GOOD SAMARITAN HOSPITAL AND HEALTH CENTER
Dayton, Ohio

QUALITY MANAGEMENT PROGRAM

Objective: To provide high confidence that by-product material or radiation from by-product material will be administered as directed by the authorized user, and the objectives of 10 CFR 35.32 are met.

A) General procedure and policy regarding brachytherapy:

1. A written directive (see attached brachytherapy form) containing the patient's identification, radioisotope, number of sources, source strength, and, after implantation, but prior to completion of the procedure, the radioisotope, treatment site, total source, source strength, exposure time, dose rate to the patient, will be completed. It also includes the names, dates, and signatures of authorized users and the therapy physicist. All the information is checked and confirmed before and after implantation by the therapy physicist or his/her designee.

2. The written directive is an order for a specific patient. The written directive shall be signed and dated by an authorized user or physician under the supervision of an authorized user before administration of brachytherapy procedure.

3. Before administering a brachytherapy dose to a patient, the patient identity is verified by asking the patient's name and after confirming the name, the identity of the patient is confirmed with at least one of the following by comparison with the corresponding information in the patient's records: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or a photograph of the patient's face. Identifying the patient by more than one method is required by 10 CFR 35.32 (a)(2).

4. Before administering the brachytherapy dose, the details of the brachytherapy administration; in particular, the radioisotope, number of sources, and source strength, shall be confirmed by the physicist to be in accordance with the written directive and plan of treatment.

5. Any individual involved in brachytherapy procedures (nurses, or technologists) are required to obtain directions from the physician or authorized user if they do not understand the written directive. This shall be discussed at the annual radiation safety education and/or annual review of quality management program.

6. The therapy physicist or his/her designee shall verify that the radioisotope, number of sources, and source strength to be used are in agreement with the written directive and plan of treatment before implanting the radioisotope sealed sources. This individual shall sign or initial the written directive. To verify the source strength for the sealed sources housed in the hospital, the licensee uses color coding. (10 CFR 35.25).

c: 7/94; revised 10/94, 8/96

7. For temporary brachytherapy implants, the procedure is done in the Operating Room. Dummy sources are placed for verification of the position of the sources. A radiograph is taken for source verification. The radiograph film may be used for computerized treatment planning and/or exposure time calculation. The film localization shall be reviewed and signed or initialed by the authorized user for verification. However, some brachytherapy procedures which may require the use of various fixed geometry applicators (e.g. appliances or templates) to establish the location of the temporary sources and calculate the exposure time to administer the prescribed brachytherapy treatment, radiography localization film or other comparable images may not be necessary, provided the position of the source is known prior to it and calculating the exposure time. The decision for when localization film is necessary or not will be made by the authorized user and the therapy physicist.

8. For the permanent brachytherapy implants, after inserting the source, in order to verify the position of the sources and calculate total dose, a radiograph shall be taken and is verified and initialed by the authorized user. However, some brachytherapy procedures may require the use of various fixed geometry applicators to establish the location of the sources and calculate the total dose. In these cases, a verification film or other comparable image may not be necessary if the authorized user and the physicist have agreed on that.

9. After insertion of temporary implant brachytherapy sources, the authorized user shall promptly record the actual loading sequences of radioactive sources (e.g. location of each sealed source in a tube, tandem, cylinder, source strength, and exposure time) and sign and initial the patient's chart or other appropriate records.

10. After insertion of the permanent implant, the authorized user shall promptly record the actual loading sequences of radioactive sources (e.g. location of each sealed source in a tube, tandem, cylinder, source strength, and exposure time) and sign and initial the patient's chart or other appropriate records.

11. The localized radiograph film may be used for computer treatment planning performed by the therapy physicist. Before the total prescribed brachytherapy dose is administered, the manual total dose calculation, shall be checked and compared with the computer treatment planning output. The authorized user or therapy physicist who, whenever possible did not make the original calculation, shall check the dose calculation done manually or by computer. As a basis for the dose calculation verification, the brachytherapy dose should be manually calculated to a single key point and the results compared to the computer generated dose calculation.

12. After insertion of the brachytherapy source, but prior to completion of the procedure, the written directive which contained the radioisotope, treatment site, total source strength, and exposure time shall be placed in the patient's chart. A record of the administered radioactive material is required by 10 CFR 35.32 (d)(2). The written directive and record of each brachytherapy procedure shall be retained for three years after administration.

13. An oral revision to the written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. An oral revision shall be documented immediately in the patient's record and a revised written directive shall be signed and dated by an authorized user or physician under the supervision of an authorized user within 24 hours of the oral revision.

14. If, because of the emergent nature of the patient's 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 provided 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.

15. The written directive may be revised for any diagnostic or therapeutic procedure. However, the revised written directive shall be signed and dated by an authorized user prior to the administration of the radiopharmaceutical dosage.

16. When an unintended deviation from the written directive is identified, the physicist shall be notified. The physicist or his/her designee, within 30 days after discovery of the recordable event, shall evaluate the unintended deviation from the written directive by a) assembling the relevant facts including the cause, b) identifying what, if any, corrective action is required to prevent recurrence, and c) retaining a record, in an auditable form, for three years of the relevant facts and what corrective action was taken. The case also shall be presented in the Radiation Safety Committee for analyzing and discussion. 10 CFR 35.32 (a)(5) and 10 CFR 35.32(c).

17. The quality management program shall be reviewed annually by a group including an authorized user, the physicist, administration representative, and the section team leader. In this meeting a) an adequate representative sample of patient administrations, b) all recordable events, and c) all misadministrations since the last review shall be reviewed and discussed. The size of the sample to be reviewed in the annual quality management program meeting shall be 20%. If the number is greater than 100, 20 cases if the number is between 20 and 100, and all cases if the number is less than 20. For the effectiveness of the quality management program, any member in this meeting shall provide recommendations and suggestions to modify the written directive or quality management program in order to increase the efficiency and effectiveness of the program. Any changes and amendments to the program shall be forwarded to U.S. Nuclear Regulatory Commission, Region III, within 30 days after the modification has been made. If a misadministration or recordable event is uncovered during that periodic review, the number of cases of patient administrations shall be expanded in the annual review meeting.

QMP Continued

B) General procedure and policy regarding therapeutic radiopharmaceutical other than I-125 or I-131.

1. A written directive (see attached radiopharmaceutical other than I-125 and/or I-131 form) containing the patient's identification, radiopharmaceutical material, dosage, route of administration of the radiopharmaceutical material, name and signature of the authorized user and person who administers the radiopharmaceutical are the items in the written directive used for verification. All this information will be confirmed before administering any by-product materials. This written directive shall be used for any therapeutic dosage of a radiopharmaceutical other than sodium iodine I-125 or I-131.

2. The written directive is an order for specific patient. The written directive shall be signed and dated by an authorized user or physician under the supervision of an authorized user for administration of any quantities of therapeutic radiopharmaceutical other than I-125 or I-131.

3. Before administering a radiopharmaceutical dose to the patient, the patient identity is verified by asking the patient's name, and after confirming the name, the identity of the patient is confirmed at least with one of the following by comparison with the corresponding information in the patient's records: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face. Identifying the patient by more than one method is required by 10 CFR 35.32 (a)(2).

4. Before administering the radiopharmaceutical dose, the radiopharmaceutical material shall be verified by the technologists to be in accordance with the written directive signed by the authorized user.

5. Any individual involved in brachytherapy procedures (nurses, or technologists) are required to obtain directions from the physician or authorized user if they do not understand the written directive. This shall be discussed at the annual radiation safety education and/or annual review of quality management program.

6. After administration of the radiopharmaceutical material, the authorized user or a qualified individual under the supervision of the authorized user, such as nuclear medicine physician, physicist, or technologist, shall record the administered dosage of radiopharmaceutical material in a written directive dated and signed. The written directive and record of each administered radiopharmaceutical dosage shall be retained for three years after administration. This is required by 10 CFR 35.32(d).

7. An oral revision to the written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. An oral revision shall be documented immediately in the patient's record and a revised written directive shall be signed and dated by an authorized user or physician under the supervision of an authorized user within 24 hours of the oral revision.

8. If, because of the emergent nature of the patient's 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 provided 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.

9. The written directive may be revised for any diagnostic or therapeutic procedure; however, the revised written directive shall be signed and dated by an authorized user prior to the administration of the radiopharmaceutical dosage

10. When an unintended deviation from the written directive is identified, the physicist shall be notified. The physicist or his/her designee, within 30 days after discovery of the recordable event, shall evaluate the unintended deviation from the written directive by a) assembling the relevant facts including the cause, b) identifying what, if any, corrective action is required to prevent recurrence, and c) retaining a record, in an auditable form, for three years of the relevant facts and what corrective action was taken.
The case also shall be presented in the Radiation Safety Committee for analyzing and discussion. 10 CFR 35.32 (a)(5) and 10 CFR 35.32(c).

11. The quality management program shall be reviewed annually by a group including an authorized user, the physicist, administration representative, and the section team leader. In this meeting a) an adequate representative sample of patient administrations, b) all recordable events, and c) all misadministrations since the last review shall be reviewed and discussed. The size of the sample to be reviewed in the annual quality management program meeting shall be 20%. If the number is greater than 100, 20 cases if the number is between 20 and 100, and all cases if the number is less than 20. For the effectiveness of the quality management program, any member in this meeting shall provide recommendations and suggestions to modify the written directive or quality management program in order to increase the efficiency and effectiveness of the program. Any changes and amendments to the program shall be forwarded to U.S. Nuclear Regulatory Commission, Region III, within 30 days after the modification has been made. If a misadministration or recordable event is uncovered during that periodic review, the number of cases of patient administrations shall be expanded in the annual review meeting.

QMP Continued

C) General procedure and policy regarding I-125 and I-131 radiopharmaceutical dosages greater than 30 microcuries.

1. A written directive (see attached I-125 and/or I-131 form) containing the patient's identification, radiopharmaceutical material, dosage, route of administration, name, and signature of the authorized user and person who administers the radiopharmaceutical are the items in the written directive used for verification. All this information will be confirmed before administering any by-product materials. This written directive will be used for any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131.

2. The written directive is an order for specific patient. The written directive shall be signed and dated by an authorized user or physician under the supervision of an authorized user for any administration of quantities greater than 30 microcuries of either I-125 or I-131.

3. Before administering a radiopharmaceutical dose to the patient, the patient identity is verified by asking the patient's name and after confirming the name, the identity of the patient is confirmed at least with one of the following by comparison with the corresponding information in the patient's records: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or a photograph of the patient's face. Identifying the patient by more than one method is required by 10 CFR 35.32 (a)(2).

4. Before administering the radiopharmaceutical dose, the radiopharmaceutical material shall be verified by the technologists to be in accordance with the written directive signed by the authorized user.

5. Any individual involved in radiopharmaceutical of I-125 and I-131 procedures (nurses, or technologists) is required to obtain directions from the physicist or authorized user if they do not understand how to carry out the written directive. This shall be discussed at the annual radiation safety education and/or annual review of quality management program.

6. After administration of the radiopharmaceutical material, the authorized user or a qualified individual under the supervision of the authorized user, such as nuclear medicine physician, physicist, or technologist, shall record the administered dosage of radiopharmaceutical material in a written directive dated and signed. The written directive and record of each administered radiopharmaceutical dosage shall be retained for three years after administration. This is required by 10 CFR 35.32(d).

7. An oral revision to the written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. An oral revision shall be documented immediately in the patient's record and a revised written directive shall be signed and dated by an authorized user or physician under the supervision of an authorized user within 24 hours of the oral revision.

8. If, because of the emergent nature of the patient's condition, a delay in the order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided 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.

9. The written directive may be revised for any diagnostic or therapeutic procedure; however, the revised written directive shall be signed and dated by an authorized user prior to the administration of the radiopharmaceutical dosage

10. When an unintended deviation from the written directive is identified, the physicist shall be notified. The physicist or his/her designee, within 30 days after discovery of the recordable event, shall evaluate the unintended deviation from the written directive by a) assembling the relevant facts including the cause, b) identifying what, if any, corrective action is required to prevent recurrence, and c) retaining a record, in an auditable form, for three years of the relevant facts and what corrective action was taken. The case also shall be presented in the Radiation Safety Committee for analyzing and discussion. 10 CFR 35.32 (a)(5) and 10 CFR 35.32(c).

11. The quality management program shall be reviewed annually by a group including an authorized user, the physicist, administration representative, and the section team leader. In this meeting a) an adequate representative sample of patient administrations, b) all recordable events, and c) all misadministrations since the last review shall be reviewed and discussed. The size of the sample to be reviewed in the annual quality management program meeting shall be 20%. If the number is greater than 100, 20 cases if the number is between 20 and 100, and all cases if the number is less than 20. For the effectiveness of the quality management program, any member in this meeting shall provide recommendations and suggestions to modify the written directive or quality management program in order to increase the efficiency and effectiveness of the program. Any changes and amendments to the program shall be forwarded to U.S. Nuclear Regulatory Commission, Region III, within 30 days after the modification has been made. If a misadministration or recordable event is uncovered during that periodic review, the number of cases of patient administrations shall be expanded in the annual review meeting.

DEFINITION OF MISADMINISTRATION

Misadministration in a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, and a brachytherapy procedure as defined in CFR 35.2 means:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium Iodide I-125 or I-131 involving the wrong patient, or wrong pharmaceutical or when the both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

2. A therapeutic radiopharmaceutical dosage other than sodium-125 or I-131 involving the wrong radiopharmaceutical or wrong route of administration or when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

3. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium Iodine I-125 or I-131, both involving the wrong patient, wrong pharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and when the dosage to the patient exceeds 5 rems effects dose equivalent to any individual organ.

4. In a brachytherapy radiation dose, misadministration defined as a) involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); b) involving a sealed source that is leaking; c) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; and d) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

NOTIFICATION, REPORTS, AND RECORDS OF MISADMINISTRATION

In cases of any misadministration the following procedures will be followed:

1. The licensee will notify by telephone the NRC Operation Center (310) 951-0550 no later than the next calendar day after the discovery of misadministration.

2. The licensee will submit a written report to the U.S. Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellen, Illinois, 60137 within 30 days after discovery of the misadministration. The written report includes the licensee'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; action taken to prevent recurrence; whether the licensee notified the patient or patient's responsible relative or guardian and what information was provided to the patient; if the patient was not notified, why not. The report does not include the patient's name or other information that could lead to identification of the patient.

3. The licensee will notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee that he will inform the patient or that, based on medical judgement, telling the patient would be harmful. If the referring physician or patient cannot be reached within 24 hours, the licensee will not delay any appropriate medical care for the patient, including any necessary remedical care as a result of the misadministration, because of any delay in notification.

4. If the patient was notified, the licensee will also furnish a written report to the patient by sending a copy of the report that was submitted to the NRC; or a separate report describing both the event and the consequences as they may affect the patient, provided that a statement is included that the report submitted to the NRC can be obtained from the licensee. This report will be sent to the patient no later than 15 days after the discovery of the misadministration.

5. The licensee will retain a record of each misadministration for five years. The record will contain the name of the patient and all individuals involved including the prescribing physician, allied health personnel, and the patient's referring physician. Also, the record includes the patient's social security number or identification number if one has been assigned, a brief description of misadministration, why it occurred, the effect on the patient, what improvements are need to prevent recurrence, and the action to prevent recurrence.

Good Samaritan Hospital and Health Center
Dayton, Ohio

THERAPEUTIC RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

I-125 and/or I-131 >30 Microcuries

Patient Name _____

Patient Social Security # _____

Patient ID Certification

Obtain at least two of the following information and compare it to a hospital record:

Name: _____
Birth Date: _____
SS#: _____
Address: _____

Authorized User Name _____

_____ _____
Name and title of individual completing this page Signature Date

NAME OF RADIOPHARMACEUTICAL: _____

DATE OF ADMINISTRATION: _____

DOSAGE: _____

ROUTE OF ADMINISTRATION: _____

	Name	Signature	Date
Authorized User	_____	_____	_____

PATIENT NAME _____

PATIENT ID _____

POST RADIOPHARMACEUTICAL ADMINISTRATION INFORMATION:

NAME OF RADIOPHARMACEUTICAL:

DATE OF ADMINISTRATION:

DOSAGE:

ROUTE OF ADMINISTRATION:

	Name	Signature	Date
Administering Physician	_____	_____	_____
Administering Technologist	_____	_____	_____

Are there any deviations from the Written Directive identified? YES_____ NO_____

If yes, corrective actions:

REMARKS:

RS/cc/94

Good Samaritan Hospital and Health Center
Dayton, Ohio

THERAPEUTIC RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

Therapeutic Radiopharmaceutical Other Than I-125 and/or I-131

Patient Name _____

Patient Social Security # _____

Patient ID Certification

Obtain at least two of the following information and compare it to a hospital record:

Name: _____
Birth Date: _____
SS#: _____
Address: _____

Authorized User Name _____

_____ _____
Name and title of individual completing this page Signature Date

NAME OF RADIOPHARMACEUTICAL: _____

DATE OF ADMINISTRATION: _____

DOSAGE: _____

ROUTE OF ADMINISTRATION: _____

	Name	Signature	Date
Authorized User	_____	_____	_____

PATIENT NAME _____

PATIENT ID _____

POST RADIOPHARMACEUTICAL ADMINISTRATION INFORMATION:

NAME OF RADIOPHARMACEUTICAL:

DATE OF ADMINISTRATION:

DOSAGE:

ROUTE OF ADMINISTRATION:

	Name	Signature	Date
Administering Physician	_____	_____	_____
Administering Technologist	_____	_____	_____

Are there any deviations from the Written Directive identified? YES_____ NO_____

If yes, corrective actions:

REMARKS:

RS/cc/94

Good Samaritan Hospital and Health Center
Dayton, Ohio

Radiation Therapy Department

BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

Patient Name _____

Patient Social Security # _____

Patient ID Confirmation

Obtain at least two of the following pieces of information and compare it to a hospital record:

Name: _____
Birth Date: _____
SS#: _____
Address: _____

Type of Procedure: _____

Expected Date of Administration: _____

Radiation Oncology
Physician _____

_____
Name and title of individual completing this page

_____
Signature Date

PATIENT NAME _____

PATIENT ID _____

PRE-BRACHYTHERAPY SOURCE INFORMATION GIVEN BY THE AUTHORIZED USER:

Radioisotope	
Type of source (line or seed source)	
# of sources	
# of strands	
Source strength/total activity/mCi	
Dose rate	
Exposure time	
Total dose	

GEOMETRY DESCRIPTION:

	Name	Signature	Date
Authorized User	_____	_____	_____

PATIENT NAME _____

PATIENT ID _____

Post IMPLANT INFORMATION, BUT PRIOR TO COMPLETION:

Date of Insertion: _____ Time_____am/pm

Radioisotope	
Type of source (line or seed source)	
# of sources	
# of strands	
Source strength/total activity/mCi	
Dose rate	
Exposure time	
Total dose	

DOSE VERIFICATION:

Localization film taken yes no
Computer Treatment Plant yes no
Computer Output Agrees with manual calculation yes no

DISCUSSION:

FINAL RADIATION DOSE EVALUATION:

Date of Insertion: _____ Time _____ am/pm

Date of Removal: _____ Time _____ am/pm

Total Exposure time: _____ hours

Dose rate: _____

Total Patient Dose: _____

PATIENT NAME _____

PATIENT ID _____

RADIATION SURVEY:

Radiation Safety Label posted on the door

Radiation Safety Label posted on the patient chart

	Patient Survey mR/hour	Room Survey mR/hour
During Implant		
After Completion		

Are there any deviations from the Written Directive Identified? YES____ NO____

If yes, corrective actions:

	Name	Signature	Date
Therapy Physicist	_____	_____	_____
Authorized User	_____	_____	_____

Remarks: