

Walt, Geralyn

From: Burkhardt III, William <William.Burkhardt@fda.hhs.gov>
Sent: Monday, December 28, 2015 5:07 PM
To: Lawyer, Dennis
Cc: Charles Watts (cwatts@clymenvironmental.com); Zelinsky, James A; Plakas, Steven M; Calci, Kevin R; El Said, Kathleen R
Subject: [External_Sender] NRC License Amendment Request
Attachments: RSO Delegation of Authority Watts GCSL December 2015 BB signed.pdf; FDA NRC License Amendment Request_Dennis Lawyer_BB Signed.pdf
Importance: High

Good Afternoon Dennis-

I thank you for the guidance that you provided us on how to proceed in amending our NRC License necessitated by the impending retirement of our facilities RSO, Dr. Steven Plakas. Please find attached a signed copy of the Amendment request as well as a Memo that will be shared with FDA/CFSAN Safety and the staff at FDA's Gulf Coast Seafood Laboratory notifying them of a change in the RSO for the facility.

I am hopeful that you will find that the request for amendment agreeable.

Thank you and have a great day.

Bill

CAPT William Burkhardt III, Ph.D.
Director, Division of Seafood Science and Technology
Office of Food Safety, CFSAN, FDA

1 Iberville Drive
Dauphin Island, AL 36528
251-406-8125
251-454-0088 BB

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NMSS/RGN1 MATERIALS-002



Food and Drug Administration
Gulf Coast Seafood Laboratory
1 Iberville Drive
Dauphin Island, AL 36528-0158
(251) 406-8125

December 28, 2015

Dennis R. Lawyer, Health Physicist
U.S. Nuclear Regulatory Commission
Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

RE: NRC License Amendment Request
NRC License No. 01-15770-01

Dear Mr. Lawyer,

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

Pending your approval, I am designating Mr. Charles Watts to replace Dr. Steven Plakas as the CFSAN GCSL Radiation Safety Officer effective January 1, 2016. A Radiation Safety Officer Delegation of Authority letter for Mr. Watts is enclosed.

This change in Radiation Safety Officer is due to Dr. Plakas' pending retirement from Federal service effective December 31, 2015.

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.

In addition, Mr. Watts currently serves as the Radiation Safety Officer at CFSAN's College Park and Laurel, Maryland facilities (NRC License 19-30771-01) and is intimately familiar with the GCSL facility, operations and staff through his current consulting role. He currently does not serve as a contract Radiation Safety Officer for any other entities other than at the aforementioned CFSAN Maryland facilities.

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.

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), 226Ra (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.

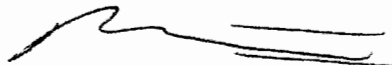
Mr. Watts will be onsite at GCSL at least quarterly for a personal review of the operations and will review and approve all surveys, documents and actions including spill and emergency response actions remotely.

Ms. El Said is an FDA employee who is onsite at GCSL and is currently an Authorized User with decades of experience with our program and with licensed materials. In her role as Assistant Radiation Safety Officer, Ms. El Said would handle day to day radiation safety responsibilities and respond to any emergency situations locally.

Given our limited use of radioactive materials, I feel the proposed arrangement coupled with both Mr. Watts' and Ms. El Said's experience and expertise will serve us well.

Should you have any questions on this matter, please contact me at 251-406-8125 or William.burkhardt@fda.hh.gov.

Sincerely,



CAPT William Burkhardt III, Ph.D.

Director

OFS/Division of Seafood Science & Technology

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: December 28, 2015
From: Director, Division of Seafood Science and Technology
Subject: Delegation of Authority for Radiation Safety Officer
To: CFSAN/OFS/DSST Staff
CFSAN Safety

Effective January 1, 2016, Mr. Charles Watts, Clym Environmental Services, will serve as the CFSAN GCSL 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.

In addition, Ms. Kathleen El Said will serve as the Assistant Radiation Safety Officer for DSST in addition to her current role as an Authorized User of radioactive material.

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.

If you have any questions regarding this matter, please contact me at 251-406-8125 or William.burkhardt@fda.hhs.gov

A handwritten signature in black ink, appearing to read "William Burkhardt III".

CAPT William Burkhardt III, Ph.D.
Director
OFS/Division of Seafood Science & Technology

This is to acknowledge the receipt of your letter application dated

12-28-15, and to inform you that the initial processing which includes an administrative review has been performed.

Amend : 01-15770-01
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 589818.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader