



Bristol-Myers Squibb Company

Worldwide Medicines Group

P.O. Box 5400 Princeton, NJ 08543-5400

609-818-3000

MS16

Q-5

2002 JAN 24 11:01

RECEIVED
FEB 1 2002

January 22, 2002

Ms. Betsy Ullrich
USNRC Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: DOCKET NO. 03005222, CONTROL NO. 130734, LICENSE NO. 29-00139-02

Dear Ms. Ullrich:

Attached please find responses to the questions requesting additional information from your letter dated December 31, 2001. We trust this information is adequate to process our amendment request. If you have any additional questions, please contact me at (609) 818-4907.

Sincerely,

Michael J. Vala, CHP
Radiation Safety Officer

MJV:bl

Attachment

MJV\NRCRESPONSE.Doc

cc: C. Woodard

130734

NMSS/RGNI MATERIALS-002

RESPONSE TO NRC REQUEST FOR ADDITIONAL INFORMATION

Question 1.

Sections 1.0 and 4.0 state that the facilities to be decommissioned are limited to Buildings 124 and 122, the B-83 tanks, the B-124 tanks, and the stack adjacent to Buildings 124 and 122. Our records indicate that activities were performed also in Buildings 74 (research and development using technetium-99, technetium-99m, molybdenum-99, gadolinium-153 and rubidium-186), 80-84 (iodine-131), 92 (radionuclide product testing), 102 (radioimmunoassay) and 104 (not specified). Confirm that you continue to use these facilities, or that the facilities were released for unrestricted use pursuant to activities previously authorized by your broad scope license.

Response 1.

This response confirms that Buildings 74 and 104 were previously released for unrestricted use pursuant to activities authorized by the broad scope license. Buildings 92, 80-84 and 102 are still in use. The facilities to be decommissioned are limited to Buildings 124 and 122, the B-83 tanks, the B-124 tanks, and the stack adjacent to Buildings 124 and 122.

Question 2.

Sections 1.0, 5.0, and 6.0 state that you will use the NRC screening values, and understand that these levels are considered to be ALARA (as low as is reasonably achievable). However, the NRC does not state that screening levels are ALARA. The screening levels are those maximum levels for each radionuclide, that if they remained present in those concentrations on building surfaces or in surface soils, would result in a dose of 25 millirem in one year to a member of the critical population. The screening levels may not be as low as is reasonable achievable, depending on the radionuclide and its chemical form, and the location of the contamination. Your statement that you plan to use the NRC screening values, but also reduce residual contamination to levels close to background, is acceptable. Revise Sections 1.0, 5.0 and 6.0 to remove the statement that screening levels are ALARA.

Response 2.

Sections 1.0, 5.0 and 6.0 are revised to state that NRC screening values will be used and that reasonable efforts will be made to reduce residual contamination to levels as close to background as practical.

Question 3.

Section 2.2 and 4.0 list the radionuclides that were used in past activities in Buildings 122 and 124. A review of our past records confirms use of tritium and carbon as late as 1978, in millicurie quantities. Past inspection records indicate that gadolinium-153 and rubidium-186 were also used at your site, in Building 74.

Response 3.

The license did allow for millicurie quantities of carbon-14 and tritium, however these radionuclides were not used in manufacturing activities in Building 124. There was waste processing (compaction) of research and development waste using these radionuclides in Building 122 and the characterization plan includes surveying, sampling and analysis for these radionuclides. Section 2.2 is revised to reflect that these radionuclides have been used within the previous 10 years. Section 4.0 already includes carbon-14 and tritium as anticipated radionuclides.

Gadolinium-153 and rubidium-86 were used in Building 74. Response to Question 1 confirmed that Building 74 was previously released for unrestricted use and is not within scope of this decommissioning.

Question 4.

Section 2.3 refers to past removal of below-grade waste decay tanks in the location where Rooms 108, 109, 116 and 118 of Building 124 are now located. Describe your survey and/or sampling plans for confirming that soil surrounding the former tanks is not contaminated, or explain why you do not plan to do any surveys or sampling of this area.

Response 4.

The survey and sampling plan to evaluate the soil surrounding the former tanks will include drilling cores through the concrete slab in the appropriate locations and taking soil core samples to the appropriate depth and then analyzing by gamma spectroscopy and gross beta.

Question 5.

Section 2.4 refers to spills on effluent tanks, but it is not clear if this refers to the B-83 tanks, the B-124 tanks, or the tanks described in Section 2.3. Clarify which tanks are discussed in this section.

Response 5.

The spills referred to in section 2.4 occurred in the B-124 tanks and are believed to have been contained within the vaults. Section 2.4 is revised to clarify the affected tanks.

Question 6.

In general, Section 3 of your plan is less detailed than the corresponding section of NUREG-1727, but provides sufficient information regarding the facilities affected by the licensed activities performed. However, expand Section 3.4 of your plan to describe the impact of your decommissioning activities on the environment, considering the meteorology and climatology, geology and seismology, surface water hydrology, groundwater hydrology, and their effect on the natural resources, the ecology and any endangered species [Sections 3.4 through 3.9 of NUREG-1727]. If you do not expect any impact on the environment from your decommissioning activities, state this and explain why. Section 10.0 should also be revised to reflect changes in Section 3.4 of your plan.

Response 6.

No environmental impact is expected from the decommissioning activities and therefore environmental monitoring will not be performed. During manufacturing operations when possession and processing quantities of radioactive materials were in the curie range, environmental monitoring requirements included fenceline TLDs for external exposure and effluent stack monitoring for airborne releases. Operations were discontinued on 6/29/01 and the remaining radionuclide inventory is now calculated to be less than 1 millicurie. The stack monitoring was discontinued on 8/2/01. The fenceline monitoring will also be discontinued.

The residual radioactivity remaining is low levels of long-lived impurities from bulk solutions and is mostly contained in the caves, drains and equipment that will be removed. Decommissioning activities that could potentially cause airborne contamination will be limited to grinding in the caves and cutting out the drains. When performing these activities, engineering controls will be used to limit the potential for airborne radioactive materials and will not generate a source term and release pathway that could cause any offsite environmental impact.

Soil samples collected around the outside tanks will be analyzed for the radionuclides contained in the effluents. If any contamination is found, then the potential impact to groundwater will be evaluated. Sections 3.4 and 10.0 are revised to state that there will be no environmental impact.

Question 7.

Figures 4-5 through 4-9 show the Class 1, Class 2, and Class 3 areas in Buildings 122 and 124. Although this is acceptable for the characterization survey, confirm that you will provide diagrams showing also the survey units in each Class area in your plans for your Final Status Survey.

Response 7.

This response confirms that the Final Status Survey Plan will contain diagrams showing the Class 1, Class 2 and Class 3 areas and their survey units.

Question 8.

Section 4.3 states that a beta/gamma screening value of 10,000 disintegrations per minute (dpm) per 100 square centimeters of area (cm^2) will be used in the characterization survey. Although this may be used during characterization, this value exceeds the NRC screening levels for cobalt-60 (7,100 dpm/100 cm^2) and strontium-90 (8,700 dpm/100 cm^2) that may be present. The final surveys must demonstrate that residual radiation from these radionuclides does not exceed the NRC screening values. Confirm that you will address this issue in your plans for your Final Status Survey.

Response 8.

Although Section 4.3 states that a beta/gamma screening value of 10,000 dpm/100 cm² will be used for characterization, actual field measurements are being made to 25% of that value. The characterization survey data will determine actual radionuclide mixture. The final status surveys will demonstrate that residual radionuclides from the actual radionuclide mixtures do not exceed the NRC screening values. If multiple radionuclides are present, the NRC screening values will be adjusted for the Final Status Survey so the total of the DCGLs for all radionuclides do not exceed the release criterion.

Question 9.

Sections 4.4, 9.4 and 9.5 describe the survey instrumentation that you plan to use during the characterization surveys. Confirm that, in your plans for your Final Status Survey, you will provide the equations used for calculation of the minimum detectable activity for the various instruments used, including those used for scanning surveys, for the different radionuclides. Particular attention should be given to any survey instruments used for detection of alpha radiation.

Response 9.

The Final Status Survey Plan will provide the equations to be used for the calculation of the minimum detectable activity for the various survey instruments and techniques to be used including the minimum detectable concentration for scanning. There are no known alpha emitting radionuclides of concern, however surveys for alpha emitters will be performed during characterization to verify that they are not present. Appropriate instrumentation and/or analyses will be used for detection of alpha radiation.

Question 10.

Sections 4.8 and 13.0 describe the biased surveys and sampling that will be performed during characterization. Confirm that your Final Status Survey will be performed using unbiased surveys and sampling in accordance with the MARSSIM guidance. In your plans for your Final Status Survey, you should provide the assumptions and calculations used to determine the number of samples that are needed in each survey unit.

Response 10.

The Final Status Survey will be designed using unbiased surveys and statistically based sampling in accordance with MARSSIM guidance. The Final Status Survey Plan will include identification and size of survey units as well as the assumptions and calculations used to determine the number of samples that are needed in each survey unit.

Question 11.

Sections 4.0 and 8.0 do not specify the radiation or contamination levels in the facilities to be decommissioned. Provide a summary of the major areas of contamination, and the levels of contamination and/or radiation in those areas, based on your routine survey program.

Response 11.

The routine survey program was conducted during manufacturing operations when radioactive material quantities normally possessed and processed were in the curie range resulting in radiation areas. These surveys are not indicative of the current radiological conditions. There are currently no radiation areas remaining. The major areas of contamination remaining are as follows:

- The iodine caves have mostly fixed contamination in limited areas up to a maximum of 1 million dpm per 100 centimeters squared.
- One glove box with Sr-82/85 fixed and smearable contamination but no exposure rates. This equipment will be removed and sent to an offsite processor.
- One Sr-82/85 source contained in a shielded lead container that is being stored which will be disposed of as rad waste.
- The interior of the strontium cave has radiation levels of approximately 10 mR/hr primarily due to the filling machine equipment that will be removed and sent to an offsite processor.

Minor areas of contamination are present in the process drains and ventilation ducts exiting the caves and on equipment that will be removed and sent of an offsite processor.

Question 12.

Section 9.5 does not provide sufficient detail regarding any expected air monitoring or respiratory protection for workers, particularly those involved in activities such as cutting pipe, grinding surfaces and scabbling floors, which could generate airborne radioactive dusts and fumes. Review Sections 10.1.1 and 10.1.2 of NUREG-1727 and provide the requested information, or an explanation of why air monitoring and respiratory protection are not necessary during your decommissioning activities.

Response 12.

The residual contamination levels remaining at the facility are minimal such that decommissioning activities such as cutting and grinding are not expected to result in airborne contamination or internal exposures. Contaminated equipment will be removed and shipped to an offsite processor. Additionally, engineering controls will be used to mitigate any potential airborne radioactive material during cutting and grinding work. Internal exposures are not expected to exceed 10% of the limits specified in 10 CFR 20.1502 and therefore the requirements of 10 CFR 20.1204, 20.1703 and 20.1704 will not need to be implemented. Air monitoring will be performed as necessary to demonstrate compliance and confirm the adequacy of engineered controls and procedures.

Question 13.

Section 10.0 does not provide sufficient explanation of why environmental monitoring is not required during decommissioning activities. Review Section 11.0 of NUREG-1727 and provide the requested information, or an explanation of why an environmental monitoring and control program is not necessary during your decommissioning activities.

Response 13.

As described in the response to Question 6, environmental monitoring will not be required during decommissioning activities. Section 10.0 has been revised to provide an explanation why environmental monitoring will not be necessary during decommissioning.

Question 14.

Section 11.0 does not discuss mixed waste. State if you do or do not expect mixed waste to be generated as a result of decommissioning activities. If so, provide the information required by Section 12.3 of NUREG-1727.

Response 14.

The physical decontamination activities are not expected to generate any mixed waste. Any contaminated lead contained in glove boxes or fume hoods will be removed and shipped to an offsite processor.

Question 15.

Section 13.4 provides a brief explanation of your Final Status Survey design. The level of detail is not sufficient for us to determine if your Final Status Survey is acceptable at this time. You may submit your detailed plan for your Final Status Survey for our review and approval prior to performing the Final Status Survey. Please note that, if you plan to use any site-specific DCGLs other than the NRC screening levels, you must obtain NRC approval to use those DCGLs. Typically, the review process for site-specific DCGLs requires approximately 6 months.

Response 15.

A detailed Final Status Survey Plan will be submitted to the NRC for review and approval prior to performing the Final Status Survey. The use of site specific DCGLs is not anticipated.

Question 16.

Section 7.2 states that you expect to complete the characterization survey in February 2002, any decommissioning activities in the second calendar quarter of 2002, and the Final Status Survey by the fourth calendar quarter of 2002. We request that you inform us of your survey schedules so that inspections can be performed of the characterization, decommissioning, and final status surveys. Such inspections allow us to evaluate these activities in progress and perform comparative surveys. This may reduce or eliminate the need for NRC confirmatory surveys to be performed after your Final Status Survey is completed. You may contact me at (610) 337-5040 or Pamela Henderson at (610) 337-6952 to provide specific information regarding your survey schedule. We can also be contacted by e-mail at exu@nrc.gov and pjh1@nrc.gov.

Response 16.

The NRC will be kept informed of the schedules for characterization, decommissioning and final status surveys to allow for inspections of these activities in progress.