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12-Oct-90

Director
Office of Enforcement
U.S.Nuclear Regulatory Commission
Washington, D.C. 20555

Docket No. 030-17512
Licence No. 34-00398-10
EA 90-128

Reply to a Notice of Violation

Sir

We have received and are responding to the September 14, 1990, Notice of Violation and proposed Imposition of a Civil Penalty submitted by Mr. A. Bert Davis, Regional Administrator, Region III, of your commission.

1. (1) Saint Luke's Hospital admits that a non-emergency first treatment was administered without the chart being checked and initialed by a physicist or dosimetrist as required by our control procedures. This was reported in our letter of May 7, 1990 to the NRC.

(2) The chart was not referred to a physicist or dosimetrist, for checking, by the technologist who prepared the treatment record, as required by our procedures. This was also overlooked during subsequent treatment of this patient.

(3) A documented inservice re-training has been given to the technologists concerning our quality control procedures and also that an independent dosimetry check by a qualified person (usually the dosimetrist or physicist) is required before therapy treatment may proceed.

(4.a) In order to avoid similar incidents from re-occuring in the future, a start-up check list

is now being used before treatment is initiated. It is placed in front of the "set-up page" in the patient's chart (see attached example - Appendix A).

(4.b) A notation is made on the pre-printed therapy record chart for the technologists to send the chart for review and signature by a qualified person (usually the dosimetrist or physicist) when approximately 20% of the total treatments have been given. This is independent of the weekly chart review conducted by the radiation oncologists. This step is intended to help ensure that our quality control procedures are being followed.

(5) The above steps were initiated on June 25, 1990 and fully implemented by July 30,1990.

II.A Saint Luke's Hospital admits that the NRC was not notified by telephone within 24 hours of the occurrence of a misadministration.

The misadministration occurred after 5.00 p.m. on Friday, June 22, 1990. The telephoned report was made on the morning of the following working day, Monday, June 25, 1990 when a written report from the technologist involved in the the incident became available.

In future, the telephoned report will be made within 24 hours (including week-ends) of the discovery of a misadministration.

B St. Luke's Hospital admits that a written report concerning a misadministration and telephoned to the NRC on April 20, 1990 was made in a letter dated May 7, 1990 (17 days after the discovery of a misadministration) and to the referring physician in a letter dated May 8, 1990.

In future, the written report will be made within 15 days.

Our Policy and Procedures Manual has been updated to include more detailed written information on our procedures. (See Appendix B). These will normally be reviewed at annual intervals, i.e. next overall review no later than the first Monday in October, 1991. Should circumstances require it. specific sections may be modified earlier.

All technologists on staff have been re-educated on the reporting requirements and also NRC Form 3.

We are in the process of arranging for our consultants, Nuclear Medicine Associates, to conduct an annual audit of our Policies and Procedures.

Our check for $1,875 is enclosed to cover the civil penalty imposed. If there are any further questions, please do not hesitate to contact me at the above telephone number or address.

Sincerely,

J.P. Mamacos

J.P.Mamacos
Radiation Safety Officer

Jeffrey Sgarey

Jeffrey Jeney
Vice President,
Ancillary Services.

CC: Regional Administrator, U.S. Nuclear Regulatory Commission, Region III

APPENDIX A

START UP CHECK LIST

Patient Name: [redacted]

Patient Number: 903619

Technologist's Name: CA Date: 9-11-90

Written Prescription On Chart ✓

TREATMENT RECORDS:

Must Have: Volume presc. = Volume Treatment Records ✓

Physics' Initial ✓

Doctor's Initial ✓

Completed: Sim Film ✓

Entered: Port Schedule ✓

Physics Review ✓

Dose Modifiers WAX Comp

Fact sheet completed* 9/11/90 (Date)

*Can be done after first treatment

APPENDIX B

PROCEDURES
SLH RADIATION ONCOLOGY

DELIVERY OF TREATMENT

1. START-UP CHECK LIST MUST BE COMPLETED BEFORE TREATMENT.
2. Only after there is both a physics/dosimetry and physician initials on the treatment records, may treatment be given. (Emergencies are an exception to this.)
3. Also, in the ideal and usual situation, two technologists at a machine should verify that the area to be treated is what is actually being treated on the patient. Should one of the technologists be called away, it is acceptable that several patients be reviewed prior to treatment so that each area to be treated on each patient is reviewed and acknowledged.
4. At each treatment, the machine technologist must recheck that the records have been initialled by both Physics and physician.
5. Finally, it is the machine technologist's responsibility to refer the charts back to physics/dosimetry for the one/fifth check.
6. IT IS THE RESPONSIBILITY OF THE CHIEF TECHNOLOGIST TO SEE THAT THERE IS AN ENTRY IN EACH PATIENT TO BE TREATED FOR A ONE/FIFTH DOSIMETRY CHECK.
7. TREATMENT MAY NOT CONTINUE UNLESS 1/5 DOSIMETRY CHECK NOTED.

7/30/90

PROCEDURES
SLH RADIATION ONCOLOGY

TREATMENT PLANNING

A. Initiation

The treatment process is initiated by a written prescription from a physician, except in highly unusual and/or emergency circumstances where a verbal authorizat ay be utilized. However, as soon as is possible, a writte. onfirmation of such orders should proceed. The prior Treatment Plans and Management Reminders worksheet remains just that, a work sheet which can be used for calculations and research efforts.

B. Generation of Treatment Plans

Treatment plans are generated in two ways:

1. The first is a simple SSD set-up which is carried out after simulation by radiation therapy technologists.
   a. Technologist's duties: The area is identified by the physician and verified by simulation films. The technologist enters this data and the prescription into the CAD (central axis dose) program.
   b. Dosimetry/Physics duties: The treatment sheets are generated and these are then referred to physics/ Dosimetry for an independent check. This independent check is done and a check sheet is produced. The

physicist/dosimetrist checks for accuracy of data entry and for correspondence of treatment times by these two separate methods. If correct, the treatment records and independent check sheets are initialled by Physics/ Dosimetry. Initials are placed on the set-up sheet and computation sheets. Also at this time, an entry is made onto the treatment sheets as to when a subsequent and (in treatment) physics/dosimetry review shall take place, (usually after one fifth of the treatment has elapsed). This is written onto the treatment record so that these charts can be referred back to Physics/ Dosimetry for this check.

c. Physician duties: After the above has been carried out, the sheets are presented to the physician by Physics/ Dosimetry for final check and initialing. The physician initials the face sheet, first and last treatment sheets if and only if the prescription is accurately carried out. Also at this time, the physician indicates that the treatment times on the independent check and those generated by the radiation therapy technologist, correspond.

2. <u>TP 11 Plans</u>

For patients to be treated by TP11, the above procedure is to be followed with the only exception that the data

entry is carried out by the dosimetrist and in unusual situations, by the physicist.

7/30/90

PROCEDURES
SLH RADIATION ONCOLOGY

WEEKLY CHECKS BY PHYSICIAN OF CHARTS

On a weekly basis, the physician checks each of the charts for patients in active treatment, interruption and treatment planning. The physician verifies that the patient has a consultation and a prescription for each area to be treated. He also ascertains that the prescription is being accurately carried out. A check of the correspondence of treatment times with the independent check and the CAD sheets are made. The physician then turns his attention to the clinical condition of the patient, noting whether laboratory tests and/or x-rays are necessary. (See check list.)

PROCEDURES
SLH RADIATION ONCOLOGY

ACUTE RADIATION REACTIONS

Charts of patients who are interrupted for acute radiation reactions are to be reviewed by Physics/Dosimetry for the accuracy of the Treatment Records. This monitoring is triggered by a problem in the Problem Index stating acute radiation reaction-interrupt. Before the patient may restart therapy, there must a note in the Physics portion of the chart indicating that the chart has been rechecked by Physics and found to be accurate.