

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Reports No. 030-02640/94001(DRSS);
No. 030-31605/94001(DRSS) and No. 030-32479/94001(DRSS)

Dockets No. 030-02640; No. 030-31605 and No. 030-32479

Licenses No. 34-00293-02; No. 34-00293-14; and No. 34-00293-15

Licensee: The Ohio State University
Columbus, Ohio

Meeting Date: March 7, 1994

Meeting At: Region III Office, Lisle, IL

Type of Meeting: Enforcement Conference

Inspection Conducted: September 27 through November 4, 1993

Inspectors:

Wayne Slawinski
Wayne Slawinski
Senior Radiation Specialist

3-11-94
Date

James R. Mullauer
James R. Mullauer
Radiation Specialist

3/11/94
Date

Reviewed By:

B. J. Holt
B. J. Holt, Chief
Nuclear Materials Inspection
Section 1

3/11/94
Date

Approved By:

Roy J. Caniano
Roy J. Caniano, Chief
Nuclear Materials Safety Branch

3/13/94
Date

Meeting Summary

Enforcement Conference on March 7, 1994 (Reports No. 030-02640/94001(DRSS);
No. 030-31605/94001(DRSS) and No. 030-32479/94001(DRSS))

Areas Discussed: A review of the findings from the September 27 through
November 4, 1993 inspection, including a discussion of the apparent violations
and other concerns, the accuracy of the facts, the causal factors, the
corrective actions taken or planned by the licensee, and the NRC Enforcement
Policy.

DETAILS

1. Conference Attendees

The Ohio State University

Joe Allgeier, Acting Director, Office of Radiation Safety
Robert Brueggemeier, Ph.D., Professor and Chairman, Radiation Safety Committee
John Olsen, M.D., Medical Director, Nuclear Medicine and Vice Chairman, Radiation Safety Committee
John Reilly, Associate Legal Counsel, Office of Legal Affairs
Ronald St. Pierre, Ph. D., Associate Vice President of Health Services and Academic Affairs

U.S. Nuclear Regulatory Commission, Region III

W. L. Axelson, Director, Division of Radiation Safety and Safeguards
Bruce A. Berson, Regional Counsel
Robert W. DeFayette, Director, Enforcement and Investigation Coordination Staff
Charles Weil, Senior Enforcement Specialist
Roy J. Caniano, Chief, Nuclear Materials Safety Branch
B. J. Holt, Chief, Nuclear Materials Inspection Section 1
* Donna Beth Howe, Office of Nuclear Materials Safety and Safeguards
Kevin Null, Senior Materials Licensing Reviewer
Wayne Slawinski, Senior Radiation Specialist
Robert Gattone, Radiation Specialist
James Mullauer, Radiation Specialist

* Denotes attendance via telecon.

2. Enforcement Conference Summary

A transcribed Enforcement Conference was held in the NRC Region III office on March 7, 1994, between members of the NRC and the Ohio State University staffs. This conference was held to discuss the findings of an NRC routine inspection conducted at the university's Columbus, Ohio campus during the period September 27, 1993 through November 4, 1993. The inspection identified numerous apparent violations and a programmatic weakness regarding a lack of effective management and Radiation Safety Office control to ensure that problems are promptly addressed. The inspection findings are documented in Inspection Reports No. 030-02640/93001(DRSS); No. 030-31605/93001(DRSS) and No. 030-32479/93001(DRSS), transmitted to the licensee by letter dated December 16, 1993.

The purpose of the conference was to: (1) discuss the apparent violations and management control concerns, their root causes and safety significance, and the licensee's corrective actions; (2) provide the licensee the opportunity to point out any errors in the inspection

report; and (3) obtain other information that would help determine the appropriate enforcement action.

Licensee representatives were informed that based upon additional information provided by the university after completion of site inspection activities on November 4, 1993, three of the thirty-seven apparent violations described in the aforementioned inspection report were withdrawn. The three items withdrawn as apparent violations are as follows:

- a. Monitor a radiopharmaceutical therapy patients room prior to room reassignment (Inspection Report Section 17).
- b. Equip the irradiator console with a source position indicator that indicates when the sources are in transit (Inspection Report Section 18).
- c. Determine the radiation levels at the handling end of the source manipulator rod (Inspection Report Section 19).

The licensee's representatives agreed with the facts detailed in the December 16, 1993 inspection report and the thirty-four apparent violations presented at the conference, with the exception of a portion of the apparent violation pertaining to physician user qualifications, as described in Section 5(c) of the report. The licensee presented a letter dated October 26, 1993, summarizing the qualifications of the physician approved by the university's Medical Use Radionuclide Committee on April 12, 1988, for use of carbon-14 in humans for excretion studies. The NRC representatives indicated that the additional information provided by the licensee would be evaluated for compliance with physician qualification requirements.

Also discussed during the conference was the concern over an apparent programmatic weakness regarding a lack of effective management and Radiation Safety Officer control to ensure that known or suspected problems are promptly addressed. In response to this concern, the licensee acknowledged its inability to adequately address certain issues and to accomplish tasks in a timely manner. The licensee attributed this problem to insufficient radiation safety office staffing caused by budgetary constraints, and failure of management and the Radiation Safety Committee to closely monitor and establish timeliness goals for correcting weaknesses in its program. The licensee indicated that the staffing shortage made it necessary to choose those areas of the program upon which to focus its improvement efforts and caused delays in strengthening other areas.

At the conclusion of the meeting, the licensee's representatives were informed that they would be notified in the near future of the proposed enforcement action.

Attachment: October 26, 1993 Letter from
Dr. Fred Thomas to Walter Carey

Attachment



Department of Internal Medicine

Gastroenterology
2 North
University Hospital
410 West 10th Avenue
Columbus, OH 43210-1228
Phone 614-293-8462
FAX 614-293-8518

October 26, 1993

Walter Carey, Ph.D.
Director, Office of Radiation Safety
3092 Grant Graves Hall

Dear Dr. Carey:

Let me update your records concerning my eligibility to use Carbon-14 for absorption studies in the Gastroenterology Laboratory.

I served as assistant director of this laboratory under the supervision of approved supervisor Hagop Mekhjian, M.D. from 1983 until 1985 prior to assuming my supervision responsibility.

My gastroenterology fellowship under the direction of Norton J. Greenberger, M.D. July 1969 to June 1971 included classroom and laboratory training and experience in the safe use of radioactive materials. I worked in the laboratory 20-25 hours per week for 2 years.

I also successfully completed a 5 credit hour course Physiology 746 "radiation biophysics" given by Professor William Myers, Ph.D. during the fall semester 1969. This course included radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity and radiobiology.

I hope this will be useful.

Sincerely,

Fred B. Thomas, M.D.
Professor of Medicine
Division of Gastroenterology

FBT/ww