29-00139-02

DECOMMISSIONING PLAN FOR RADIODIAGNOSTIC MANUFACTURING OPERATIONS

E.R. Squibb & Sons, Inc.
One Squibb Drive
New Brunswick, NJ 08903
July 2001

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1. General Information

This decommissioning plan is specific to the facilities associated with the manufacture of radiodiagnostic products authorized by the U.S. Nuclear Regulatory Commission in radioactive materials license #29-00139-02 and the State of New Jersey in radioactive material license #NJSL 10071.

The licensee's name and address:

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2.1 Decommissioning Objectives, Activities, Tasks, and Schedules

2.1.1 Decommissioning Objectives, Activities, and Tasks

The objectives of this Decommissioning Plan are to:

- decontaminate the facilities utilized for manufacturing radiopharmaceuticals in compliance with all pertinent New Jersey Department of Environmental Protection (NJDEP) and Nuclear Regulatory Commission (NRC) requirements
- maintain radiological exposure to personnel and the environment ALARA
- minimize the generation of radioactive waste through decontamination, storage, and other techniques.

To accomplish these objectives, several activities must be implemented as indicated by the Plan. The following activities will be required to fulfill the objectives of the plan:

- Review Decommissioning Plan
- Determine areas to be included in Plan
- Evaluate manpower requirements
- Update and/or submit SOPs
- Dispose or transfer radioactive material from all areas
- Preliminary survey of areas to determine decontamination effort
- Establish a schedule for the decontamination effort
- Re-evaluate manpower requirements
- Decontamination, dismantle, and packaging of contaminated items
- Verification of decontamination effort
- Further decontamination, if necessary
- Removal of remaining radioactive waste
- Perform final radiation survey
- Further decontamination, if necessary
- Perform final radiation survey of areas that required additional decontamination
- Request approval for free release of the manufacturing facilities from NJDEP and the NRC

Each of these activities will allow the implementation of the plan to progress to a successful conclusion. The scope of each activity is discussed in the next section.

2.1.2 Method Used for Completion of Decommissioning

It will be necessary to review this Plan prior to its implementation. The purpose of this review is to ensure the Plan is current and accurately reflects the licensed activities at the time of its implementation. This will include the location, quantity, and use of licensed materials and other relevant operational elements that will effect decommissioning. Specific attention will be give to any changes in regulatory requirements that may effect the Plan. The activities will also be reviewed to determine if any modification is required due to a change in objectives, industry standards, equipment, or waste disposal criteria. The review will be conducted by the RSO and the Health Physics staff. The RSO will approve any modifications to the Plan.

The RSO or his/her designee will produce of list of all the areas where radioactive material was stored or utilized. These locations will be surveyed for licensed material. Locations of sealed sources can be obtained from the semi-annual sealed source leak testing report. Areas that utilize licensed material with a half-life less than 65 days will be maintained in survey logs and other historical information. From these sources, an inventory will be generated of material that must be removed. This inventory will only consist of discrete sources of licensed material. Contaminated equipment and facilities will be addressed separately.

Based upon the number of locations and sites where licensed material is present, an assessment of the manpower required to complete the subsequent decommissioning activities will be made. Anticipated activities will be reviewed to determine the level of experience required to complete each task. It is expected that contractors will be hired to perform the majority of the tasks required for decommissioning. In accordance with standard corporate policy, contractors will be chosen based upon expertise, personnel, and competitive bid. Preference will be given to contractors with experience in projects of similar scope and complexity.

Any 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.

Discrete sources of licensed material must 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 returned 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 BMS's radioactive waste policy. All transfers, packaging, and disposal of licensed material will be done in accordance with all applicable NRC and DOT regulations.

A preliminary survey of all areas where unsealed sources of licensed material were used will be conducted to evaluate the extent of contamination that requires further action. This survey will be more extensive than routine contamination surveys and may be as comprehensive as a final radiation survey. It will consist of collecting samples from plumbing, hood baffles, and duct work. These samples will be analyzed for the characteristic radiation of the radionuclides used in the area. In addition to these samples, the floor, benchtops, hoods, and other equipment will be surveyed for direct and removable contamination. A diagram of the area being monitored and the approximate location of the smear samples will be made and included in the report. These wipe samples will be analyzed by an instrument sensitive to the radionuclides in the area. It may be necessary to analyze a swipe on more than one instrument. The report shall contain sufficient information to allow a person who was not involved in the survey to identify any areas that were positive for residual contamination.

Based upon the results of the preliminary survey, a schedule will be developed for the decontamination of contaminated areas and the final radiation surveys that need to be conducted under the plan. Scheduling will also determined by management plans for the decommissioned facilities.

The removal of residual contamination and contaminated equipment will be conducted in accordance with written SOPs, BMS radiation safety policy and all pertinent regulations. All areas identified in the preliminary 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 radioactive waste procedures. The waste may be stored for decay, shipped for processing, and/or shipped for disposal. 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, a survey of the areas identified in the preliminary 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 verification survey will be decontaminated or disposed in the same manner as previously discussed. Any waste generated should be packaged in accordance with radioactive waste procedures. The decontamination should be verified and documented in a subsequent survey.

Waste from the decontamination phase will be packaged and shipped for processing/disposal at the conclusion of the decontamination phase. After the waste is shipped, the area should be surveyed for residual contamination. Any contamination should be decontaminated, surveyed, and documented. Every attempt will be made to minimize the volume of waste shipped for disposal. Storage for decay, compaction, incineration and other volume reduction techniques will be utilized as practical.

The final radiation survey is a detailed radiological survey of all areas where unsealed licensed material was used or stored. This survey will conform with the protocols established by the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM).

The results of the decommissioning survey will be compared to the appropriate limits in the NRC Regulatory Guide *Guidelines For Decontamination of Facilities and Equipment Prior to Release For Unrestricted Use or Termination of Licenses For Byproduct, Source, or Special Nuclear Material.* Any areas that exceed the limits in the Regulatory Guide will be decontaminated or disposed as radioactive waste. The decontamination should be verified and documented in a subsequent survey. Areas that were positive for removable contamination, but were below the applicable limits, will be decontaminated to minimize the remaining residual licensed material to the extent practical.

After all the final radiation surveys are completed, BMS will formally request that the NJDEP and NRC release the manufacturing facilities from license restrictions. This request will include documentation pertaining to the transfer and/or disposal of licensed material and a comprehensive report detailing the results and locations of the final radiation surveys. Any additional material requested by the NJDEP or NRC will be provided upon written request. It is anticipated that the NRC may perform radiological surveys of selected areas to confirm the absence of licensed material.

2.1.3 Procedure

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-01.

2.1.4 Schedule

The implementation of the Plan will take place as discussed in Subsection 2.1.2. The estimated time for the plan to be completed will depend upon the availability of manpower and equipment, and the allowance for radioactive decay in high use areas. It is anticipated that decommissioning activities will commence in September, 2001 and be completed in 2002.

2.2 Decommissioning Organization and Responsibilities

The RSO will be responsible for the implementation of the plan. The RSC and senior 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 as specified in Subsection 2.3.

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 fulfill 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.

2.3 Training

The management of Bristol-Myers Squibb 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 safety.

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
- 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.

2.4 Contractor Assistance

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 Prequalification 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 and performance guidelines, and site expectations procedures.

3.1 Facility Radiological History Information

The manufacturing and processing of radiopharmaceuticals were conducted on the ground floor in the rear of the Building 124 production plant. A storage facility, Building 122, is located in the rear of the production plant. Both structures occupy approximately 1.75 acres at the southwest end of the New Brunswick 90.1 acre site.

Various radionuclides in significant quantities typical to a radiopharmaceutical production operation were processed and stored in isolated areas within these structures. Specific isotopes and possession quantities normally possessed and processed are as follows:

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. Although most of these isotopes have half lives less than 65 days, there may have been long lived contaminants in the bulk solutions that require action under this plan.

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 contaminants. Leaded 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 gloves boxes are provided with forced 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, ^{3}H, ^{99}Tc, ^{54}Mn, ^{57}Co, ^{125}I, ^{85}Sr, and other low energy beta/gamma emitter.

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 though 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.

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 Ensuring Occupational Radiation Exposures Are As Low As Is Reasonably Achievable

The management of Bristol-Myers Squibb 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.

3.3 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, **A**s **L**ow **A**s **R**easonably **A**chievable (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:

A. Personnel Monitoring

It is the policy of Bristol-Myers Squibb 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.

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.

B. **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 or solid state detectors. These detectors are connected to various types of scalars or rotameters, 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 every Monday 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.

C. **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.

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.

D. **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

E. **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.

3.4 Contractor Personnel

The licensee is concerned with the quality of life and has great respect for the safety and health of its employees, contract personnel, and the environment in which it operates. This same level of commitment is demanded of all personnel performing work at any licensed facilities.

To ensure that all contract personnel are fully aware of the protective measures they must adhere to while in radiological restricted areas, each individual must attend a radiation safety orientation prior to entrance in a restricted area. This orientation will be provided by the Health Physics department and will cover topics such as:

- Special work permits
- Badge issuance and maintenance
- Survey requirements for work area, tools and personnel
- General radiation safety practices and policy
- Personal protective devices
- Proper attire
- Emergency procedures
- Housekeeping

Frequent interaction with contract personnel and monitoring will be performed by the licensee to ensure that all activities conform with established radiation protection practices and policies, and meet or exceed all applicable local, state and federal regulations.

3.5 Radioactive Waste Management

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.

4.0 Planned Final Radiation Survey

In order to assure all areas where licensed material was used or stored will meet the criteria established in NRC Regulatory Guide *Guidelines For Decontamination of Facilities and Equipment Prior to Release For Unrestricted Use or Termination of Licenses For Byproduct, Source, or Special Nuclear Material*, a final radiation survey of these areas will be conducted. The final radiation survey will be conducted in accordance with the MARSSIM.

5.0 Funding

Funding for the estimated cost of the D&D process has been budgeted and approved.

6.0 Security

Site security will be maintained during the decommissioning process via the onsite Security Department and the facility fenceline. As stated above, the affected manufacturing facilities represent only a small portion of the larger New Brunswick facility, which will continue normal operations.

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	----------
	:	
License Fee Management Branch, ARM	:	Program Code: 03211
and	:	Status Code: 0
Regional Licensing Sections	:	Fee Category: 3A
	:	Exp. Date: 20080930
	:	Fee Comments: _____
	:	Decom Fin Assur Reqd: Y
	::	

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: E. R. SQUIBB & SONS, INC.
   Received Date: 20010919
   Docket No: 3005222
   Control No.: 130308
   License No.: 29-00139-02
   Action Type: Amendment

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

3. COMMENTS

Signed Sheryl Villar
Date 9/19/01

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 _____