

Certified Mail



December 1, 2004

Berlex Laboratories, Inc.

Dr. Sattar Lodhi
Nuclear Materials Safety Branch
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

6 West Belt
Wayne, NJ 07470-6806
Telephone: (973) 694-4100

REF: Berlex Laboratories, Inc. – Wayne, NJ
NRC License #29-30621-01

03035646

04
DEC -6 110:48
RECEIVED
REGION I

Dear Dr. Lodhi:

This is a request to amend our license to both add and delete authorized users at our Wayne, NJ facility and to remove Samarium 153 from our license. Following is the information in support of this amendment request.

Authorized User Addition –

Harish Champaneri – Harish Champaneri has been employed at Berlex Laboratories as a Chemist since May 1999. Harish is also part of the quality control function in the RAM laboratory and as such has worked in this laboratory here in Wayne under the direct supervision of other Authorized User's. Harish has undergone training in both the quality control functions of the laboratory and in radiation safety. Harish has been working with Tc99m as a solution eluted from a Mo99/Tc99m generator.

Harish has received his Master's degree in Organic Chemistry from South Gujarat University, India. Based upon the observations of the Authorized User's and myself, Harish is capable of working unsupervised in the RAM laboratory.

Training included:

- An introductory training session with the facility RSO to review the facility layout and the types of isotopes in use;
- A review of atomic structure, radiation, radioactivity, types of radiation and radiation sources in the typical Berlex lab environment;
- Radiation characteristics, the mathematical equations needed in the lab, and units of measure;
- Federal exposure limits, risk estimates, ALARA concept, dosimetry, film badge records, NRC 10 CFR 20 occupational dose limits, pregnancy declaration and lab technique;

136090

NMSS/RGNI MATERIALS-002

Dr. Sattar Lodhi
Nuclear Materials Safety Branch
December 1, 2004

- Warning labels, radiation signage, lab monitoring and personal responsibilities were reviewed;
- Contamination control, measurement, reduction techniques, use of survey equipment and dosimetry were also covered; and
- Posted Occupational Radiation Exposure Report location and data contained were also reviewed.

Harish was then allowed to work under controlled conditions and under full supervision of a qualified User for a 30-day period following this training to get hands on experience working with isotopes. When the User ascertained he had sufficient training and had demonstrated the skills needed to work safely without supervision, the User notified the RSO. The RSO conducted an in-lab review of the trainee's techniques in isotope handling, knowledge of lab environment conditions, use of monitoring equipment and training in contamination surveys following daily lab use. Proficiency was demonstrated and the RSO approved Harish for unsupervised lab work.

Please add Harish Champaneri as an Authorized User under the license at this facility.

Authorized User Deletion

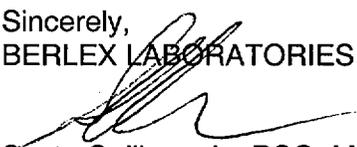
JC Santa Teresa, an Authorized User, has left the employ of Berlex Laboratories. Please remove his name as an Authorized User for the license at this facility.

Samarium 153 Deletion

In December 2002 a request was made to add Samarium 153 (Sm-153) to our license. Sm-153 was contained in a product marketed by Berlex. It was anticipated that we would be receiving up to 10 vials of this product, containing 150 mCi of Sm-153, in a typical week. We would be storing this product for up to 24-48 hours prior to shipping it offsite to other facilities. The December 2002 request was approved and the isotope was added to our license. However, we have never received any of this material and this product was sold to another manufacturer/marketer. Therefore, we request that Sm-153 be removed from our license.

If you have any additional questions, or require any further information, please contact me at 973-305-5408.

Sincerely,
BERLEX LABORATORIES



Santo Guillermain, RSO, Manager
Environmental Health and Safety

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

12/10/2008, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-30621-01 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** 136090.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 03620
: Status Code: 0
: Fee Category: 3M
: Exp. Date: 20110331
: Fee Comments: _____
: Decom Fin Assur Reqd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: BERLEX LABORATORIES, INC.
Received Date: 20041206
Docket No: 3035646
Control No.: 136090
License No.: 29-30621-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed M. A. Perkins
Date 12/10/04

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /___/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____