

ENCLOSURE 1

NOTICE OF VIOLATION

Veterans Affairs Medical Center
Memphis, Tennessee

Docket No. 030-03253
License No. 41-00119-08

During the Nuclear Regulatory Commission (NRC) inspection conducted on September 18, 1990, 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 (1990), the violations are listed below:

- A. 10 CFR 35.50(b)(1) requires, in part, that a licensee test each dose calibrator for constancy at the beginning of each day of use.

Contrary to the above, on 16 occasions between January 6, 1990 and September 16, 1990, the constancy of the dose calibrator was not checked at the beginning of each day it was used to assay radiopharmaceutical doses administered to patients.

This is a Severity Level IV violation. (Supplement VI)

- B. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over its range of use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, dose calibrator linearity tests performed on August 21, 1990; March 26, 1990; December 13, 1989; July 24, 1989; and February 27, 1989 did not evaluate instrument linearity down to 10 microcuries.

This is a Severity Level IV violation. (Supplement VI)

- C. License Condition 17 requires that licensed radioactive material be possessed and used in accordance with the statements, representations, and procedures contained in the license applications dated September 23, 1983, September 24, 1984, July 15, 1986 and December 17, 1986 as well as other documents submitted in support of those applications.

1. Item 10(a)(4) of the application dated September 23, 1983 states that the results of daily dose calibrator constancy tests will be evaluated to verify that the measured result is within $\pm 5\%$ of the expected value.

Contrary to the above, on numerous occasions prior to September 18, 1990, the results of daily dose calibrator constancy tests were not evaluated prior to the instrument's use for the assay of patient doses to verify that the measured result was within $\pm 5\%$ of the expected value.

This is a Severity Level IV violation. (Supplement VI)

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2. Item 10(b)(5) of the application states that dose calibrator linearity errors greater than $\pm 5\%$ indicate the need for instrument repair or recalibration.

Contrary to the above, the dose calibrator was not repaired or recalibrated on June 15, 1987 and June 11, 1990 when linearity tests indicated errors of 12 percent and 31 percent, respectively.

This is a Severity Level IV violation. (Supplement VI)

3. Items 14(B)(1)(b) of the application requires that individuals unpacking radioactive material shipments wear protective gloves.

Contrary to this requirement, on September 18, 1990, protective gloves were not worn by nuclear medicine technologists when unpacking a radiopharmaceutical shipment.

This is a Severity Level IV violation. (Supplement VI)

4. Item 15(A)(7) of the application requires that individuals refrain from using food, beverages, cigarettes, cosmetics, medicines, or similar items in the vicinity of unsealed radioactive material.

Contrary to the above, on September 18, 1989, unwrapped food was found in Research Laboratory BE-103, a room in which unsealed hydrogen 3, carbon 14, and phosphorus 32 was being stored and used.

This is a Severity Level IV violation. (Supplement VI)

5. Item 17(A) of the application states that radiopharmaceutical preparation and injection areas will be surveyed daily after the use of radioactive material.

Contrary to the above, on sixteen occasions between January 1, 1990 and September 18, 1990, daily radiation surveys of radiopharmaceutical preparation and injection areas were not performed in the nuclear medicine department after the use of radioactive material.

This is a Severity Level IV violation. (Supplement VI)

- D. 10 CFR 35.21(b)(2)(v), in part, requires that the Radiation Safety Officer establish and implement written policies and procedures for using radioactive material safely.

Contrary to the above, as of September 18, 1990, written policies and procedures established and implemented by the Radiation Safety Officer for using radioactive material safely were inadequate in that nuclear medicine personnel were not wearing protective gloves when handling unsealed radioactive material.

This is a Severity Level IV violation. (Supplement VI)

- E. 10 CFR 35.70 requires that the licensee perform weekly radioactive contamination surveys of areas in which radiopharmaceuticals are routinely prepared for use, administered and stored; and that the Radiation Safety Officer (RSO) be notified immediately when such surveys detect radioactive contamination in excess of the licensee's established trigger levels.

Contrary to the above, on eight occasions between July 1989 and July 1990, the RSO was not notified after weekly surveys identified areas where removable radioactive contamination levels exceeded the licensee's trigger level of 2000 counts per minute (cpm)(equivalent to approximately 3,300 dpm/100 cm). The contamination levels ranged from 8,300 to 91,000 cpm (approximately 14,000 to 152,000 dpm/100 cm²).

This is a Severity Level IV violation. (Supplement VI)

- F. 10 CFR 35.70(a) requires that a licensee survey all areas in which radiopharmaceuticals are prepared and administered at the end of each day of use with a radiation detection instrument. 10 CFR 35 defines a radiation detection instrument as an instrument capable of detecting dose rates over the range of 0.1 millirem per hour (mRem/hr) to 100 mRem/hr.

Contrary to the above, on 65 occasions between January 1, 1990 and September 18, 1990, surveys were not performed with a radiation detection instrument in the fifth floor nuclear cardiology room at the end of each day of use of radiopharmaceuticals in the room.

This is a Severity Level IV violation. (Supplement VI)

- G. 10 CFR 35.59(g) requires, in part, that a licensee in possession of sealed sources or brachytherapy sources conduct a quarterly physical inventory of all such sources in its possession and maintain a record of each inventory which includes the location of each source.

Contrary to the above, as of September 18, 1990, physical inventory records of sealed sources did not list the location of each source.

This is a Severity Level V violation. (Supplement VI)

- H. 10 CFR 35.92(b) requires, in part, that licensees maintain records of byproduct material disposed of in accordance with 10 CFR 35.92(a) (Decay-in-Storage) and that the records must include the date on which the waste was put into storage and the radionuclides disposed.

Contrary to the above, as of September 19, 1990, records of radioactive waste disposed in accordance with 10 CFR 35.92(a) did not list the date the waste was placed into storage or the radionuclides disposed.

This is a Severity Level V violation. (Supplement VI)

Veterans Affairs Medical Center
Memphis, Tennessee

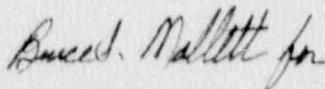
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Docket No. 030-03253
License No. 41-00119-08

Pursuant to the provisions of 10 CFR 2.201, the Veterans Affairs Medical Center is hereby required to submit a written statement or explanation to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D. C. 20555, with a copy to the Regional Administrator, Region II, within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as "Reply to a Notice of Violation" and should include for each violation: (1) admission or denial of the violation, (2) the reason for the violation if admitted, (3) the corrective steps which have been taken and the results achieved, (4) the corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

Where good cause is shown, consideration will be given to extending the response time. If an adequate reply is not received within the time specified in this Notice, an Order may be issued to show cause why the license should not be modified, suspended or revoked, or why such other actions as may be proper should not be taken.

FOR THE NUCLEAR REGULATORY COMMISSION



J. Philip Stohr, Director,
Division of Radiation Safety
and Safeguards

Dated at Atlanta, Georgia
this day of November, 1990

ENCLOSURE 2

ENFORCEMENT CONFERENCE SUMMARY

On October 18, 1990, the attendees listed in Enclosure 3 met at the licensee's facility to discuss the results of the inspection, proposed corrective actions, and the NRC's enforcement policy.

The Deputy Director of the Division of Radiation Safety and Safeguards discussed the NRC's concerns, particularly the apparent failure of the licensee's management to maintain effective oversight of the radiation safety program and the apparent lack of familiarity with NRC's regulatory requirements on the part of certain individuals involved in the licensee's radiation safety program.

Licensee representatives acknowledged that the hospital's management had not provided sufficient oversight to the radiation safety program to be assured that all licensed activities were conducted in full compliance with the NRC's requirements. The licensee representatives emphasized the licensee's commitment to conduct its authorized activities safely and in complete compliance with the NRC's regulatory requirements. The licensee's representatives also provided the NRC a handout which addressed the inspection findings, their root cause and the proposed or completed corrective actions (see Enclosure 4).

Based on discussions of the findings and additional information provided by the licensee during the Enforcement Conference, the NRC determined that the following apparent violations identified in NRC Inspection Report No. 41-00119-08/90-01 were not violations.

- (1) Failure to make surveys to assure compliance with 10 CFR, Part 20.101(a) [extremity radiation exposure limits]. Licensee representatives presented data indicating that they had performed an evaluation of the extremity radiation exposures received by persons working with phosphorus 32 (P-32) prior to those persons working with P-32. The results indicated that extremity radiation exposures of research personnel routinely handling P-32 did not approach 25% of the maximum quarterly limits established in 10 CFR, Part 20.101(a).
- (2) Failure to survey patient and place of use immediately after implantation of brachytherapy sources, and failure to survey patient after removal of brachytherapy sources. The Radiation Safety Officer presented records which documented that all the required surveys had been performed and documented as required. The licensee's representatives stated that previous to the inspection, there had been no standard format to be used by the several persons involved in performing these surveys to record their results, and that no one person had responsibility for maintaining these records. Therefore, the licensee stated there was some difficulty in establishing whether the proper survey was performed at the time of the inspection. The licensee representatives stated that new standardized brachytherapy survey results forms had been developed and that all personnel involved in making such surveys had been instructed to use these forms.

- (3) Failure to evaluate counting system used to assay weekly radioactive contamination samples to assure that it had a Minimum Detectable Activity (MDA) of 2,000 dpm/100 cm². The licensee representatives presented a Minimum Detectable Limit calculation for the counting system which indicated that the system's MDA was less than 2,000 dpm/100 cm².

The NRC representatives explained the NRC's Enforcement Policy.

ENCLOSURE 3

VETERANS AFFAIRS MEDICAL CENTER - MEMPHIS, TENNESSEE

ENFORCEMENT CONFERENCE ATTENDEES

October 18, 1990

Licensee Representatives:

- K. Mulholland, Director
- D. Mervis, M.D., Chief of Staff
- C. Irving, Ph.D., Chairman, Radiation Safety Committee
- N. Duhe, Administrative Chief of Staff
- R. Scott, M.D., Chief, Radiology Service
- S. Cowles, M.D., Chief, Nuclear Medicine Section
- S. Lott, Ph.D., Radiation Safety Officer
- D. Tinner, Supervisor, Nuclear Medicine Section
- R. Wilson, Ph.D., Associate Radiation Safety Officer

Nuclear Regulatory Commission Representatives:

- B. Mallett, Ph.D., Deputy Director, Division of Radiation Safety and Safeguards (DRSS)
- G. Jenkins, Director, Enforcement and Investigation and Coordination Staff
- J. Pelchat, Health Physicist, Nuclear Materials Safety Section, Nuclear Materials Safety and Safeguards Branch, DRSS

We should like to respond to the various violations in the following manner; making comments concerning the violation followed by corrective measures to assure the violations do not reoccur.

1. Failure to make surveys to assure compliance with 10 CFR 20.101(a)[Extremity radiation exposure limit] (Section 5).

Section 5 states that we failed to perform an evaluation of the extremity radiation exposures to the hands and forearms resulting from research activities using P-32 to insure that the resultant dosage did not exceed the limits established in 10 CFR 20.101(a).

Comment: We have performed evaluation of extremity exposures in several departments. Our procedure has been to ring badge personnel who, upon evaluation, are considered appropriate for such due to anticipated hand exposure. For example, 6 people are ring badged in Nuclear Medicine, 2 in Special Procedures, 3 in Research, and 4 are assigned wrist badges in Heart Cath. In addition, we have had discussions with other Research personnel concerning isotope, quantity and frequency of use to evaluate the need for ring badges. The 3 researchers who are ring badged seemed reasonably representative at the time of the other Research personnel. The badging results from these groups are as follows:

<u>Nuclear Medicine</u>	
<u>Number of Reports</u>	<u>Avg. Fract of Quarterly MPD</u>
1. 162	0.0012
2. 150	0.014
3. 156	0.030
4. 128	0.0063
5. 96	0.017
6. 2	0.0040

<u>Special Procedures</u>	
<u>Number of Reports</u>	<u>Avg. Fract of Quarterly MPD</u>
1. 67	0.045
2. 97	0.014

<u>Heart Cath (Wrist)</u>	
<u>Number of Reports</u>	<u>Avg. Fract of Quarterly MPD</u>
1. 160	0.0051
2. 114	0.067
3. 31	0.060
4. 17	0.0019

<u>Research</u>	
<u>Number of Reports</u>	<u>Avg. Fract of Quarterly MPD</u>
1. 14	0.0038
2. 21	0.0003
3. 11	0.0000(M)

As can be seen, the personnel in Research, who are representatively badged, have received only a small fraction of the average quarterly MPD. There is no indication that Research activity with P-32 is causing exposures approaching the limits specified in 10 CFR 20.101(a). Attached is a list of lab personnel who have, subsequent to the inspection, been ring badged, along with the amount of P-32 worked with in an unshielded form and the frequency. It may be noted that the three researchers who are badged (Ilardi, Woo and Palazzola) are reasonably representative of the Research group and have low extremity exposure results. Researchers working with say, 10 times these amounts might be expected to receive approximately 4 - 5% of MPD.

The senior research investigator in BB-120 does not routinely work with 5 millicuries of unshielded P-32. Instead, he removes approximately 50 - 200 microcuries from the shielded P-32 container and actively works with the 50 - 200 microcuries. Five millicuries is 25 - 100 times this amount. The need for ring badges has been evaluated in light of 10 CFR 20.101(a) and has not been felt to be generally required. Nevertheless, we have already issued ring badges to any person who works for an Authorized User approved to possess 1 millicurie or more of P-32, regardless of actual working amounts.

Correction: Personnel working for Authorized Users, who have a possession limit of 1 millicurie or greater for P-32, will be issued ring badges, the results will be tracked for an appropriate time, and an evaluation made.

Responsibility: Dr. Adams and Mrs. Warren (Radiology Quality Control technician).

Followup: Dr. Adams will evaluate the badge results. Dr. Lott will follow up on the badge distribution and use. Dr. Wilson and Dr. Lott will review the evaluation results with Dr. Adams.

Root cause: The Radiation Safety Office has provided a ring badge to Research Personnel who desire one but has not insisted on ring badging if the activity worked with is below the 1000 microcurie range of unshielded P-32. Amounts of

unshielded P-32 routinely used customarily fall under the 500 microcurie range.

Future prevention: Change policy so as to initially provide ring badge to any and all personnel who work for an Authorized User approved for a possession limit of 1 millicurie or more of P-32, regardless of the activity with which the person actually works. Review results after appropriate time and base continued monitoring on prior exposure results, work done, activity of P-32 which personnel handled.

2. Failure to survey patient and place of use immediately after implantation of Brachytherapy sources (Section 6)

The statement is made that no surveys were made after the implantation of I-125 temporary implant sources into a patient on August 29, 1990.

Comment: The patient was Mr. Alvin Langston and all needed and required surveys were done by Mr. Al Wheatly. Mr. Wheatly personally loaded the catheters. He inventoried the seeds into the catheters, and inventoried the catheters in the patient. During loading, one seed dropped onto the floor and the survey meter was used to locate it. At that point Mr. Wheatly re-inventoried all the sources. Thus, there was strict control and measurement of the sources. After insertion into the patient was completed, Mr. Wheatly then surveyed the patient while still in Oncology. No abnormal readings were noted. Mr. Langston, accompanied by Mr. Wheatly, was then transported to his room, where Mr. Wheatly again surveyed the patient in his room. The results of this survey are noted on the sticker put on the patient's chart, which was subsequently removed and is in our records. It indicates that the maximum radiation reading at 1 meter from the patient was 0.25 mR/hr. The patient was fitted with a lead lined helmet which was worn for the duration of the treatment. Mr. Wheatly states that the seeds could not have gotten loose as they were physically under his control. Therefore, adequate surveys were made on this patient and the reading in the patient's room was recorded.

Correction: Mr. Wheatly will be asked to first draw the outline of the room and bed, and then write down the survey results.

Responsibility: Mr. Wheatly

Followup: Dr. Lott

Root cause: The lead line helmets we use at VAMC for I-125 patients (30 Kev photons) are quite effective. Documenting radiation level at 1 meter after source insertion appears to yield the safety information needed, especially since portable shields are not needed in this case, nor is dosimetry for the Nursing staff.

Future prevention: We will provide Mr. Wheatly with a form where he may additionally draw in the room outline and bed location.

3. Failure to survey patient after removal of Brachytherapy sources (Section 6):

The statement is made that no radiation surveys were performed after temporary implant sources had been removed at the end of Brachytherapy procedures performed on or about April 7 and December 18, 1989, and March 26 and August 29, 1990.

Comments: At the VAMC, the patient and room are always surveyed after source removal. A reminder form already exists to remind the surveyor to make the final survey. In the past 4 years, at total of 7 Brachytherapy patients have been treated, not 4 or 5 each year.. Dr. Tai states he personally performed final room and patient surveys per his written procedure, but does not know where the survey records are now. This is for the 2 patients, Mr. Christopher Adamson and Mr. Corbin McAlister, whose treatments started December 6, 1988 and April 5, 1989, respectively. (See attached memo.) Dr. Wilson states he performed the final surveys for the December 18, 1989, patient on Christmas Eve. (See attached memo.) There are specific final survey records for the other 4 patients. A final survey was done for each of these Brachytherapy patients and no patient was allowed to be released from VAMC until these surveys were done. } *

Correction: The room survey form will be altered to include specific blanks for writing in the results of the patient survey and room survey after the Brachytherapy sources are removed. The inspector wanted this information written by hand and did not want it checked off on a form.

Responsibility: Survey form addition will be done by Dr. Lott

Followup: Followup will be done by Dr. Wilson

Root Cause: Surveys were always done. Written results of final surveys could not always be found, especially when surveys were done by personnel based outside the Hospital.

Future prevention: Reminder list plus specific blanks on Survey Form. Surveys are now generally done by in-house personnel. On-call personnel based across the street will be familiarized with location of our forms and checklist for use should backup be needed.

4 Violation:

Failure to test dose calibrator constancy at the beginning of each day it was used to assay patient radiopharmaceutical doses.

This violation only occurred on weekends, when the on-call technologist performed the procedure. The constancy check should have been made but was not. Unit doses are pre-calibrated and have recorded on them the dose as measured by the central radiopharmacy for the time of injection. The technologist measured the pre-calibrated doses with the dose calibrator to assure patient dose prescribed; they never failed to do this. Nuclear Medicine personnel have had an in-service on this particular item from Dr. Wilson after an NRC notification that this was a recurrent violation in VA hospitals. We have repeated this in-service after the inspection. Dr. Wilson and the Nuclear Medicine Supervisor will conduct periodic audits monthly initially, finally quarterly, in order to assure adherence to the procedure.

5 Violation:

Failure to evaluate the results of dose calibrator constancy tests to assure that measured values were within +/- 5% of the expected value.

Again, this was covered by the same short in-service by Dr. Wilson. Our understanding that "eye-balling" meant all the numbers recorded on each day were essentially the same as the day before. The +/- 5% limits were in the log book and the limits vs. the recordings were routinely checked by the Nuclear Medicine Supervisor. The +/- 5% limits will be placed at the top of each log page and a new log will have the explicit instruction concerning checking the numbers before they are recorded to be within the 5% limits. The Nuclear Medicine Supervisor and Dr. Wilson will assure compliance of this activity, initially monthly and finally quarterly.

6 Violation:

Failure to evaluate dose calibrator linearity to over its range of use down to 10 microcuries.

The linearity test source is brought from central radiopharmacy and the recording sheet filled out. (The time for recording did not allow for 10 μ Ci.) The original recording sheet, as used by the central radiopharmacy did include a 10 microcurie level.

We will revert to the old recording form in order to get to the 10 microcurie level. Dr. Wilson will review all linearities to make sure they extend to the 10 microcurie level.

7 Violation:

Failure to repair/recalibrate the dose calibrator when measured linearity errors exceed +/- 10%.

The linearities showed just a few points outside our 5% limit. At the time it was decided that the error was probably due to improper measurement. Therefore, it was not judged a true non-linearity, since these were a consistent set of points within 5%. At the time it was suggested to repeat the linearity, but no record could be found for the repeat. Almost all quarterly measurements indicated linearity within 5%.

Dr. Wilson will review each linearity to be sure all points are within 5% or corrective action be taken.

8 Violation:

Failure to wear protective gloves while unpacking a radiopharmaceutical shipment.

Our written rules, entitled "General Rules for the Use of Radioactive Materials", include the use of gloves. We have posted a very specific "receipt of package procedure" from the central radiopharmacy that includes the use of gloves.

Adherence to this policy will be monitored by the Nuclear Medicine Supervisor and Dr. Wilson, first on a weekly basis, then monthly, and finally quarterly.

9. Failure to restrict the consumption of food and beverages in radioactive use areas (Section 6)

Comments: The consumption of food and beverages in areas where unsealed radioactive materials were used and stored was identified as an apparent violation.

The laboratory worker in Room BE-103 did have a brownie lying on a napkin on a desk and an empty cup with coffee stains in the bottom. Simply to set the record straight, there had been no consumption of the brownie and there was no actual cup of coffee in the room. There was no food being eaten by any research assistant in the laboratory. However, having any food in the laboratory is absolutely against VAMC laboratory policy and will not be tolerated. There are specific other dangers in these laboratories as serious as, or even more serious than the radioactive material due to the large variety and toxicity of chemical compounds used in laboratory work.

Correction: A meeting was held with the researcher and the principal investigator of the lab so as to counsel both concerning the policy of not eating, drinking, or smoking in laboratories marked for use of radioactivity. In addition, this was stressed again in the regular Friday Research lectures where most Department personnel are in attendance.. Signs to this effect have been posted on all laboratory doors that are also posted with radioactive material signs. This will be expanded to all laboratories containing chemicals that do not have radioactive materials.

Responsibility: Dr. Lott held a special meeting with the researcher and laboratory head and has re-emphasized these points in the Friday seminar to all researchers. Dr. Lott will be responsible for the signs.

Followup: Dr. Wilson and Dr. Stewart, ACOS R&E, will review what was done

Root Cause: Negligence on the part of individual researcher.

Future prevention: These items will be included in the self-audit procedures and periodically checked by Dr. Irving's audit sub-committee.

10 Violation:

Failure to perform daily surveys of radiopharmaceutical preparation and injection areas.

This only occurred on weekends. All doses come from a central radiopharmacy in unit doses and generally only a single injection was used. It was thought a sufficient enough survey was to account for all the paraphernalia, since the empty syringe was returned in its shielded container to the central radiopharmacy.

Dr. Wilson and the Nuclear Medicine Supervisor will instruct all personnel that meter surveys are to be carried out, even on weekends. An audit will be made to insure that this is adhered to at least monthly by Dr. Wilson and the Nuclear Medicine Supervisor.

11 Violation:

Failure to perform adequate daily surveys of radiopharmaceutical injection areas located in the Nuclear Cardiology imaging room.

It was thought a sufficient enough survey was to account for all the paraphernalia, since the empty syringe was returned to the hot lab in its shielded container.

Dr. Wilson and the Nuclear Medicine Supervisor will instruct all personnel they are to carry out a meter survey in the Nuclear Cardiology area. Since the Nuclear Cardiology area is distant from Nuclear Medicine, a new survey meter will be obtained for that area. An audit will be made on a monthly basis by Dr. Wilson and the Nuclear Medicine Supervisor to insure adherence to this policy.

12 Violation:

Failure of the Radiation Safety Officer to establish and implement written policy for the safe handling of radioactive materials (failure to wear protective gloves while handling unshielded radioactive material).

The technologist was observed to be handling a small (250 microcuries) "sealed needle" of Technetium 99m used as a flood source. The technologist considered this as "a small sealed source" of Technetium 99m. We have specific rules that require the use of gloves when using radioactive material. All personnel in Nuclear Medicine have been told they are to handle all radioactive material with the use of gloves.

The Nuclear Medicine Supervisor will observe the actions of the personnel in order to insure that they are using gloves. A reminder of the use of gloves will be made at each general in-service given to the personnel by Dr. Wilson.

13 Violation:

Failure to notify the Radiation Safety Officer of areas in which weekly surveys identified levels of removable radioactive contamination in excess of action limits.

All the areas exceeding the action level of 2000 cpm were circled on the wipe tests. The wipe tests were conducted on Friday and, therefore, the contamination was left in place to decay over the weekend to below 2000 cpm. It was presumed that the contamination was Technetium 99m.

The disposition of each wipe area that exceeds the set level, will be logged into the wipe test record. An audit of the wipe test record on a monthly basis by Dr. Wilson will insure that this procedure is properly carried out.

14 Violation:

Failure to evaluate counting system used for the assay of weekly pharmaceutical contamination samples to insure it has a minimum detectable activity of 2000 dpm per 100 cm².

On a weekly basis the counting instrument efficiency was being determined. Because a 1 millicurie source of Technetium 99m was diluted in order to get an aliquot of 0.1 microcurie, Dr. Wilson decided that this was an "overkill" and had to be discontinued because of the increased hazard to personnel and the increased chance of contamination. The use of the known activity to check the efficiency needs to be done only initially so long as the counter is properly calibrated (the efficiency remains the same). To increase sensitivity for counting other radionuclides in Nuclear Medicine the counting window was increased to a "wipe window" to include all the other radionuclides. The efficiency for these other radionuclides is on our agenda but had not been completed. The large efficiency for Technetium 99m (~60%) implies that we have sensitivity enough to count all radionuclides down to 2000 dpm. The well counter is our most sensitive counter in Nuclear Medicine. The test count increased in the "wipe window" for Cesium-137 because more of the spectrum from Cs-137 was included in the larger window. The use of the 2000 cpm instead of dpm in our instructions was arbitrarily left until we finished the calibration for all the other radionuclides, since we needed only investigate areas at 20,000 dpm per 100 cm² of Technetium contamination. We have since decreased the number to 1000 cpm after the inspection to allow for sufficient sensitivity.

We will probably leave the number at the lower number for all radionuclides, even Technetium-99m, to allow for increased vigilance in the areas that are contaminated. We do not feel this is a violation.

15. Failure to include source location information in quarterly sealed source and Brachytherapy source physical inventory records (Section 6)

Correction: The room number (source location) has been written on the forms.

Responsibility: Written in by hand by Dr. Lott

Followup: Check by Dr. Wilson

Root Cause: There are 4 sealed sources. Two sources were located in Oncology, across the hall from the Radiation Safety office, under the control of the physicists there. They are stored in a marked cabinet which is locked inside a room and this room is locked inside a second room. A third source was chained to a pipe in the Radiation Safety Office. The fourth source is a 4000 curie irradiator in a 3000 pound container, which again is in a fixed, locked location. The location was known and fixed for each source and recording room number information was not considered.

Future prevention: Location written on leak test inventory form and will be checked quarterly.

16 Violation:

Failure to include date of radioactive waste storage or the identity of radionuclides disposed of in records of radioactive materials disposed of by decay in storage.

The individual packages put into storage for decay had the radionuclide, the date of storage, and the minimum date to be taken out of storage recorded on their top. The survey record only indicated the number of boxes which were surveyed before disposal. The additional information concerning the date, the radioactivity and approximate quantity, and the date surveyed, will be put into the log for both the storage and survey, for disposal.

Dr. Wilson will audit this log book on a quarterly basis to insure the proper information is recorded.