U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 93-02
Docket No. 030-14522
License No. 53-16533-02
EA No. 93-291

Licensee: The Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813

Enforcement Conference Conducted: December 2, 1993

NRC Medical Consultant's Report Received: December 27, 1993

Conference held at: The Queen's Medical Center
Honolulu, Hawaii

Report Prepared by: _____ 12/28/93
T. W. Pruett, Radiation Specialist Date Signed

Approved by: _____ 12/28/93
G. P. Yuhas, Chief, Radioactive Materials Safety Branch Date Signed

Summary:

Enforcement Conference on December 2, 1993 and Medical Consultant's Review of December 2, 1991 Event (Report No. 030-14522/93-02)

An Enforcement Conference was held to discuss the apparent violations from an NRC inspection conducted on September 28 and October 25-27, 1993, and described in NRC Inspection Report 030-14522/93-01, dated November 23, 1993. The Medical Consultant's Report of the December 2, 1991 event was received by the NRC on December 27, 1993.

Results:

The licensee agreed that five of the apparent violations occurred as described in NRC Report 93-01, contested one apparent violation involving training of personnel, and recommended that the violation involving the failure to monitor hands be changed to the failure to monitor hands with a crystal probe.

DETAILS

1. Enforcement Conference Participants

Licensee Representatives:

Donna Christle, Director, Imaging Services
Scott Dube, Radiation Safety Officer
Nora Nagai, Nursing Supervisor
Carl Boyer, Medical Director, Radiation Oncology
Les Liyeda, Director, Radiation Oncology
Terry Ichinose, Supervisor, Nuclear Medicine
Marc Coel, Authorized User, Nuclear Medicine

NRC Region V Representatives:

Gregory P. Yuhas, Chief, Radioactive Materials Safety Branch
F. R. Huey, Enforcement Officer
Troy W. Pruett, Radiation Specialist
John Jacobson, Radiation Specialist

State of Hawaii Representative:

Russell Takata, Department of Health, Supervisor, Radiation Section

2. Discussion

On December 2, 1993, an enforcement conference was held at The Queen's Medical Center (Queens), Honolulu, Hawaii, with the individuals listed above participating. Matters discussed during the enforcement conference related to the NRC inspection conducted on September 28 and October 25-27, 1993. The inspection reviewed licensee activities involving the use of radioactive materials which were authorized under NRC license. The inspection findings were documented in NRC Inspection Report 93-01, dated November 23, 1993.

Mr. Yuhas began by explaining the purposes of the enforcement conference, and stating his concerns regarding the repeated failure to provide training to individuals attending therapy patients and the unplanned exposure of the nursing infant in December 1991. Mr. Dube began by submitting the attached "Queens Report" dated December 2, 1993, which included the licensee's position and corrective actions for each apparent violation and stating that the Vice President of Organizational Services could not attend but that she agreed with the items described in the Queens Report.

10 CFR 35.310 and 35.410: Instruction of Personnel Attending Therapy Patients

The licensee disagreed with the apparent violation of 10 CFR 35.310 and 35.410, which require that training be provided to individuals providing care to therapy patients.

The Queens Report stated that only nursing personnel required training

pursuant to 10 CFR Part 35 and that all other personnel only required training pursuant to 10 CFR Part 19. The NRC staff has determined that any individual who provides patient care (e.g., nurse, respiratory therapist, IV therapist, doctor, etc...) must be trained pursuant to 10 CFR 19.12, 35.310, and 35.410. Individuals who frequent a therapy patient room but do not provide patient care (e.g., housekeeping or maintenance staff) must be trained pursuant to 10 CFR 19.12.

The Queens Report stated that nurses with deficient training had in fact been trained by a fellow nurse at the beginning of the shift and that the training included use of the digital dosimeter, lead shields, source control, visitor control, and contamination control. The RSO submitted a memorandum dated September 17, 1993 (Figure 1.2 of the attached Queens Report) from the Radiation Safety Officer to various departments explaining the "Radiation Safety Instructions for Non-Nursing Staff." The memorandum did not include a description of contamination control, patient and visitor control, size and appearance of brachytherapy sources or safe handling and shielding instructions in case of a dislodged source. The nursing supervisor stated that instruction was provided to "float" and "flyer" nurses but that the training did not include contamination control or size and appearance of brachytherapy sources. In addition, the licensee stated that it was possible for temporarily assigned nurses to enter a therapy patient room without receiving instruction from the nursing staff or RSO.

10 CFR 35.25(a)(2): Failure of a Technologist to Follow Instructions of the Authorized User

The Queens Report stated that a technologist had administered a low activity dose of iodine-131 to a patient who was breast feeding and that the dose did not present a hazard to the infant. Dr. Coel stated that the patient had been instructed at approximately 9:00 AM on December 3, 1991, to stop breast feeding for twenty-four hours and that at 11:45 AM on the same day the patient was instructed to completely stop breast feeding.

License Condition 20: Failure to Monitor Hands

The Queens Report stated that there was no required minimum sensitivity for instruments used to perform hand monitoring and that the violation should be changed from "not performing hand monitoring" to "using a GM probe instead of a crystal probe to perform hand monitoring." The RSO acknowledged that the Victoreen 808E Radiation Area Monitor was inadequate for use in detecting personal contamination and that Regulatory Guide 10.8 specified that the action level for skin contamination is 2,200 disintegrations per minute (dpm) for technetium-99m and 200 dpm for iodine-131. Even though personnel used the Victoreen 808E Area Monitor to perform hand monitoring, the violation of License Condition 20, Item 10.4.3, of the license application dated August 25, 1989, failure to perform hand monitoring, is being cited based on the RSO's statement that the Victoreen 808E Area Monitor was unable to detect levels of technetium-99m below 75 microcuries (1.7E8 dpm).

10 CFR 35.32 Quality Management Program for Sr-90 Eye Applicators

Even though the NRC Staff has determined that strontium-90 eye applicators are to be included in the Quality Management Program, this violation is not being cited based on the confusion concerning the need for a written directive for strontium-90 eye applicators. The NRC is developing an Information Notice for medical licensees which will explain the staff position.

Remaining Violations

The remaining violations were agreed to by the licensee as stated in the Queens Report.

Unresolved Item: Strontium-90 Eye Applicator

The use of a strontium-90 eye applicator which was received from a licensee not authorized to package and distribute byproduct material for medical use as required by 10 CFR 35.49 is not being cited based on the misunderstanding between the NRC Staff and the licensee over the use of the eye applicator.

Concluding Remarks

Mr. Huey restated the purposes of the Enforcement Conference and explained the NRC enforcement process, including base civil penalties, adjustment procedures, and aggregation of violations.

Mr. Yuhas concluded the meeting by emphasizing the safety significance of the failure to train personnel attending therapy patients. Mr. Yuhas also stated that the number of violations provided an indication that management needed to improve its oversight of the radiation safety program. Mr. Yuhas explained the significance of correcting violations so that they do not recur.

3. Medical Consultant Review of December 2, 1991 Event

As part of the review of the licensee's radiation safety program, NRC medical consultant Dr. Barry Siegel reviewed the licensee's actions in response to the administration on December 2, 1991, of fifteen microcuries of iodine-131 to a patient who had stated that she was breast feeding. The review consisted of an examination of licensee documents related to the event, NRC Inspection Report 030-14522/93-01, and a telephone conversation with the Inspector on December 10, 1993.

The medical consultant concluded that the licensee's decision not to obtain either thyroidal or whole-body iodine-131 retention measurements on the infant or any assessment of the infant's thyroid functional status complicated the estimate of the infant's radiation dose. In the absence of in-vivo measurements, the thyroidal dose calculated by the consultant ranged from 16 to 65 rem. In addition, the consultant stated that: (1) assumptions used by the RSO to estimate the infant's thyroid radiation

dose (25 rad) were reasonable, (2) no medical consequences are likely for the infant, (3) a deterministic effect from iodine-131 will not occur from a thyroidal absorbed radiation dose in this range, (4) it is unlikely that the infant is at a significant risk for a stochastic effect, (5) the impact of the iodine-131 administration on the health and safety of the infant is negligible, and (6) no long term disability is expected.

THE QUEEN'S MEDICAL CENTER

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NRC Enforcement Conference

December 2, 1993

The following report is submitted in response to the apparent violations, unresolved item, and stated concerns discussed in the NRC Inspection Report No. 030-14522/93-01.

The purpose of this response is to:

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

Scott Dube

Scott Dube, M.S.
Radiation Safety Officer

12/2/93

Date

Apparent Violation #1

Failure to provide instruction to individuals caring for therapy patients. (10 CFR 35.310 and 35.410) This is an apparent repeat violation, third occurrence.

Background Radioactive therapy patients are hospitalized for up to four days while the radioactive material is present. As for any inpatient, nursing care is required during that time. There is also occasional need for ancillary staff to enter the room and perform specific duties. Such individuals would include housekeepers, IV therapists, respiratory therapists, pharmacy staff, attending physicians, and social workers.

The QMC 8/25/89 license application Item 8.1.2 specifies training shall be provided to nurses attending to therapy patients. This condition is in compliance with 10 CFR 35.310 and 35.410, which identifies specific topics to be covered. A record of this training is required by 10 CFR 35.310 and 35.410.

The ancillary personnel working in the patient room must also be inserviced, as required by 10 CFR 19.12. The paragraph concludes by stating, "the extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area". A record of this training is not required pursuant to 10 CFR 19.12.

A Nursing Exposure Logsheet is posted outside the therapy rooms for nurses and ancillary personnel to log their radiation exposure as measured by a digital dosimeter. Many individuals on these Logsheets have no record of training.

RSO Comment The RSO disagrees that all personnel entering the therapy rooms require training pursuant to 10 CFR 35.310 and 35.410. Rather, it is only the nurses who require this training, for the following reasons:

The license application Item 8.1.2 as well as 10 CFR 35.310 and 35.410 requires training of "personnel caring for the patient". The American Heritage Dictionary provides one definition of "care" as "supervision; charge: (i.e.) in the care of a nurse". In the language of 35.310 and 35.410, it is the nurse who has authority in the areas of patient control, visitor control, contamination control, waste control, brachytherapy source control, and notification of the RSO in case the patient dies or has a medical emergency.

The RSO asserts that ancillary personnel do not satisfy this definition of "caring for the patient", in that they have no authority in the above specified areas. Ancillary personnel perform a specific technical procedure. They do not "supervise", but instead often are instructed by the nurse. They are not in "charge" to make any decisions or take any actions regarding radiation safety. Therefore, the training necessary for ancillary staff is of the more limited nature addressed by 10 CFR 19.12.

Because the two groups (nurses and ancillary staff) must meet different regulatory requirements, they shall be addressed separately in the following two sections.

Apparent Violation #1 - Nurses

This is an apparent repeat violation, third occurrence of the conditions pursuant to 10 CFR 35.310 and 35.410.

QMC Response Section 10 of the Inspection Report states, "the licensee failed to instruct approximately 58 of 205 individuals who provided patient care and recorded their entry on the Nursing Exposure Logsheet." The RSO has reviewed the Nursing Exposure Logsheet and Inservice data for the period of 1/1/92 - 11/16/93. (see Appendix I and II) The RSO disagrees with the Inspection Report statement for the following reasons:

1. As argued above, it is only the nurses who require a record of training pursuant to 10 CFR 35.310 and 35.410.

2. There were 49 nurses who appeared on the 1993 Logsheets also appeared on the 1992 Logsheets. These individuals should not be double-counted.

3. Excluding the non-nurses and double-count nurses, there were approximately 116 individuals who required training pursuant to 10 CFR 35.510 and 35.410 during this period.

4. Of those 116 nurses, a total of 25 have no record of training. There were 12 in 1992 and 13 in YTD 1993.

It is agreed that are a number of nurses who have no record of training. However, it is important to put the radiation safety significance in perspective when determining the appropriate enforcement action. The majority of nurses who lack a record of training have been "floats", "flyers", and call-in staff. These individuals are not permanently assigned to the two therapy floors, and are therefore difficult to schedule for training.

For that reason, the RSO did state that it was unreasonable to expect one hundred percent compliance with the training requirements of the license and 10 CFR Parts 19 and 35. However, that is not to say the RSO condones the practice of nurses caring for therapy patients without training. Rather, the RSO meant the training should be tailored to meet the needs of the occasion rather than the requirements of the regulation.

It must be understood that nurses with deficient training records have in fact been trained. These nurses receive training from a fellow nurse at the shift change before caring for the therapy patient. This training includes use of the digital dosimeter, use of the lead shields, source control, visitor control, and contamination control. Unfortunately, this adhoc training is not documented.

The majority of the training deficient nurses have received radiation exposures of less than ten millirem and only appear in one calendar quarter. This is indicative of the brief time they spend with the patient, and represents a diminished radiation safety significance.

Corrective Action The RSO relies on a computerized audit of the Nursing Exposure Logsheet and the Nursing Training Records to identify training deficient nurses. Those nurses which are deficient are to be scheduled for training.

In the past, ancillary personnel would enter their names and exposures on the Logsheet without identifying themselves as non-nurses. This undermined the effectiveness of the audit report, in that the RSO did not which names needed the nursing training.

The Nursing Exposure Logsheet has been revised to include the individual's department.

The RSO will also provide a list of authorized nurses each calendar quarter to the Patient Care Coordinators (PCC) of the therapy floors. It will be the PCC responsibility to ensure only authorized nurses care for the therapy patients.

In addition, the RSO will audit the Nursing Exposure Logsheets each calendar quarter for compliance with the training requirements of 10 CFR 25.310 and 35.410. Immediate corrective training will be provided for deficient nurses.

Apparent Violation #1 - Ancillary Staff

This would be a first time apparent violation of the conditions pursuant to 10 CFR 19.12.

QMC Response The RSC meeting minutes dated 5/28/92 indicate a memo would be sent to the ancillary departments instructing those staff not to use the Nursing Exposure Logsheet when entering a therapy room. The RSO desired that the Nursing Exposure Logsheet include only the nurses, who are exclusively required to receive documented training pursuant to 10 CFR Part 35.

The RSO does understand that 10 CFR 19.12 requires training of any individual who enters a restricted area. The ancillary staff are provided training specific to their duties in several ways:

1. Immediate Nursing Supervision - The ancillary staff will typically check with the nurse before entering the therapy room. In fact, this is when they are given a digital dosimeter. The nurse will then provide specific instruction commensurate with the individual requirements at that time.

2. Annual Memorandum to Departments - A memorandum is sent to each ancillary department to remind the staff of the radiation safety precautions for therapy rooms. (see Figures 1.1 and 1.2)

3. Safety Fair - Radiation safety is one of the eight mandatory inservices at the annual Safety Fair. The majority of the medical center receives basic instruction regarding the precautions to be taken in the vicinity of a therapy room.

4. Occasional Departmental Inservices - The RSO will occasionally provide training to individual departments, such as EKG (10/4/93) and IV Therapy (7/26/93).

There is no record of the training provided by immediate nursing supervision. There are attendance records for the 1993 Safety Fair, EKG, and IV Therapy training.

However, the language of 10 CFR 19.12 does not require records of this training. Therefore, the lack of such records should not constitute a violation.

Corrective Action The RSO will petition the Personnel Department to include radiation safety training as part of the new hire orientation. This will reach an even greater number of ancillary personnel who might enter a restricted area.

Apparent Violation #2

Failure of a supervised individual to follow the instructions of the authorized user. (10 CFR 35.25(a)(2))

Background The nuclear medicine technologists have been instructed to screen female patients who may be pregnant or breast feeding. The technologists are to stop the procedure and notify the authorized user if a patient indicates she is pregnant or breast feeding. On one occasion, a patient indicated she was breastfeeding, yet the technologist administered the low activity dose of iodine-131 anyway without notifying the authorized user. Fortunately, the dose did not present a hazard to the infant.

QMC Response The instruction to the technologist was two-fold. First, question the patient regarding pregnancy and breast feeding. Second, notify the authorized user if the either condition is met. The technologist failed to perform the second part of the procedure. However, consideration should be made for his compliance with the first part of the procedure.

When determining the appropriate enforcement action, it is important to consider the safety significance of this apparent violation. The RSO estimated the infant might have ingested as much as 3.15 uCi of I-131. This activity would result in a thyroid dose of 25 rem and an total body dose of 6 millirem. This is well below the annual whole body dose limit of 500 millirem for minors.

Corrective Action The nuclear medicine staff was notified by memo to be diligent in the screening procedure. (see Figure 2.1)

The screening procedure has been documented and reviewed by each of the technologists. The procedure is now incorporated into the clinical procedure manual. (see Figure 2.2)

The clinical procedure manual will be reviewed by all new technologists and will be reviewed at the annual radiation safety inservice.

Apparent Violation #3

Failure to perform dose calibrator linearity tests up to the highest dosage administered. (10 CFR 35.50(b)(3))

Background The dose calibrator is used to measure all dosages before they are administered to the patient. The linearity test makes sure the dose calibrator is accurate over the full range of doses used in the department. On several occasions, the linearity test used a source which was much less than the highest dose given to a patient.

QMC Response The linearity test was once performed using a single source which decayed for several days. The entire range was presented on one page, and was easy to review. Since 1990, the test has been performed using a Lineator tool. This requires using two separate sources (high and low strength) to cover the full range. The two tests are reported on separate pages.

During the 12/91 inspection, Frank Pang identified two occasions when the linearity test did not measure down to 10 uCi. At the exit conference, he stated this was one of the four potential violations. Since that time, the RSO has been diligent to audit the quarterly linearity tests to make sure the range goes down to 10 uCi. Unfortunately, the RSO was not as careful to check the high end, which is reported on a separate page.

Corrective Action The RSO reviewed the range requirement with the nuclear medicine supervisor. The high range was tested on 10/28/93 and found to meet the linearity specifications.

The nuclear medicine supervisor was later notified by memo to be diligent in the linearity testing to cover the full range of 200 mCi to 10 uCi. (See Figure 3.1)

Apparent Violation #4

Failure to adequately monitor hands after each procedure or prior to leaving the area. (License Condition 20, Item 10.4.3, 8/25/89)

Background The QMC license application dated 8/25/89 states the nuclear medicine technologists will monitor their hands for radioactivity after each procedure or before leaving the area. The instrument shall be a crystal probe or gamma camera. In the past, the technologists have always used one of the gamma cameras to monitor their hands.

On 3/30/93, the renovated Hot Lab was commissioned. A new instrument in the Hot Lab was the Victoreen 808E Area Monitor. This GM detector came with a manufacturer's calibration report. The RSO recommended the technologists use the 808E to monitor their hands because of the proximity to the fume hood. In that way, the staff would identify hand contamination in the Hot Lab, and prevent contaminating the door handles and other surfaces in the department.

The 808E has a sensitivity of 0.1 millirem per hour. This is the same sensitivity required for the end of day survey of the ambient radiation exposure rate of the nuclear medicine department. (10 CFR 35.70(c)) At that sensitivity, the minimum detectable activity (three times background) is 75 uCi of Tc-99m.

QMC Response During the inspection, the RSO mistakenly believed the 808E did not meet an established minimum sensitivity for hand monitoring. However, the RSO could not subsequently find any license condition or statement from the CFR which specifies such a minimum sensitivity requirement. The RSO does recognize that Reg Guide 8.23, Section C.1.6 refers to Line 5 of Table 2 which specifies an action level of 2,200 dpm for Tc-99m and 200 dpm for I-131. However, the recommendation of a Reg Guide does not constitute a license requirement unless specified in the license application.

Therefore, the RSO asserts the apparent violation is not a result of the minimum sensitivity of the 808E. Rather, it is due to the 808E using a GM detector rather than a crystal probe. It must be recognized that the technologists did follow the procedure as instructed, and that the 808E is adequate to detect low levels of contamination.

Corrective Action The nuclear medicine supervisor was notified by memo to instruct the staff to continue using the gamma camera to monitor their hands until further notice. (See Figure 4.1)

The RSO is investigating a more suitable instrument for personnel contamination monitoring. The most likely choice is the Nuclear Associates Model 05-695 Contamination Monitor. (see Figure 4.2) The instrument uses a xenon-filled proportional counter, and has a sensitivity of 200 dpm/100 sqcm. The RSO understands a license amendment would be required to use this instrument with a non-crystal probe.

Apparent Violation #5

Failure to hold by-product material for decay a minimum of ten half-lives prior to disposal (10 CFR 35.92(a))

Background Radioactive waste from nuclear medicine procedures must be held for ten half-lives before disposal as non-radioactive trash. (This does not apply to isotopes with a $T_{1/2}$ > 64 days.) Historically, the waste has been segregated into two groups: short-lived (exclusively Tc-99m) and long-lived (all others, including I-131, Ga-67, Tl-201, I-131, P-32, I-125, etc.).

The bulk of the long-lived waste includes I-131 and Tl-201. These and most other isotopes can all be disposed after three months. However, there is occasionally a minute amount of I-125 which must be held for 600 days. This I-125 waste is generated by plasma volume studies and Neoprobe procedures.

On several occasions, a container of mixed long-lived waste was disposed after 90 days, which is the typical decay period. The technologist failed to recognize there was a minute amount of I-125 present in the container, which should have been held for 600 days.

QMC Response The waste disposal system worked well for the majority of the containers. It is understandable that failure would occur for those infrequent containers which included I-125 waste. Nonetheless, the RSO and technologists should have been diligent over time in identifying those exceptions.

When determining the appropriate enforcement action, it is important to consider the safety significance of this apparent violation. The I-125 waste described in the Inspection Report consisted of syringes used to inject doses of 10 uCi or 2 mCi for the plasma volume or Neoprobe studies, respectively. It is extremely unlikely a post-injection syringe would contain more than 0.1 uCi or 20 uCi of residual I-125 for the plasma volume or Neoprobe syringes, respectively. Such waste would be indistinguishable from background at the final disposal survey. The safety significance of such activity is negligible.

Corrective Action The nuclear medicine supervisor was notified by memo to hold all waste for ten half-lives. (See Figure 5.1)

A new procedure has been adopted whereby the waste will be segregated into three different containers:

Short-lived:	$T_{1/2}$ < 24 hours	(Tc-99m exclusively)
Mid-lived:	1 day < $T_{1/2}$ < 10 days	(I-131, Tl-201, etc.)
Long-lived:	10 days < $T_{1/2}$ < 65 days	(P-32, Sr-89, I-125)

This procedure has been documented for inclusion in the procedure manual. (see Figure 5.2)

Apparent Violation #6

Failure to maintain a record of radioactive waste disposal which included the radionuclide disposed. (10 CFR 35.92(b)

Background Radioactive waste is generated in the course of the nuclear medicine procedures. Vials, syringes, swabs, gloves, and other items are routinely and unavoidably contaminated. Such waste is deposited in appropriately labeled containers throughout the department. When a container is full, it is sealed and put into the Waste Room for decay-in-storage.

In order to ensure the waste is held for a minimum of ten half-lives, it is necessary to maintain records which identify all the isotopes collected in each container. Historically, these records were maintained manually.

In May 1992, the Nuclear Medicine Department began using the computerized Nuclear Medicine Information System (NMIS) for such recordkeeping. The NMIS did not provide a convenient method to identify the different isotopes which may be in each general collection container. Therefore, the contents were simply identified as "TRASH". It was assumed that the longest-lived isotope included in the container was I-131, unless otherwise noted.

QMC Response The conversion of recordkeeping from the manual system to the NMIS introduced a non-compliance with regards to the recordkeeping requirements. This was not identified by the RSO. However, the practice of holding trash for ten half-lives was not compromised by this recordkeeping deficiency, with the exception of those isolated events identified in Apparent Violation #5.

Corrective Action The nuclear medicine supervisor was notified by memo to identify all isotopes in each container. (see Figure 6.1) If NMIS could not accommodate this requirement, then he must revert to the manual recordkeeping.

The supervisor has established a procedure using NMIS whereby all isotopes are identified for each container. (see Figure 6.2) Generic identification shall no longer be used.

Apparent Violation #7

Failure to develop written policies and procedures for written directives associated with the use of strontium-90 eye applicators. (10 CFR 35.32(a))

Background The Nuclear Regulatory Commission required all licensees to implement a Quality Management Program (QMP) in January 1992. The QMP included requirements for the use of sealed sources to perform radiation therapy brachytherapy procedures. These requirements include preparing a written directive prior to the administration of a brachytherapy dose. 10 CFR 35.400 lists strontium-90 eye applicators as a brachytherapy source.

QMC Response The RSO assumed the NRC did not intend to include strontium-90 treatments in the QMP rule. The beta radiation delivered by these applicators is used to treat a benign condition. A single treatment delivers approximately 10 rem to the center of the lens and less than 5 rem effective dose equivalent. Also, the RSO is confident the EDE is less than 100 millirem, but cannot find a published reference to substantiate this figure. These doses are below the thresholds for misadministration as well as exposure to members of the general public.

Furthermore, Regulatory Guide 8.33 includes references to patient specific source loadings, radiographs to verify source positions, temporary and permanent implants, computer generated dose calculations, and acceptance testing of treatment planning computer software. This language is foreign to the use of strontium-90.

This assumption was substantiated by Larry Camper, MBA, M.S., at the USNRC Region V Workshop on September 1-2, 1993 in South San Francisco. The RSO asked Mr. Camper if the NRC intended to include strontium-90 treatments in the QMP. He said it was intentionally not included in the original design of the QMP rule. The NRC task group thought strontium-90 was an obsolete technology. However, the task group is now reconsidering that decision.

Upon returning from the Workshop, the RSO submitted a revised QMP which explicitly excluded strontium-90 treatments. There was no written response from the NRC regarding this communication.

Corrective Action The RSO instructed the brachytherapy authorized users to begin preparing a written directive for all strontium-90 treatments. A handwritten directive will suffice until a standard form can be implemented. (see Figure 7.1)

A written directive form has been implemented on 11/29/93. (see Figure 7.2)

Unresolved Item #1

Use of strontium-90 eye applicator which was received from a licensee not authorized to package and distribute byproduct material for medical use. (10 CFR 35.49(a))

Background Over the period of July 1991 through November 1992, QMC accepted six strontium-90 eye applicators from local ophthalmologists. These physicians chose to terminate their respective licenses rather than pay the NRC annual fee. As a public service, QMC accepted these applicators at no cost. The NRC was fully aware of these transfers.

In November 1991, the RSO presented all the applicators to the QMC authorized users. The optimal applicator was chosen, and replaced the twenty seven year old QMC applicator. The RSO believed the NRC was fully aware of this decision.

In June 1993, the RSO received a phone call from the USNRC Region V regarding the use of the transferred applicator. It was the RSO's understanding that a license amendment requesting exemption from 10 CFR 35.49 may be necessary if QMC wanted to continue to use the applicator. However, the RSO was under the impression the matter was still under consideration at Region V and Headquarters.

At the USNRC Region V Workshop on September 1-2, 1993, USNRC Region V staff repeated his recommendation that the RSO submit a license amendment request for an exemption. Once again, the RSO thought there was still some question whether an amendment was required or recommended.

There was never a written instruction from the NRC regarding this matter prior to the inspection.

The RSO stated in his 9/10/93 audit report that he would not immediately submit the recommended amendment request. It was his intent to wait for a final written instruction from NRC.

QMC Response The RSO regrets the misunderstanding between himself and the USNRC staff. The RSO did not realize an absolute immediate need for a license amendment had been established by Region V or Headquarters. In the future, written instructions regarding such requirements would be appreciated.

The good news is that the patients have benefitted from the superior applicator which offers a faster treatment time and a more comfortable design.

Corrective Action QMC understands 10 CFR 35.49(a) was established to ensure the integrity of radioactive sources used in medicine. Therefore, we do not request an exemption from this well intentioned regulation.

Rather, QMC will purchase a new strontium-90 applicator from a licensed manufacturer. A capital budget request has been approved for the purchase a new strontium-90 eye applicator from Medi-Physics.

In the interest of optimal medical care, QMC requests permission to use the unauthorized applicator for the next few weeks until the new applicator arrives.

Stated Concern #1

There may not be enough resources assigned to overseeing the radiation protection program based on the number of apparent violations, the growth of the program, and the commitments on the RSO's time at other facilities in Hawaii. (Section 18)

Background A review of the NRC inspection history since the inception of the Medical Physics Department in July 1988 indicates:

Jan 5-6, 1989	1 violation
Nov 14-15, 1989	4 violations
Dec 9-10, 1991	2 violations
Sep 28 and Oct 25-27, 1993	8 possible violations

During that same period, the Medical Physics program has grown to serve QMC, KMC, SFMC, HMG, and Hilo. There has also been an increase in staff from 4 to 11 FTE's.

QMC Response The number of violations during this most recent inspection is indeed more than the previous three. However, the RSO believes this is not necessarily indicative of inadequate program oversight, but instead may be due to:

a. The most recent inspection was conducted over four days, rather than two days as in the past. More time allows for more review and more discovery.

b. The most recent inspection was conducted by an inspector who is known in Hawaii to be more thorough than other inspectors. He not only inspects the records, but also conducts a performance based inspection through observation and staff interviews.

Regarding the growth of the program, the RSO is fortunate to work with many extremely capable and supportive individuals. Most clinical duties have been delegated within the physics group. The supervisor of Nuclear Medicine provides invaluable service to the radiation safety program. The nuclear medicine staff at HMG and Hilo are largely self directed and require minimal supervision.

Nonetheless, the RSO did identify a need for more staff to support the radiation safety program at QMC. A request was made on 6/21/93 for two new physicists to serve teletherapy, HDR, and the general safety program. This request has been approved, and two physicists have been hired.

Corrective Action Brent Murphy has been hired to serve in-part as assistant RSO as of January 1994. Brent was the RSO at Tripler Army Medical Center during 1991-1992. He is fully qualified to conduct radiation safety audits, provide inservices, and perform equipment calibrations under the supervision of the RSO.

Douglas Schumacher has over five years experience with HDR at the Swedish Tumor Institute in Seattle. He will oversee the HDR program at QMC, including clinical treatments, quality control, and radiation safety. Doug is scheduled to arrive in February 1994. The first HDR source will be delivered April 1994, assuming the NRC license request is approved by then.

The recruitment of these two physicists is indicative of QMC's commitment to radiation safety and program excellence.

Positive Indicators

The Queen's Medical Center requests consideration of the following positive indicators when determining the appropriate enforcement action:

Facility Improvements The Radiation Safety Committee decided a renovation of the Nuclear Medicine Hot Lab would provide better organization and reduce errors. The cost to enlarge the area and provide a larger fume hood was approximately $32,000. Nonetheless, the project was approved and completed during the past two years. The new area now has adequate space for isotope storage, inventory management, and the NMIS workstation.

Additional Equipment Within the last two years, The Queen's Medical Center has purchased several major capital items to improve the radiation safety program:

NMIS - software designed to improve regulatory compliance

Capintec CAPRAC Well Counter - more sensitive wipe analysis

Victoreen Area Monitor - continuous monitoring of Hot Lab

Ludlum Trash Monitors (2) - detect radioactive trash

Develop Staffing Like many nuclear medicine departments, Queen's has faced high turnover of technologists. This can compromise the continuity and effectiveness of the radiation safety program. In 1992, Queen's began an in-house nuclear medicine technologist training program. It is anticipated that this will lead to a stable staff in the future.

Nursing Training Despite the apparent violation, improvements and recognition of the training program have occurred this past period:

Audit Program - The computerized audit program was developed in-house to provide inservice and dosimetry data.

Self Learning Module - Although not fully utilized, the self learning module provides an excellent resource to the nurses.

Inservice Quality - At the Region V Workshop, special mention was made of the inservice provided by the RSO to QMC nurses.

These indicators demonstrate a commitment to radiation safety at the departmental as well as management level. The Radiation Safety Committee has been proactive in many areas. While apparent violations have occurred, they are not representative of the program as a whole.

QMC Employee Radiation Exposure Report

By Quarters *1992*

Employee	1	2	3	4	Total	Inservice
[redacted]	5	7.8	2.9	1.1	**16.8**	10/16/92
	0.1				**0.1**	Sec.
				15.2	**15.2**	Pharm.
		0.8	0.6		**1.4**	10/16/92
				8	**8.0**	10/16/92
		26.9	13	0.8	**40.7**	06/09/92
			2		**2.0**	
		8.2	5	1.2	**14.4**	10/08/92
			5.6		**5.6**	09/29/92
	5	3			**8.0**	
	9	15.5	5.3	2.2	**32.0**	09/29/92
	5.5	3.1	24.7	5.7	**39.0**	10/16/91
	6	3.8	22.2	27.1	**59.1**	09/28/92
	4.7	3.1	1.3		**9.1**	10/27/92
	1.1				**1.1**	10/17/91
			3.9		**3.9**	10/08/92
				1.4	**1.4**	8/12/93 *
	11.3	0.5	0.9	16.1	**28.8**	12/27/91
	8	7.5			**15.5**	11/13/92
	11				**11.0**	
			2		**2.0**	
	33.8	24.6			**58.4**	7/22/93 *
	0.3				**0.3**	10/17/91
	10.6				**10.6**	10/23/91
				0.1	**0.1**	n/a
			0.2		**0.2**	n/a
	2				**2.0**	
	3.3	21.2			**24.5**	10/16/91
	6			4.6	**10.6**	06/06/91
	14.9	4.2	11.7	3	**33.8**	10/05/92
	4.3	12.4	0.5		**17.2**	10/17/91
	15	56.5	6.2	8.1	**85.8**	09/10/92
				0.3	**0.3**	10/16/92
		27.9	39	13.6	**80.5**	06/12/92
		0.2			**0.2**	Soc. Wk.
	6	14.4	13.1		**33.5**	09/28/92
	17.2	22.4	25.7	15.5	**80.8**	10/27/92

Appendix I.

QMC Employee Radiation Exposure Report

By Quarters *1992*

Employee	1	2	3	4	Total	Inservice
[redacted]	5.6		12.2	2.2	20.0	11/13/92
	79	27.3	42.4		148.7	10/05/92
		25			25.0	09/28/92
	54.3	0.7			55.0	6/25/91
	6.6	9			15.6	09/28/92
			5.7		5.7	10/27/92
	2.3	31.9			34.2	10/16/91
		20.2	22.6	13.4	56.2	09/29/92
			0.3		0.3	10/16/92
	5.5	20.3	11	0.6	37.4	10/13/92
	14.7	37.5	1.2	9.5	62.9	10/05/92
				5.8	5.8	12/27/91
	0.7	24	1.2	4.7	30.6	10/05/92
	1.1	1.6	3		5.7	09/28/92
	2.2	28.4			30.6	10/16/91
	2.8	3.4			6.2	10/16/92
			1		1.0	IV
			0.2		0.2	09/30/92
		0.1			0.1	Pharm
	26.7	17.3	27.6	3.1	74.7	09/29/92
	9	14.3	30.6		53.9	10/16/92
				0.4	0.4	10/08/92
		2.7	8.8	3.8	15.3	06/12/92
	0.9		1.6	1.1	3.6	9/29/93 *
	1.4				1.4	Resp.
	2.5	31.3			33.8	
		36.5			36.5	12/27/91
		0.5			0.5	
	11.6	10	33.3	11.1	66.0	09/29/92
	5	5.2		6.1	16.3	10/27/92
	0.2	0.1			0.3	Diet.
		20.5	15.2	2.8	38.5	10/05/92
	5.3	1.3	7.2		13.8	10/16/92
		9.9	2.3		12.2	10/08/92
			0.1		0.1	09/29/92
			0.7		0.7	Soc. Wrk.
	32.8				32.8	06/06/91

QMC Employee Radiation Exposure Report

By Quarters *1992*

Employee	1	2	3	4	Total	Inservice
[redacted]	6.4	6.2	22.3	5.4	40.3	05/29/91
				9.1	9.1	10/13/92
			5.3		5.3	07/24/92
			13.4		13.4	
	1.4				1.4	(")
	1.1				1.1	
		8.3	1.1	3.7	13.1	07/24/92
	11.4	8.9			20.3	IV
		8.9			8.9	12/27/91
		11.6			11.6	IV
			3.2	14.2	17.4	08/18/92
		5.4			5.4	Chemo
		11.2			11.2	IV
	0.4	5.5	19.5	0.9	26.3	10/08/92
	17.9		6.3		24.2	09/29/92
	8.7	11.2	1		20.9	10/17/91
	7.4				7.4	Resp
	23.9	6.2		6.9	37.0	12/27/91
	1.1				1.1	Resp.
				2.3	2.3	12/27/91
		8	4.2		12.2	10/16/92
		57	12.7		69.7	05/22/92

Average	10.0	13.9	9.9	6.2	40.0

1992 = 79 nurses

Deficiencies = 12 nurses

other = 15 non-nurses

1

QMC Employee Radiation Exposure Report

By Quarters *1993*

(through 11/16/93)

1992

Employee	1	2	3	4	Total	Inservice
[redacted]	10.6	18.7	6.2		35.5	10/17/93
[redacted]			1.1	0.5	1.6	10/17/93
[redacted]	0.4	15	9.3		24.7	06/17/93
[redacted]	3.8	43.3	7.9	0.7	55.7	03/10/93
[redacted]		0.5	2.4	1.1	4.9	06/14/93
[redacted]	0.3				0.3	09/29/92
[redacted]	4.3	6.3	1.7	6.5	18.8	06/14/93
[redacted]		0.7			0.7	MD
[redacted]	25.7	9.2		1.7	36.6	06/14/93
[redacted]	1.6	3	3.4	1.9	9.9	09/14/93
[redacted]			6	5.7	11.7	06/14/93
[redacted]			1.3	3.1	4.4	
[redacted]	7.1	0.2			7.3	10/08/92
[redacted]		4.2			4.2	IV
[redacted]			1.6		1.6	8/12/93
[redacted]	6.7	22.4			29.1	06/14/93
[redacted]			19.3		19.3	7/22/93
[redacted]		0.9			0.9	Resp.
[redacted]		1.5			1.5	Pt. Supply
[redacted]		2.5			2.5	Resp.
[redacted]			2		2.0	MD
[redacted]		6.5	3.2	6.5	16.2	07/22/93
[redacted]		1.5	5.7		7.2	07/20/93
[redacted]				3.3	3.3	10/17/91
[redacted]		0.1			0.1	
[redacted]	9.5	17.2	14.9	0.8	42.4	01/12/93
[redacted]	17.5	4.1	2.8	19.5	43.9	06/17/93
[redacted]	4.6	16.4	12.1	0.7	33.8	10/17/91
[redacted]			0.6		0.6	
[redacted]		1.5	8.4	0.1	10.0	06/14/93
[redacted]	5.5				5.5	3/20/90
[redacted]		0.3	5.4		5.7	Resp.
[redacted]	35.9	23.3	13.3		72.5	06/12/92
[redacted]				5.1	5.1	6/14/93
[redacted]	4.6	12.1			16.7	10/22/92
[redacted]		5.2		2.8	8.0	Resp.
[redacted]			0.6		0.6	IV

Appendix II.

QMC Employee Radiation Exposure Report

By Quarters *1993*

1992

Employee	1	2	3	4	Total	Inservice
[redacted]		2.8			**2.8**	
[redacted]	3.1	49.4	9.3	12.9	**74.7**	06/17/93
[redacted]				1.4	**1.4**	
[redacted]			30		**30.0**	06/14/93
[redacted]	4.7				**4.7**	6/25/91
[redacted]			2.2	4.6	**6.8**	06/17/93
[redacted]	0.1	0			**0.1**	07/22/93
[redacted]		8.3	9.8		**18.1**	06/15/93
[redacted]			1.1	0	**1.1**	7/21/93
[redacted]	11.6	2.5	15.9	19.2	**49.2**	06/14/93
[redacted]	6.6	24	9.3	0.5	**40.4**	06/17/93
[redacted]				0.4	**0.4**	
[redacted]	1.4				**1.4**	06/15/93
[redacted]	0.7	15.3	5.9		**21.9**	06/15/93
[redacted]	6.3	34.9	9.2		**50.4**	09/13/93
[redacted]			3.5		**3.5**	Resp.
[redacted]	2.5		6.4	18.4	**27.3**	06/15/93
[redacted]				15.6	**15.6**	
[redacted]		9.5	16.2	2.4	**28.1**	07/22/93
[redacted]		1.5	1.1	0.1	**2.7**	10/16/92
[redacted]			19.6	22.9	**42.5**	07/22/93
[redacted]	2.2	15	[illegible]	1	**31.6**	09/13/93
[redacted]			[illegible]		**0.0**	Maint.
[redacted]		2.6	0.2		**2.8**	03/03/93
[redacted]	2	6.1	12	6.6	**26.7**	07/20/93
[redacted]	31.1	37.7	5		**73.8**	09/14/93
[redacted]		9.3		5.3	**14.6**	09/14/93
[redacted]	3.7				**3.7**	06/12/92
[redacted]			0.3		**0.3**	9/29/93
[redacted]	20.6	26.1	16.3	59.9	**122.9**	06/17/93
[redacted]		0.4			**0.4**	
[redacted]		5.3	8.2	1.4	**14.9**	06/17/93
[redacted]	7.4	6.5	14.9	5.4	**34.2**	06/15/93
[redacted]		1.3			**1.3**	
[redacted]		2.3	3.2	0.2	**5.7**	09/13/93
[redacted]			18.4	0.2	**18.6**	06/14/93
[redacted]	0.1	27.8			**27.9**	12/27/91

QMC Employee Radiation Exposure Report

By Quarters *1993*

1992

Employee	1	2	3	4	Total	Inservice
[redacted]				8.9	**8.9**	11
[redacted]	7.6	13.2	20.6	11.3	**52.7**	07/20/93
[redacted]		26.7			**26.7**	06/14/93
[redacted]		15.1	4.8		**19.9**	06/15/93
[redacted]		1.2			**1.2**	Resp.
[redacted]	1.6	8.3	0.9	0.1	**10.9**	01/12/93
[redacted]			0		**0.0**	07/21/93
[redacted]		0.6		2	**2.6**	IV
[redacted]			1.6		**1.6**	Resp.
[redacted]			18.8		**18.8**	IV
[redacted]			0.9		**0.9**	
[redacted]		0.1			**0.1**	
[redacted]				11.2	**11.2**	10/17/93
[redacted]	1.8	28.3		0.2	**30.3**	09/16/93
[redacted]		16	[illegible]		**86.1**	08/18/92
[redacted]		1			**1.0**	Resp.
[redacted]				0.7	**0.7**	
[redacted]		2.8			**2.8**	Chemo.
[redacted]	0.3	9.9	19.9		**30.1**	06/15/93
[redacted]	19.5	43.8	12.3	18.2	**93.8**	06/14/93
[redacted]				1.5	**1.5**	06/17/93
[redacted]			0.2	0.7	**0.9**	07/20/93
[redacted]		0.2	9		**9.2**	IV
[redacted]			0.8		**0.8**	06/17/93
[redacted]		4.1	6.2	17.6	**27.9**	06/17/93
[redacted]		3.8		2.5	**6.3**	Resp.
[redacted]	1.3	3	12.4	1	**17.7**	09/14/93
[redacted]		1.9		5.1	**7.0**	06/14/93
[redacted]		35.6	8.6	1	**45.2**	10/17/93
[redacted]	0.4	10.5	8.9	8.7	**28.5**	06/15/93
[redacted]		3.6			**3.6**	Resp.
[redacted]		0.6			**0.6**	
[redacted]			12.4	2.2	**14.6**	06/14/93

Average	7.2	10.7	8.8	6.3	**32.9**

1993 YTD = 86 nurses

1992 Repeats = 49 nurses

1992+1993 = 116 nurses

1992+1993 = 25 deficiencies

(80% compliance)

1993 Deficiencies = 13 nurses

1993 Other = 20 non-nurses.

M E M O R A N D U M

TO:	Clergy	Dietary	EEG	EKG
	IV Therapy	Maintenance	Pharmacy	Radiology
	Resp. Therapy	Security	Volunteers	

FROM: Scott Dube, M.S.
Radiation Safety Officer

DATE: September 17, 1993

SUBJECT: Radiation Safety Instructions for Non-Nursing Staff

Approximately 100 in-patients are treated each year using radioactive sources placed directly in the body. This technique is called "brachytherapy". The rooms are visibly posted with a "Caution Radioactive Materials" sign.

You and your staff may need to enter these rooms on occassion. With that in mind, I have attached a set of instructions which should prove useful.

Please call me if you have any questions, or would like a radiation safety inservice for your staff. Thank you for your consideration.

Figure 1.1

THE QUEEN'S MEDICAL CENTER

RADIATION SAFETY GUIDELINES FOR BRACHYTHERAPY:
INSTRUCTIONS FOR NON-NURSING SERVICES

An important part of the radiation therapy program is Brachytherapy, or the use of radioactive sources implanted directly in the body. There are certain precautions to be followed when encountering these patients. The following guidelines should be followed by the staff of the non-nursing services, including:

Clergy, Dietary, EEG, EKG, IV Therapy, Maintenance, Pharmacy, Radiology, Respiratory Therapy, Security, Volunteers

1. The Medical Physics Department shall be responsible for identifying each brachytherapy patient's room and chart with a "Caution Radioactive Materials" label. (see attached example)

2. Pregnant women as well as individuals under the age of 18 are not allowed in the brachytherapy room.

3. Only the floor nurses who care for brachytherapy patients are required to wear a dosimeter. Non-nursing personnel will not be issued a digital dosimeter on a routine basis.
However, digital dosimeters can be worn by non-nurses for academic interest. Please identify yourself as a non-nurse on the dosimeter logsheet.

4. Work efficiently so that you can limit your time in the room to a minimum.

5. Try to maintain a six foot distance from the patient whenever possible.

6. The staff should work behind the lead bedside shield whenever possible. However, it is permitted to work on the unshielded side whenever necessary to perform clinical services.

7. Lead aprons from Radiology do not provide significant shielding from brachytherapy sources. Therefore, lead aprons are not to be worn while caring for the patient.

8. Wear rubber gloves when caring for the patient. Leave these gloves in the trash in the patient's room when leaving.

9. Do not remove anything from the room. Physics will monitor the trash and linen before disposal.

10. Please report all concerns and questions to the Radiation Safety Officer. He can always be reached through the Queen's Medical Center's switchboard.

scott dube, 9/17/93

Figure 1.2

M E M O R A N D U M

TO: Terry Ichinose
Supervisor, Nuclear Medicine

FROM: Scott Dube
Senior Medical Physicist

DATE: November 19, 1993

SUBJECT: NRC Inspection Violations and Corrective Actions

The NRC called today to schedule the Enforcement Conference. I want to reiterate the corrective actions we have discussed these past weeks since the inspection. These actions must be completed and documented before the December 2, 1993 Enforcement Conference:

1. Pregnancy/Breastfeeding Screening - It is imperative that you review the documented procedure for screening women who may be pregnant or breastfeeding. Have your staff sign the procedure and keep it on file for the NRC.

2. Linearity Test - The dose calibrator linearity test must cover the full range of doses which might be assayed. Therefore, it is mandatory to test from 200 mCi to 10 uCi each calendar quarter. This requires ordering a single vial of 200 mCi Tc-99m from PRP to perform the test.

3. Monitoring Hands - Our license requires the staff to monitor their hands after each procedure. The Victoreen Area Monitor is not sensitive enough for this test. The staff must use a gamma camera until we purchase a suitable instrument.

4. Waste Retention - All waste must be kept for ten halflives. Strontium-89 must be kept for 505 days. Iodine-125 must be kept for 600 days. There can be no early disposals.

5. Identify Waste Contents - The decay-in-storage records must identify what isotopes are included in each container. This includes sharps buckets. If the NMIS cannot meet the requirements, then we must return to manual record keeping.

The NRC will be favorably impressed if we can demonstrate prompt corrective action to the violations. Therefore, it is very important to provide them with documentation regarding the above issues at the Enforcement Conference. Please call me if I can help in any way.

cc: Pat McGuigan
File

Figure 2.1

Nuclear Medicine Pregnancy and Breast Feeding Screening

Policy

It is the policy of the Department of Nuclear Medicine of The Queen's Medical Center, to prevent unnecessary radiation exposure to the general public.

In order to reduce the potential risk to a fetus or nursing child the staff of the Nuclear Medicine Department will ensure that the following procedures are adhered to:

Procedure

1. Posting of signs notifying pregnant or breast feeding individuals to report such conditions to the Nuclear Medicine staff.

2. A Nuclear Medicine questionnaire will be given to all female patients upon checking into the Nuclear Medicine Department.

3. The administering nuclear medicine technologist will scrutinize the questionnaire.

4. If the answer to the question regarding pregnancy is "YES", or is the answer to the question regrading breast feeding is "YES", then the technologist will bring the matter to the attention of the nuclear medicine physician.

5. If the answer to the question regarding pregnancy is "MAYBE", a review of remaining questions may help to clarify this response. This information will be brought to the attention of the nuclear medicine physician.

6. In the event of an administration of a radiopharmaceutical to a patient who is either pregnant or breast feeding, the nuclear medicine technologist will notify the supervisor of nuclear medicine and the nuclear medicine physician immediately. The supervisor or nuclear medicine physician will then notify the Radiation Safety Officer.

7. Forms to document an event will include:
   Misadministration and Recordable Event Form
   Risk Management Event Form

8. A review process of the event will be initiated and documented by the supervisor, nuclear medicine physician and RSO.

9. If any disciplinary action is to be instituted, the supervisor, manager, physician and RSO will determine appropriate action based on severity of the violation in accordance with medical center policy.

10. This form shall be filed in the patient's Nuclear Medicine subfolder.

Figure 2.2

M E M O R A N D U M

TO: Terry Ichinose
Supervisor, Nuclear Medicine

FROM: Scott Dube
Senior Medical Physicist

DATE: November 19, 1993

SUBJECT: NRC Inspection Violations and Corrective Actions

The NRC called today to schedule the Enforcement Conference. I want to reiterate the corrective actions we have discussed these past weeks since the inspection. These actions must be completed and documented before the December 2, 1993 Enforcement Conference:

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3. Monitoring Hands - Our license requires the staff to monitor their hands after each procedure. The Victoreen Area Monitor is not sensitive enough for this test. The staff must use a gamma camera until we purchase a suitable instrument.

4. Waste Retention - All waste must be kept for ten halflives. Strontium-89 must be kept for 505 days. Iodine-125 must be kept for 600 days. There can be no early disposals.

5. Identify Waste Contents - The decay-in-storage records must identify what isotopes are included in each container. This includes sharps buckets. If the NMIS cannot meet the requirements, then we must return to manual record keeping.

The NRC will be favorably impressed if we can demonstrate prompt corrective action to the violations. Therefore, it is very important to provide them with documentation regarding the above issues at the Enforcement Conference. Please call me if I can help in any way.

cc: Pat McGuigan
File

Figure 3.1

M E M O R A N D U M

TO: Terry Ichinose
Supervisor, Nuclear Medicine

FROM: Scott Dube
Senior Medical Physicist

DATE: November 19, 1993

SUBJECT: NRC Inspection Violations and Corrective Actions

The NRC called today to schedule the Enforcement Conference. I want to reiterate the corrective actions we have discussed these past weeks since the inspection. These actions must be completed and documented before the December 2, 1993 Enforcement Conference:

1. Pregnancy/Breastfeeding Screening - It is imperative that you review the documented procedure for screening women who may be pregnant or breastfeeding. Have your staff sign the procedure and keep it on file for the NRC.

2. Linearity Test - The dose calibrator linearity test must cover the full range of doses which might be assayed. Therefore, it is mandatory to test from 200 mCi to 10 uCi each calendar quarter. This requires ordering a single vial of 200 mCi Tc-99m from PRP to perform the test.

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cc: Pat McGuigan
✓File

Figure 4.1

Hand monitoring with wall-mounted 05-695.

Left: Checking clothing with removable probe of 05-695 Monitor (5-foot cable included).

Right: Optional Floor Adapter with monitor.

Also Available:

FLOOR MONITOR ADAPTER

This handy tool permits checks of floor contamination without stooping or bending. A long-handled steel dolly holds the monitor so that its probe easily detects contamination as the adapter is rolled across the floor. The 05-694 Adapter accepts the ratemeter and probe of the 05-695 Monitor.

AC ADAPTER

An AC-to-DC converter allows the 05-676 Monitor to operate on 110V AC.

Radio-Nuclide	05-695 CPM (per 10^{-4} $\mu Ci/cm^2$)	05-695 Detection Limits (x 10^{-5} $\mu Ci/cm^2$)	05-676 CPM (per 10^{-4} $\mu Ci/cm^2$)	05-676 Detection Limits (x 10^{-5} $\mu Ci/cm^2$)
^{125}I	1900	0.5	780	1
^{14}C	2100	0.5	1170	0.7
^{99m}Tc	1050	1	500	1.6
^{131}I	11,000	0.1	5760	0.1

05-676	^{125}I Contamination Monitor with integral probe/detector (100 cm^2). Battery-operated	$1900.00
05-695	^{125}I Contamination Monitor with cable-connected probe/detector (200 cm^2) and wall-mount assembly. 110VAC	2695.00
05-694	Floor Adapter for 05-695 Monitor	775.00
05-699	110VAC Adapter for 05-676 Monitor	95.00
05-678	Probe/Detector (200 cm^2) and Cable	1100.00

Specifications

	05-676	05-695
Detector	Xenon-filled proportional counter. Detects gamma, x-ray and beta ($\bar{E}$ max. >150 keV). 6 mg/cm^2 titanium foil window.	
Window Area	100 cm^2	200 cm^2
Operating Voltage	1900 V	
Plateau	Length 200 V. Slope 4%/100 V.	
Background	Approx. 500 cpm	Approx. 900 cpm
Temperature Range	−5°C to +50°C	
Ranges	300, 3000 cps.	
Time Constants	2, 20 seconds	
Count Rate Indication	Panel meter. Single-pulse clicks. Loud buzzer alarm.	
Power	Batteries. 110V AC converter optional.	110V AC
Check Source	Included	
System Size	9" x 8¾" x 3¾" deep	12" x 11¼" x 6" deep
System Weight	3¼ lbs.	10¼ lbs.

Figure 4.2

Hand monitoring with wall-mounted 05-695.

Left: Checking clothing with removable probe of 05-695 Monitor (5-foot cable included).

Right: Optional Floor Adapter with monitor.

Also Available:

FLOOR MONITOR ADAPTER

This handy tool permits checks of floor contamination without stooping or bending. A long-handled steel dolly holds the monitor so that its probe easily detects contamination as the adapter is rolled across the floor. The 05-694 Adapter accepts the ratemeter and probe of the 05-695 Monitor.

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	05-695		05-676	
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Figure 4.2

M E M O R A N D U M

TO: Terry Ichinose
Supervisor, Nuclear Medicine

FROM: Scott Dube
Senior Medical Physicist

DATE: November 19, 1993

SUBJECT: NRC Inspection Violations and Corrective Actions

The NRC called today to schedule the Enforcement Conference. I want to reiterate the corrective actions we have discussed these past weeks since the inspection. These actions must be completed and documented before the December 2, 1993 Enforcement Conference:

1. Pregnancy/Breastfeeding Screening - It is imperative that you review the documented procedure for screening women who may be pregnant or breastfeeding. Have your staff sign the procedure and keep it on file for the NRC.

2. Linearity Test - The dose calibrator linearity test must cover the full range of doses which might be assayed. Therefore, it is mandatory to test from 200 mCi to 10 uCi each calendar quarter. This requires ordering a single vial of 200 mCi Tc-99m from PRP to perform the test.

3. Monitoring Hands - Our license requires the staff to monitor their hands after each procedure. The Victoreen Area Monitor is not sensitive enough for this test. The staff must use a gamma camera until we purchase a suitable instrument.

4. Waste Retention - All waste must be kept for ten halflives. Strontium-89 must be kept for 505 days. Iodine-125 must be kept for 600 days. There can be no early disposals.

5. Identify Waste Contents - The decay-in-storage records must identify what isotopes are included in each container. Thi. includes sharps buckets. If the NMIS cannot meet the requirements, then we must return to manual record keeping.

The NRC will be favorably impressed if we can demonstrate prompt corrective action to the violations. Therefore, it is very important to provide them with documentation regarding the above issues at the Enforcement Conference. Please call me if I can help in any way.

cc: Pat McGuigan
✓File

Figure 5.1

THE QUEEN'S MEDICAL CENTER
DEPARTMENT OF NUCLEAR MEDICINE

WASTE DISPOSAL PROCEDURE

The purpose of this procedure is to assure that all radioactive waste is disposed of within the guidelines of the Nuclear Regulatory Commission and State rules and standards.

1. Radioactive Waste will include the following items: Radiopharmaceutical vials, syringes, needles, tubing, connectors, bandages, and any other items that may become contaminated.

2. Sharps containers will be used to hold the radioactive waste until time of disposal, with the exception of large items that can be bagged securedly. Each container will be labeled with a "BIN" number that is specific to that container and its contents.

   Bins will be labeled as to its contents.
   i.e. Tc99m, or I131, T1201, Ga67, In111, Xe133, or P32, Sr89, I125, Cr51
   Radioactive waste will be held for storage in the following BIN types:
   Short Lived [S] - Tc99m
   Mid lived [M] - 1 to 10 day halflife. T1201, I131, Ga67, Xe133, In111
   Long lived [L] - more than 10 to 60 day halflife. I125, Sr89, P32, Cr51

3. Disposal Time will be designated as 10 halflives of the longest lived isotope in the Sharps container. i.e. Tc99m with a 6 hr halflife will be stored for 60 hrs. prior to disposal, I131 with a 8 day halflife will be stored for 80 days prior to disposal.

4. The Sharps container will be labeled with a "Caution Radioactive Material" sticker with the following information: Longest lived isotope, date of storage, survey in mR/hr, Bin number and initials of the storer.

5. Disposal will be handled as Biohazard waste after reaching the 10 halflife state and disposed of as "TRASH".

6. Documentation will be by entry into the NMIS in the Hot Lab. Procedure to enter waste disposal data is in the HotLab Bible.

7. If storage occurs in the absence of the supervisor or senior technologist, notification as soon as possible upon their return is mandatory.

tsi 11/93

Figure 5.2

M E M O R A N D U M

TO: Terry Ichinose
Supervisor, Nuclear Medicine

FROM: Scott Dube
Senior Medical Physicist

DATE: November 19, 1993

SUBJECT: NRC Inspection Violations and Corrective Actions

The NRC called today to schedule the Enforcement Conference. I want to reiterate the corrective actions we have discussed these past weeks since the inspection. These actions must be completed and documented before the December 2, 1993 Enforcement Conference:

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The NRC will be favorably impressed if we can demonstrate prompt corrective action to the violations. Therefore, it is very important to provide them with documentation regarding the above issues at the Enforcement Conference. Please call me if I can help in any way.

cc: Pat McGuigan
File

Figure 6.1

QUEENS MEDICAL CENTER

NUCLEAR MEDICINE DEPARTMENT

HONOLULU, HAWAII

November 19, 1993

Disposal Report: Bin:H604 [FINAL] 11-18-1993 12:22

#	Radiopharm.	Dsp.Act	ml	#	Radiopharm.	Dsp.Act	ml
1	Thallous Chlor	----	0.4	2	Tl-201	----	0.6
3	Thallous Chlor	----	0.0	4	In-111 OXINE	----	
5	Sodium Iodide	----					

Report Total: 1.0ml

Disposal Type: LONG TERM
Survey Date__: 08-27-1993 14:21
Survey Instr.: EBERLINE ESP-1
Manufacturer_: EBERLINE
Survey Bkg.__: 0.060 mR/hr

Bin____: H604
Tech___: TC
Serial#: 02282
Nxt Cal: 03-23-1994
Surface: 25.700 mR/hr

Disposal Type: FINAL DISPOSAL
Survey Date__: 11-18-1993 12:22
Survey Instr.: EBERLINE ESP-1
Manufacturer_: EBERLINE
Survey Bkg.__: 0.030 mR/hr

Bin____: H604
Tech___: TC
Serial#: 02282
Nxt Cal: 03-23-1994
Surface: 0.030 mR/hr

Survey trigger: 0.05mR/hr
Comment_____: SYRINGES, VIALS, NEEDLES
Disposition__: INCINERATOR
Contents Passed 10.00 Halflives on 11-15-1993 22:57 from 08-27-1993 14:21

Disposing Tech. Signature: Sammy Cay

Figure 6.2

M E M O R A N D U M

TO: Dr. Boyer, Dr. Brown, Dr. DeMare, Dr. Huynh, Dr. Lederer, Dr. Loh, Dr. Mastro, Dr. Yamashiro

FROM: Scott Dube, M.S.
Senior Medical Physicist

DATE: November 19, 1993

SUBJECT: NRC Requirements Regarding Sr-90 Treatments

The Nuclear Regulatory Commission inspected our radiation safety program on October 25-27, 1993. Among the eight potential violations, there were two regarding our use of the Sr-90 applicator.

Firstly, Sr-90 treatments must meet the requirements of the Quality Management Program (10 CFR 35.32), which include:

Written Directive — Prior to each treatment, you must make a Written Directive specifying:
treatment site (left or right eye)
radioisotope (Sr-90)
source strength (73 mCi)
treatment time (21 seconds)
total dose (1000 cGy)
your signature and date

Written Record — After each treatment, you must make a Written Record specifying:
treatment time (21 seconds)
your signature and date

The NRC Inspector felt the current Treatment Summary does satisfy the Written Record requirement.

However, we currently do not make a Written Directive. The easiest way to satisfy the Written Directive requirement is to handwrite the above information on the Requisition Sheet which all patients must present. This document must be kept in the chart along with your Treatment Summary page.

Secondly, we can only use a Sr-90 applicator if it comes directly from the manufacturer. (10 CFR 35.49) The purchase order for the new Sr-90 applicator has been signed. It should take only a few weeks to receive the new device from Amersham. In the meantime, we can continue to use Dr. Minatoya's applicator.

cc: Lester Uyeda

Figure 7.1

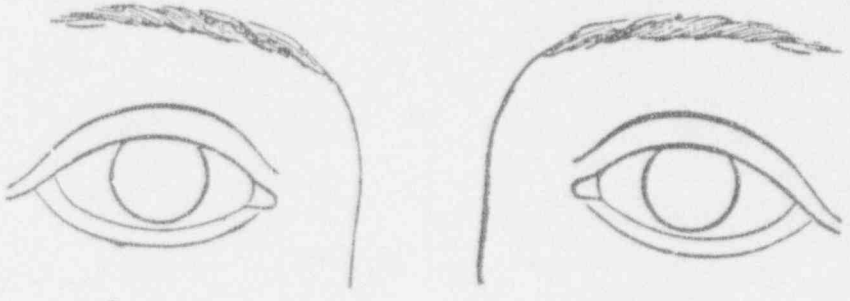
The Queen's Medical Center
Radiation Therapy Department

Sr-90 Written Directive

Patient _____

Referring Physician _____

Request Date _____

Right  Left

Treatment Area _____

_____

_____

QMC Sr-90 Ophthalmic Applicator, Activity _____

Time/Fraction _____ Dose/Fraction _____

Total Fractions _____ Total Dose _____

Authorized User _____

Date _____

Figure 7.2