U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket:	030-01625
License:	13-06009-01
Report:	030-01625/96-001(DNMS)
Licensee:	Community Hospitals of Indiana, Inc.
Facility:	Community Hospital East
Location:	1500 North Ritter Avenue Indianapolis, Indiana 46219
Dates:	August 21, 1996 through October 2, 1996
Inspector:	D. G. Wiedeman, Senior Radiation Specialist
Approved:	John R. Madera, Chief Nuclear Materials Inspection Branch 1

Attachments:
A: partial list of persons contacted, items opened and discussed and list of acronyms used;
B: written directive;
C: patient notification document;
D: licensee's 30 day report;
E: NRC's Medical Consultant's report

9611-

EXECUTIVE SUMMARY

Community Hospitals of Indiana, Inc.
Indianapolis, Indiana
NRC Inspection Report 030-01625/96-001(DNMS)

This special inspection focused on the implementation of the licensee's Quality Management Program (QMP), with particular emphasis on the circumstances relating to an HDR brachytherapy misadministration involving an underdose to the intended treatment site and additional exposure to an unintended area of a patient's esophagus during the first of four proposed treatments. The misadministration was caused by an error in the calculation of the length of the catheter hub that was used during the treatment. The patient is expected to have no adverse effects as a result of the misadministration.

Regulatory Issue

Based on the findings of the inspection, it was determined that the HDR brachytherapy treatment performed on August 16, 1996, constitute a misadministration in that the treatment occurred to an unintended area of the patient's esophagus and the administered dose to the tumor volume deviated by more than 20 percent from the prescribed dose. A violation of 10 CFR 35.32(a)(3) was identified for failure of the licensee to establish written procedures to meet the objectives that the final plans of treatment and related calculations for brachytherapy are in accordance with the respective written directive. Specifically, the licensee's QMP did not contain written procedures or specific instructions regarding how to determine the correct off-set value when using 1,500 millimeter catheters (Violation 030-01625/96-001(01).

Report Details

1. Program Overview

1.1 Inspection Scope (IP 87100, 83822, TI 2800/025)

The inspector reviewed the license application, supporting documents, Quality Management Program (QMP), NRC letter dated August 19, 1994 to the licensee describing deficiencies in the written QMP, the NRC license, and the previous NRC inspection report. These documents describe the Community Hospitals of Indiana, Inc. HDR afterloader brachytherapy treatment program. The inspector discussed the current implementation of the QMP with the licensee and toured the treatment room.

1.2 Observations and Findings

Community Hospitals of Indianapolis, Inc. is authorized under its NRC license to possess 30 curies (1,100 GBq) of iridium-192 for use in a Nucletron MicroSelectron-HDR remote afterloading brachytherapy irradiator for interstitial and intracavitary treatment of cancer. The license authorizes one source of 15 curies (555 GBq) in the HDR unit and one source of 15 curies stored in its shipping container incident to a source exchange. This licensee performs approximately 150 treatments per year with the HDR unit. The last routine inspection was conducted on November 15-16, 1995 and no violations of NRC requirements were identified. The licensee's original written QMP was submitted on December 14, 1992. The most recent version of the QMP submitted to the NRC was dated June 29, 1994.

1.3 Conclusions

The licensee conducts an intermediate sized HDR brachytherapy program and no significant discernable changes in the program have occurred since the last inspection in November 1995.

2. Background

2.1 Inspection Scope (IP 87100, 83822, TI 2800/025)

The inspector toured the licensee's HDR therapy facility and discussed the implementation of the written QMP for brachytherapy treatments.

2.2 Observations and Findings

The HDR treatment facility was as described in the licensee's application and as described in the previous (November 1995) inspection report. A current copy of the licensee's QMP was available to all of the oncology staff and the NRC inspector's interviews of the licensee staff indicated that all of the licensee staff were aware of the QMP procedures and were knowledgeable of the requirements of the QMP.

2.3 Conclusions

The licensee's last annual QMP review did not identify any recordable or reportable events. Therefore, prior to the August 16, 1996 misadministration , the licensee's QMP was effective in providing high confidence that byproduct material was administered as directed by the AU.

3. Medical Misadministrations Sequence of Events

3.1 Inspection Scope (IP 37103)

The inspector interviewed the AU, medical physicist, RSO and reviewed the records for the HDR treatment performed on August 16, 1996.

3.2 Observations and Findings

- On August 16, 1996, the AU prepared a written directive prescribing a 500 cGy dose to the tumor volume in the esophagus with the 5.64 curie (208 GBq) iridium-192 source delivered by the MicroSelectron HDR unit. The written directive was dated and signed by the AU on August 16, 1996, see Attachment B.

- In preparation for the HDR treatment, a 1,500 millimeter catheter was inserted into the patient's esophagus via endoscopy, however, approximately 4 inches of the proximal end of the catheter was trimmed off. The Nucletron dummy source No. 1 was inserted into the catheter and an x-ray was taken to localize the dummy source train. The treatment plan was prepared by the medical physicist and reviewed by another independent medical physicist who agreed with the calculations and assumptions in the treatment plan. The finalized plan was then reviewed and approved by the AU.

- In setting the treatment parameters on the HDR console, the physicist entered an off-set value of 1,458 millimeters and the treatment progressed without any indication that the off-set value was in error. At the termination of the treatment, the medical physicist realized that the off-set value may have been slightly in excess of the value that would be needed to deliver the full dose to the tumor volume.

- After the treatment was completed and the esophageal catheter was removed from the patient, the medical physicist tested the source location in relation to the catheter and determined that the distal end of the source cable extended approximately 2.7 centimeters further than assumed. After checking all calculations and assumptions associated with the treatment plan, it was determined the off-set value of 1,458 millimeters should have been 1,437 millimeters. This error in source off-set value resulted in an exposure to an unintended area of the esophagus approximately 2.7 centimeters inferior to the center of the tumor volume.

- The licensee calculated that the unintended area that received the radiation exposure would have normally received a dose of 50-100 cGy if all treatment parameters were correct; however, because of the error in the off-set value, the unintended area of the esophagus received a dose of approximately 465 cGy and part of the tumor volume received approximately 35 cGy.

- At the time of the inspection it was determined that the licensee had no previous experience of using a 1,500 millimeter catheter and the No. 1 dummy source train. Of the remaining ten (10) 1,000 millimeter dummy sources in the Nucletron HDR unit, the licensee had previously preformed Quality Control/Quality Assurance (QC/QA) procedures for determining the off-set values. These procedures are part of the licensee's QMP. It was also determined that all previous cases of HDR treatments of the esophagus were performed with a 1,000 millimeter catheter and included the off-set values noted in the QC/QA manual.

- On the day of the HDR treatment (August 16, 1996) the patient was notified of the misadministration and a note was prepared and placed into the patient's chart that documented the misadministration, see Attachment C, and the NRC was immediately notified by telephone. The licensee provided a 30-day written report in accordance with 10 CFR 35.33, which includes its corrective actions, see Attachment D.

3.3 Conclusions

In accordance with the definition of misadministration in 10 CFR 35.2, the HDR treatment performed on August 16, 1996 constitutes a misadministration based on a wrong treatment site and the administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

4. Direct Cause of the Misadministration

4.1 Inspection Scope (IP 87103)

The inspector interviewed the AU, medical physicist, RSO and reviewed the records available.

4.2 Observations and Findings

It was determined that the licensee had no previous experience of using a 1,500 millimeter catheter and the No. 1 dummy source train. Of the remaining ten (10) 1,000 millimeter dummy sources in the Nucletron HDR unit, the licensee had previously preformed Quality Control/Quality Assurance (QC/QA) procedures for determining the off-set values. Therefore, on the day of the treatment, the licensee made an error in determining the off-set value for the 1,500 catheter using the Nucletron dummy source No. 1.

4.3 Conclusions

The root cause of the misadministration was: (a) An error on the part of the medical physicist when she calculated the off-set value for a 1,500 millimeter catheter and the failure of the second physicist to detect the error, and (b) Inadequate procedures for verification of the off-set value when using a 1,500 millimeter catheter.

5. Effect of Misadministration on Patient

Inspection Scope (MC 1360)

The inspector reviewed the licensee's report dated August 16, 1996, and the NRC medical consultant's report dated October 8, 1996.

Observations and Findings

The licensee indicated that it expects no adverse effect from the extension of the treatment area past the intended lower boundary.

An NRC medical consultant, Dr. Judith Stitt, was contacted on August 20, 1996, to review the misadministration and evaluate the likely medical effect on the patient. Dr. Stitt concluded that this misadministration will not exhibit any adverse consequences.

Conclusion

Both the licensee and the NRC medical consultant concluded that the misadministration that occurred on August 16, 1996, will not result in adverse effects to the patient.

6. Regulatory Issues (87100)

10 CFR 35.32(a) requires, in part, that each licensee establish and maintain a written QMP to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. The program must include written policies and procedures to meet the following objectives: (1) prior to administration, a written directive is prepared for any brachytherapy radiation dose, (2) prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive, (3) final plans of treatment and related calculations for brachytherapy are in accordance with the respective written directive, (4) each administration is in accordance with the written directive, and (5) any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

Based on the findings of the inspection, it was determined that the independent verification of the treatment plan performed by the second (verifying) medical physicist did not include a review of the assumptions made to determine the off-set value using a 1,500 millimeter catheter. If the assumptions and calculations for

determining the off-set value had been reviewed, the second physicist, in all likelihood, would have noticed the error and prevented the misadministration from occurring.

The licensee's QMP procedures require that before source insertion the final plans of treatment and related calculations for brachytherapy are reviewed by the Physics Staff to determine that they are in accordance with the written directive, for accuracy of data, source activity, number of sources and placement of source(s).

The licensee's failure to establish adequate procedures to ensure that the final plans of treatment and related calculations for HDR brachytherapy are in accordance with the written directive is an apparent violation of 10 CFR 35.32(a)(3).

Exit Meeting Summary

The inspection findings, as noted in the report were discussed with the licensee during an exit briefing conducted on August 21, 1996, at the licensee's facility at 1500 Ritter Avenue, Indianapolis, Indiana and during a telephone conversation on October 2, 1996. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary.

ATTACHMENT A

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Andrea Browne, Ph.D., RSO and Medical Physicist
Morgan Tharp, M.D., Authorized User (AU)
Debra Rasper, Corporate Operations Officer (COO), South Hospital

INSPECTION PROCEDURES USED

IP 87100:	Appendix B, Nuclear Medicine Inspection Field Notes
IP 87103:	Inspection of Incidents at Nuclear Materials Facilities
IP 83822:	Radiation Protection
TI 2800/025:	Quality Management Program and Misadministration Rule, Revision 1

ITEMS OPENED

030-01625/96-001(01)	VIO	failure to establish adequate procedures to ensure that the final plans of treatment and related calculations for HDR brachytherapy include procedures for determining the off-set values for 1,500 millimeter catheters.

LIST OF ACRONYMS USED

AU	Authorized User
cGy	Centigray
Gy	Gray
GBq	Gegabequerel
IP	Inspection Procedure
Ir-192	Iridium-192
MC	Manual Chapter
M.D.	Medical Doctor
NRC	Nuclear Regulatory Commission
QMP	Quality Management Program
TI	Temporary Instruction
VIO	Violation

Community Hospitals Indianapolis
Regional Cancer Center

High-Dose Rate Ir-192 Brachytherapy

Patient: [redacted] Site to be Treated: Esoph

Physician: ☐ Arve W. Gillette, M.D. ☐ Nini Bermudez-Webb, M.D. ☑ Morgan E. Tharp II, M.D.

Directive/Prescription

Fraction No.	Date	Dose to Volume (cGy)	ROI/Distance from catheter	Physician Full Signature (Authorized User)	Comments
1	8/16/96	500	1 cm	[signature]	
2					
3					
4					
5					

Source Information

	Fraction 1	Fraction 2	Fraction 3	Fraction 4	Fraction 5
Source #	568				
Calibration Date	7/1/96				
Activity (Ci)	8.667				
Tx Date	8/16/96				
Tx Activity (Ci)	5.64				

Quality Assurance

	Fraction 1	Fraction 2	Fraction 3	Fraction 4	Fraction 5
Patient ID**	(Yes) No	Yes No	Yes No	Yes No	Yes No
Dwell Positions and Dwell times Checked and Documented	(Yes) No	Yes No	Yes No	Yes No	Yes No
Film Views Checked	(Yes) No	Yes No	Yes No	Yes No	Yes No
By (Initials)	AJ				

**At least two different methods.

Assurance continued on back.

ality Assurance continued

	Fraction 1	Fraction 2	Fraction 3	Fraction 4	Fraction 5
No. of Catheters	1				
otal No. of Dwell Positions	# 9				
tal Tx Time (~~min.~~)	140.7 Sec.				
10 cm pt mputer Calc (cGy)	8.73				
cm pt Hand alc (cGy)*	8.96				
Difference	2.6				
(Initials)	AB				
kgnd level (mR/hr) 0.1 mR/hr	~0.02-				
(Initials)	AB				

and Calculated Dose at 10 cm:
Dose (cGy) = 0.7456 x 0.91 x Activity (Ci) x Time (min.)

mments/Notes:

Community

S

Regional Cancer Center

East Pavilion
1500 North Ritter Avenue
Indianapolis, Indiana 46219

North Pavilion
7229 Clearvista Drive
Indianapolis, Indiana 46256

General Information:
(317) 841-5656

Radiatic

Patient:
Hosp:
DOB:

Chart Note
8/16/96

After the patient had been discharged, it was brought to my attention by the physics staff that the dummy strands did not match adequately with the catheter. The reference point is in the middle of the coupler, and the dummies were not made with this taken into account for the 1500 mm catheter, as they are for the 1000 mm catheter. As such, there was a discrepancy in the prescribed point of dose and what was actually calculated by physics and delivered. I asked physics to review this carefully, and went over measurements with them. The treatment delivered was actually 2 cms inferior to what I had prescribed. I personally called the patient and she was informed that no significant damage has occurred, however the area designed to be treated was not treated adequately. This may necessitate one further implant at the end of therapy to give adequate tumor doses. NRC was also contacted by Andrea Browne, Ph.D., and formal written documentation also sent. This will also be reviewed in depth with physics for further quality assurance.

M.D.

Morgan E. Tharp II

cs

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ATTACHMENT C

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Community Hospitals Indianapolis

Community Hospital East

16th Street and Ritter Avenue
P.O. Box 19805
Indianapolis, Indiana 46219-0805
Telephone (317) 355-1411

US Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Aug. 16, 1996

Materials License 13-06009-01

Dear Sirs:

In accordance with 10 CFR 35.33 this a written report of a brachytherapy misadministration. The NRC Operations Center was notified by phone on 8/16/96.

LICENSEE: Community Hospitals, Indianapolis
PRESCRIBING PHYSICIAN: Morgan Tharp, MD
DATE OF MISADMINISTRATION: 8/16/96
DESCRIPTION OF EVENT: Treatment area described in directive misplaced by 2.7 cm inferiorly .
CAUSE OF EVENT: Length of dummy sources not corrected for length of catheter hub.
EFFECT ON PATIENT: No adverse effect. Volume of tumor not included in field will be corrected at next fraction.
IMPROVEMENTS TO PREVENT RECURRENCE: A table will be prepared with a listing of all dummy sources and their corrected length.
ACTION TO PREVENT RECURRENCE: Table of dummy vs length placed in QC manual.
NOTIFICATION: The patient was notified by Dr. Tharp of the error on 8/16/96.
CONTENT OF NOTIFICATION: Patient informed that we had undertreated area of tumor, that the dose difference would be corrected during the next treatment. No adverse effect was expected from the extension of the treatment area past the intended lower boundary.

If more information is required, please contact me at 317-355-5865.

Sincerely,

Andrea D. Browne, Ph.D.
Radiation Safety Officer

ATTACHMENT D
PAGE 1 of 1 pages

UNIVERSITY OF
WISCONSIN-MADISON
MEDICAL SCHOOL

October 8, 1996

Darrel Wiedeman
Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Il 60532-4351

Dear Mr. Wiedeman

Attached is the Medical Consultant Report on the Community Hospitals of Indiana regarding a misadministration. I have reviewed the records, described the incident and the medical consequences of the exposure. I agree with the written report submitted by the licensee. If you have any questions, please feel free to contact me (608/263-8500).

Sincerely,

Judith Anne Stitt, M.D.
Professor of Human Oncology

Enclosures

ATTACHMENT E
PAGE 1 of 3 PAGES
REPORT No. 030-01625/96-001

Department of Human Oncology

K4/B100 Clinical Science Center 600 Highland Avenue Madison, WI 53792 608/263-8500 FAX 608/263-9167

Medical Consultant: Judith Anne Stitt,MD Date: 10-8-96

Signature: _____

Licensee Name: Community Hospitals of Indiana License No. 13-06009-01

Patient Identification: Not identified

Incident Date: August 16, 1996

Patient's Physician Name: Morgan Tharp,MD

Individuals Contacted During Investigation: Morgan Tharp, MD

Records Reviewed: NCR Preliminary Description of Incident
CHI brachytherapy records

Description of Incident:

The patient has a diagnosis of carcinoma of the esophagus treated with combination chemotherapy and external beam therapy to 45 Gy. She was undergoing a course of high dose rate intraluminal brachytherapy with a planned dose of 5 Gy at 1 cm for 3 fractions every 2 weeks. The radiation oncology staff used a 1500 mm catheter that had not been calibrated by physics to deliver the first fraction. The dosimetrist who commonly performs the treatment planning was out for the day. The catheter was calibrated after the first fraction was given. The 1500 mm length has a 2.5 cm coupler attached to the end of the tube. The 1000 mm tube used for most treatments at this institution has the coupler included in the total length. As a result, there was a 2.5 cm inferior displacement of the catheter causing an underdose of the treatment site and a 2.5 cm length of esophagus receiving unintended dose. The patient will receive 4 fractions to achieve the desired total tumor dose.

Medical Consequence of Exposure:

The 2.5 cm length of esophagus that received 5 Gy will exhibit no adverse consequences from this fraction. This small volume was in the external beam treatment volume and received 45 Gy.

Was individual or individual's physician informed of DOE Long-Term Medical Study Program? Y N-

Would individual like to be included? Y N-

Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC (10 CFR 35.33) in the following areas:

a. Why the event occurred Y+ N

b. Effect on patient Y+ N

c. Licensee's immediate actions upon discovery Y+ N

c. Improvements needed to prevent recurrence Y+ N

e. Licensee's plan for follow up of patient Y+ N

f. Report submitted to patient or guardian Y+ N

Comments:

Briefly describe the medical condition of the exposed individual and the cause of the short-term medical care being provided to the individual.

No medical attention was needed as a result of the dose delivered to the 2.5 segment of the esophagus. Medical care is being provided according to standard oncologic practice for this patient who is being treated for her third malignancy of the aero-digestive tract.