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October 14, 2008

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US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415
Attention: Elizabeth Ullrich

RECEIVED
REGION 1
2008 OCT 20 AM 11:04

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SUBJECT: BIORELIX, INC REQUEST FOR AN AMENDMENT TO NRC
LICENSE 06-31263-01 – Addition of four new radioisotopes

Dear Ms.Ullrich,

This letter is pertaining to BioRelix, Inc. NRC license 06-31263-01. We are asking to modify our current license to permit the use of H-3, P-33, S-35 and I-125 for the purpose of research and development at our New Haven facility...

Item: 5 Radioactive Material

Biorelix is requesting permission to possess the following radionuclides up to the indicated possession limits:

Radionuclide	Limit (mCi)	Chemical form
H-3	25	Any
S-35	25	Any
P-33	25	Any
I-125	5	Any

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NRC/RGN MATERIALS-002

We are requesting to be authorized to possess and use these new radionuclides in any chemical form. These radionuclides will generally be received from commercial vendors in liquid form, and most often will be nucleoside triphosphates, and other biological compounds commonly used in biomedical research.

In general, microcurie quantities of radioisotope will be used per experiment, most often in the range of 50-250 uCi. The possession limits requested above are to provide for possession of multiple chemical forms, having multiple experiments in progress at any one time, and to provide for storage of waste. For I-125, we will not be performing radioiodinations, but rather will only be using commercially available compounds labeled with I-125. Because only microcurie quantities of I-125 will be used per experiment, routine thyroid bioassays will not be necessary.

Item 8 Training

Current training will be modified to include safe handling information about the four new radionuclides to be possessed and used in the laboratories. Training regarding the four new radionuclides will be provided before workers begin use of the newly licensed materials.

Item 9: Equipment and Facilities

The new radioisotopes will be used in the same laboratory rooms as currently authorized for use. In addition to the equipment and facilities described in our prior application, we will obtain scintillation probes for some of our GM survey meters to have increased efficiency of detection of I-125 for radiation contamination surveys. The current radioactive waste room will be used to store waste generated from work involving the new radionuclides. The waste will be segregated in containers by radionuclide to facilitate waste management and disposal.

Item 10 Radiation Safety Program

- All personnel working with radioactive material in the laboratory will be supplied with a lab coat, and appropriate gloves. Safety goggles will be available, as will calibrated Geiger counters. Because tritium can not be detected using a GM survey meter, liquid scintillation counting of wipe tests will be performed. The main component of our

Radiation safety program will be post experimental laboratory surveys. These will include personal contamination surveys performed with a GM meter for workers who have handled beta emitters capable of being detected with the portable instrument.

- For P-33 and S-35 a pancake probe will be used. For I-125 surveys a scintillation probe will be used to perform the contamination surveys.
- Workers using such beta emitters will also perform limited area surveys to detect radioactive contamination. For workers using tritium wipe tests will be conducted at the end of each day in which tritium compounds were used.

In addition to the post experimental surveys, a comprehensive laboratory radiation contamination survey will be performed and documented monthly. These comprehensive monthly surveys will include both meter and LSC surveys.

Item 11: Waste Management.

The waste generated using the new radionuclides will be similar to the waste currently generated, that is, tubes, tips, gloves, bench paper and other typical biomedical waste items. The wastes will be collected in designated containers which are labeled as to specific radionuclide. Sharps will be collected in puncture resistant containers. Any liquid waste collected will be stored in plastic jugs which will also be appropriately labeled. Secondary containment will be provided for liquid waste jugs being held for decay in storage.

We would like to be authorized to use decay-in-storage for P-33, S-35 and I-125 compounds. In addition, we request permission to transfer any radioactive waste to authorized commercial waste facilities via authorized waste brokers. The waste may be sent for incineration, compaction, vitrification, burial or other licensed disposal methods or licensed waste disposal options. In addition, we are requesting permission to dispose of liquid radioactive waste via the sanitary sewer system as per 10 CFR 20. 2003. Any liquid waste that is disposed of via the sanitary sewer will be soluble or readily dispersible and biological in origin. Further, we are requesting permission to dispose of liquid scintillation vials under 10 CFR 20. 2005., with liquid scintillation counting vials containing only H-3 of less than 0.05 uCi/g being able to be disposed of without regard for their radioactive content.

If you have any questions or concerns please do not hesitate to contact us.

Sincerely,

Kenneth Blount, Dir of Biology
203.785.9282 ext 302


10/16/08

Izabela Puskarz, Laboratory Manager/RSO
203.785.9282 ext 305

 10/16/08

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

10/14/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-31263-01) 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** 142923.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.