



November 7, 2008

Mr. Thomas Thompson
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, PA 19406

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REGION I

License No. 06-30693-01
Docket No. ~~030-3868~~ *RLT*
Control No. 137647

03035868

Subject(s): Request for Hot Lab No. 2 Close-out, changes in Management Representative and authorized users.

Dear Mr. Thompson,

Protometrix, an Invitrogen Company, requests the following changes to its specific research and development NRC License # 06-30693-01. As part of a reorganization goal, Protometrix is requesting that the hot lab no. 2 no longer be used and designated for research involving licensed radioactive materials. A close-out survey has been performed in this room and a survey summary along with a brief room history is provided below for your review. Therefore, Protometrix requests that this small room no longer be designated for work with licensed materials under its NRC License No. 06-30693-01. Survey records along with a room history will be maintained by the RSO to be included with final surveys if and when Protometrix, an Invitrogen Company, requests to decommission its facility. Protometrix will keep you informed of our plans and record keeping efforts regarding this initiative.

In preparation for this reorganization within Protometrix, all uses and storage of licensed radioactive materials were terminated in the hot lab no. 2 in August 2007 and subsequently transferred to the previously approved hot lab no. 1. Hot lab no. 1 is directly adjacent to hot lab no. 2 within the facility. A thorough room history of hot lab no. 2 was performed covering the entire duration of its authorization under the NRC License no. 06-30693-01. Reviews of research protocols, authorized user limits, Principal Investigators', Authorized Users' and/or RSO's surveys, purchase orders, radioisotope inventories, emergency response or spill history, sanitary sewer disposals, radioactive waste storage and disposal records were conducted. There were no significant spills or releases that occurred or were reported in hot lab no. 2. Any radioactive contamination detected during routine work and/or radiation safety inspections were documented to be decontaminated to levels well below the NRC's release guidance criteria, NRC License requirements and/or Regulatory Guide 8.23 limits. Radioactive materials use was performed in the approved research laboratory area only. All uses, including storage, of licensed materials were ceased prior to August 31, of 2007. Further, since this hot lab no. 2 was only designated for phosphorus-33 licensed work and storage, this room was inactive for a period of at least 4 months, or approximately four half-lives, prior to performing the final close-out surveys.

The focus of research in the hot lab No. 2 involved minimal tracer levels of phosphorus-33. Over the three years following its approval under the NRC license no. 06-30693-01, there were approximately 24 radioisotope orders of phosphorus-33 only, ranging from 0.25 mCi to 3.0 mCi per order, an approximate total activity of 27.25 mCi, used in this room. Even though this work was confined to very limited area of the hot lab No. 2, extensive final close-out surveys of

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accessible areas were performed by the Radiation Safety Officer and qualified Radiation Safety Consultant. As an added precautionary measure, the sink drain was monitored. These surveys included wipe tests and meter surveys. No removable and/or fixed radioactive contamination was found in excess of NRC Guidelines as provided in NUREG/CR, Appendix Q to NUREG – 1556, Volume 7, dated December 1999, Regulatory Guide 8.23 and/or were significantly below those limits. Copies of all records will be maintained by the Radiation Safety Officer.

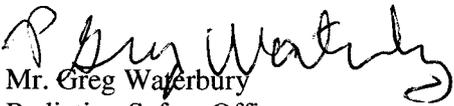
There were no documented sanitary sewer disposals or emergency spills involving sanitary sewer disposals in this hot lab No. 2. per the RSO's internal policy. Accordingly, the annual sanitary sewer release limits for this room were Alara and, therefore, significantly well below the limits designated in 10 CFR part 20.2003. Copies of all records will be maintained by the Radiation Safety Officer.

As part of this reorganization, Protometrix, "an Invitrogen Company, is proposing to name Mr. Barry Schweitzer, Ph.D., Director R&D, Protein Analysis replacing Mr. Charles Piazza as the Management Representative for this NRC license no. 06-30693-01. In his current position, Dr. Schweitzer will oversee and direct all general business operations at the 688 East Main Street, Branford, CT 06405 facility.

In addition, as part of the overall annual review of the radiation safety program, reorganization and typical personnel attrition, Protometrix is requesting to update the names of authorized users listed on its NRC license no. 06-30693-01. Therefore, the addition of Ms. Lisa Freeman Cook, Ph.D., Mr. Gregory Korbel, Ph.D. and Ms. Christine Stalder, as supervisors and authorized users is being requested. Further, we are requesting that Mr. Gary Martone, Mr. Lihao Meng, Ph.D., Ms. Zhenyu Sun., Ms. Guene Thio, Ph.D., and Mr. Patricio Tomas and be listed as supervised authorized users. Summaries are attached of supervisors radiation safety training and radioactive materials experience for your review. Protometrix is also requesting the deletion of the following names of authorized users from its NRC license no. 06-30693-01: Mr. Gregory Michaud, Ph.D., Mr. Paul Predki, Ph.D., Mr. Fang Zhou, Ph.D. and Ms. Jaclyn Bonin including the associated statement referencing her name under Conditions, item no. 11, of NRC form 374, page 1 of 3.

Please do not hesitate to contact me at (203) 848-1104 if you have any questions or require additional information. Thank you for your consideration and support in these matters.

Thank you,


Mr. Greg Waterbury
Radiation Safety Officer
Laboratory Safety Manager

cc: Mr. Barry Schweitzer, Ph.D.

November 7, 2008

- Christine Stalder has worked for Invitrogen Corporation for 14 years, the last 10 in a supervisory capacity. Ms Stalder gained experience in the use of ^{32}P , ^3H and ^{33}P radioisotopes as a Manufacturing Associate and Manufacturing Team leader responsible for conducting enzymatic activity quality control assays, and later trained her manufacturing team to perform these assays. She was responsible for initial set-up of the radioisotope lab at Invitrogen's Carlsbad, CA manufacturing plant in conjunction with the radiation safety officer at that site. She currently leads the manufacturing effort at Invitrogen's Branford site and is responsible in this capacity for the safe use of ^{33}P by her team in assays to detect protein phosphorylation. Ms Stalder holds a BS in Biochemistry and Cellular Biology from the University of California, San Diego.
- Lisa Freeman-Cook is manager of ProtoArray R&D. She was trained as a radioisotope user at Carleton College (primarily ^3H and ^{32}P use), University of Colorado, Boulder (primarily ^{35}S and ^{32}P use), Yale University (primarily ^{32}P , ^{125}I , and ^{14}C use), and ProtoMetrix/Invitrogen (primarily ^{33}P use). She has been using radioisotopes in a research setting for 15 years and has supervised undergraduates, graduate students, post-doctoral fellows, and research scientists performing experiments with radioisotopes.
- Gregory Korbelt has worked for Invitrogen Corporation for 13 months, the last 4 in a supervisory capacity. Mr. Korbelt gained experience in the use of ^{35}S , and ^{125}I radioisotopes as a post-doctoral fellow at Harvard Medical School and the Whitehead Institute at the Massachusetts Institute of Technology. Mr. Korbelt has gained experience in the use of ^{33}P and ^3H radioisotopes during his employment with Invitrogen Corporation. He currently leads the Services team at Invitrogen's Branford site and is responsible in this capacity for the safe use of ^{33}P and ^3H by his team in assays to detect protein phosphorylation and small molecule-protein binding interactions, respectively. Mr. Korbelt holds a BA in Chemistry from Vanderbilt University and a PhD in Chemistry from Harvard University.

This is to acknowledge the receipt of your letter/application dated

11/7/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-30693-01)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142981.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader