



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

July 25, 2014

Farrah C. Gaskins, Health Physicist
U.S. Nuclear Regulatory Commission
Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Br. 2
03036120

REC'D 1073114M0704

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

RE: NRC License Amendment Request

This correspondence is a request for a license amendment regarding a change in Radiation Safety Officer at the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN).

Pending your approval, I have designated Mr. Charles Watts to replace Mr. Peter Doob as an authorized user (License Condition 11.A) and as the CFSAN Radiation Safety Officer (License Condition 11.G) effective July 25, 2014. A Radiation Safety Officer Delegation of Authority letter for Mr. Watts is enclosed. This change in Radiation Safety Officer is due to Mr. Doob's retirement from Federal service.

Mr. Watts is a principal owner of Clym Environmental Services and is under contract to FDA CFSAN for radiation safety support services and has over twenty years of hands-on radiation safety experience.

During this time, he has served as the interim radiation safety officer for a large research licensee (200 users), a radioactive and mixed waste manager, an Authorized User on multiple licenses and has provided years of health physics consulting and radiation safety training to clients throughout the country. His experience includes management of a radioanalytical laboratory, an outsourced radiation safety officer, and manager of a service provider license (leak tests, decommissioning services and instrument calibration). He has also been involved with CFSAN's radiation safety program since the early 1990's.

Mr. Watts holds a degree in Environmental Management (BS, University of Maryland University College) and has received hundreds of hours of training in radiation safety related disciplines.

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He has safely handled many radionuclides in varying activities, including 3H (100 mCi), 14C (100 mCi), 32P (50 mCi), 33P (10 mCi), 35S (50 mCi), 125I (100 mCi), 51Cr (50 mCi), 137Cs (50 mCi), 226 Ra (50 mCi) and 63Ni (100 mCi) among others. He has managed research license operations, large scale decommissioning projects, waste management programs and currently serves as an Authorized User on Clym Environmental Services, LLC State of Maryland radioactive materials license.

His 20 plus year relationship with the CFSAN radiation safety program has provided him extensive familiarity with CFSAN's research community, procedures and facilities; this coupled with his extensive experience will provide for a smooth transition between Radiation Safety Officers.

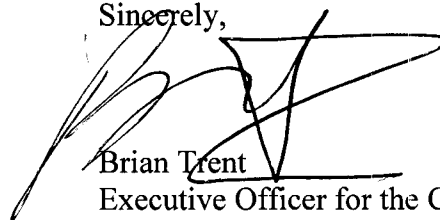
Mr. Watts will be onsite on a regular and re-occurring basis (e.g., 2-4 times per month) and as needed to fulfill his responsibilities as the Radiation Safety Officer. In addition, Mr. Watts will be available to the staff via cellphone and email. He currently does not serve as a contract Radiation Safety Officer for any other entities.

Mr. Watts will report to and coordinate his Radiation Safety Officer duties with CFSAN's Occupational Safety and Health Manager, Mr. James Zelinsky.

The organizational management structure between the Executive Management Representative and the CFSAN Occupational Safety and Health program remains the same as the structure provided in our current license amendment.

Should you have any questions on this matter, please contact me at 240-402-2471 or Mr. James Zelinsky at 240-402-1599.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Trent", is written over a horizontal line.

Brian Trent
Executive Officer for the Center for Food Safety and
Applied Nutrition

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: July 25, 2014

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

Subject: Delegation of Authority for Radiation Safety Officer

To: See Below

Effective July 25, 2014, Mr. Charles Watts, Clym Environmental Services, will serve as the CFSAN Radiation Safety Officer and will be responsible for ensuring the safe use of byproduct material.

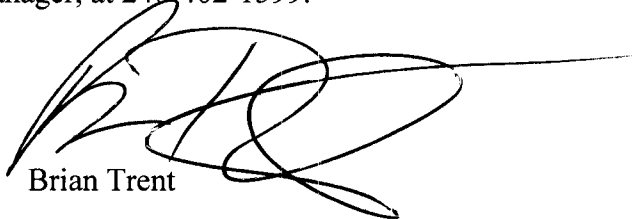
The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material.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

Mr. Watts 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. Watts can be contacted at 301-694-6000 (office), at 410-320-2344 (cell) or via email at cwatts@clymenvironmental.com.

The Radiation Safety Officer role will continue to be aligned with the CFSAN Office of Management, Safety Management Team.

If you have any questions regarding this matter, please contact James Zelinsky, CFSAN Occupational Safety and Health Manager, at 240-402-1599.



Brian Trent

Addressees:
Authorized Radionuclide Users
CVM Safety Manager
FDA Safety Manager
FDA Radiation Safety Officer

This is to acknowledge the receipt of your letter application dated

7-25-14, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amend: 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** 584498.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.