



Docket: 030-31258
License: 35-01164-03

January 10, 1994

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

SUBJECT: Reply to a notice of violation

We are responding to the seven violations of NRC requirements which were identified during your routine, unannounced inspection of our facility by Mr. Gilbert L. Guerra, Jr., on November 18, 1993.

The first violation noted was a failure to specify the overall treatment period on the written directives for teletherapy treatments done between December 2, 1992 and November 18, 1993. The reason for this violation was failure on the part of the previous radiation safety officer to perform the required chart Quality Assurance as required by our departmental policy here at Jane Phillips Episcopal-Memorial Medical Center. Corrective action has been taken to assure that the written directive will include the overall time of treatment as written by the authorized user. To facilitate compliance, a Physician Chart Screen, has been developed (See enclosure) by the radiation safety officer. This chart screen will be placed in each teletherapy chart and become part of the permanent record. Questions #1 through #10 will be answered in the affirmative by the authorized user prior to the first administration. Further, the treating radiation therapy technologist will cross-check the chart screen for completeness of items #1 through #10 prior to the first teletherapy administration. This corrective action will be implemented January 1, 1994.

The second violation was a failure to perform an annual review to evaluate the effectiveness of our quality management program between January 27, 1992, and November 18, 1993, an interval greater than twelve months. The reason for this violation was a failure on the part of the previous radiation safety officer to perform the required annual chart review as required by our departmental policy. Corrective action has been taken to complete this review for the years 1992 and 1993, and to begin another review as of January 1, 1994. The review will be conducted by the radiation safety officer, the chief radiation therapy technologist, and the department director of Radiation Therapy for Jane Phillips Episcopal-Memorial Medical Center. The focus of this review will be on the completeness of the written directive,

046001

JANE PHILLIPS EPISCOPAL - MEMORIAL MEDICAL CENTER

3500 E. Frank Phillips Blvd. Bartlesville, Oklahoma 74006

Phone 918/333-7200

9402070136 940110
PDR ADDOCK 03031258
C PDR

1007
11

SUBJECT: Reply to a notice of violation - Cont.
Page 2

specifically the dose per fraction, specific treatment site, overall treatment time, signature by the authorized user, and whether the patient received the prescribed daily and total teletherapy dose. By departmental policy, the results of this review will be reported annually to the Radiation Safety Committee.

The third violation involved a failure to maintain the written directives for teletherapy treatments given on January 27, February 24, and June 9, 1993, a retention period of less than the required three years. The reason for this violation was laxity on the part of the authorized user and chief technologist regarding what constitutes chart completeness and in particular a deviation from established department policy stating that "No patient will be treated without a written directive." Corrective action has been implemented immediately; this action calls for a departmental policy that requires a complete teletherapy chart to have, among other documents, a written directive signed by the authorized user. This complete chart and the written directive will be filed alphabetically in a designated storage area at the facility for a period of seven years from the date of the first teletherapy administration. Compliance will be the responsibility of the radiation safety officer and the chief radiation therapy technologist.

The fourth violation involved a lost film badge by one of the staff teletherapy technologists at the facility between July 20, 1993 and August 19, 1993. Corrective action has been immediately taken to insure compliance. Department policy states that "All employees who lose their radiation exposure monitoring devices, will be assigned an exposure equal to an employee of equal status." Compliance of this directive will be the responsibility of the radiation safety officer. Janet Coonfield, who lost her film badge, will therefore be assigned an exposure equal to that of fellow technologist, Bobbie Dostart, for the period of time in question.

The next two violations pertain to the failure of the Radiation Safety Committee to meet during the third quarter of 1993 and for the failure of the then radiation safety officer to be present at Radiation Safety Committee meetings held between October 8, 1992 and October 18, 1993. The reason for this violation was apparently due to a laxity on

SUBJECT: Reply to a notice of violation - Cont.
Page 3

the part of the previous radiation safety officer to enforce NRC regulations and to insure their compliance. Corrective action has been taken in the form of a recently devised schedule of quarterly Radiation Safety Committee meetings for the 1994 calendar year. All committee members including the newly appointed radiation safety officer have been notified of the time, date, and location of these meetings. Further, the radiation safety officer and other committee members will be paged immediately in the event they are not present at the scheduled time and location of the appointed meeting. If the radiation safety officer and department director are not present for any reason or quorum is not available, a new meeting time will be set for that quarter.

The final violation involved the omission of the required signature of the Radiation Safety Officer on the leakage test results as of November 18, 1993. The reason for this violation was apparently a failure of communication between previous radiation safety officer and the prior consulting medical physicist to facilitate the prompt and required signature of the radiation safety officer on the leakage tests performed by the physicist. Current department policy calls for the consulting medical physicist to perform the leakage tests and review these results with the radiation safety officer, who will then sign these records at the time the tests are done. Further, the new radiation safety officer has reviewed the leakage test results and has signed these records as of December 30, 1993 bringing the facility into compliance with 10 CFR 35.59 (d).

It is the goal of Jane Phillips Episcopal-Memorial Medical Center's Radiation Therapy Department to improve the effectiveness of our quality management control program so as to prevent further violations. The cornerstone of this QM program involves the addition of a new experienced, motivated, and highly trained staff, starting first with a newly appointed radiation safety officer with over eighteen years of clinical and NRC experience. In addition, a new consulting medical physicist has been hired; he has over twenty years of clinical and NRC experience in Cobalt teletherapy. We also have a new registered radiation therapy technologist with over thirty years of Cobalt⁶⁰ and Quality Management experience that has joined our team. This team has reviewed and fine-tuned the existing QM program. The foundation of our program is improved communication between all members of the team and the department director regarding compliance of NRC requirements pertinent to our facility.

SUBJECT: Reply to a notice of violation
Page 4

The Physician Chart Screen was developed by this team. The radiation safety officer will review each chart screen for completeness at the time of treatment termination.

The radiation safety officer will perform a monthly review of the screens for compliance; he will then dictate a summary of these results and detail the corrective measures taken to prevent further noncompliance. This summary will then be given to the chief radiation therapy technologist for review and to be filed in the appropriate QM notebook, which will be kept in audible form at the facility for three years. A copy of the radiation safety officer's summary will be sent to the department director for his review and comments.

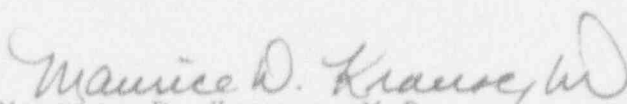
Sincerely,



Scott Smith
Vice President of Clinical Services



David Stire
Director of Diagnostic Imaging



Maurice D. Krause, M.D.
Radiation Safety Officer
Radiation Therapy

CC: Oklahoma Radiation Control Program Director

MDK/DS/DA/jd

MEMO TO: Maurice D. Krause, M.D., R.S.O. for Radiation Therapy
Don Howard, M.D., R.S.O. for Diagnostic Imaging
Scott Smith, Vice President of Clinical Services
Cathy Abrams, Vice President of Patient Care Services
Michael Davis, Chief Tech for Nuclear Medicine

FROM: David Stire, Director of Diagnostic Imaging

DATE: January 3, 1993

SUBJECT: 1994 Quarterly Radiation Safety Committee Meetings

The following is a complete list of the dates for the quarterly Radiation Safety Committee meetings for the 1994 calendar year. Each meeting will be held at noon in the Diagnostic Imaging Conference Room. Your attendance is essential to the ongoing efforts of this committee and is required by the regulating bodies. Please mark these dates on your calendar. You also will receive a follow-up memo from myself, one week prior to each scheduled meeting. Please contact me if you have any questions or comments.

1994 meeting dates are as follows: February 2, 1994
May 4, 1994
August 3, 1994
November 2, 1994

DS/jd

PHYSICIAN CHART SCREEN

Patient's Name: _____ Referring Physician: _____

- 1. Is the diagnosis stated? () ()
- 2. Is the stage of disease stated? () ()
- 3. Is the pertinent histopathology report on chart? () ()
- 4. Was a h/istory/P.E. done by radiation oncologist? () ()
- 5. Was a consultation letter sent to the referring physician and placed in the chart? () ()
- 6. Is there a signed and witnessed consent form in the chart? () ()
- 7. Is there a written directive (prescription) for teletherapy signed and dated by the authorized user (radiation oncologist) prior to the first treatment? () ()
- 8. Does the prescription state the dose per fraction? () ()
- 9. Does the prescription state the specific treatment site? () ()
- 10. Does the prescription state the overall treatment time? () ()
- 11. Was each treated area, documented by weekly port films? () ()
- 12. Were the initial dose calculations signed by the radiation oncologist and checked by the treating technologist or physicist prior to the first treatment? () ()
- 13. If a computer treatment plan was done, was it reviewed and signed by the radiation oncologist before treatment? () ()
- 14. Was the patient periodically examined by the radiation oncologist? () ()
- 15. Was the chart checked weekly by the treating technologist? () ()
- 16. Were dosimetry calculations and daily patient doses checked weekly by the physicist/dosimetrist? () ()
- 17. Did the patient complete the prescribed course of treatment? () ()
- 18. Is there a completion of therapy letter sent to the referring physician and placed in chart? () ()

Periodic MD Exam

Weekly Port Film

Weekly Physics Check

Date: _____

Date: _____

Date: _____

INFORMATION:

OWNER OF SOURCE JANE PHILLIPS OUTPATIENT CLINIC

ADDRESS OF OWNER BARTLESVILLE, OK

TYPE OF ISOTOPE AND ACTIVITY Co 60 5250 Ci Nov 1, 87

IDENTIFICATION OR MODEL NO. T-908

DATE WIPE WAS TAKEN 3-5-92

WIPE MADE BY David S. Gooden
(SIGNATURE)

CONTENTS:

1. ONE (1) SWAB FOR DRY WIPE (RED)
2. ONE (1) SWAB FOR WET WIPE (WHITE)
3. ONE (1) VIAL FOR DRY WIPE
4. ONE (1) VIAL FOR WET WIPE
5. ONE (1) INSTRUCTION-REPORT SHEET
6. ONE (1) RETURN MAIL PACKET

DO NOT WRITE BELOW THIS LINE

REPORT:

REMOVABLE CONTAMINATION (WET SWAB)

REMOVABLE CONTAMINATION (DRY SWAB)

| |
|-------------------|
| BETA-GAMMA μCi |
| <0.0003 |
| <0.0003 |

SCINTILLATION DETECTOR

LOWER WINDOW: 750 keV

UPPER WINDOW: 1500 keV

B.G. 63 C/MIN.

(RED) DRY + B.G. 65 C/MIN.

(WHITE) WET + B.G. _____ C/MIN.

B.G.+STANDARD (0.0004 μCi of Co 60): 153 C/MIN.

CERTIFIED BY

David S. Gooden

DAVID S. GOODEN, PH.D.
RADIOLOGICAL PHYSICIST
6161 SOUTH YALE AVENUE
TULSA, OKLAHOMA 74136

W. Krause
Radiation Safety Officer
12/30/93

Note: Last wipe 9/6/91

Recorded in documentation of calibration
Correspondence dated 9/20/91

*NOTICE: THIS PAPER MUST BE RETURNED WITH WIPE SAMPLES

PLEASE SEE OTHER SIDE

INFORMATION:

OWNER OF SOURCE

Jane Phillips Outpatient

ADDRESS OF OWNER

Bartlesville, Oklahoma

TYPE OF ISOTOPE AND ACTIVITY

Cobalt 60; 5250 Curies

IDENTIFICATION OR MODEL NO.

T-908 (11/1/87)

DATE WIPE WAS TAKEN

9/3/92

WIPE MADE BY

David S. Gooden

(SIGNATURE)

CONTENTS:

1. ONE (1) SWAB FOR DRY WIPE (RED)
2. ONE (1) SWAB FOR WET WIPE (WHITE)
3. ONE (1) VIAL FOR DRY WIPE
4. ONE (1) VIAL FOR WET WIPE
5. ONE (1) INSTRUCTION-REPORT SHEET
6. ONE (1) RETURN MAIL PACKET

DO NOT WRITE BELOW THIS LINE

REPORT:

REMOVABLE CONTAMINATION (WET SWAB)

REMOVABLE CONTAMINATION (DRY SWAB)

| |
|------------------------------|
| BETA-GAMMA μCi |
| <0.0003 |
| <0.0003 |

SCINTILLATION DETECTOR

LOWER WINDOW: 750 keV

UPPER WINDOW: 1500 keV

B.G. 81 C/MIN.

(RED) DRY + B.G. 72 C/MIN.

(WHITE) WET + B.G. _____ C/MIN.

B.G.+STANDARD (0.0004 μCi of Co 60): 150 C/MIN.

CERTIFIED BY

David S. Gooden

DAVID S. GOODEN, PH.D.
RADIATION PHYSICIST
6161 SOUTH YALE AVENUE
TULSA, OKLAHOMA 74136

Maurice D. [unclear]
Radiation Safety Officer
12/30/93

Tom Sackard, [unclear]

NOTICE: THIS PAPER MUST BE RETURNED WITH WIPE SAMPLES

PLEASE SEE OTHER SIDE

INFORMATION:OWNER OF SOURCE Jane Phillips Outpatient ClinicADDRESS OF OWNER Bartlesville, OklahomaTYPE OF ISOTOPE AND ACTIVITY Co-60 5250 CuriesIDENTIFICATION OR MODEL NO. # T-908 (11/1/87)DATE WIPE WAS TAKEN 3-10-93WIPE MADE BY David S. Gooden

(SIGNATURE)

CONTENTS:

1. ONE (1) SWAB FOR DRY WIPE (RED)
2. ONE (1) SWAB FOR WET WIPE (WHITE)
3. ONE (1) VIAL FOR DRY WIPE
4. ONE (1) VIAL FOR WET WIPE
5. ONE (1) INSTRUCTION-REPORT SHEET
6. ONE (1) RETURN MAIL PACKET

DO NOT WRITE BELOW THIS LINE

REPORT:

REMOVABLE CONTAMINATION (WET SWAB)

REMOVABLE CONTAMINATION (DRY SWAB)

| |
|------------------------------|
| BETA-GAMMA μCi |
| <0.0003 |
| <0.0003 |

SCINTILLATION DETECTOR

LOWER WINDOW: 750 keVUPPER WINDOW: 1500 keVB.G. 42 C/MIN.(RED) DRY + B.G. 45 C/MIN.

(WHITE) WET + B.G. _____ C/MIN.

B.G.+STANDARD (0.0004 μCi of Co-60): 153 C/MIN.

CERTIFIED BY

David S. Gooden

DAVID S. GOODEN, PH.D.
RADIOLOGICAL PHYSICIST
6161 SOUTH YALE AVENUE
TULSA, OKLAHOMA 74136

*NOTICE: THIS PAPER MUST BE RETURNED WITH WIPE SAMPLES12/30/93

PLEASE SEE OTHER SIDE