U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 30-00001/82-01(DETP); 30-12559/82-01(DETP)

Docket Nos. 30-00001; 30-12559

License No. 24-04206-01	Priority I	Category B
License No. 24-17450-01	Priority IV	Category E(1-A)

Licensee: Mallinckrodt, Incorporated
Box 10172 Lambert Field
St. Louis, MO 63145

Facilities: Mallinckrodt/Diagnostic, Research and Development

Inspections At: Maryland Heights and Hazelwood, MO

Inspection Conducted: May 3-7, 1982

Inspectors: W. J. Adam, Ph.D. W. J. Adam 6/18/82

C. T. Oberg D. G. Wiedeman for 6/18/82

Approved by: D. G. Wiedeman, Acting Chief
Materials Radiation Protection
Section 1 D. G. Wiedeman

Inspection Summary

Inspection on May 3-7, 1982 (Reports No. 30-00001/82-01(DETP)
Areas Inspected: Routine, unannounced inspection of license action on previous inspection findings for License No. 24-04206-01; and a review of matters involving a few of the licensee's shipments under this license. For both Licenses: organization; licensee audits; training, retraining, and instructions to workers; radiological protection procedures; materials, facilities, and equipment; receipt and transfer of material; shipping incidents; exposure controls, external, internal, and ALARA program; posting, labeling, and control; surveys; radioactive effluents and waste disposal; notification and reports; quality assurance; environmental monitoring programs; emergency preparedness programs; confirmatory measurements; and independent inspection efforts. The inspection involved a total of 53 inspector-hours onsite by two NRC inspectors.
Results: Within the areas inspected under these licenses, no item of noncompliance were identified.

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24-04206-01 PDR

DETAILS

Persons Contacted

Maryland Heights, MO Location, License No. 24-04206-01

*R. J. Costic, Plant Manager
*D. W. Soldan, Corporate Radiation Safety Officer
*R. W. Brown, Supervisor of Regulatory Compliance and Radiation Safety Officer
**M. J. Castello, Director of Operations

Hazelwood, MO Location, License No. 24-17450-01

T. O. Oesterling, Ph.D., Vice President
*J. L. Brown, Director
*D. W. Soldan, Corporate Radiation Safety Officer
*R. G. Wolfangel, Ph.D., Assistant Director
*H. Anderson, B.S., Site Radiation Safety Officer
W. Petty, H.P. Technician

*Those present at both entrance and exit interviews.
**Present only at the entrance interview.

The inspectors also contacted other workers and supervisory personnel during these inspections.

Licensee Action on Previous Inspection Findings

Noncompliance 30-00001/80-01 (Closed): License Condition No. 17, Radiation level surveys are being recorded and the item has been corrected as described in the licensee's letter dated October 21, 1980. An audit of the file by Health Physics personnel and a check list for the technicians has corrected the problem.

General

Various aspects of the licensee's operations were reviewed during this inspection. This included the scope of operations and operating practices. This was a routine inspection of two Mallinckrodt, Incorporated Licenses No. 24-04206-01 (process and distribution) and No. 24-17450-01 (Type A, Broad for research and development). In addition, the inspectors reviewed the circumstances surrounding some situations involving licensed material shipped by the licensee under License No. 24-04206-01.

Unless stated otherwise, the inspection information herein presented refers to both of the licenses inspected.

1. Organization

For License No. 24-04206-01, the administrative management organization is outlined in Table I of this report. Table II identifies the members of the Radiation Safety Committee (RSC), and Table III is a tabulation of the management control personnel under this license.

For License No. 24-17450-01, Thomas W. Oesterling, Ph.D., is the Vice President of Research and Development for the Medical Products Group and the Radiation Safety Committee for this license is tabulated in Table IV.

The RSC's are meeting at the required frequency and proper documentation is maintained.

No items of noncompliance were identified.

2. Licensee Audits

Individual workers perform routine and daily survey audits in restricted areas. Problems are passed along to the RSO or RSC as necessary to achieve corrective action. Weekly survey and general type audits are performed by Health Physics (H.P.) personnel. Quarterly reports of high personnel exposures are prepared and reviewed by the RSC's. The corporate RSO audits the overall radiation protection programs.

Based upon the inspection samplings, the licensee appears to be in compliance with license conditions relating to the implementation of systems of internal inspections and management control.

No items of noncompliance were identified.

3. Training, Retraining, and Instructions to Workers

As specified by the licenses' conditions, the licensee is in compliance with their requirements to provide radiation safety indoctrination and formal training programs, including testing, commensurate with job classifications and duties. On-the-job training is provided by area supervisory and H.P. personnel as needed. Training includes a review of the licensee's Manuals, Regulatory Guide 8.13, and the NRC regulations. Retraining is performed annually in the form of a review plus updating on new developments, procedures information, regulations, guides, etc. This retraining includes some written testing of personnel.

The licensee is in compliance with 10 CFR 19.12, "Instructions to Workers."

No items of noncompliance were identified.

4. Radiological Protection Procedures

The licensee has implemented radiological protection programs required by their license conditions. These include a Manual of Radiation Protection Programs, Standard Operating Procedures (SOP), Emergency Procedures, and a Respiratory Protection Program under License No. 24-04206-01. The radiation protection staff and H.P. Department conducts and implements an overall radiological protection program to assure compliance with established standards and procedures.

A review of these written procedures showed them to be adequate for the existing programs. The procedures appeared to be properly implemented and utilized by licensee personnel.

No items of noncompliance were identified.

5. Materials, Facilities and Equipment

Materials

Licensed materials are possessed, used, and distributed in quantity and kind as authorized.

The licensee maintains no formal inventory of materials. This information can be obtained from the existing receipt, transfer, distribution, and waste records that the licensee does maintain.

Facilities

Inspection of the physical facilities showed that the facilities conform with descriptions in the applications and letters referenced by the License's Conditions.

Methods and systems utilized by the licensee to maintain security of licensed material and preventing unauthorized entry into controlled areas, and/or unauthorized removal of material appear adequate. The licensee is in compliance with license conditions referencing requirements relating to security and access controls.

The licensee is in compliance with 10 CFR 20.207, "Storage of Licensed Material," and 10 CFR 20.203, "Caution Signs, Labels, Signals, and Controls." They are also in compliance with the requirements referenced by the license conditions regarding utilities, services, emergency power and/or lighting, fire protection systems, sewer systems for liquid waste release, storage areas, and shielding.

Equipment

A review of the licensee's process and fume hoods, glove boxes, hot cells, remote handling devices, shielding devices, ventilation systems and retention tanks, air samplers, and survey instruments was made and determined to be in accordance with the systems described in applications and letters to the US NRC referenced in the License Conditions.

No items of noncompliance were identified.

6. Receipt and Transfer of Material

The licensee is in compliance with the requirements of 10 CFR 20.205(a) and (d) (Procedures) and 10 CFR 20.205(b) and (c) (Surveys) for incoming packages.

Material transfers are made in accordance with 10 CFR 30.41, 71.5, 71.51, 71.55, and DOT requirements under Title 49 of the Code of Federal Regulations.

Records of receipts and transfers of materials are maintained in accordance with 10 CFR 30.51.

No items of noncompliance were identified.

7. Shipping Incidents

The inspectors reviewed the circumstances surrounding a situation in which a Mallinckrodt shipment containing 151 millicuries of iodine-131 arrived at the Walter Reed Army Medical Center (WRAMC) on July 28, 1980, without DOT labels.

The inspectors were informed by the licensee that the individual package may have been part of a "consolidation shipment" to WRAMC consisting of several smaller packages in one large over-pack, properly labeled. In this case, the consolidated internal packages would not necessarily be labeled. The package in question may have been removed from the over-pack at one receiving area and then transferred to the Field Guard Station, WRAMC, Forest Glen Annex for its designated use. The licensee also explained that it would have been difficult for a package to be shipped without the required DOT labeling.

They have taken appropriate action to ensure that shipment of packages have proper DOT labeling. Procedures have been established to perform a weekly, unannounced H.P. audit of the Shipping Department and the packages being shipped. In addition, a new check list shipping form has been designed for utilization by shipping personnel whereby they must certify with their employee I.D. number that each package shipped has been properly packaged and labeled (see upper right corner of the attached Exhibit A). This item is closed.

The inspectors reviewed the possible unauthorized shipment of five and ten millicurie (mCi) sources of I-131 by Mallinckrodt, Incorporated. The material was ordered by Fairless-Hills Diagnostic Labs, Inc. and received on August 7, 1980. The I-131 was shipped by Mallinckrodt in accordance with their customer's authorization for possession and use of diagnostic radiopharmaceuticals delineated in 10 CFR 35.100, Groups I, II, and III. The licensee presumed that the material would be used in the preparation of diagnostic doses because of the license authorization. They did not believe the I-131 would be used for therapeutic treatment which was not authorized (Groups IV or V) by their customer's license. Mallinckrodt, Incorporated has taken corrective action to preclude similar occurrences. They have since installed a computerized system which utilizes a CRT readout that displays the license authorizations and effective dates. Orders of this type are challenged by the ordering personnel. The material use is verified by telephone whenever there is no clear distinction for the utilization. This item is closed.

The status of as many as 100 or more Tc-99m generators discovered in New York City (NRC memorandum dated March 11, 1980) was reviewed. Mallinckrodt representatives informed the inspectors that the generators were probably used and were to have been returned. Instead, the driver apparently set these aside for financial profit by some type of sale of the integral lead shielding. These units were subsequently confiscated by the State. This item is closed.

The inspectors reviewed the status of the trace on a misplaced package reported to the NRC, Region III, on February 27, 1981, with a followup letter dated March 4, 1981. The misplaced package was lost within the transportation system and was never located. This item is closed.

No other incidents involving shipping of licensed material have occurred since the previous inspection.

No items of noncompliance were identified.

8. Exposure Control - External

All of the licensee's employees are supplied whole body Thermoluminescent Dosimeters (TLDs) incorporated into their identification badges. These are read on a quarterly frequency by the licensee and the exposure, if any, is assigned to the individual.

Personnel working in, or who may have a need to enter, restricted areas are assigned whole body TLDs. They are also assigned extremity (finger) TLD ring monitors and self-reading pocket dosimeters depending upon their job assignment. Production and radiation workers wear the TLD ring monitors. These whole body and extremity monitors are read on a weekly frequency by the licensee and the exposure results are maintained.

In addition to personal monitoring, the licensee controls external exposure by direct reading radiation survey measurments and evaluation of the most probable exposure which could be received from specific tasks, procedures, and techniques prior to actual performance of the work.

The Form NRC 5, or equivalent, is maintained for each badged individual. Form NRC 4 must be complete and in an individual's file before he or she is allowed up to 3 rem per quarter.

Under the Priority I license, No. 24-04206-01, the maximum exposures assigned for the year of 1980 were 5,090 mrem whole body and 37,700 mrem extremities. For 1981, the annual exposures for the personnel working in specific building were as indicated in the following tabulations:

Annual Maximum Personnel Dosimetry Results for 1981

Building No.	Whole Body (mrem)	Extremities (mrem)
200	705	17,365
300	4,310	9,600
400	4,385	10,060
500	3,195	11,380
600	4,530	37,940
700	2,215	7,005

There have been no quarterly exposures in excess of 3 rem whole body or 18.75 rem extremities since the last inspection.

The licensee goal to attain a maximum average quarterly exposure of less than 1,250 mrem was achieved during the last quarter of 1981. They are hopeful that this trend can be maintained, accordingly, they have further reduced the whole body exposure goal for the second quarter of 1982 to 1,200 mrem.

The maximum direct reading radiation level measured in a restricted area was 95 mR/hr in the Mo/Tc generator production area. This was obtained during a production run when levels are expected to be high. At other times the radiation levels are significantly less and remain about 2mR/hr.

Since the last inspection, radiation level surveys have been performed and recorded as required by license conditions.

Direct reading, weekly radiation level surveys along the perimeter fence line occasionally exhibit levels in excess of 0.6 mR/hr. These have been obtained within the region just south of the concrete block, radioactive waste, storage "fort" located West of (behind) Building 200 in the employee parking lot. The maximum reading recorded was 1.5 mR/hr which was subsequently reduced by the addition of concrete block shielding to the storage fort. On less frequent occasions, readings of up to 0.2 mR/hr were obtained at the fence line South-West of Building 500. These radiation levels have not existed such that the limits specified in 10 CFR 20.105(b) have been exceeded. The licensee plans to eliminate the waste storage fort in the near future and thus correct this situation.

For License No. 24-17450-01, the maximum quarterly TLD whole body exposures were 55 mrem for the weekly badges and 90 mrem for the quarterly badges. The maximum TLD extremity ring badge reading was 540 mrem.

Daily, direct reading radiation survey levels have averaged between 0.2 and 0.8 mR/hr with high readings of about 1 to 2 mR/hr in the general research lab areas.

The licensee is in compliance with the requirements of 10 CFR 20.101(a) and (b), 20.102, 20.104(a), 20.202(a) and 20.401(a) for both licenses.

No items of noncompliance were identified.

9. Exposure Controls - Internal

The licensee's program for internal exposure control consists of surface contamination surveys, airborne radioactivity monitoring, thyroid counting, and urinalyses.

Routine in-plant air samples are collected on a weekly basis in areas restricted for work with radioactivity. In addition, air samples are collected any time a special project is undertaken, such as hot cell, hood or glove box decontamination work and during filter change operations, or under unusual circumstances.

Under License No. 24-04206-01, radioassay of the routine in-plant air samples taken in approximate breathing zones has identified the presence of airborne I-125, I-131, Mo-99 and Se-75. The airborne concentrations, based upon the limit for mixtures of radionuclides, have occasionally exceeded the restricted MPC(a) limit. During 1981, airborne concentrations in Building 200 exceeded the limit on three occasions. The levels measure were 105%, 165%, and 285% of MPC(a). During these periods, however, no individuals were exposed to the levels indicated and no thyroid burdens exceeded the 40 MPC hours control level.

Thyroid radioiodine uptake results for individuals working under License No. 24-04206-01 have been exhibiting a general diminution as shown in the following tabulation:

Results of Uptake of Radioiodine by Thyroid Monitoring and Evaluation of Causal Parameters

Date	MPC-Hours	Cause
02/06/80	45.0	Not Identified.
07/22/80	127.0	Contamination on hands.
09/03/80	58.6	Disposal of therapy capsules from capsule box to overpack.
09/26/80	66.4	Overpack was overfilled with disposals and not closed properly.
11/16/81	50.2	Working in hood.
12/30/81	57.4	Problems with waste overpack.

Between 1980 and 1981, the number of uptake incidents that exceeded the 40 MPC-hour control level has decreased as well as the average uptake levels. The averaged thyroid monitoring results for the fourth quarter of 1981 were between 1.0 and 5.0% of the fractional permissible thyroid burden.

Individuals participating in the urinalysis bioassay program have shown no significant intake of radionuclides. No radionuclide concentration limits for excretions have been exceeded.

The licensee has established a respirator program under this license in accordance with Regulatory Guide 8.15 and 10 CFR 20.103(c). They have available for use, pressure demand type respirators with protection factors of 2,000. Use of these units have not been needed for routine operations. The licensee has provided specific SOPs for fitting, inspection and testing, and for cleaning these respirators.

Since the last inspection, area contamination levels have ranged between 5,100 and 21,000 counts per minute (cpm). All such areas were decontaminated on the same day that the surveys were made. The results of the survey and the decontaminations have been documented and the records maintained.

Under License No. 24-17450-01, with the exception of the first floor Waste Storage Room, the restricted area radioactive airborne concentration levels have remained below 25% of MPC(a) for I-125. The waste storage room has attained a FMPC(a) for I-125 of up to about 50%. This has been because of the disposal of some iodine labeled compounds in which the radioiodine has not been strongly bound. The waste storage room is a low occupancy area that is frequented by only a couple of individuals as necessary to perform the functions associated with radioactive waste handling.

Bioassay work in the form of thyroid monitoring and urinalyses, has been performed on radiation workers in accordance with the license conditions. Nine individuals are participating in a urinalyses program under which no radionuclide concentration limits for the excretions have been exceeded.

Depending upon the work schedules, between 35 and 50 individuals participate in the thyroid monitoring program at a given time. Individuals for whom thyroid monitoring results exhibit readings in excess of 5% FPTB (Fractional Percent Thyroid Burden) will be restricted from further work until the FPTB is below the 5% limit. Thyroid measurements have shown that individuals range between 1.0 and 6.4% of FPTB. The individual with the 6.4% FPTB was appropriately restricted until the thyroid burden deminished.

Daily wipe samples for removable radioactive contamination have been taken as required. Results of these samples have shown that where the established limit of 100 cpm above background has been exceeded, the contaminated surfaces have been effectively decontaminated.

No items of noncompliance were identified.

10. Exposure Controls - ALARA Program

The licensee has not developed and implemented a formal ALARA program but does very strongly abide by the ALARA concepts. An example of

this is the personnel exposure reduction goal (Section 8 of this report) established and discussed during the RSC meetings held under the 24-04206-01 license. At the meeting of November 5, 1981, the attainment of the established goal of 1.25 rem per quarter was discussed. The January 12, 1982, meeting minutes discuss keeping the same in-house exposure limits in the first quarter of 1982 as was used for the fourth quarter of 1981. The minutes also pointed out the fact that external exposures had been reduced in 1981 over those of 1980 and that the 1981 liquid waste effluents had been substantially reduced over previous years because of the additional 10,000 gallon retention tanks installed in Building 500A. Radioactive effluent air levels had also been reduced because of the addition of more charcoal filters in the exhaust systems. During the RSC meeting of April 16, 1982, the members agreed to further reduce exposure limits during the second quarter of 1982. According to the meeting minutes, the limits set were 1,200 mrem whole body, 3,750 mrem for the skin of the whole body, and 11,500 for extremities.

Statements in their license conditions affirm that the licensee is committed to the best possible Radiation Protection Program and ALARA concepts.

No items of noncompliance were identified.

11. Posting, Labeling, and Control

Based upon the tours of inspection and samplings observed, the licensee appeared to be in compliance with the requirements of 10 CFR 20.203, 20.207, and 19.11. The licensee also appeared to be in compliance with posting, labeling, and control requirements specified in the licenses inspected.

No items of noncompliance were identified.

12. Surveys

As discussed in Sections 8 and 9 of this report, surveys are being performed as required. In addition, sealed source leak testing is also being performed as required. Records of these surveys and leak tests are being maintained as required.

No items of noncompliance were identified.

13. Radioactive Effluents and Waste Disposal

Gaseous and volatile byproduct material effluents are monitored by the licensee. Material released from the exhaust stack systems is continuously monitored. The annual discharges for the past two years have remained below the control limits specified for unrestricted releases.

Liquid effluents to the sanitary sewer system are made through the licensee's retention tanks. Liquid radioactive waste is held for

decay for several months, analyzed, and then discharged. For License No. 24-04206-01, the licensee discharged a total of 289 millicuries (mCi) during 1980 and 174 mCi during 1981. For License No. 24-17450-01, the annual liquid discharges for 1980 and 1981 were 15.63 mCi and 29.07 mCi respectively.

The licensee's waste packaging and handling programs were reviewed by the inspectors and no apparent deficiencies were observed. Records were reviewed of the waste shipments made to the licensed commercial waste burial sites over the past two years and no apparent problems were observed. The licensee performs an annual audit of their waste handling program to verify compliance with the various agencies (NRC, DOT, State, etc.).

During the past year, an "Environmental Release Study" was performed for the NRC by Oak Ridge Associated Universilies, at the Marlyand Heights, MO, site, License No. 24-04206-01. The study included such things as Wind Rose Analyses, Soil Sample Analyses, Effluent Water Analyses, Radiation Level Measurements, etc. The study provided good agreement with the licensee's results.

The inspectors reviewed the September 1979 reburial of Se-75 and Co-60 that had been incorrectly buried in 1976. The material, 0.33 mCi of Se-75 and 1.3 mCi of Co-60 plus th[illegible]ontaminated soil, was reburied in two separate trenches in accorda[illegible]h 10 CFR 20.304. The licensee maintains a record of the buria[illegible]t plans, and sketches in which all the pertinent information is documented. The site of the burial was toured by the inspectors. It is within the fenced area of the licensee's property and within view of the licensee's security guard station at the rear entrance to the facility. Direct reading survey measurements were made at the burial site. None of the readings made were significantly different from background measurements (0.02 to 0.04 mR/hr).

During the progress of these inspections, several waste drums in various stages of preparation for disposal were viewed by the inspectors. Of these, approximately 25 opened drums were visually inspected and appeared to be in compliance with the requirements of the NRC, DOT, and the burial sites.

At the Hazelwood, MO location, under the 24-17450-01 (R&D) license, an incident involving the discharge line from the facility retention tank occurred during August of 1980. The discharge line connection from the retention tank system inside the basement of Building 20 (tunnel to Building 30) to the sanitary sewer soil pipe, outside of the building, separated at the joint and prevented routine discharge by pumping. The licensee excavated to a depth of 12 feet to get to the break. Radioassay of the soil removed during the excavation showed no levels of radioactivity significantly different from background until just beneath the break.

At this point, analyses of a half, right cylinder volume of soil, 15 cm long with a radius of 15 cm, gave a total activity of between 2.12 and 0.29 microcuries (μCi) of I-125 (I-125 was the only radionuclide found)

and a concetration of about 2.4E-4 μCi/cm³ of soil. A larger volume of soil, 61 cm long with a radius of 61 cm, from the same location and of the same geometric configuration, was also analyzed. The results of this gave between 5.4 and 0.47 μCi of I-125 and a concentration of about 3.3E-5 μCi/cm³ of soil.

After repairs, the pipes were braced in place from underneath with concrete block, the contaminated soil was replaced at the bottom of the 14 foot deep excavation, which was then filled in with the remaining removed soil. No further problems have occurred with this system. The burial was in accordance with the existing NRC Regulations, 10 CFR 20.304 at the time.

No items of noncompliance were identified.

14. Notifications and Reports

The licensee is in compliance with the NRC notification requirements of 10 CFR 20.402, 20.403, 20.405, 20.407, and 20.408. They also advise the NRC of situations regarding licensed material shipped by them which becomes involved in some type of incident within the transportation system.

The licensee is also in compliance with the requirements of 10 CFR 19.13 (20.409) to provide specified notices to individual workers.

No items of noncompliance were identified.

15. Quality Assurance

Quality assurance of licensed materials and products manufactured is performed as required for product verification in compliance with various agencies such as the NRC, FDA, Bureau of Biology (BOB), DOT, etc.

No items of noncompliance were identified

16. Environmental Monitoring Program

Unrestricted area environmental air sampling under License No. 24-04206-01 is performed at an off site location and at the fence line. These air sampling stations are located North of the plant site. The off site station is on the property of the local Fire Department at the Fire Station. Environmental fence-line radiation surveys are also performed on a weekly frequency under this license as discussed in Section 8 of this report.

There is no formal environmental sampling program under License No. 24-17450-01.

No items of noncompliance were identified.

17. Emergency Preparedness Program

SOPs delineated for both of these licenses implement programs for contending with various emergencies, accidents, or incidents. For the

Maryland Heights, MO, site (License No. 24-04206-01) the licensee has submitted a Radiological Contingency Plan dated December 2, 1981, amended by letter dated March 2, 1982, in compliance with NRC Order dated May 22, 1981.

No items of noncompliance were identified.

18. Confirmatory Measurements

During the course of this inspection, many direct reading survey measurements were made by the inspectors using the following portable survey instruments:

NRC SURVEY INSTRUMENTS

Type	NRC I.D. No.	Calibration Date
Xetex 305B Eberline E-520	8363	April 6, 1982
w/End Window Detector	9576	March 9, 1982
Eberline PRM-5-3 w/LEG Thin Crystal Detector	7309	February 3, 1982

The results of these surveys were not significantly different from those made by the licensee's personnel.

No items of noncompliance were identified.

19. Independent Inspection Effort

License No. 24-04206-01

On May 7, 1982, the inspectors observed the assembly and production of the licensee's "Ultra Technekow" (UTK), Mo-99/Tc-99m generators in Building 600 and the subsequent packaging and staging of these for shipment. The inspectors reviewed the various innovations and engineering design modifications implemented by the licensee to reduce personnel exposure.

The UTK units are produced on an assembly-line basis employing both automation and manual techniques. Each UTK is eluted for an operational verification and QA-QC purposes. Subsequent to this final check, the conveyor system conducts the UTKs to the shipping and staging area in Building 400 where the units are packaged and staged in specific locations awaiting pickup by the assigned carriers for transport and ultimate distribution.

Personnel performing manual operations on the assembly line wear lead aprons and work from behind shielding. Shielded glove boxes have been designed and are used for specific operation. Individuals are working in radiation fields that could be as high as 20 mR/hr. The specially designed shielding and lead aprons reduce the actual whole body exposures to less than a total of 1,200 mrem per quarter. This represents a maximum exposure of about 92 mrem per week or about 10 to 15 mR/hr while working on the UTK production line.

Personnel working in the packaging, staging, and shipping area of Building 400 could be exposed to radiation fields of up to 100 mR/hr at six to twelve inches from the staged UTKs. This is not the case, however, because the staging is done in selected areas shielded by solid concrete blocks and because these areas are not high occupancy locations. These areas are occupied only as necessary to stage and then finally transfer the packages for loading in vehicles. Building 400 personnel who receive the highest exposures are those packaging the UTKs from the conveyor system. These individuals work within shielded areas and wear lead aprons. The shielding provided is sufficient to limit whole body exposures to just slightly less than the exposure level received by the assembly line workers as discussed in preceeding paragraphs. The inspectors recommended that the licensee consider utilization of longer lead aprons for more effective protection for those packaging the UTKs.

Further, while touring the licensee's facilities a radiation level of about 10-20 mR/hr was detected coming from a refrigerated trailer parked within the restricted area at the loading dock in back of Building 200. This unit is used for the storage of animal carcasses and waste until enough has been accumulated for a waste shipment. One package with a maximum surface reading of 140 mR/hr had recently been placed in the trailer. Normally, these packages contain short lived material and are held in an interim freezer storage until the radiation level has decreased significantly. The license material contained in this package was Tc-99m and had been placed in the trailer because of its very short half life. The package was removed and transferred to an interim storage freezer.

License No. 24-17450-01

With the exception of the inspection tour of the licensee's facilities and operations, the only other independent inspection effort was the review of the leak in the retention tank discharge system as discussed under Section 13 of this report.

No items of noncompliance were identified.

Exit Interviews

The exit interview for the inspection of License No. 24-04206-01 took place on May 5, 1982 at the Maryland Heights, MO, location. Licensee personnel in attendance at this exit interview are identified in the opening section of this report, "Persons Contacted."

The inspectors informed the licensee that no items of noncompliance had been identified and reviewed the findings of the inspection. The status of the various occurrences involving material shipped by the licensee, as discussed in Section 7 of this report, was reviewed and the licensee was informed that these were closed. Concerns were expressed by the inspectors with regard to the waste storage fort behind Building 200 and the radiation levels from it at the licensee's fence line. The inspectors were informed that the licensee plans to construct a proper type of storage facility in the near future and will eliminate this concrete storage fort. The new facility may also include

other services such as refrigeration and freezer storage. The inspectors stated that the item of noncompliance identified during the previous inspection was closed. They also informed the licensee that they would be back on May 7, 1982, to observe the production, assembly, and staging of "Ultra Technekow" generators for distribution.

The exit interview for the inspection of License No. 24-17450-01 at Hazelwood, MO, was held on May 6, 1982, and included licensee personnel specified under the section "Persons Contacted" in this report. The inspectors reviewed their findings and informed the licensee that no items of noncompliance had been identified.

Attachments:
1. Table I - Mallinckrodt Diagnostics Organization, 1982 (License No. 24-04206-01)
2. Table II - Mallinckrodt Diagnostics Radiation Safety Committee (License No. 24-04206-01)
3. Table III - Mallinckrodt Diagnostics Personnel (License No. 24-04206-01)
4. Table IV - Mallinckrodt Medical Products Group, R&D Division, Radiation Safety Committee Members (License No. 24-17450-01)
5. Exhibit A - Shipper's Certification Sheet

TABLE I

MALLINCKRODT DIAGNOSTICS

ORGANIZATION 1982

David W. Mitchell, Chairman of the Board-Avon Inc.

Raymond F. Bentele, Chief Executive Officer

John L. Ufheil, Chief Operating Officer

Harry E. Rich, Group Vice President-Medical Products Group

David A. Maupin, Vice President and General Manager

Michael J. Costello, Director of Operations

Richard J. Costic, Plant Manager

George E. Gerth, Manager Plant Services

Roy W. Brown, Supervisor Regulatory Compliance

TABLE II

MALLINCKRODT DIAGNOSTICS

RADIATION SAFETY COMMITTEE MEMBERS

Albert E. Hall, Assistant Plant Manager

James H. McClellan, Distribution Manager

Ralph E. Nuelle, Physicist-Quality Control

Art E. Sheller, Assistant Quality Control Manager

R. Tracy Sherman, Manager Technical Evaluation and Cyclotron Operations

Donald W. Soldan, Corporate Radiation Safety Officer

Dale L. Cowen, InVivo Production Manager

Warren K. Fadling, InVitro Production Manager *Secretary-RSC

Joseph E. Beaver, Manager Cyclotron Operations

Roy W. Brown, Supervisor Regulatory Compliance *Chairman-RSC

John R. Adams, Supervisor Health and Safety *Vice Chairman-RSC

Richard J. Costic, Plant Manager

TABLE III

MALLINCKRODT DIAGNOSTICS PERSONNEL

Richard J. Costic, Plant Manager

Michael J. Costello, Director of Operations

Albert E. Hall, Assistant Plant Manager

James H. McClellan, Distribution Manager

George E. Gerth, Manager Plant Services

Dale L. Cowen, InVivo Production Manager

Donald W. Soldan, Corporate Radiation Safety Officer

Roy W. Brown, Supervisor Regulatory Compliance

Milt V. Simer, Supervisor InVivo Quality Control

Lee A. Borcherding, Health Physics Specialist

John R. Adams, Supervisor Health and Safety

TABLE IV

MALLINCKRODT MEDICAL PRODUCTS GROUP

RESEARCH AND DEVELOPMENT DIVISION

RADIATION SAFETY COMMITTEE MEMBERS

James L. Brown, Director, Radiopharmaceuticals R&D

Donald W. Soldan, Corporate Radiation Safety Officer

*Chairman-RSC

Robert G. Wolfangel, Ph.D., Assistant Director, Radio-
pharmaceuticals R&D

Ron M. Hopkins, Ph.D., Director, Pharmacology and Toxicology

Richard T. Dean, Ph.D., Assistant Director, Chemical R&D

Leon R. Lyle, Ph.D., Assistant Director, Radiopharmaceuticals R&D

Howard Anderson, B.S., Research Chemist and Site RSO

Phil N. Hanson, R&D Division Controller

Exhibit A

MCP® MOORE BUSINESS FORMS, INC. PATENT 3,429,827

Mallinckrodt DIAGNOSTICS

2703 WAGNER PL., MARYLAND HTS., MO. • PHONE 800-325-3689

Charges	PACKED BY

Date Shipped	Cust. P.O. Number	Invoice No./BL	Control No.	LABELED BY
Cust. No.	Airport Code			

Ship To

Special Inst.

CARRIERS (Check One)

- ☐ Purolator Courier Corp., New Hyde Park, N.Y.
- ☐ Caspersen Inc., Chicago, Ill.
- ☐ Associated Courier, St. Louis, Mo.
- ☐ American Parcel Express, Los Angeles, Calif.
- ☐ Falcon Delivery, San Francisco, Calif.
- ☐ USPTC, Huntington Station, N.Y.
- ☐ Airport Drayage, Seattle, Wash.
- ☐ Medical Delivery Service, Flural Park, N.Y.
- ☐

It is mutually agreed that goods herein described are accepted in apparent good order (except as noted) for transportation as specified herein. Common carrier. Shipments subject to rules, classification and tariffs in effect as of the date hereof which are filed in accordance with law, copies of which are available for inspection, are hereby incorporated into and made part of this contract.
This is to certify that the materials below are properly classified, described, packaged, marked and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.

X PRESSLER — *Shipper's Signature*

RADIOACTIVE MATERIAL N.O.S. NA 9181

RADIONUCLIDE	GROUP	FORM		ACTIVITY IN CURIES
I-131	III	RADIOIODINATED COMPOUND LIQUID	I-131	
I-125	III	RADIOIODINATED COMPOUND LIQUID	I-125	
GA-67	III	GALLIUM CITRATE LIQUID	GA-67	
TL-201	IV	THALLOUS CHLORIDE LIQUID	TL-201	
P-32	IV	RADIOPHOSPHATE COMPOUND LIQUID	P-32	
CR-51	IV	SODIUM CHROMATE LIQUID	CR-51	
SE-75	IV	SELENOMETHIONINE LIQUID	SE-75	
FE-59	IV	FERROUS CITRATE LIQUID	FE-59	
MO-99	IV	SODIUM MOLYBDATE SOLID	MO-99	
XE-133	VI	XENON GAS	XE-133	

RADIOACTIVE MATERIAL LIMITED QUANTITY N.O.S. UN 2910

RADIONUCLIDE	GROUP	FORM		ACTIVITY IN CURIES
I-125	III	RADIOIODINATED COMPOUND LIQUID	I-125	
CO-57	IV	CYANOCOBALAMIN SOLID	CO-57	
CR-51	IV	SODIUM CHROMATE LIQUID	CR-51	

(CHECK ONE) COMMODITY DESCRIPTION NOT RADIOACTIVE NOT HAZARDOUS

- ☐ MEDICAL SUPPLIES
- ☐ PRINTED MATERIAL

PACKAGE DESCRIPTION TOTALS	NO. OF PACKAGES	ACTIVITY IN CURIES	LABEL CATEGORY WHITE I YELLOW II YELLOW III	TRANSPORT INDEX FOR YELLOW II AND YELLOW III CATEGORY ONLY	TYPE	WEIGHT (LBS)
RADIOACTIVE MATERIAL N.O.S. NA 9181					A	
RADIOACTIVE MATERIAL LIMITED QTY. N.O.S. UN 2910			NOT REQUIRED			
MEDICAL SUPPLIES NOT RADIOACTIVE		NOT REQUIRED				
TOTAL PIECES AND WEIGHT		NOT REQUIRED				

CARRIER'S SIGNATURE	DATE	TIME	ROUTE NO.	CONSIGNEE SIGNATURE	DATE	TIME