FOIA/PA NO: 2016-00010

GROUP: A

RECORDS BEING RELEASED IN THEIR ENTIRETY

U.S. Nuclear Regulatory Commission
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SET III

677 / Mallinckrodt, MO

[redacted]

NRC Lab Analyses Request

RFTA # 97-6 Site # 677 Docket # ____

NRC Contact (name) Donna Moser 301 415 6753 Region HQ

Facility Sampled Mallinckrodt Group Inc., Chesterfield, MO

Fee Recoverable [X] Non-Fee Recoverable [ ]

Sample Type: Media Soil Number 4-6

Condition ____

Contaminants U, Th, Ra

Anticipated levels ____

Analysis Units (e.g., pCi/g, pCi/L) ____ MDA Requirements ____

Lab/Field Conference ____

Guideline or Comparison Requirements ____

Requested Analysis ____

Turn Around Time ____

Sample Holding

Time: ____ Months after report

Indefinite/Archive Yes [ ] No [ ]

Other ____

Residual Sample: Hold [ ] Discard [ ]

w/Donna 12/10/96
on hold

Cost Estimate Completed Start 12/

Login & Custody completed ____

LWR Submitted ____

Review Analysis Data ____

Report Prepared ____

677 / Mallinckrodt, MO

[redacted]

NRC Lab Analyses Request

RFTA # 97-6 Site # 677 Docket # ______

NRC Contact (name) Donna Moser 301 415 6753 Region HQ

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Requested Analysis ______

Turn Around Time ______

Sample Holding
Time: ______ Months after report

w/Donna 12/10/96
on hold

Indefinite/Archive Yes [ ] No [ ]

Other ______

Residual Sample: Hold [ ] Discard [ ]

Cost Estimate Completed Start 12/

Login & Custody completed ______

LWR Submitted ______

Review Analysis Data ______

Report Prepared ______

U.S. Nuclear Regulatory Commission
Pages from Mallinckrodt Folders
SET VIII

CORRESPONDENCE 81 (MAL)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

September 29, 1981

Mr. James D. Berger
Program Manager
Radiological Site Assessment
Program
P.O. Box 117
Oak Ridge, TN 37830

Dear ~~Mr. Berger~~: Jim

The proposed environmental survey plan for the Mallinckrodt Nuclear Facility in Maryland Heights, Missouri, has been reviewed and is acceptable.

Sincerely,

Ralph M. Wilde

Ralph M. Wilde
Program Assistant
Division of Fuel Cycle and
Material Safety

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

4-2-1

JAN 7 1982

Mr. James D. Berger
Program Manager
Radiological Site Assessment Program
Oak Ridge Associated Universities
P.O. Box 117
Oak Ridge, TN 37830

Dear ~~Mr. Berger:~~ Jim

The draft environmental survey report for Medi-Physics, Arlington Heights, Illinois, has been reviewed. We have no comments on the draft report.

Sincerely,

Ralph M. Wilde

Ralph M. Wilde, Program Assistant
Division of Fuel Cycle and
Material Safety

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 24 1992

Mr. James D. Berger
Program Manager
Radiological Site Assessment Program
Oak Ridge Associated Universities
P.O. Box 117
Oak Ridge, TN 37830

Dear ~~Mr. Berger~~: Jim

The draft environmental survey reports for Mallinckrodt and New England Nuclear, Billerica, have been reviewed. We have no comments on the draft reports.

Sincerely,

Ralph M. Wilde

Ralph M. Wilde, Program Assistant
Division of Fuel Cycle and
Material Safety

U.S. Nuclear Regulatory Commission
Pages from Mallinckrodt Folders
SET X

PRELIMINARY REPORTS ON 81 SURVEY (MAL)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 24 1982

Mr. James D. Berger
Program Manager
Radiological Site Assessment Program
Oak Ridge Associated Universities
P.O. Box 117
Oak Ridge, TN 37830

Dear ~~Mr. Berger~~: Jim

The draft environmental survey reports for Mallinckrodt and New England Nuclear, Billerica, have been reviewed. We have no comments on the draft reports.

Sincerely,

Ralph M. Wilde

Ralph M. Wilde, Program Assistant
Division of Fuel Cycle and
Material Safety

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

September 29, 1981

Mr. James D. Berger
Program Manager
Radiological Site Assessment
Program
P.O. Box 117
Oak Ridge, TN 37830

Dear ~~Mr. Berger~~: Jim

The proposed environmental survey plan for the Mallinckrodt Nuclear Facility in Maryland Heights, Missouri, has been reviewed and is acceptable.

Sincerely,

Ralph M. Wilde

Ralph M. Wilde
Program Assistant
Division of Fuel Cycle and
Material Safety

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

SEP 5 1980

Mallinckrodt, Incorporated
ATTN: Mr. Donald Soldan
Director of Regulatory Affairs
675 Brown Road
St. Louis, MO 63134

Gentlemen:

The Nuclear Regulatory Commission has initiated a program of evaluating environmental radioactivity near selected facilities of byproduct and source materials licensees. These surveys will be performed by Oak Ridge Associated Universities (ORAU) under contract with NRC. The first group of facilities to be surveyed will include firms licensed to process substantial quantities of radionuclides. We have selected your facility, which operates under License No. 24-04206-03G, to be included among those surveyed.

Connie Johnson - Tom Carter secretary

In order for ORAU to prepare a monitoring plan, their staff will need to visit your facility and gather information concerning your operation. In the near future, a representative of ORAU will contact you directly to arrange a visit and we would appreciate your cooperation in providing ORAU with the necessary information.

The surveys should not interfere with your plant operations. If you wish, you may collect duplicate samples with ORAU. After ORAU completes its survey and analysis of samples, they will submit a report to NRC. NRC will send you a copy of the survey report.

Any questions or inquiries concerning the survey program should be directed to Mr. Ralph M. Wilde of my staff. Mr. Wilde may be reached at (301)427-4155.

We would appreciate your cooperation with ORAU so that this work can be accomplished as expeditiously as possible.

Sincerely,

R. E. Cunningham

Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

cc: R. J. Cloutier, ORAU

U.S. Nuclear Regulatory Commission
Pages from Mallinckrodt Folders
SET X-A

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

MAY 12 1988

Oak Ridge Associated Universities
Radiological Site Assessment Program
ATTN: Mr. Glenn L. Murphy
Assistant Manager
Post Office Box 117
Oak Ridge, TN 37831-0117

Gentlemen:

We have reviewed your May 11, 1988 letter with its enclosures which presented Mallinckrodt's request for a "nondisclosure" agreement between your organizations. We understand this basically consists of an extension of a 1981 document (copy enclosed) to cover our pending inspection dates.

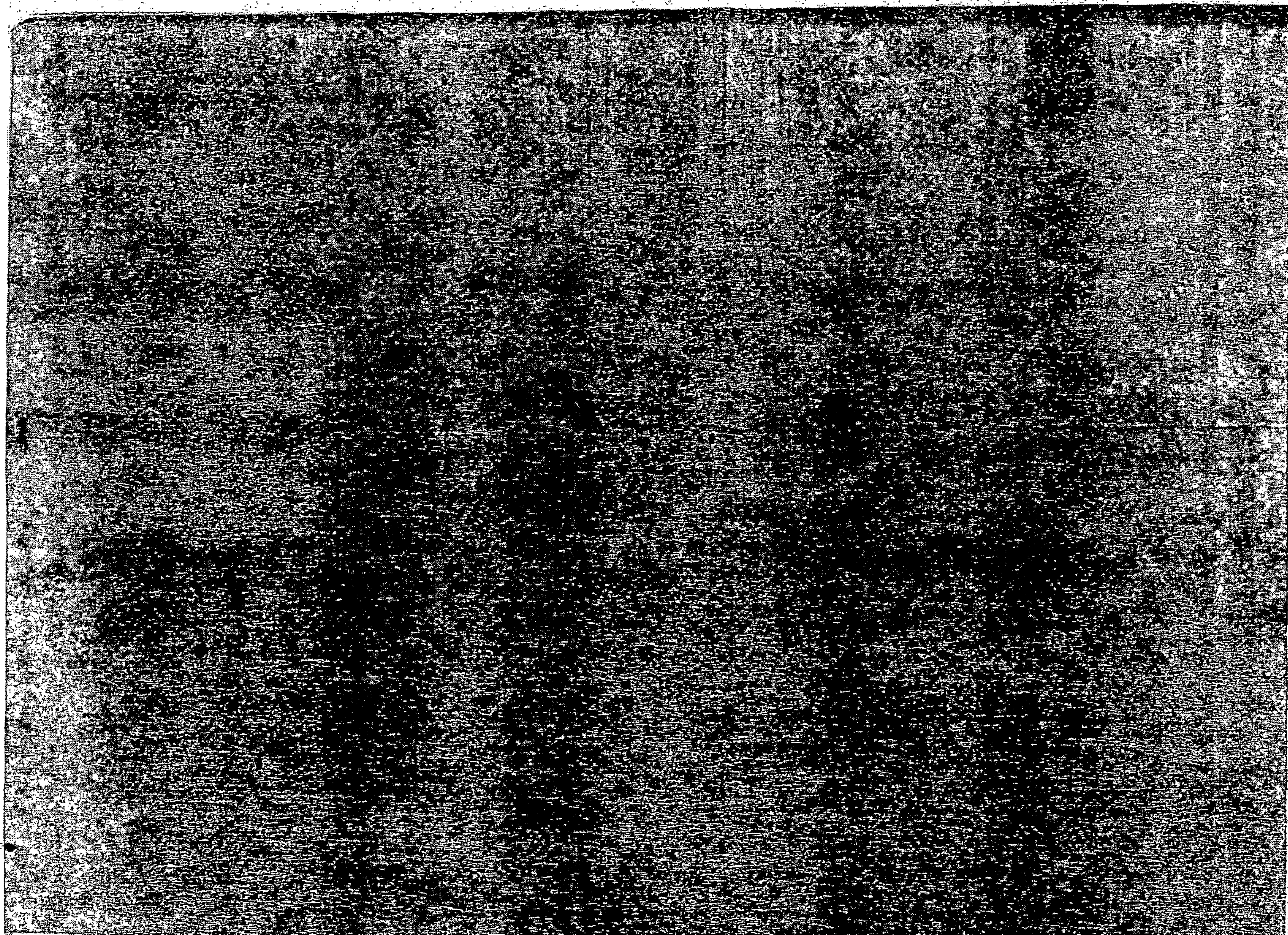
We have no objection to Oak Ridge Associated Universities (ORAU) signing the agreement in that your findings would be documented as a part of the NRC Region III report, and we foresee no occasion for ORAU to release any of its finding on its own authority. As a point of clarification, we have no objection to ORAU agreeing to request NRC to keep Mallinckrodt Proprietary Information as a trade secret and confidential and entitled to protection by NRC from public disclose as on page 2 of the 1981 agreement. However, the NRC makes no commitment to protect the material via this mechanism. Any request of this nature must come from Mallinckrodt to the NRC in accordance with Section 2.790 of 10 CFR Part 2.

Sincerely,

Bruce S. Mallett

Bruce S. Mallett, Chief
Nuclear Materials Safety
and Safeguards Branch

Enclosure: As Stated



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

Glenn Murphy

JUL 1 - 1988

Mallinckrodt Incorporated
ATTN: Mr. Ron Hopkins
Business Unit Director
675 McDonnell Blvd.
Hazlewood, MO 63042

License No. 24-04206-01
License No. 24-17450-01

Gentlemen:

This refers to the safety inspection conducted by Messrs. D. J. Sreniawski and R. J. Caniano, other members of the NRC Region III and Headquarters staff and representatives from Oak Ridge Associated Universities (ORAU), Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) on May 16 through June 3, 1988. The purpose was to review conditions in your facilities to determine if there are potential safety hazards that, when combined with facility operations, could adversely impact upon the health and safety of the public or workers at the facilities.

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

The report does not include the results of the inspection efforts of ORAU and FDA since both agencies efforts were not completed by the end of this inspection. The results of their findings will be made available to you in separate correspondence at a later date.

During this inspection, certain of your activities appeared to be in violation of NRC requirements, as described in the enclosed Notice. The inspection showed that action had been taken to correct the identified violation and to prevent recurrence. The actions are described in Section 4.j. of this report. Consequently, no reply to the violation is required and we have no further questions regarding this matter at this time.

In addition to the identified violation, we are also enclosing a list of conditions observed by team members related to your facilities which warrant the attention of management. Therefore, we are requesting within 30 days of the date of this letter, a response from you describing the actions you have already taken or plan to take relative to the areas described in the attachment. As was discussed with you at the completion of the inspection, the EPA and OSHA inspectors who participated in the inspection effort will be providing the results of their findings to the local EPA or OSHA offices to determine if the concerns warrant any followup type of inspections.

In general, we conclude that with the exception of the items addressed in the enclosed appendices, you have established adequate controls and work policies as required by your NRC license and adequate industrial safety and fire protection programs to protect members of the public and your employees. In addition, we appreciate your responsiveness to the team inspection effort, and recognize that you promptly corrected many of the areas of concerns in an expedient manner once they were brought to your attention.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The responses directed by this letter and accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Charles E. Norelius

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards Division

Enclosures:
1. Notice of Violation (Appendix A)
2. List of Conditions/Recommendations (Appendix B)
3. Inspection Reports
   No. 030-00001/88-002(DRSS); and
   No. 030-12559/88-001(DRSS)

See Attached Distribution

Distribution

cc w/enclosures:
DCD/DCB (RIDS)
Richard E. Cunningham, Director,
Division of Fuel Cycle, Medical,
Academic and Commercial Use Safety
Glen L. Sjoblom, Deputy Director,
Division of Fuel Cycle, Medical,
Academic and Commercial Use Safety
Donna Beth Howe, Ph.D., Health Physicist,
NMSS
Mr. Emil Golias, Industrial Hygienist, U.S.
Department of Labor, OSHA
Mr. William Brink, P.E, U.S. E.P.A.
Mr. John Bosky, U.S., E.P.A.
Mr. Glenn Murphy, Assistant Manager,
Radiological Site Assessment Program
Mr. Sal Comodo, U.S., F.D.A
Mr. Harvey Goranson, Professional
Loss Control Inc.
Mr. Al E. Hall, Plant Manager
Mr. Roy W. Brown, Manager of
Regulatory Compliance

APPENDIX A

NOTICE OF VIOLATION

Mallinckrodt, Incorporated License No. 24-04206-01

As a result of the inspection conducted on May 16 through June 3, 1988, and in accordance with 10 CFR Part 2, Appendix C - General Statement of Policy and Procedure for NRC Enforcement Actions (1987), the following violation was identified:

Condition 12B of your license requires, in part, that you test your sealed sources containing byproduct material for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, between June 25, 1987 and March 3-5, 1988, you failed to test nine of your sealed sources containing byproduct material for leakage at an interval not to exceed six months. These nine sources, all containing cesium-137, are described below:

Source Activity	Model No.
5 curies	28-8A
1 curie	28-6A-D798GN
770.8 microcuries	Q.C.-5
713.7 microcuries	Pd-8
1 millicurie	1978
1.45 millicurie	QC-2-QC-600
700.3 microcuries	I9 (C#1)
1.209 millicuries	Pd-3
1.024 millicuries	Pd-2

This is a Severity Level IV violation (Supplement VI).

The inspection showed that action had been taken to correct the identified violation and to prevent recurrence. Consequently, no reply to the violation is required and we have no further questions regarding this matter.

JUL 1 - 1988

Dated

Charles E. Norelius

Charles E. Norelius, Director
Division of Radiation Safety and Safeguards

APPENDIX B

Conditions/Recommendations/Observations Necessitating a Response

As a result of the inspection effort, the following conditions, recommendations, and observations requiring a response were discussed with you at the end of the inspection concerning radiation safety, industrial safety, fire protection and EPA issues.

A. Radiation Safety Program Recommendations/Observations

1. During the course of this inspection, it was learned that, from approximately October 1987 through May 1988, the positions of Radiation Safety Officer and Manager of Regulatory Compliance were being filled by the same person. This is of concern since, according to job descriptions, the same person was serving as a developer of rules and regulations and as an auditor to assure that the rules and regulations were being implemented adequately.

2. During the course of the inspection, it was noted that you had conducted informal meetings of the Radiation Safety Committee on four occasions during 1987. The purpose of these meetings was to review personnel exposures, which is a basic function of the Committee. The documentation pertaining to those meetings did not reflect the fact that the meetings were a part of the Radiation Safety Committee's commitment to meet on a quarterly basis. This lack of documentation caused confusion in determining whether or not you did in fact meet on a quarterly basis during 1987.

3. Upon reviewing your environmental monitoring program, it was noted that you do not have a formal written quality assurance program for your counting laboratory. Your current quality assurance program primarily consists of non-written policies on detector calibrations, geometry determinations, sample collections, preparations and analyses, etc. This lack of written procedures was addressed to you as an area of concern.

4. During a review of the results of your radiological effluent samples, it was noted that there was a discrepancy in the calculation of iodine-131 activity based upon the fact that there has been no correction factor added in the calculations to account for sample

loss due to decay. In discussions with you on this matter, you stated that this discrepancy will be evaluated further but until that time a correction value will be added to future calculations.

5. During our review of your off-site air sampling stations, a suggestion was made by both the NRC and EPA to install an additional monitoring station approximately one and one-half miles from the licensee's facility to better assess off-site releases to assure compliance with 10 CFR Part 20 and 40 CFR Part 61, and to also assist the licensee with assessing any radioactive releases which may occur at non-licensee facilities in the area. This was discussed with you during the inspection and, according to statements from your staff this recommendation will be evaluated further.

6. During our review of meteorological data, obtained from the Lambert Field Airport, you indicated that major downward wind concerns are toward the northeast; however, upon reviewing your air monitoring data, higher results are seen toward the southeast. In discussing this with your staff the inspectors were informed that in the past the use of meteorological data from the Lambert Field Airport has been compared to meteorological data obtained at the facility and no discrepancies had been noted regarding predominant wind direction. In your response to this observation, please provide what types of data had been reviewed in the past, and reevaluate as to whether the airport meteorological data is appropriate for your facility. As was stated during the inspection, you may wish to use meteorological data taken by Oak Ridge Associated Universities during the inspection to assist you in your evaluation.

7. During the review of written exams required to evaluate individual's competency in lecture/hand-out material, it was noted that the feedback which examinees receive on the results of the exams is limited to whether they passed or failed. They are not informed of which questions were answered incorrectly in order that they may learn the correct answers.

8. During the course of the inspection, the inspectors observed two instances where individuals were working with potentially contaminated materials and were not wearing any gloves. The first instance observed was during the receipt of raw molybdenum-99m. The individual

checking in the packages (performing radiation surveys and smears) was not wearing gloves and was handling the packages directly. These packages had not yet been checked to assure that they were free of contamination. In addition, it was noted that this individual does not perform any "on-the spot" analysis of the smears taken on the packages. If there was contamination, it would not be found until the smears were analyzed back at the health physics area. This delay could result in spread of contamination throughout your facility.

The second instance noted was during the observation of an individual removing decayed vials of radioactive materials from their lead holders. Again, this individual was observed not wearing protective gloves. (The individual was monitored by a TLD ring badge and the licensee assured the inspectors that the individual does check his hands for contamination prior to leaving the area.)

9. During our review of your emergency preparedness plan for your facility, the following observations/recommendations were noted which we feel necessitate a response.

   a. During an inspection of lockers housing emergency equipment, it was recommended that an inventory list of items be posted in the lockers to prevent delays in searching for equipment in the event of an emergency. This recommendation was also made during the 1986 evaluation of your emergency plan conducted by Oak Ridge Associated Universities.

   b. It was noted that Letters of Agreement with offsite support agencies responsible for responding to emergencies have not been updated since 1981. In fact, one letter was found to be obsolete. This recommendation was also made during the 1986 evaluation by Oak Ridge Associated Universities.

B. <u>Industrial Safety Recommendations/Observations</u>

1. The company has a written hazard communication program, but it appears to be generic in nature. Several inadequacies were observed as follows:

   a. The list of hazardous chemicals, known to be present, was a list showing all materials found throughout the establishment and made no attempt to show hazardous chemicals as defined.

The list should be selective for hazardous chemicals in the workplace or it could be broken down further for individual work areas. This will facilitate the evaluation of hazardous chemical usage and better enable employees to be trained on the hazardous substances they will encounter in their work areas.

b. There was no section in the written program on how the employer will inform employees of the hazards of non-routine tasks and the hazards of unlabeled pipes.

c. There was no section on what methods the employer will use to inform any outside contractor with employees working in Mallinckrodt's facilities of the hazardous chemicals their employees may be exposed to while performing their work, and any suggestions for appropriate protective measures.

d. There was no section in the written program detailing how each container of materials leaving the workplace will be labeled and how each container used inside the work place will be labeled, tagged, or marked with the identity of the hazardous chemicals and the appropriate hazard warnings. During the walk around in Buildings 600 and 500, instances were observed where an ethylene oxide sterilizer was not labeled, a hydrochloric acid container had an inadequate label, an isopropyl alcohol container was not labeled, a sodium hydroxide container was improperly labeled, and several containers of ink wash, various alcohols and acids had improper or nonexistent labels.

e. There was no section in the written program detailing how material safety data sheets will be collected, evaluated, and updated for each hazardous chemical in the work place. During the inspection, material safety data sheets could not be found for S-85 Ink Wash (a red label chemical) and Formula 700 cleaner.

f. There was no section in the written program detailing how employee information and training will be provided during orientation and when new hazards are introduced.

2. In several areas at the plant, employees were observed wearing either safety glasses and/or face shields when handling corrosive materials. Since these materials could splash up under shields and safety glasses, chemical splash goggles sealed to protect the eyes should be worn either over the safety glasses or under the face shields. Areas where these conditions were noted were: (A) Building 600 standards laboratory handling various acids; (B) UTK Production area handling hydrochloric acid and hydrogen peroxide; (C) Battery charging area when adding water to batteries containing sulfuric acid; (D) Staging laboratory when handling acids and other corrosives.

3. In Building 600, standards laboratory, there was an improper eye wash mounted on the sink that was hand held and did not meet the ANSI standard for eye washes. Employees in the area handle various acids. The employee who adds water to the batteries for the golf carts should do so in an area where a proper eye wash is present. Currently, he only has a running water hose in the immediate area.

4. The company had a written respirator program but in several areas of the plant it was not being implemented. Employees in the UTK production area shared a chemical cartridge respirator among nine people. No one had been fitted for the respirator nor was it cleaned, disinfected or stored in a sanitary manner after each usage. If employees are to use respiratory protection, then it must be used properly in compliance with OSHA code 1910.134. In addition, one employee questioned on respirator usage had never been trained on how to use a respirator in any manner at all. In the RA fill room, a respirator was observed being stored in a cabinet where biohazards had been previously stored and still had biohazard labels on the door. The face piece was laying uncovered on a shelf. Improper storage or usage of respiratory protection could cause employee exposure to hazardous substances. In Building 500 within the emergency equipment storage cabinet, three negative pressure respirators were improperly stored on shelves. For all negative pressure respirator usage a proper program must be developed, implemented and maintained if employee protection is to be assured.

5. In several areas of the plant, self contained breathing apparatus are stored for emergency use. In the emergency equipment storage cabinet in Building 600, two air cylinders were less than full. In addition emergency respirators were not inspected on a monthly basis to assure air cylinder hoses, face pieces, regulators and warning devices are functioning properly. A record should be maintained of inspection dates and findings.

6. In several areas in Building 600, extension cords were used in place of the fixed wiring of a permanent installation: (A) In the Standards laboratory, an extension cord was utilized for fixed wiring and an improper plug box, which was designed for permanent mounting was utilized; (B) In the battery charging area, an extension cord was used in place of permanent wiring; (C) In the staging laboratory, three extension cords with improper plug boxes were used in place of fixed wiring. If extension cords are used, they cannot replace fixed wiring and they must not be homemade, but of the approved type. An extension cord was also utilized on the refrigerator.

7. In Building 500, there was an open sided floor or platform by the dumpster, with the door opened continuously, that was 52 inches high and was not guarded by a standard railing or its equivalent.

A standard railing consists of a top rail, midrail, and has a vertical height of 42 inches from top rail to floor.

8. In the cylinder storage area, three oxygen cylinders were not separated from three hydrogen, five acetylene and one helium cylinders by the minimum distance of 20 feet.

9. In the Building 500 radioactive waste area, there are three hammer mills for the reduction of material. The existing ventilation system is not periodically checked to assure that it is functioning as designed. All three systems should be monitored on a routine (six months or less) basis to assure adequate collection efficiency.

10. In the Building 600 sterile core lypholizer front (2) units, there is no warning sign indicating that ethylene oxide (ETO) is contained within. A warning sign should be installed on the front of the ETO sterilizer.

11. This company falls under the hazardous waste standard as it handles hazardous materials, is a small quantity hazardous waste generator and has an emergency response team that is trained to handle anticipated emergencies throughout the establishment. The company currently has not addressed this standard and needs to develop a program to meet all elements. In other plant programs, the majority of the elements have been previously covered so it is only a matter of evaluating what has not been covered and consolidating it into existing programs.

12. In several areas of the plant, exits were not clearly visible or the route to reach it were not clearly marked so that every occupant will readily know the direction to escape from any point. Each path of escape in its entirety, shall be so arranged or marked that the way to a place of safety outside is unmistakable. Several doorways or passage ways not constituting an exit or way to reach an exit, but of such a character as to be subject to being mistaken for an exit, were not arranged or marked as to minimize its possible confusion with an exit. This contributed to the danger of persons attempting to escape from a fire and instead, finding themselves trapped in a dead end space.

13. In Building 500, several containers of material requiring red labels were stored on the floor. All flammables should be stored in approved storage cabinets and removed only for daily usage. All flammables should be placed in approved safety cans and bonding and grounding utilized where required during liquid transfer. This company's handling procedures for flammable materials needs to be evaluated and updated where applicable.

C. Fire Protection Recommendations/Observations

Manufacturing Facility; Maryland Heights, Missouri

1. The hazards of high stack piling and plastic storage should be reduced as follows:

   1.1 Remove bags of polystyrene chips from the liquid waste pit of Building 500.

   1.2 In Buildings 600 and 700, warehousing procedures should be reviewed to ensure that all flammables and oxidizers are stored in their designated areas and that adequate space is maintained from flammables.

   1.3 In Building 600, all plastics and products containing more than a limited amount of plastic should be stored in the north portion of the warehouse. The south portion of the warehouse should be limited to Class III commodities.

   1.4 Excessive quantities of combustible oil, filters, and bottles in combustible packaging in Building 600 penthouse should be removed.

   1.5 The design density of the warehouse portion of Building 700 should be determined and an analysis of the area be conducted. In the interim, plastics should be removed to the north end of Building 600 and storage heights in Building 700 should be limited to 19 feet for Class IV commodities.

2. To limit the possibility of radioactive release to the environment from fire department operations, some form of fire suppression and/or detection should be considered for the hot cells.

3. Standing water was noted in the valve pit for Buildings 300, 400, and 500. This water should be pumped out and drainage within the pit improved.

4. The following minor deficiencies in the sprinkler system should be corrected:

   4.1 Obstructions to sprinkler water distribution by light fixtures, partitions, ducts, and drop ceilings in Buildings 100, 200, 300, 600, and 700. Correction involves relocation of either the sprinkler or the obstruction.

   4.2 Nonsprinklered areas in Buildings 100, 200, 300, 500, 600, and 700A. Any areas having properly installed central station fire detection may be omitted from this recommendation.

4.3 The trash can and chair should be removed from the ceiling space above Building 600 laboratories. The sprinkler design for this area (which omits sprinklers in noncombustible spaces) does not contemplate such storage.

4.4 Sprinklers should be provided in the mechanical equipment areas of Building 700A. Such protection would be in addition to detectors which are already installed in this area.

4.5 Missing ceiling panels. These should be replaced in the rear second floor area of Building 100.

4.6 Sprinklers at excessive distances below the ceiling. Sprinklers over the Building 600 mezzanine should be relocated to be within 16 inches of the ceiling. Where this relocation results in beams blocking water spray from sprinklers, additional sprinklers should be provided in the beam pockets.

5. Integrity of fire walls and vertical openings should be improved as follows:

5.1 Employees should be notified that fire doors are not to be blocked opened. Fire doors should be prominently marked.

5.2 Consideration should be given to upgrading the walls between Buildings 600 and 700, and between the warehouse and production areas of Building 600, to a three-hour rating. This will necessitate replacing any fire doors that are damaged or not at least three-hour rated, revising sliding doors to conform to Figure A-36 or NFPA 80, and verifying a three-hour fire resistance for wall materials. If the block walls have less than a three-hour fire resistance, they should be coated with at least one half-inch of plaster on each side.

5.3 All stairwells should be protected by one and one-half hour self-closing fire doors. Any doors that do not close properly should be adjusted. This recommendation applies to Buildings 100 and 200.

5.4 The wall between Buildings 100 and 100A should be upgraded to a three-hour firewall, combustibles removed from Building 100A or extending sprinkler protection to Building 100A.

6. Additional dry chemical (ABC) extinguishers should be provided where the travel distance to a Class A rated extinguisher or hose station exceeds 75 feet.

7. Flammable liquids used in cleanup or other operations not affecting the final product should be dispensed from UL-listed self-closing containers (this applies to all shop and lab areas). In the

maintenance shop, all unneeded flammable or combustible liquids should be be properly disposed of. Cans of spray paint should be removed from all combustible packaging. Spray paint and all other flammables should be stored in UL-listed or FM-approved storage cabinets.

8. The heat detectors in the former in vitro lab should be spaced in accordance with their listings (which will require three additional detectors) or sprinkler protection extended to this area.

9. The heat detector in the cooler in building 400 should be relocated to the ceiling, or on the wall within 12 inches, but over four inches below the ceiling.

10. Thermal detectors on the first floor of Building 100A, below the roof of the Building 700A mechanical equipment room, and below the Building 700A mezzanine should be relocated from the bottom of beams or joints to the beam pockets. Additional detectors to meet the spacing requirements of the respective detector listings may be necessary to meet NFPA 72E requirements.

Research and Development Facility, Hazelwood, Missouri

1. Flammable liquids used in cleanup or other operations not affecting the results of an experiment should be dispensed from safety containers having spark arrestors and self-closing caps. This will reduce the potential for a spill fire. Bulk storage of flammables should be limited to the first floor solvent room with quantities for use dispensed into safety cans within this room.

2. Combustible metals such as sodium should be stored separately from solvents, oxidizers and solutions containing water to limit the possibilities for ignition. The storage cabinet should be prominently marked as a Class D extinguisher located nearby. The storage cabinet should prevent the penetration of water from sprinklers or other sources.

3. Oxidizers should be stored in a location physically segregated from organic chemicals. (During the survey, nitric acid was found stored next to oil cans.) This segregated area should be prominently marked.

4. The present plan to replace ordinary metal five-gallon liquid waste cans with non-reactive safety cans should be instituted as soon as possible to limit flammable liquid exposures at laboratory work stations.

5. Mallinckrodt should review the sprinkler design of this facility with Industrial Risk Insurers to determine if the proper ceiling sprinkler densities for the laboratory and maintenance shop were

chosen. The available density in those areas should meet the requirements of NFPA 13 for Ordinary Hazard (Group 3) occupancies.

6. In the maintenance shop, sprinklers are located over 12 inches below the ceiling. These heads should be reallocated to be within 12 inches of the ceiling.

D. Environmental Protection Agency Recommendations/Observations

During the inspection effort at Building 600, the inspector noted that your hazardous waste storage area contained barrels of hazardous waste (non-radiological in nature). When questioned as to the quantities of hazardous materials contained in the barrels, members of your staff were not able to provide the inspector with documentation that would have enabled quantification. This information which was not available during the course of the inspection is necessary to assure that your facility is in compliance with EPA regulations under the Resource Conservation and Recovery Act. This information should be available for review at all times.

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.
Maryland Heights, MO 63042

Inspection Conducted: May 16 through June 3, 1988

Inspectors: D. J. Sreniawski, Chief
Nuclear Materials Safety Section 2 — 6/30/88 (Date)

R. J. Caniano, Technical Assistant
Division of Radiation Safety
and Safeguards — June 29, 1988 (Date)

T. Simmons, Radiation Specialist — 6/30/88 (Date)

C. C. Casey, Radiation Specialist — 6/30/88 (Date)

P. J. Whiston, Senior Licensing Reviewer — 6/30/88 (Date)

J. P. Patterson, Emergency Preparedness
Specialist — 6/30/88 (Date)

R. Bocanegra, Health Physicist — 6/30/88 (Date)

Other Accompanying Individuals:

G. L. Murphy, Assistant Manager
Radiological Site Assessment Program
Oak Ridge Associated Universities

Harvey Goranson, P.E.
Fire Protection Specialist
Professional Loss Control Co.

Emil Golias, Industrial Hygienist
Occupational Safety and Health Administration

Donna Beth Howe, Ph.D., Health Physicist
USNRC Headquarters

Sal Comodo, Inspector
U.S. Food and Drug Administration

William Brinck, Specialist
U.S. Environmental Protection Agency

John Bosky, Environmental Engineer
U.S. Environmental Protection Agency

Approved By: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety and
Safeguards Branch

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. <u>Radiation Safety Committee</u>

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. <u>Exposure Controls - Internal</u>

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	19(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. The 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	0.5 mr/hr
facility conformance calibration lab J. L. Shepherd cs-137 calibrator (1 curie as of 7/22/83) - surface	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. <u>Organization, Emergency Plan and Procedures</u>

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. <u>FDA Effort/Product Evaluation</u>

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^R PYP, Sodium Iodine^R I-131 Capsules [therapeutic], and the Ultra-TechneKow^R FM generators) for evaluation; examining customer complaint files for incidents of misadministrations, radioactive surface contamination, high transportation indexes, and trends; observing the Ultra-TechneKow^R 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^R FM generators, and a small volume parenteral product, and a "New Drug Approval" (NDA) inspection for the TechneKow^R 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[R] 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[R] 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[R] 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.

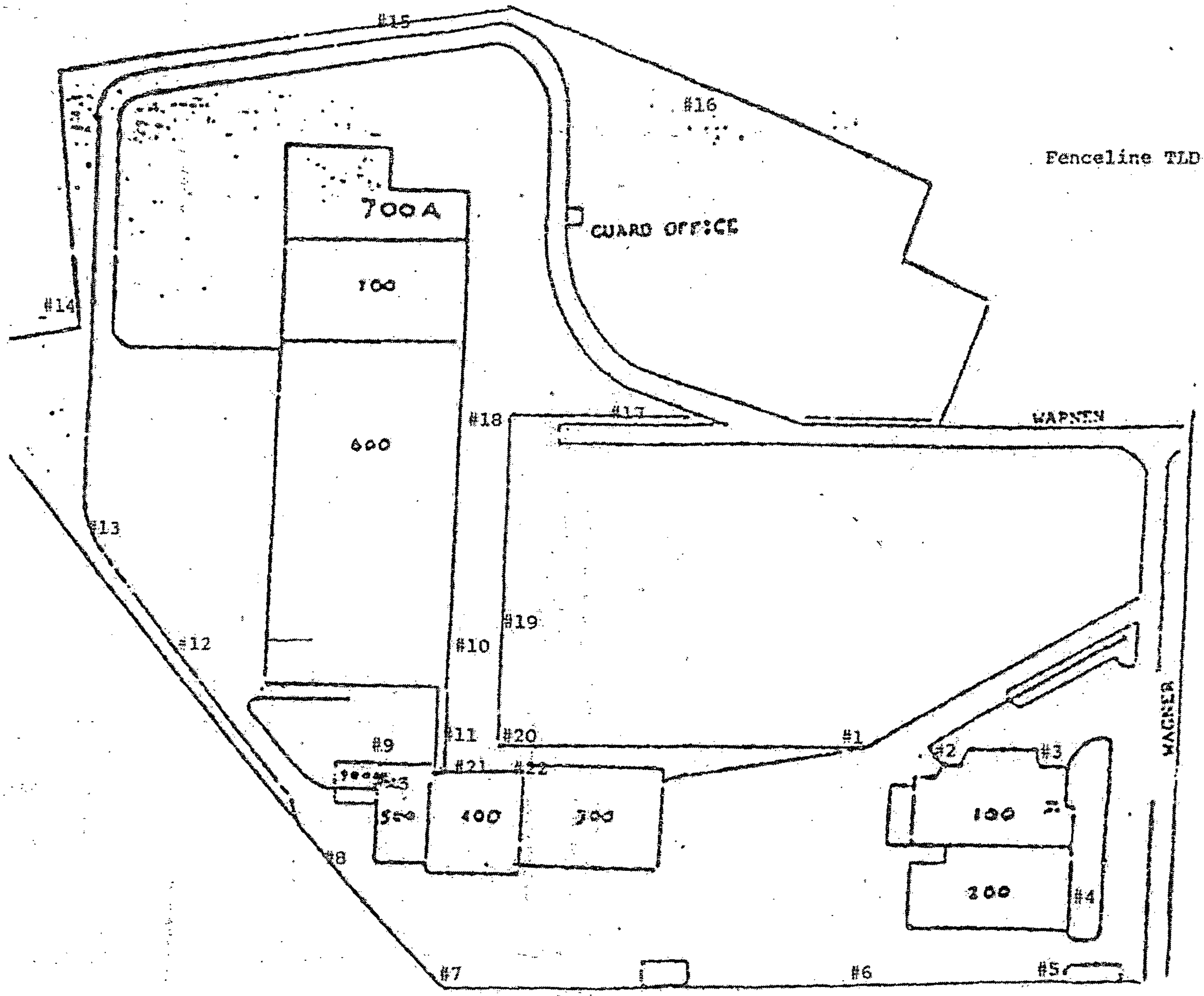
10. <u>Exit Interview</u>

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.

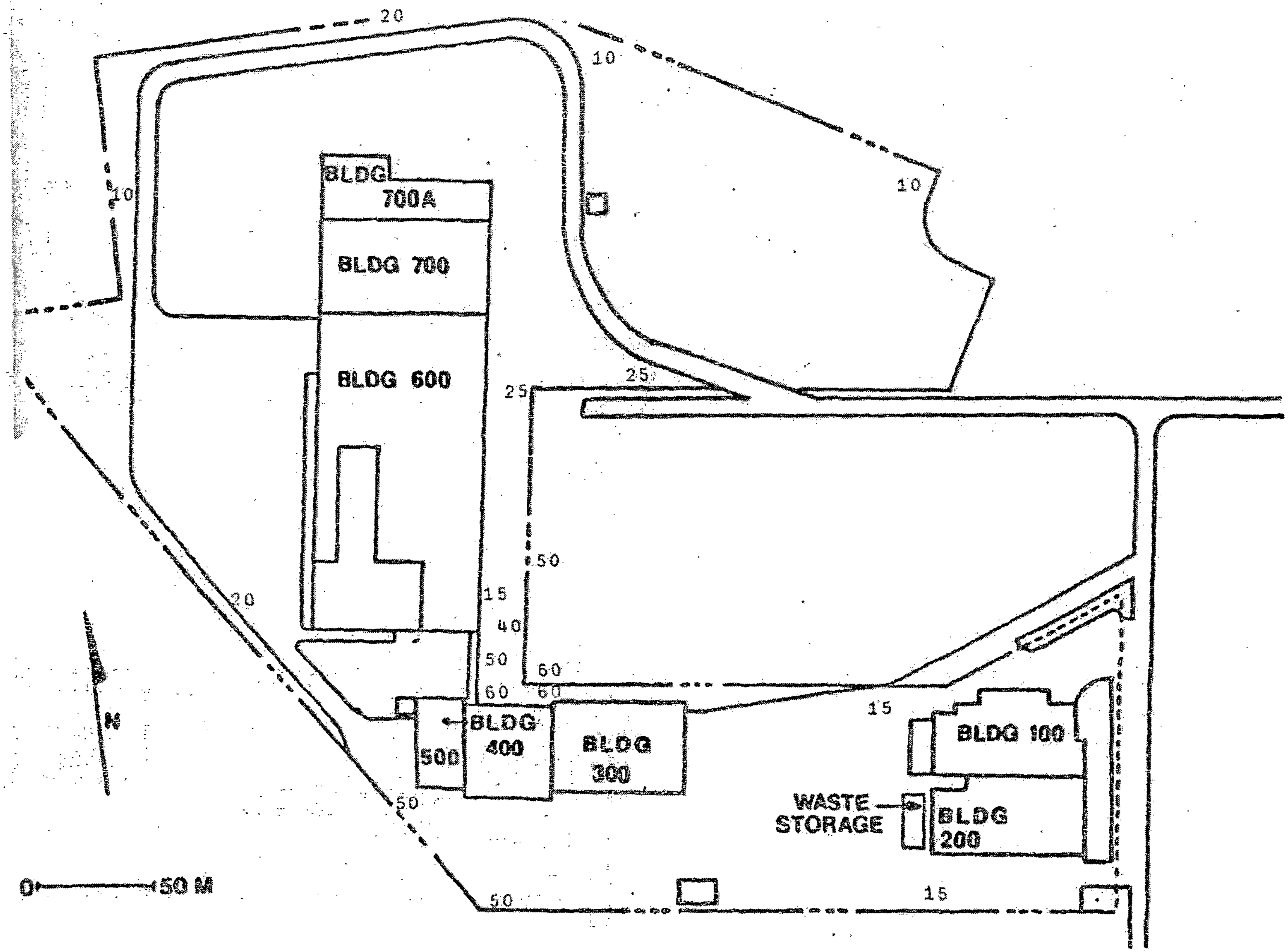
Attachments:
1. Fenceline TLD Locations Map
2. Results of Radiation Surveys
3. Reevaluation of Fire Protection at Mallinckrodt, Inc.
4. OSHA Ltr dtd 05/26/88

Fenceline TLD Locations Map



ATTACHMENT 1

ATTACHMENT 2



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

ATTACHMENT 3

PROFESSIONAL LOSS CONTROL, INC.

RE-EVALUATION OF FIRE PROTECTION

AT

MALLINCKRODT, INC.

DIAGNOSTIC PRODUCTS DIVISION

2703 WAGNER PLACE

MARYLAND HEIGHTS, MISSOURI 63043

Submitted: May 31, 1988

Revision: 0

Prepared by: Harvey Goranson

Harvey E. Goranson, P.E.
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Appendix A - Evaluation of Corporate Center

RE-EVALUATION OF FIRE PROTECTION
AT
MALLINCKRODT, INC.
DIAGNOSTIC PRODUCTS DIVISION
2703 WAGNER PLACE
MARYLAND HEIGHTS, MISSOURI 63043

1.0 INTRODUCTION

An inspection of the captioned facility was conducted on May 16-17, 1988, to evaluate the plant's capability to protect against and handle radiological emergencies. Professional Loss Control, Inc., (PLC) was contracted by Oak Ridge Associated Universities (ORAU) to evaluate the fire protection program at this location, including fire protection systems and equipment, hazards, construction, exposure, and fire department response. This report details the results of that survey.

Mallinckrodt personnel contacted during this survey include the following:

Roy W. Brown	- Manager, Regulatory Compliance
Albert Ball	- Plant Manager, Mallinckrodt
John R. Adams	- Manager, Plant Services, Mallinckrodt
James Rogers	- Supervisor, Security

Mr. Adams is responsible for matters affecting fire protection at the property.

Mallinckrodt's Maryland Heights facility produces and distributes radiopharmaceuticals, technetium kits, and immunoassay kits for a world-wide market. Process and laboratory operations are conducted using hot cells and enclosed gloveboxes. Two small cyclotrons are used to produce certain radioisotopes on site; other radioactive materials are shipped to the site.

2.0 DESCRIPTION OF THE FACILITY

2.1 Construction

Buildings are of predominantly noncombustible construction. Walls are typically nonbearing hollow concrete block adjacent to unprotected steel columns, although the north and south walls of Building 400 are metal with vinyl-backed fiberglass insulation. Floors are concrete on earth or concrete on unprotected steel beams. Roofs are composition covered and insulated unprotected steel decks, except that Building 400 has a metal deck roof on steel purlins and beams with fiberglass insulation below the metal roof surface.

Building 250 differs from the above in that it is constructed of 16-inch solid concrete block walls supporting precast concrete roof planks.

Interior finishing consists of noncombustible drop ceilings, sheetrock ceilings, and sheetrock on steel or wood stud partitions. Warehouse and waste handling areas are typically unfinished.

Elevators and stairways are enclosed by masonry shafts. Elevator doors are metal. Stairway fire doors, where installed, are UL listed with a 1-1/2 hour rating. In Buildings 100 and 200, some fire doors were either not installed or did not close properly.

Buildings 100, 100A, and 200 are considered to form a single fire division having a ground floor area of 30,251 sq. ft. Former fire walls have not been maintained; however, this is not considered to be a problem due to the high degree of compartmentation, relatively light hazard occupancy, and sprinkler and/or fire detection systems covering most areas.

Building 250 is a fire division separated from other buildings by open space.

Buildings 300, 400, and 500 are considered a single fire division having ground floor area of 29,500 sq. ft. The masonry wall between Buildings 300 and 400 has three openings provided with fire doors. Two of these are 3-hour rated sliding doors with minor deficiencies in the installation of fusible links per NFPA 80. The third door is a single swinging fire door which has been degraded by the installation of a wired glass window in the door. This masonry wall is 8 inches thick and appears to be of unlisted hollow concrete block construction. While not a standard 3-hour fire barrier, this wall may have at least a 1-1/2 hour fire resistance. The masonry wall between Buildings 400 and 500 has unprotected openings. Upgrading both walls to a 3 hour rating does not appear to be warranted due to the installation of sprinklers in all buildings and relatively low values in this structure relative to other buildings on the property.

Building 500A is separated by an 8-inch hollow concrete block wall from Building 500. This should provide at least 1-3/4 hour fire resistance which is adequate due to the low combustibility in Building 500A.

Buildings 600, 700, and 700A have continuous exterior walls. The first floor of Building 600 (65,664 sq. ft.) is separated into approximately equal areas by an 8-inch hollow concrete block wall with a 3-foot parapet. The south area contains production facilities; the north area is a warehouse. The division wall has six openings protected by fire doors: two are 3-hour rated sliding type, one is 3-hour rated single swinging, and three are 1-1/2 hour single swinging. One door was observed to be blocked open. The sliding doors are slightly nonstandard in that links are not provided on the opposite side of the wall (one door has no closing device) and electric actuating mechanisms have been attached to one of the doors. This latter modification should not abnormally affect the doors. The three 1-1/2 hour doors are to the penthouse stairway, lunchroom (19A), and door No. 11A. The penthouse extends over this wall; neither the wall nor the parapet are extended into the penthouse.

Building 600 contains a high concentration of values and is critical to Mallinckrodt's operations. Maintenance of a fire wall between the two one-story sections is considered necessary although it would not appear justified to extend this wall through the penthouses due to the low combustibility of this area.

The small hydrogenerator room on the east side of Building 600 is cut off by a masonry wall with a 3-hour door. Building 700-700A is a single fire division and communicates with Building 600 through a single sliding fire door and one swinging 3-hour door. THe sliding fire door is in poor repair. The rating of materials used in the parapeted concrete block wall separating Buildings 600 and 700 was not available. Due to high values, maintenance of a fire wall between these buildings is considered necessary.

2.2 Occupancy

The buildings at this facility are occupied as follows:

Buildings 100 & 200	- Administrative offices, quality control laboratories, health physics offices, other laboratories, records storage, and maintenance shop
Building 100A	- Storage of lab equipment (2nd) and vacant (1st to be maintenance shop)
Building 250	- Storage of radioactive "hot" waste materials. These are allowed to decay to an environmentally safe level prior to disposal.
Building 300	- Dispensing, order pulling, packing, and shipping.
Building 400	- Warehousing, order staging, and shipping.

Building 500	- Waste processing and reclamation. Technetium generators are pulled apart. The plastic case, lead container, and other materials are salvaged. Liquids are stored in holding tanks.
Building 500A	- Contains one 10,000 gallon waste holding tank and other waste materials in plastic jugs.
Building 600	- Production and warehousing of radiopharmaceuticals. Warehousing is considered to be high rack storage. Maintenance operations are conducted on a central mezzanine. Production areas utilize gloveboxes and hot cells with remote manipulator arms.
Buildings 700 & 700A	- Cyclotron operations used to manufacture radioisotopes. 30-Kev and 40-Kev cyclotrons are each located in concrete bunkers having 7-foot walls and 5-foot ceilings. Hot cell processing of thallium and gallium targets from the cyclotrons. Warehousing is considered to be high rack storage. Welding shop is located in Building 700A.

2.3 Hazards

The hazards at this facility include high stock storage, use of flammable liquids, high voltage electrical equipment, boilers, combustible metals, and maintenance activities.

Stock Storage - NFPA 13 provides guidelines for the installation of sprinkler systems. However, the designs in this standard do not contemplate storage in excess of 12 feet in height on pallets in piles or on racks, or solid pile storage over 15 feet high. Storage above these levels would be governed by NFPA 231 and 231C. Also, NFPA 231C does not consider predominantly plastic or flammable materials. Where plastics or flammables are stored, the guidelines of Factory Mutual (FM) or Industrial Risk Insurers (IRI) should be followed.

Several areas of the plant property contain storage in excess of NFPA 13 requirements, and some of this storage includes plastics and flammable liquids.

In Building 400, plastic materials re stored in boxes in a small solid pile 10 feet high. These materials are foamed polystyrene shipping carton inserts for the technetium generator kits. The sprinkler system in this are is of ordinary hazard design and does not contemplate storage of plastic materials in piles exceeding 5 feet. Due to a good water supply, 5-head branch lines, and the small size of the pile (under 300 sq. ft.), no recommendation has been made.

In Building 500 returned technetium generators are stored on a 4' x 40' rack up to 16' high. The generators are contained within high-density plastic containers. The sprinkler system is designed using the extra hazard pipe schedule of NFPA 13. Due to the pipe sizing used, a good water supply, and relatively small rack, additional protection is not considered necessary. Bags of polystyrene chips are stored in the nonsprinklered liquid waste pit. A postulated fire in this material could spread undetected.

The north one-half of Building 600 is the principal warehouse of this facility. It is equipped with hydraulically calculated sprinkler systems, draft curtains, and automatic roof vents. Various commodities are stored up to 20 feet high on double-row racks with 8-foot aisles. However, these aisles are not always maintained as some stock was stored within the aisles. Such storage may allow a fire to cross the aisle easily and spread a fire to an adjacent rack. Sprinkler lines run perpendicular to racks, and this improves sprinkler hydraulics during fire conditions.

Commodities stored include lead, cardboard packing materials, tape, plastic containers (probably polyethylene), decaying technetium generators having a plastic case, drums of nonflammable liquids, and nonflammable chemicals. A few plastic pallets are in use. A designated 4' x 8' x 10' high rack is used to store ethyl alcohol, benzyl alcohol, isopropyl alcohol, hexane, and combustible ink in small containers (typically 4-liter glass bottles in cardboard boxes). This area is to be kept clear of stock for at least 10' surrounding the rack.

The north portion of the warehouse is hydraulically calculated to provide a minimum water application of 0.40 gpm/sq. ft. over the most remote 3750 sq. ft. HOst of the south portion of the warehouse is calculated for 0.24 gpm/sq. ft. of 4000 sq. ft. A small portion of the warehouse area along the west wall is calculated for 0.40 gpm/sq. ft. over 2340 sq. ft.

The presence of plastics in a high rack warehouse such as this introduces a severe hazard if a fire cannot be controlled in its early stages. Without prompt control the fire can spread rapidly prior to sprinkler operation and cause a large number of sprinklers to fuse. Depletion of water supplies may result and the sprinklers would be unable to control the fire.

Using NFPA 231C as a guide, the north portion of the warehouse should protect rack storage of ordinary commodities having an appreciable amount of plastics (Class IV commodities) up to 19 feet high. The south portion should protect Class IV commodities up to 12 feet high. If the amount of plastics are limited (Class III commodities), then stock may be stored up to 22' in the north 17.5' in the south portions of the warehouse.

The percentage of plastics stored in Building 600 is not known. If under 15%, the rules for Class IV commodities should be followed. If over 15% plastic, the rules contained in FM 8-9 should be followed.

Minor amounts of combustible filters and glass bottles in boxes are stored in the mechanical equipment penthouse of Building 600. Drums of lubrication oil (four 30-gallon, one 55-gallon, and two 5-gallon) are stored near the stairway entrance to this area.

The southeast corner of Building 700 is a warehouse with a similar arrangement to that in Building 600. Storage includes syringes, various chemicals, several finished products in plastic containers (Class IV), and empty plastic containers. Storage is up to 16' high. The sprinkler density is not known although the system appears to be hydraulically calculated.

Oxidizers (nitric acid, hydrogen peroxide) are stored separately from other reactive materials. Two cases of hexane were discovered in the same rack as nitric acid; this condition was brought to the attention of the warehouse supervisor and corrective action was promised.

Flammable liquids - In several maintenance, laboratory, and process areas (particularly Building 600) flammable liquids are dispensed from original containers, typically 4-liter glass bottles. Due to FDA restrictions on product quality control, any of these substances used in a final product cannot be dispensed into another container for use during manufacture. This would prohibit use of safety cans for these materials. However, liquids used as solvents during cleanup should be dispensed from safety containers.

On the first floor of Building 100, paints, thinner and lubricants are stored in original containers on an open shelf, one non-standard cabinet, and one labeled flammable liquids cabinet. This storage includes six cartons containing aerosol spray enamel. Thinner is kept in a 5-gallon safety can, but remaining materials (epoxy solvent, paint remover, ethyl alcohol, etc.) are stored and presumably dispensed from original containers. Although this storage is in a separate room, a standard flammable liquids storage room complying with NFPA 30 has not been recommended due to the small quantities involved.

Flammable liquids in laboratory and process areas are kept in standard ventilated cabinets which are prominently marked. Liquids include various alcohols, acetone, toluene, cyclohexane, and ether.

It was stated that no flammables are used in the unprotected hot cells except for cell No. 3 in Building 700. Ether in quantities not exceeding 30 ml. is used in this cell. There is an electric hot plate within the cell that is UL listed for flammable atmospheres (Class I, Group D). Approximately three years ago a small fire occurred in this cell when the ether flashed over. This fire burned out quickly and did not spread to the filter units. It should be noted that several of the cells and gloveboxes contain electrical equipment and plastic materials.

High Voltage Electrical Equipment - The Building 600 penthouse contains several high voltage motor control circuits for the HVAC and air filtration units. Building 700/700A contains the mechanical equipment, two cyclotrons, their control consoles, and related circuitry. Sprinklers are omitted from these areas and portable extinguishers are provided.

Boilers - Two boilers (5021 MBH and 1339 MBH capacity) are located in an HCB enclosed room in the penthouse of Building 600. Boilers have standard gas fuel train equipment including double block and bleed. The room is cut off by an oversized unlabeled metal door and a swinging metal door.

Combustible Metals - Sodium is used in the capsule production area of Building 600. Glass jars of sodium are kept within a portable metal container. Protection against moisture is considered adequate. A class 'D' extinguisher, used to combat metal fires, is in the area.

Maintenance Activities - A maintenance shop is located on the first floor of Building 100. Woodworking processes are conducted in this area occasionally and consist of, among other things, cabinet manufacture for the lab areas. These cabinets are typically covered with formica. Housekeeping at the time of the survey was good. It was stated that this operation may be moved from this sprinklered area to the nonsprinklered first floor (detection only) of Building 100A. If this move occurs, an exhaust system for the woodworking machines is to be installed.

Maintenance activities include painting using enamel in spray cans and latex paints in 1-gallon cans. The paint storage hazards were discussed previously. There is no evidence of spray painting operations being conducted in the maintenance shop on a regular basis.

2.4 Exposures

These buildings are located in an industrial neighborhood. South of Building 300 and 150' away are three 500,000 gallon tanks containing automobile oil. These tanks are surrounded by a 4-foot earth dike on three sides and a 6-foot concrete dike to the Mallinckrodt property. East of these tanks are nine similar tanks no smaller than 150,000 gallons each without a diked enclosure. The Pennzoil Corp. oil processing plant (sprinklered) which utilizes this oil is 75' south of Building 200. A railroad siding is also located on the south.

East of the plant property and over 50' away is a plastics processing plant. North of Building 300 (32') and east of Building 600 (55') is a sprinklered cardboard box manufacturer.

A buried Shell Oil Company pipeline extends through the property on a right-of-way between Buildings 250 and 300. A railroad siding for the box plant is located between Buildings 500 and 600.

Overall, the exposure is considered severe, principally due to the close proximity of railroad sidings and the box plant, as well as the oil tanks on the south.

2.5 Existing Fire Protection

Fire protection systems and equipment at this plant include sprinklers, fire alarm systems, and extinguishers. Defense against fire also relies on fire department response, preventive maintenance of equipment, and 24-hour watchman service.

Sprinklers - Sprinkler protection is provided throughout the facility. Where piping was visible, the installation appears to follow NFPA 13 guidelines for ordinary hazard occupancies. Exceptions are Building 500 (extra hazard pipe schedule), Building 600 Warehouse (hydraulically calculated - densities described under section 2.3 of this report), and Building 700 Warehouse (hydraulically designed - density unknown).

Numerous minor deficiencies exist in the sprinkler protection. These include sprinklers obstructed by lights, ducts, beams, partitions, etc.; small areas not sprinklered; missing ceiling panels; and sprinklers too far below the ceiling. Several of the nonsprinklered ares have heat detection to a central station alarm service. While not as desirable as sprinklers, this is acceptable.

Missing ceiling panels are a deficient condition as this allows heat to escape to the ceiling space, bypassing the sprinkler fusible element. Similarly, sprinklers installed too far below the ceiling will take a longer period of time to actuate as the heat will not build up near the sprinkler.

Deficiencies in sprinkler protection are as follows:

Building 100/100A	- Nonsprinklered areas (some have fire detection) including the first floor maintenance shop and HP areas. - Sprinkler blocked by duct outside HP office in hallway. - Two sprinklers blocked by lights in HP sampling lab (system needs to be redesigned to provide proper coverage). - Sprinklers are obstructed in the maintenance shop paint storage room.
Building 200	- Nonsprinklered areas (some have fire detection). - Two sprinklers blocked by lights in the Animal Test Lab (or reduce or remove obstructions from light units). - Nonsprinklered cooler in first floor QC lab (detection installed). - Partitions obstruct sprinkler spray patterns and create nonsprinklered areas in a hallway on the second floor near the southeast stairway (including a nearby office) and on the first floor lobby near the base of these stairs.
Building 250	- Nonsprinklered building (justified due to low combustibility and low value).
Building 300	- Nonsprinklered offices and adjacent telephone equipment rooms. - Need additional sprinkler in the passage to the dispensing order office. - Partition blocks one sprinkler in the shipping department office.
Building 400	- Nonsprinklered cooler (detection installed).
Building 500	- Nonsprinklered liquid waste pit (this area normally has a very low fire loading and this omission is justified due to the need for control of liquids in radioactive waste areas. However, bags of polystyrene should be removed from this area). - Nonsprinklered office on mezzanine.

Building 500A	- Nonsprinklered building (justified due to low combustibility and cutoff from Building 500).
Building 600 (Penthouse)	- Nonsprinklered monitor room. - Sprinklers capped over control circuit boards. (The water released by sprinklers will be in a fine spray which is not conductive. Omission of sprinklers above these boards is not justified but may be required by the fire marshal.)
Building 600 (Lab Areas)	- Nonsprinklered coolers, sterile areas, hot cells, gloveboxes, and tunnel to Building 400. - A plastic curtain blocks three sprinklers in the Sublimator Room (Room 9P). - The nonsprinklered ceiling space was observed to contain combustible trash and a chair.
Building 600 (Warehouse)	- Nonsprinklered warehouse office, QC offices, cooler below mezzanine (with detection), cooler in northeast corner (no detection), and manipulator arm repair room on mezzanine. - Nine sprinklers are about 24" below the ceiling over the maintenance shop. - Light blocks sprinkler in hydrogenerator room.
Building 700/700A	- One sprinkler blocked by exit sign in the corridor near Door No. 715. - Nonsprinklered gloveboxes, hot cells, cyclotron vaults (detectors), and cyclotron control and switchgear room (detection). - Three sprinklers are over 7-1/2 feet from a partition in Room 709. - Mechanical equipment rooms are not sprinklered.

Water over 12 inches deep was noted in the valve pit for Buildings 300/400/500. This standing water can cause corrosion problems for the sprinkler supply piping and valves located within the pit.

Fire alarm systems - All fire alarms are monitored by Central District Alarm (CDA), a UL listed central station. These alarms include smoke detectors, heat detectors, manual pull alarms, boiler monitoring, sprinkler waterflow, and valve tamper switches. Upon alarm receipt CDA notifies the local fire department. The alarms are not monitored locally. Sprinkler systems are provided with outside water motor alarm bells.

Heat detectors are installed in several offices and labs in Building Nos. 100/100A/200, several coolers, and mechanical equipment areas of Building 700A. Most heat detectors are typically Alarm Device Mfg. Co. Model 502. This detector has a listed spacing limit of 20 ft. between detectors and 10 ft. from walls and partitions. These limits are exceeded in Building 100 (former Invitro Lab, 35' x 25'). On the first floor of Building 100A two detectors are mounted on the bottom of beams spaced 6 ft. apart, forming 5 beam pockets. Detector spacing is about 29' x 32'. Three detectors should be installed (one in every other beam pocket) unless sprinklers are to be installed. The two existing detectors can then be removed.

In Building 400 a detector for a 14' x 30' cooler is installed 16" below the ceiling. NFPA 72E requires wall-mounted detectors to be from 4" to 12" below the ceiling.

Smoke detectors are installed in the vaults, control rooms, and electrical equipment rooms for the cyclotrons in Building 700/700A. In the mechanical equipment areas of Building 700A detectors are mounted on the bottom of beams and steel bar joists.

Manual pull fire alarm stations are provided throughout most buildings.

Extinguishers - Fire extinguisher types at this facility include CO_2, pressurized water, and dry chemical. These extinguishers are checked monthly by plant personnel. A more detailed check is conducted yearly by plant personnel, including weighing of the cylinders. As hydrostatic tests are needed they are conducted by an outside contractor. Tags on the extinguishers indicate they were inspected in May, 1988.

Extinguisher distribution is generally adequate although some deficiencies exist where CO_2 extinguishers are not augmented by extinguishers for Class 'A' fires. No extinguishers are provided for Building 250, but the possibility of fire in that building is considered low. A Class 'D' extinguisher is provided in Building 600 where sodium is in use.

Inside manual hose stations, each with 75 feet of hose, are provided in Building 300, 400, and 500, and the warehouse areas of Buildings 600 and 700.

Halon 1302 extinguishers are not desired by plant personnel in computer and electrical areas due to presumed toxicity problems concerning its use on electrical fires. However, recent Dupont data indicates this toxicity, if any, is no more dangerous than the fire gases themselves.

Fire Department Response - The Maryland Heights Fire Department (Station No. 1) is located 0.6 miles from the plant. A conversation with Captain Robert Brengartner revealed a high degree of familiarity with the Mallinckrodt property.

Mallinckrodt has prepared a set of drawings for fire department use showing where radiological hazards, valves, etc., are located. These diagrams are kept at the Mallinckrodt guard house and in the cab of the first responding engine company.

Mallinckrodt conducts yearly evacuation drills,usually in August. The drill scenario usually involves a response from the fire department although this does not appear to be required. After the drill, the fire department members tour the facility to reinforce familiarity with the buildings.

There is no formal pre-fire plan for this facility maintained by the fire department. Although this is advisable, preparation of such pre-fire plans would be the responsibility of the fire department and as such no recommendation for Mallinckrodt would apply. The normal response would consist of three pumpers, one pumper-ladder unit, and one ambulance. The personnel on the first-in company will stop at the guard house and get film badges prior to entry to the property. In an emergency, HP personnel wear orange vests and the fire department will contact an HP prior to building entry, unless a severe emergency exists.

Backup response is available from Maryland Heights Fire Department Station No. 2 and the Overland Fire Department (West Overland Station).

Preventive Maintenance and Other Items - Besides the monthly and yearly extinguisher checks, other periodic inspections of fire protection equipment take place. CDA tests the central station alarm devices monthly. IRI visits the property semi-annually. Yearly, the valve pits are checked and hydrants flushed.

Mr. Adams maintains a log of all of these activities, including visits from the fire department.

A Halon 1301 extinguishing system is to be installed in the Building 300 computer room, including the underfloor space.

Watchman Service - Periodic rounds are conducted using guards from National Industrial Security Corporation. A watchman's clock is used to record tours between various key stations. Clock tapes are checked and attached to watchman's reports filed in Mr. Adams' office. Rounds typically occur 13 times per working day and 18 times per non-working day.

3.0 CONCLUSIONS AND RECOMMENDATIONS

The primary fire protection concern in this facility is that any postulated fire cannot result in the uncontrolled release of radioactive material. Secondary concerns include limiting fire and water damage to an acceptable level, and compliance with applicable codes and standards.

Some of the recommendations of this report are based on information contained in "Fire Prevention and Protection in Hot Cells and Canyons" by Arthur J. Hill, Jr., dated April, 1971. Also used as references are the following standards published by the National Fire Protection Association (NFPA) and Factory Mutual (FM):

NFPA 10-1984	Standard for Portable Fire Extinguishers
NFPA 13-1987	Standard for the Installation of Sprinkler Systems
NFPA 72E-1984	Standard on Automatic Fire Detectors
NFPA 80-1986	Standard for Fire Doors and Windows
NFPA 231-1987	Standard for General Storage
NFPA 231C-1986	Standard for Rack Storage of Materials
FM 8-9	Solid, Palletized, and Rack Storage of Plastics

Overall this facility has a high degree of protection against fire hazards and would be considered a "Highly Protected Risk." Several improvements since the 1986 evaluation have been noted. The following recommendations will enhance the existing fire protection program. Particular attention should be given to Recommendations 3.1 and 3.2

3.1 The hazards of high stock piling and plastic storage should be reduced as follows:

3.1.1 Remove bags of polystyrene chips from the liquid waste pit of Building 500 since this area has no sprinkler protection. (Mr. Adams stated this would be completed immediately.)

3.1.2 In Buildings 600 and 700 warehousing procedures should be reviewed to ensure that all flammables and oxidizers are stored in their designated areas, and that adequate space is maintained from flammables. These procedures should also address the practice of temporarily storing stock in aisles, and this practice discontinued.

3.1.3 In Building 600 all plastics and products containing more than a limited amount of plastic should be stored in the north portion of the warehouse. If the percentage of purely plastic products in the north section then exceeds 15%, the system should be hydraulically redesigned in accordance with FM 8-9 to protect rack storage of plastics. This will necessitate the installation of in-rack sprinklers or sprinkler protection of exposed steel columns, and will require verification that the existing sprinkler system will provide a density as high as 0.60 gpm/sq. ft. over the most remote 2500 sq. ft. area.

If plastics are found to constitute less than 15% of the commodities stored, stock storage levels in the north portion of the warehouse should be limited to 19 feet in height (limit for Class IV commodities in this area).

The south portion of the warehouse should be limited to Class III commodities. (NFPA 231C defines these as ordinary combustibles (wood, cloth, paper, etc.) with a limited amount of plastics. Stock levels should be limited in this area to 17.5 feet in height. An alternative would be to complete IRI Recommendation 86-1.

(NOTE: This recommendation and Recommendation 3.1.5 are to receive attention. Sprinkler systems in the warehouse areas are to be redesigned and modifications completed by July, 1988.)

3.1.4 Excessive quantities of combustible oil, filters, and bottles in combustible packaging in the Building 600 penthouse should be removed. ("Excessive" is considered to mean any quantities above those needed for one month's use in this area).

3.1.5 The design density for the warehouse portion of Building 700 should be determined. Once this is known, an analysis similar to that presented in 3.1.5 should be conducted. In the interim, plastics should be removed to the north portion of Building 600. Storage heights in Building 700 should be limited to 19 feet for Class IV commodities. (See note under Recommendation 3.1.3.)

3.2 To limit the possibility of radioactive release to the environment from fire department operations, some form of fire suppression and/or detection should be considered for the hot cells. This is recommended in Hill's paper and is also standard procedure in DOE facilities, such as Oak Ridge National Laboratories. Due to the low quantities of combustibles within most cells, their small size, and sprinkler protection outside the cells, fire suppression may be omitted within the cells. Detectors should be located within the cells and their associated exhaust ducts. Duct detectors should be listed for such installation. These detectors should transmit a distinct, separate alarm to the central station. Preferred detector types are rate compensation (where flammable liquids are used) and ionization smoke detectors (Pyrotronics high voltage or equivalent). Detectors should be suitable for high-rad environments.

Fire suppression and detection is not considered necessary for the gloveboxes. In an emergency, extinguishing agents can be inserted through the glove location.

Since fire suppression systems can be omitted from the cells, it would be advisable to place a small open can of dry chemical powder or hose line from any faucets for use in extinguishing small fires within each cell. Such extinguishment would take place manually using the remote manipulator arms.

Acceptable forms of automatic fire extinguishment (if installed) would include a wet pipe sprinkler system, a self-restoring wet pipe or pre-action sprinkler system, or a Halon 1301 extinguishing system. Halon 1301 is expensive, but there is virtually no clean up problem to deal with following actuation. Sprinkler systems are less expensive, but the water release may result in costly clean up procedures later. Pre-action or self-restoring systems will result in less water release and also reduce the possibility of accidental (non-fire) water release.

Carbon dioxide extinguishing systems were not considered due to the life safety hazards to personnel from a major CO_2 release. Dry chemical systems are unacceptable due to clean up problems associated with system discharge.

3.3 Standing water was noted in the valve pit for Buildings 300/400/500. This water should be pumped out and drainage within the pit improved.

3.4 Numerous minor deficiencies in the sprinkler system installation should be corrected. These are defined in Section 2.5 of this report and include:

3.4.1 Obstructions to sprinkler water distribution by light fixtures, partitions, ducts, and drop ceilings in Buildings 100, 200, 300, 600, and 700. Correction involves relocation of either the sprinkler or the obstruction.

3.4.2 Nonsprinklered areas in Buildings 100, 200, 300, 500, 600, and 700A. Any areas having properly installed central station fire detection may be omitted from this recommendation.

3.4.3 The trash can and chair should be removed from the ceiling space above Building 600 laboratories. The sprinkler design for this area (which omits sprinklers in noncombustible spaces) does not contemplate such storage.

3.4.4 Sprinklers should be provided in the mechanical equipment areas of Building 700A. Such protection would be in addition to detectors which are already installed in this area.

3.4.5 Missing ceiling panels. These should be replaced in the rear second floor area of Building 100.

3.4.6 Sprinklers at excessive distances below the ceiling. Sprinklers over the Building 600 mezzanine should be relocated to be within 16 inches of the ceiling. Where this relocation results in beams blocking water spray from sprinklers, additional sprinklers should be provided in the beam pockets.

3.5 Integrity of fire walls and vertical openings should be improved as follows:

3.5.1 Employees should be notified that fire doors are not to be blocked open. Fire doors should be prominently marked.

3.5.2 Consideration should be given to upgrading the walls between Buildings 600 and 700, and between the warehouse and production areas of Building 600, to a 3-hour rating. This will necessitate replacing any fire doors that are damaged or not at least 3-hour rated, revising sliding doors to conform to Figure A-36 of NFPA 80, and verifying a 3-hour fire resistance for wall materials. If the block walls have less than a 3-hour fire resistance, they should be coated with at least 1/2-inch of plaster on each side.

3.5.3 All stairwells should be protected by 1-1/2 hour self-closing fire doors. Any doors that do not close properly should be adjusted. This recommendation applies to Buildings 100 and 200.

3.5.4 The wall between Buildings 100 and 100A should be upgraded to a 3-hour fire wall, combustibles removed from Building 100A, or sprinkler protection extended to Building 100A.

3.6 Additional dry chemical (ABC) extinguishers should be provided where the travel distance to a Class A rated extinguisher or hose station exceeds 75 feet.

3.7 Flammable liquids used in clean up or other operations not affecting the final product should be dispensed from UL listed self-closing containers (this applies to all shop and lab areas). In the maintenance shop all unneeded flammable or combustible liquids should be properly disposed of. Cans of spray paint should be removed from all combustible packaging. Spray paint and all other flammables should be stored in UL-listed or FM-approved storage cabinets.

3.8 The heat detectors in the former Invitro Lab should be spaced in accordance with their listings (which will require three additional detectors) or sprinkler protection extended to this area.

3.9 The heat detector in the cooler in Building 400 should be relocated to the ceiling, or on the wall within 12 inches but over 4 inches below the ceiling.

3.10 Thermal detectors on the first floor of Building 100A, below the roof of the Building 700A mechanical equipment room, and below the Building 700A mezzanine should be relocated from the bottom of beams or joists to the beam pockets. Additional detectors to meet the spacing requirements of the respective detector listings may be necessary to meet NPFA 72E requirements.

APPENDIX A

APPENDIX A

Evaluation of Corporate Center

675 McDonnell Blvd.

Hazelwood, MO 63134

1.0 SUMMARY

As part of the evaluation of Mallinckrodt's Maryland Heights facility, a visit was made to the corporate headquarters location to determine the degree of fire safety for radiological hazards in laboratories at that facility. This evaluation was limited to the west half of Building No. 20. Mallinckrodt employees contacted during this evaluation included James Peterson (Director, Technology Planning & Administration) and Karla Drenner (Laboratory Safety Officer).

Laboratories and adjacent areas were inspected on floors 1, 2, and 3. On August 2, 1984, a fire occurred in the second floor in-VIVO radiological lab. The cause of the fire is believed to have been spontaneous combustion in the HEPA filter unit charcoal. Following this fire, automatic sprinklers with manual shutoff valves were installed in all radiological ventilation systems.

The hazards noted in the laboratory areas relate to the use and storage of flammable liquids, combustible metals, and oxidizing agents. Bulk storage of flammable liquids is properly controlled. A first floor flammable liquids room has a 3-hour fire door mounted above a 6-inch sill, explosion vents to the outside, floor level mechanical ventilation, enclosed lights, and adequate provisions for bonding and grounding.

In laboratory areas flammable chemicals are generally stored in approved cabinets. In many cases these cabinets are ventilated to the outside. Dispensing is from original containers which introduces the hazard of an uncontrolled spill. Waste cans have self-closing lids. Waste chemicals are disposed of in ordinary 5-gallon containers, but this process is to be changed.

Available information indicates the sprinkler system was designed for a light hazard density of 0.10 gpm/sq. ft. over the most remote 1500 sq. ft. This density may be inadequate for laboratories utilizing flammable liquids and the maintenance shop area where woodworking operations are conducted.

2.0 RECOMMENDATIONS

2.1 Flammable liquids used in clean-up or other operations not affecting the results of an experiment should be dispensed from safety containers having spark arrestors and self-closing caps. This will reduce the potential for a spill fire. Bulk storage of flammables should be limited to the first floor solvent room with quantities for use dispensed into safety cans within this room.

2.2 Combustible metals such as sodium should be stored separately from solvents, oxidizers, and solutions containing water to limit the possibilities for ignition. The storage cabinet should be prominently marked and a Class D extinguisher located nearby. The storage cabinet should prevent the penetration of water from sprinklers or other sources.

2.3 Oxidizers should be stored in a location physically segregated from organic chemicals. (During the survey, nitric acid was found stored next to oil cans). This segregated area should be prominently marked.

2.4 To accomplish 2.1, 2.2, and 2.3 above, consideration should be given to having centralized control of all chemical purchasing, storage, and issuance. In this way the segregation and limitation of hazards from chemicals can be controlled.

2.5 The present plan to replace ordinary metal 5-gallon liquid waste cans with non-reactive safety cans should be instituted as soon as possible to limit flammable liquid exposures at laboratory work stations.

2.6 Mallinckrodt should review the sprinkler design of this facility with Industrial Risk Insurers to determine if the proper ceiling sprinkler densities for the laboratory and maintenance shop were chosen. The available density in these areas should meet the requirements of NFPA 13 for Ordinary Hazard (Group 3) occupancies.

2.7 In the maintenance shop, sprinklers are located over 12 inches below the ceiling. These heads should be relocated to be within 12 inches of the ceiling.

File Ref: W47-1601

ATTACHMENT 4

USAF[AI]
FOLDER: EMIL
FILE: CONFERENCE
DATE: MAY 26, 1988

On May 17, 1988 through May 20, 1988 an inspection was conducted at Mallinckrodt Incorporate Diagnostic Products Division located in Maryland Heights, Missouri. This site visit was a team inspection with the NRC where OSHA served as a consultative agency for the NRC in evaluating Mallinckrodt's compliance with OSHA's safety and health standards. Areas reviewed were Production Building 600 and Radioactive Waste Processing Building 500. In addition all programs relating to employee safety and health in these locations were evaluated.

Findings and recommendations are as follows:

1. 1904.2 The companies injury and illness logs (OSHA 200's) were reviewed and evaluated. All record keeping was in compliance and no recommendations were made. A lost work day injury rate (LWDI) was calculated as follows:

	Year	Lost Work Day Cases	Man Hrs Worked
225 employees	1987	3	232,260
Average	1986	3	225,200

$$\frac{6 \text{ X } 200.00}{232,260 + 225,200} = 2.623$$

The companies rate was well below the national average of 4.3. Injury and illness logs were examined from 1988 back to 1985 looking for injury and illness trends in any area. No areas were observed where a partial inspection should be conducted, as most injuries were of the simple sprain or strain type, and did not appear to be caused by any common unsafe factor. In all instances an incident investigation was conducted and corrective action taken.

2. 1910.20 The company periodically conducts sampling, medical examinations of employees, and collects material safety data sheets for various substances. Section 1910.20 access to employee exposure and medical records was followed completely and no recommendations were made as the company is in compliance.

3. 1910.38 The company to comply with the Nuclear Regulatory Commission standards has an in-depth Radiological Contingency Plan which covers all aspects of emergency actions to be followed in a catastrophic occurrence. This plan includes sections on chemical emergencies, fires and how to evacuate the plant safely. Alarm systems, evacuation procedures, employee assembly, and trained response teams are all an integral part of the plan. These procedures all appear very through and no recommendations were made as the company is in compliance with applicable OSHA standards. Their primary directive is to evacuate the plant and let the local fire department and trained radiological response teams handle fires and other emergencies.

MAY 31 1988

4. 1910.1200 The company has a written hazard communication program but it appears to be generic in nature. Several inadequacies were observed as follows:

A. The list of hazardous chemicals, known to be present, was a list showing all materials found throughout the establishment and made no attempt to show hazardous chemicals as defined. The list should be broken down further for individual work areas. This will facilitate the evaluation of hazardous chemical usage and better enable employees to be trained on the hazardous substances they will encounter in their work areas.

B. There was no section in the written program on how the employer will inform employees of the hazards of non-routine tasks and the hazards of unlabeled pipes.

C. There was no section on what methods the employer will use to inform any outside contractor with employees working in Mallinckrodt's facilities of the hazardous chemicals their employees may be exposed to while performing their work, and any suggestions for appropriate protective measures.

D. There was no section in the written program detailing the method how each container of materials leaving the work-place will be labeled and how each container used inside the work-place will be labeled, tagged, or marked with the identity of the hazardous chemicals and the appropriate hazard warnings. During the walk around in buildings 600 and 500 instances were observed where an ethylene oxide sterilizer was not labeled, a hydrochloric acid container had an inadequate label, an isopropyl alcohol container was not labeled, a sodium Hydroxide container was improperly labeled, and several containers of ink wash, various alcohols and acids had improper or non-existant labels.

E. There was no section in the written program detailing how material safety data sheets will be collected, evaluated, and updated for each hazardous chemical in the work place. During the walk around material safety data sheets could not be found for S-85 Ink Wash (a red label chemical) and Formula 700 cleaner.

F. There was no section in the written program detailing how employee information and training will be provided at the time of their initial assignment and whenever a new hazard is introduced into their work area.

5. 1910.133 In several areas at the plant employees were observed wearing either safety glasses and/or face shields when handling corrosive materials. Since these materials could splash up under shields and safety glasses, chemical splash goggles sealed to protect the eyes, should be worn either over the safety glasses or under the face shields. Areas where these conditions were noted were: A) Building 600 standards laboratory handling various acids; B) UTK Production area handling hydrochloric acid and hydrogen peroxide; C) Battery charging area when

adding water to batteries containing sulfuric acid; D) Staging laboratory when handling acids and other corrosives.

6. 1910.151 & ANSI Z358.1-1981 In building 600 standards laboratory there was an improper eye wash mounted on the sink that was hand held and did not meet the ANSI standard for eye washes. Employees in the area handle various acids. The employee who adds water to the batteries for the golf carts should do so in an area where a proper eye wash is present. Currently he only has a running water hose in the immediate area.

7. 1910.134 The company had a written respirator program but in several areas of the plant it was not being implemented. Employees in the UTK production area shared a chemical cartridge respirator among 9 people. No one had been fitted for the respirator nor was it cleaned, disinfected or stored in a sanitary manner after each usage. If employees are to use respiratory protection then it must be used properly in compliance with 1910.134. In addition, one employee questioned on respirator usage had never been trained on how to use a respirator in any manner at all. In the RA fill room a respirator was observed being stored in a cabinet where biohazards had been previously stored and still had biohazard labels on the door. The face piece was laying uncovered on a shelf. Improper storage or usage of respiratory protection could cause employee exposure to hazardous substances. In building 500 emergency equipment storage cabinets: 3 negative pressure respirators were improperly stored on shelves. For all negative pressure respirator usage a proper program must be developed, implemented and maintained if employee protection is to be assured.

8. 1910.134 In several areas of the plant self contained breathing apparatus are stored for emergency use. In building 600 emergency equipment storage cabinet two air cylinders were less than full. In addition emergency respirators were not inspected on a monthly basis to assure air cylinder hoses, face pieces, regulators and warning devices are functioning properly. A record should be maintained of inspection dates and findings.

9. 1910.305 In several areas in building 600 extension cords were used in place of the fixed wiring of a permanent installation A) Standards laboratory an extension cord was utilized for fixed wiring and an improper plug box, which was designed for permanent mounting was utilized B) In the battery charging area an extension cord was used in place of permanent wiring C) In the staging laboratory 3 extension cords with improper plug boxes were used in place of fixed wiring. If extension cords are used they cannot replace fixed wiring and they must not be home made but of the approved type. An extension cord was also utilized on the refrigerator. It is recommended that all aspects of electrical usage be re-evaluated and a regular inspection of boxes, plugs, cords, and grounding be established. In several areas improper cover plates, inadequately secured receptacles, and missing ground plugs were noted.

10. 1910.23 In building 500 there was an open sided floor or platform by the dumpster, with the door opened continuously, that was 52 inches high that was not guarded by a standard railing or its equivalent. A standard railing consists of a top rail, midrail, and have a vertical height of 42

inches from top rail to floor.

11. 1910.252 In the cylinder storage area 3 oxygen cylinders were not separated from 3 hydrogen, 5 acetylene and 1 helium cylinders by a minimum distance of 20 feet.

12. In building 500 radioactive waste there are 3 hammer mills for the reduction of material. The existing ventilation system is not periodically checked to assure that it is functioning as designed. All 3 systems should be monitored on a routine (6 months or less) basis to assure adequate collection efficiency. Emergency stop switches are readily accessible for each hammer mill.

13. 1910.95 The company has evaluated the work area for noise exposure and their are no areas over 85 dBA for an 8 hour time period. Employees are given ear protection if they request it. No problems observed in regard to sound exposures.

14. 1910.1047 ethylene oxide. This company utilizes about 168 lbs. per year of ETO. The ETO comes in 140 lb. cylinders which are 12% ETO and 88% Freon. 1 to 2 cylinders per week are utilized to sterilize various materials. The entire system is ventilated in a locked area with limited employee access. All employees are sampled every 3 months for an 8 hour period and results since 1984 have been zero. Each employee receives a physical and training once a year for ETO exposure. There are 3 fixed monitors for ETO in the area set to alarm at 10 p.m. An alarm light goes off if the ventilation system should fail at any point in the ETO operation. Employees are notified of the results of all monitoring.

    Employees wear supplied air respirators when handling ETO cylinders or entering in the restricted ETO area. There is a written plan for emergency situations and the ETO warning sign at the entrance to the regulated area complies with the standard. The yearly training program is thorough and completely addresses all of OSHA's training requirements.

    In building 600 sterile core lypholizer front (2) unit there is no warning sign indicating that ETO is contained within. A warning sign should be installed on the front of the ETO sterilizer.

15. 1910.120 This company falls under the hazardous waste standard as it handles hazardous materials, is a small quantity hazardous waste generator and has an emergency response team that is trained to handle anticipated emergencies throughout the establishment. The company currently has not addressed this standard and needs to develop a program to meet all elements. In other plant programs the majority of the elements have been previously covered so it is only a matter of evaluating what has not been covered and consolidating it into existing programs.

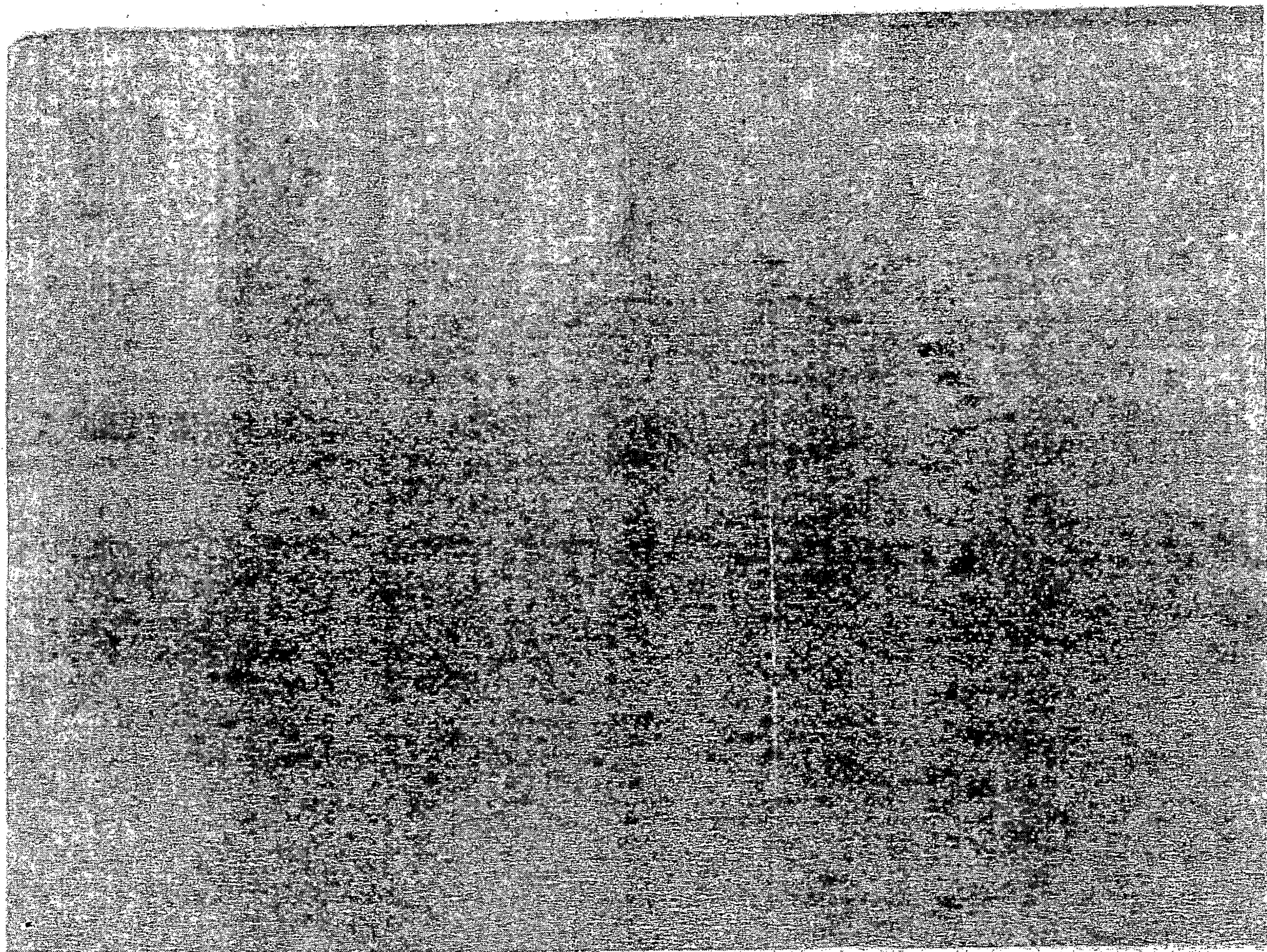
16. 1910.36 In several areas of the plant exits were not clearly visible or the route to reach them were not clearly marked so that every occupant will readily know the direction to escape from any point. Each path of escape in its entirety, shall be so arranged or marked that the way to a place of safety outside is unmistakable. Several doorways or passage

ways which were not constituting an exit or way to reach an exit, but of such a character as to be subject to being mistaken for an exit, were not arranged or marked as to minimize its possible confusion with an exit and the resultant danger of persons endeavoring to escape from a fire finding themselves trapped in a dead end space.

SIC

17. 1910.96 This company is in compliance with OSHA's standard for ionizing radiation. The Nuclear Regulatory Commission has done an extensive evaluation of their program on a continuing basis and has found no major discrepancies in relation to employee exposure. All employees are monitored with a TLD dosimeter in their identification card and film badges, film rings, thyroid uptakes, and urinalysis are utilized in various areas. Radiation detection devices are utilized when entering and exiting areas and the company has an elaborate surveying process for evaluation and control of their source materials and effluents. Caution signs, labels, signals, and employee access restrictions are excellent and the emergency warning evacuation program is well developed. Their training programs are well designed and thorough and utilized on a continuing basis. No problems observed.

18. 1910.106 In building 500 several containers of a red label material were stored on the floor. All flammables should be stored in approved storage cabinets and removed only for daily usage. All flammables should be placed in approved safety cans and bonding and grounding utilized where required during liquid transfer. This company's handling procedures for flammable materials needs to be evaluated and updated where applicable.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

JUL 31 1986

Oak Ridge Associated Universities
ATTN: Mr. Glenn L. Murphy
Assistant Program Manager
Radiological Site Assessment Program
Post Office Box 117
Oak Ridge, TN 37831-0117

Gentlemen:

We have reviewed your draft Evaluation of the Emergency Preparedness and Fire Protection Programs at the Mallinckrodt, Inc. facility, Maryland Heights, Missouri and have no recommendations for changes.

Please furnish ten copies of the final report as soon as possible.

Sincerely,

W. L. Axelson

W. L. Axelson, Chief
Nuclear Materials Safety
and Safeguards Branch