



Bristol-Myers Squibb Company

Worldwide Medicines Group

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December 14, 2001

Ms. Pamela Henderson
USNRC Region I
475 Allendale Road
King of Prussia, PA 19406

030-05222

**RE: DECOMMISSIONING PLAN FOR RADIODIAGNOSTIC MANUFACTURING
OPERATIONS – LICENSE #29-00139-02**

Dear Ms. Henderson:

E.R. Squibb & Sons, a wholly owned subsidiary of Bristol-Myers Squibb Company, wishes to amend its radioactive material license #29-00139-02 to proceed with decommissioning of the buildings and equipment associated with radiodiagnostic manufacturing operations at our New Brunswick, New Jersey facility. These operations were terminated in June of this year and were removed from our licensed activities under amendment #99 of our license.

Two copies of a decommissioning plan are attached for your review. An electronic copy will also be submitted via e-mail. This plan supercedes the plan that was submitted with our amendment request dated July 18, 2001. The scope of this plan is limited to the buildings and equipment associated with radiodiagnostic manufacturing operations. It is our intention to release the manufacturing facility and associated equipment from all radiological license, NRC and NJDEP restrictions. We will not be terminating our license at the end of this process.

It is our intention to commence decommissioning activities in February of 2002. We therefore request an expedited review of this plan. If you have any questions or wish to discuss the decommissioning plan, please contact me at (609) 818-4907.

Sincerely,

Michael J. Vala, CHP
Radiation Safety Officer/Manger, EHS

MJV:bl

Attachments (2)

MJV\D&SUBMITTAL-NRC.DOC

cc: C. Woodard

130734

NMSS/RGNI MATERIALS-002

RADIOLOGICAL DECOMMISSIONING PLAN
FOR
RADIOLOGICAL MANUFACTURING
FACILITY AND ASSOCIATED EQUIPMENT

E. R. Squibb & Sons*
New Brunswick, NJ

NRC License #29-00139-02
NJDEP License #NJSL-10071

Radiation Safety Officer: Michael J. Vala, CHP
December, 2001

**a wholly owned subsidiary of BMS Company*

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1.0 EXECUTIVE SUMMARY

This decommissioning plan is being submitted for:

NRC License #29-00139-02 and NJDEP License #NJSL-10071
E.R. Squibb & Sons
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903

E.R. Squibb & Sons, a wholly owned subsidiary of Bristol-Myers Squibb Company (BMS), has voluntarily committed to a radiological decommissioning of parts of the E.R. Squibb & Sons site in New Brunswick, NJ (25 miles southwest of Newark), formerly used as a radiopharmaceutical manufacturing facility. The site map is shown in Figure 1-1 and the areas to be decommissioned are shown in Figure 1-2. The scope of this decommissioning plan is limited to these facilities.

The radiopharmaceutical manufacturing plant (Building 124) and its storage facility (Building 122) were utilized for the processing, storage and decay of radioactive materials generated during the manufacture of radiopharmaceuticals. Both structures are located at the southwest end of the New Brunswick 80.1 acre site and occupy approximately 1.75 acres. Manufacturing and processing operations were terminated on June 29, 2001. License amendment 99 was approved by the NRC to reduce possession limits and remove the requirement for a Radiological Contingency Plan due to the reduced possession quantities.

A Historical Site Assessment was conducted and the information is summarized in the Radiological Status Section of this Plan. An initial classification of areas based on NUREG-1575, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) criteria was established and is outlined in Section 4.0, Radiological Status of Facility. The radionuclides used at E.R. Squibb & Sons were primarily short-lived radionuclides and the estimated remaining nuclide inventory from the radiodiagnostic manufacturing operations which could be available for remediation, will have decayed to less than 10 millicuries as of December 31, 2001. (See Table 2-1). A more detailed characterization survey will be conducted to further define the nature and extent of contamination.

The decommissioning objective is to decontaminate the facilities and release for unrestricted use. After NRC and NJDEP approval of the Final Status Survey, a major portion of the buildings will be demolished to accommodate future expansion plans for the site.

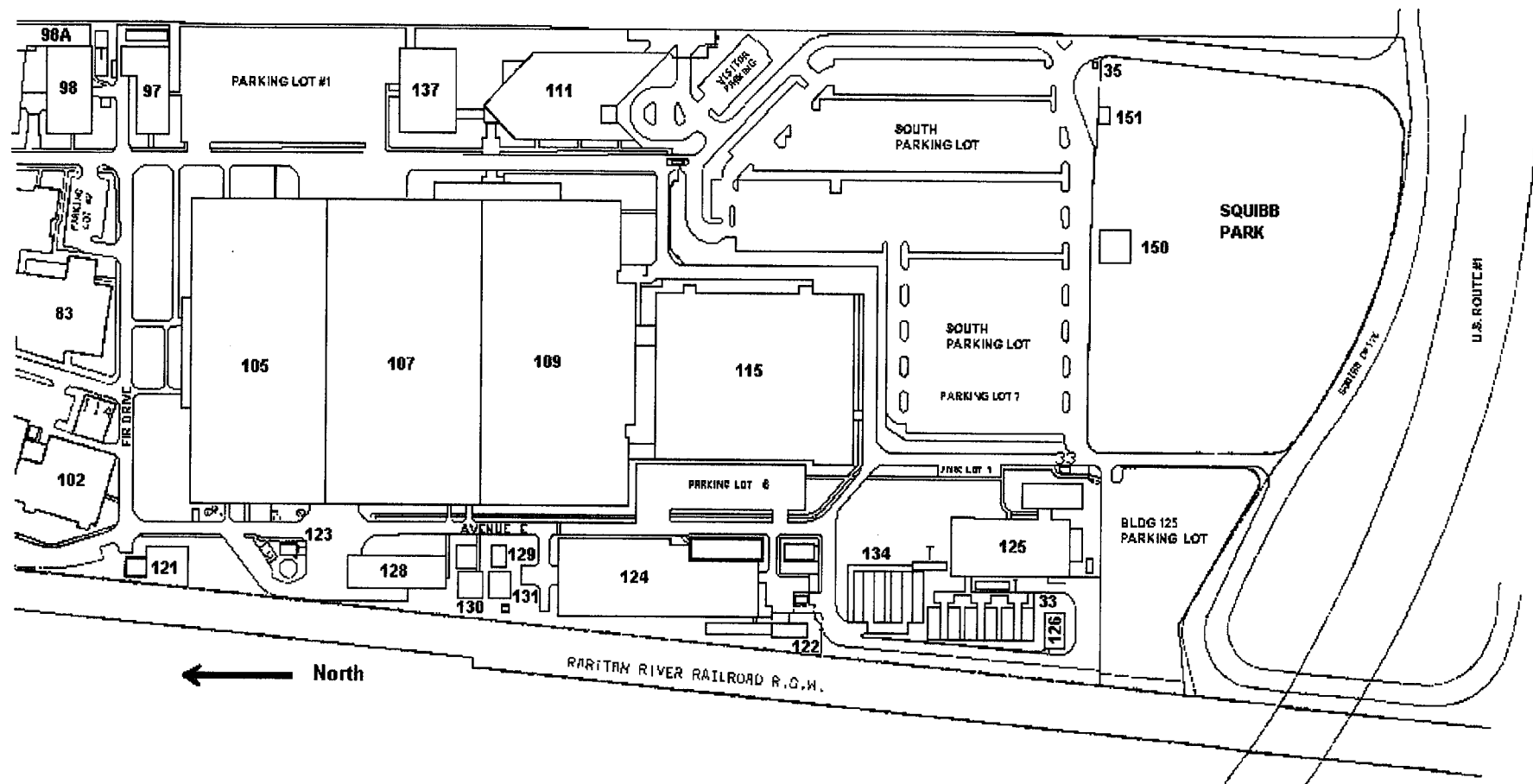


FIGURE 1-1
E.R. Squibb & Sons Site Map

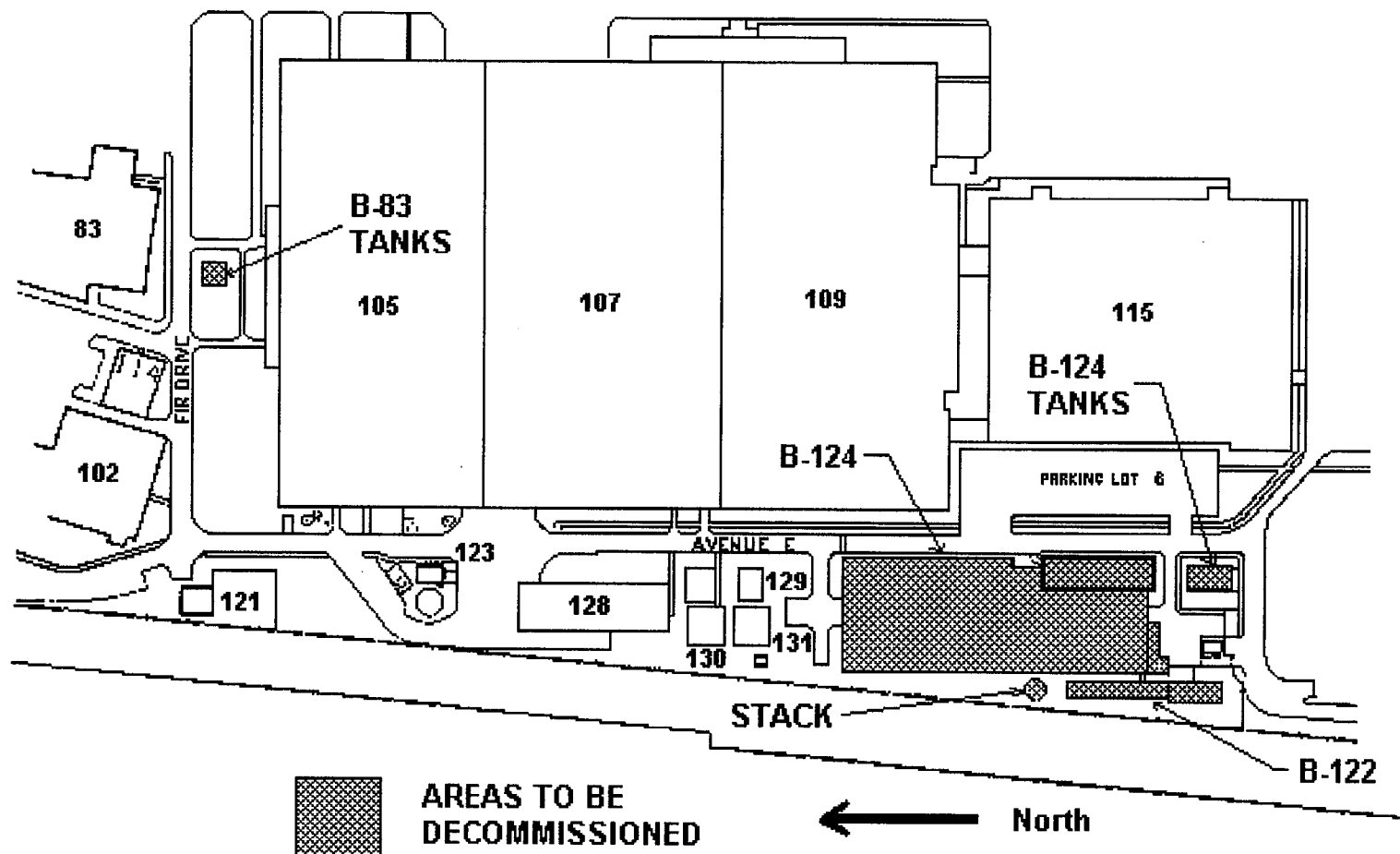


FIGURE 1- 2
Areas To Be Decommissioned

EXECUTIVE SUMMARY (cont)

The release criteria to be used are the NRC Screening Values for Building Surface and Soil and DandD Version 2.1 using default values equivalent to the 25 mrem per year total effective dose equivalent to an average member of a critical group. E.R. Squibb & Sons will use the NRC screening values and understand that by doing so, these levels are considered to be ALARA. However, reasonable efforts will be made to remediate the facility below these levels when practicable.

E.R. Squibb & Sons has initiated the Site Characterization Plan and expects to be completed in February 2002. E.R. Squibb & Sons expects to begin decommissioning activities by second quarter 2002 and complete decontamination work and Final Status Survey by fourth quarter 2002.

E.R. Squibb & Sons is requesting that its license be amended to incorporate this decommissioning plan. The Final Status Survey Report will formally request that the NRC and NJDEP release the manufacturing facilities from license restrictions.

2.0 FACILITY OPERATING HISTORY

2.1 License Number/Status/Authorized Activities

E.R. Squibb & Sons, Inc. of New Brunswick, New Jersey is the holder of Broad Scope License No. #29-00139-02 issued by the U.S. Nuclear Regulatory Commission (USNRC) and the State of New Jersey radioactive materials license #NJSL 10071. The radiopharmaceutical manufacturing plant (Building 124) and its storage facility (Building 122) were utilized for the processing, storage and decay of radioactive materials generated during the manufacture of radiopharmaceuticals. Both structures are located at the southwest end of the New Brunswick 80.1 acre site and occupy approximately 1.75 acres. Figures 1-1 and 1-2 show the layout of the buildings and the locations of use and storage of the various radionuclides.

Manufacturing and processing operations were terminated on June 29, 2001. License amendment 99 was approved by the NRC to reduce possession limits and remove the requirement for a Radiological Contingency Plan due to the reduced possession quantities and in particular ^{131}I .

Specific isotopes and estimated remaining nuclide inventory are shown in Table 2-1:

TABLE 2-1
Estimated Remaining Nuclide Inventory from the Former
Radiodiagnostic Manufacturing Operations (December 31, 2001)

Isotope	Maximum Inventory	Form
^{51}Cr	0.19 mCi	Sodium Chromate
^{57}Co	0.29 mCi ⁽¹⁾	Cobalt Chloride
^{82}Sr	0.51 mCi	Strontium Chloride
^{85}Sr	86.73mCi ⁽¹⁾	Strontium Chloride
^{131}I	0 mCi	Sodium Iodide

Note ⁽¹⁾: Approximately 90 % of this radioactivity is located in vials and columns which will be disposed of as radwaste and will not need to be remediated.

This estimated remaining nuclide inventory was developed based on the license material inventory and accountability procedure. Radioactive materials were controlled by maintaining records and procedures to ensure accountability at all times. All receipts of radioactive material were logged into the site's inventory. All site radioactive material inventories were maintained by the Health Physics staff. Records indicated total site possession, responsible person, location of material, date delivered, and date and method of material disposition.

License Number/Status/Authorized Activities (cont)

The last license renewal application was completed on February 18, 1997 and was issued by the NRC on September 25, 1998. The list of amendments since the last license renewal is as follows:

- Amendment No. 95 issued on September 25, 1998.
- Amendment No. 96 issued in accordance with the application dated May 26, 1999.
- Amendment No. 97 issued in accordance with the application dated January 17, 2001.
- Amendment No. 98 was issued by the NRC March 15, 2001.
- Amendment No. 99 was issued in accordance with the application dated July 18, 2001.

2.2 License History

Various radionuclides in significant quantities typical to a radiopharmaceutical production operation were processed and stored in isolated areas within these structures. Although the license authorizes the possession and use of various nuclides in significant quantities, typical production operations are limited to the use of approximately five isotopes with maximum inventories ranging from 0.05 to 150 Curies. Specific isotopes and possession quantities normally possessed and processed are in Table 2-2 as follows:

TABLE 2-2
Possession Quantities Normally Possessed and Processed

Isotope	Maximum Inventory	Form
^{131}I	150 Curies	Sodium Iodine
^{82}Sr	15 Curies	Strontium Chloride
^{85}Sr	75 Curies	Strontium Chloride
^{51}Cr	5 Curies	Sodium Chromate
^{57}Co	0.05 Curies	Cobalt Chloride

In addition to the isotopes above, various isotopes had been used historically in manufacturing. These included: ^{60}Co , ^{137}Cs , ^{14}C , ^{90}Sr , ^{99}Mo , ^{123}I , ^{125}I , ^{198}Au , ^{32}P , ^{197}Hg , ^{203}Hg , ^{192}Ir , ^{201}Tl , ^{89}Sr , and ^{75}Se . There is some evidence that ^3H and ^{14}C may have been used in Building 124 in the 1960's for research activities.

Although most of these isotopes have half lives less than 65 days, there may have been some long lived impurities in the bulk solutions that require action under this decommissioning plan such as ^{99}Tc , ^{54}Mn , ^{57}Co , ^{60}Co , ^{137}Cs and ^{129}I .

2.3 Previous Decommissioning Activities

In the early 1970's, two below grade waste decay tanks were removed and offices were constructed where they were formerly located. Figure 4-1 shows the former location of these tanks in areas now designated by rooms 116, 118, 108 and 109 of Building 124.

2.4 Spills

There have been some spills of radioactive material outside of Building 124. In addition, there were some work activities that may have resulted in radioactive material transfer to outdoor areas, even though no such contamination was ever reported. These spills and activities include the following items:

- ^{131}I was spilled in front of the Hot Barn Door (south end of Building 122) many years ago.
- ^{32}P was spilled in the area of the Building 124 old west entrance to Building 122 in 1964. This area was paved over to prevent the spread of contamination.
- ^{32}P was spilled in the area of the storm water collection vault many years ago.
- There was equipment stored to the west of Building 122 that could have exhibited activity above background levels.
- Many years ago, manipulators were occasionally steam cleaned prior to maintenance at the live steam outlet on the south side of Building 124. The manipulators at the time exhibited activity above background levels. Manipulators would have been used for the production of molybdenum and iodine products.
- The effluent tanks would occasionally float due to infiltration of groundwater in the vaults and break the glass piping resulting in small spills on the top of the tanks but not to the environment.

In addition to minor contamination events that occurred incidental to normal manufacturing operations, the following incident was documented in a deviation report and reported to the NRC.

- In September of 1990 30 Curies of ^{131}I was released into the vacuum system. The system was flushed with sodium hydroxide and the cave in which the work was being conducted was decontaminated.

2.5 Prior On-Site Burials

There were never any on-site burials of radioactive materials.

3.0 FACILITY DESCRIPTION

3.1 Site Location and Description

E.R. Squibb & Sons, Inc. owns and operates a pharmaceutical manufacturing and research facility located in Middlesex County, New Jersey. The site occupies approximately 80.1 acres primarily in the township of North Brunswick, at the crossroads of Route 1 and Squibb Drive.

Geographically, the site can be represented at 40 degrees, 28 minutes, and 25 seconds North; and 74 degrees, 28 minutes, and 25 seconds West.

The topography of the site is relatively flat. Elevations near the center of the site are close to 120 feet above sea level, while elevations near either end of the site are approximately 105 feet above sea level.

There are approximately 40 individual structures, ranging in height from 10 feet to 75 feet above grade. Structure sizes are variable but can be considered to contain between 5,000 and 150,000 square feet. Uses include warehousing of raw materials and finished products, animal facilities, analytical and pilot plant laboratories, bulk chemical processing; finished product and packaging, and utilities, maintenance and administrative services.

Parking facilities cover about 17 % of the entire site. Approximately 5 ½ acres, at the southern end of the site, are set aside as a picnic grove and recreational area.

Primary routes used to service the Squibb New Brunswick, New Jersey site are US 1, Highway 130 and the New Jersey Turnpike.

The radiopharmaceutical manufacturing facility is a two-story brick structure located on the southwest end of the site. All manufacturing and processing of radiopharmaceuticals are conducted in the rear of the plant (Building 124).

Unrestricted administrative offices are located on the first and second floor in front of the plant away from the normal manufacturing operations. There are no elevators and the only stairways are those located in the unrestricted office areas and those leading to the second floor machine room.

The facility design was such that movement of supplies, equipment and materials into processing areas did not interfere with adjacent work areas. The layout provided for easy access for purposes of maintenance and efficiency of operation. No unnecessary movement of materials was permitted through areas in which exposure to radiation could occur. Personnel movement in the facility did not require passage through radiation areas to gain access to non-radioactive materials areas.

Site Location and Description (cont)

Clean areas, radiation areas and high radiation areas were situated and segregated so that no unnecessary exposure was received by personnel. This layout also provided for contamination control. A personnel monitoring area and a protective clothing change room was located adjacent to the radioactive materials area. Shower and locker room facilities were also provided. The layout of the facility was such that the products progressed in sequence of operations from the manufacturing, filling and packaging areas to the final holding area for shipment. The loading dock is adjacent to the holding area. By use of conveyor belts and by judiciously locating the various stations in the complete manufacturing process, contact with and handling of any radioactive material was minimal.

The manufacturing facility is equipped with several hot cells, which are constructed of steel, concrete and lead, and used in the production processes. They serve as primary containments. Lead glove boxes and hoods are used to manufacture and fill radiopharmaceuticals of different concentrations. Additional shielding, when necessary, is provided in glove boxes and fume hoods to shield the bulk material to maintain radiation levels on the outside of enclosures as low as practicable. Rooms and glove boxes are provided with ventilation to protect operators from volatile radioactive material.

Holding tanks, waste and storage facilities for radioactive materials decay are remotely located, and are not in the normal path of travel for personnel or equipment. Four ten thousand gallon holding tanks were utilized to decay liquid effluent from the manufacturing facility. The four tanks are located below grade in a concrete vault south of Building 124. Radioactive waste from R&D and manufacturing was stored and processed by compaction in Building 122. Specific isotopes that were processed in the waste stream include millicurie quantities of ^{14}C , ^3H , ^{99}Tc , ^{54}Mn , ^{57}Co , ^{125}I , ^{85}Sr , and other low energy beta/gamma emitters.

The manufacturing areas are serviced by a non-recirculating air conditioned supply system utilizing all outside air introduced through a pre-filter and a high efficiency particulate filter. A general system exhausts the various spaces through filtration equal to that of the supply system. Fume hoods, wherein particulate matter is the expected contaminant, are exhausted through a F-85 and a HEPA filter followed by two 1" high efficiency carbon filters.

Each of the 12 fume hood system filter banks service from one to five fume hoods or other ancillary equipment. Each fume hood system has a manual air bypass to be used during filter changes.

Each glove box filter bank services up to five glove box units or similar equipment. Each glove box system has access to an auxiliary system offering identical filtration. There are no bypasses to allow passage of unfiltered exit air. There are 11 glove box systems and six auxiliary systems available for use during filter changes or maintenance.

Site Location and Description (cont)

Filtration for three hot cells is accomplished by employing two identical exhaust systems. One is in continuous operation, while the other exhaust system services as an auxiliary system when the primary is shut down for decay prior to filter changes and/or maintenance. Each system is filtered by three Flanders roughing, three Flanders HEPA, and nine 1" equivalent MSA activated charcoal filters. There are no bypasses to allow passage of unfiltered cave system air. All exhaust systems are discharged to the effluent exhaust stack.

3.2 Population Distribution

Resident population within a five-mile radius from the Squibb New Brunswick plant site is estimated to be 300,000 individuals, based on 1990-1992 census data. Approximately 200,000 individuals are employed within a five mile radius with 100,000 daily commuters passing the site.

3.3 Current/Future Land Use

The decommissioning objective is to decontaminate the facilities and release for unrestricted use. After NRC and NJDEP approval of the final release survey, a major portion of the buildings will be demolished to accommodate future expansion plans for the site. The decommissioned property will remain under the ownership of E.R. Squibb & Sons.

3.4 Meteorology and Climatology

Requirements for a Radiological Contingency Plan and effluent monitoring are no longer applicable for the current configuration of the facilities. Therefore this information is not applicable.

4.0 RADIOLOGICAL STATUS OF FACILITY

4.1 Historical Site Assessment

The purpose of the Historical Site Assessment was to identify all locations inside and outside the facility, where radiological spills, operational activities or other radiological incidents that occur or could have resulted in contamination of structures, equipment, storage areas or soils. A Historical Site Assessment was conducted using the following methodology:

- Review of licenses
- Review of audit, inspection and deviation reports
- Review of operational survey records
- Review of product certificate of analysis and QC records
- Interviews with past and present employees

Information was gathered about the following areas:

Building 124

Building 124 was a radiopharmaceutical production building (Figures 4-1 and 4-2). It is a large (about 70,000 ft²), two story building containing office areas, laboratories, hot cells (caves), radiopharmaceutical packaging areas, HEPA ventilation systems, mechanical rooms, machine shop, receiving area, a shipping dock and related infrastructure (sanitary sewer and process sewer). With the majority of the radioactive materials consisting of short half-lived isotopes, it is anticipated that very few areas will have activity in excess of guideline values. Areas anticipated to exhibit activity above background levels include the process caves and some ventilation system components. In addition the glove boxes, hoods, ventilation system and process drains have the potential to exhibit activity above background levels.

Building 122

Building 122 is a radiopharmaceutical storage facility (Figure 4-3). It is a single story building of approximately 3,500 ft² with old and new sections. Operations in this building included the following:

- Hold-for-decay radioactive waste,
- Returned radiopharmaceutical and source package breakdown,
- Radioactive waste disposal shipment preparation, and
- Compaction of waste for licensed R&D activities.

With the majority of the radioactive materials consisting of short half-lived isotopes contained in packages, this facility has little potential to exhibit elevated activity.

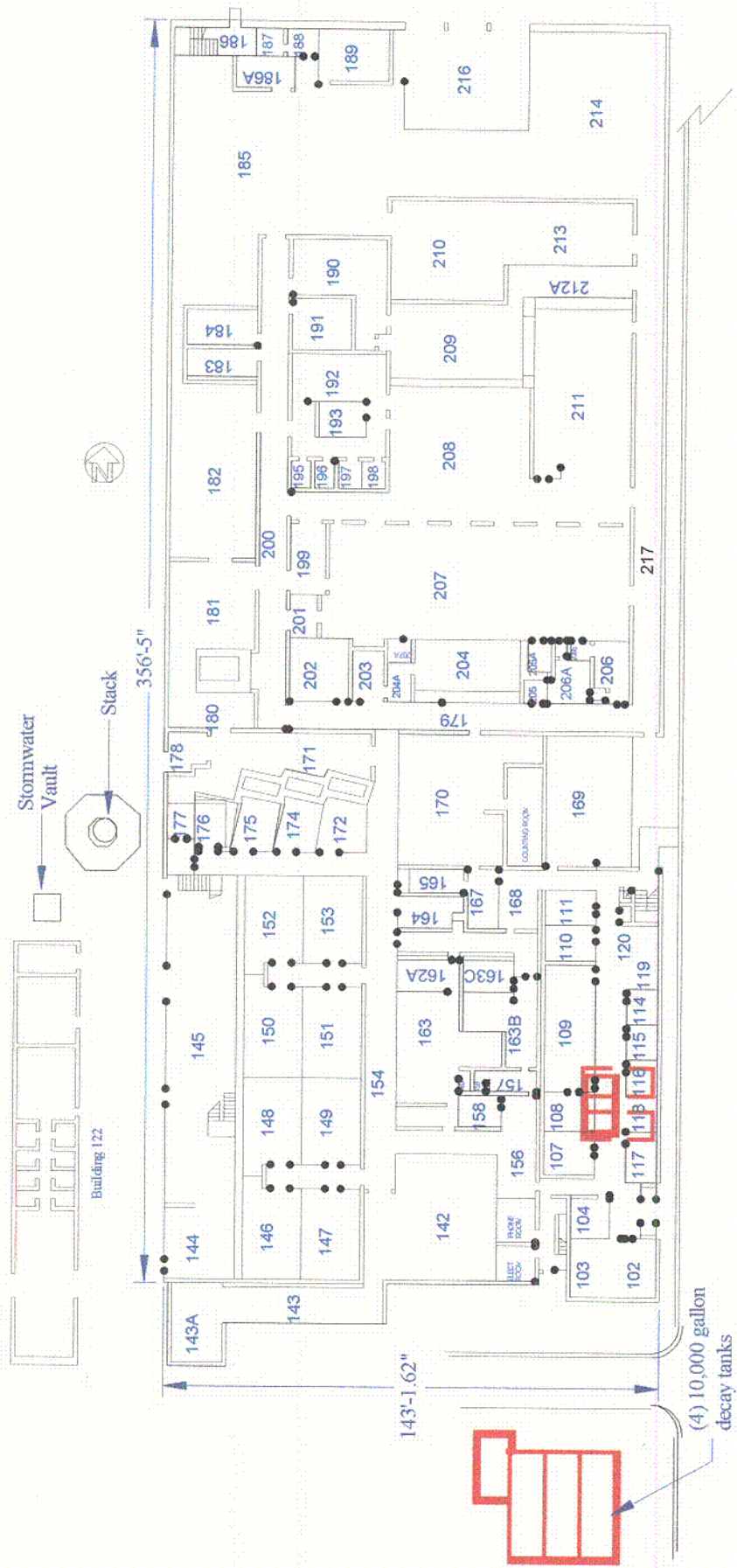


FIGURE 4-1
Building 124 Ground Floor Plan

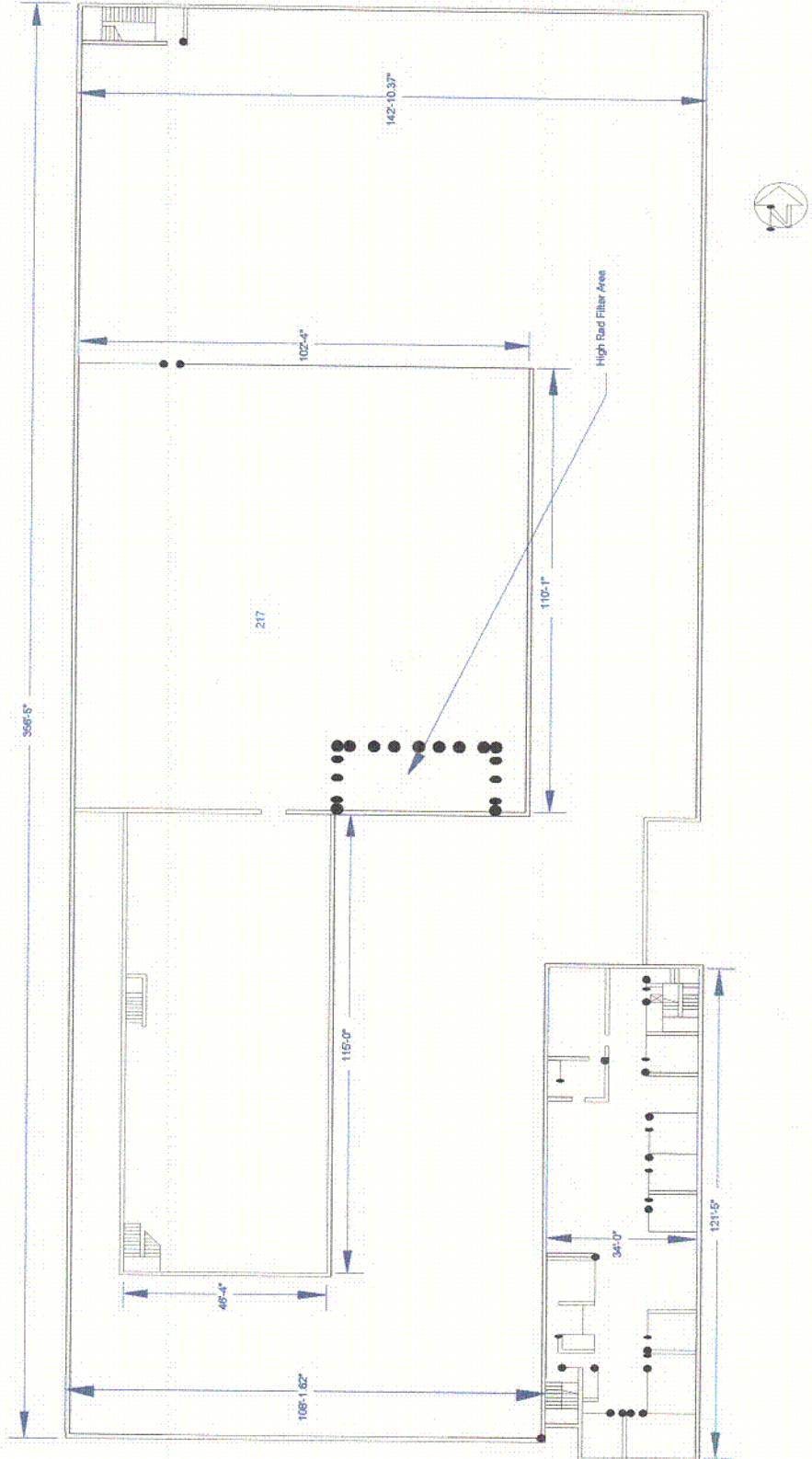


FIGURE 4-2
Building 124 Second Floor Plan

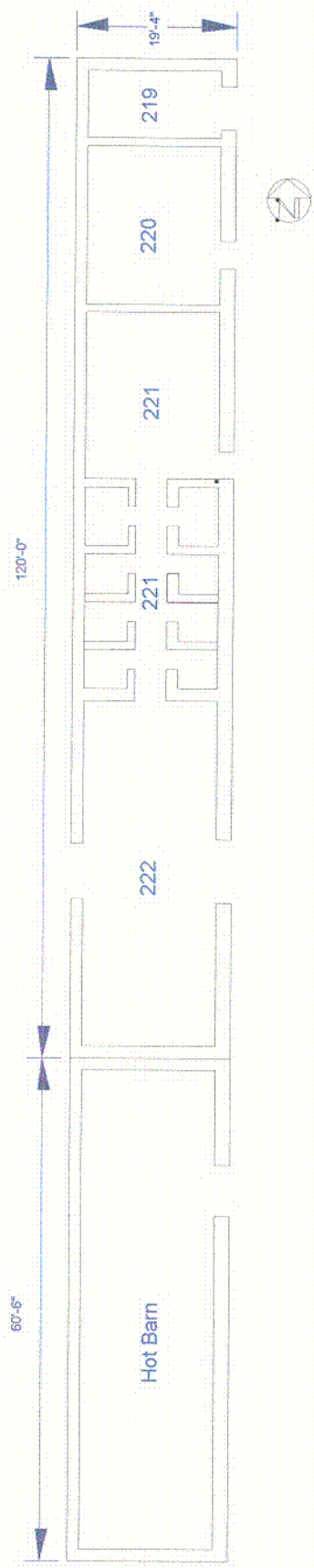


FIGURE 4-3
Building 122 Floor Plan

Historical Site Assessment (cont)

Outside Areas

- Building 83 Tanks and Tank Pit (Figure 4-4) : There are two 8,000 gallon below grade wastewater containment (decay) tanks located to the south of Building 83. These tanks previously received radiopharmaceutical wastewater and therefore may exhibit activity above background levels.
- Building 124 Stack (Figure 4-1) : There is a 98-foot tall steel stack to the east of Building 124 that exhausts from Building 124 ventilation systems. Because of the presence of activity above background levels in portions of the facility exhausted to the stack, the stack may exhibit elevated activity.
- Building 124 Decay Tanks Tank and Pit (Figure 4-1) : The four 10,000 gallon decay tanks located adjacent to building 124 and the pumps and equipment in the adjacent valve pit have a history of internal activity above background levels.
- Storm Water Holdup Tank (Figure 4-1) : The storm water holdup tank at the north end of Building 122 does not have a history of internal activity above background levels.
- Storm Sewers: The storm sewers around Building 124 do not have a history of internal activity above background levels.
- Open Land Areas: There have been some spills of radioactive material outside of Building 124. In addition there were also some work activities that could have resulted in radioactive material transfer to outdoor areas, even though no such contamination was ever reported. These spills and activities include the following items:
 - ^{131}I was spilled in front of the Hot Barn Door (south end of Building 122) many years ago.
 - ^{32}P was spilled in the area of the Building 124 old west entrance to Building 122 in 1964. This area was paved over to prevent the spread of contamination.
 - ^{32}P was spilled in the area of the storm water collection vault many years ago.
 - There was equipment stored to the west of Building 122 that could have exhibited activity above background levels.
 - Many years ago manipulators were occasionally steam cleaned prior to maintenance at the live steam outlet on the south side of Building 124. The manipulators at the time exhibited activity above background levels. Manipulators would have been used for the production of molybdenum and iodine products.



FIGURE 4-4
Building 83 Below Grade Wastewater Tanks

Historical Site Assessment (cont)

Based on historical survey data and the decay of the short-lived isotopes, the outdoor areas have little potential to exhibit activity above background levels.

Some isotopes that were impurities to manufacturing operations were also detected. ^{99}Tc and ^{54}Mn were found in the Building 124 liquid effluent decay holding tanks along with the production isotopes ^{57}Co , ^{60}Co and ^{137}Cs .

The radionuclides used at E.R. Squibb & Sons are primarily short-lived radionuclides but traces of longer lived radionuclides present as trace impurities and the site history indicate that some longer-lived nuclides are potentially present. The anticipated radionuclides along with approximate decay information are provided in the Table 4-1 below. Radionuclides with half lives shorter than 65 days are not of concern unless they continue to be produced by a longer- lived parent radionuclide.

There are no isotopes with atomic numbers exceeding 83 or any alpha emitting radionuclides of concern, however the characterization will include surveying for alpha emitters to verify that they are not present. The goal is to detect all radionuclides, anticipated or not. The radionuclides with long enough half-lives to be of concern are ^{54}Mn , ^{57}Co , ^{60}Co , ^{75}Se , ^{99}Tc , ^{129}I and ^{137}Cs .

TABLE 4-1
Anticipated Radionuclides with Decay Information

Isotope	Half-life	Gamma (Mev)	Gamma (Mev)	Gamma (Mev)	Avg. Beta (Mev)	Max. Beta (Mev)
^{14}C	5730 yr	-	-	-	0.049	0.0156
^3H	12.28 yr	-	-	-	0.0057	0.0186
^{32}P	14.29 d	-	-	-	0.695	1.71
^{51}Cr	27.7 d	0.32 (10%)			none	none
^{54}Mn	312.7 d	0.835	-	-	none	none
^{57}Co	270.9 d	0.014 (10%)	0.122 (86%)	0.136 (11%)	none	none
^{59}Fe	44.63 d	0.335 (0.3%)	1.099 (56.5%)	1.2916 (43.2)	0.1175	1.565
^{60}Co	5.271 yr	1.173 (100%)	1.332 (100%)	-	0.096	0.318
^{75}Se	119.78 d	0.136 (59%)	0.265 (60%)	0.280(25%)	none	none
^{82}Sr	25 d	0.0133 (17%)	0.0134 (32%)	0.015 (9%)	none	none
^{82}Rb	1.25 min	0.698 (0.15%)	0.776 (14%)	1.4 (0.51%)	1.474	3.36
^{83}Rb	86.2 d	0.52 (46%)	0.53 (30%)	0.55 (16%)	none	none
^{84}Rb	32.9 d	0.88 (68%)	1.02 (0.3%)	1.9(0.9%)	0.546	1.658
^{85}Sr	64.84 d	0.514 (100%)	-	-	None	none
^{89}Sr	50.55 d	0.91 (0.015%)	-	-	0.583	1.491
^{90}Sr	28.6 yr	-	-	-	0.1958	0.546
^{90}Y	64.1 hr	-	-	-	0.934	2.284
^{99}Mo	66.02 hr	0.181 (6%)	0.74 (13%)	0.78 (4%)	0.387	1.214
$^{99\text{m}}\text{Tc}$	6.02 hr	0.14 (89%)	-	-	none	none

TABLE 4-1
Anticipated Radionuclides with Decay Information (cont)

Isotope	Half-life	Gamma (Mev)	Gamma (Mev)	Gamma (Mev)	Avg. Beta (Mev)	Max. Beta (Mev)
⁹⁹ Tc	2.13x10 ⁵ yr	-	-	-	0.0846	0.293
¹²³ I	13.13 hr	0.027 (70%)	0.031-(16%)	0.159 (83%)	None	none
^{123m} Te	119.7 d	0.159 (84%)	-	-	None	none
¹²³ Te	1x10 ¹³ yr	0.0261 (13%)	0.0264 (25%)	0.0297 (9%)	None	none
¹²⁵ I	60.14 d	0.035 (7%)	-	-	None	none
¹²⁹ I	1.57x10 ⁷ yr	0.03 (57%)	0.034 (13%)	0.04 (7.5%)	0.041	0.15
¹³⁰ I	12.36 hr	0.536 (99%)	0.668 (96%)	0.739 (82%)	0.091	1.176
¹³¹ I	8.04 d	0.284 (6.1%)	0.364 (82%)	0.637 (7.3%)	0.182	0.806
¹³⁷ Cs	30.17 yr	-	-	-	0.174	1.173
^{137m} Ba	2.552 min	0.662 (90%)	-	-	None	none
¹⁵⁶ Eu	15.19 d	0.812 (10%)	1.23 (9%)	1.1 (Avg)	0.394	2.45
¹⁹² Ir	74.02 d	0.30 (59%)	0.316 (83%)	0.468 (48%)	0.18	0.845
¹⁹⁷ Hg	64.14 hr	0.067 (21%)	0.068 (35%)	0.078 (34%)	None	none
¹⁹⁸ Au	2.696 d	0.412 (96%)	0.676 (1%)	1.088 (0.2%)	0.312	0.961
²⁰⁰ Tl	26.1 hr	0.368 (87%)	0.579 (14%)	1.21 (30%)	0.495	1.12
²⁰¹ Tl	73.06 hr	0.069 (74%)	0.08 (21%)	0.167 (10%)	None	none
²⁰² Tl	12.23 d	0.439 (92%)	0.52 (0.9%)	0.96 (0.12%)	None	none
²⁰³ Pb	52.02 hr	0.279 (77%)	0.401 (3.3%)	0.681 (0.7%)	None	none
²⁰³ Bi	11.8 hr	0.264 (6%)	0.381 (9%)	0.82 (78%)	-	1.35
²⁰³ Hg	46.6 d	0.279 (77%)	-	-	0.058	0.212
²⁰⁹ Tl	2.2 min	0.12 (77%)	0.47 (97%)	1.57 (100%)	0.659	1.83
²⁰⁹ Pb	3.253 hr	-	-	-	0.198	0.645

The Historical Site Assessment information was used to develop an initial classification of the site in accordance with the MARSSIM guidelines.

- **Class 1 Areas:** Areas that have, or had prior to remediation, a potential for radioactive contamination (based on operating history) or known contamination (based on previous surveys) above the Derived Concentration Guideline Level (DCGL).
- **Class 2 Areas:** Areas that have, or had prior to remediation, a potential for radioactive contamination, but are not expected to exceed the DCGL.
- **Class 3 Areas:** Any impacted area that is not expected to contain any residual radioactivity, or is expected to contain levels of residual radioactivity at a small fraction of the DCGL.

Historical Site Assessment (cont)

Class 1 areas are shown in Figures 4-5, 4-6 and 4-7 and include the following:

- Building 124 Caves
- Building 124 Exhaust Ventilation System
- Building Exhaust Stack
- Building 124 Tanks
- Building 83 Tanks
- Class 1 Lab Areas
- Formerly decommissioned waste decay tanks

Class 2 and 3 areas are shown in Figures 4-8 and 4-9 and include the following:

- Laboratory, Office and Production areas inside Buildings 122 and 124
- Exterior of Buildings 122 and 124
- Building Exterior Open Land Areas (Buildings 122, 124, and Building 83)
- Subsurface Areas

4.2 Characterization Surveys

Additional characterization surveys will be conducted. The Data Quality Objectives (DQO's) of this survey are:

- To verify the historical characterization data obtained by interviews, document reviews, and facility walk-downs.
- To accurately assess the radioactive contamination and residual activity levels, including activity in normally inaccessible areas such as ventilation systems, drains, and buried tanks as well as all impacted areas of the facility.
- To show that areas previously considered non-impacted by radioactive materials are truly not impacted in accordance with MARSSIM protocols.
- To collect sufficient isotopic data such that accurate DCGL's can be determined and established for the upcoming decommissioning work.
- To characterize waste streams that will result from the future D&D process.
- To provide data by which future D&D tasks can be assessed for safety impacts, such that sufficient controls may be implemented during the D&D process

The surveys will include measurements and sampling in the areas known to require remediation (impacted areas). The surveys will also examine the surrounding areas, structures, and environs that are believed to be non-impacted.

The survey design, sampling and measurement protocols will be conducted in accordance with the MARSSIM guidelines.

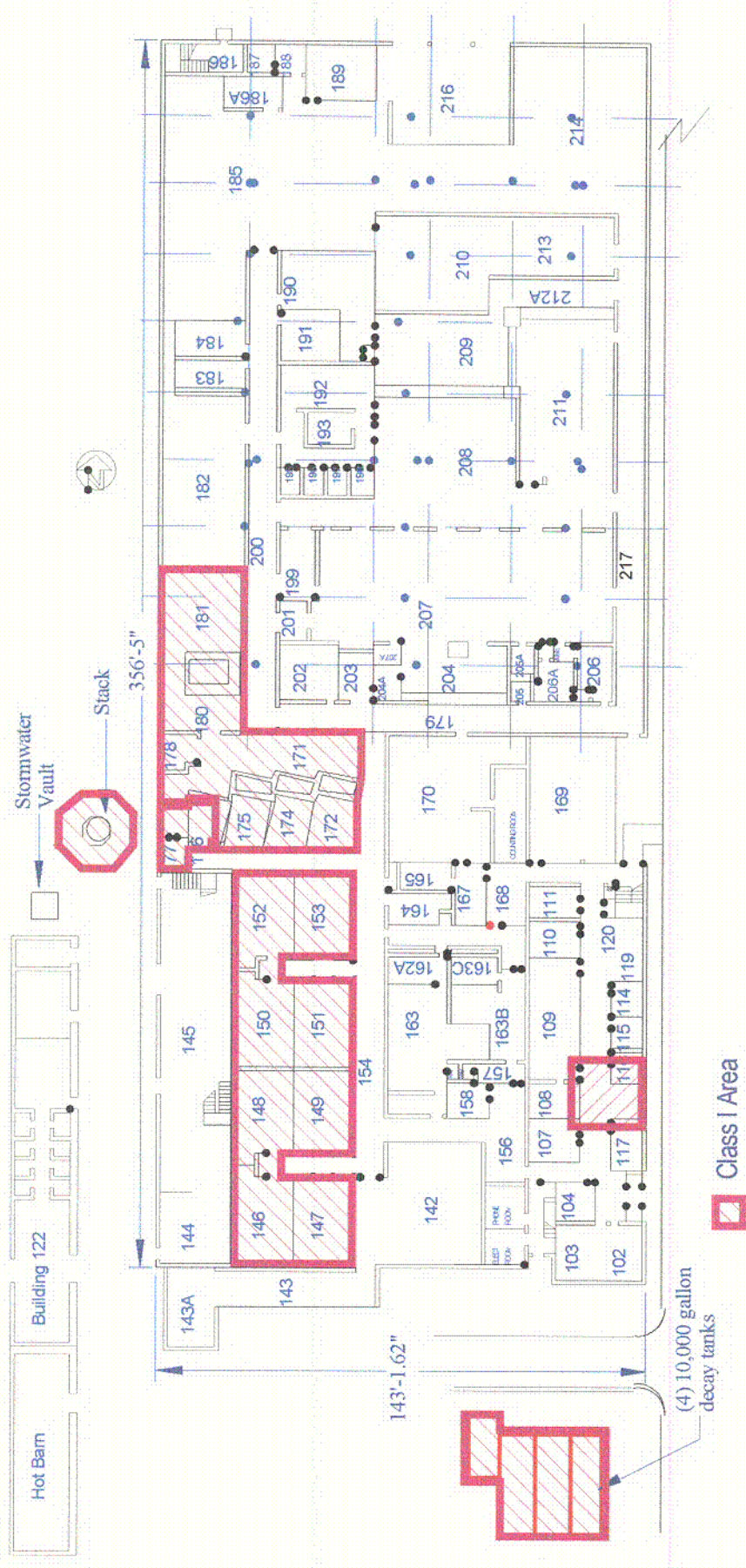


FIGURE 4-5
Building 122 and 124 First Floor Class 1 Areas

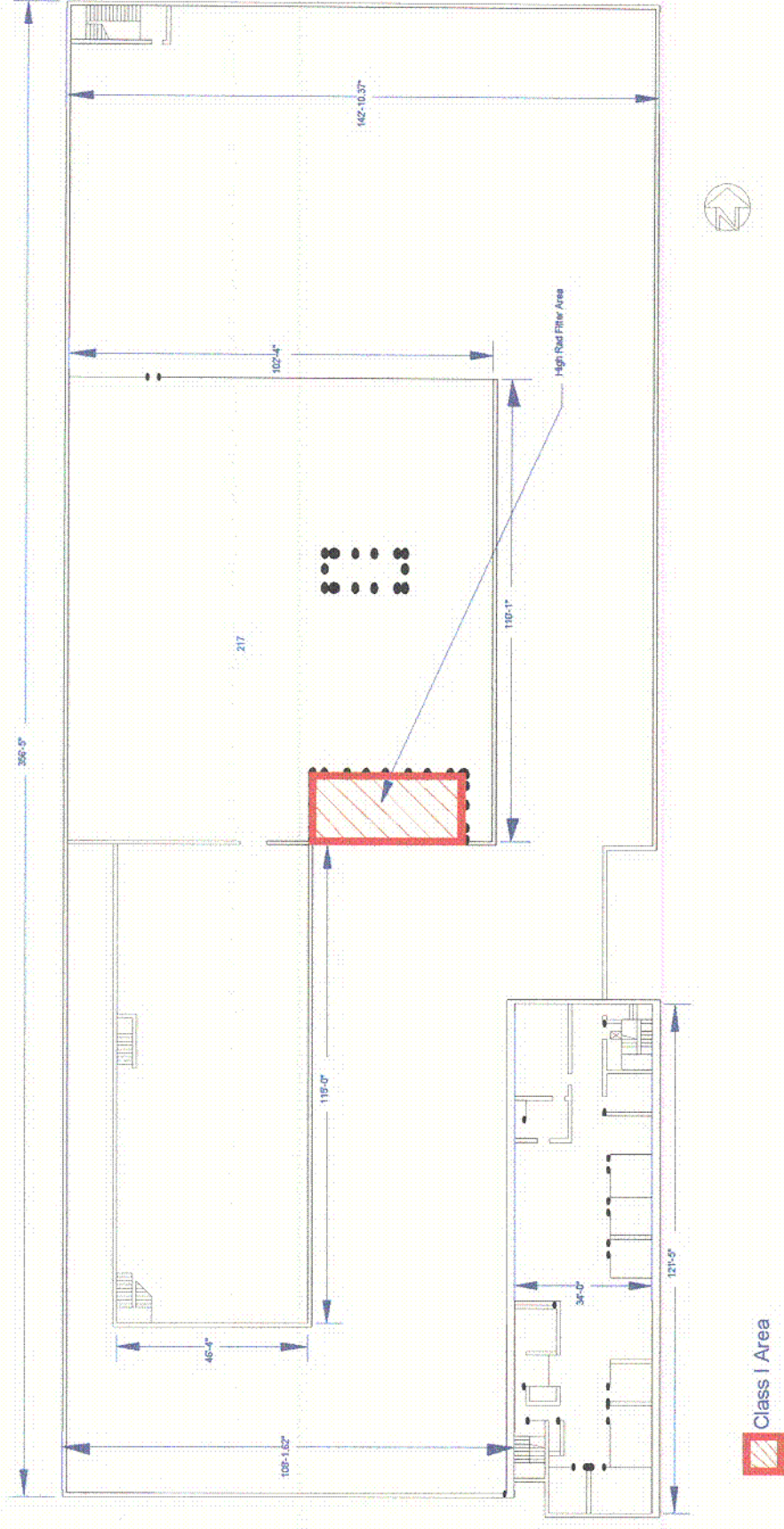


FIGURE 4-6
Building 124 Second Floor Class 1 Areas



FIGURE 4-7
Building 83 Tank Class 1 Area

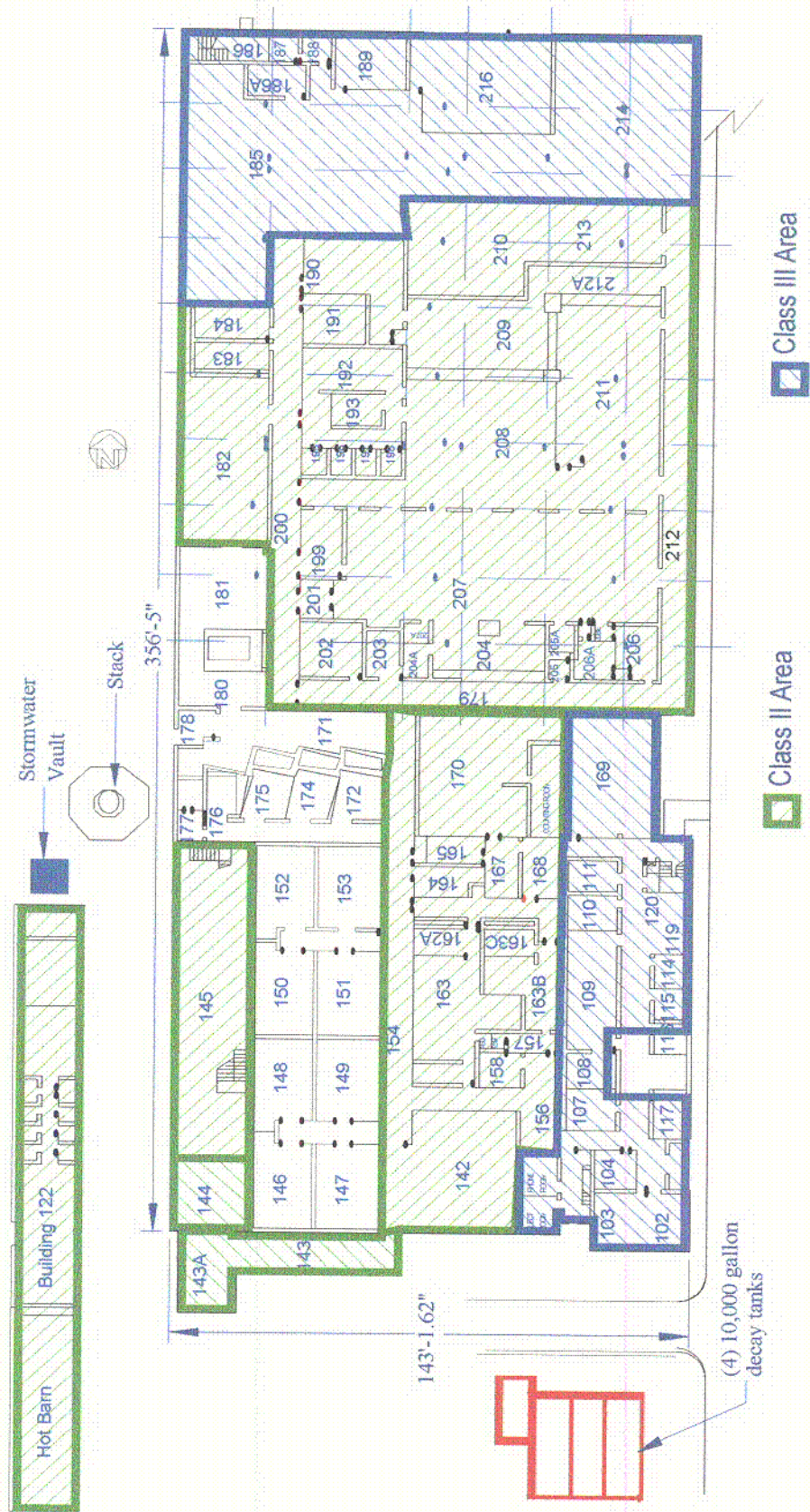


FIGURE 4-8
Building 122 and 124 First Floor Class 2 and Class 3 Areas

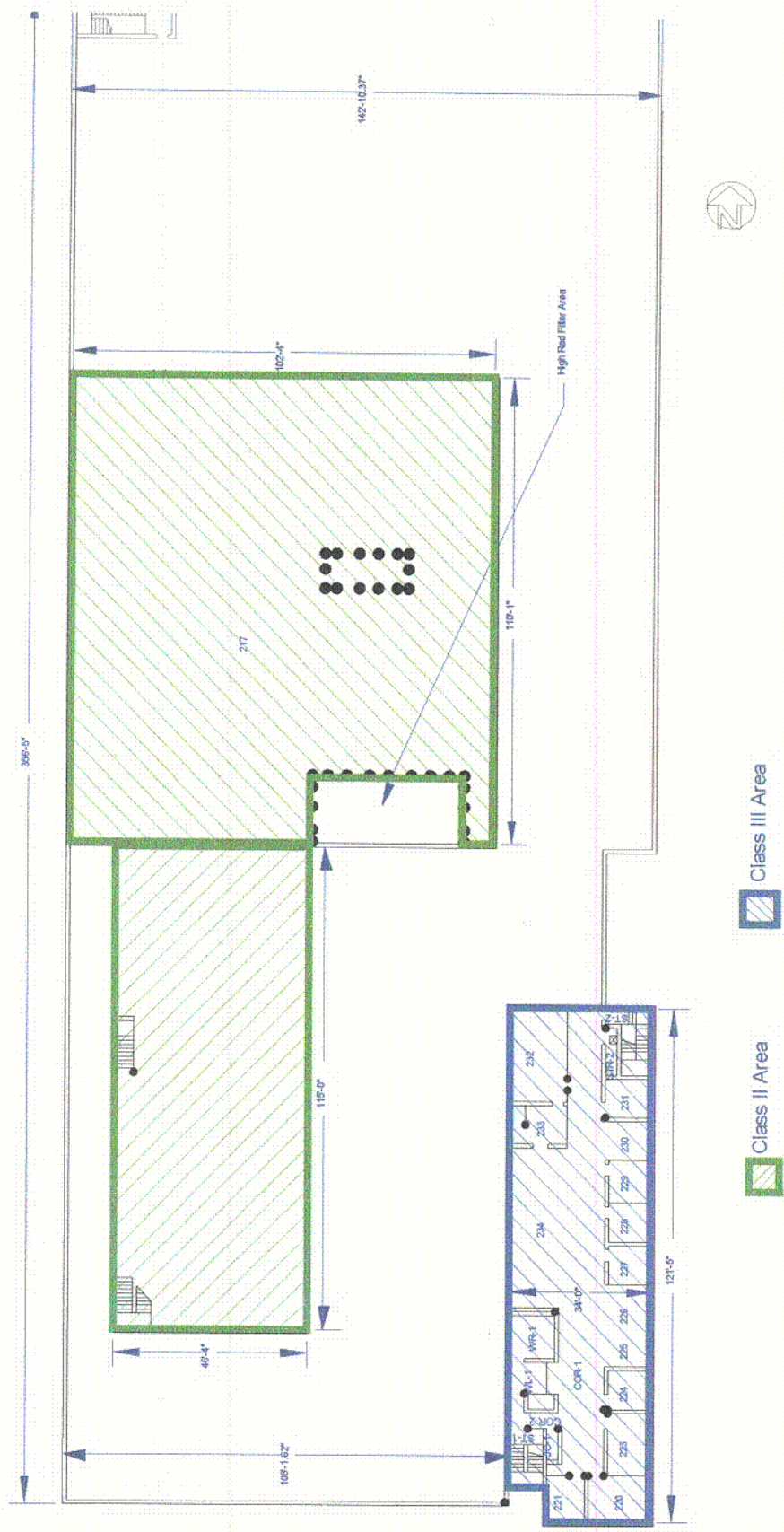


FIGURE 4-9
Building 124 Second Floor Class 2 and Class 3 Areas

4.3 Survey Guideline Values

For the characterization survey a beta/gamma screening value of 10,000 dpm/100 cm² will be used. This is based on a hypothetical beta emitter with an endpoint energy of 0.15 Mev. This is a small fraction of the guideline value for Iodine-129 (35,000 dpm/100 cm²) which has an endpoint energy of 0.15 Mev. Screening guideline values provided by the NRC directly or values calculated using default values for the NRC DandD Code version 2.1 are provided in the table below. Soil screening values equal to 50% of the NRC values will be used. Preliminary DCGLs and equivalent NRC screening values are in Table 4-2.

Some radionuclides such as ⁹⁰Sr and ⁹⁹Tc, which are beta emitters only, will require that samples be sent offsite for radionuclide specific analysis. The offsite analysis will provide the fraction of the detected beta activity attributable to ⁹⁰Sr and ⁹⁹Tc. For the gamma emitters, ⁵⁴Mn, ⁵⁷Co, ⁶⁰Co, ⁷⁵Se, and ¹³⁷Cs the fraction of the detected beta activity attributable to each of these radionuclides will be determined onsite by gamma spectroscopic analysis. The ¹²⁹I activity will be determined either onsite or offsite using a liquid scintillation detector.

TABLE 4-2
Preliminary DCGLs and Equivalent NRC Screening Values

Isotope	NRC ¹ Building Surface Screening Levels (dpm/100cm ²)	NRC ² Soil Surface Screening Values (pCi/g)
⁵⁴ Mn	32,000	15
⁵⁷ Co	210,000	150
⁶⁰ Co	7,100	3.8
⁷⁵ Se	107,000	58
⁸⁵ Sr	139,000	27
⁸⁹ Sr	1,250,000	240
⁹⁰ Sr	8,700	1.7
⁹⁹ Tc	1,300,000	19
^{123m} Te	262,000	190
¹²³ Te	4,500,000 ³	10,000 ³
¹²⁵ I	688,000	110
¹²⁹ I	35,000	0.5
¹³⁷ Cs	28,000	11
¹⁹² Ir	74,000	41
²⁰³ Hg	385,000	98

¹Screening values are from 63 FR 64132, Nov. 18, 1998 or NRC DandD, Version 2.1 using default values.

²Screening values are from 64 FR 68395, December 7, 1999 or NRC DandD, Version 2.1 using default values. ¹²³Te was an exception because it is not listed in NRC DandD, Version 2.1.

³The values for ⁵⁵Fe are used here because ⁵⁵Fe has similar radioactive emissions and a higher specific activity so this assumption is conservative.

Survey Guideline Values (cont)

The characterization survey data will be used to develop decommissioning guideline values utilizing the guidance specified in NUREG-1575 (MARSSIM) and NUREG-1727. Project specific guidelines will be established following residential and building occupancy scenarios equivalent to 25 mrem/year or less based upon the future use of the property, site specific dose assessments, the detection capabilities of the field instrumentation and the desire on the part of E.R. Squibb & Sons to keep residual activity as close to background levels as possible.

4.4 Survey Instrumentation

Selection and use of instruments will ensure sensitivities are sufficient to detect the identified primary radionuclides at the minimum detection requirements. Table 4-3 provides a list of the instruments, types of radiation detected and calibration sources. The hard-to-detect radionuclides that include low energy beta emitters cannot be measured using these field instruments. These radioisotopes will be quantified through off-site laboratory analysis on an as-needed basis.

The Ludlum Model 2350-1 Data Logger will be used with a variety of detectors for direct measurements of total alpha and beta surface activity as well as exposure rate measurements. The Data Logger is a portable micro-processor computer based counting instrument capable of operation with NaI(Tl) gamma scintillation, gas-flow proportional, GM and ZnS scintillation detectors. The Data Logger is capable of retaining in memory the survey results and instrument/detector parameters for up to 1000 measurements. This data is then downloaded to a personal computer for subsequent reporting and analysis.

Detector selection will depend on the survey to be performed, surface contour and survey area size. The project team will normally use the 126 cm² gas-flow proportional detector for direct alpha and beta measurements and a 1" x 1" Sodium Iodide (NaI) gamma scintillation detector for exposure rate measurements. Other detectors that may be used for direct surface measurements include the 50 cm² Zinc Sulphide (ZnS) alpha scintillator and the 15.5 cm² GM detector.

In addition to the standard detector systems, a series of GM and gas-proportional detectors will be used for direct surface measurements of the interiors of system piping. These detectors, coupled to the Model 2350-1 Data Logger, have been used successfully during both characterization and final status surveys, thus allowing clean piping to remain in place, and effectively separating clean from contaminated waste.

Survey Instrumentation (cont)

Smears for removable activity will be analyzed using a Packard Tricarb Alpha/Beta Counter or equivalent or sent offsite to an independent laboratory for analysis.

Isotopic quantification and identification will be performed on soil, water, sediment, and debris samples using a Canberra High Purity Germanium (HPGe) Gamma Spectroscopy System, or equivalent.

TABLE 4-3
Survey Instrumentation

Instrument/Detector	Detector Type	Radiation Detected	Calibration Source	Use
Ludlum Model 2350/43-68	Gas-flow proportional (126 cm ²)	Alpha or beta	⁹⁹ Tc (β) ²³⁰ Th (α)	Direct measurements and smear counting
Ludlum Model 2350/43-37	Gas-flow proportional (550 cm ²)	Alpha or beta	⁹⁹ Tc (β) ²³⁰ Th (α)	Direct measurements
Ludlum Model 2350/43-94 or 43-98	Gas-flow proportional Pipe Detector	Alpha or beta	⁹⁹ Tc (β) ²³⁰ Th (α)	Direct measurements
Ludlum Model 2350/SP-113-3m or SP-175-3m	GM Pipe Detector	Beta	⁹⁹ Tc (β)	Direct Beta measurements
Ludlum Model 2350/44-2	1" x 1" NaI scintillator	Gamma	¹³⁷ Cs (γ)	Gamma exposure rate
Ludlum Model 2350/44-40	Shielded GM (15.5 cm ²)	Beta	⁹⁹ Tc (β)	Direct Beta measurements
Packard M11302 Alpha/Beta Counter	Liquid Scintillation	Beta	⁹⁹ Tc (β)	Low Energy Beta counting
Canberra Gamma Spectroscopy System	High Purity Germanium	Gamma	Mixed Gamma	Nuclide identification and quantification

Instrument Calibration

The data loggers and associated detectors are calibrated on a semi-annual basis using National Institute of Standards and Technology (NIST) traceable sources and calibration equipment. The calibration includes:

- High Voltage calibration,
- discriminator/threshold calibration,
- window calibration,
- alarm operation verification, and
- scaler calibration verification.

The detector calibration includes:

- operating voltage determination,
- calibration constant determination, and
- dead time correction determination.

Calibration labels showing the instrument identification number, calibration date and calibration due date are attached to all portable field instruments. The user will check the instrument calibration label before each use. Written procedures for calibration, maintenance, accountability, operation and quality control of radiation detection instruments will be used.

All sources used for calibration or efficiency determinations for the survey will be representative of the instrument's response to the identified nuclides and are traceable to NIST.

Radiation Protection Technicians will control radioactive sources used for instrument response checks and efficiency determination. Sources will be stored securely and signed out by survey technicians when needed in the field.

4.5 Survey/Sampling Design

Implementation of the sampling and survey plan will include the following:

- Survey packages or other tracking mechanisms will be developed for each of the survey units. These survey packages will provide the survey technicians with specific sampling and measurement instructions.
- The project team will take survey measurements and analyze samples as defined in the survey package. Measurements will be performed using appropriate calibrated instruments and daily instrument quality control (QC) checks will be performed before and after each day's work.

Survey/ Sampling Design (cont)

- Sampling locations for asbestos containing materials and lead based paint will be defined during the radiological survey work and samples will be taken as required.
- The project team will mark or map the survey locations as applicable.
- Survey data collected during the project will be downloaded from the survey instrument into a database for storage, analysis, and reporting.
- Supervisory personnel will review the completed survey packages to ensure that all required surveys have been performed and that the completed survey packages contain all necessary information.

4.6 Survey Requirements

Survey protocols consist of a mix of surface activity measurements and sampling. Depending upon sample analytical results, selected samples may be shipped off-site for additional analyses such as alpha spectroscopy and/or low energy gamma and beta analysis for hard-to-detect radionuclides.

4.7 Background Study

A background study will be conducted to determine environmental nuclide concentrations and direct measurement levels from areas similar but not associated with the operation of E.R. Squibb & Sons. The local background determination will serve as the baseline for decommissioning criteria. The background study will be used in the evaluation of the onsite survey data and, as such, measurements, sampling, sample preparation, and sample analysis will be similar to those to be used for the onsite measurements.

Typical nuclides found in significant levels in background materials (soil, sediments, water, building materials, etc.) include progeny from the naturally occurring uranium, thorium, and actinium series, Tritium (^3H), ^{14}C , ^{40}K , and ^{137}Cs .

The background study will be performed on soils, sediments, and waters which have common characteristics with the samples and measurements to be collected onsite, but which are unaffected by E.R. Squibb & Sons operations. Background measurements and samples will also be taken from construction materials that are expected to include asphalt, concrete, brick and block. The data collected during the background study will be reviewed for trends, and statistics performed on the various data sets. The background data will be used for evaluation of the site radiological survey data. Data collected from the E.R. Squibb & Sons site will first be compared to the background data to determine if it is statistically different. If site residual activity levels are near the site release limits then a background statistic will be developed which can be added to the residual radioactivity criteria to establish the cleanup goals.

Background Study (cont)

The number of samples and measurements to be taken for the various background parameters will be as indicated below.

- (30) Surface (0-6") Soil Samples
- (30) Shallow Subsurface (6-12") Soil Samples
- (3) Surface Water Samples
- (3) Sediment Samples
- (30) Micro-R Measurements (1 at each soil sample location)
- (30) Direct Beta Measurements on Concrete
- (30) Direct Beta Measurements on Asphalt
- (30) Direct Beta Measurements on Ceramic Tile, if needed
- (30) Direct Beta Measurements on Brick, if needed

4.8 Class 1 Areas

These are areas which are known to be radioactively contaminated based upon operations conducted in the area, current survey data or releases that are known to have occurred and subsequent sampling has verified the presence of radioactive material that may require disposal as low-level waste.

The objective of sampling in Class 1 areas will be to determine the lateral and vertical extent of radioactive material in construction and environmental media through a program of biased sampling. Biased sampling locations and the base number of samples has been estimated from facility layout, operational history, interviews with E.R. Squibb & Sons staff, site walk-downs, and previous sampling results. Class 1 areas are shown in Figures 4-5, 4-6 and 4-7.

Measurement protocols for each of the identified Class 1 areas will be as follows. It should be noted that these protocols might vary as more is learned about specific conditions and facility layout during the survey:

Building 124 Caves

Direct beta and removable alpha and beta measurements will be performed on the accessible interior surfaces of the caves. The floor pan will be lifted and direct and removable measurements will be performed under the floor pan. Measurements will also be performed in any ducting to and from the caves.

Isotopic quantification and identification of activity found on cave surfaces will be performed by either direct measurements or analyses performed on removed activity.

Exposure rate measurements will be performed on the cave surfaces and any items, tools or equipment that exhibit elevated activity.

Direct beta and removable alpha and beta measurements will be performed in the shield door track area at the back of these caves.

Class 1 Areas (cont)

Direct beta and removable alpha and beta measurements will be performed on the interior of the ventilation ducts from the caves to the main ventilation system. Holes will be cut through the building floor adjacent to the under-slab ducts to allow direct beta and removable alpha and beta measurements to be made on the exterior of these ducts and to allow sampling of the soil around these ducts.

Building 124 Exhaust Ventilation System

Direct beta and removable alpha and beta measurements will be performed on accessible interior surfaces of ventilation ducts, blowers and filters systems throughout the building interior. Direct alpha measurements will be performed at the highest 10% of beta measurements to determine the (potential) beta to alpha activity ratio.

Exposure rate measurements will be performed on any equipment that exhibits elevated activity.

Building 124 Exhaust Stack

Direct beta and removable alpha and beta measurements will be performed on the accessible interior surfaces of the facility ventilation stack. This will involve the removal of an access panel at the foot of the stack. It is quite common to find natural activity on stack interior surfaces if the stack is lined with ceramic materials.

Isotopic quantification and identification of activity found on stack surfaces will be performed by either direct measurements or analyses performed on removed activity.

Exposure rate measurements will be performed on the stack surfaces.

Direct and removable measurements will be performed on the roof surfaces in the area of the stack tower.

Building 124 Tanks

Four 10,000-gallon below grade holding tanks in a concrete vault receive effluent from Building 124 which is held-up and sampled prior to discharge into the city sewer system. These tanks are no longer in active service, but there is some effluent and sediment in the tank bottoms. In addition there was a discharge into the tank concrete vault area from a broken glass pipe that feeds the tanks.

The manways of the tanks will be opened and samples collected of any remaining sludge or debris inside the tanks. These sediments will have a 10CFR61 type analysis performed on them.

Direct and removable measurements will be performed on the accessible interior surfaces of the tanks. Where possible, sampling and measurements will be accomplished using long handled tools rather than entering the tanks. Measurements will also be performed in any accessible piping both to and from the tanks.

Class 1 Areas (cont)

Direct and removable measurements will be performed on the structural surfaces of the tank vault.

If activity is found on the tank vault surfaces, concrete core samples will be collected to determine the depth of contamination penetration into the vault concrete.

Building 83 Tanks

Two 8,000-gallon below grade holding tanks received effluent from Building 83 which was held-up and sampled prior to discharge into the city sewer system. These tanks are no longer in service, and have been emptied, but there is probably some sediment in the tank bottoms. There is no history of spills from the tanks.

The manways of the tanks will be opened and samples collected of any remaining sludge or debris inside the tanks.

Direct and removable measurements will be performed on the accessible interior surfaces of the tanks. Where possible, sampling and measurements will be accomplished using long handled tools rather than entering the tanks. Measurements will also be performed in any accessible piping both to and from the tanks.

Direct and removable measurements will be performed on the structural surfaces of the tank vault.

If activity is found on the tank vault surfaces, concrete core samples will be collected to determine the depth of contamination penetration into the vault concrete.

Class 1 Lab Areas

Lab rooms 146 through 153 are Class 1 areas along with cave production support rooms 171, 176, 177, 178, 180 and 181. In these rooms direct and removable measurements will be performed on structural surfaces. Measurements will be primarily for beta-gamma emitters, with alpha measurements at any locations exhibiting high beta activity.

Direct and removable measurements will be performed on and in glove boxes, fume hoods, autoclaves, and ventilation ductwork.

Direct and removable measurements will be performed on miscellaneous equipment, in sinks and floor drains.

Former Decay Tank Area

Soil sampling and analysis will be performed in the area of the previously located tanks.

4.9 Class 2 and 3 Areas

These are areas in which the need for remediation is unknown and radioactive material may be present in low concentrations. The objective of sampling in Class 2 and 3 areas will be to confirm with 95 percent confidence the presence or absence of radioactive material in excess of the DCGL's. This objective will be met through implementation of a limited biased sampling program, which will be based on facility layout, operational history, interviews with E.R. Squibb & Sons staff and previous sampling results, if available. The number of samples will be sufficient to confirm the absence of radioactive material requiring remediation by comparisons to DCGLs and data in the background study. Class 2 and 3 areas are shown in Figures 4-8 and 4-9.

Measurement protocols for each of the identified Class 2 and 3 areas will be as follows. As with Class 1 areas above, these protocols may vary as more is learned about the facility during the survey. In addition surface scans of all potentially contaminated areas, (e.g., indoor areas include expansion joints, stress cracks, penetrations into floors and walls for piping, conduit, and anchor bolts, and wall/floor interfaces) outdoor areas include radioactive material storage areas, areas downwind of stack release points, surface drainage pathways, and roadways that may have been used for transport of radioactive or contaminated materials.

Laboratory, Office, and Production areas inside Buildings 122 and 124

Direct and removable measurements will be performed on structural surfaces throughout the facility. Measurements will be primarily for beta-gamma emitters, with alpha measurements at any locations exhibiting high beta activity.

Direct and removable measurements will be performed on and in glove boxes, fume hoods and ventilation ductwork throughout the facility.

Direct and removable measurements will be performed in sinks and floor drains throughout the facility. The radioactive drain system that runs through Building 124 will receive special attention. The covered drains in the floor will be opened to allow direct and removable measurements.

Direct and removable measurements will be performed on miscellaneous equipment inside the buildings.

Exterior of Building 122 and 124

Direct and removable measurements will be performed on various surfaces outside the facility. These areas include but are not limited to exterior walls, roofs, windows, doors, and vents.

Class 2 and 3 Areas (cont)

Building Exterior Open Land Areas (Buildings 122, 124, and Building 83)

All paved areas will receive the following:

- 10% scan for beta contamination to identify areas of elevated activity requiring further investigation. The location for scanning will be chosen by the technician performing the survey, and will be based on most probable areas for contamination.
- Minimum of 30 measurements for fixed beta, and removable alpha and beta contamination for each survey area. This should include measurements in locations where contamination could likely accumulate.
- Exposure rate measurements at 1 meter above the corresponding direct measurement location to identify any elevated areas requiring additional investigation.

Areas of particular interest include the following:

- The area in front of the Building 122 entry door where there is a documented spill of an Iodine-131 product.
- The asphalt south of Building 124 where there was a Phosphorus-32 spill that has subsequently been covered with new pavement.
- Area outside of maintenance room where steam cleaning of manipulators took place.
- Outside storage areas west of Buildings 122 and 124.

All open land areas will receive a gamma scan covering at least 10% of the accessible areas. In addition a minimum of 30 surface (0-6 inches) soil samples will be collected at biased locations.

Subsurface Samples

Soil samples will be collected from below the surface at various locations based on an assessment of likely leak locations and surface contamination scan results. All samples will be separated by depth, dried, sifted, and analyzed by gamma spectroscopy.

4.10 Non-Impacted Areas

These are areas in which the presence of radioactive material is not expected. These areas comprise all portions of the E.R. Squibb & Sons property not falling within the two preceding categories. Up to 30 samples will be taken in non-impacted areas. If radioactive materials are encountered during the sampling, the area will be re-classified, and a sampling plan for determining the lateral and vertical extent of radioactive material will be developed in consultation with E.R. Squibb & Sons.

4.11 Survey Records

Records will be maintained of surveys in the survey packages for each area according to project procedures. The survey package may include the following records depending upon the survey design and protocols:

- Survey Package Worksheet giving the package identification, survey location information, general survey instructions and any specific survey instructions.
- Survey Comment Addendum containing comments from the survey technician regarding any unusual situation encountered while surveying.
- The Survey Unit Diagram of the area to be surveyed as available.
- Photographs of the survey area, as necessary, to show special or unique conditions.
- Printout of laboratory analysis results (if performed).
- Ludlum Model 2350-1 data files and Microsoft Access® database converted values for all radiation survey measurements.

The survey team will take direct measurements for total alpha and beta surface activity using the Ludlum Model 2350-1 Data Logger system. Upon completion of a survey, the contents of the Data Logger's memory will be downloaded to a database.

A computer program will be used to generate a survey report that presents all raw data, converted data, and information by survey location. The survey technician and supervisor will review these reports for completeness, accuracy, and suspect entries and compare the data to the guideline values.

Any changes to the database tables such as detector efficiency and background, which could affect survey results, will require supervisor approval. In addition, changes to data in the primary table will require a written explanation on a change request. The change request will be attached to the survey report and maintained as a permanent record.

Survey Records (cont)

Data and document control will include the maintenance of the raw data files, translated data files (Microsoft Access® database files) and documentation of all corrections made to the data. The databases will be backed up on a daily basis. Survey records, reports and data will be maintained by E.R. Squibb & Sons.

5.0 DOSE MODELING

5.1 Unrestricted Release Using Screening Criteria Survey Guideline Values

On July 21, 1997, the NRC published its final rule on radiological criteria for release from license restrictions for unrestricted use if the residual radioactivity results in a total effective dose equivalent to an average member of a critical group of less than 25 mrem per year and the residual radioactivity has been reduced to levels that are as low as reasonably achievable. The NRC published building screening levels in 63 FR 64132, November 18, 1998 and soil screening values in 64 FR 68395, December 7, 1999. DCGLs may also be developed using NRC DandD Version 2.1 and default values. E.R. Squibb & Sons is proposing to use the above release criteria along with the desire to keep residual activity as close to background levels as possible.

6.0 ALARA ANALYSIS

E.R. Squibb & Sons will use the NRC screening values and understand these levels are ALARA. However, reasonable efforts will be made to remediate the facility below these levels when practicable.

7.0 PLANNED DECOMMISSIONING ACTIVITIES

7.1 Method Used for Completion of Decommissioning

Based on the results of the characterization survey, a more detailed list of decommissioning tasks and schedule will be prepared. Any decommissioning task involved with licensed material requires a written Standard Operating Procedure (SOP). The SOP must be approved by the RSO and the chairperson of the RSC. The format of an SOP can be found in HP-01. The length and complexity of the SOP is commensurate with the associated task. SOPs that are already approved should be reviewed and modified if required.

All areas identified in the characterization survey as contaminated will be addressed. An effort will be made to decontaminate items in lieu of disposal as radioactive waste. Items that are determined to be waste shall be packaged in accordance to current waste acceptance criteria. The waste may be stored for decay, shipped for processing, and/or shipped for disposal in accordance with current waste acceptance criteria. Large items such as fume hoods will require dismantling prior to packaging. Any sectioning of large items will be conducted in a manner that protects personnel from airborne dusts generated by the cutting process. Where possible, items will be sectioned in locations of the item that are free of contamination. During this phase of the decommissioning, contamination control measures will be implemented to prevent the spread of contamination to areas that are not contaminated.

After the decontamination phase is complete, remedial action support surveys of the areas identified in the characterization survey will be conducted to verify the decontamination effort. This survey should also verify that contamination was not spread to non contaminated areas during the decontamination phase.

Any areas or equipment found to be contaminated in the remedial action support surveys will be decontaminated or disposed in the same manner as previously discussed. Any waste generated should be packaged in accordance with radioactive waste procedures.

Discrete sources of licensed material will be removed from areas prior to those areas being surveyed or decontaminated. The method of removal depends upon the type of material. To minimize costs, disposing of any licensed material as waste will be the final option. Every attempt will be made to return sealed sources to the manufacturer. Unsealed licensed material will be transferred to other licensees, who are licensed to receive it, for use. If there is no other licensed facility that will accept the material, it will be packaged and disposed as waste in accordance with the E.R. Squibb & Sons radioactive waste policy. All transfers, packaging, and disposal of licensed material will be done in accordance with all applicable NRC and DOT regulations.

Method Used for Completion of Decommissioning (cont)

Anticipated decommissioning tasks will include the following types of activities for which specific work procedures will be developed:

- Contaminated pipe and metal cutting
- Contaminated concrete decontamination
- Disposition of equipment and materials including but not limited to tanks, glove boxes, fume hoods, etc.
- Radioactive waste packaging and disposal

Generic descriptions of D&D methods follow.

Pipe and Metal Cutting

Whenever cutting techniques which could generate loose or airborne contamination are used, suitable contamination control techniques will be employed. These techniques will be deployed on a case by case basis as is warranted by contamination levels and the dispersal potential of the cutting techniques used. Control techniques may include, but not be limited to, use of HEPA ventilated containment tents, glove boxes, or localized use of HEPA vacuum cleaners/air filtration units to catch generated particulate, fumes or vapors. The procedure will call for good housekeeping in the work area and collection of debris produced in the cutting process.

Contaminated Concrete Surface Removal

Concrete surfaces can be decontaminated by such techniques as scarification or grinding. Scabbling techniques remove up to a ¼ inch layer of concrete surface per pass. Commercially available scabblers can be modified to include HEPA ventilated shrouds to preclude airborne release of contaminated dust during the scarification process. After the surface areas have been scarified the resulting pulverized concrete would be removed using high powered HEPA vacuums which can directly place the concrete dust into disposal containers. Small deeper "hot spots" or contaminated cracks or seams will be cut out using standard concrete pavement breakers. Localized HEPA ventilation units or vacuums would be used to preclude release of contaminated dust. The grinding technique removes thin layers of surface contamination from concrete. In many cases, the contamination is limited to the paint coating or concrete sealer finish. This technique like scabblers has the ability to control the release of airborne contamination.

Equipment Decontamination

The equipment and materials can be handled as described below:

- Surveyed and released on site using NRC Regulatory Guide 1.86.
- Items may be shipped directly for disposal as radioactive waste.
- Items may be shipped to a licensed radioactive material processing facility for survey and release, decontamination followed by survey and release, or shipment for disposal as radioactive waste.
- No contaminated items as listed above will be left on site.

In general contaminated equipment will be disposed of as radioactive waste or packaged for shipment to a decontamination recycling facility. However, when feasible, contaminated equipment may be decontaminated to reduce radioactive waste volume. The choice of complete disposal versus in-situe contamination will be made on a case by case basis given financial, safety and ALARA factors.

Dry type decontamination processes that may be used are vacuuming, wire brushing, dry wiping, and similar techniques either singularly or in combination to achieve the desired decontamination. Wiping employing solvents with a sorbent material dampened with detergent or chemical cleaners may also be used. When using damp wiping processes, only cleaning agents which are non-hazardous and are compatible with radioactive waste processing and disposal site requirements will be used.

7.2 Schedules

Implementation of the Site Characterization Plan is underway and is expected to be completed by the end of February 2002. It is anticipated that decommissioning activities will commence in the second quarter of 2002 and the Final Status Survey will be completed by fourth quarter 2002.

8.0 PROJECT MANAGEMENT AND ORGANIZATION

8.1 Decommissioning Management Organization

The RSO will be responsible for the implementation of the plan. The RSC and upper management will be responsible for ensuring the RSO has adequate resources and manpower to complete the required activities. The RSO and the Health Physics staff will monitor the progress of the plan and ensure the activities are conducted in compliance with all procedures, policies, and regulations to ensure overall safety and to maintain radiation exposures ALARA. The RSO and the Health Physics staff will also be responsible for training all personnel involved in the decommissioning in radiation safety.

Since contractors will be utilized to complete the decommissioning activities, a project engineer will be assigned to administrate the contractor's activities and ensure the contractor fulfills their responsibilities under the Plan. Technical specifications for any bid requests will be provided to the project engineer by Health Physics. The project engineer will be responsible for working with the RSO and the Health Physics staff to ensure all radiation safety concerns are addressed in a timely manner. Once a contractor is chosen, the project engineer will act as an intermediary between the contractor and the Health Physics department.

A contract executive engineer with experience in decommissioning has been designated by E. R. Squibb & Sons to provide oversight of the project and assist and advise with compliance, technical management and administration of the decommissioning contract.

8.2 Training

The management of E.R. Squibb & Sons recognizes its responsibilities for assuring that all employees and contractors are aware of rules and procedures governing their general safety. Through proper training, all personnel can develop the confidence needed to work efficiently and safely.

All employees are given a radiation safety orientation which delineates the employee's rights and responsibilities dictated by Title 10 of the Code of Federal Regulations, Parts 19 and 20, prior to working with radiation sources. These orientations cover the following topics:

- General radiation rules and procedures
- Departmental radiation safety procedures
- Biological effects of radiation
- Risks of exposure to radiation
- Emergency procedures
- ALARA

Training (cont)

- Radionuclides and their characteristics
- Radiation theory, etc.
- Waste disposal

Recognizing that techniques and procedures can change as new and/or additional information is obtained, general refresher training seminars are provided to all operating personnel. These seminars provide a means of not only disseminating new information, but also reinforcing the knowledge previously obtained.

Records are maintained of all training seminars presented to assure all personnel receive instructions commensurate with their responsibilities and duties.

8.3 Contractor Support

It will be necessary for the licensee to employ contractors to assist in the decommissioning activities. Any contractors who wish to bid on a decommissioning project, shall submit the following for evaluation by Engineering, Health Physics and Environmental Health & Safety:

- A contractor's Pre-qualification Statement
- A detailed description of the scope of the work to be performed
- The qualifications of contracting personnel to perform work with radioactive materials
- A description of the administrative controls that will be used by contractor's personnel to ensure adequate protection of the health and safety of individuals and the environment.

Subcontractors will also be evaluated by the licensee's Health Physics staff, Engineering and EH&S personnel in the same manner as contractors. It shall be at the discretion of either of the licensee's evaluating groups to approve or deny any contractor or subcontractor a contract to perform work with radioactive materials at licensed sites.

Contractors and subcontractors who are awarded contracts to perform decommissioning activities shall require all personnel assigned to perform such task to attend an on-site orientation to review the licensee's safety, radiation protection, performance guidelines, and site expectations procedures.

9.0 HEALTH AND SAFETY PROGRAM DURING DECOMMISSIONING

9.1 Ensuring Occupational Radiation Exposures Are As Low As Is Reasonably Achievable

The management of E.R. Squibb & Sons has adopted the ALARA philosophy as an operating policy. It requires all personnel to be aware of these concepts and to implement them in their daily work activities. The ALARA concepts have been incorporated into the design of the facility and in procedures used for working with radioactive materials. Employees, contractors and maintenance personnel receive instructions in these concepts in training sessions prior to working in a radiologically restricted areas. Each person is expected to minimize their exposures, the exposures of their fellow workers, exposures to members of the public, and environmental releases as low as practical when performing their duties.

Individuals' exposures and releases will be maintained ALARA during normal operations and when performing decommissioning activities. This will be accomplished through workers' orientations, procedural review, auditing, etc., as stated in the guidelines of the licensee's ALARA manual.

9.2 Health Physics Program

The licensee's Health Physics program outlines the radiological protection standards and controls that are used to maintain the risks to workers, ancillary personnel and the general public of exposure to radiation and radioactive materials, **As Low As Reasonably Achievable (ALARA)**. It is designed to ensure that all rules and regulations are followed by all users of radioactive materials, as well as all personnel who perform services, maintenance and decommissioning activities within radiological restricted areas. The implementation of and adherence to this program is enhanced by the development and use of detailed procedures and policies instituted by the Radiation Safety Officer and Radiation Safety Committee. This program shall remain in effect during decommissioning activities. The Health Physics program addresses many issues including the following:

9.3 Personnel Monitoring

It is the policy of E.R. Squibb & Sons to provide personnel monitoring to all personnel (including contractors) who are engaged in work with radiation or radioactive materials which may result in a radiation dose greater than ten percent of the regulatory limits.

Personnel Monitoring (cont)

Any dose received from external sources outside the body will be measured by a film badge or thermoluminescent dosimeter (TLD) and recorded as the deep dose equivalent.

Internal exposures to personnel shall be monitored as necessary and by the means most suitable for the radionuclides being evaluated.

9.4 Equipment and Instrumentation

Various types of equipment are required to perform the necessary surveillance, counting and monitoring functions. Sufficient laboratory and field instrumentation is available for this purpose.

Laboratory counting equipment (gamma counters and liquid scintillation counters) is used to quantify the results of samples taken through the facilities to ensure regulatory compliance and personnel safety. All laboratory instrumentation is calibrated on a routine basis and documented.

Field survey instruments consist of geiger-mueller tubes, ionization chambers and a variety of solid state detectors. These detectors are connected to various types of scalars or ratemeters, and can detect very low levels of beta or gamma radiation at low dose rates, or very high levels of beta and gamma radiation at high dose rates.

All portable survey meters are calibrated. Operational checks are performed routinely or the first time an instrument is used in a given week. These checks are performed with standard sources appropriate for the radioisotopes to be detected by the specific instrument. The frequency of surveys varies depending on the type of radionuclides and the quantity in use at a specific location. Surveys will be performed prior to, during, and upon completion of decommissioning activities.

9.5 Air Sampling Equipment and Monitoring

Several different types of air sampling equipment are available for use to protect the worker and monitor areas where there may exist minor contamination:

Portable air samplers may be setup to evaluate or monitor an area for a short period of time. They are generally used to perform rapid assays of known or suspected spills or inadvertent releases.

Fixed air samplers are positioned in various locations within facilities where there is minor contamination. These units operate continuously, with changes made of the filters at some preestablished frequency, consistent with anticipated levels of air contamination.

Air Sampling Equipment and Monitoring (cont)

Personal air samplers are small devices which can be attached to a worker's clothing, to measure air intake near the breathing zone while he or she performs specific tasks which may generate airborne radioactivity.

All air sampling devices are calibrated periodically by comparing the airflow of the devices with that of a calibrated rotameter. Air sample filters are removed and analyzed with an appropriate detector.

9.6 Surveillance Program

To ensure all processes are being conducted in a safe manner, routine surveillance such as radiation and contamination surveys, air sampling, perimeter security, posting and exhaust operation checks will be performed.

Airborne contamination surveys are performed for the following reasons:

- To protect personnel working in areas
- To ensure personnel exposures are maintained ALARA
- To ensure rapid detection of process or equipment malfunction
- To properly post areas as necessary

9.7 Reviews and Audits

The Radiation Safety Committee has the responsibility for ensuring all operations are conducted in accordance with the regulations and license conditions. To accomplish this objective, the D&D process will be routinely evaluated during the project. An audit function will be conducted by an additional contractor which report to the RSO and the RSC.

10.0 ENVIRONMENTAL MONITORING AND CONTROL PROGRAM

During manufacturing operations, effluent and environmental monitoring programs were implemented. The monitoring programs confirmed that releases to the environment were minimal and in compliance with the applicable regulations. No buildup of radioactivity or increased radiation levels were detected. Due to the significantly reduced radioactive material inventory and the lack of release modes, these programs are not required and have been discontinued.

11.0 RADIOACTIVE WASTE MANAGEMENT PROGRAM

All radioactive contaminated waste materials generated by the licensee during normal operations and decommissioning processes will be handled, stored and disposed of as follows:

- Using good Health Physics practices and procedures, which are designed to minimize radiation exposure.
- In accordance with the licensee's existing radioactive waste procedures.
- In accordance with all applicable regulations, license conditions and disposal site criteria.

No waste will be disposed of on the licensee's site. All waste will be transferred to a licensed broker or processor. No waste will be incinerated onsite.

12.0 QUALITY ASSURANCE PROGRAM

Prior to the commencement of work with radioactive materials under this Plan, written Health Physics standard operating procedures (SOP) must be submitted and approved by the RSO. This policy is identical to the approval of SOPs in other activities under the current license. Instructions for the format and content of an SOP can be found in the SOP HP-1.

Management planning takes into consideration the complexity and impact on safety and the need for special controls. Management ensures that people are trained and appropriate resources are available before its subcontractors undertake a quality affecting activity. Project personnel will receive training and indoctrination that is appropriate to their work activities. At a minimum, this includes indoctrination to the applicable quality requirements, health and safety, and applicable project procedures.

Plans, procedures, and instructions issued in support of this project shall be controlled and approved in accordance with approved procedures. Project-specific procedures may be developed as necessary to augment existing E.R. Squibb & Sons procedures but shall be approved and issued prior to the commencement of work.

Management shall be responsible for verifying that decommissioning processes are planned and performed under controlled conditions that ensure conformance to quality system requirements and applicable standards and regulations.

Quality Assurance Records will be identified, developed and maintained. These will include but are not limited to the following:

- Approved plans and procedures
- Training records
- Sample analysis results
- Sample chain of custody
- Daily instrument source checks
- Survey records and sample logs

13.0 FACILITY RADIATION SURVEYS

13.1 Release Criteria

On July 21, 1997, the NRC published its final rule on radiological criteria for release from license restrictions for unrestricted use if the residual radioactivity results in a total effective dose equivalent to an average member of a critical group of less than 25 mrem per year and the residual radioactivity has been reduced to levels that are as low as reasonably achievable. The NRC published building screening levels in 63 FR 64132, November 18, 1998 and soil screening values in 64 FR 68395, December 7, 1999. DCGLs may also be developed using NRC DandD Version 2.1 and default values. E.R. Squibb & Sons is proposing to use the above release criteria along with the desire to keep residual activity as close to background levels as possible.

13.2 Characterization Surveys

Historical Site Assessment information was used to develop the characterization survey plan. The characterization survey will be based on the guidance in MARSSIM. Data Quality Objectives (DQO's) were established for performing the characterization survey to assure that appropriate survey data is obtained. The characterization survey plan was discussed in detail in Section 4.0.

13.3 Remedial Action Support Surveys

Remedial action surveys will be conducted throughout the decommissioning activities and determine when an area is ready for the final status survey. Field screening methods and instrumentation will be capable of detecting residual radioactivity at the DCGL values.

13.4 Final Status Survey Design

A final status survey will be performed to demonstrate compliance with the release criteria. Information obtained from the Historical Site Assessment, Characterization Survey and Remedial Action Support Surveys will be used in the design of the Final Status Survey (FSS). The Final Status Survey Plan will be prepared using the guidance provided in MARSSIM.

Final Status Survey Design (cont)

A general overview of how the Final Status Survey will be conducted is as follows:

- Classify areas by residual radioactivity levels.
- Select size and location of survey units.
- Select background reference areas and materials.
- Determine methods to evaluate survey results.
- Select and calibrate instruments.
- Establish scanning coverage fractions and investigation levels.
- Determine the number of samples needed.
- Determine sample locations.
- Evaluate compliance.
- Prepare records and documentation.
- Demonstrate that actions are ALARA.

The Final Radiation Survey Plan will contain the criteria used to assess all final survey data including the statistical tests performed and state the conclusion based upon statistical test results. The final status survey plan will be developed based upon the following assumptions:

- The null hypothesis recommended for use in MARSSIM is: "The residual radioactivity in the survey unit exceeds the release criterion."
- The decision error rates will be set to 0.05 for Type I (alpha) error and 0.05 for Type II (Beta) error.
- The sign test, nonparametric statistical test, will be used to compare the distribution of a set of measurements in a survey unit to the DCGL. Note that values from a background study for materials of construction performed during the characterization survey will be used to adjust final survey direct measurement for background radiation. The material background adjustment to the final survey direct measurements will eliminate the need for a background reference area required if using the Wilcoxon Rank Sum (WRS) test.
- Once the final survey has been performed, survey data will be converted to DCGL units and compared to the DCGLs. Individual measurements and sample concentrations will be compared to DCGL levels for evidence of small areas of elevated activity. Data will then be evaluated using the Sign test statistical method to determine if they exceed the release criterion. If the release criterion has been exceeded (null hypothesis proven true) or if results indicate the need for additional data points, appropriate further actions will be assessed.
- If the release criterion has not been exceeded (null hypothesis proven false), the results of the survey will be compared with the data quality objectives established during the planning phase of the project. If the data quality objectives have been satisfied, the survey unit will be suitable to release for unrestricted use.

Final Status Survey Design (cont)

The Final Status Survey Plan will include sufficient information to allow the NRC and the NJDEP to determine that the final status survey design is adequate to demonstrate compliance with the radiological criteria for unrestricted release. The information will include:

- A brief overview describing the final status survey design.
- A description and map or drawing of impacted areas classified by residual radioactivity levels (Class 1, Class 2, or Class 3) and divided into survey units, with an explanation of the basis for division into survey units.
- A description of the background reference areas and materials, if they will be used, and a justification for their selection.
- A summary of the statistical tests that will be used to evaluate the survey results, including the elevated measurement comparison, if Class 1 survey units are present, a justification for any test methods not included in MARSSIM, and the values for the decision errors (and) with a justification for values greater than 0.05.
- A description of scanning instruments, methods, calibration, operational checks, coverage, and sensitivity for each media and radionuclide.
- For in-situ sample measurements made by field instruments, a description of the instruments, calibration, operational checks, sensitivity, and sampling methods, with a demonstration that the instruments, and methods, have adequate sensitivity.
- A description of the analytical instruments for measuring samples in the laboratory, including the calibration, sensitivity, and methodology for evaluation, with a demonstration that the instruments and methods have adequate sensitivity.
- A description of how the samples to be analyzed in the laboratory will be collected, controlled and handled.
- A description of the final status survey investigation levels and how they were determined.
- A summary of any significant additional residual radioactivity that was not accounted for during site characterization.
- A summary of direct measurement results and/or soil concentration levels in units that are comparable to the DCGL and, if data is used to estimate or update the survey unit.
- A summary of the direct measurements or sample data used to both evaluate the success of remediation and to estimate the survey unit variance.

Final Status Survey Design (cont)

The Final Status Survey Report will be prepared and submitted to the NRC and the NJDEP and include the following information:

- An overview of the results of the final status survey.
- A discussion of any changes that were made in the final status survey from what was proposed in the Decommissioning Plan.
- A description of the method by which the number of samples and a justification for these values.
- A summary of the values used to determine the numbers of samples and a justification for these values.
- The survey results for each survey unit.
- A description of any changes in initial survey unit assumptions relative to the extent of residual radioactivity.
- If a survey unit fails, a description of the investigation conducted to ascertain the reason for the failure and a discussion of the impact that the failure has on the conclusion that the facility is ready for final radiological surveys.
- If a survey unit fails, a discussion of the impact that the reason for the failure has on other survey unit information.

The Final Status Survey Report will formally request that the NRC and the NJDEP release the manufacturing facilities from license restrictions. It is anticipated that these agencies may perform radiological surveys of selected areas to confirm the facilities satisfy the release criteria.

14.0 FINANCIAL ASSURANCE

A "Parent Company Guarantee" was submitted to the NRC in April 1994 for this license to comply with the financial assurance requirements specified in 10 CFR 30.35. The financial standards required under a parent company guarantee are verified on an annual basis to ensure that this method of financial assurance meets the requirements specified in Regulatory Guide 3.66.

Funding for the estimated cost of the decommissioning of the radiodiagnostic manufacturing facilities and associated equipment has been budgeted and approved.

This is to acknowledge the receipt of your letter/application dated

12/14/2001, and to inform you that the initial processing which includes an administrative review has been performed.

☒ ATTEND. 29-00139-02
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 130734
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

Sincerely,
Licensing Assistance Team Leader

BETWEEN: : (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 License Fee Management Branch, ARM : Program Code: 03610
 and : Status Code: 0
 Regional Licensing Sections : Fee Category: 3A
 : Exp. Date: 20080930
 : Fee Comments: _____
 : Decom Fin Assur Req'd: Y
 ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION *I*

1. APPLICATION ATTACHED
Applicant/Licensee: E. R. SQUIBB & SONS, INC.
Received Date: 20011217
Docket No: 3005222
Control No.: 130734
License No.: 29-00139-02
Action Type: Amendment

2. FEE ATTACHED
Amount: _____
Check No.: _____

3. COMMENTS

Signed *M. A. Perkins*
Date *12/13/2001*

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

- 1. Fee Category and Amount: _____
- 2. Correct Fee Paid. Application may be processed for:
Amendment _____
Renewal _____
License _____
- 3. OTHER _____

Signed _____
Date _____