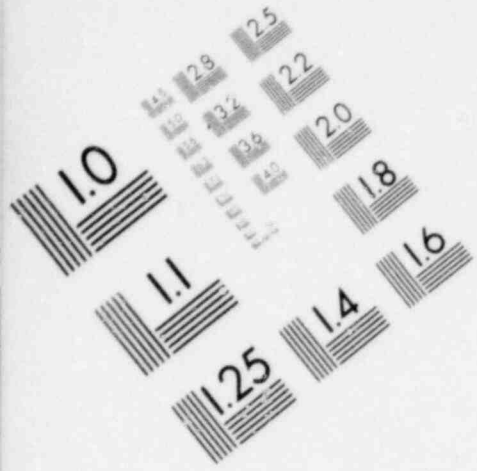
3. DESIGN CONTROL

Although the shipping containers currently used are relatively straightforward in design, being meant to provide radiation shielding and accident protection for routine shipments, it is recognized that appropriate design control measures must be exercised to assure compliance with applicable regulatory provisions and to ensure safety during transport. For this reasons, all aspects of design of such containers will be approved by the Business Manager, Radiochemicals, with the aid and concurrence of the Manager of Health, Safety, and Environmental Affairs. Such approval will include a review to ensure (1) that all pertinent inspection and test criteria are identified and delineated in the appropriate documentation and/or drawings, and (2) that all design characteristics may be adequately controlled, inspected, or tested. Since the shipping containers under consideration are neither complex nor fragile, such centralized control will be most effective in maintaining high standards of quality and guaranteeing compliance with regulatory requirements. The job requirements of these two positions are such that a thorough understanding of the pertinent regulatory areas and of engineering requirements for safety is assured. Inclusion of the Manager of Health, Safety, and Environmental Affairs in the review and approval process for package design will in all cases provide design verification by an individual of authority in a completely separate line of responsibility from that of the designer.

In most cases where any major changes in package design or application are envisioned, design criteria will be verified through testing of such packages prior to their use. All such design, application, or specification changes are subject to the same design controls and approvals as were applied to the original design of the item. Such testing will subject the package design under consideration to the most adverse design conditions, and will be directed and approved by the Business Manager, Radiochemicals. Engineering studies or computational methods may be substituted for such testing in cases where the use of these means is more appropriate.

Package or container designs will not be approved unless design criteria and parameters necessary to ensure regulatory compliance and safety are correctly and clearly translated into specifications and drawings. Specific procedures and instructions will be provided in writing where necessary to facilitate such compliance. Such instructions may include selection of suitable parts, materials, or components, or such other information as necessary. Where specific regulatory criteria are pertinent to a package design, such criteria will be included in package design documents.

All package design drawings and documentation will be circulated to individuals listed on the following checklist, a copy of which must accompany such drawings and documentation. No fabrication of any type will be authorized without written approval on this checklist.



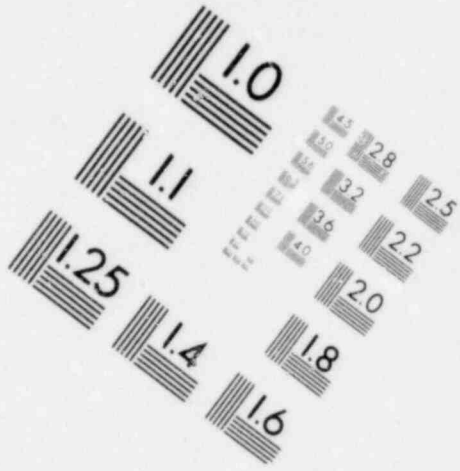
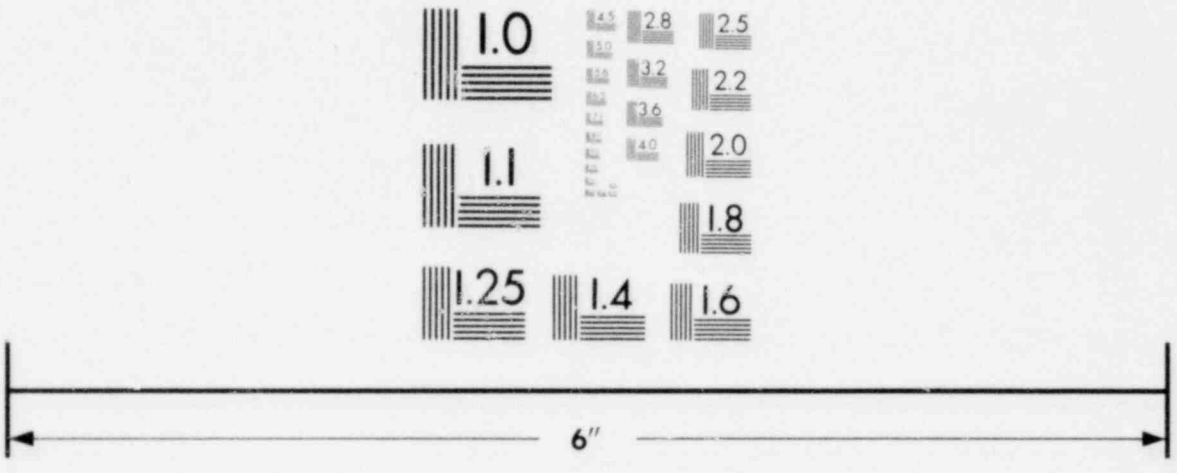
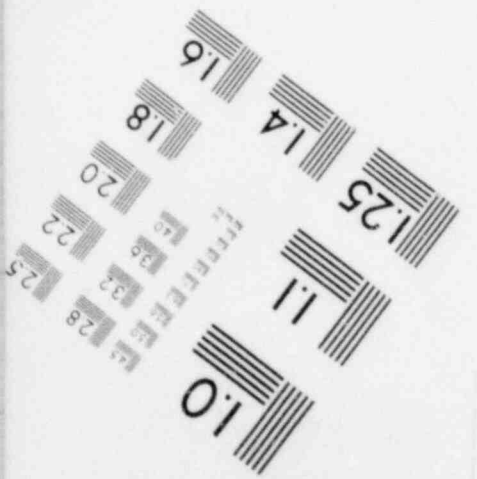
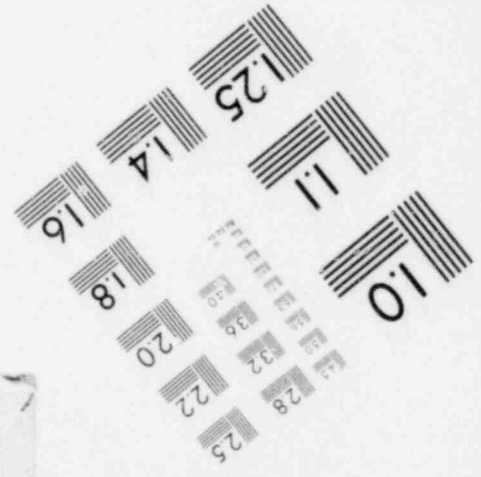
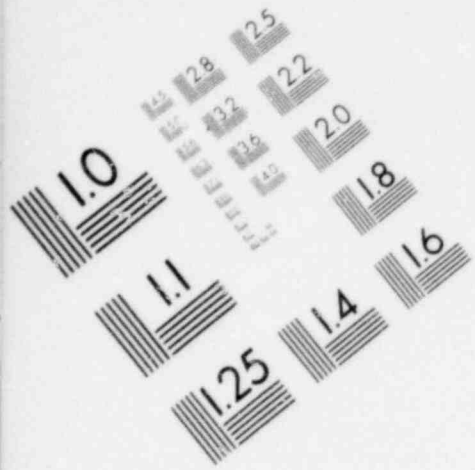


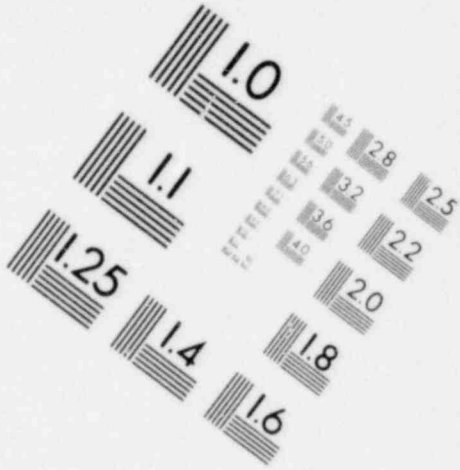
IMAGE EVALUATION TEST TARGET (MT-3)











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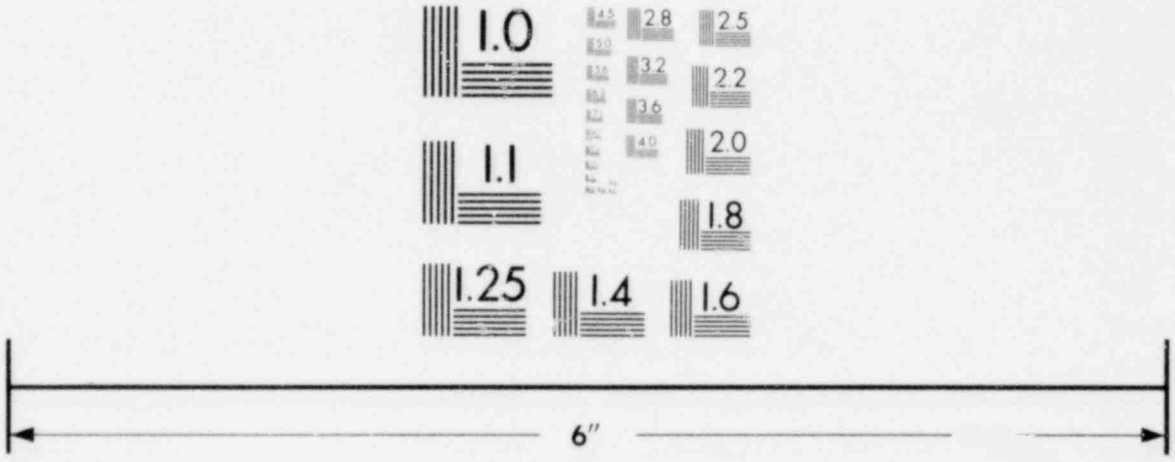

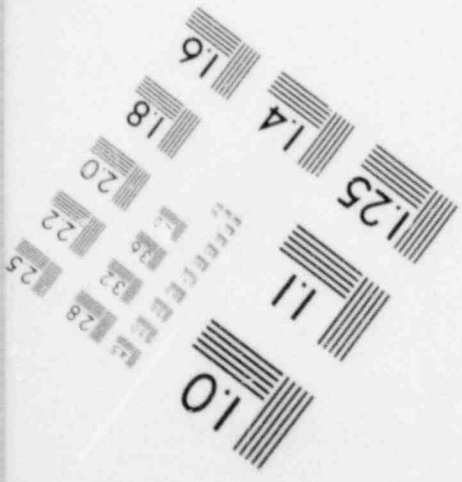

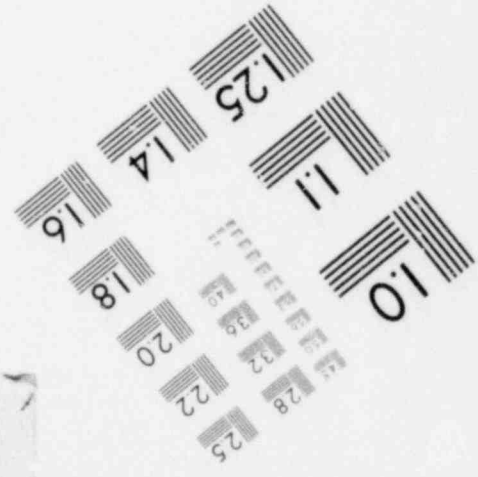

PACKAGE DESIGN AND DOCUMENTATION REVIEW AND APPROVAL CHECKLIST

Package Type and Description:

New Item #:_____ or Revision #:_____ to Item #:_____

Test and Inspection Criteria:

Designed By:_____

Checked By: _____

Review:

Level 1 (Manager of Nuclear Operations or Supervisor of Radiochemical Production)

Comments:_____

Supervisor, Health Physics:

Comments:_____

Verification and Approval:

Business Manager, Radiochemicals

Approved:
(or) Changes Needed:_____

Manager, Health, Safety, & Environmental Affairs:

Approved:
(or) Changes Needed:_____

4. PROCUREMENT DOCUMENT CONTROL

In any case where material, equipment, or services whose use is governed by 10CFR Part 71 are procured from an outside supplier, the applicable requirements of 10CFR Part 71 will be clearly included in the procurement documentation. Particular attention will be devoted to such provisions as are related to safety of shipments, and in such instances the supplier will be required to document his compliance with the appropriate sections of 10CFR Part 71. In addition, the supplier will be required to provide a quality assurance program in compliance with the pertinent provisions of Part 71 whenever such a program is deemed appropriate.

Preparation of procurement documents and any changes or revisions thereto are under the supervision of Level 1. Such documents will either contain or reference the necessary design basis technical requirements for each item or type of item being purchased as to ensure compliance with these requirements, and will clearly identify the documentation required from the supplier for review and approval by the purchaser. This identification will also specify which documents and records are to be prepared and retained by the supplier, as well as those which are to be delivered to or controlled by the purchaser.

All procurement documents, changes, or revisions, will be reviewed by the Health Physics Supervisor or the Manager of Health, Safety, and Environmental Affairs prior to approval to ensure agreement with all appropriate design specifications and compliance with applicable regulatory requirements. Final approval of procurement documentation including changes and revisions will be provided by the Business Manager, Radiochemicals only after this review has been accomplished. Also, no procurement document will be approved unless the purchaser's right of access to the supplier's facilities and records for source inspection and audit is clearly specified.

Control of procurement documents will be exercised by the Business Manager, Radiochemicals, who will see to it that they are properly maintained and filed in such a way as to be traceable to the specific item.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

General instructions meant to ensure a high level of quality and safety in the packaging of radioactive materials for transport are included in this program, under the headings of "Handling, Storage, and Shipping" (Section 13), and "Inspection, Test, and Operating Status" (Section 14). Where appropriate or necessary, specific

instructions, procedures, and drawings will be provided to maintain or improve standards of quality and safety. Included in such instructions will be any quantitative or qualitative acceptance criteria pertinent to the particular package or shipment under consideration. Means will be provided, through check-off sheets, logbook entries, or other applicable records, to document the satisfactory accomplishment of such activities.

Instructions, procedures, and drawings are subject to similar measures of control as are applied to designs (Section 3) and must be accompanied at all times by appropriate review and approval checklists. No such documentation will be accepted as official until such checklists have been completely filled out, indicating approval. All such completed checklists will be filed with the original documentation and all revisions in a master file for the item maintained by the Radiochemicals group.

6. DOCUMENT CONTROL

All documents relative to any particular shipping package will be under the control of the individual responsible for the shipment of such a package. In most cases, such documents will be controlled by the Supervisor of Radiochemical Production, as most shipments made by the licensee consist of packages containing radiochemical products. Documents relevant to other types of packages, such as shipments of radioactive waste materials for disposal, or service irradiations, or spent reactor fuel will be under the control of supervisory personnel from the particular group directly involved with such packaging. In addition, documentation regarding non-routine packages or shipments which may pose particular safety or radiation hazards will be available to the Health Physics Supervisor for approval and confirmation that all applicable Q.C. and Q.A. provisions have been complied with.

No changes will be made to any document regarding the packaging and shipment of radioactive material without the approval of a competent individual in a position of authority regarding the preparation and shipment of such a package. The specific individual involved will, of course, depend on the particular type of package under discussion. No changes in such documentation which are pertinent to the safety of a particular shipment will be made without the concurrence of the Health Physics Department.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

All purchased material, equipment and services will be examined to ensure conformance with procurement documents. The supplier of such items will be required to provide documented evidence of the quality of these items and their compliance with all pertinent regulatory requirements. Such evidence will be provided by the supplier before any such purchased material or equipment is placed into service. This documentation, and any objective evidence of quality, shall clearly reference the specific regulatory or quality assurance provisions met by the purchased items. All such records shall be retained in a form traceable to the specific item, or, if more appropriate, group or type of times, whose quality is under consideration. To further control the quality of such purchased products, UCC representatives will, when appropriate, inspect the supplier's facility, work in progress, and quality assurance program. In addition, UCC will, on occasion, perform such tests on purchased items as are necessary to guarantee the maintenance of high standards of quality and safety.

Included in the evaluation of potential suppliers will be their capability to comply with the applicable portions of Appendix E to 10 CFR Part 71 as demonstrated by past performance in supplying such items to UCC or other purchasers. If records of previous performance are not available, the supplier's production facilities and Q.A. program will be studied by competent personnel to determine that the capability is available to meet the requirements for compliance.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

As specified under the heading "Design Control" (Section 3), applicable regulatory requirements and quality assurance criteria will be clearly translated into specifications, drawings, procedures, and instructions. Where appropriate, such instructions will call for the positive identification of material, parts, or components throughout fabrication, installation, or use of the item. This identification will be made on the basis of heat number, part number, or other such means as is specifically appropriate to the piece under consideration. Such identification will be traceable to a particular completed item, or type of item, either at the item itself, or through documentation specific to that item. Particular care will be taken to ensure that through this procedure no incorrect or defective parts, material, or components are put into use.

The method and location of this identification will be individually determined by each item under consideration to ensure that the fit, function, or quality of the item is in no way compromised by the identification system. No item will be accepted for use unless documentation and verification are provided establishing the correct identification of all critical materials, parts, and components.

9. CONTROL OF SPECIAL PROCESSES

Special processes, such as welding, heat treating, or non-destructive testing, will be performed only by qualified personnel. Prior to the start of such processes, an evaluation will be performed by the Supervisor, or such other competent individual as may be appropriate, to determine the applicability of the various codes, standards, specifications, criteria, or regulatory provisions which may have a bearing on the process under consideration. A procedure for performance of the process will then be established to ensure compliance with such requirements and assure that the quality and safety characteristics of the item under process are maintained. Upon completion of such processing, the item will be inspected by the Health Physics Supervisor or another competent individual to guarantee that all requirements have been met and the quality of the item has not been compromised.

As such special processes are performed, a record of the procedures developed, the equipment utilized and the qualifications of the personnel involved will be established, filed in such a way as to be traceable to the appropriate items, and kept current as changes occur.

10. INSPECTION

All activities which could affect the quality of packages containing radioactive material for shipment will be subject to inspection under the direction of the Business Manager, Radiochemicals. Such inspections will be conducted to verify conformance of the activity with documented drawings, instructions, and procedures for its accomplishment, and to maintain high standards of quality and safety. In general, such inspections will be carried out by individuals having line authority over those who perform the activity. In addition, such activities may be inspected by other individuals possessing special competence to evaluate the accomplishment of the activity.

These inspections will be carried out on a regular basis, the timing of which will be dictated by the safety significance of the activity in question and the need to maintain a high level of quality. Instructions for performance of manufacturing and production processes will include provisions for such inspection, including tests and examination, by mandating specific hold points beyond which work cannot progress without approval by a designated inspector, or by specifying particular processes which must be monitored by such an inspector or witness, or both, as necessary.

All modifications, repairs, or replacements will be subject to the same mode of inspection as required by the original design, where this is practical. If this is not feasible, inspection methods will be required to establish that the original technical criteria are met through alternate inspection techniques.

In the event that specific codes or standards are applicable to such inspections, specific inspectors will be trained and certified, where necessary, in the appropriate methods and techniques. In other cases, company training programs will be utilized to develop the necessary expertise to perform these inspection functions competently. Qualification, certification, and training records of such inspectors will be kept on file to provide ready reference so that the appropriate individual may be assigned responsibility for each such inspection.

11. TEST CONTROL

Specific written test procedures will be used to verify that all packaging components will perform satisfactorily in service. Such tests will be written in accordance with the requirements of 10 CFR Part 71 and the requirements and acceptance limits of the specific package approval. These tests will be conducted under the direction of the Health Physics Supervisor, with the assistance of such other competent individual as may be appropriate in each case. Test procedures will be written in such a manner that all prerequisites for the test are met, adequate test instrumentation is available and properly utilized, and the test is performed under suitable environmental conditions. Test results will be clearly documented with particular reference to the specific items under evaluation and the type of package or component being tested. These results will be evaluated by the Health Physics Supervisor or other competent individual to assure that test requirements have been met and that all applicable criteria have been satisfied. Such results shall be kept on file and referenced to the particular item or type of item which has been tested.

Where feasible, all modifications, repairs, or replacements will be tested in the same manner as that required by the original design. Where this is not practical, alternate methods will be selected on the basis of their ability to satisfy the same criteria as specified in the original design and testing criteria.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

All measurement and testing devices which are used in activities affecting the quality of packages containing radioactive material for transport, or which are used to evaluate the quality of such packages, will be controlled. Prior to the use of any such device it will be calibrated or adjusted as necessary to ensure its proper performance. The accuracy of such devices will be verified by periodic calibration, and they will not be released for use unless they are accurate within the necessary limits.

Logs documenting such calibration or adjustment will identify the measuring and test equipment and provide traceability to the calibration test data for each item. Calibration of measuring and test equipment will be performed and documented in such logs prior to its use to ensure that no inspections or tests are performed with equipment which is out of calibration. Where possible, all standards used will be traceable to nationally recognized standards. Where this is not practical, the basis for calibration will be selected and evaluated by the Health Physics Supervisor, who will see to it that the needed verification and documentation are recorded along with the appropriate data.

13. HANDLING, STORAGE, AND SHIPPING

Safety shall be the paramount consideration in the handling, storage, and shipping of packages for radioactive material. Upon receipt of a returned package for such material, the entire package will be visually inspected by Level 2 personnel to determine the extent of any damage which may have occurred during shipment. Typical items to be checked consist of: (1) status of outer 20 WC-2 jacket - secure fit of top and clinch ring; no puncture of outer steel drum or splitting of laminated plywood; no gross damage to threaded fasteners which would hinder subsequent closure of package; (2) condition of stainless steel clad lead or depleted U shipping pig - No significant radioactive contamination; no damage to lifting rings or eyes which could cause a hazard when the pig is lifted; no damage to threaded components which could prevent lid from being securely fastened; (3) condition of inner Type 2R container - Level of radioactive contamination and/or radiation readings below hazardous levels (100 mR/hr.); lifting bail in satisfactory condition; no damage to threaded closure; (4) type B-3 containers for shipment of radioactive waste - level of radioactive contamination; gasket condition; presence of drain plugs; condition of lid bolts.

Unless such packages are destined for immediate re-use, they shall be stored in a designated area, safe from possible damage. They should be stored in a closed condition, with all parts in place, until they are to be used again. An exception will be made in the case of any part which is not ready for use by virtue of damage or excessive contamination. Such parts may be removed for repair or decontamination and subsequently stored separately until ready to be re-used.

No shipments will be made using any type of package unless all applicable tests, certifications and inspections have been completed. In general, such tests will include: leak testing under vacuum of primary containers (bottles) containing sufficient radioactive material in liquid form that spillage may be a hazard; testing of Type 2R containers after closure under vacuum to ensure that they are sealed; written certification on the order/invoice from accompanying such shipments that these tests have been performed; certification that the contents of the cylinders containing gaseous radioactivity are packaged at less than 1/2 atm absolute pressure; visual inspection of all shipping containers to ensure that all gaskets, packing material, and fasteners are properly located and secure; determination that the level of radiation emitted from any single package or array of such packages does not exceed applicable limits through the use of appropriate monitoring devices; wipe tests to ensure that no significant removable radioactive contamination is present on any package to be shipped; and a final visual inspection to ensure that all necessary and appropriate seals, labels, signs, or other identifying devices are properly and securely affixed to each package.

In order to minimize unnecessary handling of radioactive materials and to ensure that all necessary tests, certifications, and inspections have been performed, responsibility is assigned as follows:

1. Certification that leak tests on primary containers have been performed will be done by the technician dispensing the material. Pressure of gaseous product cylinders will be similarly checked and certified.

2. Secure, leak tight closures on Type 2R containers will be certified by either a member of the Health Physics Dept. or by supervisory personnel from the Radiochemical Production Department.

3. The Senior Technician of the Packaging group will check that the above tests and certifications have been performed before accepting any such container for final packaging.

4. Visual inspection of shipping containers, radiation monitoring, and wipe tests will be performed by members of Level 3 personnel under direction of Level 2 personnel or by a Health Physics Technician.

5. Final visual inspection of each completed package will be performed by a Level 2 individual. Each package will be so inspected prior to being loaded into a transport vehicle, and will not be loaded unless all identifying tags, labels, seals, or signs are properly affixed and all shipping documentation is completely and correctly filled out.

The above procedures apply to all routine shipments of radioactive products, and shall be performed under the directed supervision of Level 2 personnel. Shipments of a non-routine nature, or those processing particular characteristics which pose a potential safety hazard, will be prepared under the supervision of an individual knowledgeable of such particular hazards and competent, through training or experience, to ensure that all safety requirements are properly met. In such instances, the Health Physics Supervisor will also take a direct role in certifying that all necessary, appropriate, and applicable actions are taken to ensure that the shipment may be made safely.

14. INSPECTION, TEST, AND OPERATING STATUS

If receipt inspection indicates that upon receipt a container is acceptable for immediate re-use, the package will be stored in a designated area, and its presence in this area will indicate its availability for shipment.

If, however, any condition exists which indicates that such a package may not be suitable for immediate use, it will be segregated in another area and tagged to indicate that it may not be shipped. In such a case, a Level 2 individual, or other individual in a higher position of authority will be notified, and this individual will personally inspect the package, determine its proper disposition, and label it to indicate the action to be taken. In addition, if any such repairs or modifications could pose a safety or radiological hazard, the Health Physics Dept. will be called upon to indicate any special precautions or actions which may have to be taken. The status of any package, or part thereof, awaiting any such action, or being worked on, will be clearly indicated by tag, label, or marking as appropriate, and any necessary information will be entered in the pertinent log, if such entries are applicable to the type of package under consideration.

In any case where such repairs are necessary, or modification of a package has been performed, the package will not be accepted for use until the repairs or modifications have been inspected and certified by either a Level 2 individual, or a member of the Health Physics Department, or other responsible individual, if appropriate to the particular type of package. Similar procedures will be followed in the case of any package which is undergoing test to determine its suitability for any specific packaging application. Such containers undergoing test will be clearly marked, and will not be accepted for use until test results have been certified by the proper authority.

In the event that any new or substantially changed packaging design is proposed for use, or a new application is proposed for an existing package design, it will be the responsibility of the Health Physics Supervisor to determine what type of tests and inspections are necessary to guarantee that all applicable safety and regulatory criteria have been met. A Level 1 individual will oversee the performance of such tests, and with the concurrence of the Health Physics Supervisor and approval of the Business Manager, Radiochemicals, certify that the package design under consideration has been adequately tested and is suitable for its proposed use.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

As mentioned under the heading "Inspection, Test and Operating Status" (Section 14), in any case where a question exists as to the suitability of a particular package, container, or piece of equipment for use, the item will be segregated by location, if possible, and tagged to indicate its non-operational status, pending inspection by a competent individual in a position of responsibility. Such tags will specifically identify the non-conforming item and briefly describe the non-conformance. After inspection, the item will either be accepted for use again, removed from service permanently, repaired, or reworked, as is necessary and appropriate. Such disposition will be under the direct control of a Level 1 individual, who will ensure that the status of the item is correctly stated, that the proper actions are taken in accordance with established procedures, and upon completion of the required action, that all necessary documentation is correct and complete.

Such documentation will include the tag described above, along with other pertinent information, and will clearly specify the test or inspection requirements which must be met to justify restoration of the item to operational status. Upon completion of the necessary tests or inspections, a report will be appended to the documentation describing their results, and delineating the further disposition of the item. Such disposition will not be accomplished until the report is approved and signed by competent authority, generally the Health Physics Supervisor.

16. CORRECTIVE ACTION

All inspections, tests, and examinations conducted under this program, from those involving new material upon its receipt, to the final inspection of each package before shipment, are aimed at maintaining the highest practical standards of safety and quality, and so are meant to promptly detect any conditions adverse to the maintenance of such standards. If, through these inspections or through other means, any deficiencies, deviations, defective material and equipment, or nonconformances are discovered, immediate action will be taken to identify their source or cause, and to correct the problem. In the event of any such discovery, the appropriate Level 1 individual will immediately be notified, and he will promptly take such action as necessary to maintain or achieve a condition of safety. In the event that a significant condition adverse to quality, or a serious hazard potential exists, other individuals having specific competence to deal with the problem will be consulted, and remedial action will be undertaken as soon as possible.

In the case of such a significant condition adverse to quality, the Level 1 individual will thoroughly investigate the situation, with such assistance as may be useful or necessary, to determine the cause of the condition. He will then institute corrective action, subject to approval of the Business Manager, Radiochemicals, to alleviate the existing situation and prevent recurrence of the condition. He will also be responsible for the generation of a clear and accurate report, documenting identification of the condition, its cause, and the corrective action which was taken. This report shall be forwarded to such levels of management as may be appropriate.

17. QUALITY ASSURANCE RECORDS

Records of the performance of Packaging Quality Assurance operations will be in designated locations providing security for such records, while still allowing ready access when necessary. The form of such records will be appropriate to the type of packaging involved and the nature of the information to be recorded. Records which are specific to one particular package, container, or piece of equipment will be referenced to that particular item through the use of logbooks, in which will be entered the results of all inspections and tests, as well as a record of all repairs or modifications which have been performed. Records referring to particular shipments will be kept in the form of completed check-off sheets or completion notices indicating that all necessary Q.A. functions have been performed and identifying the responsible individuals. Those records which are of a general nature, such as audit results or the results of tests applicable to types of packages will be filed in the same location.

Copies of all current and past packaging procedures will also be maintained in this area, along with a copy of the Quality Assurance program. In addition, all personnel currently involved in the packaging of radioactive materials or engaged in the Q.A. program will have copies of such documents available for their use. Included will be a clear description of the tasks for which each of the various positions involved in the packaging or shipment of radioactive material is responsible, as well as a listing of what areas of authority regarding the Q.A. program are to be exercised by personnel at different levels of responsibility or operating groups.

All such records will be maintained on file in such a manner that any specific information required will be readily accessible and traceable to a particular container or shipment. A listing of the records on file and their location will be kept up to date to ensure that these documents are identifiable and retrievable. It will be the responsibility of the individual completing each record to forward it to the proper area for further disposition, and the appropriate Level 1 individual will see to it that this is accomplished and that all such documents are properly recorded and/or filed.

Design related records will be maintained on file throughout the entire period during which shipping package, or type of package, is kept in use. All other records relating to quality of such packages or shipments will be kept available for inspection for at least two years.

All inspection and test records will describe the type of observation involved, and will include evidence that all pertinent manufacturing, inspection, and testing operations have been completed and verified. This evidence will include the date on which such operations were performed, identification of the individuals involved, and the results of the test or inspection. In addition, where necessary, information will be included describing any conditions which could adversely affect the quality of the item or the acceptability of the tests results.

18. AUDITS

The packaging quality assurance program will be audited on a yearly basis by a representative of the Nuclear Safeguards Committee, and the results of such audits will be reported to the Vice President and General Manager of Nuclear Products. The primary concern in such audits will be the hazard potential involved in all aspects of the packaging operation, and audits will be intended to improve or maintain a high level of safety, for employees of the licensee, for

the ultimate recipient of packages containing radioactive material shipped by the licensee, and for members of the general public who may be in proximity to such packages during their transport.

The Vice President and General Manager of Nuclear Products will evaluate the reports of all audits, with the assistance of such competent authority as he deems necessary, and direct that areas of deficiency be corrected. The Business Manager, Radiochemicals, shall direct such corrective activity, and approve its completion. Audit reports and reports of corrective actions shall be maintained on file as part of the packaging quality control records, and will be traceable to such other items in these records as are pertinent.

FIGURE 2

RESPONSIBILITY MATRIX

Q.A FUNCTIONS	BUSINESS MANAGER, RADIOCHEMICALS	LEVEL 1*	LEVEL 2*	LEVEL 3*	MANAGER, HEALTH, SAFETY AND ENVIRO-MENTAL AFFAIRS	HEALTH PHYSICS SUPERVISOR	NUCLEAR SAFEGUARDS COMMITTEE
1. Q.A. Program	A,C,D	B,C	B,E	E	A,C	B,C	
2. Training	A,D	B,D,E	E			C,E	
3. Certification	A,D	B				C	
4. Testing	A	B,D	D,E	E		A,C,D	
5. Document Change	A,C,D	B,D,E				B,C	
6. Inspection	A	B,D,E	D,E	E		C,D,E	
7. Shipping	A	A,D	B,D	E			
8. Specifications	A	B,C				C	
9. Audits	A	B				D,E	D,E

A: Approve

B: Accept

C: Concur

D: Initiate

E: Perform

*See Figure 1 for definition of Levels 1, 2 and 3

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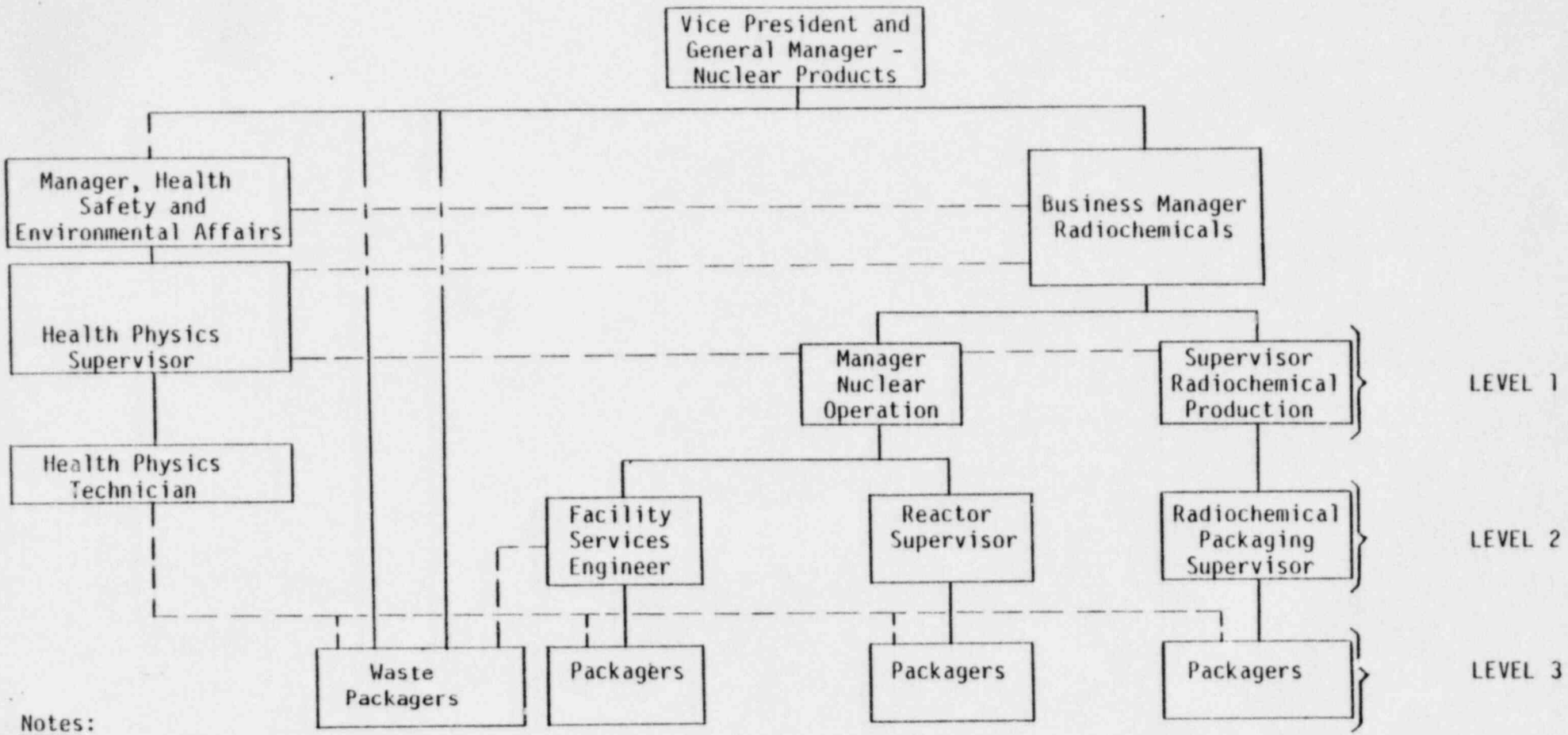
FIGURE 1 ORGANIZATION CHART



Notes:

1. Horizontal dashed lines indicate paths along which responsibility may be shared or concurrence achieved on items of concern.

2. Vertical dashed lines indicate paths along which approval must be achieved or upon which an audit function is involved.

3. A function or responsibility designated for a certain level individual may be assumed by a higher level individual provided the effectiveness of the program is not decreased.

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