



SMALL MOLECULE THERAPEUTICS, INC.

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7 April 1998

Mr. James M. Bondick, Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Docket No. 030-34681
Control Number 125524

Dear Mr. Bondick,

We are providing the following additional information as requested in your letter dated 27 March 1998 to Dr. Prabhavathi Fernandes. The following refer to the seven questions asked by you.

1. As mentioned in our application, Dr. David Elsemore will be our Radiation Safety Officer and will register for and attend three courses in radiation safety at Rutgers University on 13, 15 and 18 May 1998. Between the time we obtain our license and 18 May 1998, we will provide coverage in radiation safety as follows. Our consultant, Wesley R. Van Pelt, Ph.D., CIH, CHP, will provide direct advice and guidance to Dr. Elsemore. Dr. Van Pelt will be present during the first use of each radionuclide and for any usage which presents substantially different potential radiological hazards.
2. We confirm that personnel will be instructed before beginning duties with or in the vicinity of licensed materials. Persons will be re-instructed appropriately whenever there is a significant change in duties, regulations, or the terms of the license.
3. Dr. Krishna Kodukula's correct usage amounts are listed on page 4 in terms of maximum quantities of materials handled.
4. We will conduct routine radiation surveys on a monthly basis in all areas where radioactive material is used or stored. In addition, we will conduct weekly radiation surveys in areas where more than 200 microcuries of radioactive material was used at any one time. Typical radioactive material use will be with less than 200 microcuries at any one time, but we anticipate that greater quantities may be used from time to time, such as when dispensing from a stock vial. Our routine radiation survey is described in our

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license application and will include the additional radiation level survey as described in answer No. 5 below.

5. Our described routine radiation surveys did not include measurement of ambient radiation levels because of the nature of the radionuclides on our license. H-3, C-14 and S-35 are all low energy beta emitters and produce no substantial external radiation hazard. P-32 is a high energy beta emitter (no gamma) which will be shielded with low atomic number material such as plastic and has a maximum range of less than 1 cm in most common materials. I-125 is a very low energy photon emitter which generates very low ambient dose rates and is easily shielded. All radionuclides on the license are easily shielded by common construction material such as glass and sheetrock (wallboard), and as a result, ambient radiation levels are not expected in unrestricted areas. However, we will add to our routine survey a procedure for scanning for ambient radiation levels. The ambient radiation level survey will include measurements of ambient external gamma dose rate using a calibrated portable GM radiation survey ratemeter reading in mR/h or mrad/h. Dose rate will be measured in occupiable areas at 30 cm (12 inches) from any surface emitting radiation. Ambient dose rates will be measured in both restricted and adjacent occupiable unrestricted areas. Trigger levels for ambient dose rate readings are as follows.

	Trigger Level Dose Rate	Action
Restricted Area	>2 mR/h	Record the dose rate on the survey form. Take any action necessary to keep radiation doses to persons ALARA.
	>5 mR/h	Be sure that the area is posted with a "Caution, Radiation Area" sign.
Unrestricted Area	>0.5 mR/h	Record the dose rate on the survey form. Determine if any individual member of the public could receive >100 mrem TEDE in a year.
	>2 mR/h	Take immediate action to reduce the dose rate in an unrestricted area to <2 mR in any single hour. Investigate the circumstances and take action to prevent dose rates from exceeding 2 mR/h and to keep doses ALARA.

6. All of our labs and storage area are restricted areas. We control access to the labs by allowing only authorized persons access thru the entrance doors. This is done with combination locks and key locks. Company personnel will escort all visitors in the labs. Our radioactive waste storage room will be locked when unattended. Radiation safety training to our employees will include instructions on proper security of licensed material.

7. Regarding how we will determine that the radioactive material disposed into the sanitary sewer is readily soluble material or readily dispersible biological material, we will apply one of the methods described in NRC Information Notice 94-07. Thank you for supplying this Information Notice to us.

Very truly yours,
SMALL MOLECULE THERAPEUTICS, Inc.

A handwritten signature in black ink, appearing to read "David A. Elsemore", with a long horizontal flourish extending to the right.

David Elsemore, Ph.D.
Radiation Safety Officer

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Krishna Kodukula, PhD

Title: Executive Director

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Roche Institute of Molecular Biology, Nutley, NJ	1989-1993, 2-3 hrs each	Initial and yearly refresher course on radiation usage and disposal given by the RSO of Hoffmann La Roche Inc., Nutley, NJ.
Bristol Myers Squibb Pharmaceutical Research Institute, Wallingford, CT	1993-1997, ~2 hrs each	Initial and yearly refresher course on radiation usage and disposal offered by the RSO of BMSPRI, Wallingford, CT

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Roche Institute of Molecular Biology, Nutley, NJ	1989-1993	S-35 P-32 P-33 H-3 C-14	5 mCi 1 mCi 1 mCi 5 mCi 250 µCi	protein purification, enzyme kinetics, metabolic labeling, DNA sequencing.
Bristol Myers Squibb Pharmaceutical Research Institute, Wallingford, CT	1993-97	S-35 P-32 P-33 H-3 C-14 I-125	5 mCi 1 mCi 1 mCi 5 mCi 250 µCi 50 µCi	radioligand binding, receptor labeling and purification, protein purification and labeling, enzyme labeling and kinetics.