U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02008/94001(DRSS)

Docket No. 030-02008

EA No. 94-137

License No. 21-01424-03 Category G3 Priority 3

Licensee: Blodgett Memorial Medical Center
Grand Rapids, MI

Inspection Conducted: June 28 through July 8, 1994

Inspector: Thomas F. Young — July 25, 1994
Thomas F. Young
Radiation Specialist
Date

Reviewed By: John A. Grobe — 7-25-94
John A. Grobe, Chief
Nuclear Materials Inspection
Section 2
Date

Approved By: Roy J. Caniano — 7-25-94
Roy J. Caniano, Chief
Nuclear Materials Safety Branch
Date

Inspection Summary

Inspection on June 28 through July 8, 1994 (Report No. 030-02008/94001(DRSS))

Areas Inspected: This special announced inspection was conducted to review the misadministration event involving a strontium-90 eye applicator brachytherapy device that was reported by the licensee to the NRC Region III Office on June 15, 1994. The inspection also evaluated the development and implementation of the licensee's Quality Management Program related to use of the device.

Results: A strontium-90 eye applicator was used for an incorrect treatment time to treat pterygium in the left eye of a patient. The intended treatment time for each of three fractions was 19.1 seconds. The treatment time used for the second fraction was one minute and nine seconds. The total calculated administered dose, 3918 cGy (3918 rads), exceeded the total prescribed dose, 2550 cGy (2550 rads), by 53 percent. The licensee completed all notifications, reports, and records for the misadministration.

Seven apparent violations were identified during the course of this inspection:

1. Failure of the authorized user to prepare, date, and sign a written directive prior to use of the strontium-90 eye applicator on June 7 and June 14, 1994, is an apparent violation of 10 CFR 35.32(a)(1). Please refer to Section 5.

2. Failure of the licensee to review all dose calculations before the total prescribed brachytherapy dose was delivered on December 23, 1992 through January 6, 1993, and on March 17 through 31, 1994, is an apparent violation of 10 CFR 35.32(a)(3). Please refer to Section 5.

3. Failure of the licensee to confirm that the total dose from the strontium-90 eye applicator agreed with a written directive and treatment plan before administration of the brachytherapy doses on June 7 and June 14, 1994, is an apparent violation of 10 CFR 35.32(a)(4). Please refer to Section 5.

4. Failure of the licensee to instruct radiation oncology technologists in the licensee's Quality Management Program for use of the strontium-90 eye applicator is an apparent violation of 10 CFR 35.25(a)(1). Please refer to Section 5.

5. Failure of the licensee's Radiation Safety Officer to investigate the misadministration and implement corrective actions as necessary is an apparent violation of 10 CFR 35.21(b)(1). Please refer to Section 7.

6. Failure of the licensee to make a record of use for the strontium-90 eye applicator is an apparent violation of 10 CFR 35.406(b). Please refer to Section 8.

7. Failure of the licensee to maintain the radiation safety and handling instructions that were supplied by the manufacturer for the strontium-90 eye applicator is an apparent violation of 10 CFR 35.59(a). Please refer to Section 8.

DETAILS

1. Persons Contacted

*#+Robert H. Smereka, M.S., Radiation Physicist
*+ Larry Genzink, Director, Diagnostic Imaging
* Sheila Susskirini, Chairperson, Radiation Safety Committee
* Ron Price, Radiation Oncology Technologist
#+ Armand Michael LaSorsa, M.D., Radiation Safety Officer
#+ Wilma Ewald, M.D., Radiation Oncology, Authorized User
William Zimmerman, M.D., Referring Physician
+ Paul Charkowski, Assistant Director, Diagnostic Imaging
+ Randy Oostra, Assistant Vice President

* Indicates persons present at the onsite exit meeting on June 28, 1994.
# Indicates individuals contacted by telephone.
+ Indicates persons present at the exit teleconference on July 8, 1994.

2. Inspection History

Since 1987, the licensee has established a trend of improving performance during recent Region III routine inspections. The 1990 inspection included a broad review of licensed activities and closeout of numerous violations identified in 1987. While one Severity Level IV violation was identified in the nuclear medicine area during each of the 1990 and 1993 programmatic inspections, NRC inspectors noted that licensee performance evaluation factors were satisfactory. An additional inspection of the high dose rate afterloader brachytherapy treatment device was performed in late 1993 with no adverse findings. Because of the very infrequent use, the NRC Region III Office did not specifically inspect the licensee's use of the strontium-90 eye applicator prior to June 28, 1994.

3. Licensed Program

The byproduct material use program authorizes 10 CFR 35.100, 200, 300, 400, and 500 material, depleted uranium for the linear accelerator, a sealed source containing 10 millicuries of strontium-90 for calibration purposes, chromium-51 kits (1 millicurie, total) for in-vitro studies, a gas chromatograph with three electron capture detector cells containing nickel-63 foils (8 millicuries each), and iridium-192 sealed sources (two sources not to exceed 10 curies each) for the high dose rate afterloading brachytherapy device that may be used for interstitial, intracavitary, or bronchial radiation therapy.

The licensee's facility is a 450-bed hospital that includes the nuclear medicine department where about 700 diagnostic nuclear medicine procedures per month are performed. Radiopharmaceutical therapy includes iodine-131 capsules for hyperthyroid treatment (about 10 per month), and thyroid ablation (about one per month).

The radiation oncology department employs a full time physicist and two dosimetrists who are involved with about two temporary implant brachytherapy procedures per month and five high dose rate remote afterloading brachytherapy patients per month. In addition they are involved with the daily use of a linear accelerator and superficial voltage x-ray unit for treatment of patients.

4. Misadministration Event Details and Chronology

In March 1994, the patient received brachytherapy without incident involving a three fraction treatment using the strontium-90 eye applicator for pterygium in the right eye. Similar difficulties developed in the patients left eye. The patient was scheduled to receive a three fraction brachytherapy treatment for pterygium in the left eye beginning on June 7, 1994. The first fraction was completed without incident on June 7, 1994. The second fraction was scheduled at 10:00 a.m. on June 14, 1994. At approximately 11:00 a.m. the authorized user requested the radiation oncology technologist to bring the patient to an exam room in the radiation oncology department. The strontium-90 eye applicator was seldom used and the technologist was not accustomed to assisting the authorized user with this type of treatment. After the treatment site was anesthetized, the authorized user requested the technologist to obtain the strontium-90 eye applicator from the radiation physicist.

The radiation physicist was unaware of the scheduled use of the strontium-90 eye applicator and had not prepared a treatment plan for the June 1994 treatment. The radiation physicist removed the strontium-90 eye applicator from the brachytherapy source storage room and brought it to the exam room where the authorized user, technologist, and patient were waiting.

The radiation physicist briefly left the radiation oncology department to calculate the treatment time to be used for the standard radiation dose fraction desired by the authorized user, 850 cGy (850 rads). The treatment time had been calculated as 19.1 seconds for the treatment fractions that were completed in March 1994. The radiation physicist determined that the physical decay of strontium-90 was negligible and it was not necessary to recalculate the treatment time for June 14, 1994.

Upon returning to the radiation oncology department, the radiation physicist informed the technologist to use the same treatment time as the last treatment, referring to the March 1994 treatment. The radiation physicist was not aware that the first treatment fraction had already been administered on June 7, 1994. He was further unaware that the treatment time for that first fraction had been incorrectly recorded in the treatment chart as 1.91 seconds instead of 19.1 seconds. A different technologist had assisted the authorized user during the treatment fraction on June 7, 1994, and that individual was not involved with the treatment fraction on June 14, 1994.

The authorized user did not specifically hear the verbal instruction given to the technologist by the radiation physicist. The authorized user asked the technologist what treatment time was needed for a radiation dose of 850 cGy (850 rads). The technologist indicated that the treatment time should be the same as the last treatment fraction. The authorized user relied on the instruction from the radiation physicist to the technologist and did not read the treatment chart for the correct treatment time.

The technologist referred to the treatment chart that indicated the last treatment on June 7, 1994. The treatment time was recorded as "1.91 sec". This notation is similar to the practice used to designate a treatment time of one minute and nine seconds for the superficial voltage x-ray unit. The technologist assumed that the treatment time should be one minute and nine seconds. The technologist's misunderstanding about the treatment time was not apparent to the technologist or the authorized user and there was no further discussion between the authorized user and the technologist prior to initiation of the treatment fraction.

The authorized user instructed the technologist to count audibly the last several seconds of the treatment time. The technologist removed the strontium-90 eye applicator from it's storage box, sterilized the applicator, and handed it to the authorized user. The technologist used a hand held stop watch to time the treatment fraction. The authorized user placed the strontium-90 eye applicator on the medial scleral surface of the patient's left eye. The authorized user was not distracted during the treatment fraction. As one minute and nine seconds was approaching, the technologist counted the last few seconds by saying,"... five, four, three, two, one, Stop!" The authorized user removed the strontium-90 eye applicator from the surface of the patient's eye and handed it to the technologist. The technologist sterilized the applicator and returned it to the storage box.

While the technologist was storing the applicator, the patient remarked that the treatment time was longer than the previous treatment fractions that had occurred in March 1994 and more recently on June 7, 1994. The authorized user noted the patient's comment and directed the technologist to immediately contact the radiation physicist.

The immediate discussion among the authorized user, technologist, and radiation physicist established that the intended treatment time had been exceeded, that the total calculated radiation dose exceeded the total prescribed dose, and that a misadministration had occurred. These individuals concluded that the root cause of the misadministration was human error, based on the inappropriate notation for the treatment time for the June 7, 1994, treatment fraction, i.e. "1.91 sec" rather than 19.1 seconds.

5. Development and Implementation of the Quality Management Program

10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a written Quality Management Program which must include policies and procedures to meet the specific objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain information including for brachytherapy, the radioisotope, the treatment site, source strength, and exposure time (or equivalently the total dose).

The licensee's written Quality Management Program implemented on January 27, 1992, section entitled, "Brachytherapy Quality Management Program", requires that, "prior to the administration of any brachytherapy dose, a radiation oncologist (authorized user) will date and sign a written directive. The written directive should include the radioisotope, number of sources, source strengths, and if applicable, loading sequence."

On June 7 and June 14, 1994, the authorized user did not prepare, date, and sign a written directive prior using the strontium-90 eye applicator to treat pterygium in the left eye of the patient. The authorized user relied on the written directive that was prepared on March 17, 1994, to treat the right eye of the patient for the same condition. The written directive appears in the treatment prescription section of the treatment chart that was placed in the patient's file and indicates for March 17, 1994: (1) the date, (2) treatment site, (3) radioisotope, (4) dose per fraction, (5) overall treatment period, (6) total dose, and (7) the authorized user's initials. The authorized user dictated some of the prescription information into progress notes that were placed in the radiation oncology department file for the patient after completing the treatment on June 7, 1994. Failure of the authorized user to prepare the written directive prior to using the strontium-90 eye applicator on June 7 and June 14, 1994, is an apparent violation of 10 CFR 35.32(a)(1).

After the discovery of the misadministration on June 14, 1994, the authorized user recorded the written directive in the treatment chart.

10 CFR Part 35.32(a) requires, in part, that the licensee establish and maintain a written Quality Management Program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR Part 35.32(a)(3), requires that the licensee's written Quality Management Program must include policies and procedures to meet the specific objective that final plans of treatment and related calculations for brachytherapy are in accordance with a written directive.

The licensee's written Quality Management Program implemented on January 27, 1992, section entitled, "Brachytherapy Quality Management Program", requires in part that, "10. All dose calculations will be reviewed before the total prescribed brachytherapy [dose] has been delivered."

The dose calculations for the strontium-90 eye applicator brachytherapy treatments administered December 23, 1992 through January 6, 1993, and March 17 through 31, 1994, were not reviewed before the total prescribed brachytherapy dose had been delivered. In December 1992 and January 1993, the radiation physicist performed dose calculations related to the use of the strontium-90 eye applicator and determined the treatment time necessary to administer 850 cGy (850 rads) to surface of the eye. However, the dose calculations were not provided to the radiation oncology physician who was using the strontium-90 eye applicator under the supervision of an authorized user. Consequently, the dose calculations were not reviewed before the total prescribed brachytherapy dose was delivered. On March 17, 1994, the radiation physicist completed the dose calculations and recorded the information that was placed in the patient file along with the treatment chart. However, the dose calculations were not reviewed or checked by the authorized user or another qualified person who did not make the dose calculations. Failure of the licensee to implement the licensee's written Quality Management Program for brachytherapy, Item 10, to ensure that final plans of treatment and related calculations for brachytherapy are in accordance with a written directive is an apparent violation of 10 CFR 35.32(a) (3).

The radiation physicist conducted in-service training for the radiation oncology staff on June 20, 1994. A purpose of the training was to ensure that in the future, the radiation physicist, dosimetrists, and technologists will review the treatment chart, treatment plan and related calculations before the total brachytherapy dose is administered. The radiation physicist prepared a physical decay chart for the strontium-90 eye applicator that indicates the surface dose rate and treatment time necessary to deliver 850 cGy (850 rads). The calculated values are updated annually through January 31, 2000. The physical decay chart will accompany the strontium-90 eye applicator and will be used by the dosimetrists and technologists to check the dose calculations.

10 CFR Part 35.32(a) requires, in part, that the licensee establish and maintain a written Quality Management Program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR Part 35.32(a)(4), requires that the licensee's written Quality Management Program must include policies and procedures to meet the specific objective that each administration is in accordance with a written directive.

The licensee's written Quality Management Program implemented on January 27, 1992, section entitled, "Brachytherapy Quality Management Program", requires that, "3. Before administration of a brachytherapy dose, the radioisotope, treatment site, and total dose are to be confirmed by the person administering the treatment to verify agreement with the written directive and treatment plan."

On June 7 and June 14, 1994, the authorized user administering a brachytherapy dose did not confirm that the total dose from the strontium-90 eye applicator agreed with a written directive and treatment plan before administration of the brachytherapy dose. Specifically, a written directive, treatment plan, and related calculations had not been prepared for the treatment and consequently the dose rate, treatment time, and total dose for the use of the strontium-90 eye applicator were not indicated for the treatment. Had the authorized user attempted to verify agreement prior to administration a misadministration may have been avoided. Failure of the licensee to implement the licensee's written Quality Management Program for brachytherapy, Item 3., to ensure that each administration is in accordance with a written directive is an apparent violation of 10 CFR 35.32(a)(4).

10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material under the supervision of an authorized user shall instruct the supervised individual in the licensee's written Quality Management Program.

The inspector interviewed the radiation oncology technologists who indicated that they did not receive training in the Quality Management Program for use of the strontium-90 eye applicator and that they are involved in the use of the strontium-90 eye applicator when they assist the radiation oncology physicians who use the strontium-90 eye applicator to treat the patients. The radiation physicist indicated that an oversight had occurred because the technologists were not included in the licensee's Quality Management Program training sessions since they are not involved with the use of the brachytherapy sources, except for the strontium-90 eye applicator. Failure of the licensee to instruct the radiation oncology technologists in the licensee's written Quality Management Program for the strontium-90 eye applicator is an apparent violation of 10 CFR 35.25(a)(1).

On June 20, 1994, the radiation physicist conducted a Quality Management Program training session for the radiation oncology department personnel. The training session dealt with the licensee's written Quality Management Program for brachytherapy, including the strontium-90 eye applicator.

Four apparent violations of NRC requirements were identified.

6. Notifications and Reports

On June 14, 1994, the radiation physicist explained the misadministration to the licensee's Radiation Safety Officer. The radiation physicist also notified the Director of Diagnostic Imaging, who requested the radiation physicist to prepare a written report of the misadministration.

On June 14, 1994, the authorized user notified the patient by telephone and explained that more radiation was given during the second treatment fraction so that the patient need not return for the third treatment fraction that was scheduled for the following week. The authorized user requested the patient to return on June 15, 1994, so that a follow up examination of the left eye could be accomplished.

On June 14, 1994, the authorized user explained the misadministration to the referring physician. They also discussed the patient's prognosis, that no adverse effect was expected. The referring physician did not object to the notification of the patient about the misadministration by the authorized user. The letter dated June 17, 1994, from the authorized user to the referring physician confirmed the June 14, 1994, discussions with the referring physician.

On June 15, 1994, the radiation physicist notified the NRC Operations Center of the misadministration and an inspector from the NRC Region III Office contacted the radiation physicist to discuss details of the event. The physicist reported that the calculated total administered dose (3918 rads) exceeded the total prescribed dose (2550 rads) by 53.6 per cent, i.e. greater than 20 per cent. The radiation physicist indicated the root cause of the misadministration was human error, based on failure of the authorized user to terminate the treatment after 19.1 seconds. The physicist indicated that the licensee's written Quality Management Program does not specifically address use of the strontium-90 eye applicator.

The licensee's written report of the misadministration dated June 16, 1994, was prepared by the radiation physicist and copies were distributed to the Radiation Safety Officer and authorized user. On June 27, 1994, this written report was sent by certified mail to the referring physician, the patient, and the NRC Region III Office. Also, the radiation physicist provided a copy of this written report to the NRC inspector on June 28, 1994.

No apparent violations of NRC requirements were identified.

7. RSO Investigations

10 CFR 35.21(b)(1) requires, in part, that the Radiation Safety Officer shall investigate misadministrations and implement corrective actions, as necessary. Since June 14, 1994, the misadministration was investigated and corrective actions were taken by other licensee staff members without the direct involvement of the Radiation Safety Officer.

After learning of the misadministration, the Radiation Safety Officer did not appear to be involved in the daily operation of the licensee's byproduct material program and did not conduct an investigation of the misadministration. Failure of the licensee's Radiation Safety Officer to investigate the misadministration that occurred on June 14, 1994, and implement corrective actions as necessary is an apparent violation of 10 CFR 35.21(b)(1).

During the week of July 11, 1994, the licensee's Radiation Safety Officer of Records resigned and the licensee designated the Radiation Physicist as the interim Radiation Safety Officer. The licensee proposed to submit a request to amend the license to name the Radiation Physicist as the Radiation Safety Officer. As of the date of this inspection report, the amendment request was not received.

One apparent violation of NRC requirements was identified.

8. Other Brachytherapy Program Areas

The licensee's administrative chain of command for the strontium-90 eye applicator includes: the Chief Operating Officer (Bruce Hagen), Assistant Vice President (Randy Oostra), Director of Diagnostic Imaging (Larry Genzink), and Radiation Physicist (Robert Smereka). The inspector evaluated other program areas relating to the use of the strontium-90 eye applicator. No problems were evident in the following areas: physical inventories, surveys, leak tests, posting, labeling, and security.

10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

As of June 28, 1994, the licensee's record of brachytherapy source usage did not include the strontium-90 eye applicator. The device is stored in an upper cabinet of the brachytherapy source storage room. The room is properly posted and locked. However, there was no specific record to account for the location of the device at all times, although the device is only used in the radiation oncology department and is not transported away from the radiation oncology department. Failure of the licensee to make a record of the names of individuals permitted to handle the device, the patient's name, date and time removed, date and time returned, and initials of the person(s) handling the device is an apparent violation of 10 CFR 35.406(b).

The Radiation Physicist prepared a log to record the date and time and other details pertaining to the strontium-90 eye applicator when it is removed from the brachytherapy source storage room.

10 CFR 35.59(a) requires that a licensee in possession of any brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer and shall maintain the instructions for the duration of source use in a legible form convenient to users.

As of June 14, 1994, the licensee did not maintain written radiation safety and handling instructions for the strontium-90 eye applicator. Failure of the licensee to maintain the instructions supplied by the manufacturer of the strontium-90 eye applicator for the duration of source use in a legible form convenient to users is an apparent violation of 10 CFR 35.59(a).

As a result of the misadministration, the Radiation Physicist prepared written rules for safe handling of the strontium-90 eye applicator and instructed the radiation oncology technologists and physicians about the rules.

Two apparent violations of NRC requirements were identified.

9. Exit Meeting

During the exit meeting with those individuals identified in Section 1 of this report, the inspector and section chief summarized the preliminary inspection findings including the violations and the apparent causes. The section chief also described the NRC's enforcement options. The licensee did not indicate that any information was proprietary.

ENCLOSURE 2

FEDERAL REGISTER NOTICE

POLICY STATEMENT FOR

TWO-YEAR TRIAL PROGRAM

FOR CONDUCTING

OPEN ENFORCEMENT CONFERENCES

Two-Year Trial Program for Conducting Open Enforcement Conferences; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing this policy statement on the implementation of a two-year trial program to allow selected enforcement conferences to be open to attendance by all members of the general public. This policy statement describes the two-year trial program and informs the public of how to get information on upcoming open enforcement conferences.

DATES: This trial program is effective on July 10, 1992, while comments on the program are being received. Submit comments on or before the completion of the trial program scheduled for July 11, 1992. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch.

Hand deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, MD between 7:45 a.m. to 4:15 p.m., Federal workdays.

Copies of comments may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301-504-2741).

SUPPLEMENTARY INFORMATION:

Background

The NRC's current policy on enforcement conferences is addressed in Section V of the latest revision to the "General Statement of Policy and Procedure for Enforcement Actions." (Enforcement Policy) 10 CFR part 2, appendix C that was published on February 18, 1992 (57 FR 5791). The Enforcement Policy states that, "enforcement conferences will not normally be open to the public." However, the Commission has decided to implement a trial program to determine whether to maintain the current policy with regard to enforcement conferences or to adopt a new policy that would allow most enforcement conferences to be open to attendance by all members of the public.

Policy Statement

Position

The NRC is implementing a two-year trial program to allow public observation of selected enforcement conferences. The NRC will monitor the program and determine whether to establish a permanent policy for conducting open enforcement conferences based on an assessment of the following criteria:

(1) Whether the fact that the conference was open impacted the NRC's ability to conduct a meaningful conference and/or implement the NRC's enforcement program;

(2) Whether the open conference impacted the licensee's participation in the conference;

(3) Whether the NRC expended a significant amount of resources in making the conference public; and

(4) The extent of public interest in opening the enforcement conference.

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orcement Conferences

Enforcement conferences will not be open to the public if the enforcement action being contemplated—

(1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

(2) Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

(3) Is based on the findings of an NRC Office of Investigations (OI) report; or

(4) Involves safeguards information, Privacy Act information, or other information which could be considered proprietary.

Enforcement conferences involving medical misadministrations or overexposures will be open assuming the conference can be conducted without disclosing the exposed individual's name. In addition, enforcement conferences will not be open to the public if the conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility. Finally, with the approval of the Executive Director for Operations, enforcement conferences will not be open to the public in special cases where good cause has been shown after balancing the benefit of public observation against the potential impact on the agency's enforcement action in a particular case.

The NRC will strive to conduct open enforcement conferences during the two-year trial program in accordance with the following three goals:

(1) Approximately 25 percent of all eligible enforcement conferences conducted by the NRC will be open for public observation;

(2) At least one open enforcement conference will be conducted in each of the regional offices; and

(3) Open enforcement conferences will be conducted with a variety of the types of licensees.

To avoid potential bias in the selection process and to attempt to meet the three goals stated above, every fourth eligible enforcement conference involving one of three categories of licensees will normally be open to the public during the trial program. However, in cases where there is an ongoing adjudicatory proceeding with one or more intervenors, enforcement conferences involving issues related to the subject matter of the ongoing adjudication may also be opened. For the purposes of this trial program, the three categories of licensees will be commercial operating reactors, hospitals, and other licensees, which will consist of the remaining types of licensees.

II. Announcing Open Enforcement Conferences

As soon as it is determined that an enforcement conference will be open to public observation, the NRC will orally notify the licensee that the enforcement conference will be open to public observation as part of the agency's trial program and send the licensee a copy of this Federal Register notice that outlines the program. Licensees will be asked to estimate the number of participants it will bring to the enforcement conference so that the NRC can schedule an appropriately sized conference room. The NRC will also notify appropriate State liaison officers that an enforcement conference has been scheduled and that it is open to public observation.

The NRC intends to announce open enforcement conferences to the public normally at least 10 working days in advance of the enforcement conference through the following mechanisms:

(1) Notices posted in the Public Document Room;

(2) Toll-free telephone message; and

(3) Toll-free electronic bulletin board messages.

Pending establishment of the toll-free message systems, the public may call (301) 492-0732 to obtain a recording of upcoming open enforcement conferences. The NRC will issue another Federal Register notice after the toll-free message systems are established.

To assist the NRC in making appropriate arrangements to support public observation of enforcement conferences, individuals interested in attending a particular enforcement conference should notify the individual identified in the meeting notice announcing the open enforcement conference no later than five business days prior to the enforcement conference.

III. Conduct of Open Enforcement Conferences

In accordance with current practice, enforcement conferences will continue to normally be held at the NRC regional offices. Members of the public will be allowed access to the NRC regional offices to attend open enforcement conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56231). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" be permitted, and that disruptive persons may be removed.

Each regional office will continue to conduct the enforcement conference proceedings in accordance with regional practice. The enforcement conference will continue to be a meeting between the NRC and the licensee. While the enforcement conference is open for public observation, it is not open for public participation.

Persons attending open enforcement conferences are reminded that (1) the apparent violations discussed at open enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by NRC employees at open enforcement conferences or the lack thereof, are not intended to represent final determinations or beliefs.

In addition to providing comments on the agency's trial program in accordance with the guidance in this notice, persons attending open enforcement conferences will be provided an opportunity to submit written comments anonymously to the regional office. These comments will subsequently be forwarded to the Director of the Office of Enforcement for review and consideration.

Dated at Rockville, MD, this 7th day of July 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 92-16233 Filed 7-9-92; 8:45 a.m.]

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Corrections

Federal Register

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Friday, July 17, 1992

NUCLEAR REGULATORY COMMISSION

Two-Year Trial Program for Conducting Open Enforcement Conferences; Policy Statement

Correction

In notice document 92-16233 beginning on page 30762 in the issue of Friday, July, 10, 1992, on page 30762, in the second column, under DATES, beginning in the fifth line, "July 11, 1992" should read "July 11, 1994".

BILLING CODE 1505-01-D