Dest/DCB

THE OHIO STATE UNIVERSITY

Associate Vice President for
Health Services and
Academic Affairs
Associate Dean,
College of Medicine

218 Meiling Hall
370 West Ninth Avenue
Columbus, OH 43210-1238

Phone 614-292-4761
FAX 614-292-1544

January 20, 1994

US Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

Attn: W. L. Axelson, Director -
Division of Radiation Safety and Safeguards

Subject: Responses to your letter of Dec 16, 93 and Inspection Reports No. 030-02640/93001, 030-31605/93001, 030-32479/93001

Dear Mr. Axelson:

Enclosed are the responses requested in your letter of Dec 16, 93 to the following issues:

- Apparent lack of management control/oversight that allowed known or suspected problems to continue uncorrected.
- Airborne Effluent.
- Physician Qualification.
- Decommissioning Funding Plan.
- 10CFR36 Applicability (to License No. 34-00293-15).

We could not respond adequately within 30 days of the date of your letter for reasons explained to B. J. Holt of your staff on Jan 13, 94. Ms. Holt agreed to an extension to Jan 21, 94.

These responses were prepared by personnel of the Office of Radiation Safety (ORS) and by me. Please direct needs for additional information to me at the letter telephone, or to Walter E. Carey, Director - ORS or Joseph P. Allgeier, Assistant Director - ORS at 614-292-0122.

Sincerely,

Ronald L. St. Pierre, Ph.D.
Associate Vice President for Health Services and Academic Affairs

RLS/

140087

Enclosures

JAN 21 1994

1/1

RESPONSES TO NRC LETTER OF DEC 16, 93 AND

INSPECTION REPORTS

No. 030-02640/93001, 030-031605/93001, and 030-32479/93001

Apparent lack of management control/oversight that allowed known or suspected problems to continue uncorrected

Re: Letter of Dec 16, 93, page 2

The NRC has characterized some of its inspection results as a lack of management control/oversight that allowed known or suspected problems to continue uncorrected, and as a lack of aggressive pursuit of some issues and tasks.

We have recognized for some time the inability of our radiation safety program to adequately address certain issues and to accomplish certain tasks; we acknowledged this openly at the inspection exit meeting with Mr. Caniano, et. al. on Nov 4, 93. Indeed, we had self-identified and corrected 80 percent of the significance of the NRC inspectors' findings.

However, our inability to address issues and to accomplish tasks is due less to a lack of management oversight than to a failure to correct recognized near-constant and inadequate resources for the Office of Radiation Safety (ORS) to handle an expanding radiation safety program.

Radiation Safety Program Growth

The program has expanded more than three-fold in ten years due to:

- Growth in research and medical uses of radiations.
- Numerous special projects such as moves of the Divisions of Nuclear Medicine and Radiation Oncology, and disposal of radium.
- Additional and/or more stringent regulations, not always productive.

Radiation Safety Staffing Level

The number of ORS regular staff has not expanded to match program growth, although a core group of seven capable and dedicated persons has given the Office important stability. These points may be seen in the following data for the Office of Radiation Safety for ten fiscal years (FY = Jul 1 - Jun 30):

FYs 85 - 92:	7.0 to 8.0 full time equivalents (FTE)
FY93:	9.7 FTE
FY94:	10.1 FTE (projected)
As of Feb 1, 94:	9.0 persons on staff (RSO will retire Jan 31, 94)
As of Feb 1, 94:	7 persons (including retiring RSO) will have served ORS over 62 person-years.

Radiation Safety Focus

Because the near-constant radiation safety staff could not match the expanding radiation safety program, it became necessary to choose those areas of the program upon which to focus. The criterion for the choices was clear: areas which directly affect radiation safety and health were pursued; areas which involve primarily regulatory or administrative details with little safety and health impact were delayed.

Thus, effort was concentrated on such areas as:

- Training
- Prompt incident response
- Laboratory surveillance
- Personnel monitoring
- Instrument calibrations
- Thorough reviews of users and uses of radioactive materials
- Management of newly-generated LLRW
- Patient support.

Effort was delayed for such areas as:

- Decommissioning Funding Plan
- Characterization and disposal of "old", but controlled LLRW
- An elegant inventory program
- Filing of reports

Corrective Actions Planned

The University is moving to address the NRC's concern with the following goals:

1. Addition of more health physics expertise on staff in the Office of Radiation Safety, with a Certified Health Physicist (if possible) added by July 1, 94, and then with the addition of more staff after further analysis by the Vice President for Finance.

2. Installation of new computer hardware and software by Feb 28, 94, with substantial operation of inventory, and record-keeping, and report-generation capabilities by Feb 28, 95.

3. Improvements to Office of Radiation facilities including office quarters, laboratory, and an interim storage facility for LLRW (to be operational after Jul 1, 94).

4. Increased participation of the University Radiation Safety Committee with emphases on:
   - Policy development
   - Resource development
   - Strategic planning
   - Awareness of regulations, and timetables current and proposed
   - Awareness of work and responsibilities of Office of Radiation Safety
   - Root cause analyses of identified problems and development of solutions

5. Acceptance of "ownership" of the radiation safety program by management.

1. Airborne Effluent

UNRESOLVED ISSUE

Re: Section 14.c, page 29, paragraphs 1 through 3

The unresolved issue is whether or not 10CFR20.106(a) airborne effluent annual release limit was exceeded for I-125. The issue is unresolved due to the following discrepancy of a factor >100 in two independent methods to determine releases:

- A calculated (i.e., estimated) release concentration of I-125 from each of two fume hoods in Nuclear Pharmacy was 10 MPC, averaged over the 12-month period ending Sep 30, 91.
- One short-term measured release concentration of I-125 from one (primary) fume hood in Nuclear Pharmacy yields <0.1 MPC, averaged over the 12-month period ending Sep 30, 93.

The two reasons for the discrepancy are differences in I-125 iodination release fractions, and differences in the 12-month activities of I-125 iodinated in the hood.

Comparisons of the parameters germane to the calculated and measured release concentrations follow:

	Release Concentration	
Parameter	Calculated	Measured
I-125 on charcoal can, µCi	-	1.125×10^{-3}
Air flow through can, l	-	3920
Activity in single iodination, mCi	-	10.2
Duration of iodination, min	-	49
Hood flow rate, ft^3/min	600	600
Release fraction	0.03, assumed	2.3×10^{-5}, measured
Total activity in iodinations, mCi		
Oct 1, 90 - Sep 30, 91 (2 through hoods)	500	-
Oct 1, 92 - Sep 30, 93	-	2414
Annual average release concentration	10 MPC(1)	0.08 MPC(2)

1. Compare to NRC letter, Dec 16, 93, page 29, paragraphs 1 and 3.
2. Compare to NRC letter, Dec 16, 93, page 29, paragraph 2.

The calculated release concentration (10 MPC) was presented in our "Response to Deficiencies" to NRC dated Dec 6, 91, page 48; it was repeated in our "Reply to Notice of Violations - Dec 19, 91" to NRC dated Mar 26, 92, page 4.

The purpose of this calculated I-125 release concentration in Dec 91 was to develop an upper bound for such releases, not a realistic estimate.

The release fraction was assumed to be 0.03 based on private communications with several researchers/users, and was regarded as conservative. It was noted on page 48 of our letter of Dec 6, 91 that "Two published sources indicate a (NaI release) rate constant $<<10^{-4}$ /min; a simple evaporation model predicts a rate of 10^{-4}/min. These data suggest that 0.001 is conservative" as a release fraction. The fraction 0.03 is even more conservative by a factor of 30, but it was used due to a dearth of hard data. Also, it was noted by the NRC in its letter of Dec 16, 93, page 29, paragraph 3, that the fraction 0.03 is overly conservative.

The measured release concentration (0.08 MPC) was determined from physical air sampling data collected by the Office of Radiation Safety (ORS) on Jul 6, 93, and from other pertinent information compiled by ORS. (The Jul 6 data were presented to NRC Inspector Wayne Slawinski on Oct 1, 93; the other pertinent information was faxed to him upon request on Oct 8, 93.)

The air sampling was done during a typical iodination procedure. It is not known if or how the release fraction may be a function of different procedures or users.

Considering the arguments and data presented above, it is reasonable to assume that the I-125 release fraction does not exceed 10^{-4}. During the period Oct 1, 92 through Sep 30, 93, the I-125 used in iodinations in the Nuclear Pharmacy fume hood totaled 2414 mCi; (this is a factor of 4 higher than the normal use rate). Also, the hood flow rate was measured by the Office of Environmental and Occupational Health and Safety at 500 ft^3/min (as compared to the 600 ft^3/min used in the table above). This information leads to an annual average release concentration for I-125 of 0.4 MPC.

Therefore, it is suggested that this analysis adequately demonstrates that I-125 releases did not exceed the 10CFR20.106(a) airborne effluent annual release limit.

APPARENT VIOLATION

Re: Section 14.c, page 30, paragraphs 1 through 5

The NRC's statements of our methodology for establishing sampling thresholds are correct and accurate.

A copy of the parametric analysis, in which the radionuclide release fraction was varied from 10^{-3} to 10^{-1}, was given to Inspector Wayne Slawinski on Oct 1, 93.

ACTIONS TAKEN AND PLANNED TO
CORRECT AND PREVENT RECURRENCE

Actions Taken

Based on authorizations for the use of I-125 throughout the campus (especially in labeling procedures) the Nuclear Pharmacy hood in 204A Doan Hall is most likely to have challenged 10CFR20.106 effluent release limits.

To date, the Office of Radiation Safety has acquired four I-125 release concentration data at the exhaust stack for that hood using charcoal canisters. (The first datum was acquired before installation of a charcoal/HEPA filter at the hood on or about Jul 23, 93; the subsequent three data were acquired after installation.) Data are as follows:

I-125 Release During Iodination					
Date	On Can, µCi	Conc'n µCi/ml	Total[1] µCi	I-125 Used, µCi	Release Fraction[2]
Jul 06, 93	$1x10^{-3}$	$3x10^{-10}$	0.2	10,200	$2x10^{-5}$
Nov 01, 93	$2x10^{-3}$	$5x10^{-10}$	0.3	10,200	$3x10^{-5}$
Nov 23, 93	$2x10^{-2}$	$3x10^{-9}$	3	180,000	$2x10^{-5}$
Jan 13, 94	$2x10^{-3}$	$5x10^{-10}$	0.4	11,000	$3x10^{-5}$

1. At 500 ft^3/min.
2. (Total activity from stack)/(activity used in iodination).

Actions Planned

The apparent violation discussed in section 14.c, p 30, is a failure to perform I-125 effluent sampling of the Nuclear Pharmacy fume hood in Room 204A Doan Hall during months in which ≥40 mCi were used in iodinations. To prevent recurrence of this apparent violation, the following actions are planned:

1. Additional I-125 effluent samples will be collected on charcoal canisters at the exhaust stack during future iodination procedures. A minimum of 10 reliable, consistent effluent concentration data will be acquired.

   I-125 activity on the canisters will be quantified by gamma analysis using a NaI(Tl)/MCA and an I-125 standard.

   All sample collection and data reduction techniques will be as refined as possible.

2. A conservative-to-realistic release fraction will be determined for the hood as it is currently configured.

3. The release fraction will be used to establish a conservative activity threshold for monthly iodinations with I-125 in the fume hood at which air sampling will be

required to meet License Condition No. 36. This threshold may differ significantly from the first-order value of 40 mCi/month based on the somewhat arbitrary release fraction of 10^{-3}.

(Note that if the release fraction is taken as 10^{-4}, as suggested by the data above in "Actions Taken", and the 10CFR20.1302 maximum effluent concentration is 3×10^{-10} µCi/ml, the threshold is over 900 mCi/month.)

4. Nuclear Pharmacy personnel will maintain a log of all I-125 (and other radionuclides) procedures and activities in the hood, and will report these to ORS once a week. If activities used in completed and projected iodinations approach the threshold, air sampling will be performed during the remainder of the month to quantify releases for the month.

   Such a log will be continued until the Office of Radiation Safety determines that air sampling may be discontinued, except for extra-ordinary conditions, and/or until use of a lower release fraction is justified, leading to a significantly higher threshold.

5. Similar procedures will be applied to other radionuclides and hoods as necessary. If it is substantiated that Nuclear Pharmacy releases are an acceptably-small proportion of permissible limits, relief from an extensive campus-wide effort should be possible. Calculations should suffice when the releases are clearly much less than permissible.

6. Complete records of all sampling data, derived effluent releases, and use-rate logs will be maintained by the Office of Radiation Safety.

7. Certain rooftop areas with fume hood stacks may be designated as restricted areas, allowing for appropriate factors for dilution and dispersion to the nearest unrestricted area, so as not to exceed 10CFR20 Appendix B, Table 2 at the boundary.

2. Physician Qualification

In response to your directive of December 16, 1993, regarding the status of re-evaluation of physician certification, all affected physicians who do not have appropriate Board Certification have been contacted by Dr. John O. Olsen, Chair of the Medical Use Subcommittee. They have been supplied with a form letter, to be returned to the Radiation Safety Officer, indicating their participation in Physiology 746, Radiology 670, or equivalent course.

However, at the January 19, 1994, Core Committee meeting, it was determined that this effort has been essentially superseded by the Quality Management Program (QMP). Under the QMP, all written directives for administrations of radiopharmaceuticals require the signature of either Dr. Olsen or Dr. Rodney V. Pozderac. Both of these physicians are certified by the American Board of Nuclear Medicine.

3. Decommissioning Funding Plan

As indicated in the November 22, 1993 letter from R. L. St. Pierre to W. L. Axelson, four consultants originally expressed interest in development of a Decommissioning Funding Plan. Three proposals have already been received.

Based on the contents of these three proposals, delivery of a completed Decommissioning Funding Plan (DFP) to the University will occur on or before March 30, 1994. The DFP and accompanying Financial Assurance Plan will be supplied to Region III within two weeks.

Consequently, an application for a license amendment will be submitted, requesting a new DFP submission deadline of April 15, 1994.

4. 10CFR36 Applicability

The licensee plans to request a license amendment requesting exemption from six of the Part 36 requirements for which the licensee appears to be in violation. The licensee plans to contest one of the alleged violations, and report progress on correction of the remaining three.

Specifically, requests for exemptions will be made for items 18.a, 18.b, 18.c, 18.d, 18.e, and 18.i, as designated in the inspection report accompanying the December 16, 1993 letter from W. L. Axelson to R. L. St. Pierre.

Procedural modifications will be made in response to items 18.f, 18.h, and 18.j to achieve compliance in those areas.

After consultation with the Core Committee, the licensee contends that even in the absence of a discrete visual indicator denoting source movement, the specific operation of

the two visual indicators that are present, and simultaneously illuminated when the source is in motion, are equivalent; and this condition should not be considered a violation of 10CFR36.31(b).