



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

NOV 6 2009

Food and Drug Administration
Mail Stop HFS-657
5100 Paint Branch Parkway
College Park, MD 20740-3835

Ms. Elizabeth Ullrich, CHP
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
Division of Nuclear Material Safety
Commercial and R&D Branch
475 Allendale Road
King of Prussia, Pennsylvania, 19406-1415

Br. 2

NRC License No. 19-30771-01
Docket No. 03036120

2009 NOV 10 AM 11:01

RECEIVED
REGION 1

RE: NRC License Amendment Request

This letter is to confirm the telephone conversation of October 29, 2009 between Ms. Elizabeth Ullrich, CHP, U.S. Nuclear Regulatory Commission, Region 1 and Ms. Constance Sims Rosser, U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) regarding a change in CFSAN's Radiation Safety Officer.

Ms. Rosser has accepted a new position outside of FDA and will be leaving effective November 20, 2009.

Pending your approval, I have designated Mr. Peter Doob to serve as the CFSAN Radiation Safety Officer effective November 17, 2009. A Radiation Safety Officer Delegation of Authority letter for Mr. Doob is enclosed.

Mr. Doob is a member of our Safety Management Team and has extensive experience in the radiation safety field.

Mr. Doob served as the Radiation Safety Officer for the National Institute on Drug Abuse, National Institutes of Health (NIH) from 1989 to 2006. In that capacity, he was responsible for a Type B broad scope license covering approximately 200 incoming shipments per annum, 85 authorized users, 45 posted areas, and a wide variety of R&D radionuclides.

In addition, Mr. Doob served from 1982 to 1989 as the Radiation Safety Training Officer, NIH, under its Type A broad scope license and from 1980 to 1982 was engaged as a health physicist for the Radiation Safety Branch, NIH, under the same license.

In his work in the above positions, Mr. Doob handled, supervised or was responsible for the handling of H-3 (100 mCi), C-14 (3 mCi), S-35 (5 mCi), P-32 (20 mCi), nonvolatile I-125 (100 uCi), P-33 (1 mCi), Co-57 (5 mCi), Cs-137 (12 mCi), F-18 (1 Ci), Th-228 (4 mCi), and I-125 as sodium iodide (10 mCi).

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NRC/RCM MATERIALS-002

Page 2 – Ms. Elizabeth Ullrich, CHP

Mr. Doob has been responsible for the safe operation of radioiodination facilities (I-125), a Th-228/Pb-212 generator, a Cs-137 irradiator, and a cyclotron with co-located positron emitter radiochemistry and imaging facilities. He has created and operated a successful decay-in-storage program, and has extensive experience providing radiation safety training for laboratory workers and support service providers.

Mr. Doob holds degrees in biology (BA, Johns Hopkins University, 1969), public health (MSPHA, Johns Hopkins School of Public Health, 1972), and law (JD, George Washington University, 1976).

The organizational management structure between the Executive Management Representative and the Radiation Safety Officer remains the same as the structure provided in our October 10, 2008 letter.

Should you have any questions on this matter, please contact me at (301) 436-2114 or Mr. James Zelinsky at (301) 436-1599.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas D. Williams', with a stylized flourish at the end.

Thomas D. Williams, M.B.A.
Executive Officer for the Center for Food Safety and
Applied Nutrition

Enclosure



Memorandum

Date: NOV 6 2009

From: Director, Office of Management Systems, Center for Food Safety and Applied Nutrition, HFS-657

Subject: Delegation of Authority for Radiation Safety Officer

To: See Below

Effective November 17, 2009, Mr. Peter Doob will serve as the CFSAN Radiation Safety Officer and will be responsible for ensuring the safe use of byproduct material.

The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material. Mr. Doob is hereby delegated the authority necessary to meet these responsibilities.

Mr. Doob has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with Nuclear Regulatory Commission requirements.

Mr. Doob can be contacted at (301) 436-2178 or at peter.doob@fda.hhs.gov.



Thomas D. Williams, M.B.A.

Addressees:
Authorized Radionuclide Users
CFSAN Leadership Team
CFSAN Radiation Safety Committee
CVM Safety Manager
FDA Safety Manager

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

11/6/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (19-30771-01) 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** 144283.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.