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REGION 1

Innovative Healthcare Solutions

2005 SEP 23 PM 2:37

NM582

August 3, 2005

Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

03036545

Amendment request for NRC License #29-30906-01

Dear Sir/Madam,

Signum Bioscience requests an amendment to our material license to add Authorized Users, an additional laboratory, and authorization to conduct *in vivo* research.

The requested Authorized Users are Gopal Sarngadharan, David Fela, and Peter Wolanin. Their experience records are attached.

The laboratory where we wish to use licensed radioactive material is on the first floor of the building where we currently occupy our second floor laboratory. It is accessible only to Signum personnel. Any radioactive material transported between the two laboratories will be placed in leak-proof secondary containers. The first floor laboratory has a vinyl floor and non-porous bench tops. A floor plan is attached. Licensed material may be used in the areas labeled Lab 1 and Lab 2, but will not be used or stored in the area labeled "office". No licensed material will be discharged via the sinks. The entire area will be surveyed and posted the same as the second floor lab, as discussed in our initial license application.

*In vivo* research will be conducted in this laboratory on mice which will be housed in the room labeled "Cages". There is no vivarium staff. All handling of "tagged" animals as well as bedding changes, feeding, etc will be by the researchers. Special instructions for handling animals, attached, will be posted.

Thank you in advance for your time and effort. Do not hesitate to contact me at 732 329-6344 if you have any questions.

Sincerely,

Maxwell Stock

137726

NRC REGION 1 MATERIALS-002

### **Instructions for Radioactive Material Research Utilizing Animals**

1. All cages containing radio-labeled animals will have a "Caution - Radioactive Material" sign attached. The isotope, date of injection, and responsible researcher information will be provided on the label.
2. Animals treated with radioactive material should be housed separately from other animals.
3. Always wear lab coats, gloves, and eye protection when handling animals, cages, or bedding.
4. Double bag all bedding and waste from labeled cages, attach a "Caution - Radioactive Material" label, and consult with the RSO for proper disposal.
5. Survey hands and feet with the appropriate meter immediately after handling radio-labeled animals, cages, or bedding.
6. Survey the cage after cleaning. Results must be less than twice "background" prior to release for unrestricted use.

September 21, 2005

**Radiation Experience and Training**

**David Fela**

Please provide the names of the companies and/or universities where you worked with licensed material.

N/A

Provide the time period (from:, to:) when you worked at each facility.

N/A

Provide the maximum amount of activity per experiment as well as the maximum amount you may have possessed in his laboratory for each radionuclide you worked with.

N/A

Provide the duration of the training sessions you attended at places where you used radiated substances (i.e. Princeton, etc...) Include information on any radiation safety training he has received at Signum Biosciences.

Received radiation training at signum biosciences

**Peter Wolanin**

Please provide the names of the companies and/or universities where you worked with licensed material.

Princeton University. (also trained at University of Michigan, but never used isotopes)

Provide the time period (from:, to:) when you worked at each facility.

Princeton: from Sept 1, 2000, though Aug 31, 2005

Provide the maximum amount of activity per experiment as well as the maximum amount you may have possessed in his laboratory for each radionuclide you worked with.

$^{32}\text{P}$  : 0.25 mCi per experiment and 0.5 mCi total

$^3\text{H}$  : 0.25 mCi per experiment, 1 mCi total

Provide the duration of the training sessions you attended at places where you used radiated substances (i.e. Princeton, etc...) Include information on any radiation safety training he has received at Signum Biosciences.

Princeton: initial training: online ~ 1 hour plus 2 hours classroom. Yearly, 1 hour classroom refresher training

University of Michigan: 3 hours classroom training

Signum Biosciences, Inc. Radiation Safety Training

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

8/3/2005 (RECEIVED) and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 29-30906-01 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 137726.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.