

Emergency Response Network (FERN)

Opportunity Reference Code: FDA-ORA-2019-0005

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-ORA-2019-0005

How to Apply A complete application consists of:

- An application
- Transcripts Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation. Your application will be considered incomplete, and will not be reviewed, unless one recommendation is submitted.

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 10/10/2019 3:00:00 PM Eastern Time Zone

Description *Applications will be reviewed on a rolling-basis.

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Winchester Engineering and Analytical Center (WEAC) located in Winchester, Massachusetts.

Proven analytical methods and proficient laboratories are essential for implementing food defense and safety measures under Food Safety Modernization Act. With growing risks posed by global aging nuclear facilities and widespread use of radioactive materials, FDA faces increasing challenges in safeguarding the nation's food supply from radioactive contaminations that may arise from nuclear accidents or acts of nuclear terrorism. In the aftermath of a large-scale nuclear or radiological incident, FDA relies on its Food Emergency Response Network (FERN) to gather radioanalytical data from analyzing a wide variety of foods for risk assessment and decision making. In view of diverse radioanalytical methods used by FERN radiological laboratories at different levels of experience, assessments of method acceptability and laboratory proficiency with respect to FERN's data quality objectives are of vital importance for preventing emerging radioactive contamination of food from evolving into large scale emergency as well as for enhancing emergency response and recovery efforts. Despite its importance, development and validation of radioanalytical methods for detecting radioactive contaminants in foods are often constrained by lack of food-based radioactive standards fitting specific methodological needs. The lack of suitable food-based proficiency test samples also makes it difficult to assess laboratory proficiency. To overcome the challenges, Winchester Engineering and Analytical Center (WEAC) in collaboration with the Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Science (ORS) is developing a performance-based radiological proficiency testing program, which enables FERN member laboratories to demonstrate proficiency with their chosen





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methods. The program will provide various fit-for-purpose food testing materials in different radionuclide/matrix combinations to support mission-critical methodology development, evaluate member laboratory proficiency, and identify essential training needs.

In this research project, the selected participant will design and apply various purpose-driven proficiency test schemes to address specific needs in methodological researches and laboratory competency evaluation for detection of radioactive contaminants in foods. The participant will collaborate with interdisciplinary scientists at WEAC in all phases of the program development and have opportunities to learn about FDA regulatory processes. Under the guidance of a mentor, the specific research activities will include but not be limited to:

- Develop and validate various sample preparation protocols for production of a broad range of food-based radiological testing materials
- Prepare food-based testing materials for screening and quantification of radionuclides by radiometric techniques including gamma spectrometry, liquid scintillation counting, alpha spectrometry, gas-flow proportional counting, etc.
- Develop supplemental instrument calibration methods for determination of accuracy, homogeneity, and stability of unconventional food-based testing materials
- Perform radioanalytical analysis to verify the quality and acceptability of proficiency testing materials
- Study novel and alternative approach to enable assessment of radioanalytical method and laboratory performance when physical foodbased testing material is nonexistent
- Improve preparation techniques and quality control in production of a wide range of food-based testing materials for radionuclide analysis
- Apply appropriate statistical analysis techniques to gain insights and better understanding of complex data gathered from interlaboratory comparison studies
- Collaborate with scientists in the field to address current challenges and needs in development of radioanalytical methods and production of food-based proficiency testing materials
- Formulate problem-solving solution to eliminate methodological deficiency or non-conforming laboratory performance identified by interlaboratory comparison study
- Establish effective feedback process supported by both post-event discussion and targeted training
- Contribute to the preparation of written-form standard operating procedures for preparation and verification of food-based radioactive testing materials
- Participate in the development of a relational database to enable easy access, management, analysis, and visualization of data and information collected from a broad range of project activities
- Present research findings at national and/or international scientific meetings
- · Author peer-reviewed journal articles



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This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. The annual stipend will be \$81,072 and a training/travel allowance of \$2,500 will also be provided. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Winchester, Massachusetts, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should have received a bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- · Strong background in instrumental analysis, sample preparation for chemical analysis, and spectrometry techniques
- · Experience with low-level radioactivity
- · Skills in developing database application
- · Experience measuring low-level radioactivity in complex matrices
- · Excellent written and verbal communication skills
- · Ability to convey ideas and concepts to non-scientific audiences

Eligibility • Degree: Bachelor's Degree, Master's Degree, or Doctoral Degree



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Requirements

received within the last 60 month(s).

- Discipline(s):
 - Chemistry and Materials Sciences (5_●)
 - Communications and Graphics Design (1...)
 - Computer, Information, and Data Sciences (2_●)
 - o Engineering (1_●)
 - Life Health and Medical Sciences (5_♥)
 - Mathematics and Statistics (1_●)
 - Other Non-Science & Engineering (1.●)
 - Physics (4_●)
 - Social and Behavioral Sciences (1_♥)