

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-02649/92001(DRSS); 030-17931/92001(DRSS)

Docket Nos. 030-02649; 030-17931

License No. 34-00466-01

Category G(1)

Priority 1

License No. 34-00466-04

Category E

Priority 3

Licensee: Cleveland Clinic Foundation (CCF)  
9500 Euclid Avenue  
Cleveland, Ohio

Inspection At: Same as above

Inspection Conducted on: January 28-29, 1992

Inspectors: W. P. Reichhold  
W. P. Reichhold  
Radiation Specialist

23 MARCH 1992  
Date

S. S. Wagner  
S. S. Wagner  
Health Physics Intern

24 MARCH 92  
Date

Approved By: W. H. Schultz  
W. H. Schultz, Chief  
Nuclear Materials Section 1

3-25-92  
Date

Inspection Summary

Inspection on January 28-29, 1992 (Reports No. 030-02649/92001;  
No. 030-17931/92001(DRSS))

Areas Inspected: This was a special, announced inspection performed to review the circumstances surrounding the brachytherapy misadministration discovered on January 17, 1992, and a routine inspection of the irradiators. The inspection included a review of records, a walk through the brachytherapy storage room and the areas where the irradiators were used, and interviews with personnel.

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Results: There were no apparent violations, but the inspectors had the following concerns:

1. Color(s) (used for coding) on the cesium-137 brachytherapy sources were faded.
2. Brachytherapy technologists were not sure of the procedure that required them to double verify the physicist's actions when he removed cesium-137 sources from the storage safe.
3. The design of the sealed source storage room makes it difficult for two individuals to observe the removal of the cesium-137 brachytherapy sources from the storage safe.

## DETAILS

### 1. Persons Contacted

\*Thomas F. Keys, M.D., Associate Chief Quality Management  
\*Gopal Saha, PhD., Radiation Safety Officer  
Melvin Tefft, M.D., Radiation Therapy Department Chairman  
Patrick Higgins, PhD., Radiation Physicist  
Deborah A. Jenkins, M.S., Radiation Physicist  
Mary Weir-Boylan, R.T.T., Department Manager Radiation Therapy  
Pam Saffle, R.T.T., Brachytherapy Technologist  
Rebecca Smith, R.T.T., Staff Technologist  
Mary Devito, R.T.T., Staff Technologist  
John Manchook, Radiation Safety Technologist  
Thomas Pauer, Radiation Safety Assistant

\*Indicates individuals at the exit meeting.

### 2. Purpose of Inspection

This was a special inspection performed to review the circumstances surrounding a brachytherapy misadministration that occurred during the first of two gynecological treatments. A physicist discovered that the wrong sources were used when he unloaded the source applicator on January 17, 1992. The physicist reported the misadministration to the NRC on January 17, 1992.

The inspection also included a routine inspection of the self shielded irradiators.

### 3. Summary of the Misadministration

On January 15, 1992, a patient received the first of two gynecological treatments. The treatment involved the use of a Fletcher-Suit afterloading apparatus, which consisted of a tandem and a pair of ovoids. A physicist and a therapy technologist worked together to load the apparatus. They both checked the treatment plan to determine the strength of the cesium-137 sources to be used in the ovoids and checked a sketch of the safe to determine the location of the cesium-137 sources they needed.

The storage safe has 6 drawers containing cesium-137 sources of different mg Ra eq (milligram radium equivalent) strengths. The cesium-137 sources are coded with a band or bands of color so that the different strengths can be determined. For example, a 22.9 mg Ra eq cesium-137 source has a yellow, black, and an orange band. A 7.8 mg Ra eq cesium-137 source has a yellow, black, and red band.

The therapy technologist checked that the physicist had opened the correct drawer and that the correct color code was on the two cesium-137 sources that were loaded in the ovoids.

Next, the physicist loaded the tandem with cesium-137 sources. The tandem was to be loaded with a 16.5, 11.9 and a 11.9 mg Ra eq cesium-137 sources. The physicist correctly put the 16.5 mg Ra eq cesium-137 into the tandem, but made a mistake on selecting the last two cesium-137 sources.

The physicist opened the wrong drawer and put the wrong cesium-137 sources in the tandem by mistake. Two 22.9 mg Ra eq cesium-137 sources were put into the tandem rather than two 11.9 mg Ra eq cesium-137 sources. The physicist did not check the colors on the last two cesium-137 sources. The therapy technologist was completing the paper work for the therapy procedure and did not watch the physicist to make sure that the correct drawer was opened and that the cesium-137 sources had the correct color code.

The cesium-137 sources were implanted on January 15, 1992, and were removed on January 17, 1992. A different physicist was returning the cesium-137 sources to the safe and discovered the error.

As a result of the error the dose to the patient was 4205 rads rather than the prescribed 2676 rads. Since this was the first of two planned treatments, the dose for the second treatment was reduced, so that the patient received the correct total prescribed dose. The referring physician and treating physician felt that the increase in the first treatment did not adversely effect the patient. The treating physician told the patient of the error and that the second treatment would be reduced.

The NRC contracted a medical consultant to evaluate this incident. His report will be provided in subsequent correspondence.

#### 4. Misadministration Causes and Concerns

- a. A specific procedure is followed when cesium-137 sources are removed from the storage safe. A physicist and a brachytherapy technologist both:
  1. Check the written prescription to determine the strength and number of cesium-137 sources.
  2. Check the sketch that shows the drawers where the cesium-137 sources are located.
  3. Verify that the correct drawer is opened and the location of the cesium-137 sources in the drawer.
  4. Verify that the color on the cesium-137 source matches the color code that corresponds to the strength of source needed for the therapy.

The procedure of double verifying the physicist's actions when removing the cesium-137 sources from the safe was a "understanding" between the physicist and the brachytherapy technologist. Currently, the brachytherapy technologist is preparing on a written procedure that describes the duties of the technologist when helping the physicist remove cesium-137 sources from the safe.

In this incident, the physicist opened the wrong drawer and removed the wrong sources by mistake. The physicist did not check the color code on the last two cesium-137 sources. Also, the therapy technologist was completing paper work for the therapy and did not verify the physicist's actions.

It was learned from interviews, that the physicist who was involved in this incident had about six years experience performing brachytherapy implants. The physicist had worked at CCF for about one year and had performed about one brachytherapy case per week. The physicist had learned the CCF's procedure for implants during on-the-job training. In this incident, the physicist had thought that the therapy technologist was watching her remove the sources from the safe.

The radiation therapy department was training two therapy technologists to work as brachytherapy technologists when this incident occurred. The therapy technologists had training on the brachytherapy procedures about six months to a year ago. Their training included watching the brachytherapy technologist and physicist remove cesium-137 sources from the safe.

In this incident, a therapy technologist was working with the physicist rather than the brachytherapy technologist. This was only the second time the therapy technologist helped the physicist prepare the sources for a brachytherapy treatment. The technologist was aware that she should have been watching the physicist remove the sources, but was completing the paper work for the therapy case instead. After interviews with the therapy technologists, it was learned that they were not sure of their duties when cesium-137 sources were removed from the safe. CCF reviewed these duties with the technologists a week after the incident. The therapy technologists stated that they now understood and were comfortable with their duties when cesium-137 sources were removed from the safe.

The training of the therapy technologists was brought to the RSO's attention at the closeout meeting.

- b. In this incident, the color code was not checked on all of the sources used. To the inspector, the colors on the cesium-137 sources appeared faded so that yellow appeared white or clear, and orange appeared pink. The colors on the cesium-137 sources were not easy to distinguish. The inspector recommended that the cesium-137 sources be repainted so that the colors can easily be seen. Faded colors on the cesium-137 sources had been expressed as a concern during an NRC inspection in May and June 1991.

During a discussion with Dr. Higgins (physicist) it was learned that CCF had tried to get the sources repainted by the manufacturer, but the company had closed. Dr. Higgins was also concerned that repainting the cesium-137 sources may increase the diameter of the source, so that they would not fit in the applicator.

During a telephone conversation between W. Reichhold (NRC inspector) and Dr. Higgins (physicist) in February 1992, it was learned that color(s) had been repainted on the ends of the cesium-137 sources.

- c. The physical arrangement of the cesium-137 storage room makes it difficult for the technologist to see that the physicist has opened the correct drawers in the safe and see the color(s) on the cesium-137 sources. There is room for only one person in front of the cesium-137 storage safe so the technologist has to look over the physicist's shoulder to see the safe's drawers and the cesium-137 sources. During the interviews, it was learned that in one case the physicist and brachytherapy technologist had shared the same stool so that the technologist could watch the physicist open the safe's drawers and see the color(s) on the cesium-137 sources.

From discussions with CCF representatives it was learned that they had plans to redesign the sealed source storage room, but no action had been taken yet.

No apparent violations were found, but the three areas that concerned the inspectors were reviewed at the exit meeting.

#### 5. Other Areas Inspected

The irradiators authorized by NRC License No. 34-00466-04 were also inspected. The inspection included a selective review of the following:

- a. kinds and quantities of radioactive material.
- b. irradiator users.
- c. area where the irradiators were used.
- d. area survey results.
- e. film badge results.
- f. G-M surveys around the irradiators.
- g. actions that were taken to correct the previous violations.

No apparent violations were found during the inspection of NRC License No. 34-00466-04 (irradiators).

#### 6. Exit Meeting

An exit meeting was held on January 29 1992, with the individuals noted in Section 1 of this report. We discussed the the concerns about the brachytherapy program and the enforcement actions the NRC could take.