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Form AEC-313 6-64 10 CFR 30	UNITED STATES ATOMIC APPLICATION FOR BYPROD	Farm approved ⁴ udget Bureau No. 38-R02					
INSTRUCTIONS. – Comple previous applications files specific. Use supplement mission, Washington, D.C. receive an AEC Byproduc Title 10, Code of Federal	the Items 1 through 16 if this is an initial applic 1 with the Commisson with respect to Items 8 thro tal sheets where necessary. Item 16 must be ca 2, 20545, Attention: Isatopes Branch, Division of t Material License. An AEC Byproduct Material Regulations, Part 30, and the Licensee is subject	ation or an application for renewal of a li ugh 15 may be incorporated by reference impleted on all applications. Mail two co f Materials Licensing. Upon approval of t License is issued in accordance with the g to Title 10, Code of Federal Regulations,	cense. Information contained i provided references are clear an pies to: U.S. Atomic Energy Con his application, the applicant wi general requirements contained Part 20.				
(a) NAME AND STREET AC perion, etc. include ZC ⁰ Mallinckrodt Nuclear Const Box 6172 Lami St. Louis, M:	DRESS OF APPLICANT (Institution from hospital Code.) Chemical Works ultants Division pert Field issouri 63145	(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED (1 different from 1 (a) Include 21P Code.) 2703 Wagner Place Maryland Heights, Missouri 63042					
DEPARTMENT TO USE BYPRO See License I	DOUCT MATERIAL No. 24-4206-1	3 PREVIOUS LICENSE NUMBER(S) (If this is an application for renewal of license please indicate and give number) See License No. 24-4206-1					
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U.S. GOVERNMENT PRINTING OFFICE : 1944 0-745-361

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

STILLET DEFE

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 Assistant 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.

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 outh 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

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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. 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

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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

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

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.

-6-



IV. Hot Cell System

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- 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"

-7-

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
 - 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.

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

 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.

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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.



<u>ITEM 15</u>

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.