Alaska Regional Hospital	Department: Diagnostic Imaging Section: Nuclear Medicine
Policy Title: Quality Management Program Brachytherapy-Sealed Sources (excluding Sr-90)	Effective Date: July, 1999
	Review Date:
	Supersedes: July 1997
Policy Number: 330.10	Authorized:

1. An authorized user will date and sign a written directive prior to the administration of any brachytherapy dose specifying the dosage and, site of administration. The written directive will be retained as part of the record of the case, for three years (or more, at the discretion of the hospital or Radiation Oncologist). Procedures for oral directions and revisions to written directives are as follows:

   If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

   Also, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose.

   If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

2. Before administering a brachytherapy dose, the authorized user or designee will verify by more than one method the identity of the patient as the individual named in the written directive.

   Before a permanent implantation procedure, the risks and benefits of the procedure are to be explained to the patient who must sign an informed consent.

3. The authorized user or designee will verify, before commencing the administration of the brachytherapy dose, that the specific details of the brachytherapy plan which were used in the computer dosimetric calculation are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of source and source strengths will be confirmed to verify agreement with the written directive and plan of treatment.

4. All occupational workers are encouraged to seek guidance if they do not understand how to assist with the written directive. Workers will ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, dosimetrist, or radiation therapist) will verify that the radioisotope, number of sources, source strengths, and if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources. Verification methods, such as checking the serial number of the sealed sources behind an appropriate shield, using a radiation detector, using a dose calibrator, using color-coded sealed sources, or using clearly marked storage locations, (i.e., one location for each source strength will be used).

The written directive may be revised during a surgical implant procedure, as the patient's anatomy requires. Based upon actual number and distribution of implanted seeds, as shown on ultrasound and follow-up radiographs or CT scans, dose profiles will be generated and filed in the Radiotherapy department.

6. a) For **temporary brachytherapy implants**, the authorized user will use radiograms or other comparable images (e.g., computerized tomography) of brachytherapy radioactive sources or nonradioactive "dummy" sources in place as the basis of verifying the position of the sources and calculating the exposure time or, equivalently, the total dose.
The radiograms or other simulator imaging studies will be reviewed by two knowledgable observers, at least one of whom will be the Authorized User and their initials affixed on the brachytherapy worksheet to confirm satisfactory geometry of the source or source applicator. Whenever possible, nonradioactive "dummy" sources will be used before inserting the radioactive sources (e.g., cesium-137 sealed sources used for intracavitary applications). However, in brachytherapy procedures requiring the use of various fixed geometry applicators (e.g., appliances or templates) radiographs or other comparable images will not be necessary since the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).

b) After witnessing the insertion of the brachytherapy sources, an authorized user will promptly record the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder). This information is checked against the loading sequence in the Written Directive and the correctness of the sequence indicated by signatures of the technologist and authorized user on the verification lines below the diag...

c) The licensed user will check the dose calculations before the total prescribed brachytherapy dose has been administered. Whenever possible, an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) who did not make the original calculation will check the dose calculations. Manual dose calculations will be checked for:

- Arithmetic errors
- Appropriate transfer of data from the written directive, plan of treatment, tables and graphs
- Appropriate use of nomograms (when applicable)
- Appropriate use of all pertinent data in the calculations

Computer generated dose calculations will be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g. position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence).

d) An authorized user will date, sign, and place in the patient's chart the Brachytherapy (written directive) form, after insertion of the brachytherapy sources. This Brachytherapy form will include the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

7. For **permanently implanted sources,** the authorized user or user under his supervision, after implanting the sources, will sign the worksheet documenting the number of implanted sources. This information is recorded on the I-125/Pd-103 Implant Survey Form.

8. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations will be performed within two working days of completion of the brachytherapy treatment.

9. Acceptance testing by a qualified person (e.g., medical radiation physicist) will be performed on each treatment planning or dose calculating computer program used for brachytherapy dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer for brachytherapy dose calculations. The authorized user will assess each treatment planning or dose calculating computer program based on specific needs and applications. This acceptance testing will be performed by Northwest Medical Physics for the Anchorage Radiation Therapy Center.

10. Acceptance testing will be performed by a qualified individual (Medical Physicist or Radiation Oncologist) of any brachytherapy alfterloading device, attachment, or accessory after new purchase, repair, service, replacement of parts or alteration prior to its clinical use.

11. The **written record of a Cs137 brachytherapy** case will consist of the Cs137 Brachytherapy Form (Written Directive), the computer dosimetry printout, the Cs 137 Implant Survey Form, a copy of the dictated procedure note, and any subsequent reports of case reviews prompted by discovery of misadministration or recordable event. Each case record is to be kept for three years (or more, at the discretion of the hospital or Radiation Oncologist).

    The record of permanent implantation procedure includes the written directive, the Seed Implantation Worksheet, computer dosimetric calculation printout, the Operating Room survey, a copy of the dictated procedure note, and any subsequent appended review (see
    below) of the case and will be kept on file for 3 years (or more at the discretion of the facility) from the date of administration of the agent.

12. Deviations from the written directive, recordable events, and misadministrations should be brought to the attention of both the radiation oncologist and the radiation safety officer as soon as possible. Such events will be discussed at the next Radiation Safety Committee meeting. Misadministrations are subject to the reporting requirements of 10CFR Part 35.33 which requires a 24 hour deadline (after discovery) for reporting misadministrations to the NRC and to the involved patient(s). Even if not yet discussed at the RSC meeting, the deviation or other problem, and the response or solution to it will be documented on the record of the case (which, as mentioned above, is kept for three years or more).

13. Annual review of the Brachytherapy QM Program will be performed and will include review of a representative number of randomly selected cases, if not all cases, from the preceding 12 months since the previous review. The number of cases to be reviewed, if not all, will be based on the statistical sampling principles and acceptance tables of 10CFR32.100, based on a 10% lot tolerance defect rate. If misadministrations or recordable events are discovered, the number of cases to be reviewed will be expanded to include all cases.

    Each case selected will be examined for the presence of a complete, signed Written Directive and compliance with the Written Directive in regards to the verification of the identity of the patient, the administered dosage and route, the documentation of the consent and instructions for the patient. The QM program review will be discussed at the following RSC meeting, distributed to relevant managers and departments, and filed for review by NRC inspectors.

14. Any revisions to the QMP are to be submitted to the NRC for review and comment within 30 days after the revisions are finalized.

15. Initial orientation training and annual training of the QM Program with the appropriate staff will be provided.

16. Recordable Events: Within 30 days of a recordable event, all relevant facts must be assembled identifying corrective action taken to prevent a recurrence. Records must be retained for a period of three years.

    A recordable event is if an administered dose is 10%-20% different than the prescribed dose, or a dose given without a Written Directive.

17. Misadministrations: Pursuant to 10CFR Part 35.33, the NRC Operations Center (301-951-0550) must be notified within one calendar day after a misadministration. The patient(s) involved in the administration must also be notified within 24 hours of the discovery of the administration. Within 15 days of the discovery, a written report must be sent to Region IV. The additional details of the reporting duties following a misadministration are spelled out in 10CFR35.33.

    A misadministration is an administered dose involving the wrong patient, wrong radioisotope, wrong treatment site, failure to remove sources for a temporary implant, or a calculated aqctual dose that differs by more than 20% from the prescribed dose.

Approved by:

Bradley K. Cuzzo — 8 July 99
Radiation Safety Officer — Date

[signature] — 7/8/99
Radiation Oncologist — Date
Authorized User
RICHARD CHUNG

C_s 137 BRACHYTHERAPY ORDER FORM

WRITTEN DIRECTIVE

Patient Name: _____ Date: _____

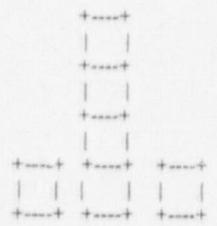
Radioisotope: **Cesium 137** Treatment Site: **Vagina** or **Other** (specify): _____

PRESCRIPTION PLAN: (see computer printout in Radiotherapy Dept. record)

Planned Dose (rads)	Therapy Rate (Rads/hrs)	Planned Duration	Planned Time In	Planned Time Out	Therapist Initials

Authorized User _____ Date: _____

LOCATION AND STRENGTH



Therapist Initials:

Authorized User:

VERIFICATIONS AT TIME OF ADMINISTRATION

_____ Verify and circle two methods of patient identification used:

Initials

___ Photo ID ___ Relative or Friend ___ ID bracelet

Patient states: ___ own name ___ birth date

_____ Verify that the specific details of the planned administration are in accordance with the Written Directive. Review the

Initials

___source strength used in calculations

___computer printout and dosimetry

___calculations above

_____ _____ Radiographs of simulation/source applicator reviewed

Initials Initials

_____ Verify that the actual radioisotope sources are correct:

Initials

___# of sources

___source strength/source identity (circle which method)

Serial # ***Color Code***

___Loading sequence

_____ Radiation Signs posted, Nursing Instructions in chart, Nursing visit log on door.

Initials

Date: _____ and Time _____sources inserted.

Plan of Treatment is in accordance with the Written Directive:

Authorized User: _____ Date: _____

AFTER COMPLETION OF PROCEDURE:

Planned Dose (rads)	Dose Rate (Rads/hrs)	Actual Time In	Actual Time Out	Actual Dose	Therapist Initials

Authorized User _____ _____ Date: _____

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SPL13

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4a Express Package Service *Packages under 150 lbs.* Delivery commitment may be later in some areas.

- [X] FedEx Priority Overnight (Next business morning)
- [ ] FedEx Standard Overnight (Next business afternoon)
- [ ] FedEx 2Day* (Second business day)
- [ ] FedEx Express Saver* (Third business day)
- [ ] FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)

*FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

- [ ] FedEx Overnight Freight (Next business day)
- [ ] FedEx 2Day Freight (Second business day)
- [ ] FedEx Express Saver Freight (1 to 3 business days)

(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging

- [ ] FedEx Letter
- [X] FedEx Pak
- [ ] FedEx Box
- [ ] FedEx Tube
- [ ] Other Pkg.

Declared value limit $500

6 Special Handling

Does this shipment contain dangerous goods?

- [ ] Yes (No per attached Shipper's Declaration)
- [ ] Yes (Shipper's Declaration not required)
- [ ] Dry Ice (Dry Ice, 9, UN 1845) x kg
- [ ] CA Cargo Aircraft Only

(Dangerous Goods Shipper's Declaration not required)

7 Payment

Bill to:

- [X] Sender (Account no. in section 1 will be billed)
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check

(Enter FedEx account no. or Credit Card no. below)

FedEx Account No.

Credit Card No. Exp. Date

Total Packages	Total Weight	Total Declared Value*	Total Charges
		$ .00	$

*When declaring a value higher than $100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

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