July 14, 2000

EA 00-143

Richard G. Johnson
Vice President
Imaging Operations
Mallinckrodt, Inc.
675 McDonnell Boulevard
P. O. Box 5840
St. Louis, MO 63134

SUBJECT: NRC REGION III AUGMENTED INSPECTION TEAM REVIEW OF MULTIPLE EXTREMITY EXPOSURES IN EXCESS OF 0.5 SIEVERT (50 REM) AT THE MALLINCKRODT, INC., MARYLAND HEIGHTS, MISSOURI FACILITY (INSPECTION REPORT 030-00001/2000-002(DNMS))

Dear Mr. Johnson:

The enclosed report refers to a special review by an NRC Augmented Inspection Team (AIT) from May 4 through 26, 2000, relative to Mallinckrodt's identification of multiple occupational extremity exposures in excess of the NRC limit. NRC's initial response to these issues began as a Special Team Inspection on April 14, 2000, following Mallinckrodt's April 13, 2000, notification of an occupational extremity exposure that was likely in excess of 2.5 sievert (250 rem) shallow dose equivalent. The special team inspection was composed of Messrs. Jamnes L. Cameron (Team Leader) and Michael M. LaFranzo of this office, and Ms. Elizabeth Ullrich of NRC's Region I office. Following Mallinckrodt's April 28 and May 2, 2000, reports to the NRC of several other extremity exposures in excess of the NRC limit, the NRC upgraded its response to an AIT. The AIT was composed of Messrs. Roy J. Caniano (Team Manager), Jamnes L. Cameron (Team Leader), John D. Jones, and Kevin G. Null of this office, Mr. Joseph DeCicco, Office of Nuclear Material Safety and Safeguards, and Mr. Charles Hooper, State of Missouri, Department of Health. The report also refers to the follow-up activities of your staff and to a discussion of our findings with you and others of your organization at a June 23, 2000 public meeting.

The enclosed copy of our AIT report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews of personnel.

The AIT was formed to assess information regarding the reported March 31, 2000 extremity exposure, and the occupational extremity exposures related to third shift "other *in vivo*" staff who hand-labeled unshielded vials containing radioactive material, and Sterility Laboratory staff who routinely handled unshielded vials and syringes containing radioactive materials. Specifically, the AIT examined the circumstances surrounding each of the exposures, and Mallinckrodt's investigation of the exposures.

The AIT concluded that Mallinckrodt responded appropriately to the initial indication that an employee exceeded your weekly administrative exposure limit and conducted a timely and thorough investigation of the incident involving the exposure to a molybdenum-99 generator column. Your investigation subsequently identified two additional extremity exposure events

involving 13 individuals. The AIT concluded that Mallinckrodt's dose assessments for each of the individuals who received extremity exposures in excess of 50 rem shallow dose equivalent were accurate and we agree with the assumptions and limitations associated with those assessments. However, several problems were identified regarding: (1) Mallinckrodt's radiological evaluations of the indium-111 packaging and molybdenum-99 generator manufacturing lines; (2) actual work practices not agreeing with associated standard operating procedures; (3) Mallinckrodt's Dose Reduction Committee efforts at addressing extremity exposures; (4) training provided to radiation workers; (5) Mallinckrodt's self-assessments of manufacturing activities; and (6) Mallinckrodt's response to precursor events. Based on these findings the NRC issued a Confirmatory Order Modifying License (Order) on June 22, 2000. The Order confirmed Mallinckrodt's commitments to perform assessments of its radiation protection program and manufacturing processes.

It is not the responsibility of an AIT to determine compliance with NRC rules and regulations or to recommend enforcement action. These aspects will be reviewed in a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available **electronically** for public inspection in the NRC Public Document Room **or** from the *Publicly Available Records (PARS) component of NRC's document system (ADAMS)*. *ADAMS is accessible from* the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

Sincerely,

/RA/

J. E. Dyer
Regional Administrator

Docket No. 030-00001
License No. 24-04206-01

Enclosure: Inspection Report 030-00001/2000-002(DNMS)

cc w/encl: Dale Simpson, Interim Plant Manager, Mallinckrodt, Inc.
Jim Schuh, Radiation Safety officer, Mallinckrodt, Inc.
Roy Brown, Director, Regulatory Compliance, Mallinckrodt, Inc.
Gary McNutt, Director, State of Missouri, Department of Health

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REGION III

AUGMENTED INSPECTION TEAM

Docket No:	030-00001
License No:	24-04206-01
Report No:	030-00001/2000-002(DNMS)
Licensee:	Mallinckrodt, Inc.
Location:	2703 Wagner Place Maryland Heights, MO 63043
Dates:	April 14 - May 2, 2000 (Special Team Inspection) May 3 - 26, 2000 (Augmented Inspection Team)
Exit Meeting:	June 23, 2000
AIT Members:	Roy J. Caniano, Team Manager Jamnes L. Cameron, Team Leader Joseph DeCicco, Health Physicist, NMSS John D. Jones, Senior Radiation Specialist, Region III Kevin G. Null, Senior Radiation Specialist, Region III Charles Hooper, Environmental Specialist, State of Missouri, Department of Health
Special Team Inspection Members:	Jamnes L. Cameron, Team Leader Michael M. LaFranzo, Radiation Specialist, Region III Elizabeth Ullrich, Senior Health Physicist, Region I
Prepared By:	Jamnes L. Cameron, Principal Inspector Materials Inspection Branch Division of Nuclear Materials Safety
Reviewed By:	Geoffrey C. Wright, Chief Materials Inspection Branch Division of Nuclear Materials Safety
Approved By:	Cynthia D. Pederson, Director Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

Mallinckrodt, Inc.
Maryland Heights, MO
NRC Inspection Report 030-00001/2000-002(DNMS)

During a Special Team Inspection conducted on April 14 through May 2, 2000, to review a licensee-reported extremity exposure in excess of 2.5 sievert (250 rem) shallow dose equivalent, the NRC formed an Augmented Inspection Team (AIT). The purpose of the AIT was to examine the circumstances surrounding that event and additional multiple occupational extremity exposures in excess of the NRC limit of 0.5 sievert (50 rem) shallow dose equivalent between 1994 and 1999. The NRC limit applies to total dose, including contributions from licensee activities that are not regulated by the NRC, i.e., dose from State-regulated activities. The exposures resulted from licensee personnel directly handling unshielded containers of radioactive material with small contributions from other routine operations. The AIT charter is included as Attachment 1 to this report. The following paragraphs summarize the team's findings in each of the AIT charter areas.

Mallinckrodt's response to the initial indication of an extremity exposure in excess of its administrative limit was thorough, timely, and included adequate depth, based on the information available to its staff at the time. The exposure was the result of a licensee contract employee holding an unshielded 19 curie molybdenum-99 generator column in his hand for up to 50 seconds. The licensee's investigation into that event subsequently identified two other exposure events. One of the additional events included ten employees handling unshielded vials of an indium-111 product. The exposures occurred between 1995 and 1999, inclusive, with several employees receiving extremity exposures in excess of the NRC limit in multiple years. The other event involved plant Sterility Laboratory personnel handling unshielded vials and syringes of radioactive materials during sterility testing. These exposures occurred between 1997 and 1999, inclusive, and involved four employees, one of whom was also involved in the hand labeling of indium product vials. Two of the four employees received extremity exposures in excess of the NRC limit in each of the 3 years identified. The other two employees received extremity exposures in excess of the NRC limit in a single year. (See Section 4 of the report).

Mallinckrodt's dose assessments for each of the exposed individuals were accurate, within the identified limitations of such assessments. The dose assessments were technically sound and reasonable, and to the extent practical, included consideration of individual practices. NRC's independent calculations agreed with the licensee's estimates. The estimates represent the best approximation of shallow dose equivalents received by the workers. The individual who handled the generator column received a calculated extremity dose of up to 25 sievert (2500 rem) shallow dose equivalent. The individuals involved in the hand labeling of indium product vials received extremity exposures between 0.5 and 6.0 sievert (50 and 600 rem) shallow dose equivalent. The personnel who worked in the Sterility Laboratory received exposures between 0.7 and 1.0 sievert (70 and 100 rem) shallow dose equivalent. (See Section 5 of the report).

Mallinckrodt's evaluations of the indium packaging and molybdenum generator manufacturing lines prior to initial production and after making modifications were not effective at identifying

potential radiological hazards associated with those activities. The team determined that Mallinckrodt had not performed any pre-production assessments of the potential radiological hazards associated with either the generator column rework station, where the first identified exposure occurred, or the hand labeling of the indium-111 product. Although supervisors and managers were aware of the hand labeling issue, none recognized the radiological implications of such actions. In addition, since health physics staff were not aware of the rework activities involved, radiological assessments had not been performed on those operations. (See Section 6 of the report).

The team also determined that, at least with regard to the generator rework and indium-111 product labeling, the actual practices were not reflected in the Standard Operating Procedures (SOPs) for those operations. In each case, licensee employees and supervisors developed unapproved work practices when either the manufacturing equipment did not allow strict adherence to the SOP or they self-initiated activities to correct manufacturing deficiencies.

Mallinckrodt's Dose Reduction Committee, established in 1997, was not effective in limiting extremity exposures. The committee placed little emphasis on extremity exposure reduction. None of the committee meeting minutes provided any substantive discussion of extremity doses received during molybdenum-99 generator manufacturing or as a result of indium-111 packaging, including the hand labeling of the product vials. The minutes did address extremity doses received in the Sterility Laboratory, including a discussion of more frequent use of shielding in the laboratory. However, the committee placed heavy reliance on a different process that would eliminate the handling of radioactive materials in the Sterility Laboratory as its ultimate dose reduction effort in this area. The new process had been in the planning stages since at least January 1999, without a definitive implementation date. (See Section 7 of the report).

Mallinckrodt's routine and event response training was not effective at ensuring that staff recognized the potential radiological consequences of handling unshielded radioactive materials or that they were knowledgeable of the SOPs that governed their work practices. However, the training was generally effective in providing its employees with the basic knowledge and skills to maintain doses As-Low-As-Is-Reasonably-Achievable (ALARA). The team identified that plant personnel erroneously believed that extremity monitor results accurately measured radiation exposures when employees handled unshielded radioactive material containers with their fingertips or with their unmonitored hands. This misconception contributed substantially to the identified extremity exposures in excess of regulatory limits.

Mallinckrodt's on-the-job (OJT) training was implemented inconsistently, depending on whether the individual was a Mallinckrodt or a contract employee. Contract employees were not always provided copies of the SOPs for the tasks they were assigned and did not have access to the plant document control system to allow review of procedures on-line. The differences in OJT did not directly contribute to any of the identified extremity exposures in excess of regulatory limits. (See Section 8 of the report).

Mallinckrodt's self-assessments of production line radiation safety were ineffective. This was due, in part, to a failure to recognize the radiological implications of handling unshielded containers of radioactive material. Three audits conducted of Quality Control Department activities, including two that were specific to the Sterility Laboratory, identified the need for the

use of syringe shields and remote handling equipment; however, neither laboratory personnel, nor Health Physics personnel who audited the activities, recognized that the contact dose rates on containers and syringes of radioactive material could be significant. The packaging line, where the indium product vials were hand labeled, had not been audited. While audits of the generator manufacturing process had not identified rework on the inlet needle, this was not unexpected given the infrequent nature of the work and the fact that the activity was not widely known outside the laboratory. (See Section 9 of the report).

Mallinckrodt identified three previous events in which personnel exceeded the weekly ALARA level (20 millisievert (2000 millirem) shallow dose equivalent) due to work involving the generator rework station. None of the root cause analyses of the incidents included a realization that the inlet needle rework was not authorized by the SOP. The Team did not identify any precursor events related to either the hand labeling of vials of indium-111 or Sterility Laboratory activities, except for the acknowledgment that the activities occurred, but without the recognition of the potential radiological consequences of those activities. (See Section 10 of the report).

Report Details

1.0 Purpose of Augmented Inspection Team

The Augmented Inspection Team (AIT) was to examine the circumstances surrounding a licensee-reported extremity exposure in excess of 2.5 sievert (250 rem) shallow dose equivalent and additional licensee-identified routine operations that resulted in multiple occupational extremity exposures in excess of the NRC limit between 1994 and 1999. The exposures resulted from licensee personnel directly handling unshielded containers of radioactive material with small contributions from other routine operations. The AIT charter is included as Attachment 1 to this report.

2.0 Description of Licensee's Program

NRC Byproduct Materials License No. 24-04206-01 authorizes Mallinckrodt, Inc., to manufacture molybdenum-99/technetium-99m generators, and prepare radiopharmaceuticals and radiochemicals, including sodium iodide-131, sodium iodide-125, xenon-133, and phosphorus-32, for medical and research purposes. In addition to NRC-licensed activities, Mallinckrodt manufactured and processed other radioactive materials, including indium-111, using four cyclotrons, for research and medical purposes under the regulatory authority of the State of Missouri, Department of Health. The licensee employs approximately 250 individuals in licensed activities. On a weekly basis, Mallinckrodt processes and distributes kilocurie quantities of molybdenum-99 as technetium-99m generators, and multicurie quantities of all other isotopes, both NRC-and State-regulated.

Mallinckrodt conducts activities at two addresses in Maryland Heights, Missouri. The main facility, located at 2703 Wagner Place, contains the licensee's primary operations, in nine buildings. Buildings 100 and 200 house the administrative operations and laboratory spaces. The licensee stores what it terms "high level waste" in Building 250. By the licensee's definition, "high level waste" includes those waste containers that exhibit surface radiation levels in excess of 0.5 millisievert (50 millirem) per hour. Mallinckrodt uses Building 300 for the storage and packaging of all products other than technetium-99m generators. Building 400 is the distribution warehouse where the licensee packages generators and prepares them for shipment. The licensee uses Building 500 for the storage, processing, and separation of low-level radioactive waste and the handling and processing of all liquid radioactive wastes. Mallinckrodt's main manufacturing facilities are in Building 600. Buildings 700 and 800 house the licensee's cyclotrons and cyclotron chemistry operations, which are regulated by the State of Missouri. The licensee's main warehouse is in Building 150, which is at 2600 Wagner Place. In one corner of the building, the licensee stores generators that have been returned from its nuclear pharmacies and customers and where it dismantles the generators for the recovery and reuse of the shielding material, or safes.

The responsibility for the overall licensed operations rests with the Director of U.S. Nuclear Medicine Operations. The licensee had established a Radiation Safety Committee (RSC) to provide oversight of the radiation safety program. The licensee had appointed a Radiation Safety Officer (RSO) to manage the radiation protection program on a daily basis. The Health Physics (HP) Department employed, in addition to the RSO, three HP and six HP technicians.

3.0 Description of Events (Charter Item No. 1)

a. Inspection Scope

The event descriptions and sequence of events were independently developed and validated by the inspectors based upon:

- A review of manufacturing and process data records, recorded results of personnel monitoring, plant standard operating procedures (SOPs), and other plant documents;
- interviews of manufacturing, quality control (QC), HP, and management personnel; and
- walkdowns of the process areas involved in the three exposure scenarios.

A significant portion of the information relative to the generator column exposure incident was developed during the initial Special Team Inspection and is included in this and other sections of the Inspection Report.

b. Observations and Findings

Exposure to Generator Column

On March 31, 2000, Individual A[1] worked at the rework and packaging stations of the licensee's dry-top-eluting (DTE) molybdenum/technetium generator manufacturing line in the "Kow Laboratory" of the Manufacturing Building (Building 600). The two stations were side-by-side and the laboratory supervisor normally assigned one individual to work both stations. The rework station involved minor repairs to generators that failed to elute during manufacturing. The repairs were typically limited to replacing the hood of the generator, which contained the valving mechanisms that allowed saline to flow through the column during use. This repair or rework was performed by hand inside a glovebox. At the time of the event, more extensive repairs were also performed occasionally, which involved removal of the column from the generator shielding, or "safe," and reinserting the inlet needle in the column. These repairs were normally performed using long-handled forceps.

On March 31, 2000, one particular generator, containing a column with 700 gigabecquerels (19 curies) of molybdenum-99 and 300 gigabecquerels (8 curies) of technetium-99m, required the second, more extensive type of rework. Individual A removed the column from the safe and noticed that the outlet needle, which was normally straight, was bent at approximately 120 degrees and the inlet needle was out of the column and wedged between the outlet needle and the body of the column. The individual, having dropped the forceps, held the column using the thumb and forefinger of the left hand and manipulated the needles into their proper alignment using the thumb and forefinger of the right hand. The individual estimated that the operation took 30 to 50 seconds to complete. During reenactments, the individual's thumb and forefinger of the left hand were located directly over the area of the column where the radioactivity was bound to the substrate. Individual A wore the assigned extremity monitor on the

[1]The identities of individuals for whom radiation exposure information has been discussed have not been included in this report in order to protect their personal privacy.

index finger of the right hand; a location where it would not be in position to monitor the highest extremity exposure.

Exposure to Indium-111 Product Vials

Mallinckrodt processed an indium-111 product on a weekly basis. The particular product was introduced in 1994 and was dispensed in 3 milliliter vials. Each vial contained approximately 740 megabecquerels (20 millicuries) in a volume of 0.5 milliliter. Due to the size of the vials, the automatic labeling machine normally employed in the packaging line could not be used. Because the labeler would not accept vials smaller than 10 milliliters in size, licensee personnel hand-labeled the vials. When the process was initially introduced, the manufacturing technicians were instructed to hold the vials upright by their caps, thus maximizing the distance between the fingers and the radioactive material. However, some technicians held the vial upright in their left hands with their index finger on the top and the thumb on the bottom of the vials and applied the labels with their right hands. In this configuration, there was approximately 1.3 millimeters of glass between the radioactive material and technicians' thumbs. Between 1994 and 1999, some technicians labeled several hundred to several thousand vials each year using the latter technique. The employees who worked that shift also handled, and received occupational exposures from, phosphorus-32, gallium-67, iodine-123, xenon-133, and thallium-201 products. The individuals wore their extremity monitors on their right hands. Thus, with the monitors in that location, they were not in a position to monitor the highest extremity exposure, in this case the thumb of the left hand which held the vials.

Exposure to Sterility Laboratory Staff

Mallinckrodt's QC staff performed sterility testing on every batch of injectable products that it distributed, including radioactive products. The QC staff performed these tests in the Sterility Laboratory in Building 200. During testing, an aliquot of the product was removed from a batch sample and placed on growth media, using aseptic techniques. Due to significant concern for the maintenance of aseptic conditions, the QC staff did not always use syringe shields when removing aliquots. In addition, since tops were not routinely used on vial shields, at least one employee held vials in place with the thumb of the left hand when the vial was inverted to remove the test sample. This practice placed the thumb in close contact with the radioactivity, separated only by the thickness of the glass vial. Other individuals completely removed the vials from their shields and held them in their hands while withdrawing the sample.

Sterility Laboratory staff handled, and received occupational exposures from, phosphorus-32, gallium-67, technetium-99m, indium-111, iodine-131, and thallium-201. In 1999, the licensee discontinued distribution of one injectable product that contained iodine-131.

c. Conclusions

The licensee's descriptions of the three exposure incidents agreed substantially with the team's development of the sequence of events for each incident. The licensee's descriptions are included in the 30-day report and its addendum in Attachments 2 and 3, respectively, to this report.

4.0 Licensee's Response to Initial Indication of Overexposure from Contacting a Molybdenum/Technetium Generator Column (Charter Item No. 2)

a. Inspection Scope

The inspectors evaluated the licensee's actions following a determination that Individual A had received an extremity exposure during the week of March 27, 2000, in excess of the 20 millisievert (2000 millirem) shallow dose equivalent administrative limit. The AIT accomplished this through:

- interviews of Individual A, and manufacturing, HP, and supervisory personnel; and
- review of the incident report and associated documents relative to the event.

b. Observations and Findings

Mallinckrodt held accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) and maintained its own dosimetry program to monitor occupational exposures to its employees. The licensee supplied thermoluminscent dosimeters (TLDs) to its workers to monitor occupational exposures, including deep dose equivalent (DDE), and extremity exposures (shallow dose equivalent (SDE)). Mallinckrodt exchanged the monitoring devices of its occupationally exposed employees weekly.

Following completion of the monitoring period in question, i.e., March 27 through April 2, 2000, the licensee processed the TLDs. The reports from that week, which were prepared on April 5, indicated that the extremity monitor of one employee (Individual A) recorded an exposure of 56.85 milllisievert (5685 millirem) SDE. The licensee had an administrative limit of 20 millisievert (2000 millirem) SDE per week for this employee's work group. Mallinckrodt established the administrative limit to maintain exposures ALARA and well below the NRC's limit of 0.5 sievert (50 rem) SDE to the extremities. Exposures above this level required an investigation. The investigations were normally initiated by the affected employee's supervisor following notification from the HP Department.

The supervisor of the Kow Laboratory interviewed Individual A and requested a written statement of any unusual occurrences that the individual could recall from the previous week. The individual was also restricted from further occupational exposure until completion of the investigation. Individual A prepared the written account of the previous week and initially believed that the exposure may have been due to incidental contamination on gloves worn during the shift on March 31, 2000. Due to the short period of time that the contaminated gloves were worn by Individual A, the supervisor discounted this explanation and requested the individual to try and recall any additional events.

In an addendum to the written account, Individual A recalled that the inlet needle on a 19 curie column had to be reinserted by hand, since the forceps normally used for this purpose had fallen to the bottom of the station and were not immediately retrievable. The individual initially indicated that the process had been performed sporadically over a 30 minute period. The supervisor did not recognize the potential radiological significance of this and forwarded the incident report and the written account to HP.

Following receipt of the incident report, HP staff did not fully understand the process described in the written account. The HP staff scheduled an interview and reenactment of the process with Individual A on April 13, 2000. During the reenactment, HP staff observed Individual A hold a non-radioactive column using the thumb and forefinger of the left hand and recognized the significant potential exposure that could arise from that action. The RSO made an immediate notification to the NRC Operations Center of the potential for an occupational extremity exposure to exceed 2.5 sievert (250 rem) SDE.

c. Conclusions

Mallinckrodt's response to the initial indication of an extremity exposure in excess of its administrative limit was thorough, timely, and included adequate depth, based on the information available to its staff at the time. The licensee's investigation subsequently identified the other two exposure events. HP staff were not aware of the type of rework performed beyond replacement of the hood, and therefore did not immediately recognize the potential significance of the exposure until they observed Individual A hold a non-radioactive column during the reenactment.

5.0 Dose Assessments for Exposed Individuals (Charter Item No. 3)

a. Inspection Scope

The inspection evaluated the licensee's methodology for assessing the SDEs to individuals who had directly handled radioactive material containers. The evaluation included:

- a review of dosimetry records and production logs;
- a review of Mallinckrodt contractor data;
- interviews of QC, Manufacturing, and HP personnel; and
- dose calculations performed by NRC staff and an independent evaluator (Oak Ridge Associated University (ORAU)).

b. Observations and Findings

Molybdenum/Technetium Generator Column Exposure

Mallinckrodt used three independent methods to calculate the potential extremity exposure to Individual A. The methods determined contact dose rates using:

- MicroShield, a commercially available software program developed to calculate dose rates from various source sizes, shapes, shielding and geometries;
- TLDs and a ring monitor phantom; and
- Monte Carlo calculations by an independent contractor.

Licensee HP staff initially used the MicroShield software due to its availability and ease of use. The program allows for different source shapes and composition and calculates dose rates at various, user-requested distances from the source. This software is an acceptable industry standard for dose rate calculations; however, it must be used with caution when calculating dose rates in close proximity to the source of radiation. The literature associated with the software includes the following caution:

“With regard to ‘close’ distances between the source and the dose point, the point kernal model in MicroShield should be considered very approximate.

“While the limitations are indeed case specific, we have chosen, somewhat arbitrarily, to issue a warning at one centimeter separation between the source and the dose point. We have also chosen not to limit the user’s ability to use closer distances. However, be aware that any cases at close distance should be investigated thoroughly. ‘Contact’ calculations should be avoided.”

Because of the product warning and limitation for contact doses, the data originally calculated using MicroShield are not included here. It is sufficient to note that the values were significant enough to warrant further investigation and calculation using more reliable and defensible methodologies.

Mallinckrodt next used TLDs from its in-house dosimetry program to measure the contact dose rate of a generator column. Mallinckrodt’s dosimetry program for recording DDE was accredited through NVLAP. NVLAP does not accredit systems used for monitoring extremity exposures. However, the extremity monitoring portion of Mallinckrodt’s dosimetry program was consistent with the American National Standards Institute (ANSI) Standard HPS N13.32-1995, “Performance Testing of Extremity Dosimeters.” The finger ring phantom used in the test exposures was constructed in accordance with ANSI N13.32-1995.

Mallinckrodt simulated the physical and geometric conditions of the exposure. The test exposures were conducted in two phases. The first phase measured the contact dose rate and resulted in a value of approximately 0.26 sievert (26 rem) per second. However, this value is dependent upon the particular dosimetry system calibration curve used, which could vary the results by 30 percent (i.e., the value may be as high as 0.34 sievert (34 rem)). Based on a maximum of 50 seconds contact time, which was determined through several reenactments, the estimated exposure was 13 sievert (1300 rem) SDE, with a range of between 10 and 17 sievert (1000 and 1700 rem) SDE. The second phase attempted to reproduce the conditions that resulted in the dose recorded by Individual A’s extremity monitor, which was worn on the index finger of the right hand. The NRC continues to review the results of the second phase of the licensee’s assessment.

Mallinckrodt’s contractor, who performed Monte Carlo calculations for the exposure, determined that the contact dose rate was 0.51 siervert (51 rem) per second. This resulted in a total dose of 25 sievert (2500 rem) SDE for the period of time in question. The dose rate calculations are included in Mallinckrodt’s 30-day report, which is included as Attachment 2 to this report.

The NRC requested that Oak Ridge Associated Universities (ORAU) perform independent dose calculations of the generator column exposure incident. ORAU determined that the contact dose rate was 0.34 sievert (34 rem) per second, with a total dose of 17 sievert (1700 rem) for the 50 second contact time.

<u>Indium-111 Product Vial Labeling Exposures</u>

In contrast to the generator column exposure incident, the doses received by some workers who hand-labeled the indium-111 product involved chronic exposures. The

likely exposure received while handling individual vials was not significant; however, the extremity doses to individuals in this case resulted from the number of vials handled during the year.

Through interviews and observations, HP staff determined that workers manipulated the vials in one of two ways. The workers either held the vial with the index finger on the top of the vial (septum end) and the thumb on the bottom with the radioactive material at the bottom of the vial, or held the vial near the neck of the vial (septum end) between the index finger and thumb, with the radioactive material on the bottom. The former method resulted in the highest dose rates due to the proximity of the radioactive material to the thumb. The latter method provided sufficient distance between the material and the finger tips, such that workers who held the vials in this manner did not receive significant exposures.

Licensee HP staff initially used MicroShield to calculate a dose rate at two locations on the surface of the 3 milliliter vials (i.e., near the neck and at the bottom). However, based on the limitations of MicroShield at these small distances (as previously described), the results were not reliable. Therefore, Mallinckrodt conducted a TLD study to calculate the surface dose rate at the bottom of the vials.

The licensee then reviewed its production records to determine the total number of vials hand labeled by those workers who held the vials with their thumbs on the bottom. Mallinckrodt also determined the average time that each of those workers held the vials while labeling them. With this information, HP staff estimated the dose to the thumb of the individuals for those who received extremity exposures in excess of the NRC limit over the period between 1994 and 1999, inclusive. A summary of the dose estimates that exceeded 0.5 sievert (50 rem) is provided in Table 1. Mallinckrodt did not identify any exposures in excess of the limit for 1994.

Identity	1995	1996	1997	1998	1999
B		1.88	1.38	1.62	0.53
C			3.72	2.45	2.19
D		0.99	0.69	4.79	4.87
E			2.95	3.33	5.91
F				3.05	
G			0.76		
H	0.77	0.85	0.68		
I	1.28	2.10	0.50		
J	2.54	0.73			
K		0.83			

Table 1 - Estimated Annual Shallow Dose Equivalents (sievert)
Associated with Indium-111 Vial Hand Labeling
NOTE: 1 sievert equals 100 rem

In addition to the individuals listed in Table 1, Mallinckrodt identified four individuals who no longer worked at its facilities and who it has not been able to contact. Depending on the method those persons used to hold the vials containing indium-111, their exposures could exceed 0.5 sievert (50 rem) SDE in a year. Mallinckrodt continued its attempts to contact those persons.

The individuals listed in Table 1 also received extremity exposures from routine operations. Those doses, once determined, will be added to the values in the Table to determine their total occupational extremity exposures. The added doses are expected to be only a few percent of the values in the Table.

Sterility Laboratory Exposures

Dose determinations for Sterility Laboratory personnel who handled unshielded containers of radioactive material required similar data collection as the indium-111 exposure above. This scenario was complicated by the number of different isotopes and products handled by the workers, and the variation of technique among the individuals in withdrawing the test samples from the product vials. Most of the information necessary to calculate dose to the extremity was contained in testing logs. HP staff observed each of the workers for technique of handling the vials and syringes to determine the geometry of the source, the proximity of the extremities to the radioactive material, and to determine the contact time for each test. HP staff then used MicroShield to determine dose rates on the various points on the surface of the vials, depending on the handling technique of the individual. Mallinckrodt did not request Monte Carlo calculations from their consultant for this scenario because of the relatively large number of different products handled and the multiple handling techniques used by the workers. For similar reasons, TLD studies had not been performed, but are planned to refine the estimated dose calculations. The estimated doses (using MicroShield) for the Sterility Laboratory workers who received extremity exposures in excess of 0.5 sievert (50 rem) SDE are provided in Table 2. These doses are also reported in the licensee's 30-day report addendum (See Attachment 3).

Identity	1997	1998	1999
J	0.81	0.90	0.68
L	0.81	0.96	0.81
M		0.76	
N	0.93		

Table 2 - Estimated Shallow Dose Equivalents (sievert)
Associated with Sterility Laboratory Testing
NOTE: 1 sievert equals 100 rem

c. Conclusions

Mallinckrot's dose assessments for each of the exposed individuals were accurate, within the identified limitations of such assessments. The dose assessments were technically sound and reasonable, and to the extent practical, included consideration of

individual practices. NRC's independent calculations agreed with the licensee's estimates in the generator column and hand labeling exposure incidents. The Team agreed with Mallinckrodt's methodologies for calculating Sterility Laboratory exposures. The estimates represent the best approximation of SDEs received by the workers.

6.0 Pre-production Radiological Evaluations of Indium-111 and Molybdenum-99 Manufacturing Lines (Charter Item No. 4)

a. Inspection Scope

The inspection reviewed the effectiveness of the licensee's evaluations of the indium-111 and molybdenum/technetium generator production lines with regard to potential radiological hazards presented by those activities. The review included:

- a search for documented pre-and post-production radiological evaluations;
- pre-and post-production engineering evaluations;
- HP audits and incident reports associated with those activities; and
- interviews of management, workers, and radiation safety personnel

b. Observations and Findings

Indium-111 Product

Initial Design

In 1993, Mallinckrodt began distribution of a new radiopharmaceutical containing indium-111. The licensee planned to package the product in 3 milliliter vials and recognized that a new packaging line would need to be built with a labeling machine that could accommodate the smaller vials. The packaging line in use at that time incorporated a labeler that would not accept vials smaller than 10 milliliters.

Mallinckrodt designed and built the new packaging line in 1994, which included a labeler that accommodated both 3 and 10 milliliter vials. However, due to engineering problems with the new line, the licensee did not use it. Several attempts to correct the problems since the line was built had not been successful.

Since the new packaging line could not be used, Mallinckrodt modified the packaging process for the indium-111 product to include labeling of the vials by hand. The licensee initially instructed the workers who performed the labeling operation to hold the vials by their neck to maximize the distance between the radioactive material and their hands. The team's review of pre-production documents concerning the new indium-111 product did not identify any evaluations of the potential radiological hazards associated with the manufacture or packaging process.

The SOP that addressed packaging of injectable products originated in 1991. The SOP included a statement that the ". . . labeler will be used to apply the vial labels to vials labeled on the . . . packaging line . . ." When Mallinckrodt began dispensing the new indium-111 product in 1994, the SOP was not revised to reflect the practice of hand labeling of the vials.

Subsequent Operation

The inspectors reviewed the revisions to the SOP addressing the labeling of the indium-111 product, through the revision dated March 1, 2000. The SOP was never revised to reflect the actual practice of hand labeling.

The inspectors reviewed post-production documents concerning the indium-111 product. The review did not identify any evaluations of the potential radiological hazards associated with the manufacture or packaging of this product.

Individuals who had managed the line did not consider the hand labeling of vials an issue since the indium-111 product vials had always been hand labeled and the exposures recorded by the workers' extremity monitors had not been significant. In calendar year 1999, the recorded extremity exposures for these employees were between 58 millisievert and 0.21 sievert (5800 millirem and 21,000 millirem) SDE. The workers typically wore their extremity monitors on their right hands; they held the vials in their left hands when labeling.

Generator Manufacturing

In 1997, Mallinckrodt began full production of a new model of molybdenum generator. The generator, referred to as dry-top-eluting, or DTE, gradually replaced the older style, which was considered a "wet" generator, since Mallinckrodt shipped it with saline in the elution lines and the packaging included a 500 milliliter bottle of saline. To manufacture the new DTE generator, Mallinckrodt designed a new production line and built it in the same laboratory where the older style generator was made. A review of pre-production documentation regarding the new generator did not identify any evaluations of the potential radiological hazards associated with the manufacture or packaging of this product.

A Mallinckrodt SOP addressed the work performed by Individual A that was one of the subjects of this inspection. The SOP, which originated in February 1992, was revised later to address "rework" of the DTE generator. The licensee performed rework on generators during the manufacturing process to address production elution assays that were out of tolerance (high or low activity) and in the case of low or no flow through the column. The rework involved replacement of the generator hood, which contained the valving mechanisms that allowed saline to flow through the column during use. The SOP directed the worker to reject the generator if replacing the hood did not correct the problem.

While hood replacement normally corrected the problem, in a small percentage of the time it was not successful. In those instances, the licensee identified the problem to be with the positioning of the inlet needles. To correct the problem, and despite the SOP's direction to reject the generator, the Kow Laboratory staff developed a more extensive rework operation that involved using forceps to remove the column from the safe, and adjusting the inlet needles with a second set of forceps. This practice had been in place since the inception of the DTE generator manufacturing. The practice was not known to anyone, including management and HP, outside the Kow Laboratory. As such, the SOP had never been revised to reflect this additional rework and Mallinckrodt had not performed a radiological assessment of this practice.

c. Conclusions

Mallinckrodt's radiological evaluations of the indium packaging and molybdenum generator manufacturing lines were not effective. The team determined that Mallinckrodt had not performed any pre-production assessments of the potential radiological hazards associated with either the generator manufacturing or the hand labeling of the indium-111 product. Although supervisors and managers were aware of the hand labeling issue, none recognized the radiological implications of such actions. In addition, since HP staff were not aware of the rework activities involving removal of columns from their safes and manipulation of the inlet needles, radiological assessments had not been performed on those operations.

The team also determined that, at least with regard the generator rework and indium-111 product labeling, the SOPs did not reflect actual practices. In each case, licensee employees and supervisors developed unapproved work practices when either the equipment did not allow strict adherence to the SOP or they self-initiated activities to correct manufacturing deficiencies.

7.0 Dose Reduction Committee (Charter Item No. 5)

a. Inspection Scope

The inspection included a review of the effectiveness of the licensee's Dose Reduction Subcommittee of the RSC. The review included:

- the charter of the Dose Reduction Subcommittee;
- minutes of all meetings held by the Subcommittee; and
- interviews of Subcommittee members, and Manufacturing and HP personnel

b. Observations and Findings

In 1991, the NRC revised its radiation protection regulations (10 CFR Part 20) to reflect the recommendations of the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, and the requirements of the Environmental Protection Agency 1987 Radiation Protection Guidance of Occupational Exposure Recommendation, approved by the President. The regulations included an annual limit of 50 millisievert (5 rem) per year DDE and 500 millisievert
(50 rem) per year SDE for occupational exposure.

In 1997, Mallinckrodt chartered a Steering Committee of the RSC to address dose reduction efforts. The minutes of the first meeting of the committee, held on June 6, 1997, included the charter and indicated that the purpose of the committee was to: (1) discuss the possibility of NRC adopting a new whole body occupational limit of 20 millisievert (2 rem) per year and a lifetime occupational limit based on 10 millisievert (1 rem) per year of age; (2) assess the impact of the new limits on Mallinckrodt's operations; and (3) oversee implementation of mechanisms to meet these new limits. The tone of the minutes indicated a perception of inevitability and imminence by Mallinckrodt that NRC would adopt the 20 millisievert (2 rem) per year limit. The committee perceived a major impact on some areas of Mallinckrodt's manufacturing and distribution of radiopharmaceuticals if NRC adopted the 20 millisievert (2 rem) per year

proposed limit. A review of exposures for calendar year 1999 indicated that approximately 70 Mallinckrodt employees, out of an occupationally exposed workforce of approximately 250, received greater than 20 millisievert (2 rem) per year DDE.

The committee developed three approaches to reduce the maximum occupational exposures to 20 millisievert (2 rem) per year DDE. The first approach was to identify areas where concentrated efforts would be required to sufficiently reduce exposures. Another approach was to develop proposals that could be implemented at relatively low cost to help reduce exposure. And the third approach consisted of developing proposals requiring greater capital expenditure to reduce occupational dose.

The committee reviewed department doses and established dose reduction teams within the departments to evaluate individual processes. The evaluations would then concentrate on engineering and work practice improvements to reduce dose. Subsequent meetings included presentations by supervisors to discuss and analyze the sources of dose in their areas and proposals for reducing dose. General approaches during these presentations included: (1) identification of processes with potentially higher exposure; (2) determining the likely source (e.g., process step or procedure) of the higher exposure; (3) determining dose during a specific process or procedure, often using additional monitoring devices; and then (4) listing recommendations for reducing exposure from the process or step.

Outcomes of the Dose Reduction Committee's activities included a heightened awareness by workers of their doses and the plant's dose reduction efforts, supervisors and managers tracking doses in their areas of responsibility, and the use of direct reading dosimeters for daily tracking of doses by the workers. The committee directed a number of innovative, low-cost initiatives utilizing minor changes in processes, using additional shielding, and rearranging work flow and storage of radioactive material. The initiatives, many of which were worker suggestions, provided some measure of dose reduction in nearly all areas of the plant.

A review of meeting minutes indicated that although efforts to reduce extremity doses for some operations was discussed (e.g., September 24, 1998, and September 6, 1999), the primary focus was identification of ways to reduce whole body exposures (DDE). The meeting held on April 29, 1999, focused exclusively on whole body doses from all manufacturing and support processes at the plant.

The committee periodically received presentations from plant manufacturing and support supervisors, including the Kow Laboratory, third shift "Other *in vivo*" (indium-111 product packaging), and Sterility Laboratory supervisors. The Kow Laboratory supervisor made a presentation to the committee during the September 24, 1998 meeting. The minutes did not provide enough detail to evaluate the content of the presentation. The minutes included the results of a TLD badge study of the various workstations in the laboratory with an entry that "(v)arious work stations and job functions were evaluated." Based on the team's understanding of Kow Laboratory activities, the results of the badge study were unremarkable.

The third shift "Other *in vivo*" supervisor made presentations to the committee of activities in his work area several times during the committee's existence. His first presentation was also at the September 24, 1998 meeting and addressed thallium-201 and iodine-123 manufacturing. The discussion of iodine-123 manufacturing highlighted extremity exposures from that activity. The supervisor made a second presentation to

the committee during the January 20, 2000 meeting. The focus of that presentation was dose reduction efforts affecting iodine-123 manufacturing processes.

The committee reviewed activities in the Sterility Laboratory several times over the previous 3 years. The supervisors of the Sterility Laboratory provided presentations to the committee on three occasions, including April 29, 1999, November 11, 1999, and February 24, 2000. The April 29, 1999 committee minutes did not include any substantive discussion of dose or dose reduction efforts in the laboratory. The minutes of the November 11, 1999 meeting included a discussion of dose reduction efforts in the laboratory, including the plan to ". . . keep vials in safes when removing samples . . ." The key contributor to significant extremity doses in the Sterility Laboratory was the staff removing the vials of radioactive material from the shielding material when removing test samples. The third meeting minutes addressed efforts in the laboratory to reduce both DDE and extremity doses, including the use of shielding materials.

In addition, the minutes of the January 12, 1999 meeting attributed a discussion regarding dose reduction in the Sterility Laboratory, to the Manager of Quality/Regulatory Compliance Department, whose oversight included this laboratory. The discussion indicated that badge studies would not be required in the laboratory to assess dose. The plant intended to implement a different process which would no longer require the handling of radioactive samples in the area to ensure sterility. As of the AIT, the licensee continued to rely on this yet-to-be implemented process to reduce, or actually eliminate, occupational dose in the Sterility Laboratory.

c. Conclusions

Mallinckrodt's Dose Reduction Committee was not effective with regard to the reduction of extremity doses. The primary focus of the committee was the reduction of annual occupational dose below 20 millisievert (2 rem) per year DDE. The Committee did not have significant focus on extremity dose, or its reduction at this facility. According to their dosimetry reports, extremity doses were well within the annual limits, and the current regulatory limit of 0.5 sievert (50 rem) per year SDE was not in the Publication 60 recommendations. None of the minutes of the committee provided any substantive discussion of extremity doses received either in the Kow Laboratory or as a result of indium-111 packaging, including the hand labeling of the product. The minutes did address extremity doses received in the Sterility Laboratory, including a discussion of more frequent use of shielding in the laboratory. However, the licensee appeared to place heavy reliance on a different process that would eliminate the handling of radioactive materials in the Sterility Laboratory as its ultimate dose reduction effort in this area. This new process had been in the planning stages since at least January 1999, without a definitive implementation date.

8.0 Training (Charter Item No. 6)

a. Inspection Scope

The team evaluated the adequacy of the licensee's radiation safety training program to determine if it enabled radiation workers to perform their jobs in a safe manner. In order to evaluate the program, the inspectors:

- observed a portion of a radiation safety class

- reviewed classroom and on-the-job training (OJT) provided to employees assigned to the Kow Laboratory;
- reviewed advanced training provided to Class 1 radiation workers; and interviewed Manufacturing and HP personnel

b. Observations and Findings

Mallinckrodt's personnel classification system divided radiation workers into two groups. Class II workers, who were the majority of the workers, were allowed to work with radioactive materials, but only under the supervision of a Class I worker. Both groups of individuals received basic radiation safety training and OJT. To be upgraded from Class II to Class I status, workers must obtain a minimum level of experience and receive additional training. Details of the licensee's training program are provided below.

Basic Radiation Safety Training

Mallinckrodt required all new employees hired as radiation workers to complete a three-day radiation safety training course. HP staff presented the classroom training. All participants were required to complete a written test, with a passing grade of 70 percent. The instructor reviewed incorrect test responses with the individuals. The instructor evaluated individuals who failed the test to assess their performance during the course. Based on that assessment, the instructor either provided one-on-one instruction to the individual, or recommended that the individual repeat the training course. Employees were not eligible to be classified as radiation workers until they successfully completed the formal training course.

The classroom training addressed the essential elements of radiation safety and safe handling of radioactive materials. Specifically, the course emphasized the use of time, distance and shielding to minimize dose, included demonstrations of the proper use of personnel protective equipment, and described the use of remote handling tools for manipulation of radioactive material.

Interviews of licensee employees, including HP staff, indicated that everyone believed that the doses recorded by extremity monitors were the absolute "dose of record" for complying with NRC's regulatory limits. No one recognized that fingertip doses could be ten or more times the doses recorded by the monitor when handling unshielded containers of radioactive material. Furthermore, in most of the instances reviewed during the AIT, such as the hand labeling of the indium-111 product vials, the extremity monitors were not worn on the hand that received the highest exposure. Therefore, even though licensee personnel, including supervisors and managers, were aware that direct handling of unshielded containers occurred, none recognized the potential radiological significance of those actions.

On-the-Job Training

After successful completion of formal classroom training, employees were assigned to specific jobs involving the handling radioactive material in the laboratories where they worked. The supervisor of the laboratory would direct the OJT of the trainee, which was completed by either the supervisor or another Class I radiation worker. The OJT included: (1) review of the written SOP for the assigned task; (2) demonstration of the task by the supervisor or Class 1 worker; and (3) observation by the supervisor or

Class 1 of the trainee performing the task.

When both the classroom training and OJT were completed, the supervisor and employee documented the successful completion of the training and the employee was allowed to perform the task on a routine basis. At this point, the employee was considered a Class II radiation worker.

OJT for approximately one-third of the contract employees who worked in the Manufacturing Building did not include review of the SOP for the tasks that they performed. Many of these employees were not aware of the existence of the SOPs. Contract employees were assigned to all of the DTE manufacturing stations positioned after the hot cell operations, including the DTE rework/packaging station. In addition, indium-111 product hand labeling was performed predominantly by contract employees. Although current copies of all SOPs were available for review on Mallinckrodt's internal computer network, contract employees did not have access to that system.

Class 1 Employee Training

Selected individuals who demonstrated proficiency as Class II radiation workers were occasionally recommended for additional training to become a Class I radiation worker. These workers had at least 6 months of experience, and usually more. The individuals' supervisors made the recommendations to the RSC. After receiving approval from the Committee, the employee would be provided additional classroom training. Class I training provided instruction in incident/event response by focusing on evaluation of events, control of an area where an event had occurred, communication with HP staff, and initiation of personnel surveillance. Interviews of selected Class I workers did not identify any deficiencies in their understanding of the responsibilities of their positions.

c. Conclusions

Mallinckrodt's routine and event response training was generally effective in providing its employees with the basic knowledge and skills to maintain doses As-Low-As-Is-Reasonably-Achievable (ALARA). However, the training was not effective at ensuring that staff recognized the potential radiological consequences of handling unshielded radioactive materials or that they were knowledgeable of the SOPs that governed their work practices. The team identified a plant-wide misconception regarding the validity of extremity monitor results when employees handled unshielded radioactive material containers with their fingertips or with the unmonitored hand. This misconception directly contributed to the extremity exposures in excess of regulatory limits.

Mallinckrodt's OJT was implemented inconsistently, often depending on whether the individual was a Mallinckrodt or contract employee. Contract employees were not always provided copies of the SOPs for the tasks they were assigned and did not have access to the plant document control system to allow review of procedures on-line. The differences in OJT did not directly contribute to any of the identified extremity exposures in excess of regulatory limits.

9.0 Audits (Charter Item No. 7)

a. Inspection Scope

The team evaluated the effectiveness of Mallinckrodt's self-assessments related to production line radiation safety. The evaluation included:

- process and area audits; and
- interviews of HP personnel

b. Observations and Findings

Dry-Top-Eluting Production Audits

Between August 7, 1998 and April 17, 2000, the HP Department performed six audits of Kow Laboratory activities. Three audits (August 7, 1998; March 15, 2000; and April 17, 2000) included observations in the laboratory during a production run. One audit (August 20, 1998) reviewed activities involving the handling of the shipping casks in which the molybdenum-99 was received from the manufacturing facility in Holland. The fifth audit documented observations in the Kow Laboratory during a general tour conducted by the RSO on August 13, 1998. The sixth audit (February 8, 1999) was limited to a review of the SOPs for Kow Laboratory activities.

None of the audits identified the practice of generator column inlet needle rework. However, inlet needle rework was an infrequent operation which was not widely known by staff outside the Kow Laboratory.

Indium-111 Production Audits

The inspection did not identify any audits of the indium-111 production or packaging processes. Interviews of several manufacturing supervisors and plant management staff indicated they were either aware of the practice involving the hand labeling of product vials, or they were not surprised that the activity occurred. Hand labeling had become openly accepted. As such, the team determined that had Mallinckrodt staff conducted any audits of the packaging line, they would not have likely identified the hand labeling negatively.

Sterility and Quality Control Laboratory Audits

The HP Department performed three audits of QC Department activities, including the Sterility Laboratory, between December 1998 and March 2000. The December 16, 1998 audit included a compliance review, observation of specific handling activities, and a review of SOPs for the laboratory. During the compliance review and observation of a sterility test, the auditor noted that syringe shields were not used when withdrawing samples from product vials for testing. The auditor also noted that several SOPs for the Sterility Laboratory did not address the use of syringe shields. The Laboratory Supervisor indicated in his response that they did not plan of using syringe shields ". . . because it takes too long to use syringe shields when we are testing ten or more samples. Additional time required to use syringe shields for multiple samples will lead to increased extremity exposure. Also, there is not any easy way to keep syringe shields sterile when using them in a sterility testing hood. Use of syringe shields for all sterility tests can lead to sterility positives." A false positive on a sterility test would result in rejection of the entire production lot subject to the test.

During a June 29, 1999 audit of QC Department activities, the auditor noted that an individual working in a QC Laboratory was wearing his extremity monitor on one hand while handling vials containing radioactive material in the other. The auditor recommended the use of forceps for conducting transfers of material between containers and training laboratory personnel regarding the wearing of extremity monitors on the hand that receives the highest exposure. The laboratory's response to the finding only addressed the training issue.

The third audit, conducted on March 31, 2000, noted that process samples in the area were handled without shielding. The audit further noted that syringe shields were not used due to visibility and sterility issues. The auditor indicated that the process would be discontinued in the near future and that since relatively low doses were received during the process, no suggestions were made for improvement at that time.

c. Conclusions

Mallinckrodt's self-assessments of production line radiation safety were ineffective. This was due, in part, to the failure to recognize the radiological implications of handling unshielded containers of radioactive material. Three audits conducted of QC Department activities, including two that were specific to the Sterility Laboratory, identified the need for the use of syringe shields and remote handling equipment. However, neither laboratory nor HP personnel recognized that the contact dose rates on containers and syringes of radioactive material could be significant. Although the packaging line had not been audited, interviews of HP staff, and plant supervisors and managers indicated that they would not have recognized the significant contact dose rates encountered during the hand labeling of product vials. Therefore, even if the practice had been observed during an audit, the auditor would not have likely identified it as a concern. Mallinckrodt's audits of the generator manufacturing process had never identified the issue regarding column inlet needle rework.

10.0 Similar or Precursor Events (Charter Item No. 8)

a. Inspection Scope

The inspection included a review of the licensee's response to previous events that were similar to those specifically subject to the AIT. The review included:

- the licensee's incident log;
- audits associated with DTE manufacturing, indium-111 product packaging, and Sterility Laboratory activities; and
- interviews of Manufacturing, QC, and HP personnel

b. Observations and Findings

Since the inception of the licensee's problem identification and corrective action program in March 1998, Mallinckrodt recorded three incidents involving Kow Laboratory rework station employees exceeding their weekly extremity dose ALARA limits. In each case, the apparent cause of the exposures was rework involving manipulation of the generator column inlet needle and the employees not taking adequate advantage of the shielding by pulling the columns too far out of the safes. When performing those rework operations, the employees used forceps to manipulate the inlet needles and held the

plug, with the column suspended, in the other hand or with a second set of forceps or pliers. A synopsis of each incident report follows:

- Incident Report 98-30, dated March 25, 1998 - Individual X received an extremity dose of 21.8 millisievert (2180 millirem) SDE during the week of March 16, 1998. The Kow Laboratory supervisor stated that the root cause of the exposure was "a large number of reworks where the inlet needle had to be placed in the column by hand." The corrective actions for this incident included the use of a custom tool in the hang cell of the hot cell to aid in replacement of the inlet needle prior to initial assembly of the generator.

- Incident Report 98-229, dated June 13, 1998 - Individual Y received an extremity dose of 26.15 millisievert (2615 millirem) SDE during the week of May 25, 1998 . The Kow Laboratory supervisor indicated that the root cause of the exposure was the removal of "columns from safes to check inlet needles" during rework. The corrective actions included rotating more employees through the rework station to share the exposure.

- Incident Report 99-1327, dated November 3, 1999 - Individual Z received an extremity dose of 105.76 millisievert (10576 millirem) SDE during the week of October 25, 1999. The Kow Laboratory supervisor determined that the dose was caused by improper technique in performing the rework functions. This individual had performed eleven reworks using the improper technique, which involved inspecting the inlet needle of every generator identified for rework to ensure that they would not return for a second hood change. The individual believed that he was falling behind at the station because of reworked generators returning for a second time.

None of the followups to these incident reports included a review of the procedure that covered rework activities. Furthermore, the team could not identify anyone outside the Kow Laboratory who was cognizant that work outside of the approved procedure had been performed.

The team did not identify any previous events relative to the hand labeling of product vials or activities in the Sterility Laboratory that pertained to the events reviewed during this inspection. Licensee staff were not aware of any similar events.

c. Conclusion

Mallinckrodt identified three previous events in which personnel exceeded the weekly ALARA level (20 millisievert (2000 millirem) SDE) due to work involving the DTE generator rework station. None of the root cause analyses of the incidents included a realization that the inlet needle rework was not authorized by the SOP.

The Team did not identify any precursor events related to either the hand labeling of vials of Indium-111 or Sterility Laboratory activities, except for the acknowledgment that the activities occurred, but without the recognition of the potential radiological consequences of those activities.

11.0 Exit Interview

The team met with licensee representatives (identified below) during a public exit meeting on June 23, 2000, and summarized the purpose of the AIT, AIT charter items, and inspection findings. The team discussed the likely informational content of the inspection report with the licensee regarding documents and processes reviewed by the team during the inspection. The licensee did not identify anything proposed for inclusion in this report as proprietary in nature.

Attachments:
1. Augmented Inspection Team Charter
2. Licensee 30-day Report of Generator Column Exposure Event
3. Licensee 30-day Report of Other Annual Occupational Extremity Doses in Excess of 0.5 Sievert (50 Rem) Shallow Dose Equivalent

PERSONNEL CONTACTED

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*Denotes those individuals attending the June 23, 2000 exit meeting.

LIST OF ACRONYMS USED

AIT	Augmented Inspection Team
ALARA	As-Low-As-is-Reasonably-Achievable
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DDE	Deep Dose Equivalent
DNMS	Division of Nuclear Materials Safety
DTE	Dry-Top-Eluting
HP	Health Physics (Department)
ICRP	International Commission on Radiological Protection
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OJT	On-the-Job Training
ORAU	Oak Ridge Associated Universities
QC	Quality Control
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent
SOP	Standard Operating Procedures
TLD	Thermoluminescent Dosimeter

MALLINCKRODT, INC.
AUGMENTED INSPECTION TEAM
CHARTER

The Augmented Inspection Team is to examine the circumstances surrounding the extremity overexposures at the Mallinckrodt, Inc., Maryland Heights, Missouri, production facility. The examination should include, but is not limited to the following:

1. Evaluate the completeness and accuracy of the licensee's event description(s).
2. Evaluate the scope and thoroughness of the licensee's response to the indication of an overexposure in the Molybdenum/Technetium generator assembly areas.
3. Evaluate the completeness and accuracy of the licensee's dose assessments for the exposed individuals.
4. Evaluate the effectiveness of the licensee's radiological evaluations of the Indium and Molybdenum product lines.
5. Evaluate the effectiveness of the licensee's Dose Reduction Committee activities.
6. Evaluate the effectiveness of the licensee's routine and event response training activities.
7. Evaluate the scope and effectiveness of the licensee's audit program for evaluating production line performance.
8. Evaluate the licensee's identification and response to precursor events, i.e., opportunities to have identified the issue(s) prior to the event(s).