

Pharmacopeia



September 12, 2007

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

NMSB2

03033542

RE: Amendment Request for NRC License # 29-30152-01

Dear Sir/Madam;

This letter represents a request to amend our NRC Materials License, No. 29-30152-01, in order to add Elizabeth Quadros to the authorized users listed in Section 11. A resume of her experience with radioactive materials is attached. Also, Doug Auld is no longer employed with us, so we would also request that he be removed from the list of authorized users

Please note that our company has changed its name from Pharmacopeia Drug Discovery, Inc. to Pharmacopeia, Inc. This is only a change of name, and does not represent a change in company ownership, personnel, location or the scope of work done using radioisotopes.

Please feel free to contact me at (609) 452-3700 for any questions regarding administrative issues. If you have any technical questions, please contact our Radiation Safety Officer, Robert Swanson, at (609) 452-3711.

Thank you in advance for your time and effort.

David M. Floyd, Ph.D.
Executive Vice President and Chief Scientific Officer

Attachment:
Resume of Elizabeth Quadros, Ph.D.

1410 75

NMSS/RGN1 MATERIALS-002

Elizabeth Quadros, Ph.D.

Research Experience Involving Radioactive Material

I have been a user of radioactive materials and Principal Investigator (supervisor of others using radioactive materials) for over 30 years, starting in 1973. The specifics of the isotopes used (all in the micro- to millicurie range) and the types of experiments performed are outlined below. In addition to laboratory work, I have served on Radiation Safety Committees and have continued to receive training updates throughout.

Specific Isotopes Used

1. ^{14}C

In vitro studies including binding, tissue and cellular uptake and permeation, using a variety of tissues including intestine, isolated hepatocytes, skin.

2. ^3H

In vitro studies including tissue and cellular uptake and permeation, using a variety of tissues including intestine, isolated hepatocytes, skin.

Radio-immunoassays for prostanoids, using small quantities of ^3H -labelled tracers.

3. ^{125}I

Radio-immunoassays for prostanoids, using small quantities of ^{125}I -labelled tracers.

4. ^{51}Cr

In vivo intestinal permeability studies in the rat. ^{51}Cr -EDTA is administered orally to rats maintained in metabolic cages and urine and faeces are collected. Preliminary experiments involved mass balance studies to select time of collection of samples. Routine experiments included 24-hour urine collections for measurement of radioactivity.

Training

I have received training in the handling, use, monitoring and disposal of radioactive materials at all the institutions where I have worked, including the Universities of Sheffield and London in the UK, Scripps Clinic and Research Foundation, La Jolla, CA, SUNY Brooklyn, Ciba-Geigy, Ardsley, NY and Summit, NJ, Novartis, East Hanover, NJ, and Pharmacopeia, Cranbury, NJ. I have received annual refresher courses since 1987, when I joined the pharmaceutical industry.

Radiation Safety Committees

I was a member of the Ciba-Geigy Radiation Safety Committee and participated in the writing of the Radiation Safety Manual for the Ardsley site, pending the hiring of a full-time RSO. I acted as Chairperson of the Novartis Radiation Safety Committee from 2003-2004.

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

9/12/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Att. GND. 29-3d52-01
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** 141075.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.