



Pharmacia & Upjohn

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Clark W. Smith, Ph.D.
Director of Research Operations

Nuclear Materials Licensing Section
Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

23 August 1999

Dear Sir or Madam:

Pharmacia & Upjohn is requesting an amendment to our byproduct material license number 21-00182-03. Attachment 1 contains a list of the specific changes that are being requested.

Please contact Mr. Timothy Popp at (616) 833-9364 if you have any questions concerning these requested changes.

Sincerely,

Clark W. Smith,
Chairman, Radiation Safety Committee

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Attachment 1

The following is a list of the requested changes to the NRC Material License and/or to any of the requirements in the documents listed in Condition 21 of NRC Material License 21-00182-03. The date in parentheses after each item reflects the date of the letter(s) that last amended the effected section.

1. Refer to Item 8.3.B of Pharmacia & Upjohn's NRC License Requirements (letter dated May 20, 1996)

The current requirement for Ancillary Radiation Worker Training requires that the training be conducted annually by means of an *informal briefing* or, alternately, on a case basis at the time a radiation work permit is approved. Pharmacia & Upjohn would like to make this requirement more flexible by allowing this annual training to be performed by any appropriate means commensurate with the needs of the workers, and not just by means of an informal briefing. Other such appropriate means may include, among other methods, a video presentation, procedure review, a radiation safety training pamphlet, formal classroom training or an informal briefing.

Item 8.3.B should be revised to read as follows:

These individuals shall receive, upon initial employment, a brochure, which communicates Pharmacia & Upjohn's use of byproduct material. Additionally, each worker should receive further instruction concerning the radiation hazards associated with their specific job assignment. This training shall be conducted on an annual basis by the Laboratory Radiation Support staff (or others designated by the RSO) and tailored to the needs of the group. Alternately, training may be given on a case basis at the time a work permit is approved. Such training shall be documented.

2. Refer to Item 10.5.C.4 of Pharmacia & Upjohn's NRC License Requirements (letter dated April 7, 1995)

This requirement currently states that thermoluminescent dosimeters (TLDs) are the primary means of monitoring external radiation exposure at Pharmacia & Upjohn. In the near future, Pharmacia & Upjohn will be changing to optically stimulated luminescent dosimeters (OSL). A vendor who is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) will provide these dosimeters in accordance with 10 CFR 20.1501(c). To provide future flexibility in changing radiation dosimeter types, Item 10.5.C.4 is being revised to simply state that Pharmacia & Upjohn will use a NVLAP approved dosimeter and no longer specify a particular type of monitoring device.

Item 10.5.C.4 should be revised to read as follows:

Personnel monitoring devices provided and processed by a vendor who is accredited by the National Voluntary Laboratory Accreditation Program, as required by 10 CFR 20.1501(c), are the primary means of monitoring external radiation exposure. Personnel monitoring devices are issued by the LRS office and will be exchanged at least every three months to demonstrate compliance with the annual occupational dose limits in 10 CFR 20.1201. Prior to assigning monitoring devices to individuals requiring monitoring in accordance with 10 CFR 20.1502, Pharmacia & Upjohn makes a reasonable attempt to determine the individual's prior occupational dose as required by 10 CFR 20.2104.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

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Clark W. Smith, Ph.D.
Director of Research Operations
Chairman, Radiation Control Committee
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001

Dear Dr. Smith:

Enclosed is Amendment No. 52 to your NRC Material License No. 21-00182-03 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

- b. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - c. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous

C. Smith

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enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original signed by
Charles F. Gill
Materials Licensing Branch

License No. 21-00182-03
Docket No. 030-04781

Enclosure: Amendment No. 52

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