U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report Nos. 030-00001/88-002(DRSS); 030-12559/88-001(DRSS)

Docket Nos. 030-00001; 030-12559

License No. 24-04206-01 Priority 1 Category B

License No. 24-17450-01 Priority 2 Category E

Licensee: Mallinckrodt Incorporated
2703 Wagner Place
Maryland Heights, MO 63043

Mallinckrodt Incorporated
675 McDonnell Blvd.
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Inspection Conducted: May 16 through June 3, 1988

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Nuclear Materials Safety Section 2
6/30/88 (Date)

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Approved By: Bruce S. Mallett, Ph.D., Chief
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for

6/30/88
(Date)

Inspection Summary:

Inspection on May 16 through June 3, 1988 (Reports No. 030-00001/88-002(DRSS) 030-12559/88-001(DRSS))

Areas Inspected: This was a special, announced inspection conducted at the licensee's facilities by a team composed of personnel from NRC Region III and Headquarters, Oak Ridge Associated Universities, the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency and the Occupational Safety and Health Administration. The scope of the inspection at the licensee's manufacturing facility (24-04206-01 License) consisted of a review of the radiation protection program, a review of the emergency preparedness plan, an evaluation of the licensee's environmental monitoring program, an evaluation of the licensee's fire protection program, a review of industrial safety, and product evaluations. The area emphasized during the inspection was that of main production. The scope of the inspection at the licensee's research and development facility (24-17950-01 License) was limited to fire protection.

The purpose of the inspection was to review conditions at the licensee's facilities to determine whether there are potential safety hazards that, when combined with routine facility operations, could impact upon public health and safety. In addition to the areas described above, the inspectors observed, during non-routine hours, molybdenum-99/technetium-99m generator production. These observations included the receipt of molybdenum-99 at the facility, the performance of radiation surveys on the incoming packages, the transfer of the material to the hot cell, the "shooting" of generator columns, autoclaving, transferring of the column to the "safe", connection of generator "plumbing," testing the elution process, assays of eluant, molybdenum-99 breakthrough tests, and packaging of the final product. The inspectors also, as part of product evaluations, visited two local NRC licensed facilities (Barnes Hospital and Diagnostic Imaging Services) to discuss their use of some of Mallinckrodt products.

Results: One violation of NRC requirements was identified: failure to perform leak tests of sealed sources at the required intervals (Section 4). In addition to the violation, the team also identified numerous issues which we feel necessitate the attention of licensee management to assure public health and safety. These issues are identified in Sections 4, 6, and 7 of this report.

DETAILS

1. Persons Contacted

*Ron Hopkins, Business Unit Director
*Albert E. Hall, Plant Manager
*Roy W. Brown, Manager of Regulatory Compliance; Radiation Safety Officer
*John R. Adams, Supervisor of Health and Safety
Donald R. Drunert, Supervisor of Health Physics Services
Chris Williamson, Senior Health Physics Technician
Dick Johnson, Receiving Clerk
George Williams, Receiving Clerk
Richard Kamler, Supervisor, Customer Service
Karen Hall, Expeditor, Customer Service
Vickey Sanders, Traffic Expeditor
Ron Hale, Lead Technician, Dispensing
Duane Hawthorne, Dispensing Technician
Ronald Sims, Supervisor of Shipping
Lee Crockett, Waste Technician
Ellis Hodges, Waste Technician
Brian Bicker, Facility Conformance Technician
Bill Petty, Supervisor, Industrial Engineering
Dan Reed, Iodine Production Technician
Dan Schapp, Supervisor of In-Vitro Area
Charles McCollum, Health Physics Technician
John Prouhet, Health Physics Technician
*Ashok Dhar, Health Physics Supervisor
Les Sabo, Site Quality Manager
Don Brencer, Chief Technologist, Barnes Hospital
Sally Schwarz, RPh., Barnes Hospital
Eric Slessinger, M.S., Oncology Department, Barnes Hospital
Jack Martin, Manager, Diagnostic Imaging Services
Todd Warren, RSO, Diagnostic Imaging Services

*Participated in exit interviews.

2. Background

As a result of the accident involving the release of uranium hexafluoride from Kerr-McGee's Sequoyah Falls Facility in Gore, Oklahoma, in 1986, the NRC is conducting team assessments at selective fuel cycle byproduct material facilities.

The team assessment is designed to evaluate existing conditions at each facility and to determine whether there are potential hazards that, when combined with facility operations, could impact upon public health and safety. During each assessment, the team determines whether the licensee has systems and procedures in place to identify and correct inplant industrial safety problems that could result in radiological safety consequences, and determines whether the licensee is adequately implementing those procedures to prevent or mitigate such problems. The areas reviewed included the licensee's overall radiation protection program, fire protection, waste management, emergency preparedness, environmental monitoring, industrial safety, and product evaluation. Upon completion of the

assessment, based upon observations made by team members, recommendations were made to the licensee. Those observations and recommendations will also be forwarded to the appropriate NRC Program Office and to appropriate regulatory agencies having jurisdiction over the particular licensee.

3. Program Overview

Mallinckrodt, Inc. Diagnostic Products Division occupies approximately 15 acres at the Maryland Heights facility, which is the foundation of the radiopharmaceutical operation.

The Diagnostic Products Division manufactures and distributes radiopharmaceuticals. The facility is involved primarily with seven manufacturing processes: radioisotopes (including cyclotron produced), encapsulation (therapeutic and diagnostic quantities of iodine-131), radioisotope labelling, lyophilization (non-radioactive process), radioactive gas filling (xenon-127 and xenon-133), organic synthesis (non-radioactive process), and radioactive liquid fills.

The Diagnostic Products Division employs approximately 200 individuals. The facility distributes approximately 5000 packages of radiopharmaceuticals per week. The distributed generators have an activity range from 0.25 curies to 12 curies, with an average activity of 1 curie per generator. The bulk of the manufacturing process occurs late Thursday evenings into Friday mornings and consists of molybdenum-99/technetium-99m generator production. In addition, the facility also houses two cyclotrons (one 40 MeV and one 30 MeV) used for the production of gallium and thallium isotopes.

The current radiopharmaceutical production operation evolved from a one building (Bldg. 100) operation which was purchased by Mallinckrodt, Inc. from Nuclear Consultants in 1966. In 1968 Building 200 was purchased; in 1970 Buildings 300 and 400 were added as distribution buildings; in 1975 Building 500, a radwaste facility, was added; in 1977 Building 600, the manufacturing facility, was added; in 1981-1982 the cyclotron building was added, and in 1983, Building 250 was added, which is used for low level radwaste storage. As a result of these additions, the operation expanded from 12,000 square feet in 1966 to over 180,000 square feet today.

4. Radiation Protection Program

a. Radiation Protection Organization

The Plant Manager is the responsible person for assuring that there is a competent Radiation Protection Organization at Mallinckrodt and that the organization is delegated sufficient authority to establish and execute the program. The Plant Manager is administratively responsible to the Director of Manufacturing.

The Radiation Safety Committee administers the Radiation Protection Program to assure the control of receipt, use and storage of radioactive materials and is administratively responsible to

the Plant Manager. The Committee currently is composed of the Supervisor of Health and Safety, the Manager of Regulatory Compliance, the Supervisor of Health Physics Services, the Manager of Quality Control, the Plant Manager, the Distribution Manager, the Manager of Cyclotron Operations, and the Supervisor of Health Physics.

The Manager of Regulatory Compliance is the responsible person for auditing the Radiation Protection Program to assure compliance with established standards, procedures and license conditions and is administratively responsible to the Plant Manager.

The Radiation Safety Officer/Health Physics Supervisor develops, implements, and maintains the Radiation Protection Program in accordance with NRC and other regulatory agencies. He is responsible for overall radiation protection at this facility. The person is administratively responsible to the Manager of Regulatory Compliance. The Radiation Safety Officer position was vacant from approximately October 1987 through May 1988. The responsibilities during that time were transferred to the Manager of Regulatory Compliance.

The Radiation Protection Staff functions as the working body of the Radiation Safety Committee and is responsible for monitoring day to day operations. The current staff consists of the Radiation Safety Officer and five Health Physics Technicians. This staff is administratively responsible to the Supervisor of Health Physics.

During the course of inspection, the team members expressed concern that the positions of Radiation Safety Officer and Manager of Regulatory Compliance were being filled by the same person from October 1987 through May 1988. Although it appears that both position responsibilities were still being carried out adequately it was evident that this was a heavy burden placed on the Manager of Regulatory Compliance. The licensee's response to the concern was that the position of Radiation Safety Officer/Health Physics Supervisor was held vacant for a longer than normal time due to difficulty in finding a person whose qualification and experience would be commensurate with the job description of the position. A person fitting the requirements for the position was hired and reported for duty on May 25, 1988.

No violations were identified.

b. Radiation Safety Committee

The Radiation Safety Committee (RSC) meets quarterly to discuss Radiation Safety Program issues. Routinely, six to eight members, including the Chairman, Radiation Safety Officer and Plant Manager, attend the meetings. The RSC primarily discusses radiation exposures and bioassay results from the previous quarter and reviews and updates the list of Class I users. In order to elevate the status of a user to that of a Class I user, management is required to initiate the action and review and approve the change. These changes are documented in the formal minutes of the RSC meetings. There are currently 51 Class I users, including cyclotron staff.

The facilities located at the Maryland Heights site have been constructed to be either radioactive laboratories or nonradioactive laboratories. Radioactive laboratories have been constructed with considerations for shielding, ventilation, disposal (drain lines), access, etc. Consequently, the RSC does not routinely approve new facilities.

The RSC approves a new use for radioactive material on a very infrequent basis, once every two to three years. New product development and research is performed under a separate license issued to Mallinckrodt, Inc., Research and Development Operations, Medical Products Group. Prior to the submission of a formal request to the RSC for a new use of radioactive material, the Class I user is required to develop the formal proposal with the assistance of the Health Physics Supervisor. The Health Physics Supervisor formally submits the proposal to the RSC for their review and approval. Once the RSC has completed their evaluation and determined that the procedure meets their criteria, the procedure is approved. The approved procedure is documented in the form of a batch sheet (e.g., standard operating procedure) which contains the step-by-step procedures for performing the operation. In addition, the Health Physics Supervisor is present during the first run (and future runs, if required by the RSC) of the new procedure to ensure all appropriate precautions have been taken.

The RSC is currently composed of eight members. The use of alternates is recommended by the RSC Chairman in the event a member cannot attend a meeting. One half of the RSC constitutes a quorum. The RSC is required to meet no less than quarterly. RSC meeting minutes reviewed during the inspection included meetings held on July 3, 1986; October 3, 1986; December 18, 1986; February 20, 1987; July 28, 1987; November 13, 1987; and March 14, 1988. According to statements made by licensee representatives and a review of those records, it initially appeared that no RSC meeting was held during the second calendar quarter of 1987. However, during the review of exposure records it was determined that the RSC did meet informally during the second quarter of 1987 to review personnel exposures which is a function of the RSC. This lack of documenting the informal meetings as a RSC meeting caused confusion on the part of the inspectors since it initially appeared that no meeting was conducted in the second quarter of 1987.

No violations were identified.

c. Radiological Protection Procedures

The licensee has implemented the procedures described in their Radiation Protection Program Manual which is referenced in License Condition No. 20, letter dated December 12, 1986. The RSO and members of the Health Physics' Department are responsible for assuring compliance with established standards and procedures.

This is accomplished through frequent laboratory surveys; conducting employee training programs; evaluating internal and external radiation exposure results; monitoring air and sewerage effluents and performing incoming package surveys.

No violations were identified.

d. Receipt of Radioactive Material

The licensee receives multi-curie amounts of certain radioactive materials for product manufacturing and processing purposes. Deliveries are based upon pre-arranged vendor contracts and activities may be adjusted up or down according to customer demand. Raw materials are normally received on specific days and dates. Receiving personnel have prior knowledge, through a computer printout, of what material is to be received on any given date. The printout covers from 3 to 12 month periods depending upon the licensee's purchase agreements. Molybdenum-99 is delivered to Building 500. All other material is delivered to Building 600. Commonly used raw materials are typically received on the following days of the week:

Xenon-133 and 127 - Wednesday
Molybdenum-99 and Iodines 131 and 125 - Thursday
Phosphorus-32 - Friday

When molybdenum-99 is received, a member of the Radiation Safety Office is present to assist the receiving personnel in the receipt procedures. No shipping incidents have occurred since the last inspection. However, on three occasions in 1987, inner lead containers of molybdenum-99 and iodine-131 exhibited low levels of surface contamination and on one occasion the vender mislabeled xenon-133 as molybdenum-99.

During the course of this inspection, the inspectors observed the receipt and check-in of the multi-curie quantities of molybdenum-99 and iodine-131 and the transfer of the materials to the appropriate hot cells.

During the observations of check-in procedures, the inspectors expressed concern that the individual performing surveys and smears of the packages was not wearing gloves while handling the containers. These containers had not been checked yet to determine if they were free of contamination. These packages do have the potential for being contaminated since they hold curie quantities of licensed materials. In addition, it was also noted that the analysis of the smears are conducted at the Health Physics Offices located in another building. If the packages were contaminated and the individual performing the smears and surveys became contaminated, there is a potential that contamination could be spread to other areas of the facility.

The licensee is also authorized to receive radioactive waste from Mallinckrodt Products from its customers and nuclear pharmacies as long as that waste is from Mallinckrodt products. This waste

consists of such material as spent generators, vials, needles and unused iodine capsules. The heaviest waste receipt days are Mondays and Wednesdays. Waste is delivered to Building 600 and is held in receiving until it is transferred to Building 500 for segregation and processing.

During the inspection, the inspectors expressed concern while observing an individual in Building 500 not wearing gloves and removing a decayed vial of radioactive material from its lead shield. Although this individual was wearing a finger type TLD and the licensee stated that the individual checks his hands for contamination prior to leaving the area, we feel that as an additional precautionary measure, gloves should be provided to individuals processing waste returned from customers.

No violations were identified.

e. Training, Retraining, and Instructions to Workers

As specified by the license conditions, the licensee is in compliance with their requirements to provide radiation safety orientation and technical training, including appropriate tests commensurate with work classifications and duties. On-the-job training (OJT) is provided by area supervisors and H.P. staff as needed. Orientation training covers a review of the licensee's manuals, NRC Regulatory Guides 8.10 and 8.13, 10 CFR 19.12 "Instructions to Workers," NRC Form-3, and other pertinent NRC regulations. Training for the technical staff is separate from training for non-technical staff. Retraining is performed at least once every three years as a review session incorporating updates on recent developments and changes in the licensed program, regulations, safety procedures, and general information. Retraining includes written testing of personnel on an annual basis.

Written exams are required to evaluate each individual's competency in the lecture/hand-out material. The exam consists of 25 questions, including some "scenario" type questions, and a score of 65% is required to pass. The inspectors expressed concern, however, that examinees are only told whether they passed or failed the test. They are not told which questions they answered incorrectly so they may learn the correct answers. The inspectors discussed this concern with the Manager of Regulatory Compliance, who agreed that some mechanism to followup with written testing may be necessary.

No violations were identified.

f. License Audits

The Manager of Regulatory Compliance is the principal individual responsible for auditing the Radiation Protection Program. Some of the current methods in place for auditing the program are as follows:

(1) Supervisors of main production areas are responsible for auditing their own areas to assure that requirements are being followed and implemented successfully. If it is determined that the procedures are not being followed this information is passed on to the Manager Regulatory Compliance to achieve corrective actions.

(2) The Manager of Regulatory Compliance periodically (at least quarterly) performs an independent walkthrough of the plant to assure that safety procedures are being followed (i.e., monitoring devices are being used, surveys are conducted, etc.).

(3) The Radiation Safety Staff, in conjunction with the Manager of Regulatory Compliance, performs routine checks to assure that individuals requiring bioassays are indeed having bioassays performed.

(4) An ALARA type of audit is conducted at least quarterly to review records including those concerned with effluent releases and internal and external exposures.

(5) An annual closeout review including exposure data, effluent releases, perimeter TLD data etc., is conducted by the Radiation Safety Committee. This closeout review is put together by the Manager of Regulatory Compliance.

No violations were identified.

g. Exposure Control - External

All of the licensee's employees are supplied with whole body thermoluminescent dosimeters (TLDs), incorporated into their identification badges. These dosimeters are read and evaluated quarterly by the licensee and the exposure, if any, is assigned to the individual. About 113 personnel working in or who may have a need to enter restricted areas are assigned separate whole body TLDs. They are also assigned extremity (finger) TLD ring badges and they have the option of using self-reading pocket dosimeters in addition to their TLD dosimeters. Production and radiation workers wear the TLD ring badges. These whole body and extremity dosimeters are read and evaluated each week and the exposure results are maintained as written records. The users of the self-reading pocket dosimeters are not required to record their readings or to zero (charge) these dosimeters every day of use. The pocket dosimeters are supplemental to the basic dosimetry program and are not calibrated in a radiation field for accuracy.

No minors currently work with licensed material. Pregnant women are removed from work areas using radioactive material as soon as they identify their pregnant status, but remain on the weekly TLD badge program. NRC Form-5 equivalent data is maintained for each badged individual. NRC Form-4 information is obtained for persons who were

monitored for occupational radiation exposure during previous employment. This data is required and maintained before a radiation worker is allowed to receive whole body exposure greater than 1.25 rem per calendar quarter (up to 3.0 rem per calendar quarter).

The licensee maintains internal action levels for exposures that are currently (as of March 1988) 900 millirem per calendar quarter for whole body and 9500 millirem for extremity exposure. Radiation worker exposures are integrated during each calendar quarter and forecasts are made, when necessary, to prevent exposures from exceeding the internal action levels. If it becomes necessary for a worker to exceed an internal action level, the RSC is petitioned to approve any additional exposure via a majority vote.

The maximum quarterly exposures recorded for byproduct material workers between May 1, 1986 and April 3, 1988 were 935 millirem whole body and 13,145 millirem extremity. No exposures in excess of 10 CFR 20.101 limits have been observed since the previous inspection. If badges are lost or the TLD's are damaged in processing, a H.P Technician files a written report and assigns a calculated exposure to the worker for the particular time period involved. The H.P. Technician generates exposure reports, which are reviewed by area supervisors, the Manager of Regulatory Compliance, and the Plant Manager on a weekly basis.

10 CFR 20.202 requires, in part, that all personnel dosimeters be processed and evaluated by a dosimetry processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Bureau of Standards (NBS). On March 22, 1988, NBS suspended Mallinckrodt's NVLAP certification. Mallinckrodt applied for retesting on April 1, 1988 to qualify for renewal and recertification. This process takes several months. In order to provide NVLAP certified personnel dosimetry services on a temporary basis, Mallinckrodt contracted with the Radiation Detection Corp. (RDC). On April 18, 1988, RDC began supplying Mallinckrodt with appropriate personnel dosimetry services. For a period of about four weeks, between March 22 and April 18, 1988, Mallinckrodt continued to process their own badges while working out the logistics (taking bids, setup procedures, etc.) of obtaining the services of an outside vendor. Normally, the failure to have personnel dosimeters processed by a NVLAP certified processor would result in a violation of 10 CFR 20.202(c). However, because the licensee identified the violation, corrected it, and has taken steps to prevent its recurrence, no violation will be issued.

No violations were identified.

h. Exposure Controls - Internal

Bioassays consisting of urinalysis and thyroid counting are performed to determine compliance with license conditions and 10 CFR 20.

Urinalysis is performed at least monthly on all individuals who routinely work in areas where significant quantities of radionuclides are processed, handled, or stored. Urinalysis is also conducted when circumstances indicate an internal body burden is possible, (i.e., a spill, contamination incident, etc.). The licensee's internal action level is 1,000 net counts per minute (cpm). Since the previous inspection in May 1986, this action level has only been exceeded on a few occasions by individuals involved in iodine-131 spills or incidents. No uptakes in excess of license condition or regulatory limits have been observed.

Individuals working with radioiodines perform thyroid assays on themselves at intervals prescribed in their operating procedures and license conditions. Frequency of assay can vary from several times per day to weekly or "as needed." The licensee restricts personnel when assays meet or exceed their internal action levels of 40% of MPC-hours equivalent (MPC) for iodine-131 or 35% of MPC for iodine-125. There are two thyroid assay stations, each consisting of two single channel analyzers, preset for I-131 and I-125; a shielded sodium iodide crystal detector with a three inch probe-to-neck spacer bar; and a calibration phantom. Standards of I-125 and I-131 are used by H.P. staff to calibrate each stations' equipment daily. The licensee's counting systems and calculations are set up so that an individual's counting result of 100 net cpm translates into 40 MPC-hours for either iodine/single channel analyzer. One of these stations is located in the Health Physics offices in Building 100 and the other is in a hallway in Building 600, with convenient access for iodine production workers.

About 100 individuals are involved in the thyroid assay program. No uptakes in excess of 520 MPC have been observed since the previous inspection in May 1986. Several persons received uptakes less than 40 MPC and one person received 104.12 MPC-hours equivalent. Incident reports of these uptakes are maintained for RSC and NRC review. Response of health physics staff to these uptakes appeared to have been swift and in consonance with good radiation safety practice. The Mallinckrodt corporate physician, David Preletsky, M.D. has established policy and guidelines to be followed during response to a radioiodine uptake, including the appropriate administration of a saturated solution of potassium iodide (SSKI) or potassium perchlorate. Individuals with an uptake receive both thyroid and urine assays every workday until their body burden decreases to normal levels.

No violations were identified.

i. Instrumentation

As stated in Section 8 of letter dated December 12, 1986, which is referenced in License Condition No. 20, the licensee appears to maintain sufficient quantities of survey and analytical instruments

to conduct its radiation safety program in accordance with standard operating procedures. Of the facilities inspected, which included Buildings 100, 200, 300, 500 and 600, numerous survey instruments were observed. Continuously used survey instruments such as those used in the shipping department are calibrated inhouse at a four month frequency. Other survey instruments are calibrated at least semiannually. Two thyroid counting units have been strategically located to accommodate those employees whose job requires them to receive weekly bioassays. These units are calibrated daily by the Health Physics staff members. Counting equipment and dose calibrators are checked for constancy and accuracy on a daily and/or weekly basis.

j. Sealed Source Inventories and Leak Tests

The licensee currently possesses approximately 44 sealed sources ranging in activity from less than one microcurie to a nominal 5 curie source. Nine of these sources require testing for leakage and/or contamination in accordance with Condition No. 12 of the license.

All sealed sources are inventoried at the time of leak testing. Condition No. 12B of the license requires, in part, that sealed sources be tested for leakage and/or contamination at intervals not to exceed six months. Since the previous inspection in May 1986, inventory/leak test checks were performed on December 10, 1986; June 25, 1987; and March 3-5, 1988. The interval between June 25, 1987 and March 3-5, 1988 exceeds the six month limit specified in Condition No. 12B of the license.

This constitutes a violation of license condition 12 which requires, in part, that sealed sources be tested for leakage and/or contamination at intervals not to exceed six months.

Nine sealed sources were tested for leakage later than the required six month interval, as follows:

Radionuclide	Activity	Model No.
Cs-137	5 Ci	28-8A
Cs-137	1 Ci	28-6A-D798GN
Cs-137	770.8mCi	Q.C.-5
Cs-137	713.7mCi	Pd-8
Cs-137	1.0mCi	1978
Cs-137	1.45mCi	QC-2-QC-600
Cs-137	700.3mCi	I9(C#1)
Cs-137	1.209mCi	Pd-3
Cs-137	1.024mCi	Pd-2

During the inspection, the Manager of Regulatory Compliance implemented corrective actions to prevent recurrence of this violation. These actions included the development of a formal written procedure on leak testing of sealed sources. This procedure describes which sources are to be leak tested, what frequency the test is to be performed, and describes the methodology

used for performing the test. In addition, the Manager of Regulatory Compliance will be reviewing the results of leak tests during his routine program audits to assure that the tests are being conducted in accordance with the newly established procedure and license conditions. Since corrective action had been taken to prevent recurrence of the violation, no response to the Notice of Violation will be required.

The licensee stated that no leaking sources nor lost sources had been observed since the previous inspection in May 1986.

One violation was identified.

k. Instrument Calibrations

The licensee possesses 137 survey instruments, 116 of which are possessed on site throughout the production facilities and other buildings. About 15 ion chamber type instruments are available, mostly Victoreen models, and the remaining instruments are Geiger-Muller type portable meters and area monitors, mostly Ludlum and Eberline models. The majority of the G-M survey meters employ Eberline HP-270 energy compensated detector probes; other instruments have thin end window detectors.

The Facility Conformance staff is responsible for calibrating G.M. survey meters and the Health Physics staff is responsible for calibrating the ion chamber instruments. These departments use cesium-137 calibration sources of 1.0 curie and 5.0 curies, respectively. Area monitors having "cpm" readout are calibrated only with an electronic pulser, Eberline MP-1, at 25% and 75% of each scale. A comparison measurement is made in an actual radiation field to verify the instrument's ability to respond but this measurement is not recorded. All other instruments are calibrated in a radiation field and are checked at 25% and 75% of each scale. Accuracy within ±10% is required or the instrument is serviced by the manufacturer. Calibrations are performed every four months for onsite instruments and every six months for off-site instruments. Staff who perform instrument calibrations and minor instrument repairs receive primarily on-the-job training in these duties.

No violations were identified.

l. Environmental Monitoring Program

The licensee's counting room was inspected, including the physical facilities, quality control, records and procedures. Housekeeping was good and all instruments were found to be in good working order.

The counting room houses three counting systems, and a fourth detector used for "real time" stack monitoring is housed in the penthouse. All the detectors are scheduled for full calibration

three times per year. The systems currently calibrated used air particulate filters, high volume charcoal cartridges, small (1/2 x 2 inch) charcoal cartridges, and one liter Marinelli beakers. Daily performance checks are done on the three counting room detectors using a europium source.

Four counting room technicians perform radiological effluent analyses for compliance with 10 CFR 20. The technicians are supervised by a Health Physics Supervisor.

Although no violations of NRC requirements were found, several weaknesses were identified during the inspection of the counting room. A review of calibration records indicated that the three counting room detectors had not been calibrated since November 1987. The inspector also found that daily performance checks on the detectors are done using the same standard used for calibration. Since it is important for good quality assurance that performance check sources be independent of calibration sources, the licensee has agreed to change the source used for daily performance checks. Another weakness identified by the inspector was the absence of written procedures for sample collection, preparation, analysis, and quality control.

The inspector identified a discrepancy due to failure to correct for sample decay during collection of iodine-131 activity in radiological effluent samples. Since the licensee has not had a major iodine-131 release and normally releases less than 0.1% of the regulatory limit, it appears that the licensee did not exceed 10 CFR 20 limits. The licensee has agreed to add a correction factory (about 1.5) to future calculations to account for sample lost to decay during collection.

The licensee has air sample stations installed at nine locations around the restricted area perimeter fence and one sampler at a fire station about 1/4 mile northeast of the site. Air samples taken from these stations are used to determine compliance with 10 CFR 20 Appendix B Table II gaseous effluent releases. The licensee has verified that the restricted area perimeter fence is the release point for stack effluents released to unrestricted areas for the purpose of determining compliance with 10 CFR 20. A review of air filter data for the second half of 1987 showed that I-131 was the primary nuclide released during this period with I-131 activity ranging from LLD to 1.33 E-11 µCi/cc for weekly measurements, with an average concentration of 1.6 E-12 µCi/cc. Air sampling Stations 6 and 7 consistently showed the highest I-131 activity throughout the period reviewed, but were well below the 10 CFR 20 yearly average limit of 1.0E-10 µCi/cc.

Airport meteorological data used by the licensee suggest that the highest airborne radioactivity levels should occur northeast of the site; however, air sampling Stations 6 and 7 where activity was highest are both southeast of the site. The licensee will review meteorological data taken by ORAU during this inspection and evaluate the appropriateness of using airport data at the Mallinckrodt facility

The licensee's environmental monitoring program was found to be in compliance with NRC requirements; however, the inspectors suggested to the licensee ways to improve their environmental monitoring program. The inspectors suggested installing a TLD station and an air sampling station 1-1 1/2 miles from the site to better determine environmental radiation levels and to be able to better distinguish between licensee and non-licensee radioactive releases.

In order to demonstrate compliance with 10 CFR 20.105, the licensee places TLD badges at 23 fixed stations on the fence surrounding the perimeter of the site. These badges were exchanged and evaluated weekly until January 20, 1988, when a monthly exchange frequency was instituted. Inspectors reviewed records of this monitoring between May 1986 and April 1988. The highest weekly reading recorded during this time was 48.72 millirem at Sampling Station No. 6, which occurred in the second calendar quarter of 1986. (This value was determined by the licensee to be an erroneous value since a duplicate TLD on the same station read only 5 millirem.) Generally, Station No. 9 (see Attachment 1 for station locations) records the highest readings. Since the previous inspection in May 1986, Station No. 9 and most other stations, have shown a steady decrease in exposure levels. For example, in the second quarter of 1986, Station No. 9 averaged approximately 8 millirem per week. By the first quarter of 1988, Station No. 9 averaged approximately 4.5 millirem per week.

No violations were identified.

m. Waste Disposal

Methods of handling and disposing of radioactive waste are as described in Mallinckrodt's referenced application dated November 26, 1985. Basically, radioactive waste is divided into categories which are described below:

High Level Waste (Overpack Waste) - This waste is generated in the hot cells during production and is greater than 50 mr/hr. It is collected in 2 gallon pails. Filled pails are placed in lead lined overpacks located in the production laboratories. The overpacks are regularly emptied by waste management department personnel and taken directly to the primary storage section of Building 250 where it decays for as long as one year.

The primary storage area of Building 250 is divided into two halves so that a FIFO (First In, First Out) system can be utilized. Only half of the primary storage area is filled at one time. When one side if filled, waste management personnel begin filling the second side and removing pails from the first side. Pails are removed from the end that was filled first enabling a FIFO system. Each side contains space to hold approximately 12 months worth of overpack waste. This gives approximately twelve months for the initial decay period.

After the initial storage and decay the pails are transferred from the initial storage area to the rad waste processing area in Building 500. As these pails are removed from initial storage, they are surveyed to assure they have decayed to safe working levels. In Building 500, the material inside the pails is fed into a shredder where it is ground into gravel size particles. This effectively reduces the volume of this waste by a factor of four. The shredded material is dropped into a polyethylene lined 55-gallon drum. These 55-gallon drums are then transported by the waste management vehicle to the secondary storage area of Building 250. At this point in the cycle, the low level radioactive waste joins the already decayed overpack waste.

Low Level Waste - "Lab trash" is composed of contaminated laboratory trash that reads less than 50 mR/hr on contact. This trash is placed in a normal trash container that is appropriately labeled as "radioactive". The trash containers are lined with polyethylene garbage bags that are collected on a routine basis.

Low level waste is collected from the laboratory by waste management personnel and transferred to Building 500 using the waste truck. In Building 500, this waste is run through a shredder. The shredders have concrete shielding walls to reduce exposure to waste management personnel and they are exhausted to eliminate airborne contamination levels in the vicinity. Like the decayed overpack waste, the shredded low level waste is placed in 55-gallon drums and transported to the secondary storage area of Building 250 for decay to background level.

Liquid Waste - Liquid radioactive waste which is disposed of by means of labeled radioactive sinks or drains, flows through underground pipes into one of eight storage compartments in tanks located in Building 500. Four additional compartments are used for storage in tanks in Building 500A. [illegible] activity in each of these compartments is monitored by Health Physics staff members on a daily basis. Tank usage is managed so as to maximize radioactive decay time and compartments are not discharged until radioactivity levels are acceptable as defined in 10 CFR 20.303.

A portion of a tank is dumped into the sewer once every two weeks. In 1987, approximately 30 millicuries of radioactive liquid was released into the sewer.

Customer Waste - This waste consists of needles, syringes, vials and spent generators. The generators are dismantled and reclaimed by waste management department personnel in Building 500. The needles, syringes, etc., are surveyed. Waste measuring above background is shredded and placed in barrels for storage until decay to background levels have been achieved.

Long Level Waste - Waste such as cyclotron targets, longer lived isotopes and sealed sources are maintained in Building 500 in a special storage bunker for ultimate shipment for burial through ADCO Company. The licensees' last shipment took place on December 17, 1986. The manifest contained the information required by 10 CFR 61.

The Waste Management Department contracts personnel from Continental Management Company (CMC). It was learned that most of the CMC employees have worked at Mallinckrodt for a number of years. Each workers exposure is monitored weekly by whole body badges, ring badges and bioassay.

n. Independent Measurements

During the course of this inspection, radiation surveys were made in various plant locations using either a Xetex 305B survey instrument or a Ludlum μR meter. Results of surveys taken during tours of the buildings in restricted areas are as follows:

Location	Maximum Reading
Building 100-HP Lab-surface of J. L. Shepherd cesium-137 calibrator (5 curies as of 9/15/82)	2.3 mr/hr
Building 250 - inside vestibule of primary storage	4.5 mr/hr
exterior door - primary storage	4.0 mr/hr
exterior door - secondary storage	0.1 mr/hr
Building 300 - dispensing area	1.0 mr/hr
iodine product holding room	40.0 mr/hr
door surface outside holding room	4.0 mr/hr
shipping department	1.3 mr/hr
Building 400 - shipping dock area	2.0 mr/hr
Building 500 - waste processing area	0.5 mr/hr
molybdenum and iodine receiving dock	1.5 mr/hr
short term waste storage area (south end bowling alley)	5.0 mr/hr
Building 600 - iodine production lab facility conformance calibration lab J. L. Shepherd cs-137 calibrator (1 curie as of 7/22/83) - surface	0.5 mr/hr 45.0 mr/hr

Direct radiation readings were also taken at the nine air sampling stations and at selected TLD stations. The results are shown in Attachment 2. Readings of 60 μR/hr recorded near Building 500 were attributed to a shipment of materials received just prior to the survey.

ORAU also performed confirmatory measurements with the licensee on stack, air, waste, and sewer samples. The results of those surveys are pending and will be forwarded to the licensee upon completion of analysis.

o. Emergency Preparedness

Since in-depth assessment of the licensee's emergency preparedness program was conducted by Oak Ridge Associated Universities in 1986, the effort during this inspection was limited to a review of emergency training and drills, equipment and facilities, organization, and emergency plan and procedures. The results are as follows:

1. Emergency Training and Drills

Training for onsite operating personnel consists of initial emergency training when first hired and any participation in an annual emergency exercise or drill. Four to five management level personnel, who have key emergency response functions, receive annual training in addition to annual exercise participation. The inspector interviewed four of these personnel with key emergency responsibilities. All were knowledgeable of their emergency response functions as described in the contingency plan. Any training or retraining is under the direction of the Manager of Regulatory Compliance.

The inspector confirmed, through review of documentation, that an annual emergency exercise has been held since 1986, the year of the last inspection. The 1987 exercise was an off-hours, unannounced drill which met the exercise criteria. This event successfully demonstrated augmentation capability for emergency responses. In addition, communication drills are now conducted quarterly, rather than semiannually as prior to 1987.

Training has also been provided for offsite fire protection agencies and ambulance services. These offsite responders as well as the local police department have also participated in the annual exercises.

2. Equipment and Facilities

The Emergency Control Center (ECC) is the central emergency response location where management level personnel meet to assess and plan steps to curtail the emergency. The ECC is located in the Health Physics offices in Building 100. One large room contains a Site Emission Monitor Board which serves as a remote alarm activation point for all the stack exhaust monitors. Also, a light for an evacuation alarm and one for an Alert declaration is mounted on this board. The central alarm panel also contains a schematic drawing of the plant

buildings and identifies air and sewer sampling points. With this information, the ECC staff can better determine steps to mitigate the radiological emergency.

Another small room in the ECC contains communications equipment and a radio console to contact emergency response teams within and outside the plant building. Spare two way radios and phone communications are also available. Accident assessment teams are also dispatched from the ECC. The Security Guard House has a similar alarm panel with audible capability for all the key emergency related monitors. All stack monitoring equipment is on an uninterrupted power supply from the Union Electric Company, thus assuring a constant source of electricity. Although some meteorological data is measured onsite, all official meteorological data is obtained from Lambert Field, St. Louis, Missouri which is approximately ten miles from the site.

The inspector reviewed the contents of three emergency lockers and found all necessary emergency type equipment including two ranges of dosimeters and radiation monitoring equipment. These lockers were located in Buildings 100, 300, and 600. An inventory list of items in the emergency lockers should be posted to the inside of each locker door. This was also a suggestion as a result of the 1986 inspection.

3. Organization, Emergency Plan and Procedures

The Manager of Regulatory Compliance (MRC) serves as the Emergency Manager (EM) as part of the emergency response organization. He is the first line of communication with the operating staff and with the emergency response staff. As EM, he is the only one who can authorize radiation doses up to 75 rem for emergency workers involved in life saving activities. His alternate as EM is the Health Physics (HP) Supervisor, a position which was vacant between September 1987 and May of 1988. Other key emergency response positions include the Health and Safety Supervisor, the Maintenance Supervisor, Area Safety Directors and the Security Staff. These individuals may be contacted by personal beepers at all times. An organizational chart of the entire emergency response organization should be included in Section 4 of the Radiological Contingency Plan (RCP) to supplement the written description. Presently only a plant organization chart is included in Section 4.

The MRC has administrative responsibility for an an annual review of the RCP. The actual review of the RCP is implemented by the HP Supervisor. The MRC is performing this function directly, in lieu of the temporary absence of an HP Supervisor. Any changes made are documented; and major changes are submitted to the NRC for approval. Procedures are also reviewed annually.

The inspector reviewed the evacuation/accountability procedures and toured some of the main evacuation routes for persons leaving Building 600. The area Safety Directors are responsible for evacuation of certain segments of the building's personnel. Each group congregates at a designated numbered location identified by a sign on the perimeter fence adjacent to the building. A metal box mounted on the fence contains a list of the names of those who should evacuate to that fence location. The area Safety Director checks those present with this list to account for everyone. Evacuation routes are posted in hallways or other conspicuous locations in each building, as well as in Procedure EP6, Evacuation During a Radiological Emergency. This aspect of emergency preparedness was considered satisfactory and is also demonstrated in each annual exercise.

Letters of Agreement with offsite support agencies, are listed in Appendix B to the RCP, have not been updated since 1981. These should be reviewed annually after being updated. If there are no changes in the conditions of services, equipment, and individual emergency responders, this should also be documented. The inspector contacted the Northwest Ambulance, Inc., using the telephone number in the Letter of Agreement. This number was incorrect. From communication telephone drill records, the correct agency was contacted, Abbott Ambulance Service. The Letter of Agreement in Appendix B of the RCP for ambulance service is obsolete and should be discarded. All seven Letters of Agreement listed in Appendix B should be thoroughly reviewed, updated and replace where necessary. The outdated Letters of Agreement were also identified in 1986 inspection report.

5. Environmental Survey By ORAU

The NRC RIII contracted with the ORAU, Manpower Education, Research and Training Division to perform an environmental survey of the Mallinckrodt Nuclear Facility in Maryland Heights, Missouri. The work was performed from May 16-27, 1988 by three ORAU staff under the supervision of Mr. G. L. Murphy, Assistant Program Manager. Their findings are to be provided to the NRC in a draft report at a later date and will be provided to the licensee as a supplemental report. The survey plan called for (1) direct gamma measurement of the entire site with scintillation detectors and ratemeter with audible indicators; (2) stack sampling of Buildings 500 and 600; (3) air sampling at the facility boundary and (4) miscellaneous water and sediment samples from the holdup tanks, main sanitary drain, storm drains, drainage ditches and standing water and soil sample at the direct measurement and air sample sites.

The finding from the survey plan will appear as an addendum to this report after it is received from ORAU in August 1988.

6. Fire Protection Summary Maryland Heights Facility

The review of the Mallinckrodt Diagnostic fire protection program was conducted by Harvey Goranson, P.E., Senior Fire Protection Engineer, with Professional Loss Control, Inc., Oak Ridge, Tennessee. The full evaluation is presented in Attachment 3. This evaluation was a followup of a fire protection audit conducted in 1986 by Mr. Goranson and included an assessment of Mallinckrodt Research and Development fire protection program at the licensee's corporate center. His conclusion was that overall this facility has a high degree of protection against fire hazards and would be considered a "Highly Protected Risk."

7. OSHA Effort

The review of the licensee's industrial safety program was conducted by Emil Golias, Industrial Hygienist from the OSHA Health Response Team located in Salt Lake City, Utah. The areas reviewed primarily consisted of Buildings 500 and 600 with specific emphasis on programs relating to employees safety and health in those locations. The results of this inspections along with recommendations is presented in Attachment 4.

8. EPA Effort

The effort to review EPA issues at Mallinckrodt Inc. was conducted on June 1-2, 1988, by Bill Brinck and John Bosky of the EPA Region 7 office located in Kansas City, Missouri.

Mr. Brinck's efforts concentrated on reviewing radiation in airborne and liquid effluents and reviewing airborne dose modeling. The results of the reviews are described below.

a. Radioactivity in Airborne Effluents

Licensee representatives stated that all airborne radioactivity leaves the plant through 13 monitored stacks. The main source is the stack for the 600 building. The "penthouse" area of 600 was visited to review the filtration, control, and monitoring provided for this stack. Air from the hot cells is passed through particulate and HEPA filters before release. The 600, 700, and 700A building stacks have real time radionuclide monitors. The ten stacks on other buildings are monitored via weekly analyses of composite samples.

A review of environmental monitoring data, as summarized by the NRC during a record review two weeks previously, was also conducted. The program consists of nine air samplers on the site boundary and one at a nearby (1/4 mile) fire station with weekly analyses of particulate and activated carbon filters; 23 TLD stations on the site boundary and the performance of weekly "walk around" surveys of the site perimeter. The NRC review of air sampler data from June 4, 1987 to December 17, 1987 showed that I-131 was frequently detected as well as In-111 (three weeks) and Xe-133

(one week). The highest frequency of detectable measurements was in the direction of sampler Nos. 5-7 (the highest frequency was No. 6 southeast of the stack, with detectable concentrations measured in 16 of the 27 weeks). The highest measured concentration was at 0.1 times the MPC value. TLD data was obtained from a review of the facility's tabulation of weekly data. Weekly data varied from 0 to 9 mR/week. The highest exposure was at TLD Site 9 (south to east of the stacks) which according to the NRC data review, averaged 4.5 mR/week during the first quarter of 1988. No background locations are monitored.

b. Airborne Dose Modeling

A computer based model for the estimation of dose to nearby residents has been recently installed to demonstrate compliance with 40 CFR 61. It uses real time effluent data combined with annual average meteorological data, to model the dose from all release points, and all radionuclides to 63 locations. Forty locations are on the site perimeter and 23 are at the nearest houses. Calculations for the month of May 1988 indicate a maximum thyroid dose of 0.01 mR to the highest offsite resident. The model has not yet been checked against the standard model, AIRDOSE-EPA. The licensee indicated that the model, while it is conservative in some respects, underestimates the actual dose. Previous estimates based on 1985 releases (somewhat higher than currently experienced) and including all exposure pathways were in the range of 30-40 mR/yr to the thyroid. After the model is completed, it will be submitted to EPA for approval for use in assuring compliance with 40 CFR 61.

The annual average meteorological data, used for the model, indicates that the major downwind concerns are toward the northeast. It was noted, however, that the facility's monitoring indicates that the predominate exposures are toward the southeast. The licensee will be reviewing this discrepancy in the near future as requested of the NRC.

c. Radioactivity in Liquid Effluents

Plant liquid waste streams are segregated into radioactive and non-radioactive portions. The radioactive liquids are analyzed and placed in storage tanks for decay before release to the sanitary sewer. According to the NRC review of the records, approximately 30 mCi of radioactivity was released to the sewer in 1987. Non-radioactive liquid wastes go directly to the sewer. Proportion sampling is conducted to assure that no radioactive liquid wastes are released in that stream. No significant radioactivity was detected during 1987, according to an NRC review of facility records.

The efforts expended by Mr. Bosky primarily was a preliminary assessment of the programs developed by Mallinckrodt to maintain compliance with environmental regulations developed pursuant to the Resource Conservation and Recovery Act, the Clean Water Act and the

Clean Air Act. This assessment consisted of a discussion regarding process operations and facility waste streams, a review of pollution control equipment/practices and an evaluation of pertinent documents. No significant observations were made during the assessment of Mallinckrodt's compliance status regarding the applicable regulations developed under the Clean Air Act and the Clean Water Act. However, insufficient information was available at the time of this inspection to determine if Mallinckrodt has properly classified themselves a small quantity generator pursuant to the hazardous water management regulations developed under the Resources Conservation and Recovery Act. Specific information regarding this issue will be provided by the EPA Investigator directly to the U.S. EPA Region 7 Waste Management Division.

No violations were identified.

9. FDA Effort/Product Evaluation

The NRC and the FDA evaluated several of Mallinckrodt's byproduct material radiopharmaceuticals. The NRC evaluation included the following: Selecting three products (i.e., TechneScan® PYP, Sodium Iodine I-131 Capsules [therapeutic], and the Ultra-TechneKow® FM generators) for evaluation; examining customer complaint files for incidents of misadministrations, radioactive surface contamination, high transportation indexes, and trends; observing the Ultra-TechneKow® FM generator production from receipt of the molybdenum-99 to final packaging; and visiting two customers to discuss their transportation, product performance or misadministration experience with Mallinckrodt radiopharmaceuticals.

FDA performed a routine inspection of Mallinckrodt's production facilities and good manufacturing procedures (GMP). The FDA inspection began on June 1 as part of the team inspection and concluded after the completion of the team assessment. This inspection included obtaining a history of business from Mallinckrodt, followup on past inspection concerns, GMP inspections for all I-131 products, TechneKow® FM generators, and a small volume parenteral product, and a "New Drug Approval" (NDA) inspection for the TechneKow® FM generators. The GMP inspection includes reviewing documentation on production records, critical components, annual product review, and customer complaint files.

The FDA inspection report will not be included in this report, but can be requested from the FDA under the Freedom of Information Act.

The customer complaint incident for each product was only a fraction of a percent. Only one customer complaint for the three products evaluated resulted in a misadministration. In this case, a defective I-131 capsule broke and the patient did not receive the full therapy dose. Almost all the I-131 capsule complaints were for radioactive contamination. Although the total number was low, it points out the need for users to follow good health physics and quality assurance practice when receiving packages, checking the integrity of the capsules and verifying radioactive dose.

The majority of the customer complaints and the production quality control failures for the Ultra-TechneKow® FM generators were low assay, failure to elute, and mechanical failure. The first two problems were discussed with a Mallinckrodt® chemist during an in-depth discussion of the Ultra-TechneKow® FM generators. The low assay was thought to be caused by channeling or incomplete formation of TcO_4 from TcO_3. The failure to elute problem is due to loss of vacuum in the generator system. Some of the mechanical failure complaints were caused by stiff elution vial springs. The elution valve spring was changed in 1987 to correct earlier self elution problems. The FDA inspection will determine if these changes were made in accordance with FDA regulations. The customer complaints are not traced back to the production history to determine whether the generators that fail in the production line also fail in the field. Followups were only done for generators the customer returned to the manufacturer.

Followup was not done to document the cause of failure for many of the capsules, kits, or generators not returned to the manufacturer. Standardization of information collection (e.g., recording radiation detection model number, scale, reading calibration, specific location of high or abnormal readings on the overpacking of the generator, and production experience) may lead to earlier trend determination.

The production process for the TechneKow® generators was observed from the receipt of the molybdenum at the receiving dock to the packaging of the completed generators in their shipping boxes.

Following the receipt of materials, the casks were opened in the hot cell; the contents were checked against the shipping papers; and the preliminary chemical preparation and quality control tests were performed. After certifying the material received was molybdenum-99 and determining its final activity, quality control released the material for column loading, processing, and sterilizing. After the assembled columns are loaded into their individual shields, they were removed from the hot cell and placed on the assembly line.

On the assembly line, the column was connected to the saline reservoir, the generator case assembled, and additional quality control tests were performed on the first sterile elution. Each generator was tested for molybdenum-99 break through (gross high energy gamma), initial activity, elution volume, and final labeling. If the generator fails any of these tests, it is removed from the assembly line and reeluted. If it fails the reelution quality control test, the generator assembly is rechecked and eluted again.

Generators passing the quality control test proceed down the line for insertion into their shipping box and measurement of the transportation index. Although each column is tested on the assembly line, the test results are only recorded if the unit fails. The activity data was recorded for each tenth generator and quality control performed more detailed tests on a smaller subject of the first elution vials.

The NRC also visited two customer sites to determine if the customers had any transportation, produce performance, or misadministration problems related to Mallinckrodt products. Diagnostic Imaging Services (DIS) and Barnes Hospital were selected as representatives of a Mallinckrodt nuclear pharmacy and a hospital with a large radiation program. Neither the pharmacy nor the hospital noted any misadministration problems associated with Mallinckrodt's products or discrepancies in transportation indexes and radiation surveys during package receipt. The oncology section in the hospital also indicated they did not have any problems with the volatility of the sodium iodine I-131 therapy solutions. The nuclear pharmacist at the hospital did receive one generator with a low initial activity problem and also is occasionally finding a coring problem with evacuated vials. Both concerns were brought to attention of Mallinckrodt by the pharmacist and it appears that Mallinckrodt is evaluating the problems adequately.

No violations were identified.

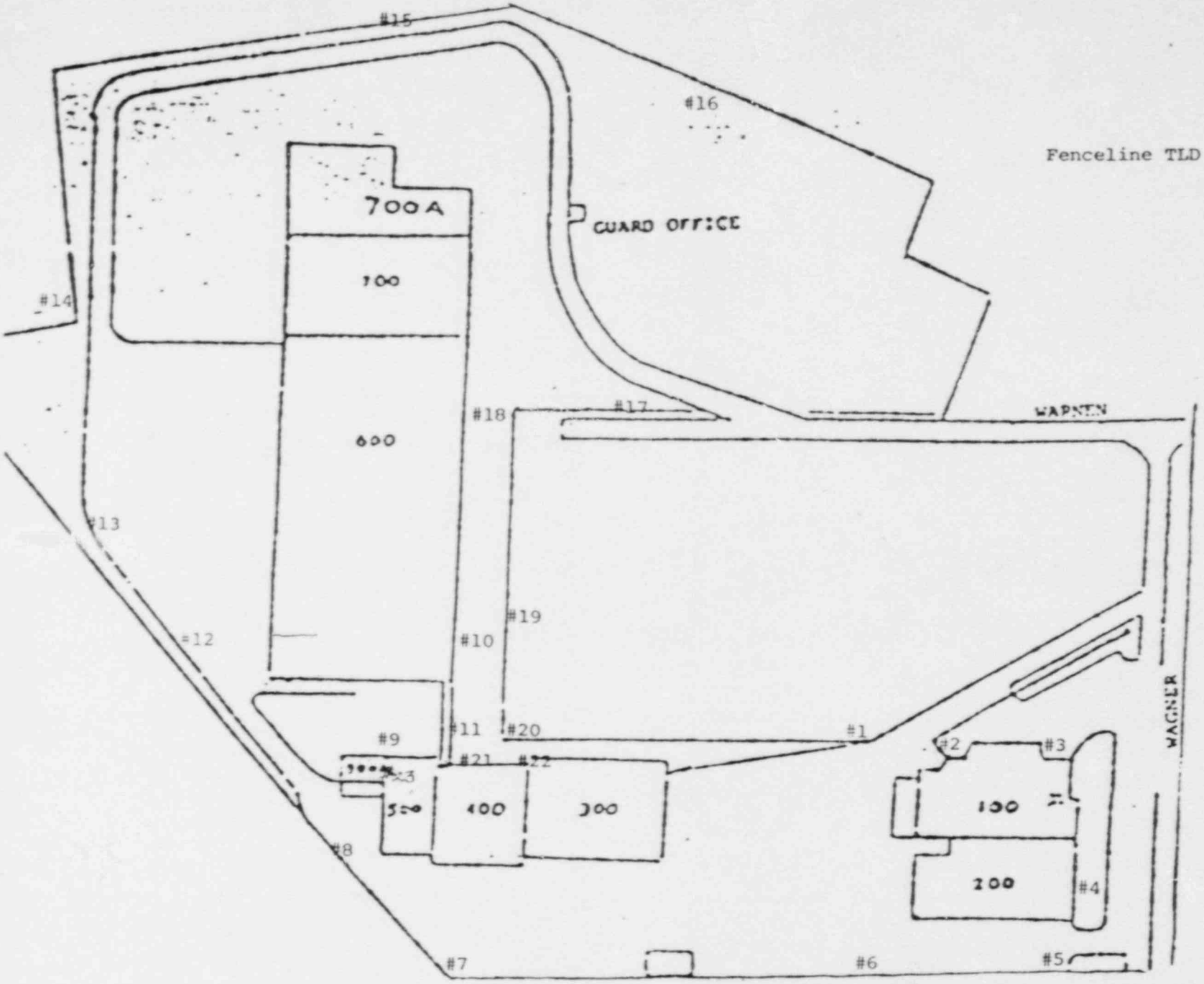
10. Exit Interview

Two separate exit interviews were conducted at the licensee's facility at the completion of this inspection effort. The first meeting was conducted on May 20, 1988, upon completion of the NRC, OSHA, and Fire Protection assessments. The second meeting was conducted on June 3, 1988, upon completion of the EPA and Product Evaluation assessments. The apparent violation and areas of concern were addressed and discussed at the meetings. There was no discussion of FDA and Oak Ridge Associated Universities findings since their efforts were not completed at the time of the meetings.

Licensee attendance at the meetings is indicated in Section 1 of this report.

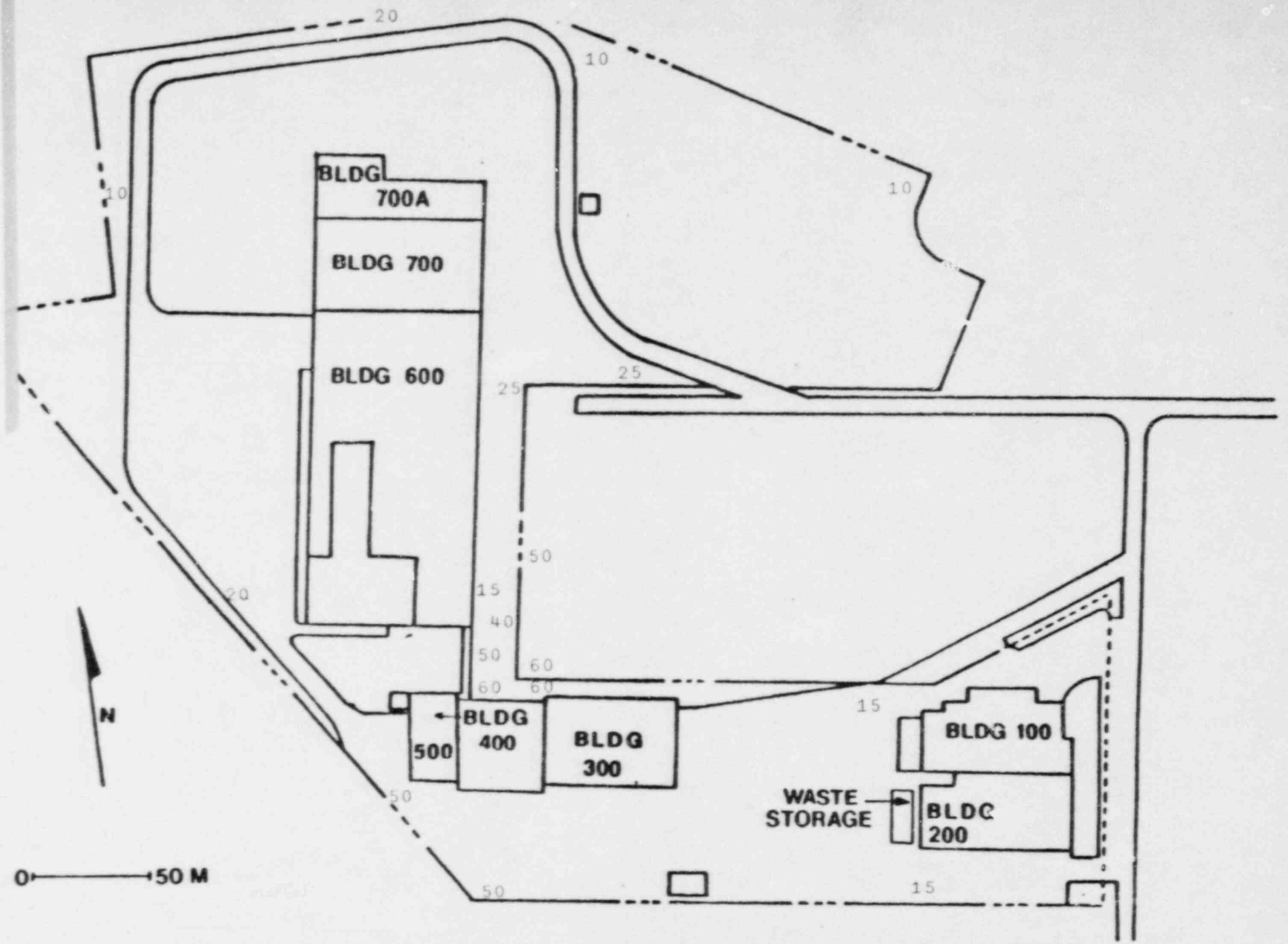
Attachments:
1. Fenceline TLD Locations Map
2. Results of Radiation Surveys
3 Reevaluation of Fire Protection at Mallinckrodt, Inc.
4. OSHA Ltr dtd 05/26/88

Fenceline TLD Locations Map



ATTACHMENT 1

ATTACHMENT 2



Layout of Mallinckrodt Diagnostics Facility showing results of a direct radiation survey in μR/hr.