DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

APR 21 1994

United States Nuclear Regulatory Commission
Washington , D.C. 20555
ATTN; Document Control Desk
Docket No 030-03917
License No. 08-00482-03 (Broad Scope)

SUBJECT: Reply to a Notice of Violation

Dear Sir:

In response to your letter of March 23, 1994 are attached the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) actions taken to correct the violations identified in your routine inspection of March 1 through 4, 1994. The inspection (No. 030-03917/94-001) was conducted by Ms. Sheri Arrendondo from the Region I office. The inspection identified activities that were not in full compliance with NRC requirements. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations were presented in Appendix A of the letter and identified as "NOTICE OF VIOLATION"

Appendix A of this letter responds to the violations identified by (1) stating the reason for the violation as presented in your letter of March 23,1994, (2) identifying corrective steps that have been taken and the results achieved, (3) identifying further measures that have been taken (or are being taken) to avoid further violations and (4) dates when CFSAN anticipates full compliance.

The Center top management has taken an aggressive approach to correcting the violations and to revising and updating its Radiation Safety Program to assure compliance with all NRC license requirements. This includes authorization to hire an additional health physicist and the dedication of funds to provide contract support to the program. In addition, the Center expects to publish a formal revised Radiation Safety Protection Manual in fall of 1994 and to be in full compliance through full implementation of the program by the first quarter of 1995. I hope you will find the actions taken to be responsive to the specific violations as well as our overall assurance that our program will remain in compliance with NRC standards.

Sincerely yours,

Janice F. Oliver

Janice F. Oliver
Acting Deputy Director
for Systems and Support
Center for Food Safety
and Applied Nutrition

220076

JEO1

Enclosure:
Appendix A; Response to Notice of Violation

cc:
NRC Regional Administrator, Region I
Fred R. Shank, Director, CFSAN
James F. Trickett, Director, Office of Management, CFSAN
James P. McKenna, Director, Division of Management Services & Policy, CFSAN
Dorie Waddick, Radiation Safety Officer, CFSAN,
Michael S. Terpilak, Certified Health Physicist, CFSAN
James T. Tanner, Chair, Radiation Safety Committee, CFSAN
Naresh Chawla, Director, FDA Safety Office

APPENDIX A

RESPONSE TO NOTICE OF VIOLATION

Department of Health & Human Services
Washington, DC 20204

Docket No. 030-03917
License No. 08-00482-03

During an NRC inspection conducted on March I through 4, 1994, violations of NRC requirements were identified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C. The violations and the corrective actions taken are listed below:

A. Violation: Condition No. 20 of License No. 08-00482-03 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the letter dated October 26, 1987.

Item 11. f. of this letter requires, in part, that areas in which monthly wipe test results are greater than 1000 dpm be cleaned and rechecked following cleanup.

Contrary to the above, from July 1991 to March 4, 1994, areas in which monthly wipe test results are greater than l000 dpm were not cleaned and rechecked following clean-up. Specifically, although the licensee performed monthly wipes, they did not routinely follow-up on all required areas to clean and/or rewipe.
This is a Severity Level IV violation (Supplement VI).

1. Reason for the Violation: The Center during the cited period employed a single Certified Health Physicist to administer the day-to-day operations of the Radiation Safety Program. Due to this person's heavy workload in the Center and his additional significant responsibility serving as the Low Level Radioactive Waste Coordinator for the Agency, as well as technical advisor for FDA on an environmental assessment project, all the wipe tests were not followed-up as required.

2. Corrective Action: Through a contract initiated with Ecology Services Inc. (ESI) all rooms using radioactive materials have been identified and an updated master list of rooms prepared. In March ESI conducted wipe tests and a compliance check in all the rooms on the master list. No rooms had wipe test results greater than 1000 dpm (≤100 dpm actual). ESI has been instructed to immediately contact the Radiation Safety Staff when wipe tests result are found in levels greater than 1000 dpm so that prompt follow-up action can be taken.

3. Follow-up Action(s): New written procedures are being prepared to formalize monthly wipe testing to include follow-up procedures. The procedures will be included in a formal CFSAN Radiation Safety Protection Program Manual.

4. Full Compliance Date: All rooms and areas have been wipe tested. No decontamination follow-up actions were necessary. *Violation A, identifying lack of routine follow-up to monthly wipe tests is, as of the date of this letter, in full compliance.*

B. Violation: License Condition No. 12 requires, in part, that sealed sources and detector cells be tested for leakage and/or contamination at intervals not to exceed 6 months.

Contrary to the above, as of March 4, 1994, sealed sources and detector cells were not tested for leakage and/or contamination at intervals not to exceed 6 months. Specifically, several sealed sources were not leak tested during the period from July 19, 1991 to March 4, 1994, an interval greater than 6 months.
This is a Severity Level IV violation (Supplement VI).

1. Reason for the Violation: The Center during the cited period employed a single Certified Health Physicist to administer the day-to-day operations of the Radiation Safety Program. Due to this person's heavy workload in the Center and his additional significant responsibility serving as the Low Level Radioactive Waste Coordinator for the Agency, as well as technical advisor for FDA on an environmental assessment project, several sealed sources were not leak tested every six months as required.

2. Corrective Action: Through the contract initiated with ESI an updated master inventory of sealed sources was prepared in March. ESI completed leak testing of all sealed sources on the master inventory in late March and identified sources that were leaking. Six leaking sources were identified (two ^{226}Ra (@ $\leq 7 \times 10^{-4}$ µCi) and four ^{63}Ni (@ $\leq .001$ µCi). The Center through ESI has taken steps to contain and place the leaking sources under the control of the Radiation Safety Office.

3. Follow-up Action(s): The Center will maintain a contract to leak test all sources every six months, and to contain and control any sources that are found to be leaking.

4. Full Compliance Date: All sources identified have been leak tested. *Violation B, identifying the lack of sealed source leak testing is, as of the date of this letter, in full compliance. The leaking sources will be properly contained, controlled, and stored by mid May. Arrangements are in progress to dispose of the leaking ^{63}Ni sources at Barnwell, SC by June 1, 1994. The ^{226}Ra sources will be stabilized and stored on-site (at FB#8) until disposal options become available.*

C. Violation: License Condition No. 17 requires, in part, that the licensee conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

Contrary to the above, as of March 4, 1994, the licensee did not conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Specifically, several sealed sources were not physically inventoried from July 19, 1991 to March 4, 1994, an interval greater than six months. This is a Severity Level IV violation (Supplement VI).

1. Reason for the Violation: The Center during the cited period employed a single Certified Health Physicist to administer the day-to-day operations of the Radiation Safety Program. Due to this person's heavy workload in the Center and his additional significant responsibility serving as the Low Level Radioactive Waste Coordinator for the Agency, as well as technical advisor for FDA on an environmental assessment project, a physical inventory of sealed sources was not updated every six months as required.

2. Corrective Action: As noted in Corrective Action B.2. above a master inventory of all sealed sources has been prepared by conducting a room-to-room physical search of all facilities under the license. All sources identified in the 1991 inventory as well as those obtained since have been accounted for in the updated master list. New written procedures have also been prepared to address the "Ordering, Receipt, & Surplus of Equipment Containing Radioactive Sealed Sources" These procedures will assure all sources are identified and accounted for on a master sealed source list.

3. Follow-up Action(s): The new procedures will be incorporated into the CFSAN Radiation Safety Protection Program Manual. The new health physicist to be hired will have responsibility to conduct a physical inventory of all sealed sources every six months.

4. Full Compliance Date: The Center has accounted for all sealed sources identified in the master inventory. *Violation C: identifying the lack of a physical inventory is, as of the date of this letter, in full compliance.*

D. Violation: 10 CFR 20.1101 (a) requires, in part, that the licensee document a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

Contrary to the above, as of March 4, 1994, the licensee did not document a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

Specifically, the radiation protection program was not documented in that the licensee's radiation protection program does not include written procedures such as a pregnancy policy, dosimetry issuance and assessment procedures or bioassay procedures. This is a Severity Level V violation (Supplement IV).

1. Reason for the Violation: The Center has in place written procedures documenting the Radiation Safety Protection Program and NRC requirements prior to January 1, 1994. Contractual arrangements to develop and implement the new regulations (CFR 10 Part 20) prior to January 1, 1994, were delayed due to unanticipated complexities in fiscal year funding and the establishment of a formal Interagency Agreement (IAG). In addition, the Center was under the initial impression that the entire 10 Part 20 requirements had to be developed prior to implementation of any individual requirement.

2. Corrective Action: The Center is in the process of contracting, through the FDA Safety Office, for the preparation of a CFSAN Radiation Safety Protection Program Manual. The manual in being prepared through an Interagency Agreement with the Department of Energy (DOE) through Martin Marietta who is in the process of establishing a subcontract to prepare the Manual. The manual will contain the written policies and procedures and will serve to formally document the program. It will contain all the required provisions of CFR 10 Part 20 to include:

(1) Implementation of an As Low As Reasonably Achievable (ALARA) program,
(2) Pregnancy declaration policy,
(3) Procedures for shipment and handling of radioactive materials,
(4) Release of effluent to the sewer policy,
(5) Security procedures for laboratories using radioactive materials,
(6) Internal dose methodology policy,
(7) Emergency response notification procedure,
(8) Quality Assurance procedures to monitor researcher's compliance with the program.

3. Follow-up Action(s): A formal agreement for preparation of the manual is expected in May with completion of the manual projected for the fall of 1994. As an interim step, the Center has contracted with ESI for the development of generic guidelines for implementation by mid May. These guidelines, as well as the formal manual, will provide the basis for training managers as well as researchers.

4. Full Compliance Date: *As noted above interim written procedures are expected to be in place in May with an annual refresher training course scheduled for June, 1994. The training will include instruction on the CFR 10 Part 20 requirements using the generic guidelines. The formal manual will be developed by the fall of 1994. Full implementation will take place immediately thereafter.*