

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-30954/94002(DRSS)

Docket No. 030-30954


License No. 34-16725-02

Licensee: Good Samaritan Hospital  
Zanesville, Ohio


Enforcement Conference At: NRC Region III Office (via Telephone)  
Lisle, Illinois

Enforcement Conference Conducted: February 17, 1994


Inspection Conducted: January 19, 1994

Inspector:   
James L. Cameron  
Radiation Specialist

3/23/94  
Date

Reviewed By:   
B. J. Holt, Chief  
Nuclear Materials Inspection  
Section I

2/24/94  
Date

Approved By:   
Roy J. Caniano, Chief  
Nuclear Materials Safety Branch

2/23/94  
Date

Meeting Summary

Enforcement Conference on February 17, 1994 (via Telephone) (Report No. 030-30954/94002(DRSS))

Areas Discussed: A review of the findings from the January 19, 1994 inspection, including a discussion of the apparent violations, the accuracy of the facts, causal factors, the corrective actions taken or planned by the licensee, and the NRC Enforcement Policy.

## DETAILS

### 1. Conference Attendees

#### Good Samaritan Hospital

Dan Sylvester, Vice President, Professional Services  
Z. Kaka, M.D., Authorized User Physician  
J. Safko, M.D., Radiation Safety Officer  
D. Phelps, Manager, Radiation Oncology  
Neal Smarra, Medical Physicist

#### Nuclear Regulatory Commission

Roy J. Caniano, Chief, Nuclear Materials Safety Branch, Region II.  
B. J. Holt, Chief, Nuclear Materials Inspection Section 1, Region III  
Bruce Berson, Regional Counsel, Region III  
James L. Cameron, Radiation Specialist, Region III  
Robert Gattone, Radiation Specialist, Region III  
Robert DeFayette, Director, Enforcement and Investigation Coordination  
Staff, Region III  
Joe Del Medico, Senior Enforcement Specialist, Office of Enforcement  
Patricia Holahan, Ph.D., Senior Health Physicist, Office of Nuclear  
Material Safety and Safeguards  
Torre Taylor, Health Physicist, Office of Nuclear Material Safety and  
Safeguards

### 2. Enforcement Conference Summary

An Enforcement Conference was held in the NRC Region III office via telephone on February 17, 1994, between members of the NRC and Good Samaritan Hospital staffs. The conference was held to discuss the findings of an NRC inspection conducted on January 19, 1994, which identified several apparent violations. One apparent violation, which is being considered for escalated enforcement, involved the licensee's failure to instruct supervised individuals in the radiation safety principles appropriate to the individuals' use of byproduct material.

The purpose of the conference was to: (1) review the apparent violations; including root and contributing causes; (2) discuss the accuracy of the inspection findings; (3) discuss the licensee's corrective actions; (4) determine whether there were any aggravating or mitigating circumstances; and (5) obtain other information that would help determine the appropriate enforcement action. NRC inspection findings are documented in Inspection Report No. 030-30954/94001(DRSS), transmitted to the licensee by letter dated February 11, 1994.

The licensee did not contest the apparent violations and agreed with the accuracy of the information presented. The licensee described its corrective actions for the apparent violations that were discussed during the conference. In summary, the licensee's corrective actions

include: (1) formalizing the licensee's dosimetrist's "rule of practice" regarding comparison of the brachytherapy ribbon and catheter lengths prior to source implantation in order to ensure that the ribbon is properly seated; (2) providing training to all radiation therapy technologists and each medical physicist in the new procedure; (3) requiring that the authorized user physically implant source ribbons; (4) requiring that each radiation therapy technologist receives hands-on training and instruction in source implantation; and (5) requiring that the "stat" post-insertion radiograph be hand carried to the prescribing physician for evaluation as soon as possible to determine proper source placement.

On February 18, 1994, the licensee transmitted a facsimile copy of its procedures for providing training and instruction to patient care providers. A copy of that facsimile transmission is attached to this report.

The NRC staff acknowledged the licensee's statements and indicated that they would be considered in the NRC's decision for enforcement action.

3. Concluding Statement

NRC representatives summarized the NRC Enforcement Policy and process and indicated that the licensee will be notified in writing of NRC's proposed enforcement actions.

Attachment: Licensee's ltr.  
dtd. 02/18/94



## Good Samaritan Medical Center

*Sponsored by the Franciscan Sisters of Christian Charity*

February 18, 1994

Mr. B.J. Holt, Chief  
Nuclear Materials Inspection  
Section I  
United States  
Nuclear Regulatory Commission  
Region III  
801 Warrenville Road  
Lisle, Illinois 60532-4351

Dear Mr. Holt:

Enclosed you will find the information requested of Good Samaritan Medical Center in the conference call regarding NRC Inspection Report No. 030-30954/94001 (DRSS). I would just like to thank you, not only for explaining the information that was presented, but also for your staff's time to help educate us on the expectations set forth by the Nuclear Regulatory Commission.

Enclosed you will find oncology procedures 76.14.62 also identified as Item A and procedure 76.14.62.1 also identified as Item B. The first procedure which I will refer to as Item A was the procedure that was in place prior to Mr Cameron's visit. This procedure under the nursing care considerations explains the requirement that radiation training and its safety was part of the nurse care considerations.

Procedure 76.14.62.1 or Item B is the policy that was written by nursing at the directive of the Radiology/Radioisotope Committee meeting. I have been informed that this policy is in effect and that nursing staff has operated under this policy and procedure on all implants since Mr. Cameron's visit of January 19, 1994. The quality management of this policy and procedure will be reviewed for its effectiveness by the Radiology/Radioisotope Committee at its next session as I mentioned in our telephone conversation. In my discussion with the nurse manager she also informed me of the following:

- The posting of the NRC mandatory material in the nursing unit was completed immediately after Mr. Cameron's visit.

- She contacted the University of Cincinnati regarding their educational and training video at the suggestion of Mr. Cameron.
- At Mr. Cameron's suggestion, the education and training inservice video will be redone in an effort to simplify its presentation to the nursing staff by April 30, 1994.
- The nursing department is developing a radiation bulletin board for awareness within their unit.
- A self study module on radiation therapy is being created and its intended completion date is March 31, 1994.

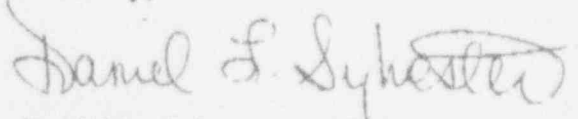
Enclosure C is a card placed in patient charts notifying the nursing staff that the patient is a radiation therapy patient. Please note that it is a requirement that all nursing staff where a radiation badge or monitor when entering the room. The only way a nursing employee can receive a monitor is after being inserviced and trained in the appropriate care of the radiation patient.

With regards to the April 13, 1993, NRC information notice # 93-31, I was unable to find documentation that we received this notice from the NRC. However, Good Samaritan Medical Center's Radiation Therapy staff and Nursing staff were made aware of this information through out consulting physics group.

I apologize for not having the above information available at the time of our conference call but having not gone through a process of this nature before, I was unprepared.

Upon your review of our policy and procedure regarding nursing staff education and training, if you have any recommendations they would be appreciated. If I can forward any additional information as you review this incident, please feel free to contact me at (614)454-5499.

Sincerely,



Daniel L. Sylvester, FACHE  
 Vice President  
 Professional Services

DLS:clh

Enclosures

A.

GOOD SAMARITAN MEDICAL CENTER  
Tanzville, Ohio

DEPT: Oncology	Policy/Procedure Applicable to:
SECTION: 76.14.62	

SUBJECT: Intracavity Cesium Implants - Care of Patient With

	DATE	DEPARTMENT HEAD	MEDICAL STAFF (if applicable)
PREPARED:	4/88	Linda Bacon, RN	
APPROVED:	8/93	Cherie Fisher, RN	
EFFECTIVE:	8/93	Shellie Heagen, RN	
REVIEWED:			

**PURPOSE**

To maintain proper placement of the cesium source and institute appropriate environmental precautions to protect the staff, while providing safe and effective care for the patient.

**NURSING CARE CONSIDERATIONS**

To provide appropriate and safe nursing care to the patient with an intracavity cesium implant. Any employee coming into direct care of the patient is required to have special training in radiation therapy and safety. The employee needs to have a basic knowledge of radiation physics, mechanisms of exposure, dosimeter readings and care of badges, concerns involving time, distance shield, sources, cesium applicators, room set up, visitor regulations, emergency care, nursing care of the patient and where to channel questions.

**DEFINITIONS:**

**BRACHYTHERAPY**

Refers to the administration of a radioactive source in close proximity to the patient. Can be permanent or temporary.

**INTRACAVITY IMPLANTS**

Involves the placement of a radioactive source into a body cavity. Generally  $^{226}\text{Ra}$  (radium) or  $^{137}\text{Cs}$  (Cesium).

**CESIUM APPLICATORS (FLETCHER - SUITE)**

Two-piece metal apparatus designed to contain the cesium source while resting within the vaginal vault and uterus. The tip of the tandem is inserted into the uterus, while the coils remain within the vagina.

**AFTERLOADING**

Procedure of inserting an empty cesium applicator in surgery and later loading or inserting the actual cesium source in the recovery room, radiation therapy or the patient's room.

**INDICATIONS/DURATION OF TREATMENT**

Cesium implants therapy may be considered for patients with cervical cancer, cancer of the vagina and/or endometrial cancer. The implant usually stays in place for 48 to 72 hours.

GOOD SAMARITAN MEDICAL CENTER  
Zanesville, Ohio

B

DEPT: Oncology SECTION: 76.14.62.1	Policy/Procedure Applicable to:
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SUBJECT: Staff Education and Training Involving Intracavity Cesium Implants

	DATE	DEPARTMENT HEAD	MEDICAL STAFF (if applicable)
PREPARED:	1/94	Donna Porter	
APPROVED:	1/94	Shellie Heagen	
EFFECTIVE:	1/94	Shellie Heagen	
REVIEWED:			

**PURPOSE**

To maintain consistent and appropriate training of staff involved in direct care of the patient with intracavity cesium implants. Provided will be an outline of the topics covered in the training.

**DEFINITIONS:**

**BRACHYTHERAPY**

Refers to the administration of a radioactive source in close proximity to the patient.

**TIME**

A short exposure time involves a small amount of radiation.

**DISTANCE**

Radiation exposure can be reduced by increasing the distance between the source of radiation and the caregiver.

**SHIELD**

Proper shielding from radiation prevents exposure.

**INTRACAVITY IMPLANTS**

Involves the placement of a radioactive source into a body cavity.

**CESIUM APPLICATORS (COLPOSTATS, TANDEMS)**

Two-piece metal apparatus designed to contain the cesium source while resting within the vaginal vault and uterus.

**IRIDIUM-192 RIBBON**

Thin nylon tube designed to contain Iridium-192 seeds/sources while in an intracavity.

**SOURCES**

Actual radioactive isotopes.



SUBJECT: Staff Education and Training  
Involving Intracavity Cesium Implants

SECTION: 76.14.62.1

PROCEDURE

Staff assigned to provide direct care to the patient during the administration of intracavity cesium implants will be required to have annual training involving the following material:

- Basic knowledge of radiation physics
- Methods of exposure
- Radiation safety
- Time distance shield
- Sources
- Cesium applicators (Examples shown)
- Dosimetry readings
- Care and use of radiation badges
- Room set up
- Visitor regulations
- Nursing care of the patient
- Emergency care
- Preop and postop care
- Directions for questions or concerns



