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December 16, 1993

U.S. NUCLEAR REGULATORY COMMISSION
ATTN. REGIONAL ADMINISTRATOR, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011

COMANCHE COUNTY MEMORIAL HOSPITAL

Randy L. Curry
President

RE: REPLY TO A NOTICE OF VIOLATION

The purpose of this correspondence is to respond to your NRC inspection conducted on August 10-12, 1993, in which several violations of NRC requirements were identified. Below are listed violations and corrective actions taken.

A. Violation 10 CFR 35.21(a) Requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures.

In Response To This Violation The Following Action Has Been Taken:

1. The Reason For The Violation:

A. Lack of continuous communication and oversight of intended radiation safety activities in the brachytherapy area of Radiation Oncology.

2. Corrective Steps Which Have Been Taken And The Results Achieved:

A. Direct involvement of the Radiation Safety Officer and the resolution of the violations to follow.

B. Radiation Safety Officer audit of brachytherapy activities on a quarterly basis to ensure compliance with the approved procedures and regulatory requirements.

C. As of the date of this letter no brachytherapy procedures have been performed. Regulatory requirements with regard to source inventory, storage, and ambient dose rate surveys have been implemented and submitted to the NRC in our last correspondence.

3. The Corrective Steps That Will Be Taken To Avoid Further Violations:

A. Intensive audits to be performed by the Radiation Safety Officer and the consultant Health Physicist as per the audit form submitted to the NRC at the enforcement conference.

4. The Date When Full Compliance Will Be Achieved:

A. As of October 15, 1993 the Radiation Safety Officer is properly involved in the oversight of the brachytherapy program.

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B. Violation, 10 CFR 35.25(A) (1) Requires in part that a licensee that permits the use of by- product material under the supervision of an authorized user shall instruct a supervised individual in the licensee's written Quality Management Program.

In Reponse To This Violation The Following Action Has Been Taken:

1. **The Reason For The Violation:**

   A. Adequate training and instruction of the Quality Management Program was not properly communicated to the designated Radiation Oncology Personnel.

2. **Corrective Steps Taken And The Results Achieved:**

   A. All brachytherapy personnel have subsequently received training in the Quality Management Program.

3. **Corrective Steps That Have Been Taken To Avoid Further Violations:**

   A. Instruction of the Quality Management Program will be performed on an annual basis as a designated agenda topic during the Radiation Safety Committee Meeting.

4. **The Date When Full Compliance Will Be Achieved:**

   A. As of October 1, 1993 the Radiation Physicist and the Radiation Oncologist were educated on the Quality Management Program and its emphasis on quality care.

C. Violation, 10 CFR 35.32 (b) requires, in part that: (1) a licensee develop procedures for and conduct a review of the Quality Management Program (QMP) including an evaluation of a representative sample of patient administrations and all record able events to verify compliance with all aspects of the QMP at intervals no greater than 12 months; (2) evaluate these reviews to determine the effectiveness of the QMP; and (3) retain records of each review, including the evaluations and findings of the review, in an auditable form for 3 years.

1. **The Reason For The Violation:**

   A. The reason given for not checking brachytherapy patient ID by two methods was that these patients are well known to the Radiation Oncology Staff because they have previously received several weeks of external beam radiation therapy prior to this implantation process.

2. **Corrective Steps Taken And The Results Achieved:**

   A. The treatment directive has subsequently been changed to require documentation by at least two methods. The brachytherapy process is also a surgical procedure so they are not only identified by the Radiation Oncology Staff but, also the Surgical Staff.

3. **Corrective Steps That Have Been Taken To Avoid Further Violations:**

A. With the ID verification by both the Radiation and the Surgical staff any possibility of misidentification will be avoided.

4. **The Date When Full Compliance Will Be Achieved:**

A. As of October 1, 1993 the written directive has been changed to show that identification by two methods is to be used .

D. Violation; 10 CFR 35.22 requires, in part, that the membership of the Radiation Safety Committee (RSC) consist of at least three individuals and include an authorized user of each type of use permitted by the license.

1. **The Reason For The Violation:**

A. The authorized user for Radiation Oncology was not on the Radiation Safety Committee.

2. **Corrective Steps Taken And The Results Achieved.**

A. Dr. Mittie Dragosljvich, the Radiation Oncologist on the license has been added to the committee.

3. **Corrective Steps That Have Been Taken To Avoid Further Violations:**

A. Dr. Dragosljvich's name will be recorded in the Radiation Safety Committees minutes showing his presence at these meetings.

4. **The Date When Full Compliance Will Be Achieved:**

A. As of October 1, 1993 Dr. Dragosljvich was added to the Radiation Safety Committee.

E. Violation 10 CFR 35.51 Requires, in part, that: (1) for survey instruments used to show compliance with 10 CFR Part 35, a licensee calibrate two separated readings with a radiation source on all scales with readings up to 1000 millirem per hour; (2) a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35, and (3) a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

1. **The Reason For The Violation:**

A. This was in part due to the infrequency of use of the survey meter since the brachytherapy procedures are not done on a regular basis.

2. **Corrective Steps Which Have Been Taken And The Results Achieved:**

B. During an Administrative meeting on 9/29/93, a decision was made for all survey meters for this license to be calibrated by the consultant physicist or by another outside vendor. All survey meters will stay in the Nuclear Medicine Department until needed at another location. The survey meter being checked with a dedicated source is a daily activity in the Nuclear Medicine Department.

3. **The Corrective Steps That Will Be Taken To Avoid Further Violations:**

A. With the survey meters being kept in the Nuclear Medicine Department and being checked on a daily basis calibration decrepancies will be alleviated because of its frequency of use.

4. **The Date When Full Compliance Will Be Achieved:**

A. Full compliance was achieved on 9/29/93 when the survey meter from the Radiation Oncology was taken out of service and transferred physically to the Nuclear Medicine Department.

F. Violation 10 CFR 35.59 (h) Requires, in part, that a licensee in possession of a sealed source or brachytherapy source measure the ambient dose rates quarterly in all areas where such sources are stored.

1. **The Reason For The Violation:**

A. This procedure was not performed on a quarterly basis.

2. **Corrective Steps Which Have Been Taken And The Results Achieved:**

A. The radiation survey of ambient dose rates surrounding the area of the source storage safe will be conducted at the same time that the quarterly physical source inventory is performed. The source inventory sheet along with the ambient dose rate sheet are placed together with one another as a reminder.

3. **The Corrective Steps That Will Be Taken To Avoid Further Violations:**

A. Again the ambient dose rate sheet will be placed on the quarterly calendar along with the physical source inventory sheet and will once again be signed by both the Radiation Physicist along with the Radiation Safety Officer.

4. **The Date When Full Compliance Will Be Achieved.**

A. As of October 22, 1993 the ambient dose rate was monitored and documented on the new form and was also signed by the Radiation Safety Officer.

G. Violation 10 CFR 35.51 (d) requires that a licensee retain a record of each survey instrument calibration for 3 years and that the record include a description of the calibration procedure; and the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

1. The Reason For The Violation:

A. The record on calibration of the Victoreen Model 471 survey instrument did not include a description of the calibration procedure and the signature of the individual who performed the calibration.

2. Corrective Steps Which Have Been Taken and The Results Achieved:

A. The survey meter that was located in the Radiation Oncology Department has been taken out of service and has physically been transferred to the Nuclear Medicine Department. Nuclear Medicines own dedicated survey meter will also be used on all brachytherapy cases.

3. The Corrective Steps That Will Be Taken To Avoid Further Violations:

A. The survey meter previously located in the Radiation Oncology Department will be listed as out of service and therefore, alleviating all documentation discrepancies.

4. The Date When Full Compliance Will Be Achieved.

A. As of 9/29/93 a decision was made for the survey meter in the Radiation Oncology Department to be taken out of service.

H. Violation 10 CFR 35.9 (d) requires that a licensee retain records of leakage test results for 5 years and that the records contain the model number, and serial number if assigned, of each source tested; the identify of each source radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the signature of the Radiation Safety Officer.

1. The Reason For The Violation:

A. The records of leakage test results did not contain the model number of each source tested, a description of the leak test method, and the signature of the Radiation Safety Officer.

2. Corrective Steps which Have Been Taken and The Results Achieved:

A. It was found out at the enforcement conference that the cesium sources located in the Radiation Oncology Department were approved for a three year leak test interval. All brachytherapy sources are now being leak tested semi-annually by the Radiation Physicist using the testing equipment and software package located in the Nuclear Medicine Department.

3. The Corrective Steps That Will Be Taken To Avoid Further Violations:

A. The leak test software package includes on the printed hard copy the model number of the source being tested, method used and upon completion the Radiation Safety Officer's signature.

4. The Date When Full Compliance Will Be Achieved:

A. As of the present time the Department of Radiation Oncology in compliance with this particular violation.

I. Violation 10 CFR 35. 59 (g) requires, in part, that a licensee retain for 5 years records of quarterly physical inventories of sealed sources and brachytherapy sources in its possession, and that the records contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

1. The Reason for The Violation:

A. Records were not retained of quarterly physical inventories of brachytherapy sources.

2. Corrective Steps Which Have Been Taken And The Results Achieved:

A. A brachytherapy source inventory document has been prepared and is being used. A source inventory map and drawer placement has been developed showing location, model number, and nominal activity and is affixed to the L-shield of the cesium source safe. The Radiation Safety Officer's signature is also part of these forms.

3. The Corrective Steps That Will Be Taken To Avoid Further Violations:

A. The Radiation Physicist and the Radiation Safety Officer will place this activity on the calendar as a quarterly check and both must sign off on the form.

4. The Date When Full Compliance Will Be Achieved:

A. As of 8/20/93 documentation of cesium source inventory was performed and signed by the Radiation Safety Officer.

J. Violation 10 CFR 35.404 (b) requires, in part, that a licenses must retain a record of each patient survey required by 10 CFR 35.404 (a) for 3 years.

1. The Reason For The Violation:

A. An exit survey was not documented upon completion of the implant procedure and source removal.

2. **Corrective Steps Which Have Been Taken and The Results Achieved:**

A. An exit survey has been added to the new Implant Information Form and will be performed immediately after removal of all sources from the patient. Sources once again are re inventoried upon returning them to the safe.

3. **The Corrective Steps That Will Be Taken To Avoid Further Violations:**

A. Once again the Radiation Physicist and the Radiation Safety Officer will have to sign the form showing that the survey was performed.

4. **The Date When Full Compliance Will Be Achieved:**

A. No brachytherapy procedures have been performed since the date of the NRC inspection but, the brachytherapy implant form has been changed to show an exit survey release.

K. Violation 10 CFR 35.406 (b) requires, in part, that a licensee make a record of brachytherapy source use including: (1) the names of the individuals permitted to handle the sources: (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from the storage. (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initial of the individual who returned the sources to storage.

1. **The Reason For The Violation:**

A. The record of brachytherapy source usage did not include: (1) the names of individuals permitted to handle sources, (2) the number and activity of sources in storage after removal, and (3) the number and activity of sources in storage after the return.

2. **Corrective Steps Which Have Been Taken And The Results Achieved:**

A. A Cesium Source Log Sheet has been implemented giving a constant location of all sources and activities.

3. **The Corrective Steps That Will Be Taken To Avoid Further Violations:**

A. The Cesium Source Log Sheet has been placed on the cesium safe and also in the brachytherapy manual located in the department directors office.

4. The Date when Full Compliance Will Be Achieved:

A. The Log Sheet has been implemented and is current.

Russ Blackwell, Senior Vice President

Richard Roberts MD., Radiation Safety Officer