Form AEC-417
(4-65)

UNITED STATES ATOMIC ENERGY COMMISSION

COMPLIANCE INSPECTION REPORT

1. Name and address of licensee

Mallinckrodt Chemical Works
Mallinckrodt/Nuclear
Box 10172, Lambert Field
St. Louis, Missouri 63145

2. Date of inspection

May 10-14, 1971

3. Type of inspection Reinspection

4. 10 CFR Part(s) applicable

20, 30, 32, and 33

5. License number(s), issue and expiration dates, scope and conditions (including amendments)

24-4206-1	10-8-58	10-31-60 - Reinspection #19
Amendment No. 25 (amended in entirety)	10-14-68	10-31-73
Amendment No. 26	7-14-69	10-31-73
Amendment No. 27	1-6-70	10-31-73

6. Inspection findings (and items of noncompliance)

The only items of noncompliance observed or otherwise noted as a result of this inspection are as set forth below:

10 CFR 20.105 - "Permissible Levels of Radiation in Unrestricted Areas"

(b)(2) in that radiation levels on the roof of a building located in an unrestricted area north of the licensee's facilities were such that, if an individual were continuously present, he could receive a dose in excess of 100 millirems in any seven consecutive days. This is a repeat item of noncompliance. (See paragraph 17 of report details.)

10 CFR 20.201 - "Surveys"

(b) in that no air surveys were performed of the stack effluents from the building 300 dispensing laboratory glove boxes during the period January 11 to May 11, 1971 to determine compliance with 10 CFR 20.106(a). (See paragraph 44 of report details.)

7. Date of last previous inspection

October 23, 1970

8. Is "Company Confidential" information contained in this report? Yes ☐ No ☒
(Specify page(s) and paragraph(s))

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E. C. Ashley (Inspector)

Approved by:

J. M. Allan, Senior Radiation Specialist, Region III (Operations Office)

June 8, 1971 (Date report prepared)

If additional space is required for any numbered item above, the continuation may be extended to the reverse of this form using foot to head format, leaving sufficient margin at top for binding, identifying each item by number and noting "Continued" on the face of form under appropriate item.

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RECOMMENDATIONS SHOULD BE SET FORTH IN A SEPARATE COVERING MEMORANDUM

6. Inspection Findings (continued)

10 CFR 20.201 - "Surveys"

(b) in that no air surveys were performed in the Building 300 dispensing laboratory during the period January 11 and May 10, 1971 to determine compliance with 10 CFR 20.103(a). (See paragraph 33 of report details.)

(b) in that radiation level surveys were inadequate outside of Building 100 during January, 1971 to determine compliance with 10 CFR 20.105(b)(2). (See paragraph 17 of report details.)

D E T A I L S

GENERAL INFORMATION

9. This was an announced reinspection of this byproduct material program conducted on May 10-14, 1971. Mr. Donald Soldan, Radiation Safety Officer, was notified of this forthcoming inspection on May 3, 1971.

10. The office of Dr. E. A. Fulgrabe, State of Missouri Department of Health, was notified of this forthcoming inspection on May 4, 1971. The inspector was unaccompanied.

11. The following licensee personnel were interviewed and supplied the information contained in this report:

Mr. Norman E. Drissell, Director of Operations
Mr. Donald W. Soldan, Supervisor, Radiological Protection Department; Radiation Safety Officer; Chairman, Radiation Safety Committee
Mr. Ralph Nuelle, Group Leader, Environmental Radiation Control Section, Radiological Protection Department
Mr. Warren Fadling, Group Leader, Intrafacility Exposure Control Section, Radiological Protection Department
Mr. Arthur L. Sheller, Assistant Manager, Quality Control Department
Mrs. Patricia Murphy, Technician, Quality Control Department

In addition to those persons listed above, various other individuals were interviewed during visits to various parts of the licensee's facilities and discussions regarding the licensee's program. All information contained in this report is presented in substance unless otherwise indicated.

12. Reinspection No. 18 of this byproduct material program was conducted on October 20-23, 1970. Nine items of noncompliance were noted as a result of that inspection.

13. Reinspection No. 19 of this byproduct material program was conducted on May 10-14, 1971, and is the subject of this report.

14. Reinspection No. 19 was limited primarily to a review of the following items:

a. Previous items of noncompliance and corrective actions.

b. Organization and administrative control.

c. New facilities.

d. Radioactive waste handling.

e. Stack and water effluents.

f. Personnel monitoring and report of overexposure.

g. Contaminated shipment complaint.

h. Independent measurements.

i. Management discussion.

PREVIOUS ITEMS OF NONCOMPLIANCE AND CORRECTIVE ACTIONS

15. As a result of the last inspection, the licensee received communication from the Commission in a letter dated December 22, 1970, spelling out each of the items of noncompliance noted. The licensee responded to this correspondence indicating their corrective actions in a letter to the Commission dated January 11, 1970. Additionally, the Commission corresponded with the licensee in a letter dated February 1, 1971, offering comments regarding the licensee's January 11, 1971 letter.

16. Each of the items of noncompliance noted during the last inspection and the licensee's corrective actions as noted during this inspection are discussed below.

17. a. The levels of radiation existing from April 11 to May 11, 1970, in the unrestricted area on the roof of the building located across a driveway north of the company's facilities were such that an individual continuously present in the area could have received a radiation dose in excess of 100 millirems in any seven consecutive days, contrary to 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas."

As part of the Commission's independent measurements program, the TLD station located on the roof area mentioned above showed a measurement during the 30-day period between April 11 and May 11, 1970, a total of 536 millirads which was equivalent to 0.75 millirad per hour continuous for the entire 30-day period. Two contributing factors appear to have lead to these radiation levels. These factors were the handling and storage of high level solid active waste in an area in the immediate vicinity of the TLD station and the air handling filter banks which serve the hot cell facility which are also directly across from the TLD station. Following the period of April 11 to May 11, 1970, the radiation levels did not exceed the limits as prescribed in 10 CFR 20.105(b)(2) until the period of December 29, 1970 to February 6, 1971. During this latest period, the TLD results on the unrestricted roof area across from the licensee's facility showed a total of 1212 millirads which again constitutes noncompliance with 10 CFR 20.105(b)(2) in that radiation levels on the roof of the building across from the licensee's property line located in an unrestricted area were such that if an individual were continuously present in the area, he could receive a dose in excess of 100 mr in any seven consecutive days. A copy of the TLD results for the period January 9, 1970 through March 16, 1971 are attached to this report as Exhibit A. For their own information, the licensee began their own TLD measurements on the subject roof area beginning on December 28, 1970. For the period of December 28, 1970 through February 8, 1971, the licensee's TLD data shows a total of 1180 millirads which compares with the independent measurements program TLD data of 1212 millirad for the same period. The licensee's TLD data is broken down into weekly periods and shows that during the week of January 4 to 11 a total of 510 millirads was measured and for the week of January 11 through January 18, a total of 560 millirads was measured. During this inspection, the licensee advised that there was no known unusual occurrence during the week of January 4 which they could contribute to the 510 millirad reading. Therefore, the failure to perform adequate radiation level surveys outside Building 100 to determine compliance with 10 CFR 20.105(b)(2) constitutes noncompliance with 10 CFR 20.201(b). However, during the week of January 11 an unusual reaction occurred in the hot cell involving molybdenum 99 processing which released a large quantity of molybdenum 99

which was caught on the absolute filters on the roof of the hot cell. Initial readings of the filter banks from the molybdenum 99 occurrence showed 1 r/hr at the surface of the housing. The absolute filter involving the molybdenum 99 occurrence was changed and the licensee's TLD data for the week of January 18 to 25 showed a total of 25 millirad. A summary of the licensee's TLD results for the period January 4, 1971 through the week starting April 26, 1971, is attached to this report as Exhibit B. As a result of the excessive radiation levels in unrestricted areas, the licensee moved his radioactive waste handling and storage from the north side of Building 100 to a new building, No. 400. This move took place between February 15 and March 15, 1971. This change will be discussed further in the section entitled RADIOACTIVE WASTE HANDLING. In addition, the licensee has just completed plans and is about to begin an extensive roof modification on the top of Building 100 which will include changing the air handling system of the hot cell and will include lead shielding on the north side of the filter banks. This modification is expected to be completed sometime during the Summer of 1971.

18. b. Contrary to 10 CFR 20.201(b), "Surveys," adequate surveys were not made to determine compliance with 10 CFR 20.203(b) with respect to the radiation area existing on the roof above the solid active waste storage room.

During this inspection it was noted that the licensee has made evaluations of the radiation levels on the roof of the building and in particular, the roof above the Solid Active Waste Room and that all accessways to the roof of the licensee's facility are posted in accordance with 10 CFR 20.203(b).

19. c. Contrary to 10 CFR 20.201(b), "Surveys," no surveys were conducted to determine compliance with 10 CFR 20 with respect to the radiation levels existing during the handling and receipt of waste packages containing radioactive materials. Also, contrary to 10 CFR 20.201(b), no surveys were made to determine the presence and extent of radioactive contamination existing on such packages.

During this inspection, it was noted that the licensee had begun, on November 9, 1970, to record in detail the results of surveys for radiation levels and contamination of all incoming waste packages. According to the licensee's records, a total of 1406 separate packages were received during the period November 9, 1970 and May 11, 1971. Maximum radiation levels noted to date had been 15 mr/hr on one package with most packages showing instrument background. The records also showed the results of loose contamination on surveys on each package in terms of the dpm/100 square centimeters. Most all of the packages have shown less than the 100 dpm/100 square centimeters with an occasional rare package showing as high as 8,000 dpm/100 square centimeters. Any package which shows contamination is wrapped in a plastic bag, set aside, cleaned and rewiped after a suitable decay time according to isotope. The results of the rewipes are also shown in these records.

20. d. The radiation area on the roof of Building 100 above the Solid Waste Room was not posted as required by 10 CFR 20.203(b), "Caution Signs, Labels, and Signals."

As noted previously under Item b above, all accessways to the roof of Building 100 were posted in accordance with 10 CFR 20.203(b).

21. e. Contrary to 10 CFR 20.206(a), "Instruction of Personnel; Posting of Notices to Employees," the individual preparing and filling iodine 125 capsules on June 18, 1970, was not adequately instructed in the safety problems associated with the exposure to radiation and in precautions or procedures to minimize exposure.

    During the inspection of this licensee conducted in October 1970, it was noted that the individual involved in the iodine 125 incident which took place on June 18, 1970, had been given specific instructions as to precautions to be taken and procedures to be followed to minimize exposure. Since that time, the licensee has begun writing specific radiation safety procedures to accompany batch sheets for all operations involving the use of byproduct materials. A copy of the iodine 125 sodium iodide capsule radiation safety procedures is attached to this report as Exhibit C.

22. f. Personnel monitoring records were incomplete, contrary to 10 CFR 20.401(a), "Records of Surveys, Radiation Monitoring, and Disposal." No personnel monitoring records were maintained for the week September 14 through September 20, 1971, nor were any such records available with respect to two technicians for the week beginning June 22, 1970.

    During this inspection, it was noted that all personnel monitoring records were complete for all individuals. Please see section entitled PERSONNEL MONITORING for further information.

23. g. The company failed to make a timely report to the Commission with respect to the high.wrist badge exposures for two employees during the second calendar quarter of 1970, contrary to 10 CFR 20.405(a), "Reports of Overexposures and Excessive Levels and Concentrations." Your written report of the exposures was not filed with the Commission until October 21, 1970.

    For further information regarding licensee's actions concerning this matter, please see the section entitled PERSONNEL MONITORING.

24. h. Records showing the receipt and disposal of byproduct material were incomplete, contrary to 10 CFR 30.51, "Records." Records did not always identify the isotopes and the quantities of radioactive material received and disposed.

    This item of noncompliance concerns the receipt of waste packages received from customers and subsequent transfer of these wastes and other wastes to a commercial waste disposal agency. A review of the licensee's records during this inspection showed that complete receipt and disposal records are made of the incoming waste and outgoing waste as well. No discrepancies were noted during a review of these records.

25. i. Contrary to License Condition No. 15 which incorporates the procedures entitled "Health Physics Procedures Manual," dated October 1, 1968, one of your employees failed to conduct radiation surveys, as specified in paragraph IV.D. one of the procedures, while handling and processing phosphorus 32 during the week of July 20, 1970. As a result, the individual received an exposure to his wrist of about 40 rem.

    During this inspection, it was noted that no person received an excessive exposure to radiation as a result of his not following the licensee's Health Physics Procedures Manual.

ORGANIZATION AND ADMINISTRATIVE CONTROL

26. On March 1, 1971, Mr. Norman E. Drissell was appointed Director of Operations. The Commission was notified of this change in a letter to R. E. Cunningham, Division of Materials Licensing, dated March 19, 1971, from Frank A. Schottelkorb, General Manager, Diagnostics Products Division.

27. The organizational structure involving those divisions performing part of their work under License No. 24-04206-01 is attached to this report as Exhibit D. For comparison, the functional administrative structure of the byproduct material program conducted at 2703 Wagner Place, Maryland Heights, Missouri, under License No. 24-04206-01 is attached to this report as Exhibit E.

28. The current membership of the licensee's Radiological Protection Committee consists of the following persons:

D. W. Soldan, Chairman (Health Physics)
R. E. Nuelle, Secretary (Health Physics)
N. E. Drissell, Director of Operations
J. L. Brown, Research and Development
R. L. Holgate, Plant Manager
J. W. Woods, Scientific Products

29. Mr. Mont G. Mason, former Vice Chairman of the Committee and Plant Engineer, has retired from the company.

30. Since the last reinspection the licensee's Radiological Protection Committee has met on three separate occasions. On January 7, 1971, the committee met to primarily discuss details of Buildings 300 and 400. During this meeting, the committee decided to approve the occupancy and use of Buildings 300 and 400 if (a) traffic study is complete and, (b) operating procedures were reviewed and okayed by the committee. On April 20, 1971, the committee met and discussed two items of noncompliance noted during the last inspection. Namely, instruction of personnel and procedures contained in the Health Physics Procedures Manual. This discussion centered on the proposed use of radiation safety instructions to be included in the batch sheets. It was decided that production supervisors would first prepare the initial sheets and then the sheets would be reviewed and approved by the Radiation Safety Group prior to incorporation into the batch sheet itself. A second item of discussion during the April 20, 1971 meeting was the possible discontinuance of the primary responsibility for health physics at the branch labs on a daily basis. In lieu of this, the committee proposed a quarterly review of those programs. During the committee meeting of May 4, 1971, Mr. Nuelle gave a brief report of his recent trip to the Glendale Branch. Mr. Soldan advised that one batch sheet radiation safety instruction had been completed (please see Exhibit C attached to this report) and also that the AEC had announced an inspection for the week of May 10, 1971. Mr. Soldan also suggested that the vacancy left by Mr. Mason's retirement should be filled. Also at this time, the committee discussed the proposed shipments of the licensee's ultrakows six days previous to the calibration date but that before this is done, a complete study of radiation levels, shielding capabilities, etc. be completed prior to this being put into effect.

31. On November 5, 1970, the licensee reorganized its Radiological Protection Department (health physics). This reorganization divided the Health Physics Department into two sections. One of the sections has the responsibility for

health physics for all incoming byproduct materials and all uses of byproduct materials within the facilities while the second section has to do with all byproduct materials leaving the facility and health physics aspects outside of the actual building itself such as environmental. The intrafacility section has one group leader and one technician while the environmental section has one group leader and two technicians. Mr. Soldan supervises the entire operation.

NEW FACILITIES

32. During the Summer of 1970, the licensee purchased adjacent property for the purpose of expansion of operations. Since the acquisition of this new property, the licensee's land site is now approximately four times greater than it was prior to the purchase of the property. A plot plan, showing the entire expanse of the licensee's property with the new acquisition, is attached as Exhibit F.

33. Located on the new property are two buildings, one of which is a 15,000 square foot concrete block building which has been modified by the licensee and is known as the Customer Service Center. This Customer Service Center is known as Building 300. Building 300 now houses the licensee's Receiving and Shipping Departments, Traffice Department, Order Department, a warehouse-type storage area, and the licensee's Byproduct Material Dispensing Laboratory. A floor plan sketch of this Building No. 300 showing the various designated use areas is attached to this report as Exhibit G. The largest portion of the byproduct material dispensing activities in Building 300 is that of filling of orders of prepackaged radiopharmaceuticals as received from production. This function is similar to that of a branch office receiving prepackaged single dose quantities from Maryland Heights. The order filling prepackaged handling section consists of an 8 inch-thick solid concrete block room temperature storage room, a refrigerated storage room and an order filling area. All prepackaged bottles are enclosed within secondary containers at all times. In the bulk item dispensing section, the licensee has an 8 inch-thick concrete walled bulk item storage room. For order filling purposes of these items, the licensee has five glove boxes. One glove box is used exclusively for iodine 131, one for gold 198 therapy orders, one for phosphorus 32 orders, and two for miscellaneous other byproduct material products. The exhaust of the iodine 131 glove box is equipped with a 12 inch x 12 inch x 8 inch charcoal filter and all five glove boxes exhaust into an absolute filter on the roof of the building. Also located within the bulk item dispensing lab are two source calibrators (for radioassay check). All outgoing items dispensed in this laboratory are checked twice (once after the initial filling and once as a final check prior to shipping out). The licensee has three inplant air sampler stations located within the dispensing area as shown on Exhibit G drawing. In addition, a stack sampler is located beyond the final filter of the one stack which serves the glove boxes. It was determined that the dispensing laboratory in Building 300 began operations on January 11, 1971, but no inplant air sampling was performed in that facility until the week of May 10, 1971, which constitutes noncompliance with 10 CFR 20.201(b) in that no air surveys were made between January 11 and May 10, 1971, to determine compliance with 10 CFR 20.103(a). Please also see paragraph 44.

34. Located immediately west and connected to Building 300 is a second building known as Building 400. Building 400 is of light-weight construction and is approximately 9500 square feet in size. Building 400 is used for

miscellaneous warehouse storage and for radioactive waste storage and handling. For further information regarding the radioactive waste storage and handling, please see the section of this report entitled RADIOACTIVE WASTE HANDLING.

35. The original north half of the licensee's main building is designated now as Building 100 while the south half of that facility is designated as Building 200. Buildings 100 and 200 are connected on the upper or main floor only.

RADIOACTIVE WASTE HANDLING

36. During the period February 15 through March 15, 1971, the licensee moved its radioactive waste handling and storage from the outside yard area just north of Building 100 down to Building 400. The licensee has constructed storage enclosures within Building 400 using solid 8 inch concrete blocks. At the same time, the licensee discontinued the use of the solid active waste room for storage and is now using it simply as a packaging room before and after storage in Building 400.

37. The handling of radioactive waste from the various departments is described as follows:

Production Department

High level radioactive waste contained in shielded containers is taken to the Building 100 waste room where the shielded container is put into a two gallon pail, sealed, and taken to Building 400 to the current accumulation bay (please see paragraph 39). At the proper cycling time, the pail is brought back to the Building 100 waste room, the bottle is removed from the pail and the shielded container and placed in an absorbent filled two gallon pail. This full pail is sealed and taken back to Building 400 and put into a fiber shipping drum (4 to 5 cubic feet), surveyed, given an identification number, labelled with a proper shipping label, and entered onto the Nuclear Engineering shipping form and is placed in the final accumulation area awaiting shipment to Nuclear Engineering. Low level radioactive wastes from the Production Department (in hot waste cans) are emptied into one larger drum in the waste room of Building 100 and placed in the waste compactor (Sears Roebuck model). The filled compacted bag is sealed and put into a 6.5 cubic foot box as supplied from Nuclear Engineering. One of these boxes contains three bags when filled. This filled box is then taken down to Building 400 where it is surveyed, identified, labelled, etc. and put into the final accumulation shipping bay. For handling hot waste generated within the hot cell of the Production Department, an overpack is put into the transfer cell of the hot cell which contains a two-gallon pail with absorvent material. The overpack pail is filled according to half life and isotope with either solids or bottled liquids from the hot cell. When filled, the overpack is closed while still in the transfer cell. It is then removed from the hot cell, surveyed as to radiation levels and contamination, and bolted shut. If the particular overpack contains a short half life (eight days or less) the overpack is taken down to the Building 400 barrel storage area (please see paragraph 39). If the particular overpack contains long lived activity, that overpack is made ready for shipment by surveying, labelling, etc. and placed in the final shipping area bay in Building 400.

Quality Control Department

The low level waste from the hot waste cans are handled the same way as from Production. In Quality Control, low level liquids, comprising entirely of culture tubes, are put into two gallon pails by the quality control people while still in the Quality Control Department. The hot waste man from the Health Physics Department picks up and takes these pails to the Building 100 waste room where absorbent material is added and the pail is crimp-sealed and identified as quality control items. The pail is then taken down to Building 400 and placed in the appropriate accumulation bay. After the proper cycling time, these pails are put into the shipping drum, surveyed, labelled, identified, etc., logged in the shipping form, and stored in the final accumulation bay awaiting shipment. For high level waste accumulation, if any, from quality control, three overpacks are located in the Quality Control Department. Each of these overpacks contain a two-gallon pail with absorbent material. Two of the pails are used for short half life material and one is for longer half life material. All the sealed bottles of waste are placed in these pails. At this time, the same procedure follows that has been described above for the hot cell overpack handling.

Research and Development Department

The licensee advised that there is no high level waste being generated currently. If needed, however, the overpack system would be used. All low level solid material from hot cans are handled with the same procedures as discussed above for Production Department. The low level liquids from R&D are placed into one polyethylene pail which is located within a hot waste can in the R&D section. This polyethylene pail is picked up and taken to the waste room in Building 100 where the material is transferred to a two-gallon pail, sealed, identified, labelled, etc. and taken to Building 400 where it is placed into a fiber shipping barrel in the appropriate accumulation bay.

Dispensing Department

The high level overpack system is used, and similarly, low level waste is handled as described above with the compactor, etc.

38. Mr. Soldan advised that the licensee has five individuals working for them from the Continental Cleaning Company on a contract basis. These five individuals perform radioactive waste pickup and handling and janitorial work in general. One of these individuals is assigned to the Quality Control Department for animal room work. This person does the initial handling of animal room waste and is supervised by the Quality Control Department. A second individual from Continental Cleaning Company is assigned to Buildings 300 and 400 for the initial handling of all waste and janitorial work. This person is supervised by Mr. Terry Sherman, Dispensing Supervisor. One of these individuals is assigned to the Production Department for initial handling of all waste and janitorial work. This person is supervised by Mr. Bill Lawson, Production Supervisor. The last two of the five individuals from the Continental Cleaning Company are assigned to the Health Physics Department. One person is involved exclusively in the transport and packaging of hot waste while the other person assigned to the Health Physics Department performs the same duties as those persons assigned to quality control,

Buildings 300 and 400, and the Production Department in Buildings 100 and 200 only, exclusive of the quality control animal room and in the Production Department. These two individuals who are assigned to the Health Physics Department are supervised by Mr. Bob Wester, Health Physics Technician.

39. In Building 400 the licensee has constructed three separate radioactive waste accumulation and storage areas. These structures are made of 8 inch solid concrete blocks and are approximately four feet high. One of these structures is known as the Accumulation Bay Area which consists of four separate cubicals. This Accumulation Bay Area is operated such that if one were to think of this as just beginning, then during week No. 1 the first cubical would be filled, during the second week, the second cubical would be filled, during the third week of operation the third cubical would be filled and during the fourth week of operation the fourth cubical would be filled and the first cubical would be emptied. This allows three to four weeks of decay time. After this decay time, material taken from the appropriate filled cubical is taken to Building 100 waste room where the waste is removed from the individual two-gallon pails and lead shielded containers and segregated by isotope and repacked in two-gallon pails and returned to the same bay in Building 400 where they are packaged into 4.5 cubic foot drums and then placed in the Accumulation for Shipment Area where they are surveyed, identified, labelled and entered onto the Nuclear Engineering shipping form. The second storage and accumulation area in Building 400 is known as the Barrel Storage Area. This area is also constructed of 8 inch solid concrete blocks and is around 4 feet high and is covered except for six holes in the cover to allow placing of waste into barrels located under the holes. Material placed in here is the short half life overpack from the hot cell and prepackaged byproduct materials which have an expired date on the label. Up to the time of this inspection, this barrel storage area has not been emptied. The third area is known as the Accumulation for Shipment Area and is constructed of 8 inch solid concrete blocks at approximately 3 to 4 feet high and is open on the top. This area is used simply for the accumulation of full shipping containers ready to be picked up by Nuclear Engineering.

40. Every other Tuesday, by schedule, Nuclear Engineering comes to Mallinckrodt/Nuclear with their truck and picks up waste. During this inspection, the Nuclear Engineering personnel came to Mallinckrodt/Nuclear on Tuesday, May 11, for their routine pickup. Observation of this operation showed that two persons were busy loading the containers onto the Nuclear Engineering truck, one person was checking off the Nuclear Engineering shipping form as to item number. The operation was being supervised by a Health Physics Technician and by another management supervisor.

41. All radioactive waste handling and storage and shipping is conducted in the south half of Building No. 400.

42. A review of the licensee's transfer records of waste going to Nuclear Engineering shows that since the last previous reinspection, a total of 15 shipments have been made involving a total of 825 separate items. The most common isotopes noted to be shipped as waste at that time have been iodine 131 and molybdenum 99.

STACK AND WATER EFFLUENTS

43. The licensee's stack effluent sampling data was reviewed for the period December 28, 1970 through May 6, 1971, during this inspection. Particular interest was devoted to stack B which serves the iodine 131 and mercury 203

processing hot cell. During that period, the average concentration in the stack beyond the absolute filters averaged 8.4×10^{-9} microcuries per cc of air sampled. During that period, the total amount of iodine 131 detected on the charcoal air sampler media was 28 microcuries. The average running time of each sample was approximately 7.5 days with the total sample volume during that time of approximately 2×10^{7} ml. A cursory check of other stack and roof top samplers showed the average concentration of those samples to be on the order of 10% or less of the appropriate MPC used. The limiting MPC used by the licensee is that for iodine 131.

44. During this inspection, it was noted that the Building 300 rooftop sampling was begun on May 10, 1971, while the stack sampling of the one stack that serves the gloveboxes in the Building 300 dispensing laboratory was begun on May 11, 1971. The dispensing operations in Building 300 dispensing laboratory began on January 11, 1971, according to licensee representatives. The failure of the licensee to perform stack and rooftop sampling at the Building 300 location between the period January 11, 1971, and May 10 and 11, 1971, constitutes noncompliance with 10 CFR 20.201(b) in that no surveys or evaluations were made to determine compliance with 10 CFR 20.106(a). It is noted that at the time that the Building 300 dispensing laboratory went into operation on January 11, 1971, the licensee has had a 12 inch x 12 inch x 8 inch Barneby Cheny Model 7DF charcoal filter serving the exhaust of the iodine 131 processing box and a 24 inch x 24 inch x 12 inch absolute filter, with a prefilter, located on the roof of Building 300 which commonly serves all of the glove boxes.

45. All liquid active waste goes to retention tanks except pure beta emitters such as phosphorus 32. These pure beta emitters are bottled and eventually transferred as active waste to Nuclear Engineering.

46. When a signal is received noting that one of the retention or accumulation tanks is full, the contents of the tank are air-jetted for mixing purposes and an aliquate of the tank content is removed. A total activity analysis is made followed by isotopic analysis for iodine 125, iodine 131, and mercury 203. The remaining activity of the total which is not included in the iodine and mercury analysis, is assigned to gold 198 which is the next most restrictive MPC. The results of these analyses are used to determine the amounts of the contained contents which can be dumped on that particular day, based on the known water usage of the facility from the water company meter readings. The licensee's liquid active waste records indicate that one dump was made approximately every 11 or 12 days during 1971 through May 1.

47. According to the licensee's liquid active waste records, during 1970 a total of 937,076 microcuries were released on 32 separate days. During 1971, through May 6, 1971, a total of 317,114 microcuries have been released. Beginning with the first release of liquid waste in 1971, the licensee has begun keeping a separate record of the number of millicuries of iodine 131 released each time. According to these records, a total of 35.63 millicuries of iodine 131 has been released on a total of 11 separate dates of release between the period January 6, 1971 and May 6, 1971.

PERSONNEL MONITORING AND REPORT OF OVEREXPOSURE

48. At the present time, the licensee has approximately 50 individuals on a thyroid counting schedule. Persons are scheduled to be counted daily, weekly, etc., according to the type and frequency of iodine handling in which they

are involved. With general supervision by the Health Physics Department, line supervisors are required to schedule their own people for this thyroid counting. Any individual who does not come to the Health Physics Department for the thyroid count according to schedule set up for that person, a written notice is sent from the Health Physics Department to the line supervisor with a copy to the department manager. The primary purpose of this notice is to have an up-to-date record of any "repeaters." Except for one individual, all employees have shown less than 0.14 microcuries averaged weekly since the last previous reinspection.

49. One person, namely, [redacted] Quality Control Department Technician, showed a thyroid burden of 133% of 0.14 microcuries for the week beginning December 7, 1970. This excessive thyroid burden occurred while [redacted] was in the process of injecting a solution into a stopper glass vial when the needle hub separated from the syringe being used. The total iodine 131, as IHSA, was 0.35 millicuries and was being injected into a bottle containing sterile saline solution in preparation for injecting rabbits for pyrogen testing. This type of operation was noted to be similar to that which is conducted at a hospital when injection syringes are being used. As stated before, the needle became disengaged from the syringe and caused contamination on various portions of [redacted] clothing, face, head, etc. [redacted] immediately showered and changed clothes and no contamination remained on her face or other parts of her body following this shower. In order to eliminate any possibility of this type of thing happening again, the licensee has set up on the counter top in the animal quarters of the Quality Control Department, a glove box (without gloves) for use in all such operations. Following the initial uptake which occurred during the week of December 7, 1970, [redacted] thyroid burden steadily decreased until during the week of January 18, 1971, when the thyroid burden showed a weekly average of 8% of 0.14 microcuries and has remained less than or equal to 5% of 0.14 microcuries average weekly. [redacted] was restricted from using iodine until after the week of December 28, 1970, when her thyroid burden showed 38% of 0.14 microcuries. This excess thyroid burden to [redacted] was reported to the Commission by the licensee in a letter dated January 6, 1971, in accordance with 10 CFR 20.405. In addition, [redacted] was notified of this exposure in a letter as required by 10 CFR 20.405(b).

50. Urine samples are collected from isotope workers on a routine schedule. These samples are collected and analyzed for carbon 14 on a weekly basis and for iodine 131 on a monthly basis. The licensee uses an in-house MPC for carbon 14 of 377 dpm/ml and for iodine, 222 dpm/ml. The highest single samples for carbon 14 since the last previous reinspection has showed 70% of the licensee's MPC while the highest iodine urine sample has shown 21% of the licensee's MPC. Most persons have shown less than 20% of the carbon 14 MPC while essentially all persons have shown less than 5% of the iodine 131 MPC.

51. Through calendar year 1970, the licensee used the R. S. Landauer Film Badge Service. During this inspection, the R. S. Landauer film badge reports as received by the licensee were reviewed for the third and fourth calendar quarters of 1970. The highest wrist badge exposure received by any one person in the third calendar quarter of 1970 was 46.32 rem received by [redacted] This exposure is discussed in the inspection report dated November 12, 1970 of the inspection conducted October 20-23, 1970. It was noted that no other wrist badge exposures and no whole body exposures exceeded the limits as prescribed in 10 CFR 20 for the third calendar

quarter of 1970. Other higher wrist badge readings for the third calendar quarter show 11.86 rem for [redacted] 10.23 rem for [redacted] and 10.16 rem for [redacted] The highest whole body exposures received by individuals during the third calendar quarter of 1970 showed 2.65 rem for both [redacted] and [redacted] A review of the fourth quarter of 1970 film badge results showed that the highest wrist badge exposures were 18.71 rem received by [redacted] 14.83 rem to [redacted] and 13.26 rem to [redacted] The highest whole body exposure during the fourth calendar quarter of 1970 was 2.49 rem received by [redacted]

6a6

52. During 1970, the licensee became dissatisfied with the R. S. Landauer Film Badge Service. This dissatisfaction stems from the licensee's apparent feeling that Landauer was unable to compensate for directionality effects, low energies, missing filters, reporting accuracies, and time delays in the reporting of the film badge exposures. As a result, the licensee performed a study of exposures which involved the comparison of three separate film badge services. At the completion of this study, the licensee decided to change their film badge service to Radiation Detection Company. The final results of this exposure study are attached to this report as Exhibit H.

53. Effective the first week of January 1971, the licensee began using the film badge service of Radiation Detection Company. The film badge service is divided up into four groups according to work assignments. Group I uses the film badges on a weekly exchange basis and involved 78 persons at the present time. Group I involves all persons in the Production Department, Process Development Department, Labelling Department, Health Physics Department, R&D Department, Maintenance Department, environmental badges and experimental badges. Persons in Group II also received their badges on a weekly exchange basis and involved 32 people at the present time. Group II includes all persons in the Shipping and Receiving and Stores Departments, Dispensing Department, and Quality Control Department. Persons in Group III received their film badges on a monthly exchange basis and involved a total of nine persons at the present time. Group III includes all persons in the Radiochemical (carbon 14) Department. Persons in Group IV received film badges on a quarterly exchange basis and involve a total of 17 persons at the present time. Group IV includes all managerial-type personnel.

54. With the institution of this new film badge service with Radiation Detection Company, the licensee has supplied a list of personnel who have high exposure potential and a separate prompt written report in letter form is submitted to Mallinckrodt/Nuclear prior to the submission of the film badge report. This prompt letter includes any exposure received by the people on the list. In addition, the licensee has notified Radiation Detection Company that their weekly dose limit of 125 millirem whole body and 550 millirem wrist requires a prompt letter for anyone on the film badge service. This new procedure allows the licensee to take quicker action in reducing whole body and wrist exposures.

55. A review of the Radiation Detection Company film badge reports for the first calendar quarter of 1971 through the week of March 29 - April 5, 1971, showed the following results:

Group I - The maximum wrist badge exposure showed 9.6 rem with most showing less than 2.5 rem. The maximum whole body exposure in Group I showed 2.51 rem with most showing less than 1.0 rem.

Group II - The maximum wrist badge exposure showed 4.75 rem with most showing approximately 3.5 rem or less. The maximum whole body exposure showed 1.71 rem with most showing less than 1.0 rem.

Group III - (Whole body only) One person showed 30 millirem while all others showed 0.

Group IV - (Whole body only) The maximum exposure shows 450 millirem with most others showing less than 200 millirem for the first quarter.

56. The film badge results for persons in Group I and II were reviewed for the second calendar quarter (weekly film badges through the week of April 26 to May 3, 1971).

Group I - The maximum wrist badge exposure shows 3.02 rem with most showing less than 1.0 rem. All whole body exposures during the second calendar quarter to date show less than 1.0 rem with most showing less than 400 millirem.

Group II - The highest wrist badge exposure for people in this group showed 1.23 rem with all others showing less than 1.0 rem. The maximum whole body exposures by any person in this group shows 660 millirem with most showing less than 200 millirem.

57. During the second calendar quarter of 1970, R. S. Landauer reported excessive wrist badge exposures for two individuals. [redacted] 22.83 rem and [redacted] 19.17 rems. These excessive exposures were not reported to the Commission at the time of the last inspection conducted in October 1970 and as a result the licensee was held in noncompliance with 10 CFR 20.405. The licensee advised that a written report of his exposures were not made to the Commission because they were debating the validity of some of the readings. The licensee questioned the validity of the exposures based on two factors, (a) filters were found missing from these employee's badges, and (b) the Maryland Heights employees were working with low energy materials during this period and the licensee feels that Landauer, the film badge processor, did not evaluate the film adequately. In a letter to the licensee from R. S. Landauer dated September 28, 1970, Mr. Robert V. Wheeler, Technical Director, R. S. Landauer, advised that the 11.9 rem reading on this [redacted] film badge dated May 25, 1970, was partially due to contamination exhibited on the film and if it is assumed that only mercury 197 and technetium 99m were involved in the exposures, then the estimated exposure would be closer to 5.0 rem. A copy of this correspondence from Landauer to the licensee dated September 28, 1970, is attached to this report as Exhibit I.

58. On June 1, 1970, the licensee's Model 555 Radocon (a line operated R-meter) was recalibrated by Victoreen Instrument Company at various low x-ray energies ranging from 32 Kev up to 660 Kev. The calibration curve supplied by Victoreen showed the relative response ranged between 0.94 and 1.06 of the actual radiation in this energy range. With this information, the licensee exposed the recalibrated R-meter to mercury 197 sources in order to determine the "true" exposure in relationship to pocket chamber readings and film badge readings. The licensee's conclusions as a result of this study and their summary as to what they feel the actual wrist exposure to [redacted] should have been is included in a Mallinckrodt/Nuclear internal report entitled

"Reevaluation of Exposures." A copy of this data is attached to this report as Exhibit J. Brief conclusions and evaluations are also summarized in the licensee's internal report entitled "Final Report - Exposure Studies" included in this report as Exhibit H as noted above in paragraph 52.

59. As a final result of all of the licensee's exposure studies, and numerous contacts with R. S. Landauer, the R. S. Landauer submitted to a licensee an adjusted film badge report showing these changes for the second calendar quarter of 1970. A copy of this adjusted film badge report is attached to this report as Exhibit K.

CONTAMINATED SHIPMENT REPORT

60. The licensee received correspondence from the California Institute of Technology in letters dated March 26 and March 29, 1971, in which the California Institute of Technology advised the licensee of leaking phosphorus 32 shipments. During this inspection, the licensee presented a documentation of their investigation into this problem which included a study of the dispensing methods, packaging, and shipping procedures. The information presented to the inspector during this inspection also included changes which the licensee has put into effect regarding the packaging of this particular byproduct material product. A copy of the licensee's investigation into this problem is attached to this report as Exhibit L.

61. Two statements included in the California Institute of Technology's March 29, 1971 letter are as follows: "The vial appears to contain more than 25 millicuries," and "With the vial removed and shielded, the absorbent packing material had a radiation level of 6 r/hr at 1 foot, measured with a Juno survey meter (gamma shield open). On page 204 of the Radiological Health Handbook, revised addition January 1970, one of the rules of thumb regarding beta particles states "For a point source of beta radiation (neglecting self-and-air-absorption) of strength Ci curies, the dose rate at 1 foot is approximately equal to 300 Ci rads per hour. The variation with energy is small over a wide range." If, in the second statement in the March 29, 1971 letter, a total of 20 millicuries of phosphorus 32 contamination in the absorbent packing material was present, and for the sake of argument, could be considered as a point source, then according to the rules of thumb, this would have a radiation level of approximately 6 r/hr at one foot. This coupled with the first statement in the March 29 letter which states that the vial appeared to contain more than 25 millicuries, would appear to cause the shipment to contain more than 45 millicuries total. As a result of this, the licensee's source strength determinations were reviewed during this inspection. Licensee representatives advised that three checks on source strengths are made of all products leaving the facility. (a) The licensee has a standard concentration of liquid byproduct material as determined by Quality Control Department. When a customer asks for a certain number of millicuries then the volume is dispensed which will give the customer that number of millicuries based on the standard concentration. (b) After dispensing a precalibrated volume the material is measured in a source calibrator by the dispensing technician to be use it is within plus or minus 10% of the labelled value of millicuries. (c) A series of final checks made in the dispensing laboratory include: a visual examination of the bottle for approximate volume, a check to see that the labels on the bottle and on the can match, and a final check in a source calibrator is made by a different technician than the one who did the original source calibrator checking. A review of the licensee's shipping records

involving the bottle which was shipped to California Institute of Technology and referenced in the March 29, 1971 letter was reviewed during this inspection. The shipping records identify the part as phosphoric acid P-32 solution biochemical grade. Remarks on the shipping record show replacement for leaking vial. The customer number is shown as C-6144, Order No. J010225, Customer Purchase No. 18-61024-B. Other information on the shipping records shows 25.0 millicuries as of March 26, 1971, noon. Volume = 0.714 ml and concentration = 35.01 millicuries per milliliter. Finally, Lot No. 466-1C1M.

62. Although the licensee could not determine the exact cause of the contamination, their best estimate is that it may have been caused by a faulty cap.

INDEPENDENT MEASUREMENTS

63. Using an Eberline Model E-500B survey meter with a 30 milligram per square centimeter GM probe, the AEC representatives conducted independent radiation level surveys at the filter banks on top of the Building 100 roof, in the old radioactive waste handling and storage yard on the north side of Building 100 and in the new radioactive waste handling and storage area in the south half of Building 400. At the filter banks on the roof of Building 100 serving the hot cell, radiation levels were noted as follows: on the south edge of the filter banks which serve the iodine 131 and mercury 203 processing cells show a radiation level of 500 mr/hr at the surface and 90 mr/hr at 18 inches. The north edge of this same filter bank showed a radiation level of 30 mr/hr at the surface. The radiation level at the surface of the filter bank which serves the other portions of the hot cell showed 50 mr/hr. The radiation level on the roof of the radioactive waste storage and handling room showed less than 1 mr/hr at the surface. The old radioactive waste storage and handling yard at ground level north of Building 100 was essentially empty of all storage at this time. Three used absolute filters wrapped in plastic showed radiation levels of 50 mr/hr at the surface and about 6 mr/hr at 1 meter (these three filters were shipped to Nuclear Engineering in the active waste shipment on May 11, 1971). In the new radioactive waste handling and storage area in Building 400, the maximum radiation level at the openings to the four accumulation bays was 6 mr/hr. The maximum radiation level over the open tops of the barrel storage area was 1 r/hr. The maximum radiation level at the side of this barrel storage area wall showed 2 mr/hr at the surface. In the accumulation for shipment area (final storage area prior to shipment) the maximum radiation level at the top of the wall showed 65 mr/hr. Each of the areas in the new storage and handling area were posted to show the conventional radiation symbol and the words "Caution Radioactive Material," "Caution High Radiation Area," and the fact that personnel monitoring is required in the area.

MANAGEMENT DISCUSSION

64. The results of this inspection were discussed with Mr. Norman E. Drissel, Director of Operations, and Donald W. Soldan, Supervisor of Health Physics. Items of noncompliance noted during this inspection which were discussed at this time included the excessive radiation levels on the unrestricted roof area of the Bennet Box Company immediately north of Building 100. At this time the licensee reiterated their corrective actions such as removing all storage of radioactive waste from the old storage yard north of Building 100, changing the radioactive waste storage room in Building 100 to a radioactive waste handling room and the modification of the roof area in the vicinity of the hot cells in order to provide shielding for the hot cell filter banks. When these items are complete, there will be little or no

radiation levels at the Commission's TLD station on the roof of the Bennet Box Company, according to Soldan. Regarding the failure to perform stack or other sampling at Building 300 between January 11 and May 11, 1971, the licensee could offer no specific reason for this. The licensee representatives were reminded that the purpose of the Radiation Safety Committee is to approve or disapprove the starting of new operations based on available health physics coverage.

65. The licensee representatives were advised that as a result of this inspection, no apparent problem with the P-32 shipment to California Institute of Technology were noted to correlate with California Technology Institute's complaint with the exception of possible faulty bottle caps.

66. Several changes were noted which appear to improve the health and safety aspects of the program and include the new active waste handling and storage procedures, the new Health Physics Department organization with specific group assignments and the prompt exposure notification arrangement with the film badge supplier and subsequent notices to department supervisors regarding their people.

67. The licensee was contacted by telephone on June 7 and June 16 regarding Region III's further evaluation of [redacted] wrist badge exposure results for the second calendar quarter of 1970. This evaluation is discussed in the covering memorandum for this report. Ex 6

68. The licensee representatives were advised that the licensee may expect to receive further communication from the Commission concerning the items of noncompliance noted during the inspection.

Attachments:
Exhibits A thru L

INDEPENDENT MEASUREMENTS PROGRAM

MALLINCKRODT TLD RESULTS

Exposure Period	Average Dose (mrads) Above Background	
	Bennett Box Company Roof	North Fence (Ground Level)
1/9-2/7/70	427	90
2/7-3/7/70	261	56
3/7-4/11/70	272	80
4/11-5/11/70	536	113
5/11-6/15/70	318	95
6/15-7/18/70	381	71
7/18-8/17/70	383	76
8/17-9/21/70	410	98
9/21-10/23/70	384	93
10/23-11/28/70	346	101
11/28-12/29/70	380	164
12/29/70-2/6/71	1,212	127
2/6-3/16/71	280	115

Attachment No. 1

EXHIBIT A

WEEK STARTING

(as received from Radiation Detection Co)

DATE	9991	9992	9993	9994	9995	9996	9997	9998
1-4-71	C	510	35	C	C			
1-11-71	C	560	45	C	C			
1-18-71	C	25	20	C	C			
1-25-71	C	85	15	C	C			
2-1-71	C	C	10	C	C			
2-8-71	C	130	150	—	60	50*	20*	
2-15-71	C	—	60	60	20	10	15	
2-22-71	C	—	15	C	25	C	C	
3-1-71	C	90	290	40	30	10	10	
3-8-71	20	60	150	C	40	—	15	
3-15-71	45	25	60	10	40	40	10	
3-22-71	C	30	20	10	25	—	—	
3-29-71	C	25	35	C	25	30	C	
1st Green Line								
4-5-71	10	30	25	C	20	15	C	
4-12-71	C	40	40	10	40	C	10	
4-19-71	C	25	25	C	35	10	C	
4-26-71	15	55	45	40	40	25	25	

*Starting L-1

9992 = ON ROOF OF BENNETT BOX BLDG. @ M/N-1-ER

9995 = ON FENCE WEST OF WASTE YARD @ M/N-5-ER (N)

9993 = ON FENCE ABOVE CONCRETE BLOCK WALL - NORTH SIDE OF WASTE YARD

EXHIBIT B

5/10/71

EBB 5-14-71

I-125 SODIUM IODIDE CAPSULES RADIATION SAFETY PROCEDURES TO ACCOMPANY BATCH SHEET

Report to the Radiological Protection Dept. for a thyroid burden measurement before starting prep.

Survey work area (preferably using thin end window probe) before starting Batch to check condition of work area.

Surveyed by _____

To insure that no contamination is present before starting Batch, gross paper towel wipes should be taken.

Surveyed by _____

Step 5 Batch sheet
The active NaI-125 solution should be drawn in a fume hood or in an enclosure under negative pressure. Protective gloves should be worn during transfer of material. After transferring solution, safe and string tag should be surveyed with survey meter (preferably using thin end window probe) for possible contamination. NaI-125 is volatile and should be considered hazardous.

Step 7 Batch sheet
The Sodium Iodide Diluent and the Na_2SO_3 should be added in a fume hood or enclosure under negative pressure. The active NaI-125 solution should never be removed from a fume hood or negative enclosure under negative pressure unsealed. Protective gloves should be worn while handling material. The vial containing active NaI-125 should be kept in a thin wall safe at all times when being handled. Never handle any radioactive material bare-handed. Always use shielding or distance.

Step 8 Batch sheet
Care should be used in withdrawing samples for assay so as no contamination of work area results. Protective gloves should be worn to prevent the spread of contamination.

EXHIBIT C

Step 10 Batch sheet
If readjustments are required, perform all operations in fume hood or in an enclosure under negative pressure being sure to wear protective gloves.

Step 11c Batch sheet
The dispensing operation should be performed within a fume hood or in an enclosure under negative pressure. Care and vigilance should be observed when dispensing to minimize contamination spread and the possibility of uptake. Protective gloves should be worn at all times during the dispensing operation. NaI-125 is volatile and should be considered hazardous.

Step 11 D Batch sheet
If capsules are to be air dried, seal off area so that occupancy time is zero, and determine whether or not air flow is into an area where occupancy time will be zero. If it is not, take appropriate actions and notify supervisor.

Step 12, 13, 14 and 15 Batch sheet
Care should be taken while handling capsules so none become separated or broken and that the spread of contamination does not occur. Protective gloves should be worn to minimize the spread of contamination.

Step 16 Batch sheet
The operator should survey himself (preferably using thin end window probe) to assure no contamination has resulted.

Step 18 Batch sheet
Survey (preferably using thin end window probe) work area after clean-up to assure no contamination persists.

Step 19
Report to Radiological Protection Dept. for thyroid burden measurement.

APPROVED FOR MANUFACTURING BY_____

APPROVED FOR RADIOLOGICAL
~~PRODUCTION~~ DEPARTMENT BY_____
PROTECTION

ORGANIZATIONAL STRUCTURE INVOLVING THOSE DIVISIONS PERFORMING PART OF THEIR WORK UNDER LICENSE No. 24-04206-01.

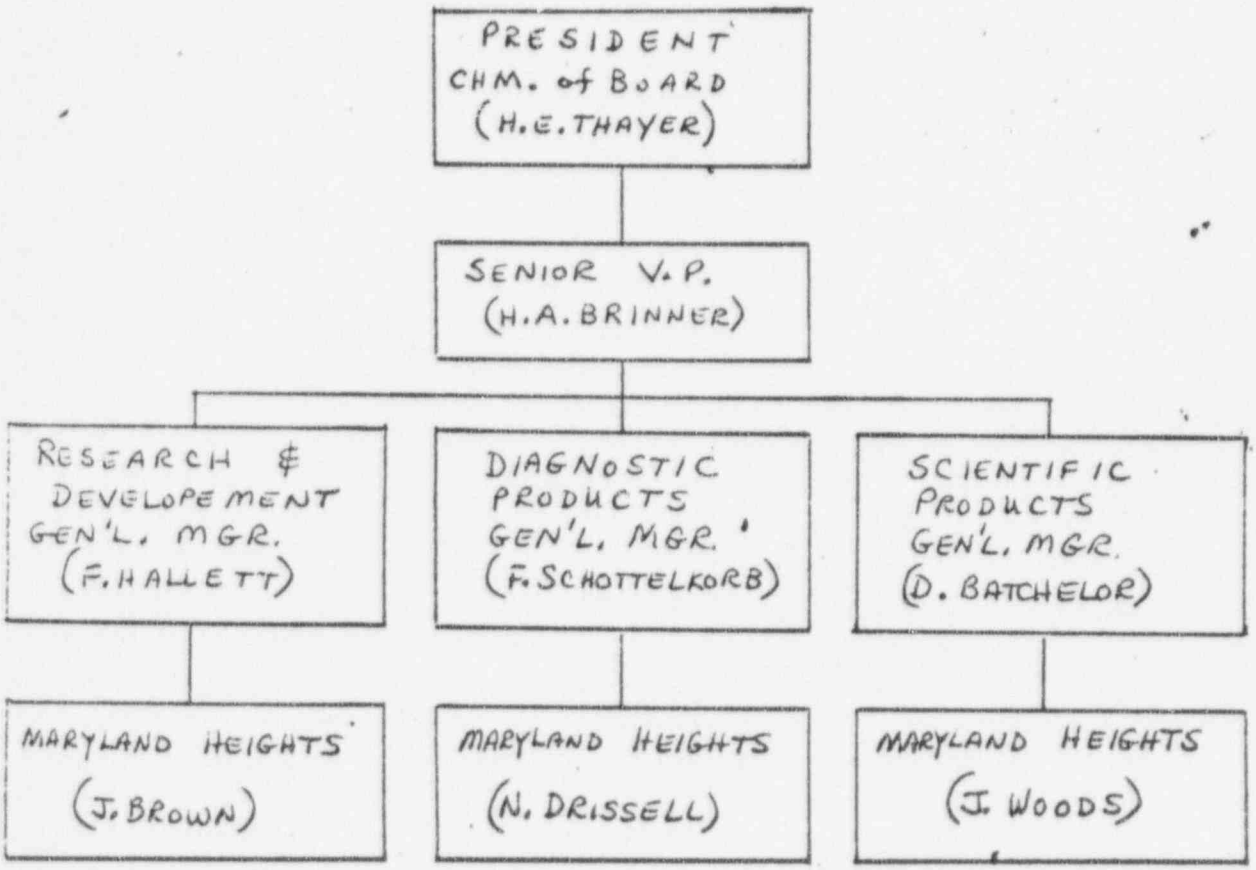

EXHIBIT D

FUNCTIONAL ADMINISTRATIVE STRUCTURE OF BYPRODUCT MATERIAL PROGRAM CONDUCTED AT 2703 WAGNER PLACE, MARYLAND HEIGHTS MISSOURI UNDER LICENSE No. 24-04206-01.

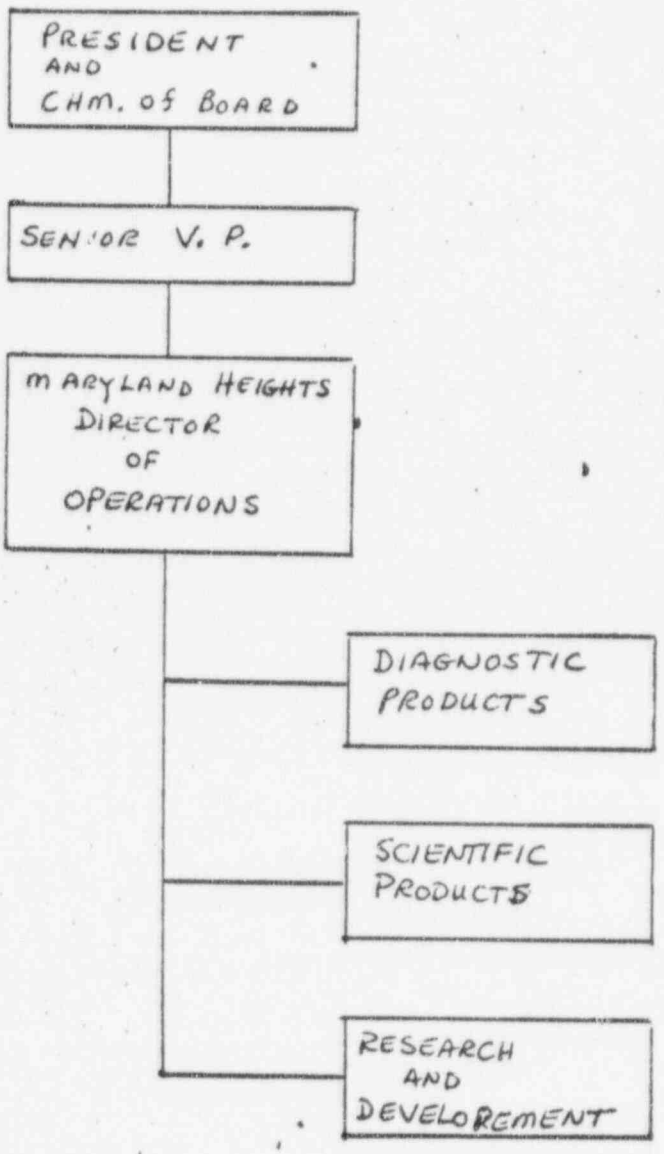

EXHIBIT E

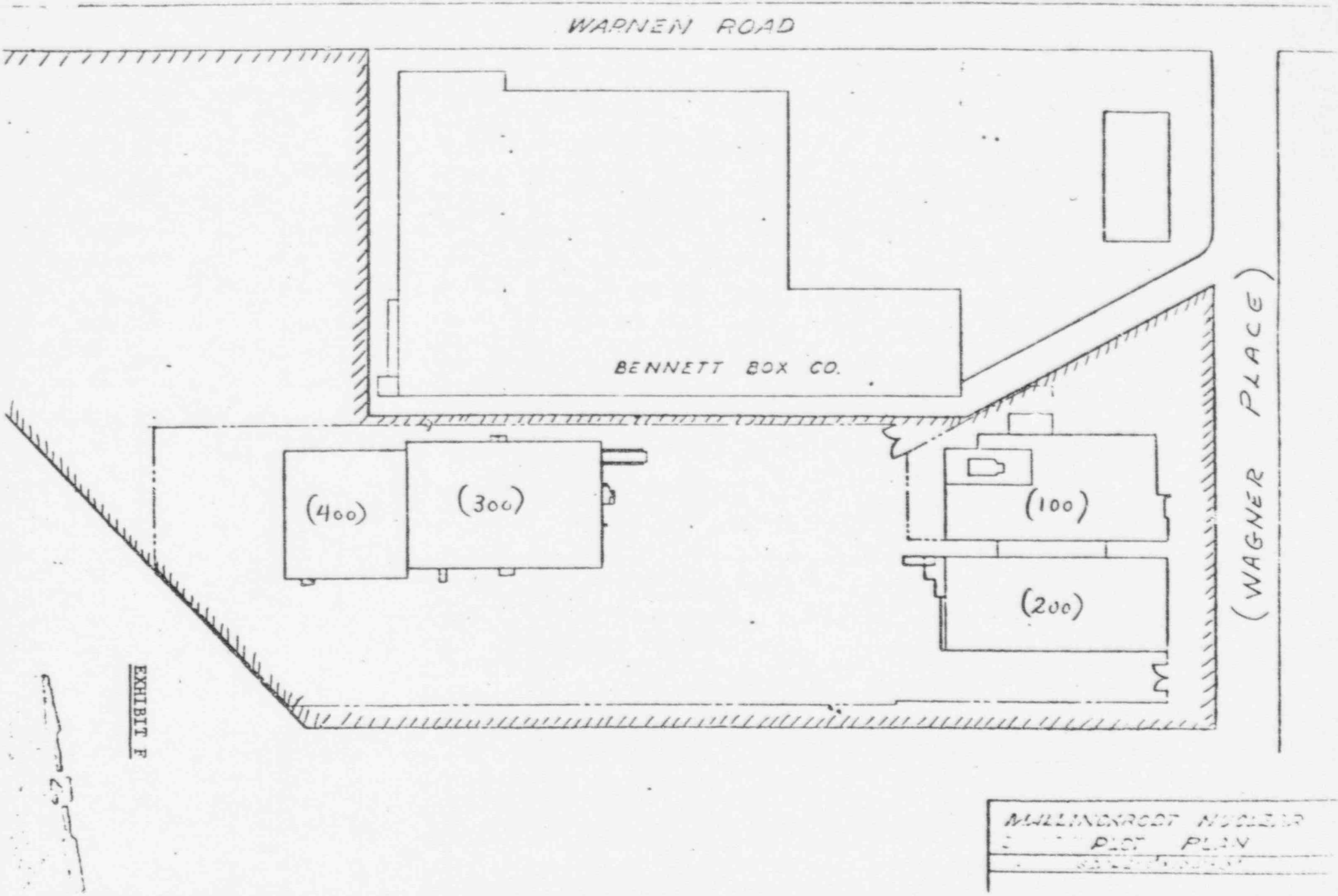

EXHIBIT F

MALLINCKRODT NUCLEAR
PLOT PLAN

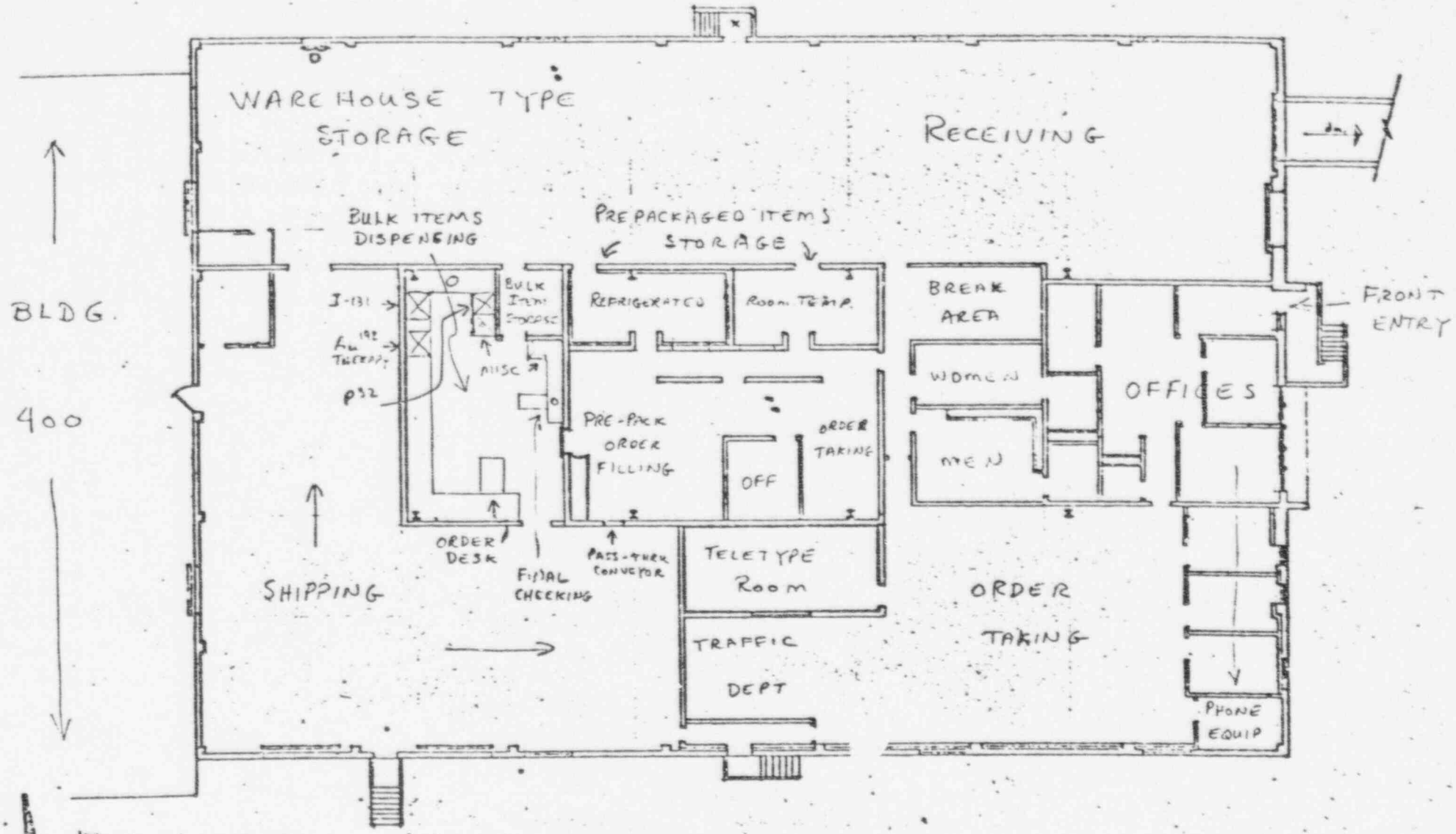

EXHIBIT G

X = GLOVE BOX

O = SOURCE GRIGNITOR (RADIO ASSAY CHECK)

IN-PLANT AIR SAMPLERS

D-1 = IN PRE PACK ORDER FILLING

D-2 = IN BULK ITEM STORAGE Room

D-3 = IN BULK DISPENSING Room NEAR I-131 & AU-198 GLOVE BOXES

MALLINCKRODT NUCLEAR BUILDING 400 PLAN

SCALE: 1" = 20'

1 -

5-13-71

ATTENTION:
N. E. Driscoll

INFORMATION:
Warren K. Faddling

FINAL REPORT--EXPOSURE STUDIES

An evaluation of our personnel external dosimetry program was begun during the first quarter of 1970 to determine if the overall quality could be upgraded. Several questions were raised which could not be adequately answered. A series of exposure studies were begun to provide answers to these questions which follow.

1. Can Landauer provide accurate reports when film is exposed under actual working conditions involving angular exposures to several different energies?

2. Are Landauer's reports accurate for film exposed under idealized conditions for different energies?

3. Are Landauer's results dose dependent?

4. What are the response characteristics of each of the three makes of pocket chambers currently used (Bendix, Victoreen, Landsverk) for different energies?

5. What are the directionality characteristics of each of the three makes of pocket chambers used?

6. What is the absolute accuracy of our Victoreen Radocon-555 and the Victoreen R-meter we use as primary calibration instruments for the gamma energies involved in our work?

7. Are other commercial dosimetry services available which are superior to Landauer in terms of accuracy of reporting?

8. Do other commercial dosimetry services provide better service than Landauer?

9. Are other commercial dosimetry services more economical than Landauer?

A summary of our findings follow with specific detailed data available at your request.

1. Landauer is unable to compensate for directionality effects at low energies such as 77 Kev introducing a factor of two error. This is an inherent fault in their badge which incorporates relatively small filters. A straight edge-on exposure was not tried but would probably have resulted in an even greater error. As expected, the error is inversely proportional to energy.

2. Landauer's results, even under ideal conditions, are high for 77 Kev gammas (and most probably are also high for 81 Kev Xe-133 gammas) which lie

EXHIBIT H

just below the energy at which the K edge in lead occurs. This error is probably due to their means of calibration over this energy region. They use an X-ray spectrum for calibration rather than monoenergic sources of radiation in this region of interest. Their results are probably pretty good for X-ray technicians.

3. Landauer uses a twin film for measuring high and low dose rates. The results for their high range film are somewhat lower than corresponding results for their low range (sensitive) film.

4. The Landsvork pocket chambers are superior to the Bendix and Victoreen pocket chambers considering energy dependence and absolute accuracy. The Bendix units are easily damaged and have the highest failure rate.

5. All three types of our pocket chambers drop off in response as the pocket chamber is rotated from side-on to the source to end-on to the source. The pocket chamber of choice is the Landsvork L-50.

6. A cross-calibration check of our primary instruments was made in September, 1970, with the cooperation of the Radiation Detection Company. We exposed TLD's furnished by RD to low energies and various doses as measured by our instruments. They, in turn, measured the exposures on their TLD instrumentation calibrated against a source, the gamma emmission rate of which they state can be traced to NBS. Their results were approximately 20 percent higher than ours. We then sent both our primary instruments to Victoreen for absolute recalibration at several energy points of specific interest to us at a cost of $500.00. A repeat of the above check was planned after calibration. However, a broken wire in a cable connector of the Radocon-555 caused damage to the circuitry requiring that the instrument be returned to Victoreen for repair and recalibration.

7. The three dosimetry services which were evaluated were R. S. Landauer, Radiation Detection, and Nuclear Chicago. Radiation Detection was able to compensate for directionality effects because of the large filters used in their badges and because each film is visually inspected. Nuclear Chicago reported a number of zero exposures for high ones and a number of very high beta exposures when the badges were not exposed to beta at all. Their entire readout is automated.

8. The service provided by Radiation Detection during the exposure studies (and to date) was excellent. It took Nuclear Chicago two months to get film to us for evaluation.

9. The cost of available services is as follows:

Tracerlab	$1.00	per badge
R. S. Landauer	0.65	" "
Radiation Detection	.55	" "
Nuclear Chicago	.35	" "

Tracerlab was not evaluated because of the high cost of their service. They probably don't want our business because of the complexities involved.

A parallel service was used during December, 1970, for a one-to-one comparison between RD and RSL. The RSL results were generally higher than RD results.

Effective January 1 and January 4 our monthly and weekly services were discontinued with RSL and begun with RD. We consider RD to be the best commercial dosimetry service available.

D.W.S.

5-13-71

R.S. Landauer Jr. & Co.
A DIVISION OF TECHNICAL OPERATIONS, INCORPORATED
GLENWOOD SCIENCE PARK ☐ GLENWOOD, ILLINOIS 60425 ☐ PHONE (312) 755-7000

September 28, 1970

Donald W. Soldan, Chief
Radiological Protection Officer
Mallinckrodt Nuclear
Box 10172 Lambert Field
St. Louis, Missouri 63145

Dear Don:

Ex 6

In reply to our telephone conversation the other day, and your previous letter to Mr. Landauer, I wish to offer the following information for your consideration:

In my opinion, the 11.9Rem exposure reported for [redacted] for the exposure period beginning May 25, 1970, was partially due to the rather extensive contamination exhibited on the film. It is quite possible that darkening from the contamination did, in fact, interfere with the interpretation of the exposure. If we assume, as you state in your previous letter, that she was exposed to Hg-197 and Tc-99m only, then I would estimate this exposure would be closer to 5000mRem. This is calculated from density values obtained under the aluminum filter and correlated with your exposure data for Tc-99m of June 29, 1970. I believe that this would be a maximum exposure, however, it certainly would require your confirmation that no other isotopes were involved and would be accurate only to the extent of the accuracy of the June 29, 1970 exposures. In my evaluation of this particular film, there was no evidence

EXHIBIT I

that the lead filter was not intact at that time since its image is clearly visible on the film.

We also examined the 5700mRem film worn by [redacted] for the period beginning June 1, 1970, in an attempt to further evaluate her total reported exposure of 19,140mRem as detailed in your letter of July 16, 1970. Again, all filters appear to be intact as of that time. This exposure appears to be valid and no adjustment can be made by us with the available information.

Ex 6

From the exposures recorded by the pocket chamber during the week of April 13, 1970, it would appear that the majority of the exposure is received during the performance of steps 24 through 28 of the production of Hg-197 Chloromerodrin. However, this apparent fact is not substantiated when we examine the pocket chamber measurements for the week of May 25, 1970, where the reported exposure of 70mr is only about 35 percent of what might be expected from the previous data.

Reviewing the information regarding the reported exposures vs. the exposure data you supplied me by telephone a few weeks ago for the test films exposed on both June 29, 1970, and July 6, 1970, we find that when the badge had all four filters intact and the exposures were made incident to the front face of the film, only one exposure set fell outside the limits of ± 20 percent. This exception was for the 151mr exposure to Hg-197. In this case, the reported exposures appeared to be 80 percent high. This was not substantiated on the July 6, 1970, film when 1520mr was received by the film. In this instance the exposure reported was only 10 percent high. It is interesting to note that in column 2 for the same source, the difference between the June 29, 1970 exposures, and the July 6, 1970 exposures differ by a factor of nine, whereas this is not true for the films in column 1.

We would appreciate your reviewing your records with regard to time, distance, and original calibration values for the 151mr Hg-197 exposure.

Also, in order to more fully evaluate all of this data, it would be helpful to learn which chambers were used in the Victoreen Radocon-555 and the Victoreen R-meter, as well as the National Bureau of Standards correction factors for these chambers. If I assume that [redacted] work remains consistent in that she usually works with basically the same isotopes, it is interesting to note in her case the results of the TLD vs. film for the six wearing periods beginning July 6, 1970. For her wrist badge, the film summarizes her exposure as 5120mRem and the TLD indicates 4710mRem. For her body badge we find 1250mRem and 1150mRem respectively.

Ex 6

For these reasons we feel her earlier exposures during the second quarter of this year are valid as reported.

One note regarding pocket chambers which I mentioned on the telephone the other day, these chambers are definitely directional dependent if we consider a 4π geometry. Normally, decent results are obtained if the source is located in a plane, perpendicular to the length of the chamber. However, as the source rotates to either end of the chamber, a significant decrease in response should be expected.

With regard to the questioned exposures received by Rodon (0017) and Daniels (0039) it appears to us that the exposures as reported are correct. I have examined the films for Rodon and Daniels for the period of May 18, 1970, and have found that as of this date the lead filters were still intact. At the conclusion of this period it seems that the majority of the exposure had already been received. These films were selected for evaluation

since in both instances they were the most recent large exposures received and, therefore, lent themselves as the best examples for evaluation.

During this evaluation we examined some of the films identified as being in wrist badges to determine what angular effects, if any, could be noted. In most instances it was quite obvious that many of the films had been exposed at an angle to the holder since the pattern of the lead filter was somewhat displaced, however, there was no indication that any difficulty in positioning the film to obtain density readings would result.

In order to further evaluate the angular effects of not only film but TLD as well, and at smaller energy intervals, we exposed a number of films with TLDs similar in geometry to those supplied you in our recent test. Our exposures were to Cesium-137 and x-rays with effective energies of 100 KVE, 60 KVE, 30 KVE and 19 KVE. In all instances the badge was attached to a tissue-like phantom simulating a wrist and continuously rotated in the radiation field. The results of this experiment indicated that both detectors were affected by the directionality of the exposure. The film indicated a maximum response at about 30 KVE to 60 KVE as expected and a minimum for Cesium which would be normal. Apparently, the same was true in your study for random rotation where approximately the same ratios were obtained.

It appears, however, that the maximum error results when the source of radiation is at 90° from the front of the badge holder, permitting all the radiation to interact with the film with minimum filtration. In application, I do not think this really represents the true situation for wrist badges. I would tend to expect the source to be angular but on the order of something like 45° to 60° and at relatively consistent directions.

The overall results of the six weeks of film vs. TLD testing indicated that there certainly was a bias between the film and TLD. This averaged about 20 percent with the TLD reading lower than the film. One exception to this case occurred for the wearing date of August 10, 1970, where the ratio of the film divided by TLD was .953.

Since one would normally expect at leas a 10 percent difference between any two dosimetry systems, I have not been able to fully explain the somewhat larger difference between the TLD and film. For low energy radiation the response of the TLD crystal becomes somewhat directional due to the rapidly changing thickness of material incident to the source of radiation as we rotate the crystal from its .035-inch dimension to its .125-inch width. Having a density of approximately 2gms/cm^3 you can easily visualize what the effect would be. By separate letter I am sending you the detailed results of our TLD study, including some specific comments I have.

If, after your final evaluation, you feel an adjustment to Miss Genova's exposure is called for, please supply us with a signed letter.

Sincerely,

R. S. LANDAUER, JR. & CO.
DIVISION OF TECHNICAL OPERATIONS

Robert V. Wheeler

Robert V. Wheeler
Technical Director

RVW/kmj

5-13-71

ATTENTION:
N. E. Driscoll

INFORMATION:
W. K. Fadling

REEVALUATION OF EXPOSURES

[redacted] - Extremities

Period	Type	Weekly	Total	Page
4/27-5/3	J1	230	810	
	M5	890	3030	30464
5/4-5/10	J1	360	1170	
	J1	240	1410	33107
5/11-5/17	J1	M	1410	
	M5	M	3030	41235

Note: On page 33107 of Landauer's reports, two J1 (body badge) entries were made, both of which were carried to the whole body total column. No M5 (wrist badge) entry was made on this page, and no total was carried in the extremities total column. Apparently, the second J1 entry should have been an M5 entry, and the record should appear as follows:

	J1 Body		M5 Wrist	
Period	Weekly	Total	Weekly	Total
4/27-5/3	230	810	890	3030
5/4-5/10	360	1170	240	3270
5/11-5/17	M	1170	M	3270

We will carry this additional 240 mrem in the totals column for the extremities exposure but will not bother to have Landauer delete this number from the whole body total, since it is of no consequence.

We also requested Landauer to reevaluate a reported exposure of 11.9 rems for the wrist badge worn for the period starting 5/25. Production records showed that during that week [redacted] dispensed Chloromerodrin Hg-197 twice, the first batch having failed Q.C. testing. She was also exposed to Tc-99 m gammas in an unusual step performed on the Ultratechnekow production line. Other operations performed would have resulted in little or no exposure. Landauer reported by letter dated September 28, 1970, that the badge showed evidence of contamination which may have contributed to the apparent exposure, but that at any rate if the exposure were due to Hg-197 and Tc-99 m gammas, the reevaluated exposure was 5000 mrem. We do not believe the exposure was as high as 5000 mrem

EXHIBIT J

but do not have any pocket chamber data for corroboration. Therefore, the total adjustment to her exposure consists of (1) the addition of 240 mrem for the period starting 5/4 and (2) the substitution of Landauer's reevaluation of 5,000 mrem for the original reported value of 11,900 mrem for the period starting 5/25. The reported data from Landauer and the adjusted exposures are as follows:

Starting Date	Reported				Adjusted	
	Weekly	Total	Page	Date	Weekly	Total
4/6	810	810	22837	5/5	810	810
4/13	790	1600	26016	5/11	790	1600
4/20	540	2140	30461	5/21	540	2140
4/27	890	3030	30464	5/21	890	3030
5/4	---	---	33107	5/25	(1)240	3270
5/11	M	3030	41235	6/9	0	3270
5/18	2100	5130	41842	6/9	2100	5370
5/25	11900	22830	55166	6/20	(2)5000	10370
6/1	2700	7830	46520	6/19	2700	13070
6/8	3100	10930	29774	6/23	3100	16170
6/15	M	22830	84074	7/6	0	16170
6/22	---	---	80677	8/6	0	16170
6/29	M	22830	77570	8/5	0	16170

These two adjustments (one addition and one subtraction) make her quarterly total exposure 16,170 mrem which is less than the regulatory limit of 18,750 mrem. Since Landauer reports are high by a factor of two on Hg-197, her actual exposure was probably much lower than 16170.

Ex 6

[redacted]--Extremities

The reported exposures were corrected by using available pocket chamber data and the following relationships:

The exposure of the film badge to Hg-197 is 1.8 times the true exposure to Hg-197.

1) $E(Hg)FB = 1.8E(Hg)true$

The measured exposure to Hg-197 (by pocket chamber worn on the wrist) is one third of the true exposure to Hg-197.

2) $3E(Hg)PC = E(Hg)true$

It then follows that:

3) $E(total)corr. = E(total)FB - E(Hg)FB + E(Hg)true$
$= " - 1.8E(Hg)true + E(Hg)true$
$= " - 0.8E(Hg)true$
$= " - 0.8[3E(Hg)PC]$

4) E(total)corr = E(total)FB - 2.4E(Hg)PC

The pocket chamber readings during the above corrected periods for Hg-197 were as follows: (See July 16, 1970, letter to R. S. Landauer.)

Starting Date	Pocket Chamber
4/13	480
5/11	358
5/25	70
6/1	270

Starting Date	Reported		Report		*Corrected	
	Weekly	Quarterly	Page	Date	Weekly	Quarterly
4/6	320	320	22837	5/5	320	320
4/13	2650	2970	26017	5/11	*1498	1818
4/20	400	3370	30461	5/21	400	2218
4/27	2300	5670	34485	5/27	2300	4518
5/4	400	6070	33107	5/26	400	4918
5/11	3490	9560	41236	6/9	*2631	7549
5/18	1150	10710	41843	6/9	1150	8699
5/25	1700	19140	55166	6/20	*1532	10231
6/1	5700	16410	46520	6/19	*6052	15283
6/8	1030	17440	49774	6/23	1030	16313
6/15	30	19170	84074	7/6	30	16343
6/22	---	---	80677	8/6	0	16343
6/29	M	19170	77570	8/5	0	16343

Although we requested by letter dated January 28, 1971, to R. S. Landauer that [redacted] exposure be changed to 16340 mrem, the value they entered was 16240. The 100 mrem is of no consequence, and therefore, I did not request R.S.L. to correct their entry.

D. W. Soldan Ex 6

MALLINCKRODT NUCLEAR
ATTN DON SOLDAN
PO BOX 1503
MARYLAND HGTS MO 6304

1501

ONE WEEK | B | 21571

R.S. Landauer Jr. & Co.
A DIVISION OF TECHNICAL OPERATIONS, INCORPORATED

J021241

RADIATION
DOSIMETRY REPORT

SCIENCE ROAD ☐ GLENWOOD, ILLINOIS 60425 ☐ PHONE (312) 755-7000

Landauer AND Gard/ray HEALTH AND SAFETY SERVICES

PARTICIPANT (BAT) NO	PARTICIPANT NAME	SOCIAL SECURITY NO	NOTE	EXPOSURE TO BADGE (IN MILLIREMS) FOR THE PERIOD OR PERIODS INDICATED BELOW — TOTAL	CUMULATIVE TOTALS - IN MILLIREMS — CALENDAR QUARTER OF ENTRY	YEAR TO DATE	PERMANENT				
		FOR EXPOSURE PERIOD 4/05/70 TO 4/12/70			0406 0705	1970					
1015	[redacted]		DS #5	6660	16170	42930	42930	C		38	470
1032			DS #5	2930	16240	22170	22170	C		40	470

THESE ARE THE SUMS OF THE INDIVIDUAL CORRECTIONS (CHANGES) WHICH LEAD TO THE NEW QTR TOTALS

THE ACCOMPANYING REPORT CONTAINS DETAILS OF CHANGES IN CUMULATIVE TOTALS AS REQUESTED BY YOU.

5-13-71

EXHIBIT K

Mallinckrodt NUCLEAR

INTER-OFFICE MEMO

May 4, 1971

TO: D. Soldan

FROM: R. Nuelle

Information:

N. Drissell
D. Shumate
L. Boyd
T. Sherman

Investigation of Dispensing Laboratory Procedure for (P^{32}) Phosphoric Acid Sources

On Tuesday, 30 March 1971, we were notified that a couple of complaints had been made by the California Institute of Technology at Berkeley about receiving grossly contaminated (P^{32}) phosphoric acid sources. An investigation was immediately begun to determine the cause and degrees of contamination, if the claim was valid, and to initiate corrective measures if such a problem existed. That afternoon the writer personally observed the dispensing procedure of a (P^{32}) phosphoric acid source for the Argonne Cancer Research Hospital. No procedural problems were observed. After the order was filled, the writer wiped the source vial and cap. At the final check station, the writer observed the assay of the source and the double check of the tightness of the cap. Another wipe of the source vial and cap was made before packaging. The results of these wipes are as follows:

vial and cap after filling	80 dpm/100cm.^{2}
vial and cap and tag before packaging	60 dpm/100cm.^{2}

(See memo to D. Soldan from R. Nuelle)

The following day, Wednesday, 31 March, you put a "hold" order in effect on the use of all 10cc. amber screw cap vials for P^{32} sources, pending further investigation and testing of these vials. The following action was taken:

I. The Dispensing Laboratory made up phosphoric acid (P^{32}) sources for testing in the following manner;

(a) Four sources in 10cc. amber screw cap vials.
(b) Four sources in ½ oz. French square screw cap vials.
(c) Four sources in 10cc. amber screw cap vials and sealed with Scotch brand "Paklon" heat shrinkable, pressure sensitive film tape.

EXHIBIT L

All sources were about 13mc. each, and the writer personally observed the filling procedure of each one. The procedures looked good and the technicians were quite knowledgeable in their job. At the final check station, the writer observed the final assays and the double check of the tightness of the caps. It was noted that the caps could be taken up an additional 30 to 45 degrees on about 40% of the vials. This is probably because the rubber gloves in the glovebox tend to give a false sense of the degree of torque because of the intermediate layer of rubber between the fingers and the vial cap. However, this is the object of the double check at the final check station. Wipes were made on each vial before packaging, and all packages were sent on a round trip to our Glendale facility and back to Maryland Heights.

II The above sources, upon return to Maryland Heights, were surveyed for surface radiation levels at the surface of the packages. The #1 can was carefully opened and the Kimpak was carefully checked for contamination. No evidence of contamination or unusual radiation levels was found. Each vial was totally wiped, including cap and tag; the results are listed in a table later in this report.

Since none of the above indicated a "material" weakness, a further test was conducted to deliberatelyintroduce a physical failure. To accomplish this, another source of (P^{32}) phosphoric acid solution was dispensed into a 10cc amber screw cap vial, but this time the cap was deliberately not tightened on the vial. The cap was carefully run down only until contact of the liner and the neck of the vial was sensed. The cap and neck of the vial was then sealed with the Scotch brand "Paklon" film tape described earlier. After sealing, a complete wipe was made on the vial and cap. Rigerous physical manipulation in the laboratory produced no evidence of leakage. (See table) This source was then sent on a round trip to Glendale and back to Maryland Heights, after which another complete wipe was made. (See table)

Effective 14 April 1971, all oral sources of P^{32} (viz. cat. #460 and 466) may be shipped in the 10cc amber screw cap vial only if sealed with shrinkable cellulose collars such as "Celon", or equivalent. This decision resulted from the above testing which indicated that, even in the event of a loose cap, the collar provided an effective seal against leakage of the contents of the vial and gross contamination of the external surfaces of the vial and Kimpak packaging material. Outside of this, no other recommendations were made to change the dispensing or packaging procedures.

Ralph

R. E. Nuelle

RNE:rp
Att.

INTER-OFFICE MEMO

NUCLEAR

April 14, 1971

TO: Carlstadt Dispensing Lab
Glendale
St. Louis Dispensing Lab
A. J. Virgona

CC: R. L. Coslet
N. E. Drissell
G. E. Gerth
D. W. Soldan
F. A. Zeloski

Effective immediately all sources of Sodium Phosphate, Catalog #460 and Phosphoric Acid, Catalog #466, should be dispensed with heat shrinkable seals. Heat guns and heat shrinkable tape will be shipped to each lab on April 14, 1971. The tape will be supplied from St. Louis and can be ordered through Purchasing when needed.

This change is the result of recent complaints indicating a leakage problem. Test shipments have indicated that this step will solve the difficulty. Tracy Sherman will follow up for proper compliance with a change to the Dispensing Lab Manual.

Donald J. Shumate, Manager
Radiopharmaceutical Distribution

/jg

INTER-OFFICE MEMO

MALLINCKRODT NUCLEAR

March 31, 1971

ATTENTION:
D. J. Shumate
R. L. Coslet

INFORMATION:
N. E. Drissell
L. E. Boyd

Amber 10 cc Round Bottle

A letter of complaint from the California Institute of Technology was received by me this morning (1005 hours). Copies of this letter were sent to several individuals in the Mallinckrodt/Nuclear organization and to the offices of the Bureau of Radiological Health in Berkley and Los Angeles and to the Department of Transportation in Washington.

I have taken the following immediate action considering the seriousness of this situation:

1. Informed the Dispensing Lab to stop all shipments of radioactive materials in amber 10 cc round bottles until further notice (1010 hours).

2. Requested the Quality Control Department to suggest an alternate bottle for the Dispensing Lab to use.

I suggest the following steps be taken to assure no further leakage occurs.

1. Use the 15 cc French square bottles which will not rotate when the cover is being tightened.

2. Use a torque wrench to tighten the cap to the optimum tightness.

3. Do not place the 10 cc amber rounds back in use until the cause of the leakage is determined and corrected.

4. Make some test shipments of P-32 in the 15 cc French squares to Glendale and back to assure that the problem is solved.

NOTE: The lids for the 10 cc amber rounds have been hand tightened in the past. A torque wrench has not been used for this bottle.

DWS:cm

D. W. Soldan