

November 17, 2004

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pa. 19406-1415

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RECEIVED
REGION 1

Attention: Mr. Steven Courtemanche, Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Re: Mail Control No. 135452

Dear Mr. Courtemanche:

This letter is in response to your correspondence dated October 29, 2004 concerning our recent renewal application for license #37-00582-02. The following information is provided for your review.

03 000953

1. Licensed material Iron-59 was never possessed at the University of the Sciences in Philadelphia.
2. We do not possess by-product material in the form of a sealed source or in a device that requires specific licensure. We understand that should we possess a sealed source or device that requires specific licensure in the future, a license amendment will be requested.
3. Shanaz M. Tejani-Butt is to be authorized for Iodine-125. This was a typographical error. Licensed material listed in Subitems 5.A, 5.C, 5.E, and 5.H may be used by or under the supervision of Shanaz M. Tejani-Butt.
4. Rodney Wigent and Alfonso Gennaro are to be removed from our list of persons authorized to use or supervise the use of licensed materials. Additionally, I would like to request the removal of Michael F. Bruist and James Johnson from our license as authorized users.

Please add Russell DiGate to our list of persons authorized to use or supervise the use of licensed material. (Training and experience enclosed) Licensed materials to be utilized are C-14, H-3, I-125 (non-volatile), P-32, and S-35.

135452

NMSS/RGNI MATERIALS-002

5. Renee Siegel is to be added to the list of persons authorized to use or supervise the use of any licensed activity authorized by our program.
6. Senior management has signed a written statement of delegation of authority to the Radiation Safety Officer and it will be available for review upon the next Nuclear Regulatory Commission inspection.
7. Occupationally exposed individuals and ancillary personnel will be required to attend or complete refresher training every other year. In addition to the methods described in the license renewal dated July 21, 2004, ancillary personnel may be provided the "Safety Reminders for Ancillary Personnel When Working in Laboratories" handout for refresher training.

The effectiveness of the training is measured during inspections by the observation of work practices. Additionally, by evaluating responses to questions presented during inspections and during training sessions. Quizzes are also utilized to measure the effectiveness of training when safety discussion guides are completed.

8. We do not possess any sealed sources that require leak testing.
9. Prior to performing radiation safety surveys, personnel are required to attend a scheduled radiation safety training session. The topics covered are listed on our license renewal dated July 21, 2004 in Item #8, for laboratory personnel. Initially, surveys are performed under the supervision and in the physical presence of an individual authorized to perform surveys. The Radiation Safety Officer will ensure that he or she has sufficient training and experience to perform surveys independently.

The action level established for removable contamination before decontamination or other appropriate action is 2000 dpm/100cm² for restricted and unrestricted areas on all isotopes, except Iodine-125. The action level established for removable contamination before decontamination or other appropriate action on Iodine-125 is 200 dpm/100cm² for restricted and unrestricted areas.

The action level established for fixed contamination before decontamination or other appropriate action is 2 mR/hr for restricted and unrestricted areas.

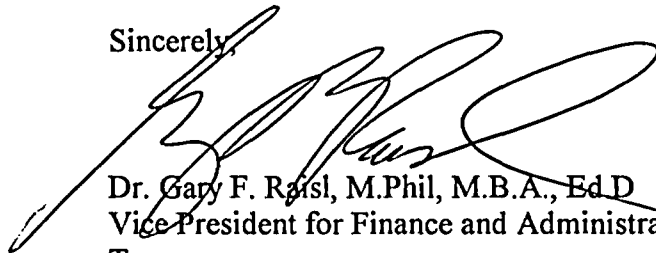
Contamination levels on equipment or facilities released for repair by maintenance personnel for unrestricted use must not exceed 1000 dpm/100 cm² on all isotopes except, Iodine-125. The level of contamination on equipment or facilities released for repair by maintenance personnel for unrestricted use for Iodine-125 must not exceed 200 dpm/100cm².

Survey records will include a diagram of the area surveyed, a list of items or equipment surveyed, specific locations on the survey diagram where the wipe test was taken, contamination levels with appropriate units, make and model number of instrument used, background levels, date of survey, and the initials of the person performing the evaluation.

10. The figure of 200 dpm/cm² in Attachment I, "Emergency Procedures," page 2, fourth bullet is a typographical error and should be 200 dpm/100cm². The sentence in the document has been corrected to read, "Decontaminate until there is less than 200 dpm/100 cm² of removable contamination."

Thank you for your support in this matter. Please feel free to contact the Safety Department at 215-596-8925 if you have any questions, or require additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'G. Ragsl', is written over the typed name and title.

Dr. Gary F. Ragsl, M.Phil, M.B.A., Ed D
Vice President for Finance and Administration and
Treasurer

Russell DiGate- Training and Experience

Radioactive license questions:

Training for radionuclide use: I have received training at each of my places of employment during my 26 years in science.

Undergraduate: University of Rochester (1978-1980) and

Graduate: University of Rochester 1980-1986 Radionuclide and hazardous waste training

Post-doctoral: (1986-1990) Memorial Sloan-Kettering Cancer Center: Radionuclide and hazardous waste training

Professional: (1990- 2004) Assistant-Professor, University of Maryland, Baltimore: Radionuclide and hazardous waste training

Place radionuclides used: I used radionuclides at all of the institutions indicated above

How long have radionuclides been used and in what capacity: I have used radionuclides for 26 years from undergraduate research (two years at the University of Rochester), graduate school (five years at the University of Rochester), post –doctoral positions (five years at Memorial Sloan-Kettering Cancer Center) through academic positions at the University of Maryland from 1990- present (assistant through full professor; 14 years at the University of Maryland School of Pharmacy and University of Maryland Biotechnology Institute).

Undergraduate and Graduate studies: used radionuclides (^{32}P and ^3H) to assay DNA polymerases. Used on average 1 mCi per month when performing assays and isolating ^3H -DNA.

Post-doctoral: used ^{32}P , ^3H , ^{14}C , ^{35}S , and ^{125}I

Isotopes used for southern and northern blots, assaying DNA polymerases and nucleases (^3H , ^{32}P)

^{125}I used infrequently in Western blots as ^{125}I labeled proteinA

^{14}C used when using radiolabeled protein markers

^{35}S is used when sequencing DNA (^{35}S -dNTP)

Professional: Same as above post-doctoral response

My lab in general uses 1-3 mCi of ^{32}P a month when experiments warrant. There is usually 1 mCi present at most times in lab. 5 mCi of ^3H is usually on hand in the form of ^3H -dNTPs. ^{35}S is used for DNA sequencing on a fairly regular basis. ^{125}I is used rarely and ^{14}C is only present as labeled protein markers ($\sim 100\text{uCi}$)

Which radionuclides have been used, and if different, which would you like to use at USP: The following nuclides have been used at the University of Maryland and I would anticipate using them at USP:

Attached are the radionuclides and possession limits that I had at UMD:

C-14	0.5 mCi
H-3	5 mCi
I-125 (non-volatile)	0.5 mCi
P-32	5 mCi
S-35	1 mCi

I anticipate that these nuclides would be as described in previous section.

Where radionuclides would be stored: Storage will be in locked frig/freezer in the laboratory and used in the laboratory.