

NOV 23 1993

License No. 06-19183-01
Docket No. 030-17101
Control No. 112947

Boehringer Ingelheim Pharmaceuticals, Inc.
ATTN: James J. Keirns, Ph.D.
Chairman, Radiation Safety Committee
900 Ridgebury Road
P. O. Box 368
Ridgefield, Connecticut 06877

Dear Dr. Keirns:

Subject: Financial Assurance for Decommissioning

This is in reference to your letter dated September 29, 1993 and the telephone conversation on November 3, 1993 between Mr. Vince Chase, myself and Anthony Dimitriadis of this office, regarding your need for an additional 60 days in order to "contact the appropriate persons" in order to reply to our letter dated September 1, 1993.

Based on your previous submittals, it appears that you are attempting to comply with the regulation by utilizing a Parent Company Guarantee. We have outlined a list of deficiencies regarding your Parent Company Guarantee in our letter dated September 1, 1993. However, we recognize that the time required to prepare a response to our letter may require longer than 30 days. Therefore, your request for a sixty (60) day extension is hereby granted. We expect a response on or before November 29, 1993.

Regarding your response to Item 1 of our letter indicating that a DFP is not required. 10 CFR 30.35 has been in effect since July 27, 1988, thirty (30) days after the regulation was promulgated. Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of 10 CFR 30.35 was required to submit, on or before July 27, 1990, a certification of financial assurance for decommissioning or a decommissioning funding plan. The regulation in 10 CFR 30.35(c)(2) references 10 CFR 30.35(a) which states:

"Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days..."

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In addition, Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72", page 1-3, states:

"The financial assurance requirements outlined in the final decommissioning rule vary depending on several factors, including:

- The amount of material a licensee is authorized to possess and use;..."

This means that the possession limits listed on your license determine the category of certification required, not the quantities possessed or used on a daily basis. The regulation listed in 10 CFR 30.35 (c)(2) is clear, in that a decommissioning funding plan must be submitted with any application for license renewal, if such license authorizes possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix C of 10 CFR Part 20. We have reviewed your "decommissioning guidelines" attached to your submittal dated August 13, 1992, and request that you provide additional information to address the specific issues listed below:

1. **Submit a Decommissioning Funding Plan or request to amend your license to lower your possession limits.**

As described above, the possession limits authorized on your license exceed 10^5 times the applicable quantities listed in Appendix C, thus requiring you to submit a decommissioning funding plan (DFP) at this time, including an actual cost estimate for decommissioning your facility(ies) in accordance with 10 CFR 30.35(c)(2) and (e). The cost estimate must include information necessary to complete Appendix F of Regulatory Guide 3.66. You also have the option of amending your license to lower your possession limits such that submission of a DFP is not required. One of the following options would accomplish that objective:

- a. Amend items 6.A., 7.A. and 8.A. as follows:

Any byproduct material with Atomic Nos. 3 through 83 with a half-life of 120 days or less	Any	Not to exceed 20 millicuries of each radionuclide and 500 millicuries total
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Radionuclides with a half-life greater than 120 days would be listed as line items, similar to current items 6.B., 6.C., 6.D. so long as the total does not require a DFP.

b. Amend items 6.A., 7.A. and 8.A. as a Type B Broad license:

As specified in 10 CFR 33.100, Schedule A	Any	See Condition 12
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Condition 12.A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

Notwithstanding Subitem A of this condition and 10 CFR 33.100, Schedule A, Column I, the applicable quantities in Condition 12.A. for the following radionuclides are changed to:

Carbon 14	10 curies
Krypton 85	10 curies
Iodine 129	10 millicuries

Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A:

10 millicuries

This condition would not require you to submit a DFP, and the amount of funds required under the decommissioning rule would be reduced to \$750,000, provided other items on your license do not exceed the unity rule.

Please submit a DFP or a request to amend your license. If you submit a DFP, you must submit a Parent Company Guarantee in an amount which coincides with the cost estimate.

2. **Provide a detailed cost estimate and description of all facilities using licensed material.**

Although your current submittal outlines some general procedures for decommissioning your facility, you provide no estimate to decommission laboratories, facility components or decontamination of equipment. Please provide a description of your facilities outlining areas where licensed material has been or is being used, storage of waste, fume hoods, glove boxes and/or exhaust system duct work. In

addition, please provide an estimate for items including but not limited to: manpower requirements, material and equipment needs, waste management/disposal requirements and decontamination alternatives. The enclosed NUREG/CR-1754, Addendum 1 may be helpful in preparing your cost estimate.

3. **Incorporate a contingency factor into the total decommissioning cost estimate and confirm that no credit is taken for salvage value.**

Regulatory Guide 3.66 "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR 30, 40, 70 and 72" June 1990, recommends that a contingency factor be included in the decommissioning cost estimate.

Incorporating a contingency factor in the cost estimate will help to ensure that licensees are prepared for unexpected circumstances that could raise decommissioning costs. NUREG/CR-1754, (copy enclosed) uses a contingency factor of 25 percent in its estimates for each of six reference laboratories. Please incorporate a contingency factor of 25 percent into your decommissioning cost estimate. You may choose to use a lower contingency factor if you can show why a lower factor is appropriate.

In addition, confirming that you have not included in the cost estimate credit for any salvage value that may be realized with the sale of potential assets after decommissioning.

4. **Describe the means to be used for adjusting cost estimates and associated funding levels over the life of the facility.**

10 CFR 30.35(e) requires that licensees describe the means they will use to adjust decommissioning cost estimates and associated funding levels over the life of the facility. Please provide such a description in your decommissioning funding plan.

Regulatory Guide 3.66 provides a method for adjusting the cost estimates and suggests that adjustments be made for inflation for site specific factors at the time of license renewal, or when the amounts/types of material at the facility change.

Adjustments should be made to account for inflation, for changes in prices of goods and services, for changes in facility conditions, and for changes in expected decommissioning procedures.

Satisfactory financial assurance is required for your license in accordance with 10 CFR 30.35(f). Furthermore, you must demonstrate that adequate financial responsibility is in place and the funds necessary for a safe decommissioning are being considered, planned for, and are in place early in facility life, thus providing adequate assurance that the facility would not become a risk to public health and safety. You must submit your DFP, or propose a schedule for providing one, by November 29, 1993.

Please reply in duplicate to my attention at the Region 1 office and refer to Mail Control No. 112947. If you have questions regarding this letter, contact Anthony Dimitriadis of my staff at (215) 337-6953.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Research and Development Section
Division of Radiation Safety
and Safeguards

Enclosures:

1. 10 CFR 30
2. NUREG/CR-1754