

February 17, 1998

Daniel Albrinck
Associate Vice President
Medical Center
University of Cincinnati
Radiation Safety Office
234 Goodman Street, M. L. 591
Cincinnati, OH 45267-0591

SUBJECT: REVIEW OF DISPUTED NOTICE OF VIOLATION DATED DECEMBER 15, 1997

Dear Mr. Albrinck:

This acknowledges receipt of your letter dated December 15, 1997, in response to our letter dated November 18, 1997, transmitting a Notice of Violation (Notice). Your letter indicated that you disagreed with one of the violations and pointed out five discrepancies (items) identified from our cover letter that need to be addressed. We have considered your position regarding the violation and the five items as documented below.

You stated the reason for disagreeing with the violation was based upon the fact that current radiation levels around the acid dilution tank and associated piping in the area could not have exposed an individual to 2 millirem in any one hour or 100 millirem in seven consecutive days. Based upon our review of the information you provided, we agree that the current radiation levels around the acid dilution tank and associated piping are unlikely to expose an individual to 2 millirem in any one hour and 100 millirem in seven consecutive days. However, the violation represents our concern that the University failed in August 1993, to make or cause to be made surveys that were necessary to comply with the regulations in 10 CFR 20, and were reasonable under the circumstances to evaluate the extent of radiation hazards that were present. Specifically, the University identified radioactive contamination in a pipe in August 1993 and failed to survey further down stream of the pipe to ensure compliance with NRC release criteria and demonstrate by way of a radiation survey or evaluation that the radiation limits specified in 10 CFR 20.105(b) would not be exceeded. In response to NRC's concern regarding potential radiation hazards that might exist down stream from the pipe in April 1997, the University conducted additional surveys and identified additional radioactive contamination. The contamination was above NRC release criteria, as described in our response to item 5, and was located in a down stream acid dilution tank. This contamination is significantly less than it would have been three years ago because of the sewage flowing through the acid dilution tank after the room housing it was released for unrestricted use.

As a result of our review, we have concluded that Violation No. 3 is valid because the University failed to perform an adequate survey or evaluation in August 1993, and this resulted in the release of facilities for unrestricted use despite the presence of contamination in excess of NRC release criteria. Specifically, compliance with the regulations in 10 CFR 20, as it pertains to the radioactive contents of the acid dilution tank and associated piping from August 1993 until April 1997, was not adequately assessed by the University. However, we acknowledge that currently

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the radiation levels around the acid dilution tank and associated piping would not likely result in an exposure to an individual of 2 millirem in any one hour or 100 millirem in seven consecutive days.

Regarding item 1, we acknowledge that Violation No. 3 was associated with the April 21-24, 1997 inspection, as stated in your letter and not Violation No. 2 as stated in our letter.

Regarding your concerns in item 2 that Violation Nos. 1 and 3 represent a need for you to enhance your radiation safety program, that Violation No. 2 represents a need for you to improve the accountability and control of your brachytherapy sources and that the NRC did not identify Violation Nos. 1, 2 and 3, we have concluded that our characterizations are accurate. Specifically, regarding Violation Nos. 1 and 2, the corrective actions implemented after the first incident involving Iodine-125 seeds in May 1996 did not prevent the second incident involving Iodine-125 seeds in August 1997. Regarding Violation No. 3, your program failed to properly identify and evaluate contamination in an acid dilution tank and associated piping released for unrestricted use in August 1993. We acknowledge that you identified Violation Nos. 1 and 2 and, in response to NRC concerns, identified conditions which resulted in Violation No. 3. The NRC recognizes that problems or violations, such as the violations identified in our Notice, do not represent a breakdown in the licensed program, but do represent a need for program enhancement to ensure that corrective actions are adequate to prevent recurrence. However, we want to emphasize that although violations of NRC requirements occurred, the University's radiation safety program, overall appears to be effective in identifying problems and responding to events.

Regarding item 3, NRC concluded portions of Room 6 of the Old Operating Pavilion contained sludge activity of "approximately 240 picocuries per gram" based on the University's reported activity of "less than 0.24 nanocuries per gram" in its letter dated June 9, 1997. Two hundred forty picocuries per gram is above NRC's release criteria. In order to release this facility for unrestricted use, the University needs to better quantify its reported activity.

Regarding Item 4, we have concluded that NRC did not misapply NUREG-1500. The NRC's use of the conservative soil concentration values as described in NUREG-1500, *Working Draft Regulatory Guide on Release Criteria for Decommissioning: NRC's Staff's Draft for Comment*, for screening residual solid contaminants (sludge) is appropriate since we assume that the sludge and potentially contaminated adjoining soils will, at some future date, be excavated. Therefore, the extent of the University's evaluation should not be limited to the radiologically contaminated sludge material contained in the acid dilution tank, but should also include potential residual contamination in sewer piping, to and from the tank, and adjacent soils. The University's use of the drinking water scenario in NUREG-1500 is not appropriate for this situation because the University did not demonstrate that the sludge and potentially contaminated piping and adjoining soils will not be excavated in the future. In addition, we disagree with your statement that the "NRC knows the contamination is limited to the sludge in a small sump. . . ." On the contrary, the University's assumption that radiological contamination is limited to the sludge within the acid dilution tank has not been substantiated by an adequate survey of the sewer piping and adjacent soils.

Regarding Item 5, we have concluded that 10 CFR 30.36 continues to apply to the areas where former licensed activities were performed because the reported values of residual radiological contamination found in the acid dilution tank exceeds NRC release criteria. Your use of 10 CFR 20, Subpart E is appropriate. However, the evaluation that you used to determine that the facility satisfies NRC release criteria was not comprehensive in evaluating adjoining soils and connecting piping, and lacked sufficient detail to support the technical assumptions used. Therefore, it is necessary for you to submit a revised evaluation to demonstrate compliance with 10 CFR 30.36 by April 17, 1998. If you have any questions regarding evaluations to determine if facilities meet NRC release criteria, please contact Mr. Mike McCann, Senior Reviewer, of the Materials Licensing Branch at (630) 829-9856.

In addition to our review of your concerns, we also reviewed your corrective actions for the remaining violations. We have no further questions regarding your corrective actions at this time. These corrective actions will be examined during a future inspection.

We appreciate your comments and will gladly discuss any further questions you may have.

Sincerely,

Original signed by

James L. Caldwell
Deputy Regional Administrator

License No. 34-06903-05
Docket No. 030-02764

cc: Vicki Morris, RSO

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***See Previous Concurrence**

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Regarding Item 5, ~~we have~~ concluded that the identified radioactive material is still covered under your license. Consequently 10 CFR 30.36 continues to apply to the areas where former licensed activities were performed. Specifically, the reported values of residual radiological contamination found in the acid dilution tank appears to exceed the NRC unrestricted release criteria. In a letter dated August 13, 1997, from the NRC's Division of Waste Management to the University, the NRC outlined guidance documents which specified acceptable unrestricted release criteria for residual radiological contamination. The letter advised the University that it must comply with the limits specified in these documents, unless the University's license contained other acceptable release values. Since the issuance of the above letter, the NRC has revised its regulation, 10 CFR Part 20, Subpart E - Radiological Criteria for License Termination, which established a dose limit for use in determining acceptable unrestricted release. Your use of the 10 CFR 20-Subpart E is appropriate. However, your evaluation was not comprehensive as far as evaluating adjoining soils and connecting piping, lacked sufficient detail to support the technical assumptions used, and used a dose method which does not appear to be appropriate for this assessment. Therefore, it is necessary to submit a revised evaluation to demonstrate compliance with 10 CFR 30.36 by April 17, 1998. If you have any questions regarding the preparation of your assessment or the application of the new rule, please contact Mr. Mike McCann, Senior Reviewer, of the Materials Licensing Branch at (630) 829-9856.

In addition to our review of your concern, we also reviewed your corrective actions for the remaining violations. We have no further questions regarding your corrective actions at this time. These corrective actions will be examined during a future inspection.

We appreciate your comments and will gladly discuss any further questions you may have.

Sincerely,

A. Bill Beach
Regional Administrator

License No. 34-06903-05
Docket No. 030-02764

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RIII Enf. Coordinator

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*O.E. CONCURRENCE
Via Phone 1/20/98
Joe Delmedico*

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University of Cincinnati



December 15, 1997

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Radiation Safety Lab
University of Cincinnati
PO Box 670591
Cincinnati OH 45267-0591

Phone (513) 558-4110
Fax (513) 558-9905

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Re: Reply to a Notice of Violation
Dated November 18, 1997

Dear NRC:

Attached to this letter is the University of Cincinnati's reply to the Notice of Violation dated November 18, 1997. The Notice of Violation listed three severity level IV violations for license number 34-06903-05. Two of the listed violations referred to the inspection conducted on October 20-22, 1997 and one violation referred to the inspection conducted April 21-24, 1997.

There are five discrepancies from the cover letter which need to be addressed.

- 1) The NRC incorrectly identified "Violation 2" as resulting from the "unresolved item that was identified during the inspection conducted on April 21-24, 1997". The University of Cincinnati's review of the Notice of Violation indicates only the violation listed as Violation 3 is associated with the April 21-24, 1997 inspection.
- 2) The NRC stated they "are concerned, however, about the three violations of NRC regulations that were identified. Violations 1 and 3 represent a need for you (UC) to enhance your (UC's) radiation survey program to improve your (UC's) evaluations of radiation hazards. The need for better accountability and control of brachytherapy sources is represented by Violation 2." These statements are very misleading. The NRC did not "identify" the violations. All the "violations" were self-identified by the University of Cincinnati. The University of Cincinnati believes it has an outstanding Radiation Control and Safety Program. If it wasn't for the "effective self-auditing", "prompt and comprehensive response to events", and detailed record-keeping and internal reporting of problems self-identified by the University of Cincinnati, the listed violations and surrounding events would not have been known to the NRC.
- 3) The letter states "Vicki Morris (was informed) on November 10, 1997, that portions of Room 6 of the Old Operating

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Pavillion exceeded NRC's release criteria for unrestricted areas". The NRC based their conclusions on the activity of the sludge being "approximately 240 picocuries per gram". First, on November 10, 1997 it was reported to Vicki Morris that the NRC would be informing the University of Cincinnati that portions of Room 6 of the Old Operating Pavillion may exceed NRC's release criteria for unrestricted areas. Second, in the letter dated June 9, 1997 (re: Reply to a Notice of Violation dated May 12, 1997) the University of Cincinnati stated the activity in the sludge was determined to be "less than 0.24 nanocuries per gram". "Less than" can be significantly different than "approximately", especially when added to information provided to the NRC inspector during the October 20-22, 1997 inspection. Specifically, Vicki Morris informed the inspector that the 0.24 nanocurie per gram was a conservatively high estimate and that more detailed analysis was in progress.

- 4) The NRC misapplied NUREG-1500. The letter states "NUREG-1500 states that concentrations above 32 picocuries per gram for natural uranium and 18 picocuries per gram of cesium-137 exceed the NRC's release criteria for unrestricted areas." The referenced concentrations are conservative default concentrations for the residential soil scenario. This scenario assumes widespread soil contamination and that a person would build on, and live on, including growing food and getting water from an on-site well, the contaminated site. As the NRC knows the contamination is limited to the sludge in a small sump which is in the sewer line in a building on the University of Cincinnati Medical Center Campus in the City of Cincinnati Ohio; therefore, the concentrations referenced are inappropriate. The more appropriate, but still conservative, scenario would be the source term drinking water scenario. The source term drinking water scenario indicates the release criteria for cesium-137 is 3.8×10^{12} picocuries and for natural uranium is 4.5×10^9 picocuries.
- 5) The NRC states "it is necessary for you (UC) to comply with the provisions of 10 CFR 30.36 as it applies to Room 6." The University of Cincinnati believes Old Operating Pavilion Room 6 was appropriately released for unrestricted use; therefore, 10 CFR 30.36 does not apply. The University of Cincinnati's opinion is supported by NUREG-1500.

A survey conducted in the presence of the NRC inspector on October 20, 1997 demonstrated there was only one spot with a dose rate above background. The dose rate for this spot was 0.01 millirem per hour and the spot was located at the corner of the sump under the floor. The survey determined background was 0.006 millirem per hour and any removable contamination is indistinguishable from background. The

survey included both a meter survey and wipe tests. The meter survey was conducted using a microR meter, a survey meter with sodium iodide probe, along with the NRC's survey meter with pancake GM probe. The wipe tests were counted on a liquid scintillation counter.

A 559.25 gram sample of the sludge was placed in a Marinelli beaker. The sample was analyzed by gamma spectrometry using a high resolution germanium detector. Two standards, one a Marinelli beaker containing NIST-traceable quantities of europium-152 and americium-241, and the other, another Marinelli beaker standard containing a known mass of uranium acetate, were used to calibrate the detector for energy and efficiency. The net photon peaks at 0.662 MeV and 1.001 MeV were used to identify and quantify cesium-137 and natural uranium respectively. The results of the analysis indicated that the sludge contains:

Cs-137	70 pCi/gram ($\pm 10\%$)
U-238	80 pCi/gram ($\pm 10\%$)

Using the dimensions of the sump, it was determined the sump contains less than 100,000 grams of sludge; therefore, the sludge contains less than 7×10^6 picocuries of cesium-137 and less than 8×10^6 picocuries of uranium-238.

10 CFR 20.1402 allows unrestricted release if the "TEDE to an average member of the critical group does not exceed 25 millirem per year." The data above provides evidence that the maximum annual dose to any individual would be much less than 25 millirem, i.e., less than 0.09 millirem.

- a) Using the measured dose rate, the maximum TEDE is calculated to be 0.08 millirem. Calculations follow.

$$\begin{aligned} D &= 0.01\text{mrem/hr}(40\text{hrs/week})(52\text{weeks/year}) \\ &= 20.8 \text{ mrem} \end{aligned}$$

Since the only area above background is under the floor and the dose rate at floor level is indistinguishable from background, D can be assumed to be an extremity dose.

$$\begin{aligned} \text{TEDE}_{(\text{gross})} &= 0.1(20.8\text{mrem}) \\ &= 2.08 \text{ mrem} \end{aligned}$$

Since the measured dose rate includes background and background contributes to 60% of the measured dose rate, the TEDE resulting from the contamination is 40% of the calculated gross TEDE.

$$\text{TEDE}_{(\text{contam})} = (40\%)(2.08\text{mrem})$$

= 0.08 mrem

- b) Using the source term drinking water scenario from NUREG-1500, the dose is calculated to be 0.09 mrem. Calculations follow.

$$\text{Cs-137: } \frac{7 \times 10^6 \text{ pCi}}{2.29 \times 10^{12} \text{ pCi/15mrem}} = 4.6 \times 10^{-5} \text{ mrem}$$

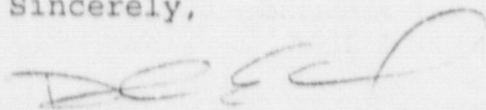
$$\text{U-238: } \frac{8 \times 10^6 \text{ pCi}}{1.34 \times 10^9 \text{ pCi/15mrem}} = 9.0 \times 10^{-2} \text{ mrem}$$

$$\text{Sum of Cs and U} = 9.0 \times 10^{-2} \text{ mrem}$$

If the NRC determines the University of Cincinnati made incorrect assumptions when describing any of the five discrepancies, contact Victoria Morris immediately. This will help ensure the University of Cincinnati's continuance of an outstanding Radiation Control and Safety Program.

If you have any questions do not hesitate to call.

Sincerely,



Daniel Albrinck, BA, CPA, JD



Victoria Morris, M.S., CHP

c: U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Ill 60532-4351

Radiation Safety Committee
Donald Harrison, M.D.

REPLY TO NOTICE OF VIOLATION
(November 18, 1997)

Violation 1:

"Contrary to (10 CFR 35.406(c)), on May 10, 1996 and August 19, 1997, the licensee failed to perform a radiation survey of the area of use to confirm that no sources had been misplaced. Specifically, the licensee failed to perform surveys of an applicator gun on May 10, 1996, and an autoclave on August 18, 1997, both of which were areas of use during implants on the respective dates, to confirm that no sources had been misplaced."

1. The reason for the violation, or if contested, the basis for disputing the violation.

On May 10, 1996, the technologist who removed the applicator gun from the procedure area thought the seeds had been removed from the gun.

On August 19, 1997, the physician who used the autoclave performed a wipe test. He did not realize he was also supposed to perform a meter survey.

2. The corrective steps that have been taken and the results achieved.

Radiation Oncology personnel have been reminded that they are responsible for ensuring meter surveys of areas of use are performed.

As stated in the 30 day report (submitted September 18, 1997 regarding the August 25, 1997 reported 3 missing I-125 seeds), "for each brachytherapy implant Radiation Safety will perform surveys (either confirmation survey or initial) of areas outside the brachytherapy storage room where the brachytherapy sources have been used or have been handled." Areas of use are communicated to Radiation Safety by Radiation Oncology staff.

3. The corrective steps that will be taken to avoid further violations.

Other than steps taken to correct deficiencies noted by Violation 2 below, no additional steps are felt to be necessary.

4. The date when full compliance will be achieved.

Full compliance has been achieved.

Violation 2:

"Contrary to (10 CFR 35.406(b)), on May 10, 1996, the licensee's record of brachytherapy source usage for May 10, 1996, did not include the number of sources returned to storage. Specifically, nine sources were returned to storage, yet the licensee recorded sixteen."

1. The reason for the violation, or if contested, the basis for disputing the violation.

The technologist thought doing a mathematical calculation to determine seeds returned to inventory from a permanent implant procedure and recording the results of the calculation was sufficient.

2. The corrective steps that have been taken and the results achieved.

When brachytherapy sources are returned to storage a physical count is performed. The result of the physical count is the number recorded to meet the requirements of 10 CFR 35.406(b).

3. The corrective steps that will be taken to avoid further violations.

Other than steps taken to correct deficiencies noted by Violation 1 above, no additional steps are felt to be necessary.

4. The date when full compliance will be achieved.

Full compliance has been achieved.

Violation 3:

"Contrary to (10 CFR 20.201(b)), on August 20, 1993, the licensee failed to perform a radiation survey under the circumstances to evaluate the extent of radiation hazards that were present in Room 6 of the Old Operating Pavilion in order to verify compliance with 10 CFR 20.105. Specifically, the licensee did not continue its survey of the sewer pipe that was downstream of the sewer pipes in Room 6 that were contaminated with radioactive material before releasing the area to unrestricted use on August 20, 1993."

1. The reason for the violation, or if contested, the basis for disputing the violation.

The University of Cincinnati does not believe a violation of the cited regulation occurred. As described in the Notice of

Violation, 10 CFR 20.105 required that an individual continuously present in an unrestricted not be exposed to radiation levels in excess of 1) 2 millirem in any one hour, and 2) 100 millirem in any seven consecutive days. A survey performed in the presence of the NRC inspector on October 20, 1997 demonstrated the maximum dose rate is by the acid sump and this maximum dose rate, which includes background of 0.006 millirem per hour, is 0.01 millirem per hour. Using the maximum dose rate (which is under the floor), the maximum dose which could be received by a small portion of the body of an individual continuously present for seven consecutive days (168 hours) is 1.68 millirem.

2. The corrective steps that have been taken and the results achieved.

Follow-up surveys performed in April, 1997 confirmed the University of Cincinnati's designation of Old Operating Pavilion as an unrestricted area was appropriate. Removal of T-portion of the pipe, which had contained low-levels of contamination, showed no further contamination in accessible areas of the pipe. Information was provided at that time, that an acid sump existed downstream of the pipe. A survey of the acid sump detected low-levels of radioactive material; however, removable surface contamination was determined to be indistinguishable from background.

Additional surveys and further analysis of the sludge in the sump has been performed. The results of the surveys and the analysis indicates the sump, in accordance with 10 CFR 20.1403 can be released as an unrestricted area.

The results of the surveys indicated no removable contamination above natural background and only one area with an exposure rate above background. The single area is below the floor and the exposure rate is 0.01 millirem per hour and includes background which has an exposure rate of 0.006 millirem per hour.

The results of the sludge analysis concluded the concentration of radioactive material in the sludge is:

Cs-137 = 0.07 nanocuries per gram ($\pm 10\%$) and
U-238 = 0.08 nanocuries per gram ($\pm 10\%$).

Using these results, a conservative estimate of the activity in the sump is (maximum amount of sludge 100 kg):

Cs-137 = 7 microcuries
U-238 = 8 microcuries

The resulting maximum dose to an average individual from this contamination is much less 0.09 millirem per year.

3. The corrective steps that will be taken to avoid further violations.

No further action is required. The University of Cincinnati will continue to perform detailed surveys, and release areas for unrestricted use as allowed by license conditions and regulations. As with this case, if contamination above background is detected and the area can be released for unrestricted use, the University of Cincinnati may generate additional documentation (e.g., labeling contaminated area with notice to contact Radiation Safety prior to removal or including area on a list of areas which could be subject to resurvey and/or further decontamination efforts).

4. The date when full compliance will be achieved.

Full compliance has been achieved.