

CERTIFICATE OF IMPLEMENTATION

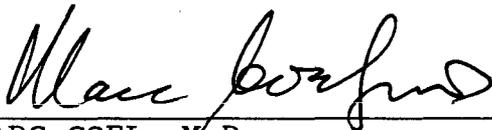
QUALITY MANAGEMENT PROGRAM

LICENSEE: THE QUEEN'S MEDICAL CENTER
1301 PUNCHBOWL STREET
HONOLULU, HI 96813

LICENSE NO. 53-16533-02

THE ATTACHED PROCEDURES AND STATEMENTS DEFINE
OUR QUALITY MANAGEMENT PROGRAM.

THIS PROGRAM SHALL BE IMPLEMENTED JANUARY 1, 1992.



MARC COEL, M.D.
CHAIRMAN, RADIATION SAFETY COMMITTEE

12/18/91
DATE

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THE QUEEN'S MEDICAL CENTER
NUCLEAR MEDICINE DEPARTMENT

QUALITY MANAGEMENT PROGRAM

I. Dosage Procedures

The following procedures shall apply only to these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Phosphorus-32 Therapy Doses

1. Before administering one of the above dosages, an Authorized User shall date and sign a Written Directive. The Written Directive shall specify the patient name, the radiopharmaceutical, the dosage, and the route of administration.

2. Before administering the dosage, the identity of the patient shall be verified as the individual named in the Written Directive by more than one method.

a. The Technologist shall first ask the patient's name and confirm the name on the request.

b. Then, the Technologist shall ask the patient's birth date and confirm the date on the request.

3. Before administering the dosage, the dosage shall be measured in the dose calibrator and the results compared with the prescribed dosage in the Written Directive.

4. Before administering the dosage, the Technologists shall be required to seek guidance if they do not understand the Written Directive. Any question regarding what to do or how to do it shall be answered before continuing.

5. After administering the dosage, the Authorized User or Technologist shall make a dated signed Written Record of the administered dosage.

6. The Written Directive and Written Record shall be retained for three years.

II. Recordable Events

1. A Recordable Event means an administration of dosage when one or more of the the following conditions occur:
 - a. No Written Directive;
 - b. No Written Record;
 - c. Administered Dosage differs from Written Directive by more than 10% and more than 15 microcuries.
2. A Recordable Event shall be investigated and documented within 30 days. A Written Report shall include the relevant facts, the cause of the event, an what corrective action, if any, is required to prevent recurrence.
3. The Record shall be retained for three years.

III. Misadministrations

1. A Misadministration means an administration of dosage when one or more of the following conditions occur:
 - a. Wrong patient;
 - b. Wrong radiopharmaceutical;
 - c. Wrong route of administration;
 - d. Administered Dosage differs from Written Directive by more than 20% and more than 30 microcuries

In addition to the Sodium Iodide and Phosphorus-32 cases, a Misadministration shall include all diagnostic doses other than sodium iodide > 30 microcuries when the above conditions are met and the dose to patient exceeds 5 rem effective dose equivalent or 50 rems dose equivalent to any individual organ.

3. The NRC Operations Center shall be notified by telephone no later than the next calendar day after discovery of the misadministration.
4. The referring physician shall be notified no later than 24 hours after the discovery of the misadministration.
5. The patient shall be notified no later than 24 hours after the discovery of the misadministration unless the referring physician personally informs the licensee that either he will inform the patient or that telling the patient would be harmful.
6. The Written Report shall be submitted to NRC Region 5 Office within 15 days after discovery of the misadministration. If the patient was notified, then a copy of this report must also be provided to the patient within 15 days.

7. The Written Report shall include:
 - the licensee's name (but not the patient's name)
 - the prescribing physician's name
 - a brief description of the event
 - why the event occurred
 - the effect on the patient
 - what improvements are needed to prevent recurrence
 - actions taken to prevent recurrence
 - whether the licensee notified the patient
 - if patient not notified, then why not
 - if the patient was notified, then what was said

8. A record of the Misadministration shall be retained for five years. The record shall include the Written Report as well as the:
 - patient's name
 - patient's social security number
 - referring physician's name
 - prescribing physician's name
 - technologist's name

IV. Periodic Review

1. The records of the Program shall be reviewed quarterly. This Review shall include:
 - All Written Directives - complete and correct
 - All Written Records - agreement with Written Directive
 - All Recordable Events - complete and accurate
 - All Misadministrations - complete and accurate

2. The Review will identify cases of deviation from the Written Directive, the cause of each deviation, and the action required to prevent recurrence.

3. All Recordable Events and Misadministrations will be presented at the Quarterly Radiation Safety Committee meeting.

4. The Quality Management Program will be reviewed annually as part of the annual Management Audit and presented to the Radiation Safety Committee. The Program will be reevaluated for its effectiveness at that time.

5. Records of the Review shall be retained for three years.

THE QUEEN'S MEDICAL CENTER
BRACHYTHERAPY PROGRAM

QUALITY MANAGEMENT PROGRAM

I. Brachytherapy Dosage Procedures

1. Before administering a brachytherapy dosage, an Authorized User shall date and sign a Written Directive in the Treatment Record. The Directive shall specify the patient name, the radioisotope, the number of sources, and the source strengths.
2. Before loading the sources, the identity of the patient shall be verified as the individual named in the Directive by more than one method. Specifically, the Authorized User shall first ask the patient's name and confirm the name. Then, the Authorized User shall confirm the name on the patient's hospital ID bracelet.
3. The source strengths shall be verified before loading. Cesium sources are color-coded, and stored in separate safe drawers as a function of activity. Iridium sources are stored in specific lead shipping containers, and are color-coded when multiple source strengths are shipped together. Iodine seeds are stored in individually labeled vicryl suture rings or glass vials.
4. Before loading the sources, the staff shall be required to seek guidance if they do not understand the Written Directive. Any question regarding what to do or how to do it shall be answered before continuing.
5. Radiographs of the actual sources or dummy sources shall be obtained for each implant to verify the source placement. Dose rate and total dose calculations shall be based on these data.
6. After loading the sources, the Authorized User shall make a dated signed Written Record of the administered dosage in the Treatment Record. This shall include the loading sequence of the sources.
7. Prior to unloading the sources, the Authorized User shall make a dated signed Prescription in the Treatment Record specifying the total treatment time.
8. After removing the sources, the Authorized User shall note the removal time in the Treatment Record.
9. The Treatment Record shall be retained for three years.

II. Dose Calculations

1. The dose calculations shall be checked before the total prescribed brachytherapy dose has been administered. This independent check will verify the appropriate use of all pertinent data in the calculations. The computer printout will be examined to verify the correct input data as well as the correct use of the output data.
2. Each brachytherapy computer program will be acceptance tested to verify its accuracy in calculating dose/dose rates. These tests will be based on the specific brachytherapy applications used clinically.

III. Recordable Events

1. A Recordable Event means an administration of dosage when one or more of the the following conditions occur:
 - a. No Written Directive;
 - b. No Written Record;
 - c. Administered Dosage differs from Written Directive by more than 10%.
2. A Recordable Event shall be investigated and documented within 30 days. A Written Report shall include the relevant facts, the cause of the event, an what corrective action, if any, is required to prevent recurrence.
3. The Record shall be retained for three years.

IV. Misadministrations

1. A Misadministration means an administration of dosage when one or more of the following conditions occur:
 - a. Wrong patient;
 - b. Wrong radioisotope;
 - c. Wrong treatment site;
 - d. Use of a leaking source;
 - d. Administered Dosage differs from the Prescribed Dose by more than 20%.
2. The NRC Operations Center shall be notified by telephone no later than the next calendar day after discovery of the misadministration.
3. The referring physician shall be notified no later than 24 hours after the discovery of the misadministration.

4. The patient shall be notified no later than 24 hours after the discovery of the misadministration unless the referring physician personally informs the licensee that either he will inform the patient or that telling the patient would be harmful.

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