



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

June 10, 1994

Docket Nos. 030-02640
030-31605; and 030-32479
License Nos. 34-00293-02;
34-00293-14; and 34-00293-15
EA 94-032

The Ohio State University
ATTN: Ronald St. Pierre, Ph.D.
Associate Vice President
of Health Services
218 Meiling Hall
370 West Ninth Street
Columbus, Ohio 43210-1238

Dear Dr. St. Pierre:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -
\$17,750 AND DEMAND FOR INFORMATION
(NRC Inspection Reports No. 030-02640/93001; 030-31605/93001; AND
030-32479/93001)

This refers to the routine safety inspection conducted from September 27 to November 4, 1993, to review the NRC licensed program at the Ohio State University (OSU). The report documenting this inspection was mailed to you by letter dated December 16, 1993. Numerous violations of NRC requirements and several regulatory concerns were identified during the inspection. These were discussed during an enforcement conference held in the NRC Region III office on March 7, 1994. Attending the enforcement conference were you, Mr. William L. Axelson, Director, Division of Radiation Safety and Safeguards, and other members of our respective staffs.

The violations are fully described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice).

The Violations in Section I. represent a very significant breakdown in the management of your radiation safety program. Among these violations are: failure to file a Decommissioning Funding Plan (DFP) with the Commission pursuant to 10 CFR 30.35 and as specifically required by license condition on or before January 1, 1993; failure to comply with 10 CFR Part 36, radiation safety requirements for irradiators, which became effective July 1, 1993; and failure to develop, implement, and submit a medical quality management (QM) program on or before January 27, 1992, as required pursuant to 10 CFR 35.32. Normally, a breakdown in management control over a licensed program is considered to be a Severity Level III problem. However, the significance of these findings is exacerbated, as discussed below, since many of the violations appear to have been known or suspected to exist by your radiation safety office and by others responsible for the radiation protection program, yet continued uncorrected. Moreover, conditions, such as a lack of radiation safety staff and adequate radiation safety office facilities, that contributed to some of the violations, were also known but were not corrected in a timely

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fashion. The failure to correct known violations and known conditions likely to lead to violations represents a careless disregard towards NRC regulations and licensee requirements by those responsible for NRC-licensed activities at OSU. Therefore, the violations in Section I are categorized in the aggregate as a Severity Level II problem in accordance with the Statement of Policy and Procedure for NRC Enforcement Actions", (Enforcement Policy) 10 CFR Part 2, Appendix C.

The violations in Section II are related to the control of licensed material. These violations involved surveys, inventories, and storing of licensed material with the potential for loss of control. In addition, on November 23, 1992, a 0.95 millicurie iridium-192 seed was found on the floor in an unrestricted patient room. On April 17, 1991, iodine-125 seeds totalling 33 millicuries were left overnight in an autoclave in an unrestricted area. In accordance with the Enforcement Policy, the violations associated with these failures are classified in the aggregate as a Severity Level III problem.

The root cause of the problems identified during the inspection is a lack of effective management involvement with NRC-licensed activities. Specifically, senior management and the radiation safety committee did not provide the direction and guidance needed by the radiation safety officer to implement timely, effective and comprehensive corrective actions for known or suspected problems. Furthermore, senior management failed to provide sufficient resources to the radiation protection program to address self-assessed deficiencies.

Some of the violations identified during the inspection were previously identified by your radiation safety office staff and by a consultant auditor together with the Audit Subcommittee of the University Radiation Safety Committee. Notwithstanding the identification of these problems, many were not corrected and continued at least to the date of the inspection. Your failure to correct known or suspected problems in a timely manner constitutes a serious weakness in your program. Some examples of this weakness are as follows:

- Your staff was aware of the newly promulgated 10 CFR Part 36; however, three months after its required implementation date, its applicability to the University's two irradiator facilities had not been evaluated.
- Your staff was aware of the January 1993 deadline to submit a DFP to the NRC; however, its submission was continuously postponed. Further, as of the dates of this inspection, you had no immediate plans to develop a DFP.
- A November 1991 NRC inspection alerted the University to overall licensed material inventory and accountability weaknesses and housekeeping problems in your waste storage areas; however, two years later, the problems continued to exist.
- A late 1991 self assessment of your radiation safety office staffing needs identified a significant shortage; however, two years later, the staffing had not been increased to the level deemed necessary.

- An April 1993 consultant audit alerted you to violations associated with your airborne effluent monitoring program and failure to complete an evaluation of a possible overexposure; however, six months later, the violations continued to exist.

It is of particular concern that the Audit Subcommittee clearly knew, by May 18, 1993 if not sooner, that there were specific directives in the University's new NRC license that the radiation safety staff had not been able to comply with completely, and that NRC had issued penalties at peer institutions for similar problems, and yet no action was taken by the subcommittee or the committee to curtail licensed activities as necessary to bring the remaining program into compliance, nor did committee or University officials contact the NRC to discuss the situation and determine a course of action. You should be aware that licensees who operate in knowing noncompliance of NRC requirements may be subject to significant enforcement sanctions including criminal sanctions. The radiation safety officer and the radiation safety committee must have authority to curtail activities as necessary and must exercise that authority to assure compliance at all times.

The broadscope license issued to OSU allows the University significant latitude in the management of the radiation safety program and entrusts great responsibility, including the authority to name and train your own users of byproduct material, to those individuals responsible for radiation safety. Therefore, the NRC expects licensees to have effective management and oversight of their licensed programs. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of its employees, by assuring that all requirements of the NRC license are met and any potential violation of NRC requirements is identified and corrected. It is noteworthy that you have yet to have a permanent RSO appointed.

A key aspect of a successful program is the ability to perform comprehensive self assessments, which includes identifying problems or potential problems and implementing timely and effective corrective actions. Although the University demonstrated the ability to identify some problems, you failed to take the necessary steps to effect timely and comprehensive corrective action. This failure is of particular regulatory concern. The failure to correct known violations and identify others demonstrates that ineffective and insufficient management oversight of the implementation of the radiation safety program exists at OSU.

To emphasize the need for strict adherence to NRC requirements, the unacceptability of continuing licensed operations in careless disregard of NRC requirements, and the importance of controlling licensed material at all times, I have been authorized to issue the enclosed Notice in the aggregate amount of \$17,750 for the violations described in Sections I and II of the Notice.

The base value of a civil penalty for a Severity Level II problem is \$4,000. The civil penalty adjustment factors were considered for the Severity Level II problem in Section I of the Notice, and the base civil penalty was increased

250 percent. NRC identified the majority of the violations in Section I; therefore, the base civil penalty amount has been increased by 50 percent based on the identification factor. Mitigation for corrective action was not warranted as your actions were neither aggressive nor comprehensive. Mitigation was not considered appropriate under the licensee performance factor because the problem reflects a substantial decline in performance that occurred over time. The base civil penalty was increased 100 percent because of the prior opportunities you had to identify additional violations and to identify the underlying problem as a result of the NRC inspection in November 1991 and the audit that you performed in April 1993. The base civil penalty was increased an additional 100 percent under the multiple occurrences factor because of the unusually large number of violations included in the Severity Level II problem. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate.

The base value of a civil penalty for a Severity Level III problem is \$2,500. The civil penalty adjustment factors in the Enforcement Policy were considered for the Severity Level III problem in Section II of the Notice and, on balance, the base civil penalty was increased 50 percent. The base civil penalty was mitigated by 50 percent because you identified both failures to control licensed material. In both cases, you took corrective action following your identification of the loss of control of material; however, you failed to conduct an inventory of brachytherapy sources after they were returned to the storage room, which caused you to be in violation of 10 CFR 35.406(a). Therefore, mitigation based on the corrective action factor is not considered appropriate. In consideration of your overall performance during the period within the last two inspections and the fact that violations involving loss of control of material occurred both in 1991 and 1992, neither escalation nor mitigation is considered appropriate based on the licensee performance factor. The base civil penalty was escalated by 100 percent because there are two examples of the failure to control licensed material. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate.

As described in our Enforcement Conference Report, transmitted to you by letter dated March 18, 1994, three apparent violations described in our December 16, 1993 inspection report were withdrawn and are not included in the enclosed Notice. One example of a violation involving approval of a physician to perform diagnostic excretion studies on humans when the physician did not meet all of the training requirements is not being cited because of the age of the violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response.

In addition to the response required above and in light of your past failures to properly manage your radiation safety program as described above and in the enclosed Notice, you are requested to develop and submit to NRC within 60 days of the date of this letter, a detailed Radiation Safety Improvement Plan that includes a description of the changes to be implemented, the specific improvements in management oversight to be instituted, and the additional

resources to be dedicated, to upgrade the radiation safety program. In developing this plan you should consider the use of independent consultants having experience in overseeing large radiation safety programs. The plan should be suitable for incorporation into the terms and conditions of your licenses and should address among other things:

1. Actions necessary to ensure a) timely and lasting improvement in the radiation safety program, and b) improvements needed in procedures and practices to achieve and maintain compliance with NRC requirements and license conditions.
2. The radiation safety organization, and assigned responsibilities and authorities within that organization.
3. The program of surveillance and audits conducted by licensee staff and independent consultants to assess your program effectiveness and to ensure that individual users of licensed materials comply with NRC requirements and the licensee's internal procedures for the safe use of radioactive materials.
4. The human, financial, and facility resources that must be provided to adequately maintain the radiation safety program.
5. The function of the radiation safety committee and its subcommittees, and the committees' methods of a) monitoring the radiation safety program to ensure that problems, when they exist, are promptly identified and corrected, and b) maintaining knowledge of regulatory requirements.
6. The authority of the radiation safety officer, and the radiation safety committee and its subcommittees, to shut down or curtail licensed activities as necessary to assure that no aspect of the licensed program continues to operate in noncompliance once a violation or problem has been identified.
7. A schedule for completing all actions described in the plan, including interim milestones for the more complex actions.
8. A system for monitoring and tracking the status and completion of all actions described in the plan.

NRC needs this information in order to have assurance that, in the future, your licensed activities will be conducted in accordance with NRC requirements. If you do not intend to develop and submit to NRC a Radiation Safety Improvement Plan that includes the information requested in Paragraphs 1. through 8. above, you are hereby required, pursuant to this Demand for Information in accordance with sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954 as amended, and the Commission's requirements in 10 CFR 2.204 and 10 CFR 30.32(b), to provide within the same 60 day period in writing, under oath or affirmation, your reasons as to 1) why the Radiation Safety Improvement Plan need not be submitted, 2) if a plan is submitted but without addressing the above items, why it does not include those items, and

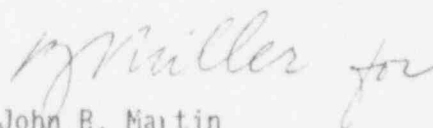
3) why your licenses should not be modified by Order to require that you develop and implement a Radiation Safety Improvement Plan. In addition, you are required to include in your response to this Demand For Information, an explanation as to why the NRC should conclude that you will in the future comply with NRC requirements, and when you know or suspect that violations may have occurred that you will take prompt and effective corrective action rather than continue to operate in potential violation of NRC requirements.

After reviewing your responses, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,



John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

cc w/enclosure:
Ms. Deborah Casto, Chairperson
Board of Trustees, OSU
John J. Reilly, Associate
Legal Counsel, OSU
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FIngram, GPA/PA

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LTremper, OC

EJordan, AEOD

RCaniano, RIII

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EA File (2)

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