



OCTOBER 11, 1991

United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

Attn: John D. Kinneman, Chief  
Nuclear Materials Safety Section B  
Division of Radiation Safety and Safeguards

Dear Mr. Kinneman:

Subject: Routine Inspection No. 030-03917/91-001

I would like to take this opportunity to respond to the recent correspondence dated September 18, 1991.

With respect to the Notice of Violation listed in Appendix A, the following course of action has been taken by the Safety Management Branch, Center for Food Safety and Applied Nutrition (CFSAN) in order to be in compliance with the U.S. NRC regulations and conditions of our license. (Enclosure A)

The Food and Drug Administration being a regulatory agency, encourages and indeed welcomes a review of their Radiation Safety Program. If there is a need to discuss this matter further, please contact Ms. Doris Waddick or Michael S. Terpilak at (202) 245-1281.

Thank you for your utmost cooperation and attention in this matter.

Sincerely yours,

Bradley Rosenthal  
Director  
Office of Management  
Center for Food Safety  
and Applied Nutrition

Enclosure

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PDR FOIA  
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Enclosure A

Item A

Refrigerators containing licensed material, located in an unrestricted corridor at the Beltsville Research Facility, were not locked and were not under constant surveillance and immediate control by the licensee.

Corrective Action:

The licensed material is presently being consolidated in refrigerators that are currently secured and locked. In addition, these refrigerators are under constant surveillance and immediate control by the licensee.

In the future all licensed material shall be placed in the refrigerators that shall be secured and locked and under constant surveillance and immediate control of the licensee.

Full compliance of this item will be completed by November 1, 1991.

Item B

Condition 20 of the FDA License requires that principal radioisotope users maintain a running inventory, including receipts and disposal, for each radionuclide possessed.

Corrective Action:

A training program in Radiation Safety was conducted by Michael S. Terpilak on September 23, 1991. A total of 28 Principal Investigators and Users of Radioisotopes attended this training seminar. An agenda of the training program conducted is enclosed. (Attachment A)

Emphasis on maintaining a running inventory including receipt and disposal of licensed materials was stressed. A written examination was required at the completion of the training program. (Attachment B)

In addition, a revised CFSAN Radiation Safety Program Manual issued in April, 1991 which reflects current Health Physics procedures and protocols is enclosed. (Attachment C)

Future training for other Principal Investigators and Users of Radioisotopes is scheduled for November 1991.

Training will be conducted during FY 1992 until all individuals using radioisotopes have received this training.

In addition, a 2 1/2 day Basic Radiation Safety Program is being developed and will be conducted during FY 1992 for all new Principal Investigators and Users of Radioisotopes authorized under our license.

Full compliance of this item will be completed by September 30, 1992.

Item C

Records of activity concentrations and total activity released to the sanitary sewerage systems were not maintained or compared to release limits to assure compliance with 10 CFR 20.303.

Corrective Action:

Records of activity concentrations and total activity released to the sanitary sewerage system are presently maintained in compliance with 10 CFR 20.303.

Full compliance of this item was completed by September 1, 1991.

Item D

10 CFR 19.11(a) and (b) require that current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments, and operation procedures be posted or that a notice describing these documents and where they may be examined be posted or that a notice describing these documents and where they may be examined be posted. 10 CFR 19.11(c) requires that Form NRC-3, "Notice to Employees", be posted. Neither the documents nor the notices were posted in sufficient number at the Beltsville Research Facility and the Center for Veterinary Medicine.

Corrective Action:

The above documents and notices have been posted in sufficient number at the Beltsville Research Facility and the Center for Veterinary Medicine.

Full Compliance of this item was completed by August 1, 1991.

AGENDA  
ANNUAL TRAINING PROGRAM FOR  
CFSAN RADIONUCLIDE USERS  
SEPTEMBER 23, 1991

Course Moderator and Instructor:

Michael S. Terpilak,  
Certified Health Physicist

<u>TIME</u>	<u>SUBJECT</u>
9:00 - 9:15 am	Preview of Training Program
9:15 - 10:00 am	FDA - NRC License and Special Conditions
10:00 - 10:15 am	Coffee Break
10:15 - 11:00 am	NRC Regulatory Guides Reg guide - 8.13 (Instruction concerning prenatal radiation exposure)  Reg guide - 8.29 (Instruction concerning risks from Occupational Radiation Exposure)
11:00 - 12:00 am	Radiation Monitoring, Survey and Recordkeeping Requirements  Reg Guide - 8.23 (Radiation Safety Surveys at Medical Institutions)
12:00 - 1:00 pm	Lunch
1:00 - 2:00 pm	Contamination Monitoring and Decontamination Techniques

2:00 - 3:00 pm  
Disposal

Low Level Radioactive Waste  
and Mixed Waste

2:45 - 3:00 pm

Coffee Break

3:00 - 3:45 pm

Current and Proposed  
Federal and State Regulations

3:45 - 4:00 pm

Examination

4:00 - 4:15 pm

Course Closing and Evaluation

RADIATION SAFETY TRAINING REFRESHER  
PROGRAM  
EXAM  
SEPTEMBER 23, 1991

1. The Code of Federal Regulations Title 10 Part 19 deals with what topic?
  
2. The Code of Federal Regulations Title 10 Part 20 deals with what topic?
  
3. Define the term risk?

What is the risk associated with a occupational radiation exposure of 5 REM in any one year?

4. As a Principal Investigator, describe the techniques used in your laboratory to conform with the ALARA principle.
  
5. What is the current permissible radiation exposure per year to an occupational worker?
  
6. What is the current permissible radiation exposure per year to a member of the general public?



7. Define the term "Mixed Waste"?
  
  
  
  
  
  
  
  
  
  
8. List the various types of "WASTE MINIMIZATION" Techniques presently in use?
  
  
  
  
  
  
  
  
  
  
9. What is the APPALACHIAN COMPACT?
  
  
  
  
  
  
  
  
  
  
10. Provide any suggestions and how the CFSAN SAFETY OFFICE can improve the Radiation Safety Program at its facilities?



## Memorandum

Date April 8, 1991

From Radiation Safety Office

Subject Update of Standard Operating Procedures for the Use of Radioactive Materials

To Principal Investigators

Attached is your copy of the updated FDA/CFSAN Standard Operating Procedures for the Use of Radioactive Materials. All employees involved in radiation activities are required to follow specific procedures regarding the possession and use of radioactive material.

Insert this attachment in section three of your Radiation Safety Handbook. Disgard the outdated "General Rules for Radionuclide Laboratories."

Please note four major changes to the Standard Operating Procedures:

1. Page 5 - Item 4. The Principal Investigator is responsible for performing laboratory surveys for radioactive contamination each time radioactive materials is used and documenting the results in their Radiation Safety Notebook.
2. Page 7, B.I. DO NOT place containers from food or drink consumed elsewhere into the posted labs trash can. It will be noted as presumptive evidence of eating or drinking in the lab.
3. Page 7, B. 2. Storage of food or drink is prohibited in posted labs, refrigerators freezers and cold rooms used for work or storage of radioactive materials.
4. Page 19. III Liquid Scintillations Vials: The tray should be labeled with the radionuclide, the activity, the name of the cocktail or the chemical constituent, the name of the Principal Investigator and the date.