OHIO VALLEY MEDICAL CENTER

QUALITY MANAGEMENT PROGRAM

POLICIES AND PROCEDURES FOR BRACHYTHERAPY

1. A written directive must be prepared prior to the administration of any brachytherapy treatment. Each written directive will be issued as an order for a specific patient, dated and signed by an authorized user or a physician under the supervision of an authorized user. The written directive will include the radioisotope, number of sources and source strengths. After implantation but prior to the completion of the procedure, the authorized user will amend the written directive to add the radioisotope, treatment site, total source strength and total exposure time (or, equivalently, the total dose).

Procedures for oral directives 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 for this therapeutic procedure 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 licensed user or designee will verify by more than one method the identity of the patient as the individual named in the written directive. The procedure use to identify the patient will be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name of the patient's medical insurance card or the photograph of the patient's face.

3. The person administering the brachytherapy treatment will verify, before administering the brachytherapy treatment, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of sources, source strengths, treatment site, loading sequence and total dose will be confirmed to verify agreement with the written directive and plan of treatment.

4. The licensed user will direct all workers to seek guidance if they do not understand how to carry out 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, oncology physician, dosimetrist or radiation therapy technologist) 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. In the case of Ir-192, the sources are usually in color coded strands for identification purposes. If not color-coded, the different strength sources are in different lead containers. In these cases, the activity of the sources will be based on the manufacturers calibration, subject to accounting for decay.

6. For temporary brachytherapy implants, the licensed user or designee will use radiographs or other comparable images (e.g. computerized tomography) of brachytherapy radioactive sources of nonradioactive "dummy" sources in place as the basis for verifying the position of the sources and calculating the exposure time (or, equivalently, the total dose). 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 provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).

7. For permanent brachytherapy implants, the licensed user or designee will use radiographs or other comparable images (e.g., computerized tomography) of brachytherapy radioactive sources in place as the basis for verifying the position of the sources and calculating the total dose, if applicable, after inserting the sources (e.g., iodine-125 sealed sources used for interstitial applications). However, in brachytherapy procedures requiring the use of various fixed geometry applicators (e.g., templates) radiographs or other comparable images will not be necessary.

8. After administering a brachytherapy treatment using a temporary implant, the authorized user or a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist) will promptly make a written record of the treatment. The record will include the radioisotope, the treatment site, the actual loading sequence (the strength of each source and its location in its applicator), and the total exposure time or the total dose. The individual will sign or initial the record. The record will be maintained in an auditable form.

9. After administering a brachytherapy treatment using a permanent implant, the authorized user or a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist) will promptly make a written record of the treatment. The record will include the radioisotope, the treatment site, the actual number of sources implanted, the strength of each source and the total dose. The individual will sign or initial the record. The record will be maintained in an auditable form.

10. The licensed user or designee 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), and
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). Alternatively, the brachytherapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. When the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis will be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

11. 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
's medical condition, the checks
of the calculations will be performed within two working days of completion of the brachytherapy treatment.

12. Acceptance testing by a qualified person (e.g., a teletherapy 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 program for brachytherapy dose calculations. The licensee will assess each treatment planning or dose calculating computer program based on specific needs and applications.

13. Upon discovery of a recordable event, the RSO will have the event evaluated by assembling the relevant facts including the cause. The RSO will identify what, if any, corrective actions are required to prevent recurrence and will retain a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

14. Reviews of the brachytherapy QM program will be performed at intervals not to exceed 12 months. The review will include a representative sample of patient administrations, all recordable events and all misadministration for the previous 12 months (or last review). Patient cases will be selected at random to eliminate any bias in the sampling procedure. The number of patient cases to be sampled will be based n the principles of statistical acceptance using acceptance sampling tables of 10CFR32.110, assuming an error rate (lot tolerance percent defective) of 10 percent. (See table) For each patient case, a comparison will be made, prior to implantation between what was administered versus what was prescribed in the written directive relative to the radioisotope, number of sources and source strengths; after implantation but prior to completion of the procedure: the radioisotope, treatment site an total source strength and exposure time (or, equivalently, total dose). Program reviews will be documented, distributed to all appropriate management and departments and held for review by NRC inspectors.

Lot Tolerance Percent Defective 10.0 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	0

Lot Tolerance Percent Defective 5 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2001 to 100,000	75	1

Should either a misadministration or a recordable event be uncovered during a review of the QMP, the number of cases sampled will be increased to those indicated by using the acceptance sampling table of 10CFR32.110 for a Lot Tolerance Percent Defective rate of 5%.

Each review of the QMP will be evaluated to determine the effectiveness of the program. Should the number of deviations discovered in the review not exceed the appropriate Acceptance Number specified by the Lot Tolerance Percent Defective table, the program will be considered effective. Should the number of deviations exceed the appropriate Acceptance Number, the program may be ineffective. In this case, the RSO shall make modifications as necessary to meet the objectives of the program as defined in 10CFR35.32(a).

15. Modifications to the QMP may be made to increase the program's efficiency provided the program's effectiveness is not decreased. Modifications will be submitted to the NRC Regional Office within 30 days after the modification is made.

16. Written records of each administered brachytherapy treatment and each written directive will be maintained for three years. Records of each QMP review and evaluation will be maintained for three years.

17. The radiation safety training program has been modified to include instruction in the Quality Management Program.

18. After implant, source positions are verified by means of fluoroscopy and/or radiography to ensure that they are in the right position. The position of applicator containing sources are frequently checked by seeing. Whenever the applicator moved from the initial position, the source position is evaluated.

OHIO VALLEY MEDICAL CENTER

QUALITY MANAGEMENT PROGRAM

POLICIES AND PROCEDURES FOR I-125 AND/OR I-131 AND
THERAPEUTIC RADIOPHARMACEUTICAL USES

1. A written directive must be prepared prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 uCi of either sodium iodide I-125 or I-131. Each written directive will be issued as an order for a specific patient, dated and signed prior to an administration by an authorized user or a physician under the supervision of an authorized user. The written directive for sodium iodide I-125 or I-131 will include the dosage to be administered. The written directive for all other therapeutic radiopharmaceuticals will include the dosage to be administered, the radiopharmaceutical to be administered, and the route of administration.

Procedures for oral directive or revisions to written directive 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 or physician under the supervision of an authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user or physician under the supervision of an authorized user prior to the administration of the radiopharmaceutical dosage.

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 radiopharmaceutical dosage, the licensed user or designee will verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient will be to ask the patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

3. The licensed user or designee will verify, before administering the radiopharmaceutical, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration will be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive. For photon emitting radiopharmaceuticals, the dosage will be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. For pure beta emitters, the manufacturer's assay of the radiopharmaceutical, as well as any calculations to correct for decay and volume, will be compared with the prescribed dosage in the written directive or the dosage will be measured in the dose calibrator using a setting and/or correction factor previously determined.

4. The licensed user will direct all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers will ask for clarification 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. The authorized user or a qualified person under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist or technologist) after administering a radiopharmaceutical, will make, date and sign or initial a written record that documents the administered dosage in an auditable form.

6. Should an unintended deviation from a written directive be identified, it shall be brought to the attention of the Radiation Safety Officer. The RSO will have the deviation investigated, will evaluate the need for corrective action and shall cause such corrective action to be implemented.

7. Upon discovery of a recordable event, the RSO will have the event evaluated by assembling the relevant facts including the cause. The RSO will identify what, if any, corrective actions are required to prevent recurrence and will retain a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

8. Reviews of the radiopharmaceutical QM program will be performed at intervals not to exceed twelve months. The review will include a representative sample of patient administrations, all recordable events and all misadministrations for the previous 12 months (or last review). Patient cases will be selected at random to eliminate any bias in the sampling procedure. The number of patient cases to be sampled will be based on the principles of statistical acceptance using acceptance sampling [illegible]s of 10CFR32.110, assuming an error rate (Lot Tolerance Percent Defective) of 10 percent. (See table.) For each patient case, a comparison will be made between what was administered versus what was prescribed in the written directive, relative to radiopharmaceutical dosage and route of administration. Program reviews will be documented and distributed to all appropriate management and departments.

Lot Tolerance Percent Defective 10.0 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	1

Lot Tolerance Percent Defective 5 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2000	45	0
2001 to 100,000	75	1

Should either a misadministration or a recordable event be uncovered during a review of the QMP, the number of cases sampled will be increased to those indicated by using the acceptance sampling table of 10CFR32.110 for a Lot Tolerance Percent Defective rate of 5%.

Each review of the QMP will be evaluated to determine the effectiveness of the program. Should the number of deviations discovered in the review not exceed the appropriate Acceptance Number specified by the Lot Tolerance Percent Defective table, the program will be considered effective. Should the number of deviations exceed the appropriate Acceptance Number, the program may be ineffective. In this case, the RSO shall make such modifications as necessary to meet the objectives of the program as defined in 10CFR35.32(a).

9. Modifications to the QMP may be made to increase the program's efficiency provided the program's effectiveness is not decreased. Modifications will be submitted to the NRC Regional Office within 30 days after the modification is made.

10. Written records of each administered radiopharmaceutical dosage and each written directive will be maintained for three years. Records of each QMP review and evaluation will be maintained for three years.

11. The radiation safety training program has been modified to include instruction in the Quality Management Program.