NOTICE OF VIOLATION

The Queen's Medical Center
Honolulu, Hawaii

Docket: 030-14522
License: 53-16533-02
EA: 94-133

During an NRC inspection conducted May 16 through July 13, 1994, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 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.
>
> The licensee's quality management program, submitted to the NRC on December 19, 1991, and revised on September 28, 1993, states, in part, that before administering a brachytherapy dosage, an Authorized User shall date and sign a Written Directive and that before loading the sources, the staff shall be required to seek guidance if they do not understand the Written Directive. It also states that "Any question regarding what to do or how to do it shall be answered before continuing."
>
> Contrary to the above, on May 2, 1994, the licensee failed to maintain its written quality management program in that an authorized user did not review or verify the information in a written directive to ensure that he understood what to do and how to do it before treating a patient with a Sr-90 eye applicator. As a result, the authorized user and the nurse performing the treatment became confused about the number of seconds that the eye applicator should be held over the patient's eye. The treatment lasted for 32 seconds, 14 seconds longer than prescribed in the written directive, delivering a radiation dose to the patient's eye that was 78 percent greater than prescribed. **(01014)**
>
> This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, The Queens's Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and the NRC Walnut Creek Field Office, 1450 Maria Lane, Walnut Creek, California 94596, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that

will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas
this 11th day of August 1994

Enclosure 2

Enforcement Conference
with The Queen's Medical Center

August 4, 1994

At The Queens's Medical Center
Honolulu, Hawaii

The Queens's Medical Center

Les Uyeda, Director, Radiation Oncology
Nora Nagai, Nursing Supervisor
Scott Dube, Radiation Safety Officer
Marc Coel, M.D., Chairman, Radiation Safety Committee
Brent Murphy, Medical Physicist/Assistant RSO

Nuclear Regulatory Commission

Frank A. Wenslawski, Chief, Nuclear Materials Branch, Walnut Creek Field Office
David D. Skov, Senior Radiation Specialist, Nuclear Materials Branch, Walnut Creek Field Office
*Ross A. Scarano, Deputy Director, Division of Radiation Safety & Safeguards
*Linda L. Kasner, Chief, Nuclear Materials Inspection Branch, DRSS
*Geary S. Mizuno, Acting Regional Counsel
*Gary F. Sanborn, Enforcement Officer

State Dept. of Health (Observer)

Jay K. Nakasone, DOH Radiation Section, EHS

*participated by telephone

Enclosure 3

NRC Enforcement Conference

August 4, 1994

The following report is submitted in response to the apparent violation stated in the NRC Inspection Report 030-14522/94-01.

The purpose of this report is to:

- discuss the apparent violation;
- discuss its cause and safety significance;
- point out any errors in the inspection report;
- present our proposed corrective actions;
- discuss any other information that will help the NRC determine the appropriate enforcement action.

Scott Dube

Scott Dube, M.S.
Radiation Safety Officer

8/4/94

Date

APPARENT VIOLATION

"The apparent violation involved the failure to establish a Quality Management Program (QMP) which met the objective that each administration was in accordance with the written directive. Specifically, the QMP did not provide written policies or procedures to ensure that information in the written directive was verified prior to each patient treatment."

I. Discussion

The Queen's Medical Center disputes this apparent violation on the basis that a Sr-90 QMP was indeed established prior to the misadministration. Therefore, the more appropriate apparent violation associated with the misadministration would be the failure of the Authorized User to follow the procedures of the established QMP. The following facts serve to substantiate this position.

A brachytherapy QMP was submitted on 12/19/91 and implemented on 1/1/92. The isotopes identified in the QMP were those used for implant techniques, such as cesium, iridium, and iodine. At that time, the RSO believed Sr-90 was excluded from the QMP requirement.

On 11/19/93, Greg Yuhas and Troy Pruitt of USNRC Region V confirmed by phone that the Sr-90 must be included in the brachytherapy QMP regardless of the RSO's intention to exclude these procedures. An exemption of Sr-90 from the brachytherapy QMP would only be possible by a license amendment which authorized a specific exemption from 10 CFR 35.32(a)(1)(iii).

That same day, the RSO reviewed the existing brachytherapy QMP to determine if the procedures met the objectives of 10 CFR 35.32 regarding Sr-90 applications. The RSO concluded the QMP did meet those objectives, although some of the wording was awkward when applied to Sr-90 procedures. At that time, the RSO intended to submit a separate QMP for Sr-90.

The RSO also evaluated the procedures followed by the Authorized Users for compliance with the QMP. The only deficiency was a failure to provide a written record immediately after the Sr-90 treatment. (The Authorized Users had been dictating that record at the time.) Therefore, a memorandum written 11/19/93 was distributed which explained how to satisfy the written directive requirement.

At the 11/24/93 Film Review, the RSO explained to the Authorized Users that Sr-90 was now to be included in the brachytherapy QMP. They were told to follow the 12/19/91 QMP procedures when

performing Sr-90 applications. The 11/19/93 memorandum was also reviewed at that time.

The first audit report of the Sr-90 QMP was presented at the 3/17/94 Radiation Safety Committee meeting. The audit included an evaluation of the Fourth Quarter 1993 patient charts. These charts were examined for compliance with the procedures as defined in the 12/19/91 brachytherapy QMP.

That same 12/19/91 brachytherapy QMP included the following requirement:

> "Before loading the sources, the staff shall be required to seek guidance if they do not understand the written directive." (Section I, Item 4)

Compliance with this requirement is only possible if the staff (i.e. Authorized Users) review the information in the written directive prior to each treatment. Therefore, the existing QMP did meet the conditions of 10 CFR 35.32(a)(4), although not in the explicit language of the revised QMP.

Therefore, the licensee asserts that a QMP was established prior to the misadministration which met the objective that each administration was in accordance with the written directive.

If a violation is to be cited, it should reflect the Authorized User's failure to verify the information in the written directive as required by the established QMP. This is the failure of an indiviual and does not demonstrate a programmatic weakness in the QMP.

II. Cause and Safety Significance

The root cause of the misadministration is entirely due to the failure of the Authorized User to review the written directive prior to treatment as required by the QMP. As the Inspection Report indicates, the physicians were aware of the need to verify that the final plan of treatment was in accord with the written record. (Section 7.1, Paragraph 4)

The Authorized User has stated in the attached letter, "The misadministration occurred because I did not adhere to the procedures that were in place to prevent such an occurrence." Also, he was "somewhat preoccupied with the other pressing agenda for the day". (Attachment 1)

The contrib ng factor of the nurse failing to properly communicate e ending treatment time does not diminish the responsiblity f the Authorized User. The nurse did communicate when full tre tment time had elapsed by announcing "eighteen", which should have been synonymous with "stop" to the physician.

The safety significance primarily relates to patient safety. The NRC medical consultant states there is a wide variation in the way Sr-90 is prescribed. As the consultant concluded, "the increased risk due to the unintended dose from the misadminiatration was small and difficult to quantify". (Section 6, Paragraph 2) Also, the "lens dose was below the threshold for induction of cataracts". (Section 6, Paragraph 3) Therefore, the patient safety significance of this misadministration is below regulatory concern.

Regarding staff safety, there was no increased radiation exposure to the physician or nurse as a result of this misadministration.

III. Errors in Inspection Report

The Inspection Report implies there was no comprehensive QMP which applied to Sr-90 procedures at the time of the misadministration. As stated above, the licensee asserts a Sr-90 QMP was indeed established prior to the misadministration. Therefore, the RSO disputes the contrary statements contained in the Inspection Report as erroneous. For example:

A. "... the QM program as defined by the November 19, 1993 memorandum ..." (Section 7.1, Paragraph 2)

The Sr-90 QMP was defined in the 12/19/91 document and implemented on 11/19/93. Contrary to the Inspection Report, the 11/19/93 memorandum was never meant to define the QMP. Instead, it was meant to explain to the Authorized Users how to comply with the pre-existing QMP requirement for a written record.

B. "... the licensee's program had no written policy or procedure to verify that the final plan of treatment and related calculations were in accord with the written directive ..." (Section 7.1, Paragraph 4)

AND

"... The licensee's failure to develop and implement written policies or procedures to meet the objective that each administration was in accordance with the written directive ..." (Section 7.1, Paragraph 6)

As stated above, the 12/19/91 brachytherapy QMP included the following requirement:

> "Before loading the sources, the staff shall be required to seek guidance if they do not understand the written directive." (Section I, Item 4)

Therefore, a written policy for verification did exist prior to the misadministration.

C. "... the licensee had no written policy or procedure for patient identification specific to Sr-90 treatments until one was prepared by the RSO after the Sr-90 misadministration ..." (Section 7.1, Paragraph 5)

The December 19, 1991 brachytherapy QMP included the following requirement:

> "Before loading the sources, the identity of the patient shall be verified as the individual named in the Directive by more than one method." (Section I, Item 2)

This condition does indeed satisfy the requirement for a written policy regarding patient identification.

IV. Proposed Corrective Actions

Many corrective actions have been implemented since the 5/2/94 misadministration:

a) Submission of revised QMP

A revised QMP was submitted 5/4/94 which separates the the LDR and Sr-90 brachytherapy procedures into two separate documents. This will facilitate a clearer understanding of the specific requirements of each program.

b) Revision of Treatment Record

The Treatment Record was revised and implemented 5/25/94. The new format prompts the Authorized User to double check the patient identity and written directive. (see Attachment 2)

c) Revision of Sr-90 Procedures

The "Rules for Safely Handling the Sr-90 Applicator" was revised on 5/3/94. The revision includes requirements for nurse training, personnel monitoring, and stopwatch operation. (see Attachment 3)

d) Training of nurses

The nurses were trained in the QMP and revised procedures on 5/3, 5/4, and 5/5.

e) Training of physicians

The physicians were individually informed of the revised procedures on 5/4/94. A group inservice was provided on 5/25/94 to review the QMP and revised procedures collectively.

f) RSO audit by observation

The RSO and Assistant RSO began auditing the Sr-90 procedures on 5/27/94 by direct observation. Each Authorized User will be observed annually. (see Attachment 4)

STATED CONCERN #1

> "The training provided to oncology nurses in the use and handling of Sr-90 applicators, and the stopwatch procedure for timing Sr-90 treatments, appeared to be very informal and limited in scope." (Section 9, Paragraph 3)

It is true that the training provided to oncology nurses regarding the Sr-90 procedures was informal and limited in scope. However, the nurse's role in the treatment procedure was to retrieve and sterilize the applicator as well as operate the stopwatch. It is the physician who is responsible for the delivery of the prescribed dose.

Each new nurse was trained by an experienced nurse before assisting the physician with the Sr-90 procedures. Although this training was not documented, it was effective as demonstrated by the many years of uneventful Sr-90 treatments.

In the future, the nurse shall receive initial training and annual refresher training from the RSO.

STATED CONCERN #2

"The licensee's efforts in reducing the frequency of unintended deviations have not been effective, and if left uncorrected, could lead to future recordable events and misadministrations." (Section 7.2, Paragraph 3)

The types of deviations noted by the inspector are largely due to incorrect or incomplete documentation:

Source strength not recorded (18 / 64 administrations)
Treatment site not recorded (6 / 64 administrations)
Treatment time not recorded (3 / 64 administrations)
Recording an incorrect date (1 / 64 administrations)

The RSO disputes that the nature of the unintended deviations cited by the inspector could ever lead to a future recordable event or misdaministration.

The Treatment Record had been revised twice to prompt the Authorized User to comply with the QM'. The final version now in use has resulted in full compliance since its introduction in May 1994.

STATED CONCERN #3

"While no violation was identified, audits of this part of the licensee's brachytherapy program have not included the direct observation of personnel handling Sr-90 eye applicators to ensure that the applicators were being used safely and in accordance with the licensee's written safety procedures and regulatory requirements." (Section 11, Paragraph 1)

It is true that the RSO did not directly observe any of the Sr-90 procedures during his quarterly audits. The decision not to include observation was based on the favorable fifteen year history of the Sr-90 program.

During that period, only one misadministration occurred in 1985 when an Authorized User treated the wrong eye of the patient. A referring physician request form was implemented at that time, and is still in use today.

Additionally, the Sr-90 procedure is relatively simple compared to LDR brachytherapy procedures. The LDR Authorized Users are observed by the RSO or his designee each time an implant is loaded or unloaded. The Authorized Users have all demonstrated great competency during these procedures.

Consequently, the RSO believed the Sr-90 applicator was being used properly based on the many years of uneventful performance of these procedures.

In the future, the RSO audit program will include direct observations of the Authorized Users and nurses performing Sr-90 procedures.

LICENSEE'S PERSPECTIVES

The licensee asserts that a comprehensive QMP was developed on 12/19/91 and implemented on 11/19/93. The requirements of these procedures were reviewed at the 11/24/93 Film Review. The 5/2/94 misadministration was due to the failure of an Authorized User to the follow the established QMP procedures.

The licensee requests consideration of the following information when determining the appropriate enforcement action:

1) Severity of the violation

The failure of the Authorized User to follow the QMP procedure was an isolated event and does not demonstrate a programmatic weakness in the implementation of the QMP. Furthermore, the misadministration had a limited consequence to the patient. Accordingly, this would constitute a Severity Level IV violation pursuant to 10 CFR Part 2 Appendix C Supplement VI(D)(3).

2) Civil Penalty Adjustment Factors

(a) Identification

The licensee identified the 5/2/94 misadministration and reported to NRC Operations Center immediately. In considering the case, the RSO identified the value of revising the established QMP to include a distinct section pertaining to Sr-90 procedures which would be separate from the LDR section. This was submitted on 5/4/94.

(b) Corrective Action

The revised QMP was submitted on 5/4/94. Also, the updated rules for handling Sr-90 were distributed on 5/4/94. Refresher training was provided to the physicians on 5/25/94. The revised Sr-90 Treatment Record was implemented at that time. The RSO and Assistant RSO have observed physicians performing Sr-90 procedures during June and July as part of the audit program.

(c) Licensee Performance

The current apparent violation is an isolated failure that is inconsistent with the licensee's good prior performance. There have been hundreds of Sr-90 applications performed during the period within the last two inspections with no other misadministrations.

(d) Prior Opportunity to Identify

The physician who administered the Sr-90 dose that led to the misadministration indicated that he may not have always checked the written directive to verify the correct treatment time. The RSO may have identified this occassional failure if direct procedural observations were included in the audit program. However, the many years of uneventful performance of the Sr-90 procedures did not indicate such audit technique was necessary.

(e) Multiple Occurrences

The failure was an isolated error.

(f) Duration

Immediate action was taken to assure another misadministration would not occur. Subsequent Sr-90 treatments were performed by informed physicians assisted by trained nurses.

3) Exercise of Discretion

The licensee petitions that the NRC refrain from issuing a Civil Penalty because the violation meets all of the following criteria:

(a) It was identified by the licensee as a result of a self-disclosing event (5/2/94 misadministration);

(b) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a violation occurring within the last two inspections (there were no previous Sr-90 misadministrations);

(c) It has already been corrected and comprehensive corrective action to prevent recurrence has been implemented (revised QMP was submitted 5/4/94 and retraining followed immediately thereafter);

(d) It was not a willful violation (the Authorized User never meant to deviate from the written directive).

ATTACHMENT 1
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To: Whom it may concern
From: Carl W. Boyer, Jr., M.D. Carl W Boyer Jr.
Subject: Strontium - 90 Applicator Dose Misadministration
Date: July 19, 1994

On May 2, 1994 a second postoperative treatment to prevent pterygium regrowth was scheduled to be performed by me on one of my patients. The misadministration occurred because I did not adhere to the procedures that were in place to prevent such an occurrence. The procedure was a very small part of a very busy agenda which had unfolded for me that day, and since it was a second application, and because I had performed such procedures innumerable times in the past, I neglected to check the identity of the applicator, and did not re-read the prescription that I had written for the procedure. I proceeded, somewhat preoccupied with the other pressing agenda for the day, and was taken back by the lack of a "stop" signal from the nurse who was timing the procedure. That had never happened in my 30 year experience in performing the procedure. While trying to determine why the counting did not stop at the usual 18 seconds, I did not communicate orally with the nurse since I did not want to alarm the patient. The possibility that perhaps this was a substitute applicator crossed my mind. I stopped the application at 32 seconds because I knew that I had never exceeded that time with applicators that I had used in the past.

ATTACHMENT 2
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THE QUEEN'S MEDICAL CENTER
RADIATION ONCOLOGY DEPARTMENT

STRONTIUM-90 TREATMENT RECORD

WRITTEN DIRECTIVE

Treatment Site _____

QMC Sr-90 Ophthalmic Applicator, SN 1005ML, 55 mCi on 9/8/93

Time/Fraction _____ Dose/Fraction _____

Total Fractions _____ Total Dose _____

Authorized User _____

Prescription Date _____

WRITTEN RECORD

Treatment Date	Double Check Patient ID	Double Check Directive	Exposure Time	Authorized User

ATTACHMENT 3
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The Queen's Medical Center
Radiation Therapy Department

Rules for Safely Handling the Strontium-90 Applicator

1. Only trained nurses shall participate in the strontium-90 procedure. The nurse shall retrieve the strontium-90 applicator from the Cesium Room. Always complete the inventory logbook before delivering the applicator. Nurses are required to wear film badges.

2. The Authorized User shall wear personnel dosimeters whenever handling the Sr-90 eye applicator. Both a TLD ring and a film whole body badge shall be worn when handling the Sr-90 eye applicator. Finger ring type dosimeters should be worn with the detector on the palm side of the hand facing the source.

3. The Authorized User shall sign a Written Directive before applying the strontium-90 applicator, per the QMP guidelines.

4. Remove the Sr-90 eye applicator from its secured location just before use. Do not leave it out any longer than necessary.

5. After removing the applicator from its secured location:
   a. Do not touch the treatment end of the applicator with your hands or other portion of your body,
   b. Always hold the applicator by its handle, and
   c. Except during patient treatment, do not point the treatment end of the applicator toward another person, especially toward the eyes.

6. The applicator shall be sterilized by a remote method, such as an alcohol soak or a cotton swab, followed by a saline rinse. Do not sterilize by holding the swab or gauze in your hand.

7. During treatment, hold the patient's eye lids open with tape or other device, not with your fingers.

8. The nurse shall use a stopwatch to time the prescribed treatment as specified in the Written Directive. The physician shall announce the start of treatment. Then, the nurse shall count off the final seconds and the announce "stop" at the prescribed treatment time. (i.e. "15, 16, 17, STOP")

9. Immediately after treatment and/or resterilization, return the Sr-90 eye applicator to its storage container. The nurse will return the applicator to the Cesium Room and complete the inventory logbook.

10. Never remove any metal or plastic inserts from the manufacturer-supplied storage container.

ATTACHMENT 4
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The Queen's Medical Center
Radiation Oncology Department

Sr-90 Observation Checklist

The following items will be monitored by direct observation during the radiation safety audit of the strontium-90 procedures:

1. Nurse trained in procedures and QMP
2. Nurse puts on body and ring badge before handling box
3. Nurse retrieves box from Cesium Room & completes logbook
4. Nurse safely handles applicator while sterilizing
5. Authorized User trained in procedures and QMP
6. Authorized User puts on body and ring badge before tx
7. Authorized User completes Written Directive before tx
8. Identity of patient is verified by two means before tx
9. Identity of applicator is verified before tx
10. Authorized User and Nurse review Directive before tx
11. Authorized User safely handles applicator during tx
12. Authorized User safely holds patient's eye lids open
13. Nurse counts off final seconds and then says "stop"
14. Authorized User completes Written Record after tx
15. Nurse safely returns applicator to box
16. Nurse returns box to Cesium Room & completes logbook