Form AEC-417

UNITED STATES ATOMIC ENERGY COMMISSION

COMPLIANCE INSPECTION REPORT

1. Name and address of licensee

Mallinckrodt Chemical Works
Mallinckrodt/Nuclear
Box 6172, Lambert Field
St. Louis, Missouri 63145

2. Date of inspection

April 24 - 28, 1967

3. Type of inspection: Reinspection

4. 10 CFR Part(s) applicable

Part 20 and 30

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

24-4206-1	10- 8-58	10-31-60	Reinspection #11
Amendment No. 17 (amended in entirety)	1- 5-66	10-31-66	
Amendment No. 18	9-15-66	10-31-68	
Amendment No. 19	10- 7-66	10-31-68	
Amendment No. 20	10-26-66	10-31-68	
Amendment No. 21	1- 6-67	10-31-68	
Amendment No. 22	2-16-67	10-31-68	

6. Inspection findings (and items of noncompliance)

The only items of noncompliance observed or otherwise noted during the course of this inspection are as set out below:

10 CFR 20.101 - "Exposure of individuals"

(a) - in that the licensee permitted an individual in a restricted area to receive a whole body exposure of 1.926 rem during the first calendar quarter of 1967. Licensee had not determined the individual's previous accumulated occupational dose. (See paragraph 100 of report details).

10 CFR 20.201 - "Surveys"

(b) - in that surveys were not made of a batch of laboratory uniforms sent to a commercial laundry during the week of April 24, 1967 to assure that significant amounts of contamination were not sent to the laundry. (See paragraph 95 of report details).

(b) - in that surveys were not made of production area "cold" waste basket contents to assure they contained no radioactivity prior to disposal through normal trash or by incineration. Independent measurements taken during the inspection revealed articles reading

7. Date of last previous inspection

November 17, 1966

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

DISTRIBUTION:

Division of Compliance
Headquarters (orig. & 1 cy)

Edgar C. Ashley for
Carroll D. Hampleman
(Inspector)

Approved by:

Eugene J. Moretti, Radiation Specialist (Review), Region III
(Operations office)

June 1, 1967
(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.

RECOMMENDATIONS SHOULD BE SET FORTH IN A SEPARATE COVERING MEMORANDUM

as high as 70 mrad/hr (beta-gamma) in these baskets. (See paragraph 60 of report details).

(b) - in that air sampling was not performed during the period December 8, 1966 to March 31, 1967 to determine compliance with 10 CFR 2.103 and 20.106. (See paragraph 90 of report details). 20.103

10 CFR 20.303 - "Disposal by release into sanitary sewerage systems"
(b) - in that the quantities of radioactive materials released to the sanitary sewerage system when diluted by the average daily quantity of sewerage released into the sewer by the licensee has, on occasion, resulted in concentrations exceeding the limits specified in Appendix B, Table I, Column 2 of 10 CFR 20. (See paragraph 64 of report details).

10 CFR 20.401 - "Records of Surveys"
(b) - in that records were not maintained of the results of surveys which were conducted of isotope worker's laboratory coats to assure no significant radioactivity was released with the coats prior to being sent to a commercial laundry. (See paragraph 95 of report details).

10 CFR 20.405 - "Reports of overexposures"
(a) - in that the licensee failed to report to the Commission the whole body exposure of 1.926 rem to one of its employees during the first calendar quarter of 1967. (See paragraph 100 of report details).

(b) - in that the individual who received the overexposure noted above was not notified of this exposure in writing as required by this section. (See paragraph 100 of report details).

DETAILS

GENERAL INFORMATION

9. This was an announced reinspection conducted April 24 - 28, 1967. The licensee was notified by telephone on April 6, 1967.

10. The inspector was accompanied by C. D. Hampleman, CO:III on April 24 - 27, and by J. M. Allan, CO:III on April 28.

11. The State of Missouri Radiological Health Unit was notified of this forthcoming inspection on April 20, 1967. Mr. Donald F. Richardson, of that organization, accompanied the inspectors on April 24 and 25.

12. The following persons were interviewed and supplied the information contained in these notes:

    W. R. Konnaker, General Manager, Mallinckrodt/Nuclear and Chairman, Isotope Committee
    D. W. Soldan, Manager, Health Physics Department
    Ray Caslet, Manager, Quality Control Department
    Dave Rhoads, Solid Source Department
    Bill Lawson, Supervisor of Chemists, Production Department
    Bill Robb, Manager, Dispensing and Shipping Department
    Hubert Sleipen, Shipping Foreman
    Jim Brown, Manager, Research and Development Department
    Walter Bushman, Health Physics Technologist
    Diana Constantine, Health Physics Laboratory Technician
    Van French, Health Physics Decontamination Technician

INSPECTION HISTORY

13. Reinspection No. 10 of this byproduct material program was conducted on November 15, 16 and 17, 1966. No item of noncompliance was found as a result of that inspection.

14. Reinspection No. 11 was conducted on April 24 - 28, 1967 and is the subject of this report.

15. Reinspection No. 11 was limited primarily to a review of the following items:

    A. Facilities and Use of Equipment
    B. General Scope of Program in each Department
    C. Air Handling System
    D. Waste Disposal
    E. Health Physics Organization
    F. Radiation Surveys
    G. Personnel Monitoring
    H. Isotope Committee
    I. Independent Measurements

FACILITIES AND EQUIPMENT

16. During the period December, 1966 to March, 1967 the licensee moved into its newly completed building addition. At the time of this inspection the move had, for the most part, been completed. The capsule filling operation, however, is still conducted in the gloved hood in the old Production Lab Iodine Room (now part of the R&D facility).

17. A sketch of the floor plan of the entire facility is attached to these notes as Exhibit A. The scale of the sketch is approximately 1 inch = 20 feet. Exhibit A shows a breakdown of areas according to departments.

18. Sketches of each departmental layout showing generalized use in each of the rooms or areas is attached to these notes as Exhibits "B-1", "B-2", "B-3", and "B-4".

19. During this inspection it was noted that the facilities and equipment were essentially the same as described in the licensee's application, dated October 12, 1966, with cover letter, dated October 13, 1966. A copy of the October 13, 1966 letter, with attachments, is attached to this report as Exhibit C.

GENERAL SCOPE OF PROGRAM IN EACH DEPARTMENT

PRODUCTION DEPARTMENT

20. The complete Hot Cell complex is not yet in full operation due to the lack of manipulators. Cells No. 5 and 8 have not been used as yet and Cell No. 6 is not currently in use for this reason. Bill Lawson stated the Cell No. 6 had been used in the past for processing Hg-197 and Hg-203, utilizing manipulators from other cells.

21. All isotopes are taken in and out of the Hot Cells by way of Cell No. 1 (the Transfer Cell). A description and typical usage of this and the other cells is spelled out in Exhibit "C-11", "C-12", and "C-13". The transfer drawer and glove box (See "C-13") are not in use yet. Also red lights, mounted on the Cell Unit, are activated whenever the main transfer door is open.

22. Cell No. 2 (double size cell) is used for processing Mo-99. Every Thursday, 24 curies of Mo-99 are received in a quartz capsule. After two days of processing the Mo-99 solution is added to sterile cold "Kows" in the cell. The new sterile Mo-99 - Tc-99m "Kows" are 50, 100, 200, 400 millicuries each, as of the following Monday.

23. In Cell No. 3, 20 - 30 curies of Au-198 as a foil are received every Tuesday. This is made into collodial solution and bottled in this cell. The newly bottled solution is transferred to Cell No. 2 and autoclaved.

24. In Cell No. 4, 10 curies of I-131 as NaI concentrate is received every Wednesday or Thursday. This processed solution is transferred to other production areas for tagging and capsule making.

25. In Cell No. 7, one irradiated multicapsule is received approximately every three months. This capsule contains Fe-59, Ca-45, Sr-85, and Cr-51, ranging in activity from about 100 mc to 500 mc for a given isotope. The individual isotopes are put into solutions and bulk bottled. When needed, portions are transferred to glove boxes for further processing.

26. Any production work which involves significant quantities of radioactive materials is done either in the Hot Cells, Glove Boxes, or other complete enclosures. A description and function of the glove boxes is spelled out in Exhibit "C-13" and "C-14".

27. Initial processing of Hg-197 and Hg-203 is done in Glove Box No. Ho-541. This work involves about 6 curies of Hg-197 on a Monday and about 2 curies of Hg-203 on a Thursday. The material is stored in shielded containers in a refrigerator overnight and taken to a Sterile Room glove box for further processing. Lawson stated that both of these initial processing jobs will be performed in the Hot Cell when additional manipulators are obtained.

28. Further processing of Fe-59, Sr-85, and Cr-51 is done about once every four weeks in Glove Box No. HO-540. After processing, these materials are autocalved (using a pressure cooker on a nearby bench top) and then placed in the Interim Storage Room to await Quality Control check.

29. Glove Box No. HO-539 is used for the weekly processing of about 220 millicuries of P-32.

30. In Glove Box No. HO-536, I-131 as NaI is used every other week to tag Rose Bengal (250 mc) and Triolein and Oleic Acid (about 200 mc each).

31. Glove Box No. HO-535 is used for the weekly tagging of IHSA concentrate (400 mc) and MAA (900 mc) with I-131 as NaI.

32. The remaining three Glove Boxes in this immediate area, namely; Nos. HO-542, HO-538, and HO-537, have not been used as yet.

33. A large hood on the west wall of the main production area is used for tagging T-3 and T-4 with iodine. I-131 (200 mc) is done weekly and I-125 (100 mc) is done monthly. This hood is not equipped with any stops to keep the front from being opened all the way. With the front fully opened the air flow across the face would be only about 75 linear feet per minute.

34. In the southwest corner of the main production area is the Iodine Room. In this room is a glove box (No. HO-544), the capsule sorting machine, and a capsule storage vault. Every Monday 121 Triolein and 70 Oleic Acid I-131 capsules are filled. Each capsule is 100 microcuries as of the following Monday. The entire capsule sorting machine is enclosed in a wood cabinet with lucite doors. The capsule collector is located under the sorter and is enclosed in a lead lined steel cabinet. Each of the seven shutes go into a lead pot inside the steel cabinet. The capsule storage vault (known as the "Fort") is made of lead, steel and cement blocks and measures approximately 4 feet wide x 3 feet high x 3 feet deep on the outside. A one-inch thick by 12 inches high open top lead enclosure is used to store pots containing standards and other low level I-131 materials.

35. Personnel must make a shoe change (or toe rubbers) upon entering the Iodine Room.

36. Along the south wall of the main production area are three Bays. These bays are "enclosed" by five foot high "walls". The bays are used for preparing cold "Kows", low level labeling, making of Isojex standards, count rate, absoluting and matching work. A hood in the center bay is used for oven drying of TBI resin, Co-57 and Co-60; also for storage of miscellaneous materials in lead pots.

37. The I-131 capsule filling machine is still located in a gloved hood in the old original production iodine room which is now part of the R and D section. Lead bricks are stacked up inside the front of the hood to about four feet from the floor. The capsule solution is in a shielded container in the rear of the hood. Filled capsules funnel down a shute to a shielded container under the hood which is enclosed in a steel cabinet. Both hood and under hood enclosures are vented to the same exhaust. Approximately 4000 capsules are made each week. Each capsule is 330 microcuries on the day of filling.

38. TBI vial kits are matched and packaged in one room set aside for this purpose. This room is located off a corridor east of the main production area.

39. The Sterile Room is located in the extreme southeast corner of the main production area. All prep work is done in glove boxes and includes: preparation of Isojex, filtering and sterilizing of Hg-197 and Hg-203, and dispensing of MAA. This room also includes a commercial two-way autoclave which opens into the Sterile Room as well as into a corridor south of the room.

40. A small interim product storage room is located in the northwest corner of the main production room. Each batch of new products is stored here until Quality Control releases the batch to Dispensing.

<u>QUALITY CONTROL DEPARTMENT</u>

41. Under the supervision of Ray Caslet, quality control checks are made of all incoming, in-process, and finished radioactive materials and products. The frequency of these checks range from daily to once every two months according to product. Approximately sixty (60) different radioisotope compounds are

41. (Contd.)
tested. Each compound is tested according to its own schedule and requirements and will include part or all of the following tests: Description, Chromatography, pH, Spectrum, Sterility, Radioactive assay, B_{12} assay, Specific Activity (Radioactive assay/B_{12} assay), Beta absorption, Pyrogens, Aluminum, Molybdenum, BioAssay (Animal Test), Rose Bengal assay, Particle size, Safety (Animal injection), and Electrophoresis.

42. Sterility quality control tests are done in a glove box while most of the others are performed on a bench top in a northwest corner of the main lab.

43. Two Animal Rooms are located at the west end of the main lab. The animal testing room adjoins the main lab while the back room is used for housing animals before and after testing and cage storage. These rooms have an outside exit to allow transfer of animals and animal matter. The maximum amount of radioactivity used in any one animal ranges from 20 to 90 microcuries.

DISPENSING AND SHIPPING DEPARTMENTS

44. Materials are transferred by cart from Production to Dispensing by way of the packaging area of the Shipping Section. This is accomplished through a set of double doors which separate Production and Shipping or by way of floor level pass-throughs. A shoe change step-over is located at the entrance to the Dispensing office.

45. All orders which are filled in Dispensing are done so in glove boxes. An open top, lead-walled hold area is used for finished orders prior to checking and passing through to Shipping. This pass-through consists of a waist high window and a one foot thick, open top concrete "tank" located on the Shipping side of the window. A similar "tank" is located at the pass-through window joining the Interim product storage room and Shipping.

46. In the Dispensing area is the licensee's Drug Storage Room. Quality control samples of each sold product batch are stored here. In addition, new material from Production is stored here prior to making up orders in the glove boxes, and, at the end of the day, finished material is taken from the boxes and stored here according to Bill Robb, Department Manager.

47. Hubert Sleipen, Shipping Foreman, stated that most products come through the Dispensing pass-through while Mo-Tc "Kows" come directly from Production. Orders are kept in the shielded "tanks" and carried, one at a time, to the packaging table and packed behind a one-inch thick lead shield. Each filled bottle is received by Shipping already packed in a lead pot and in a closed cardboard "can". Final packages are stored in a specially designed, shielded shelf area to await shipment. Sleipen stated that about 70 orders are packaged daily, Monday through Friday and about 200 are packed on Saturday. Of the 200 on Saturday, about 100 are Mo-Tc "Kows". Each finished box is surveyed for radiation levels with a Ludlum, Model 14A beta-gamma portable survey instrument.

48. A heavy safe, measuring about 30 inches x 30 inches x 30 inches is located outside the building for the temporary storage of some products awaiting pickup by a commercial carrier. The licensee has arranged this set-up with the American Courier Corporation, Bayside, New York. Only the Shipping Department and the carrier driver have keys to the safe.

RESEARCH AND DEVELOPMENT DEPARTMENT

49. The R&D lab is located entirely within the old production facility. Six hoods (3 large and 3 small) are utilized for R&D work. One of the large hoods is equipped with gloves and sliding front face. A shoe change step-over is located at the entrance to the lab.

50. Jim Brown, R&D Department Manager, stated that development work with up to one curie of Mo-Tc Kows is carried out weekly. Other development work involves: I-131 (20-100 mc), Hg-203 (20-500 mc), Hg-197 (10-500 mc), I-125 (5-20 mc), P-32 (60-250 mc), Cr-51 (10-100 mc), Fe-59 (0.1-5 mc), and C-14 (2-5 mc). R&D work includes new products, present products, new methods, etc.

51. The Production Department uses a corner of one of the R&D rooms for its capsule filling machine operations. (See paragraph 37).

SOLID SOURCES DEPARTMENT

52. The Solid Source Room is located in the basement. The room was part of the old facility and was not affected by the new building addition. The facility is equipped with two in-the-floor storage tubes, a modified laboratory counter with a recessed shield storage tube, solid concrete blocks, lead glass viewer, mirror, radium safe, tongs, and various counting equipment.

53. Dave Rhoads, the only person who works in this room described the various activities conducted here. The supply of irradiated stainless steel (Co-60) wire is stored in the in-the-floor tubes. Portions of the wire - about one to two curies at a time - are transferred to the counter recessed tube, and from there, smaller wires are cut for working stock. Individual wires (about 8 mc each) are used to fill cell orders. Rhoads went through a dry run to illustrate his method of transferring wires, making up individual wires, counting with a well counter, loading the cell, and finally, placing the new cell in a lead shipping container. Rhoads used 10-inch tongs to show his wire and cell handling procedures.

54. Cs-137, 1 microcurie and 4 microcurie each, sealed sources are made for use in McDonnell Aircraft Corporation bucking bars. Rhoads stated that McDonnell is the licensee's sole customer for Cs-137 sources and involves one to three orders per year of 1000 - 2000 sources per order. Three lambda aliquots of liquid Cs-137 is placed in a small copper cylinder 1/4-inch long and 1/16 inch in diameter after one end is sealed with Sauerisen cement sealer. The liquid is dried by air or infrared, after which the open end is sealed with Sauerisen. This is then placed in a case hardened steel cylinder and filled and sealed with Sauerisen. A few hundred of these sources are produced at one time currently. This room is not now equipped with any exhaust. The licensee representatives stated that an exhaust is being planned for this room and will be in operation by the time a new process, now under development, is put into effect to allow production of 1000 Cs-137 sources at a time.

55. Also in this room Radium is loaded into Ernst Applicators. These are supplied to customers on a rental basis.

AIR HANDLING SYSTEM

56. Air is supplied to the new building addition through two systems. One system serves only the Production Laboratory and the other system serves the rest of the building addition. Approximately 80 percent of the Production Laboratory air system is recirculated, and approximately 75 percent of the remaining new addition air system is recirculated. There are eight points of discharge from the new addition and four points from the original section of the building. Following is a list of these exhaust points: (See Exhibit D)

Points	Remarks
N	Animal Room exhaust. Not filtered. 575 CFM. This is an exhaust for general room air.
O	"Venturi" exhaust, filtered, and serving the capsule room, P-32 box, Hg-203 & 197 boxes, Fe-59 box. 1,750 CFM exhaust with additional outside air induced via the Venturi effect.

56. (Contd.)

Points	Remarks
P	Filtered with absolute and charcoal filters, 490 CFM, serving the iodine glove boxes, cells #4 and #8, capsule sorter, and fort.
R	Waste Room exhaust, 1,400 CFM, general room air exhaust, no filters.
S	Exhaust for hood in Quality Control. Also serves as exhaust for a glove box in the southwest corner of Quality Control. 750 CFM. Filtered.
T	Production hood in center bay. Filtered. 750 CFM.
U	Hot cells 1, 2, 3, 5, 6, and 7. Filtered. 750 CFM.
V	Sterile Room. Filtered. 200 CFM.
W	Research and development hoods. Filtered. 1,700 CFM.
X	Research and development hoods. Filtered. 1,000 CFM.
Y	Dispensing glove box and drug storage area.
Z	Hood in Health Physics area. Filtered.
(AA)	Office air return. Unfiltered.
(BB)	Office air, stairwell return. Unfiltered.
(CC)	Basement cold air return. Unfiltered.

It should be noted that the only charcoal filtered system above is "P" serving cells 4 and 8 and the iodine glove boxes in the Production Building. In addition, stack "W" also serves the iodine capsule filling operation. (See paragraph 37).

WASTE DISPOSAL

57. All solid active waste from the hot cells, glove boxes, hoods and dry active waste cans located throughout the various work areas are collected as required and stored in in-the-floor storage tubes in the Waste Storage Room and in the fenced in area outside the building as described in Exhibit "C-15" and "C-19". The Waste Storage Room is also used for storing other miscellaneous items such as empty lead pots, extra cans and cartons, etc.

58. Periodic shipments of solid active waste are made to Nuclear Engineering, Morehead, Kentucky. All waste is packaged in fiber drums ranging in size from 2.2 to 5.5 cubic feet each. The licensee maintains completed packing slips and invoices for each shipment. These records show the maximum quantity of any byproduct material in any shipment to be 640 millicuries of Hg-203 with all others less than 100 mc. Radiation surveys of each outgoing drum has shown maximum readings of 200 mr/hr at two-inches and 10 mr/hr at one meter.

59. During 1966, shipments were made on nine separate dates and so far in 1967, shipments have been made on six separate dates up to April 19.

60. Waste baskets are located throughout all work areas for the collection of "cold" trash. Except in the main Production Lab, these waste baskets are surveyed by Health Physics personnel prior to disposal by way of the licensee's incinerator (combustible) or by trash pick-up (non-combustible). John Kellerman, a Production Department Technician, collects and dumps all "cold" trash from the Production Department. The licensee representative stated that no surveys are conducted of this trash to assure that no radioactive materials are incinerated or released to the normal trash. The licensee representatives were advised that failure to perform such surveys of his "cold" trash prior to

60. (Contd.)
incineration and/or disposal to commercial garbage pick-up constituted noncompliance with 10 CFR 20.201(b). Independent measurements conducted by the AEC representative of the "cold" waste baskets in the main production laboratory showed baskets to contain waste articles reading as high as 70 mr/hr beta-gamma. (For further information concerning Independent Measurements please see also paragraphs 107 and 108). During telephone conversations with Soldan following the inspection, Soldan stated that a Health Physics meeting was held which resulted in the decision to train Kellerman to use a survey meter, number each "cold" waste basket, and prepare a waste basket survey log book. The proposed procedure is to have Kellerman to make a survey of each basket at the end of the work day and record the survey results, by basket number, in the log book; then remove any contaminated articles prior to emptying the baskets into normal trash. Soldan advised that by numbering each basket, any contamination could be traced to a particular area and therefore to the persons involved. Also, the production area glove boxes are not equipped with drains and the inclusion of the glove boxes as one of the items emptying liquid active waste into the retention tank (See Exhibit "C-10") was an error on Soldan's part and should be deleted.

61. The licensee's liquid active waste handling system was found to be essentially as described in Exhibit "C-8", "C-9", "C-10", and "C-19". The metering instruments, pump controls, and sampling points for both high level and low level retention tanks are located on a common panel in the Laundry Room. In addition, a clean water discharge by-pass system is controlled from this area. This by-pass system allows the licensee to add clean water downstream from the retention tank thereby diluting the retention tank discharge, as needed, prior to the liquid leaving the licensee's property. A normal water usage of approximately 2500 gallons per day was derived from the water company's data. This was a daily average taken over a two to three month period, according to Soldan. The total volume of water required was calculated per the one curie per year limit and the MPC_w for I-131 (most restrictive). Using the equation: $V = \frac{1 \text{ curie/year}}{MPC_w \ \mu c/ml}$, Soldan determined the total daily water requirements to be 12,100 gallons. It was assumed that the maximum number of days/year the licensee discharged liquid waste would be 260. Soldan then multiplied 12,100 gallons x $\frac{260}{365}$ to give 8,600 gallons/day actually needed. To achieve this, the by-pass was adjusted to add 6100 gallons/day to the known 2500 gallons/day water consumption. This 6100 gallons/day was added continuously whether or not any dumps were made. Soldan stated that this was done in order to lower the average monthly concentration.

62. Assuming a daily discharge (260 days per year) and a maximum daily discharge of 1000 gallons, Soldan calculated the maximum permissible counts per minute (cpm) per tank sample as follows:

$$\frac{4 \text{ mc/day}}{1000 \text{ gal/day}} \times \frac{1 \text{ gal}}{3.785 \times 10^{-3} \text{ M}^3} \approx 1 \text{ mc/M}^3 \text{ or } \frac{1 \text{ muc}}{\text{ml}}$$

$$\frac{1 \text{ muc}}{\text{ml}} \times \frac{10 \text{ ml}}{\text{sample}} = \frac{10 \text{ muc}}{\text{sample}}$$

Using approximately 25% counting efficiency:

$$\frac{5 \times 10^6 \text{ cpm}^{**}}{\text{uc}} \times \frac{10 \text{ muc}}{\text{sample}} = \frac{50 \text{ K}^* \text{ cpm}}{\text{sample}}$$

It was pointed out to Soldan that this data appeared to show about 250% counting efficiency. The decimal correction therefore changes this calculation to:

$$\frac{0.5 \times 10^6 \text{ cpm}}{\text{uc}} \times \frac{10 \text{ muc}}{\text{sample}} = \frac{5 \text{ K cpm}}{\text{sample}}$$

*K=1000 **Overall yield factor (efficiency)

62. (Contd.)

Combining the above data, Soldan determined, at the time of the inspection, the total number of millicuries contained in each dump to date as follows:

$$Act_{mc} = \frac{4\ mc}{1000\ gal} \times \frac{\text{Count Rate (K cpm)/sample}}{\text{5 K cpm/sample}} \times \text{Volume discharged from tanks (gallons)}$$

The licensee's records of dumps and analysis are listed below:

Date	Count Rate (K cpm)	Gallons Discharged From Tank	mc
3-2-67	12.9	900	9.3
3-7	-	-	7.3
3-10	7.52	900	5.4
3-14	12.9	900	9.3
3-20	16.2	900	11.7
3-23	48.7	500	19.5
3-27	30.7	500	12.3
3-29	17.4	900	12.5
4-4	9.8	900	7.1
4-10	7.4	900	5.3
4-14	6.1	900	4.4
4-19	7.3	900	5.3
4-24	13.5	900	9.7
4-25	213.0	200	34.1
4-26	106.0	400	33.9

63. Using a daily diluted output of 8600 gallons, the concentrations discharged on the above noted days range from $1.6 \times 10^{-4}\ \frac{uc}{ml}$ to $1.25 \times 10^{-3}\ \frac{uc}{ml}$. It was pointed out to Soldan that if discharges were planned for only 260 days/year it appears that the continuous daily requirement of 12,100 gallons should have been multiplied by $\frac{365}{260}$ to show actual "dumping day" needs, of about 17,000 gallons instead of 8600 gallons. This assumes no water usage at other times of the year.

64. The following list of byproduct materials includes some of those which the licensee possesses and uses and therefore, likely to dispose of as liquid waste.

Byproduct Material (Soluble)	10 CFR 20 Appendix B Table I Column 2	Equivalent Millicuries per 8600 gallons
I-125	4×10^{-5} uc/ml	1.30
I-131	6×10^{-5} uc/ml	1.94
Hg-203	5×10^{-4} uc/ml	16.2
P-32	5×10^{-4} uc/ml	16.2
Au-198	2×10^{-3} uc/ml	65.0
Rb-86	2×10^{-3} uc/ml	65.0
Fe-59	2×10^{-3} uc/ml	65.0
S-35	2×10^{-3} uc/ml	65.0
Mo-99	5×10^{-3} uc/ml	162.0

Soldan stated that a spectrum made of the activity discharged on April 26, 1967 showed that about one third (or about 11 mc) was due to I-131. The licensee representative was advised that the discharge of 35×10^{-5} uc/ml of I-131 plus about 7×10^{-4} uc/ml of other miscellaneous isotopic concentrations during the course of one day exceeded the average concentration specified in Appendix B, Table I, Column 2, Part 20, therefore this constituted <u>noncompliance with 10 CFR 20.303(b)</u>.

65. Soldan stated that he was under the impression that only the one curie per year total activity limit and the average daily concentration <u>based on an average water dilution over a several day period (including dilution for days when no radioactive materials were discharged) had to be met</u>.

66. Soldan advised that the diluting by-pass water could be increased on days when the retention tanks are discharged to a point where the concentrations or radioactive materials being released on any one day will be less than those specified in 10 CFR 20, Appendix B, Table I, Column 2 for any byproduct materials discharged by the licensee.

67. The licensee analyzes his retention tank samples with a modified single channel analyzer using a scintillation well counter. (Please also see paragraph 73). Although this system does not allow beta detection, Soldan stated that glove boxes in which significant quantities of P-32 areprocessed are not equipped with drains, therefore, P-32 liquid waste is stored for decay and contaminated articles are disposed of by way of dry active waste.

68. The licensee representative stated that the retention tank contents are aggitated by compressed air jet when a smaple is taken prior to dumping. Also the discharge pipe opening is located about half way down in the tank.

HEALTH PHYSICS ORGANIZATION

69. The Health Physics Department organizational chart of Mallinckrodt/Nuclear consists of the following named personnel: (See also paragraph 77).

Donald W. Soldan, Manager
Wally Bushman, Technologist
Diana Constantine, Laboratory Technician
Peggy Reagan, Secretary
Van French, Decontamination Technician

70. Donald Soldan is considered the manager of the St. Louis office plus all of the branch offices. In this position, he has the complete responsibility of the Health Physics Organization and practices of Mallinckrodt/Nuclear. He establishes and implements all programs, procedures, controls, isotope inventories, prepares license amendments and complies radiation histories.

71. Wally Bushman, Technologist, a former Health Physics employee of Welden Springs is a recent new employee of Mallinckrodt/Nuclear as of November 21, 1966. At that time the licensee was in the process of moving from the old building into the new building addition. Bushman assisted Soldan and John Shrader (maintenance man) in the installation of the air sampling system. This work was in progress for a considerable length of time, finally being completed at the end of March of 1967. Mrs. Diana Constantine was hired during February of 1967, and therefore, most of the health physics work prior to that time was left to Bushman and Soldan. Roberta Beckham, who formerly was the health physics assistant to Mr. Soldan, terminated in December of 1966.

72. At the present time, Wally Bushman is considered a Technologist and, as such, he is the most responsible health physics person immediately under the supervision of Mr. Soldan. In general, Mr. Bushman's duties are collection and counting of air samples, making physical radiation surveys, personnel contamination checks, contamination surveys, handling of radioactive waste, and general routine health physics. Mr. Bushman routinely handles all of the health physics work which needs to be performed in the restricted area. Routine work performed in the unrestricted area is usually done by Mrs. Constantine. Bushman changes all of the in plant air sampling heads inside the restricted areas and performs all of the physical radiation surveys which are done inside the restricted areas. These physical radiation surveys are performed daily and the results of the surveys are recorded once or twice a week according to Bushman. Mr. Bushman also collects all of the smears for contamination which are taken daily inside of the restricted area. Recently, spot wipes have been taken of outer surfaces of radioactive shipments, according to Mr. Soldan.

73. Mrs. Diana Constantine, Laboratory Technician, performs duties primarily in the counting room involving counting and collection of samples. She collects air sample cartridges from unrestricted areas, measures initial and final air flow rates of these samples, and performs most of the routine laboratory counting of these samples. Thyroid uptake measurements are performed by Constantine, Bushman, or Soldan as building personnel come to the Health Physics Laboratory for this routine measurement. Mr. Soldan plans to initiate Mrs. Constantine on the collection and counting and recording of radioactive liquid waste. At the present time, this duty is being performed mostly by Mr. Soldan. Mr. Soldan collects a sample of the liquid waste from the retention tank, places it into the single channel analyzer, performs any counting or scan measurements necessary, calculates the radioactive concentration, and measures the discharge rate necessary for the discharge of the radioactive liquid into the sewer system. (S also paragraphs 61-68).

74. Mrs. Constantine performs all of the physical radiation surveys and the contamination smears taken in the unrestricted areas. She exchanges all film badges on a weekly basis and performs urinalysis duties by collecting the samples, preparing the samples for counting, and making the final count. Approximately 74 smears are taken each day and analyzed by Mrs. Constantine for contamination. This smear counting takes about two hours of Mrs. Constantine's time per day. On Mondays, Wednesdays, and Fridays all in-plant, environmental, and stack air samples are collected and counted. The counting of these samples require about three hours.

75. Van French, Decontamination Technician, performs most of the routine duties of washing, decontamination, and handling of waste. Mr. French collects, washes, and dries all gloves, lab coats, shirts, pants, and dresses, which are washed by Mallinckrodt/Nuclear and not sent out to a commercial laundry. His duties also include daily surveys of protective clothing for contamination, and he will rewash contaminated clothing or store them for decay. (See paragraph 95). A major duty of Mr. French is the collection, washing, and testing of glove box gloves and toe rubbers. The glove box gloves are changed once per week. All this work is done using an automatic washer and dryer in the laundry room. The washer drain goes directly to the retention tank system. The exhaust of the dryer goes directly to the outside of the building. Mr. French collects all of the waste from the low level waste containers in the Quality Control, Dispensing, Research and Development, and Health Physics Departments. The hot and cold waste is separated and surveyed before incineration of the cold waste. Another of Mr. French's duties is the decontamination of any floor areas which may be found contaminated as a result of the daily smear surveys made.

76. Peggy Reagan, Secretary, spends about 1/3 of her time performing duties for Mr. Soldan. Her general secretarial duties include typing of final versions of reports, etc. that are actually done by Mr. Soldan or others.

77. Included with this inspection report as Exhibit E, is a flow sheet of the Health Physics Department organization and a breakdown of the duties of all personnel presently within the health physics organization.

RADIATION SURVEYS

78. The licensee maintains a log book which contains the results of routine radiation surveys performed. Each radiation survey consists of measurements of the radiation levels in the following locations:

   a. General working area in all rooms
   b. Working area at hood and glove box fronts
   c. Measurements taken exterior to the building

   All measurements are taken with portable beta-gamma instruments. Mrs. Constantine obtains all readings in the unrestricted areas and Mr. Bushman takes all restricted area readings.

79. The record book of "Radiation Level Surveys" was reviewed by the AEC representatives during this inspection. All records of physical radiation surveys performed from November of 1966 to the date of this inspection were reviewed. During November and December of 1966, these surveys were performed on an almost daily basis. Only two were recorded during January, 1967, two were recorded during February, 15 were recorded during March, and four had been recorded during April, 1967.

80. A review of the results of these records indicated that all general room working area radiation levels were 1 mr/hr or less. Radiation levels at the front of some glove boxes ranged up to 50 mr/hr. The survey sheets contained a section for "comments" and a section for "corrective measures". It was noted that on many occasions Bushman had commented on specific areas of interest and had also listed the action which had been taken in order to "correct" the existing radiation levels found.

81. The licensee maintains a notebook entitled "Smear Results". In this notebook are the results of daily smears taken. At the present time approximately 74 smears are taken daily and counted - Mr. Bushman takes the smears in the restrictive area and Mrs. Constantine takes all smears in the unrestrictive area. One-inch diameter paper is used for the smear. Two fingers are placed on the paper and moved approximately 50 centimeters across the surface to be smeared. The licensee considers a limit of 200 d/m/100 cm^2 for unrestricted areas and a limit of 2,000 d/m/100 cm^2 for restricted areas. All smears are counted each day in a laboratory counter utilizing an end window GM tube. Any area exceeding the limit is cleaned and resmeared until the smear meets minimum requirements. Approximately two to three man-hours are spent each day in the counting of these smears.

82. The licensee's record book of "Smear Results" was reviewed during this inspection. Particular attention was given to the smear results for the period of November, 1966 to date. This period represented the time that most moving was done, and the records showed that considerable contamination was detected during these months. At the end of November, 1966, almost all smears in the restri[illegible] areas were in the order of 10,000 to 100,000 d/m/100 cm^2 and offi[illegible] areas generally ranged from 200 to 1,000 d/m/100 cm^2. On December 5 the rec[illegible]s were maintained on new data sheets showing the new building addition, and this new form was primarily used from that time on. By the end of January, 1967 smear results indicated contamination of up to 258,000 d/m/100 cm^2. Bushman had entered information on the record of January 31, 1967 stating that two and three moppings were done of the entire Production Lab and R&D before the contamination was brought under control.

83. On February 7 contamination of up to 60,000 d/m/100 cm^2 was detected in R&D. Bushman had entered a note in the record indicating that R&D and Dispensing had been cleaned. On February 9 a note from Soldan was written to Dr. Hallett, Dick Holgate, and Dr. Konnecker stating that contamination was being spread to the Shipping Room because personnel from Production were transferring activity to Dispensing through Shipping with carts taken through the double doors. In this note, Soldan also stated that carts were being wheeled from Production direct to R&D.

84. Another note dated February 27, 1967 from Soldan to Dr. Hallett and Jim Brown was written requesting that personnel in R&D decontaminate their horizontal surfaces. This was done in about a week. Recent administrative procedures, by way of a memo from Hallett, gives the responsibility of decontamination of table tops and other lab horizontal surfaces to the lab occupant.

85. The only instance of contamination (as determined by isotopic analysis) was Hg-203 and 197 when 88,000 d/m/100 cm^2 was detected in R&D and Production. The records indicated that from the period March 3, 1967 to the date of this inspection no similar amounts of gross contamination incidents have occurred.

86. The licensee depends upon toe rubbers for routine control of floor contamination. Toe rubbers are required prior to entrance into the following areas

a. Production
b. Dispensing
c. Research and Development

In addition to these three main areas maintained specifically for contamination control, toe rubbers are also locally required on entry into the animal room and into the iodine room. At the above listed three toe rubber control areas, a small lab rate-meter is provided to allow monitoring of toe rubbers, lab coats, hands, shoes, etc., before personnel leave the area. According to Mr. Soldan, all personnel have been instructed to survey themselves before leaving these controlled areas. By observing plant personnel as they routinely left these areas, the AEC inspectors noted that some people did not in fact perform this survey. Mr. Soldan also stated that no routine personnel check is currently being required at the end of the day.

87. The licensee maintains a record book of all air sample results. These records were reviewed during this inspection. All air sample results from November, 1966 to the date of this inspection were reviewed with the following results:

a. Intermittant Air Samples (in-plant)

Dates	Areas	f MPC
11/14-16/66	ABCDEFGM	A-.32; B-.27; C-.24; all remaining were less than 1.0
11/16-18	"	"
11/18-21	"	"
11/21-23	DEFG	Less than 1.0
11/23-25	All 8	"
11/21-22	ABE	"
11/25-11/28	"	"
11/28-11/29	All 8	"
11/30-12/1	"	"
12/ 1-12/5	"	"
12/5 -12/8/66	"	"

(Results are listed as fractions of the in-plant MPC f 9×10^{-9} mc/cc.)

The above listed locations are in the old Production Room and are in-plant air samples taken in front of the following hoods:

A - Iodine Capsule
B - Iodine Dispensing
C - Iodine Production
D - Moly Production
E - Hg Production
F - Au Production
G - Tc Production
M - Sterile Room

Samples taken from A to F had a millipore filter in series with the charcoal. Samples G and M had charcoal only with no millipore filter.

b. Continuous Air Samples

Dates	Areas	f MPC
11/14-18/66	1, 2, 3, 4, 5, 6, 7	All results less
11/18-21	8, 9, 10, 11, 12, 13	than one MPC
11/21-23	27, 28, 29, 30, 31	
11/23-28		
11/28-29		
11/29-12-5-66		

This group of air samples included those taken in both restricted and unrestricted areas, in-plant, stack, and environmental sampling.

c. Starting March 31, 1967, a completely new system of air sampling was begun. Beginning on this date, 44 samples are taken 3 times per week. This list includes 18 in-plant samples numbered from 1 through 18, 13 environmental air samples lettered A through M, 13 stack samples lettered N through Z, and 3 in-plant recirculating air samples lettered (AA), (BB), and (CC). At the present time each is being monitored except Q, (BB), and (CC). The licensee's records showed that since March 31, 1967 of all the air samples taken, the MPC has been exceeded twice:

Date	Location	Results
4/17 to 19/67	A	2.5 X MPC
	G	1.4 X MPC
	H	1.0 X MPC
4/19 to 21/67	#14	72.56×10^{-9} = 8 X MPC "Noted to be Hg 197 with MPC of 1×10^{-6} mc/ml"

88. The above itemized results of air sampling as obtained from the licensee's records show that no in-plant or environmental sampling was performed from December 8, 1966 until March 31, 1967. Discussion with Mr. Soldan and Mr. Bushman revealed that this period of time was during the moving into the new facilities. Work was in progress on the installation of the new sampling system consisting of the in-plant vacuum line and the roof PVC lines. During this period of time Soldan was aware that no sampling was being performed.

Mr. Bushman had joined the program during November, Miss Beckham had quit during December, and Mrs. Constantine had not been hired until the middle of February, 1967. This arrangement had left only Soldan and Bushman to perform all the Health Physics duties at the facility until Mrs. Constantine's arrival in February. It was also during this period of time that considerable gross floor contamination incidents were occurring. (See paragraphs 82 - 85). Bushman stated that freezing conditions on the roof considerably hindered the work of installing the elaborate system of PVC tubing. In addition to ice on the roof, the roof PVC tubing would freeze up inside the lines due to the freezing of condensation as room temperature exhaust air was being drawn from the exhaust through the cold tubing and back into the building to the vacuum pump.

89. Mr. Bushman was specificallly questioned relative to their plans for next winter concerning methods of possible remedy of the plugging up of the PVC lines due to freezing. Mr. Bushman stated that at the present time no specific plans have been made to correct this situation.

90. The licensee's records show that no in-plant, stack, or environment air sampling was performed between December 8, 1966 until March 31, 1967. Mr. Bushman stated that he thought that "some" were taken during January of 1967 in the old Production area at hoods A, B, and C, however no records were available to indicate that these samples were in fact taken, and Soldan stated that he could not specifically remember that any were taken during this time. The licensee was informed that his failure to perform air sampling surveys constituted noncompliance with 10 CFR 20.201(b) in that no air sampling surveys were performed during the period December 8, 1966 to March 31, 1967 to determine compliance with Sections 20.103 and 20.106 of 10 CFR 20.

91. The licensee's new air sampling technique consists of two systems. A 1½-inch PVC vacuum line has been installed throughout the new facility for the purpose of taking the in-plant samples. The 1½" line is tapped and a smaller line is attached with the charcoal sampler attached to the smaller line. Exhibit F shows the location of the PVC line. At the present time 18 sample locations are installed on this line as follows:

21. (Contd.)

Sample #	Location
1	Lunch Room
2	Laundry Room
3	Quality Control
4	Animal Room
5	Animal Room
6	Hallway
7	Hallway
8	Receiving
9	Hallway
10	Production Center Bay
11	Production Right Bay
12	Iodine Room
13	Production Hood Area
14	Production Hood Area
15	Production Area, NW
16	Production Area, NE
17	Waste Facility
18	Interim Product Storage

The vacuum pump serving the PVC line for these 18 in-plant samples is located in the old furnace room. The pump is timed to be in operation from 8:00 a.m. to 5:00 p.m. (nine hours) a day for 6 days per week. These samples are sometimes called "intermittant" by the licensee. The licensee plans to soon add two more sampling areas to this system that is, the drug storage area and dispensing. The flow rate of the in-plant system is adjusted to be 2 liters per minute.

92. The second system of air sampling also has a vacuum pump also located in the old furnace room but instead of a single vacuum line running through the building, it has a total of 27 individual ½" PVC lines running to the roof area. At the roof area the lines branch out to terminate in the air stream of the 13 stack exhausts (see Exhibit D) and 13 roof environmental stations. One line samples air from (AA). The licensee plans to add sampling lines to (BB) and (CC) at a later date. O, a sampling line to the incinerator, has not yet been installed. The flow rate of these "continuous" sampling lines (24 hours per day, 7 days per week) is limited to one liter per minute. Soldan stated that no attempt was made to put into effect isokinetic sampling in the stacks. The PVC lines were cut on an angle and terminated at right angles to the air stream in the exhaust duct.

93. For continuous sampling, the charcoal cartridges are located at the manifold in the old pump room. These cartridges are in series with a limiting oriface. The cartridges for the in-plant samples are located at the point of sampling. In the past Mr. Soldan also had a millipore filter in series with the cartridge, immediately preceding the limiting oriface, however, none are now provided in the new system. Soldan stated that counting the charcoal for particulates was just as effective as counting the millipore filter for particulates considering the level of activity observed.

94. The counting of all air samples is done on the single channel analyzer located in the Health Physics Lab. The charcoal cartridge is placed on the shielded crystal and two counts are run; one under the iodine 131 peak and the second for all energys above a specified Mev. The first count can be calculated directly in units of uc/cc of iodine 131 by the calibration of the analyzer with charcoal samples spiked with known amounts of iodine 131. The second count represents a count of the "particulate" or all other than I-131. The licensee uses an iodine MPC of 9×10^{-9} uc/cc for restricted areas and 1×10^{-10} uc/cc for unrestricted, or roof top, samples. The licensee is capable of also analyzing any sample which he counts. As noted in paragraph 87, a sample taken at Station #14 (Production Glove Box Area) indicated 72.56×10^{-9} uc/cc, or approximately 8 times MPC of 9×10^{-9} uc/cc. With the sample yet in place on the crystal, an analysis had been made which indicated the principal activity to be Hg 197. With this knowledge the licensee is stating that the sample is below permissible levels.

95. The licensee has recently begun furnishing uniforms for isotope workers. Discussion with Soldan revealed that during the week of April 24, 1967, the first batch of uniforms worn by isotope workers had been sent to a commercial laundry without prior monitoring. The licensee was informed that this constituted noncompliance with 10 CFR 20.201(b), in that no surveys were performed to assure that no significant amounts of contamination were sent to the commercial laundry.

Lab coats are kept at the toe rubber areas. Discussion with Soldan revealed that these lab coats had been surveyed prior to being sent to a commercial laundry but that no records of these surveys were kept. Soldan was informed that failure to keep records of these surveys constituted noncompliance with 10 CFR 20.401(b).

PERSONNEL MONITORING

96. At the present time, there are seventy-nine (79) full-time employees working in the licensee's St. Louis facilities. Sixty-four (64) of these persons are assigned film badges for the determination of whole body exposure (49 on a weekly schedule and 15 on a monthly). In addition, thirty-seven (37) persons whose routine duties require working with byproduct materials are assigned wrist film badges for extremity exposure determination.

97. A definite improvement in exposures is seen from the fourth quarter 1966 to the first quarter 1967. This appears to have been due to the move from the old facilities to the more adequate new facilities. During the fourth quarter, 1966, five persons received whole body exposures in excess of 2.6 rem with the highest being 2.937 rem [redacted] Also during the fourth quarter, 1966, two persons received extremity exposures (as indicated by wrist badges) in excess of 18 rem with the highest being 18.378 rem [redacted]. These high extremity exposures were a result of Mo-Tc "Kow" work, according to licensee representatives. Ex 6

98. For the first quarter, 1967 the maximum whole body and extremity exposure for any persons were 2.204 rem and 8.114 rem, respectively.

99. The licensee supplies its own film badges. Mr. Soldan stated the licensee performs a better film badge service than other companies could because the licensee knows what their people work with (isotopes, energies, etc.). If a film badge reads high, an evaluation of the actual reading is made on a case by case basis. Soldan advised that in the past the license utilized R. S. Landauer, Jr. film badge service, and during that time the licensee requested Landauer to reevaluate one particular, unusual film badge reading based on three different licensee exposure conditions. As a result, three different sets of data were reported for that same film. In addition, Soldan stated that, with their own film badges, there is no time lag in badging new people or getting results of film data from the previous week.

100. The licensee's film badge exposure records consist of a report (weekly or monthly) similar to the type of report submitted by other film badge suppliers. In addition, a weekly, running exposure report is submitted to the Department Managers and to the member of the Isotope Committee. Also, a summary listing of all exposures greater than 1.25 rem is complied and distributed at the end of each quarter. A scan of the licensee's personnel exposure records showed that Form AEC-5 is completed and on file for all film badge persons and Form AEC-4 is completed and on file for all film badged persons except for one person. [redacted] received a whole body exposure of 1.926 rem during the first quarter, 1967 (1/2/67 - 4/3/67). Through a mix-up, [redacted] exposure history from Mallinckrodt's Weldon Springs, Missouri facility to this licensee was not forwarded when [redacted] transferred jobs from the Weldon Springs facility to the licensee in November, 1966. The licensee's representatives were advised that allowing a person to receive a whole body exposure in excess of 1.25 rem per quarter constituted noncompliance with 10 CFR 20.101(a). A Form AEC-4 history was not established by the licensee for Bushman.

95. The licensee has recently begun furnishing uniforms for isotope workers. Discussion with Soldan revealed that during the week of April 24, 1967, the first batch of uniforms worn by isotope workers had been sent to a commercial laundry without prior monitoring. The licensee was informed that this constituted noncompliance with 10 CFR 20.201(b), in that no surveys were performed to assure that no significant amounts of contamination were sent to the commercial laundry.

Lab coats are kept at the toe rubber areas. Discussion with Soldan revealed that these lab coats had been surveyed prior to being sent to a commercial laundry but that no records of these surveys were kept. Soldan was informed that failure to keep records of these surveys constituted noncompliance with 10 CFR 20.401(b).

PERSONNEL MONITORING

96. At the present time, there are seventy-nine (79) full-time employees working in the licensee's St. Louis facilities. Sixty-four (64) of these persons are assigned film badges for the determination of whole body exposure (49 on a weekly schedule and 15 on a monthly). In addition, thirty-seven (37) persons whose routine duties require working with byproduct materials are assigned wrist film badges for extremity exposure determination.

97. A definite improvement in exposures is seen from the fourth quarter 1966 to the first quarter 1967. This appears to have been due to the move from the old facilities to the more adequate new facilities. During the fourth quarter, 1966, five persons received whole body exposures in excess of 2.6 rem with the highest being 2.937 rem [redacted]. Also during the fourth quarter, 1966, two persons received extremity exposures (as indicated by wrist badges) in excess of 18 rem with the highest being 18.378 rem [redacted]. These high extremity exposures were a result of Mo-Tc "Kow" work, according to licensee representatives. Ex 6

98. For the first quarter, 1967 the maximum whole body and extremity exposure for any persons were 2.204 rem and 8.114 rem, respectively.

99. The licensee supplies its own film badges. Mr. Soldan stated the licensee performs a better film badge service than other companies could because the licensee knows what their people work with (isotopes, energies, etc.). If a film badge reads high, an evaluation of the actual reading is made on a case by case basis. Soldan advised that in the past the license utilized R. S. Landauer, Jr. film badge service, and during that time the licensee requested Landauer to reevaluate one particular, unusual film badge reading based on three different licensee exposure conditions. As a result, three different sets of data were reported for that same film. In addition, Soldan stated that, with their own film badges, there is no time lag in badging new people or getting results of film data from the previous week.

100. The licensee's film badge exposure records consist of a report (weekly or monthly) similar to the type of report submitted by other film badge suppliers. In addition, a weekly, running exposure report is submitted to the Department Managers and to the member of the Isotope Committee. Also, a summary listing of all exposures greater than 1.25 rem is complied and distributed at the end of each quarter. A scan of the licensee's personnel exposure records showed that Form AEC-5 is completed and on file for all film badge persons and Form AEC-4 is completed and on file for all film badged persons except for one person. [redacted] received a whole body exposure of 1.926 rem during the first quarter, 1967 (1/1/67 - 4/3/67). Through a mix-up, [redacted] exposure history from Mallinckrodt's Weldon Springs, Missouri facility to this licensee was not forwarded when [redacted] transferred jobs from the Weldon Springs facility to the licensee in November, 1966. The licensee's representatives were advised that allowing a person to receive a whole body exposure in excess of 1.25 rem per quarter constituted noncompliance with 10 CFR 20.101(a). A Form AEC-4 history was not established by the licensee fo[redacted]

100. (Contd.)

No report o[redacted]exposure was submitted to the Commission. The licensee was advised that failure to report this personnel overexposure to the Commission constituted noncompliance with 10 CFR 20.405(a). Also, [redacted] was not notified in writing of this overexposure which constituted noncompliance with 10 CFR 20.405(b). Ex 6

101. All byproduct material workers are given a thyroid count to determine their internal exposure to I-131. Currently, twenty-four (24) persons are routinely counted twice a week and twenty-three (23) persons are routinely counted once per week. Mr. Soldan stated that if a person's thyroid count shows greater than 0.07 uc (50% of the 0.14 uc weekly average limit), that person is recounted daily until the thyroid count is less than 0.07 uc.

102. The thyroid counting is performed by Soldan, Bushman, or Constantine, all Health Physics personnel. This counting is not done at any set time of day or on any pre set day, although it was noted that the routine counts are usually performed on Tuesdays and Thursdays. The licensee's weekly thyroid count data was reviewed for the period November 14, 1966 through April 22, 1967. These records showed that no person had received a weekly average I-131 thyroid burden of greater than 0.14 uc. A blank sample copy of the licensee's current thyroid count data sheet is attached to details as Exhibit G.

103. Urinalysis bio-assays are used by the licensee to further determine internal exposures to various isotope workers. At the present time twenty-six persons submit a monthly urine sample which is analyzed for "Au-198" and "Fe-59". The "Au-198" analysis is gross gamma for all energies greater than 10 Kev and the "Fe-59" analysis is gross gamma for all energies greater than 1.0 Mev. The licensee's urinalysis procedures, methods, and MPC's have been spelled out in detail. This information was attached as Exhibit "I" to the report details of the June, 1966 inspection.

104. Urinalysis records for 1967 show the maximum sample to be 2.59 X MPC for "Au-198". As noted in the licensee's procedure, Au-198 has the lowest MPC of all their isotopes in this energy range.

ISOTOPE COMMITTEE

105. The current committee membership is the same as shown in Exhibit "C-3". The committee has met for general purposes only twice since its inception. These meetings were held on October 20, 1966 and again on March 6, 1967. During the March 6, 1967 meeting it was decided that weekly meetings (beginning on March 7) were to be held with the membership and the heads of each department solely for the purpose of discussing and reviewing Health Physics problems and procedures. During the first of these weekly meetings, weekly personnel exposure action points were established. For thyroid uptakes, the action point is 0.07 uc; and for whole body exposures, 100 mrem. W. R. Konneker, Chairman, or F. P. Hallett, Vice Chairman, submit summaries of these meetings to all concerned. A review of these summaries revealed that the licensee management is currently taking an active part in lowering personnel exposures. To this end, changes in procedures and equipment usage is discussed and proposed action is determined per individual and general case.

106. Soldan stated that no arrangements have been made with hospitals or doctors in the area in the event of acute personnel exposure or contamination, although arrangements are in effect with Barnes Hospital in cases of on-the-job personnel injuries.

INDEPENDENT MEASUREMENTS

107. Independent measurements of various work areas in the main production room were conducted by the AEC representative using an Eberline Model E-500B survey meter with a 30 mg/cm^2 probe. Locations and results of these measurement are as follows:

107. (Contd.)

a. Radiation level through the rear of the glass backing on a work bench near Hot Cell No. 4 . . . . 150 mr/hr
b. Radiation level in the aisle near work bench (item a) - (assay samples of Mo-Tc on bench). . . . . 50 mr/hr
c. Radiation level at the surface of the glass window of Glove Box No. Ho-535 . . . . 60 mr/hr
d. Radiation level at the front surface of Glove Box No. HO-536 . . . . 5 - 10 mr/hr
e. Contents in "cold" waste basket in Glove Box area . . . . 70 mr/hr
f. Radiation level at the surface of the glove parts of the P-32 Glove Box No. HO-539 . . . . . greater than 200 mr/hr
g. Radiation level at 6 to 8 inches from P-32 glove parts . . . . 125 mr/hr
h. Radiation level at the front surface of Glove Box No. HO-541 (Hg-197 and Hg-203). . . . . greater than 200 mr/hr
i. Radiation level at 6 to 8 inches from front of HO-541 . . . . 110 mr/hr
j. Radiation level at surface of glass window of HO-541 . . . . 130 mr/hr
k. Radiation level at 4 inches from glass window of HO-541. . . . . 110 mr/hr
l. Radiation level in doorway leading to Iodine Room . . . . 0.3 mr/hr

108. The Production Laboratory is posted with numerous signs showing the radiation symbol and colors and the words "Caution - Radioactive Materials", "Caution - Radiation Area", and "Caution High Radiation Area". Soldan stated that radiation levels noted during the survey were only temporary and that most materials causing these high backgrounds are only used one or two days at a time and these are stored in shielded containers during off-hours. Also, the high background from the P-32 box was due to a spill in the box on the previous afternoon and had not been cleaned up at the time of the independent measurements. The contamination found in the "cold" waste basket was discussed previously. (Please see paragraph 60 and 107(e)).

MANAGEMENT DISCUSSION

109. The results of this inspection were discussed with licensee management at the conclusion of the inspection on April 28, 1967. Licensee representives present were: W. R. Konneker, D. W. Soldan, R. E. Nuelle, and L. G. Struttman. AEC representatives present were: J. M. Allan, CO:III, and E. C. Ashley, CO:III.

110. Items of noncompliance noted during the inspection were discussed. These items included:

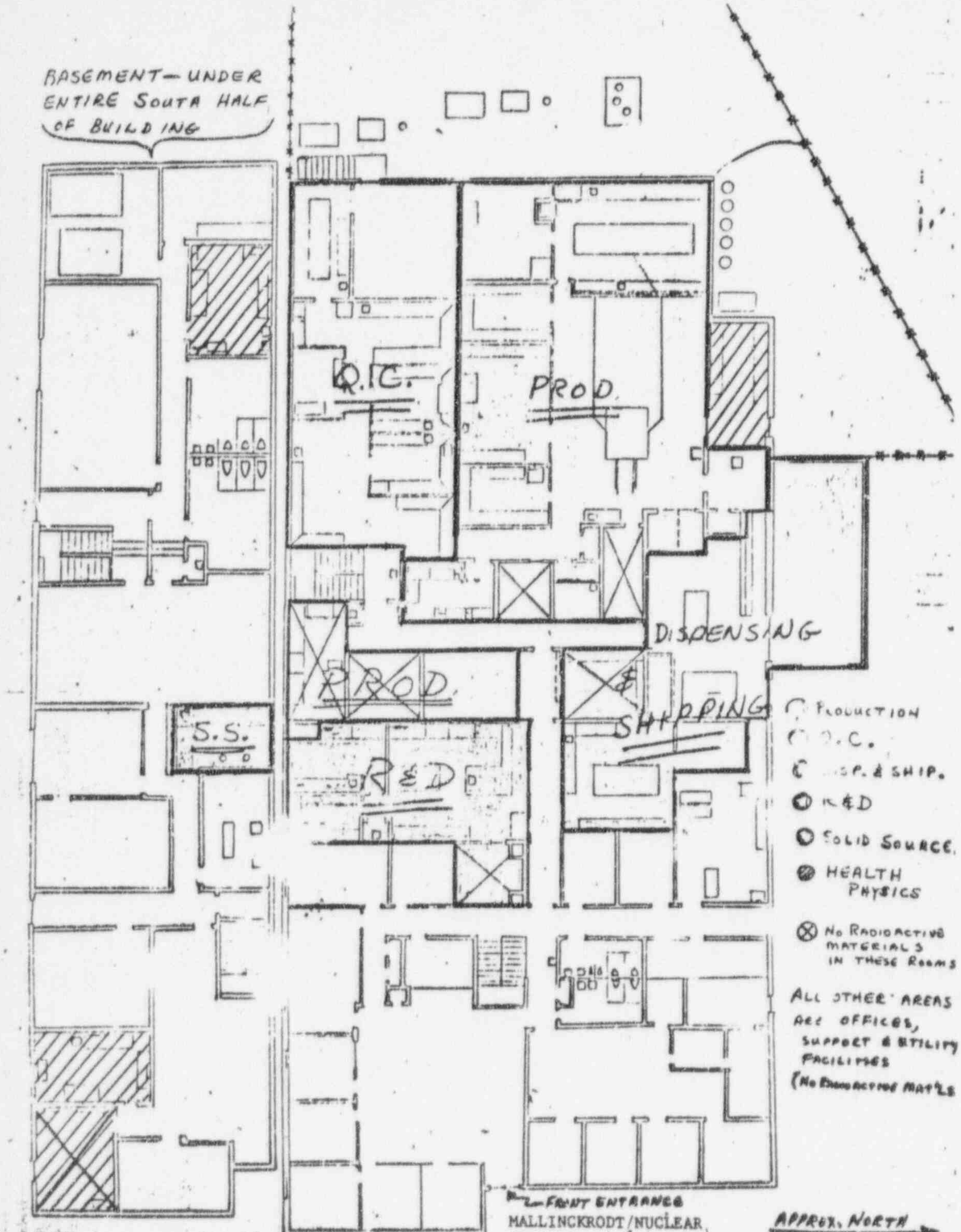
1. No surveys were made of first set of new uniforms prior to being sent to a commercial laundry.
2. No surveys of "cold" waste prior to incineration or disposal to normal trash.
3. No records of surveys made of lab coats prior to being sent to a commercial laundry.
4. No exposure history information (Form AEC-4) was obtained prior to allowing a person (Mr. Bushman) to receive a whole body exposure in excess of 1.25 rem during the first quarter, 1967. Also, failure to report this overexposure to the Commission or to the exposed individual.
5. No in-plant, stack, or environmental air samples were taken during a period between December, 1966 and March, 1967.
6. The concentrations of liquid waste discharged to the sanitary sewer system exceeded the limits specified in 10 CFR 20.

111. The licensee's corrective action and/or intentions to correct these items of noncompliance are given in the order presented above in paragraph 110.

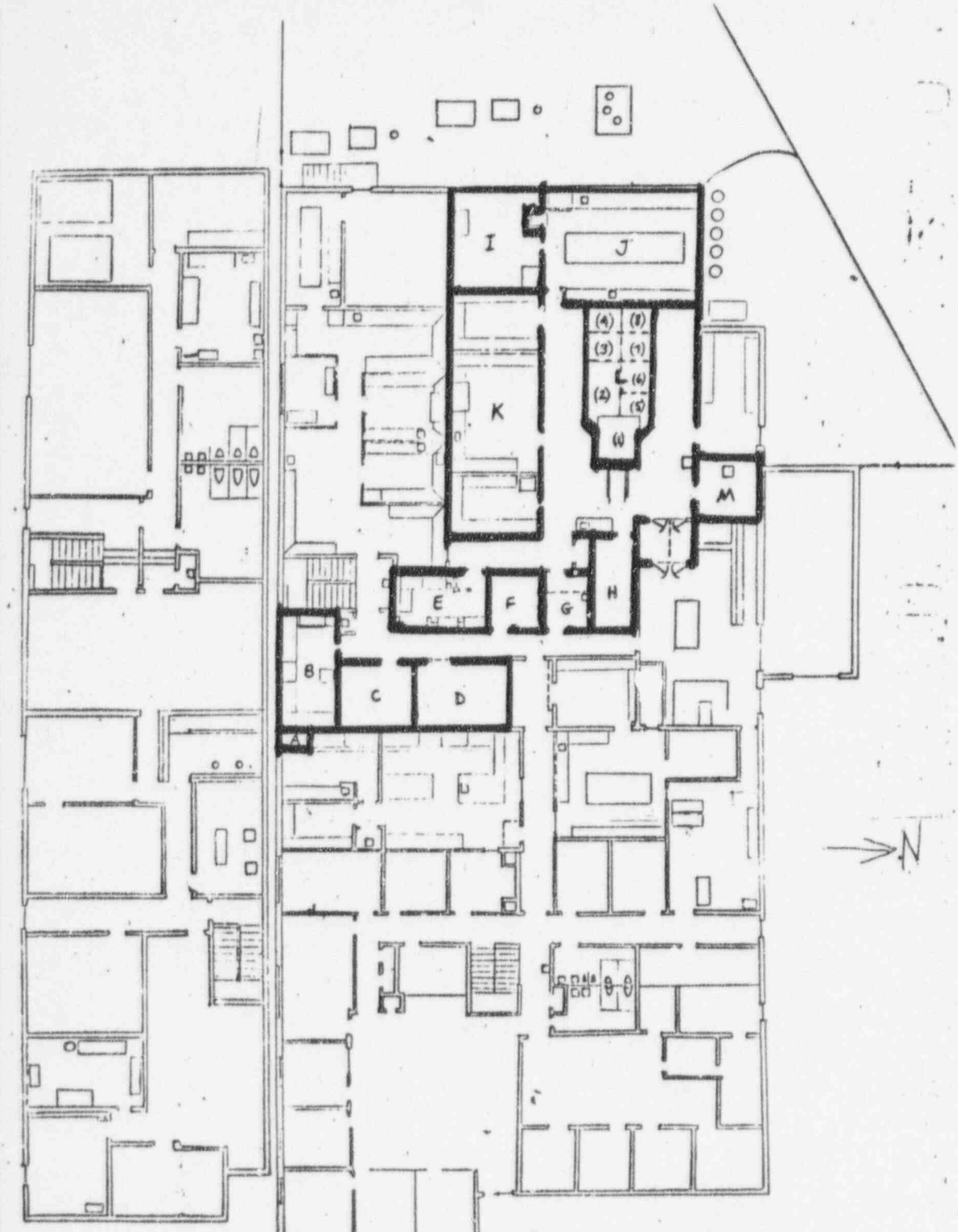
1. All laboratory uniforms will be surveyed to assure that no contaminated clothing is sent to a commercial laundry and records of surveys will be maintained.
2. "Cold" waste survey procedures are discussed in paragraph 60.
3. Surveys of lab coats going to a commercial laundry will be recorded in a log book in the future.
4. Mr. Bushman's exposure history will be obtained immediately.
5. Beginning March, 1967 the new air sampling system was put into effect. During the move of the licensed program into the new building addition during December, 1966 - March, 1967 no air samples were taken due to the lack of parts and equipment for the new system. The licensee representatives added that no significant personnel internal exposures resulted during the no air sample period as indicated by routine thyroid counts and urinalysis.
6. Corrective action concerning excess concentrations in liquid waste discharge is discussed in paragraph 66.

112. Other items noted during the inspection were discussed. The lack of stops on hood fronts could easily cause internal exposures if the hoods were fully open during isotope operations; the movement of radioactive materials from Production to Dispensing by way of Shipping as a possible source of needless external exposures; the potential of tracking contamination from various work areas to "non-active" areas including locker room is ever present without adequate Health Physics surveys of people leaving their work areas or by other definite methods of determining if people are surveying themselves. The licensee did not indicate any definite action regarding these items but did say that a sign-off sheet may be used at the exits of work area. This sheet would require a person to initial the fact that he surveyed himself prior to leaving the area.

Enclosures:
Exhibits A thru G



MALLINCKRODT/NUCLEAR
EXHIBIT A

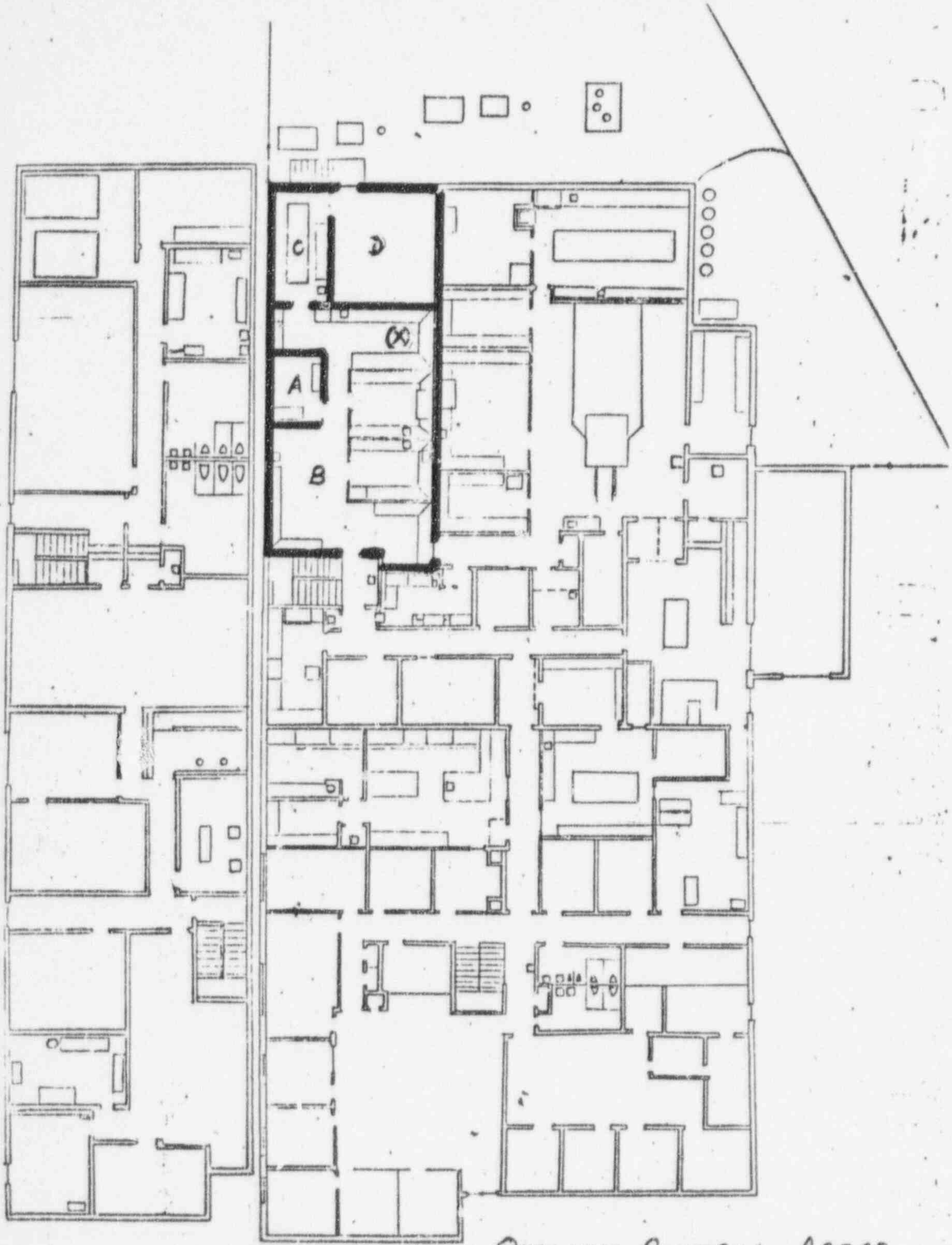


PRODUCTION AREAS

A. CAPSULE FILLING
B. BOTTLE WASHING
C. "COLD" STORAGE
D. T. .L. ASSAY & PKG.
E. STERILE ROOM
F. SUPERVISOR'S OFFICE
G. SHOE CHANGE AREA

H. "COLD" STORAGE
I. IODINE ROOM (CAPSULE SORTER, STORAGE "FORT" & GLOVE BOX)
J. GLOVE BOX AREA
K. GENERAL LOW LEVEL "BAYS"
L. HOT CELLS
M. INTERIM PRODUCT STORAGE

MALLINCKRODT/NUCLEAR
EXHIBIT B-1



QUALITY CONTROL AREAS

A. SUPERVISOR'S OFFICE

B. GENERAL LAB AREA

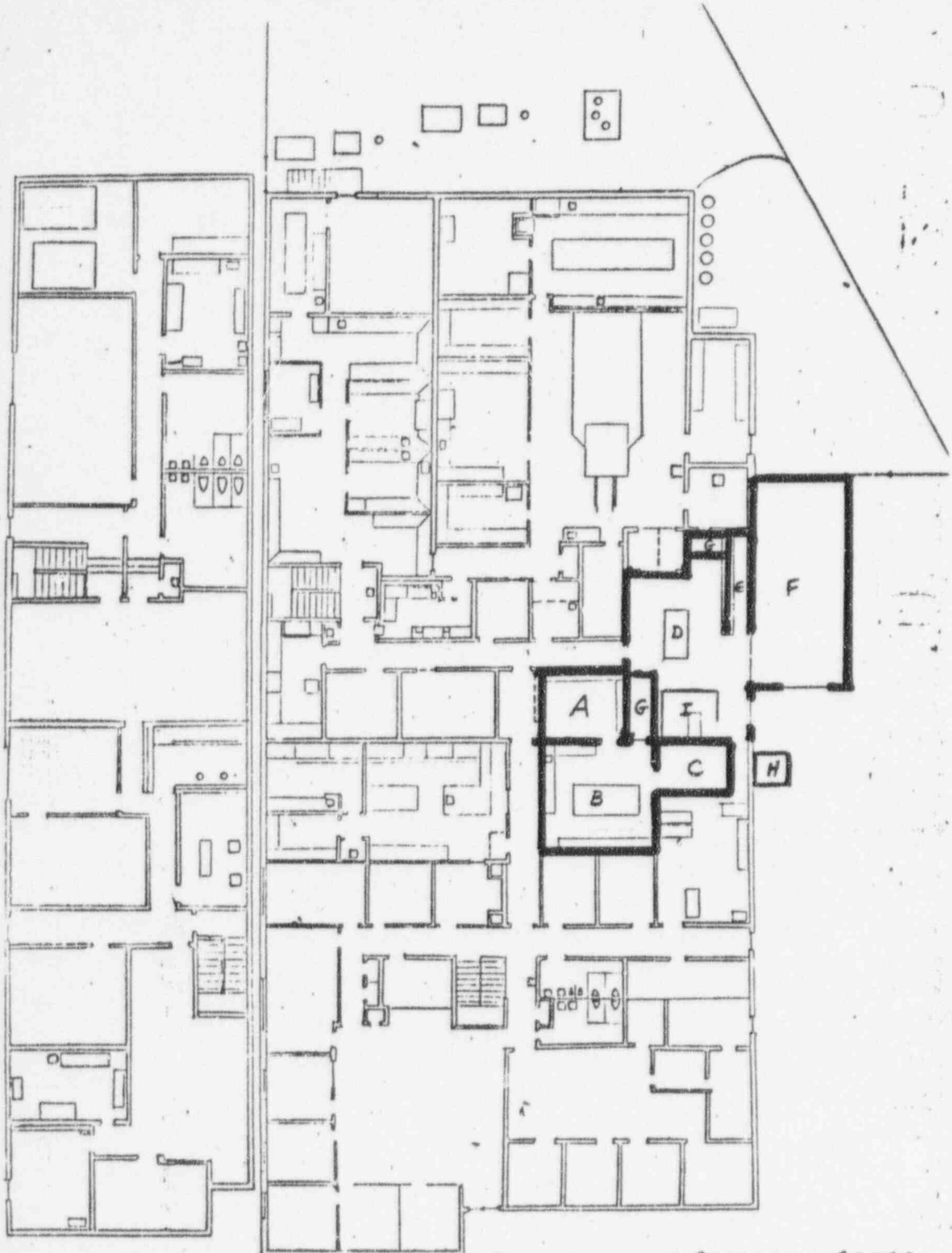
(X)- MOST BPM WORK DONE HERE

C. ANIMAL TESTING

D. GENERAL ANIMAL ROOM & CAGE STORAGE

MALLINCKRODT/NUCLEAR

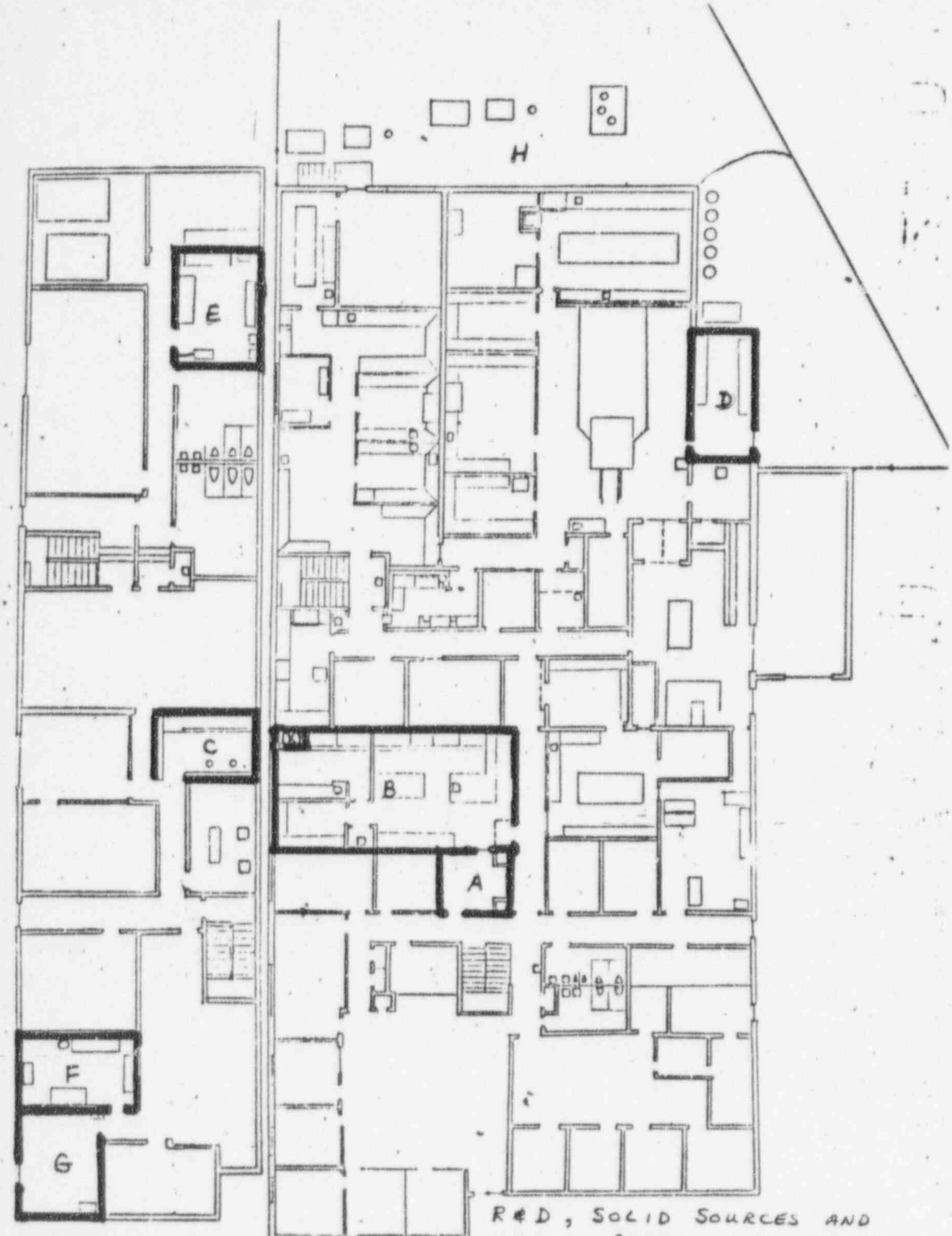
EXHIBIT "B-2"



DISPENSING & SHIPPING AREAS

A. DISPENSING OFFICE
B. DISPENSING LAB
C. DRUG STORAGE ROOM
D. PACKAGING AREA
E. PACKAGED PRODUCT STORAGE
F. SHIPPING "DOCK"
G. SHIELDED PASS-THROUGHS
H. SAFE - TEMPORARY OFF SHIFT STORAGE OF PACKAGES AWAITING PICK UP
I. TRAFFIC MANAGER OFFICE

MALLINCKRODT/NUCLEAR
EXHIBIT B-3



R&D, SOLID SOURCES AND HEALTH PHYSICS USE AREAS

A. R&D MANAGER OFFICE

B. R&D LABORATORY

☒ - PRODUCTION CAPSULE FILLING OPERATION IN GLOVED HOOD

C. SOLID SOURCES ROOM

D. SOLID "HOT" WASTE STORAGE

E. "HOT" LAUNDRY ROOM

F. HEALTH PHYSICS COUNTING LABORATORY

G. HEALTH PHYSICS OFFICE

H. UNDERGROUND RETENTION TANKS

MALLINCKRODT/NUCLEAR

EXHIBIT "B-4"

Nuclear Consultants
St. Louis, Missouri

October 13, 1966

Mr. Robert Brinkman
Division of Licensing & Regulations
U. S. Atomic Energy Commission
Washington 25, D. C.

Dear Mr. Brinkman:

As per our conversation during my recent visit to Washington, I am enclosing our application for an amendment to our by-product license No. 24-4200-1. This amendment covers the extension of our activities into our nearly completed new facility.

I left with you a complete set of drawings of our new facility which covered in detail not only the building, but also the special air handling systems, waste disposal systems and hot cell facilities.

In the attached application I have tried to cover in writing the description of the facility as we covered during our last meeting (see item #13). I have also covered Items 14 and 15 as they will be affected by the new facilities.

It is our intent to get moved into these facilities just as quickly as possible and immediately start to accumulate data on;

(1) Our air concentrations inside and outside the building (the system is already installed and ready to go).

(2) Contamination control.

(3) Radiation control.

(4) Personnel exposures and liquid waste disposal.

After a two or three month shakedown period we will summarize the data, review it, make such changes as may be indicated, and present it to your office. We will probably, at that time,

MALLINCKRODT/NUCLEAR
"EXHIBIT C-1"

October 13, 1966

request substantial increases in our possession levels.

Since we have had some rather major changes in personnel in the past year, you will also note we have changed the make-up of our isotope committee.

Since we are now only days away from completion of this facility we would appreciate any help you may give us in expiditing this application. Should you have any questions, please do not hesitate to contact me by collect phone.

Very truly yours,

NUCLEAR CONSULTANTS DIVISION
MALLINCKRODT CHEMICAL WORKS

W. R. Konneker, Ph.D.
Vice President

WRK/js

Enc.

OCT 17 1966

MALLINCKRODT/NUCLEAR
EXHIBIT "C-2"

ITEM 4

INDIVIDUAL USERS

The make up of the new Isotopes Committee, including names of individuals and company titles and committee titles, are as follows:

W. R. Konneker, Ph.D., General Manager, Chairman

Floyd P. Hallett, Ph.D., Technical Director, Vice Chairman

Mr. Donald W. Soldan, Manager of Health Physics Department, Vice Chairman, Secretary

Mr. Ralph E. Nuelle, Manager of Instrument Calibration Department

Mr. Lloyd G. Struttman, Manager of Medical Consulting Department

MALLINCKRODT/NUCLEAR

EXHIBIT "C-3"

00601

ITEM 8

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4

RESUME - Floyd P. Hallett, Ph.D.

EDUCATION

Dr. Hallett attended the University of Wisconsin and received his B.S. degree in pharmacy in 1947. He received his Ph.D. in pharmacy and chemistry in 1951 from the University of Wisconsin.

JOB EXPERIENCE WITH MALLINCKRODT CHEMICAL WORKS

1951-1955 - Supervisor, Pharmaceutical Control

1956-1960 - Assir` t Director, Product Development

1960-1962 - Director of Product Development, pharmaceutical products

1962-1965 - Assistant Director of Research and Development and Director of Clinical Development

December 27, 1965-Present - Technical Director, Nuclear Consultants Division

Experience at Mallinckrodt Chemical Works included setting up sampling, testing and other control procedures for medicinal chemicals and drug products.

In addition, it included responsibility for pharmacological, pharmaceutical and clinical research and development on drug products.

During the period of 1951 to 1965 Dr. Hallett was responsible for the contacts with Government agencies such as the FDA and NIH, including application of submissions and applications to these agencies.

He has been gaining experience in the administration of technical aspects and problems relating to the production of radioactive pharmaceuticals for ten months and has been responsible for the direction of the production, quality control, dispensing, shipping and research and development departments.

He is a member of the American Chemical Society, American Pharmacy Association, Sigma Xi, Parenteral Drug Association and the Research and Development Section of the Pharmacist Manufacturers Association.

MALLINCKRODT/NUCLEAR

EXHIBIT "C-4"

ITEM 13

FACILITIES AND EQUIPMENT

I. Description of Building and Immediate Surroundings

The building occupied wholly by Nuclear Consultants, Division of Mallinckrodt Chemical Works, is a two-story cement block structure 169 feet in length and 80 feet in width. The first floor extends the full length and width of the building. Located under the south half of the first floor is the ground floor which extends the full length of the building. The land on which the building is situated is in an area zoned "heavy industry." The location of the building on the property and its relationship to adjacent buildings is indicated on the Plot Plan Figure 1. Minimum distances between buildings are indicated and are approximate.

II. Air Handling System (New addition)

A. Supply System

There are two separate main air supply systems for the new addition. One system serves only the Production Laboratories, and the other serves the Quality Control Laboratories and the entire rest of the addition. The supply air for both systems is taken through the south wall into the heating and air conditioning room located in the southwest corner of the building on the ground floor.

1. Production Laboratory

The Production Laboratory is maintained at approximately 1/4 inch w.g. negative pressure with respect to the hallway. Approximately 80 percent of the supply air is returned and recirculated. The I-131 Tagging Room, located in the southwest corner of the Production Laboratory, has a dampered air supply but is not connected to the cold air return. This room is maintained at a slightly negative pressure with respect to the main laboratory by removal of air from the room through the glove boxes and vault connected to the iodine exhaust system and a separate exhaust duct. The Drug

MALLINCKRODT/NUCLEAR
EXHIBIT "C-5"

Storage Room and the Radioactive Waste Storage Room, the doorways to which are located on the north wall of the Production Laboratory, are also maintained at a negative pressure with respect to the Production Laboratory. Approximately 1000 cubic feet of air per minute is exhausted directly into the atmosphere from the Waste Storage Room to maintain air concentrations within permissible limits. A portion of the air is supplied by an auxiliary blower installed on the roof of the Waste Storage Room. The balance of the air is obtained through a register connecting the Drug Storage Room and the Waste Storage Room. A duct connected to the main Production Laboratory supply system furnishes the air to the Drug Storage Room. There is no cold air return in the Drug Storage Room or Waste Storage Room. A separate blower installed above the ceiling in the Production Laboratory supplies the Sterile Room through a bacteriological filter. Air is exhausted from this room through the glove boxes and finally through an absolute filter. The air balance is such that the Sterile Room is at a slightly positive pressure with respect to the Production Laboratory.

2. Quality Control Laboratory and Balance of the Addition

The Quality Control Laboratory and the balance of the building is maintained at approximately atmospheric pressure. Approximately 75 percent of the air is recirculated via cold air return ducts in all areas except the Animal Room and Animal Testing Room. Air from these rooms is exhausted directly into the atmosphere through the roof.

B. Exhaust System

There are eight points of discharge from the new addition--six of which exhaust areas, hoods, glove boxes or hot cells in the Production Laboratory, and two of which exhaust air from the Quality Control area. The exhaust fans are equipped with sail switches and electrically actuated spring loaded positive closure dampers to prevent back flow. If the air flow is reduced below some minimum value, an annunciator light located near the area of interest is actuated, and power to the damper is cut off which returns the damper to a closed position.

MALLINCKRODT/NUCLEAR

EXHIBIT "C-6"

1. Production Laboratory

a. Fan EF-2

Fan EF-2 is connected to the glove boxes used for processing radioisotopes other than I-131 and to the hood located on the west wall. Additionally, this fan exhausts the I-131 Tagging Room. Approximately 1750 cfm of air is discharged from this fan and diluted by the Venturi principal giving an effective 4500 cfm discharge. The filtration consists of a prefilter followed by an absolute particulate filter.

b. Fan EF-3

Fan EF-3 is connected to the hood on the south wall of the Production Laboratory. The filtration consists of a prefilter followed by an absolute particulate filter.

c. Fan EF-5

Fan EF-5 exhausts air from the Sterile Room. The filtration consists of a prefilter, absolute particulate, glove boxes, and absolute particulate.

d. Fan EF-6

Fan EF-6 exhausts air from the Waste Storage Room.

e. System K-2.5

System K-2.5 is located on the west end of the roof of the raised bay section and consists of dual fans 2.5-1 and 2.5-2. This system exhausts air from all glove boxes for processing I-131 in the main laboratory area and from the glove boxes in the I-131 Tagging Room and from hot cells 4 and 8, wherein large quantities of I-131 will be processed. The filtration system consists of the following: prefilter, absolute particulate, absolute activated charcoal, and absolute particulate. The enclosure for these filters has been designed such that the first absolute particulate filter

MALLINCKRODT/NUCLEAR
EXHIBIT "C-7"

may be changed without disrupting the pressure balance in the system. One of the two fans is in operation at all times, and the other is on standby. If the pressure differential increases above a preset value for any reason, the standby fan is automatically switched on. This fact is indicated on the annunciator panel. In case of a power failure, a spring loaded damper seals the air outlets from the hot cell.

f. System K-1.5

System K-1.5 consists of dual exhaust fans No. 1.5-1 and 1.5-2 located on the east end of the roof on the raised bay. This system is connected to hot cells No. 1, 2, 3, 5, 6, and 7 and is identical in operation to System K-2.5. It is equipped with a prefilter and a particulate absolute filter only. I-131 will not be handled in any of these hot cells.

2. Quality Control Laboratory

a. Fan EF-1

Fan EF-1 is located on the southwest corner of the roof and exhausts the Animal Testing Room and Animal Room.

b. Fan EF-4

Fan EF-4 exhausts the hood located on the north wall of the Quality Control Laboratory and also some driers located in the southwest corner of the main Quality Control Laboratory.

III. Liquid Waste Handling System

A. Radioactive Liquid Waste Effluent

1. High Level Retention Tank

A 2000 gallon concrete retention tank is buried under 3 feet of earth in the fenced off area to the rear of

MALLINCKRODT/NUCLEAR

EXHIBIT "C-8"

the building. This retention tank is connected only to the hot cell system. Sink drains in the individual cells and drains on either end of the hot cell floor discharge to this retention tank. A control panel for operation of the metering pump to discharge the retention tank is located on the north wall of the laundry room on the ground floor of the new addition. This control panel also indicates liquid level in the retention tank. An alarm system may be set to trigger at any predetermined liquid level. A sample line from the retention tank is brought through the wall at this location. After assaying the radioactive contents of the tank, the metering pump may be set to discharge a predetermined volume. The metering pump automatically turns off when this volume is discharged. Relatively high levels of radioactive materials in small volumes of liquid will be discharged to this retention tank. At a rate of 10 gallons per day, it would take approximately 10 months to initially fill the tank. Radioactive materials discharged at the beginning of this interval will have decayed down to the point that the liquid originally associated with this material will be acting merely as a diluent. Once the tank is filled, we anticipate discharging small daily quantities of the order of 10 gallons per day. The tank is vented to the atmosphere through an absolute filter installed above ground level in the fenced off area. An emergency retention tank consisting of a concrete encased 50 gallon stainless steel drum is buried between the building and the high level retention tank. In case of a gross spill of radioactive materials in one of the hot cells, the discharge from the hot cells may be diverted to the emergency retention tank by manually operated valves. The 50 gallon capacity is sufficient to provide thorough decontamination of the affected hot cell. After an indefinite decay period, this tank may be discharged to the high level retention tank by manually controlled valves, all of which are located in the fenced off area behind the building.

2. Low Level Retention Tank

The low level retention tank is identical to the high level retention tank except that the predetermined

MALLINCKRODT/NUCLEAR
EXHIBIT "C-9"

volume setting may be set to discharge large volumes at a given time. The controls for the low level retention tank are similar to those of the high level retention tank and are on a common panel. Located adjacent to the control panel is a valve and flow meter for increasing and regulating the total water consumption of the building for dilution purposes. The flow meter discharges to a standpipe connected directly downstream of the retention tank systems. Relatively low quantities of radioactive material in large volumes of water will be discharged to this retention tank. The retention tank is connected to standpipes in the individual cells in the hot cell to all hoods, sinks, floor drains and ~~glove boxes~~ in the main production laboratory, the Quality Control Laboratory and Animal Room, and to the utility sink, laundry drain and floor drains in the laundry room.

B. Nonradioactive Liquid Waste Effluent

All other sinks and floor drains outside of the laboratory restricted areas in the new addition are discharged directly to the sanitary sewer system. Included are the sinks in the change areas to the Production Laboratory and to the Research and Development Laboratory, the Bottle Washing Room, the lunchroom, the men's and ladies' rooms, and utility sinks.

MALLINCKRODT/NUCLEAR
EXHIBIT "C-10"

IV. Hot Cell System

A. Dimensions

1. Outer overall dimensions

a. Length 27'6"

b. Width 11'0"

c. Height 9'0"

2. Concrete shielding thickness

a. Walls 2'0"

b. Top 1'0"

3. Internal individual cell dimensions

a. Cell No. 1

(1) Depth 3'6"

(2) Width 3'6"

(3) Height 10'0"

b. Cell No. 2

(1) Depth 3'5 1/2"

(2) Width 9'0"

(3) Height 8'0"

c. Cells No. 3, 4, 5, 6, 7, and 8

(1) Depth 3'5 1/2"

(2) Width 4'6"

(3) Height 8'0"

MALLINCKRODT/NUCLEAR

EXHIBIT "C-11"

4. Zinc bromide windows

(1) 24" x 24" x 24"

5. Transfer door

(1) Depth (concrete thickness) 2'0"

(2) Width 3'6"

(3) Height 3'9"

B. Manipulators

1. Master Slave Manipulators Model H, Central Research Labs, Inc.

C. Windows

1. Zinc bromide windows, Ameray No. AM 868-3

D. Cell face penetrations

1. Water

2. Vacuum

3. Special

4. Master slave manipulators

5. Plug

6. Power

7. Monitoring

E. Cell interior

The hot cell is divided into compartments with carbon steel partitions painted with Carboline protective paint. The partitions have sliding doors to permit transfer of materials from cell to cell in a transfer basket.

MALLINCKRODT/NUCLEAR

EXHIBIT "C-12"

F. Typical Cell Usage

A typical procedure for utilization of the hot cell is as follows: The transfer door is withdrawn on its tracks from the face of the hot cell. A shipping container is transferred into the hot cell, and the cell transfer door is closed. An electric hoist located at the top of the transfer cell is used in conjunction with the manipulators to remove the shipping container lid. The manipulators are used to remove the radioactive material from the shipping container. At this point, the interlock is activated assuming the source is strong enough to produce a radiation level within the cell of 100 mr/hr. The radioactive material is transferred to the transfer basket and then to the cell in which it will be chemically processed. After processing, the material is removed through a transfer drawer. A glove box may be installed at this point for decontamination of materials being removed from the cell if this becomes necessary.

V. Production Equipment

A. Glove Boxes

1. Description

The glove boxes are of plywood construction laminated inside and outside with formica for ease in cleaning. They have been designed with high fronts such that, if necessary, shielding in the form of lead plates may be added to protect the major portion of the operator's body. One series of glove boxes will be arranged end to end and back to back in a double row. Where necessary, lead plates will be sandwiched between the glove boxes. Each box is equipped with a transfer box having airtight double door system. Ultraviolet, fluorescent light, electrical outlets, and where necessary, vacuum and water are provided in the boxes. Almost all operations which previously were performed in fume hoods will be performed in the hot cell or in glove boxes of this type.

2. Filtration System

The glove boxes are supplied air through a common absolute bacteriological filter connected to the transfer

boxes. Each individual glove box is equipped with an absolute filter which permits filtered air to flow from the transfer box to the main glove box. When the outer door of the transfer box is opened, the glove box remains at a negative pressure with respect to the room equal to the pressure drop developed across these filters. Sterility is also maintained under these circumstances. After closing the outer door, the air within the transfer box is purged with filtered air from the common filter. At this point, the glove boxes are at a negative pressure with respect to the room equal to the pressure drop across both filters. After purging, the inner door of the transfer box may be opened, and materials may be passed into or out of the main box. The glove boxes are never opened directly to the atmosphere except during cleaning operations and thus are always maintained at a negative pressure. Air removed from all glove boxes except those handling Iodine-131 is passed through a common absolute radiological filter before being discharged to the atmosphere. Those handling Iodine-131 are discharged through the special air handling system K-2.5 as described in Item 13, Section II, Part B.

B. Hoods

There are two hoods of the type currently in use in the present Production Laboratory which will be installed in the new Production Laboratory. Only those production functions which need not or cannot easily be fit into glove boxes or cells will be performed in these hoods. The anticipated face velocities for these hoods will be in the range of 80 to 120 linear feet per minute.

VI. Shielding

A. General Shielding

1. Wall Construction

All outer and inner walls of the Production Laboratory are of concrete block construction to minimize radiation levels in adjacent areas. An 8-inch solid concrete block wall separates Quality Control from the main

MALLINCKRODT/NUCLEAR
EXHIBIT "C-14"

Production Laboratory. A 4-inch solid concrete block wall is erected around the Sterile Room. A cyclone-type fence is erected around the outer walls of the Production Laboratory providing distance to further reduce radiation levels in unrestricted areas to well below permissible limits.

2. Earth Shielding

The Production Laboratory is constructed on the north side of the first floor level (nothing beneath) thus providing a large amount of earth shielding between it and areas located on the ground floor level on the south half of the building.

B. Specific Shielding

1. Hot Cell

The hot cell provides shielding as previously described in Item 13, Section IV.

2. High Level Radioactive Waste Storage Tube

Ten high level stroage tubes are located in the Waste Storage Room. They are 12 inches in diameter and extend through the concrete floor down to a depth of 10 feet. Materials, such as high level radioactive waste or contaminated equipment and glassware, will be sealed in steel containers before being stored in these tubes.

3. Low Level Waste Storage Tubes

Five low level tubes sufficient in size to accommodate a 30-gallon container are located in the Waste Storage Room. Low level radioactive waste will be packaged in fiber drums and stored in these tubes. Five additional low level storage tubes are located outside adjacent to the Waste Storage Room within the fenced-off area.

4. Shields at Activity Pass Through Windows

Poured concrete shields are installed at activity pass through windows from the Dispensing Laboratory to the

MALLINCKRODT/NUCLEAR
EXHIBIT C-15

Shipping Department and from the Production Laboratory to the Shipping Department. These shields have open tops and provide shielding in all other directions.

5. Packaged Pharmaceuticals Awaiting Shipment in Shipping Room

A solid "L" shaped concrete block wall is erected in the Shipping Room for shielding of Shipping Room personnel. Packaged pharmaceuticals will be stored on shelves erected along this wall prior to shipment.

6. Diagnostic Capsules Storage Shield

A shield will be erected in the Iodine-131 Tagging Room for storage of diagnostic capsules. This shield will be connected to the air handling system to maintain it at a negative pressure with respect to the Tagging Room.

7. High Level Activity Storage Tubes

Two high level storage tubes 12 inches in diameter and 10 feet deep are located in the Production Laboratory near the glove box operations. These will be used as required by production personnel.

8. Lead Cubicle Shields for Tabletop Storage

Lead cubicle shields 12 inches in height with a wall thickness of 1 inch with varying internal dimensions currently in use in the present Production Laboratory will be transferred to the new Production Laboratory and utilized as required.

VII. Air Sampling System

A. Continuous Air Sampling Stations

1. Environmental Stations

Environmental stations will be located around the entire periphery of the roof. Sampling stations will also be located atop of the raised bay enclosing the hot cell

operation. These particular stations will draw samples at points approximately 25 feet above the first floor ground level.

2. Points of Discharge

Samples will be taken from all points of discharge described in Item 13, Section II, Part B. All the above samples are taken on a continuous basis.

B. Intermittent Air Sampling Stations

1. Present Production and Dispensing Laboratories

The air sampling stations located in front of each hood in the present Production Laboratory and in the Dispensing Laboratory will be continued.

2. New Addition

A PVC pipe run exposed at the ceiling throughout the entire new building enables us to collect samples in any and all areas in the new addition. Samples may be collected by drilling and tapping into the PVC pipe and connecting a dropper line to the point of interest. All the above samples are collected from 8:00 in the morning until 5:00 in the evening, Monday through Saturday.

MALLINCKRODT/NUCLEAR

EXHIBIT "C-17"

ITEM 14

RADIATION PROTECTION PROGRAM

All control measures in our current radiation protection program shall be extended to include all areas within the new addition. We shall accumulate records and data for several months, after which time a summary report will be submitted to you. As demonstrated by monitoring and survey results, we may decide to revise our license to better fit the new working conditions. At this time we will more than likely request increased possession limits on most of our isotopes.

MALLINCKRODT NUCLEAR
EXHIBIT "C-18"

ITEM 15

WASTE DISPOSAL

One major change in our waste disposal handling will be in the area of liquid waste. To date we have restricted the disposal of liquid waste material down our sewer system. With the two new retention tanks as described in Item 13, Section III, Part A, such waste will be accumulated in these tanks for decay prior to release to the sanitary sewer system.

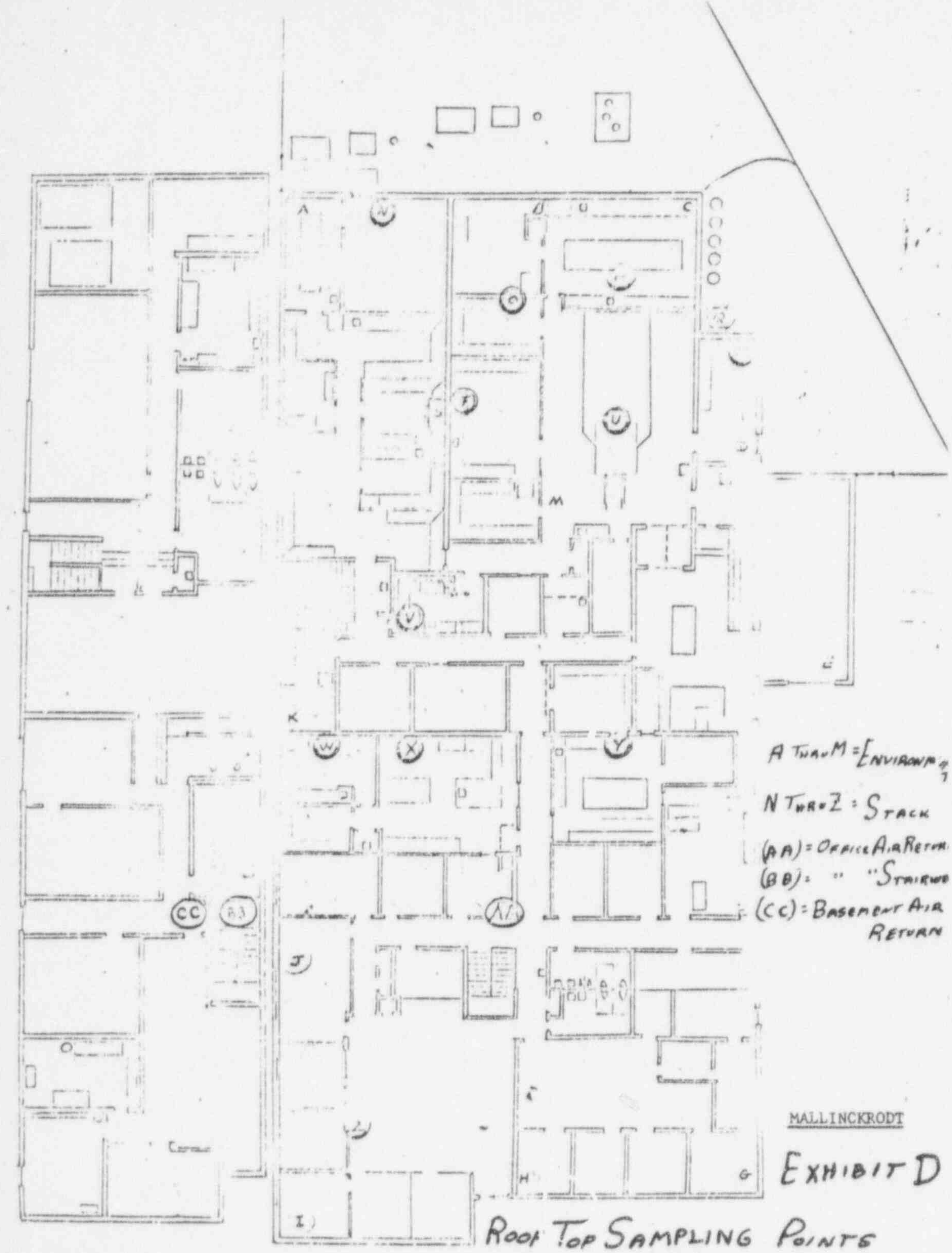
High level and/or long-lived radionuclides will be stored in the ten high level storage tubes as described in Item 13, Section VI, Part B. Low level and/or bulky material will be stored for decay in the low level waste storage tubes located inside the Waste Disposal Room.

After an adequate decay period, the low level waste will be monitored with a suitably sensitive instrument, and that material found to be nonradioactive will be released through normal trash. The remainder will be repackaged in ICC approved drums and then stored in the outside underground storage tubes until released to an authorized radioactive waste disposal agency. The agency we are currently using is Nuclear Engineering Corp.

MALLINCKRODT NUCLEAR

EXHIBIT "C-19"

00601



Roof Top Sampling Points

PROPOSED 1967 HEALTH PHYSICS DEPARTMENT ORGANIZATIONAL CHART

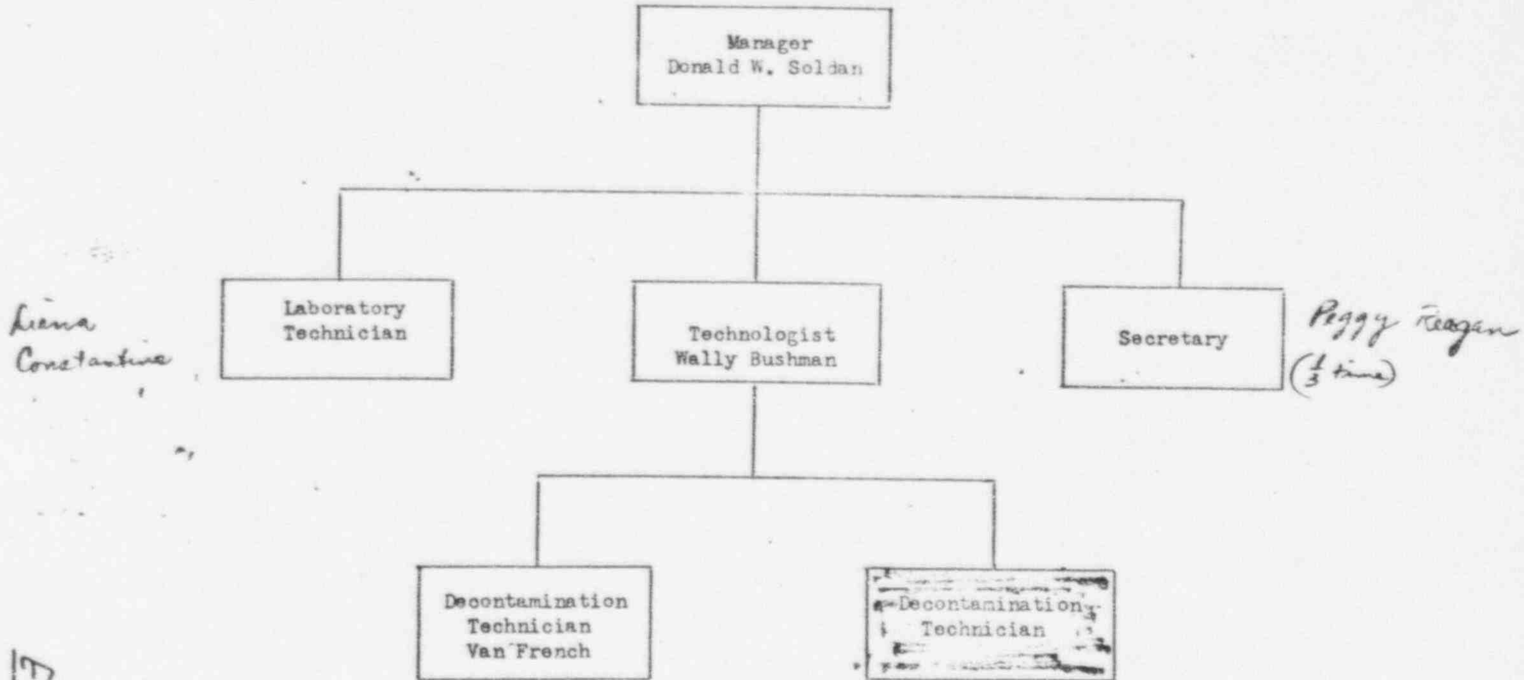


EXHIBIT E

<u>Manager</u> (St. Louis and Branches)

A. Establish and implement programs and procedures.
B. Control isotopes inventories and possession limits.
C. Prepare license applications and amendments.
D. Compile radiation histories.
E. Compile survey records and reports.
F. Prepare overexposure reports or reports of excessive levels or concentrations.
G. Take corrective measures to reduce excessive exposures, levels or concentrations.

Peggy <u>Secretary</u> [illegible] types final version of reports, etc that are actually done by others

A. Compilation of:
   1. Radiation Histories (St. Louis and branches).
   2. Requests for previous radiation histories.
   3. AEC-4's.
   4. AEC-5's.
   5. RMA-1's or equivalent.
   6. Thyroid Burdens
   7. Bioassays. Diana does [illegible] & write [illegible] report
   8. Reports to individuals on overexposures. (original by Sol Bam)
B. Reports to the AEC of overexposures or excessive levels or concentrations.
C. Film Badge Records (St. Louis and branches).
   1. Weekly results.
   2. Weekly fractional permissible exposures.
   3. Running quarterly totals.
   4. Running quarterly fractional permissible exposures.
D. Reports to department heads on exposures, etc.
E. Branch correspondence.
F. License amendments (St. Louis and branches).
G. License applications (St. Louis and branches).
H. Forms (St. Louis and branches).
I. Filing.

Diana <u>Laboratory Technician</u> Primarily counting room & record duties

A. Air Sampling.
   1. Collect general restricted and unrestricted area air sample cartridges.
   2. Measure initial and final air flow rates for above samples.
   3. Count all laboratory and general restricted and unrestricted area air samples.
   4. Calculate airborne radioactivity concentrations.
B. Thyroid Uptake Measurements
   1. Perform twice weekly uptake measurements.
   2. Perform once weekly uptake measurements.
   3. ~~Perform monthly uptake measurements.~~
   4. Calculate weekly averages.
   5. Calculate running quarterly totals.

Just begun C. → Radioactive Liquid Waste. As needed.
   1. Collect liquid waste samples. Wally or Sol Bam have done this til now
   2. Count sample aliquots. Sol Bam has done this

3. Analyze samples.
4. Calculate liquid radioactivity concentrations.
5. Calculate permissible volume of liquid which may be discharged.
6. Discharge permissible quantities.
7. Inventory activity discharged.

D. Radiation Level Surveys.
Measure radiation levels in all general restricted and unrestricted areas.

E. Loose Contamination Level Surveys.
1. Collect wipe samples in all general restricted areas.
2. Count wipe samples from laboratory and general restricted areas.

F. Film Badges.
Change and collect all film badges.

G. Urinalysis.
1. Collect urine samples.
2. Prepare samples for counting.
3. Count samples at all energies greater than 10 Kev.
4. Count all samples at energies greater than 600 Kev.
5. Count samples at greater than 1 Mev as required.
6. Run spectra as required.
7. Calculate body burdens.

Wally Technologist

A. Air Sampling.
1. Collect laboratory restricted air samples.
2. Measure initial and final air flow rates.

B. Radiation Level Surveys.
Measure radiation levels in all laboratory restricted areas.

C. Personnel Contamination Check.
Check all personnel for contamination.

D. Loose Contamination Levels.
Collect wipe samples in all laboratory restricted areas.

E. Contamination Surveys.
1. Check all protective clothing in the lab for contamination (glovebox gloves, shoe covers, lab coats, etc.).
2. Check hoods, gloveboxes, waste containers, etc., for contamination.

F. Radioactive Waste.
1. Package and label high level radioactive waste and transfer to the storage room.
2. Package, label and prepare shipping papers for radioactive waste.
3. Package, label, inventory and store contaminated safes, glassware, equipment, etc.

French Decontamination Technicians

A. Laundry (Technician No. 1).
1. Collect, wash and dry gloves, shoe covers, gowns, lab coats, shirts, pants and dresses.
2. Check all protective clothing for contamination.
3. Rewash contaminated clothing or store for decay.

4. Check all gloves for tears or pinholes. Rallige - Cl... method (daily),
5. Inventory and store all protective clothing.

B. Radioactive Waste ~~[illegible]~~

1. Collect all waste from the low level radioactive waste containers in the Quality Control, Dispensing, R & D, ~~[illegible]~~ and Health Physics departments.
2. Segregate hot and cold waste and incinerate cold waste. sure ... but No records
3. Repackage and relabel hot waste. under Wally's direction

C. Decontamination ~~(...[illegible])~~.

1. Decontaminate floors. ... R&D, exc. Q.C., ... P.
2. ~~Decontaminate hoods and glove boxes.~~
3. ~~[illegible]~~

"Person responsible for own work bench area.

Production ...

"B" Waste "Johnson - Hot waste, picked up by ...
"Cold" " " " Kellerman (Prod. Lab. Asst.)

... "Cold" incinerated by Kellerman (No Surveys)

"C" Decon ... All dec ... new facility, except laundry - ... includes ... room - is responsibility of Prod. Dep. (... Holgate)
All oth... area - H. P. duty

Roy AuBuchon Evaluates F. B. Data
Donna ... Develops & Reads F.B.

Daily Time Requirements

A.	Manager		7½ hours
B.	Secretary (Secretarial time has averaged 2¼ hours per day since February, 1966.)		3 hours
C.	Laboratory Technician		7½ hours
D.	Technologist		7½ hours
E.	Decontamination Technicians		~~10½~~ hours 7½
	1. Laundry	3½ hours	
	~~2. Hoods and gloveboxes (4 to 5 per day) and safes and equipment~~	~~10 hours~~	
	3. Floors	1½ hours	
	4. Hot waste	3½ hours	
	5. Spills	½ hour	
Total Time Required			~~44~~ 33 hours
Current Available Time			~~22½~~ hours 33

Equipment Requirements

A. Immediate

Magnascaler IIIA Have one in Prod area + when new spectra Scaler arrives this will come back [illegible]

Ludlum Survey Meter Model 12 (Have)

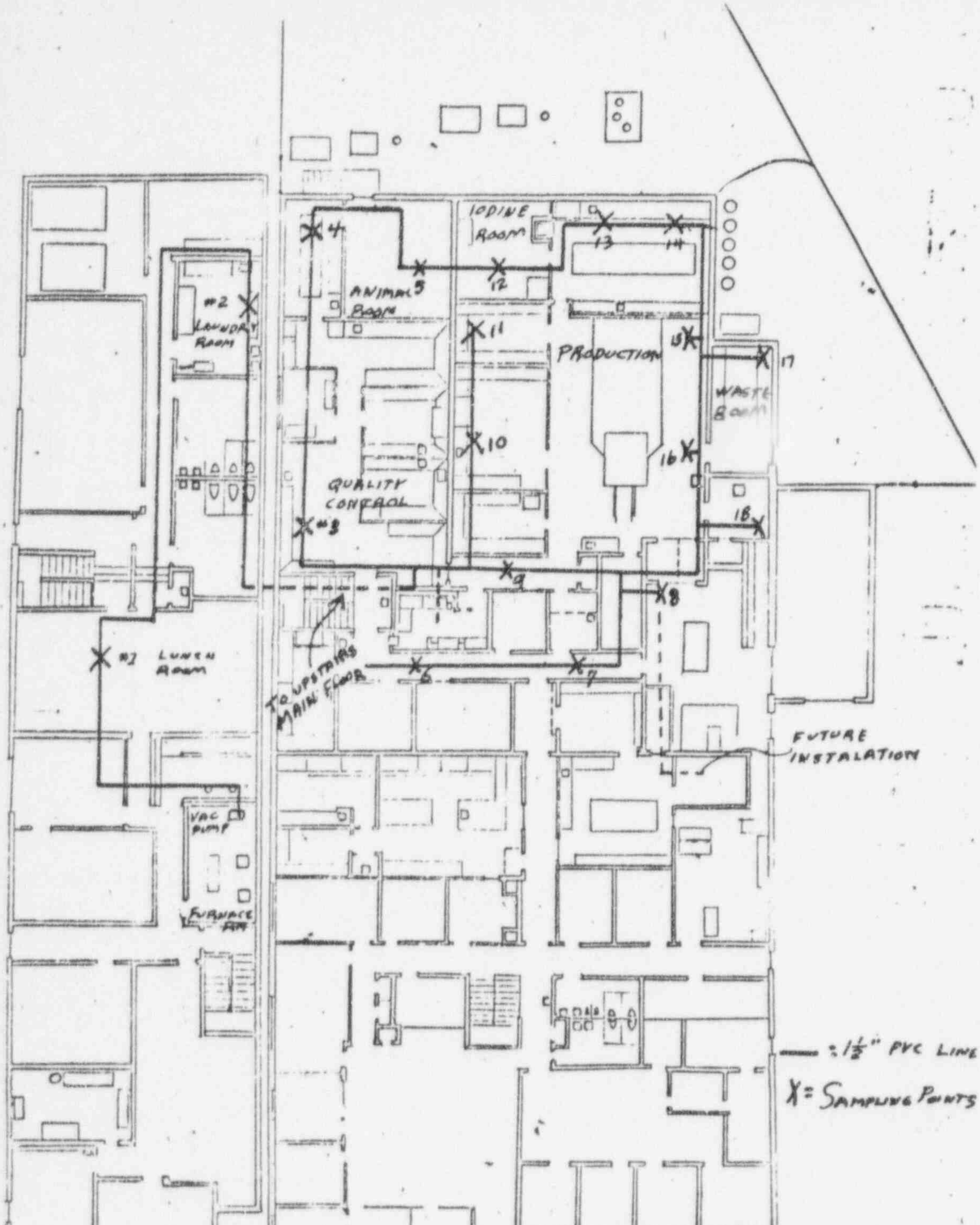
Air sampling pump and motor Have

B. 1967

Automatic sample changer - Pending

Absolute [illegible] cleaner [illegible]

Alpha [illegible] scintillation detector



LOCATIONS OF PVC LINES
MALLINCKRODT/NUCLEAR
EXHIBIT F

MALLINCKRODT/NUCLEAR

IODINE-131 FRACTIONAL PERMISSIBLE THYROID BURDEN WEEKLY AVERAGES

Quarter Start.____________ Week No.______ Week Start.____________

NAME	MON	TUES	WED	THURS	FRI	SAT	WKLY AVER	RUN TOTAL	WKS OBS	CORP TOTAL
Ballentine										
Beiermann										
Borne										
Brinner										
Brown, J.L										
Bushman										
Condie										
Cox										
French										
Frick										
Genova										
Granger										
Greenberg										
Grummon										
Hamilton										
Kellerman										
Lawson										
Lehmann										
LePere										
Milsark										
Orbin										
Robb										
Rodrian										
Smith										
Strubel										
Background										

ROUTINELY TWICE A WEEK

Performed by________________ Reviewed by________________

MALLINCKRODT/NUCLEAR

EXHIBIT G-1

MALLINCKRODT/NUCLEAR

IODINE-131 FRACTIONAL PERMISSIBLE THYROID BURDEN WEEKLY AVERAGES

Quarter Start.________________ Week No.______ Week Start.______________

NAME	MON	TUES	WED	THURS	FRI	SAT	WKLY AVER	RUN TOTAL	WKS OBS	CORP TOTAL
AuBuchon										
Barlow										
Constantine										
Coslet										
Deer, C.										
Deer, G.										
DuVall										
Greeves										
Guthrie										
Holgate										
Jordan										
Kuzins										
Kelly										
Schroeder			ROUTINELY ONCE A WEEK							
Scrivner										
Sneller										
Sliepen										
Soldan										
Spradling										
Rhoads										
Temme										
Whiteside										
Yancy										
Zebura										
Background										

Performed by________________________ Reviewed by________________________

MALLINCKRODT/NUCLEAR
EXHIBIT G-2