

PUBLIC / PDR

MERCY HOSPITAL-FAIRFIELD/HAMILTON, OHIO
NUCLEAR MEDICINE DEPARTMENT

QUALITY MANAGEMENT PROGRAM

030-12859

34-13663-01

Quality Management Program, QMP, is required to establish a quality management program. Basic recommendations by the NRC are as follows:

- . Policies to have authorized user date and sign a written directive prior to the administration.
- . Procedures to identify the patient by more than one method
- . Procedures to be sure the plans of treatment are in accordance with the written directive.
- . Procedures to confirm that, prior to administration, the person responsible for the treatment will check the specific details of the written directive (e.g. verify the radiopharmaceutical, dosage, and route of administration)
- . Procedures to record the radiopharmaceutical dosage actually administered.

These policies and procedures are to be reviewed by the Radiation Safety Committee at least annually.

Modifications to the QMP will be submitted to the NRC within 30 days after the modification has been made.

All records regarding any part of the QMP are to be retained for a minimum of three years unless otherwise stated.

INT_QMP
3/97 MB

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QUALITY MANAGEMENT PROGRAM

RECORDABLE EVENTS

Recordable event means the administration of:

- 1) A radiopharmaceutical or radiation without a written directive where a written directive is required.
- 2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate records.
- 3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:
 - a. The administered dosage differs from the prescribed dose by more than 10 percent, and
 - b. The difference between the administered dosage and prescribed dosage exceeds 15 microcuries.
- 4) A therapy radiopharmaceutical (Other than the Above) when:
the administered dosage differs from the prescribed dose by more than 10%.
- 5) A brachytherapy Radiation dose when the administered dosage differs from the prescribed dose by more than 10%.

If a recordable event is found during an audit, that case will be evaluated and corrective action will be taken by:

- a. assembling the relevant facts including the cause
- b. identifying what, if any, corrective action is required to prevent recurrence; and
- c. all recordable events will be reviewed by the Radiation Safety Committee
- d. all cases since the last audit involving the administration of I-125 and/or I-131 greater than 30 microcuries will be reviewed.

Records will be retained, in an auditable form, for three years, of the relevant facts and what corrective action if any was taken.

QUALITY MANAGEMENT PROGRAM

MISADMINISTRATION

Misadministration means the administration of:

- 1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:
 - a) involving the wrong patient or wrong radiopharmaceutical
 - b) when both the administration 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 iodide I-125 or I-131:
 - a) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration or
 - b) when the administration 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 iodide I-125 or I-131, both:
 - a) involving the wrong patient, wrong radiopharmaceutical, wrong route of administration or when the administered dosage differs from the prescribed dosage; and
 - b) when the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.
- 4) A brachytherapy dose.
 - a) involving the wrong patient, wrong radioisotope, wrong treatment site (excludes seeds that migrate outside the site).
 - b) Leaking Sealed Source
 - c) One or more sealed sources are not removed at completion of treatment (temporary brachytherapy).
 - d) The administered dose differs from the prescribed dosage by more than 20%.

FOR A MISADMINISTRATION:

- 1) Notify Dr. James Kereiakes (751-6288) of the possible misadministration. Dr. Kereiakes will calculate patient dose and verify if the incident was a misadministration. OR
If the misadministration involves brachytherapy, notify John Freshcorn, Medical Radiation Physics (872-2636).

- 2) Notify by telephone the NRC Operations Center (630-829-9500) no later than the next calendar day after discovery of the misadministration.
- 3) Submit a written report to the NRC Regional Office within 15 days after discovery of the misadministration.

U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

The written report must include 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 improvement are needed to prevent recurrence, whether the licensee notified the patient or the patient's responsible relative or guardian, and if not, why not and if the patient was notified, what information was provided to the patient.

Fill out Misadministration report- also send a copy to the Safety Committee with In-house Incident report.

If the misadministration involved a radionuclide controlled by the State of Ohio, they must be notified.

Ohio Department of Health
Radiological Health Program
P.O. Box 118
Columbus, Ohio 43266-0118

- 3) The RSO or the Radiologist on duty should notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs us either that he will inform the patient of that, based on medical judgement, telling the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, we shall notify the patient as soon as possible thereafter. We may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of the delay in notification.
- 4) If the patient was notified, we shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:
 - a) a copy of the report that was submitted to the NRC; or
 - b) a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the

report submitted to the NRC can be obtained from the licensee.

- 5) We shall retain a record of each misadministration for five years.
The record must contain:
 - a) the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician).
 - b) The patient's medical record number
 - c) a brief description of the misadministration
 - d) why it occurred.
 - e) the effect of the patient
 - f) what improvement are needed to prevent recurrence
 - g) the action taken to prevent recurrence.
- 6) All misadministration are to be reviewed by the Radiation Safety Committee. The In-house Safety Committee will also review the incident.
- 7) When a misadministration is uncovered, all cases involving I-131 or I-125 greater than 30 microcuries, and all therapeutic cases since the last audit will be reviewed. If the misadministration involves a diagnostic radiopharmaceutical other than I-131 or I-125, review all cases for that month immediately.

MISAD

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QUALITY MANAGEMENT PROGRAM

Procedure for Use of Iodine 131 and Iodine 125 > 30 microcuries

1. All orders for the administration of any radiopharmaceutical dosage greater than 30 microcuries of Iodine 131 and/or Iodine 125 must have a prescription or worksheet filled out by an authorized user showing the DATE, SIGNATURE and ROUTE of ADMINISTRATION prior to administration.

This WRITTEN DIRECTIVE must include Radiopharmaceutical, Dosage and Route of Administration. This must be an order for a specific patient.

An oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

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.

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

2. Prior to the administration of a radiopharmaceutical dosage, verification of the patient must be established by at least two of the following methods: Ask patient's name and confirm by comparison with corresponding information to patient's record: (birthdate), (address), (social security number), (ID bracelet), (signature) (Driver's license), or (Medical Insurance Card). Confirm methods by listing on Q.C. check list and initialing.
3. Prior to administration of the radiopharmaceutical dosage, the radioisotope is placed in the dose calibrator and dosage is verified with the written prescription, the dosage read on the dose calibrator

is recorded on the dose slip, worksheet and the requisition, and a copy of the prescription is attached to the requisition. The dosage and route of administration is verified by an authorized user present prior to the administration of any dosage. The authorized user is to sign the worksheet stating that he verified this information

4. Administration of any Iodine 131 and/or Iodine 125 radiopharmaceutical may be given only by registered nuclear medicine technologists who have seen this procedure performed and then performed it themselves under the observation of prior trained staff. No procedure should be performed if any doubt or question is present as to the proper performance of that procedure. Contact the Chief Technologist or authorized user before administration of Iodine 131 and/or Iodine 125 if there are any questions.
5. After the administration of the radiopharmaceutical, the physician user will document the amount given, the date, and sign the patient consent form and the Progress Notes. He will also dictate a report for the attending physician. The nuclear medicine technologist will complete the Checklist for Iodine 131 Therapy and Worksheet.
6. An audit will be performed at least annually to identify and evaluate any unintended deviation from a written directive. The records of all patients who received NaI I-125 or I-131 greater than 30 microcuries will be audited. The written directives will be reviewed to make sure that it includes order for a specific patient, has been dated and signed by an authorized user or a physician under the supervision of an authorized user, and contains the dosage to be administered and the route of administration.

If there has been an oral directive, verify that the oral directive was documented in the patient's record and a written directive was prepared within 24 hours of the oral directive.

If there has been an oral revision, verify that the oral revision was documented in the patient's record and a written directive was prepared within 48 hours of the oral revision.

Verify that the patient's identity was verified by more than one method.

Verify that the person administering the dose recorded the radiopharmaceutical, dose and route of administration.

For each patient case, comparison is to be made between Radiopharmaceutical, Dosage, and Route of Administration which was administered versus prescribed for in the written directive.

7. A summary of administration of these radiopharmaceuticals will be reviewed at least annually by the Radiation Safety Committee. The committee will determine if the radiopharmaceutical, dosage, and route of administration were in accordance with the written directive. For any deviation from the written directive, the committee will document cause of deviation and the action required to prevent recurrence. The action may include new revised policies, new revised procedures, additional training, or increased supervisory review of work. Any summary must be maintained for a minimum of three years.
8. Written directives and a record of each administered dosage will be retained for a minimum of three years after the date of administration.
9. This quality management program will be reviewed annually for its effectiveness and need for change.

QMP131

3/97 mb

CHECKLIST FOR IODINE 131 HYPERTHYROID THERAPY

NUCLEAR MEDICINE DEPT. MERCY FAIRFIELD _____ MERCY HAMILTON _____

MR Number _____ Date _____ Tech _____

1. How was the patient's ID verified? List at least two methods.
2. Was the written directive (worksheet) filled out by an authorized user? Dated? Signed? And with Amount?
3. Was there an oral revision or oral directive?

If so, was the written directive completed within 24 hours for the oral directive and with 48 hours for the oral revision?

4. Was the dosage and route of administration verified by an authorized user present during administration?
5. Was the thyroid uptake in the hyperthyroid range?
6. Was the T3/T4 elevated?
7. Did the radiologist counsel the patient?
8. Was the consent form signed?
9. Was the patient given a schedule of follow-up visits?

10. DOSAGE ROUTE of ADM.

PRESCRIBED	_____	_____
ACTUAL	_____	_____
DEVIATION	_____ %	_____

THIS FORM IS TO BE COMPLETED BY THE TECHNOLOGIST AFTER EACH THERAPY, AND PLACED IN THE PATIENT'S FILE FOR ANNUAL REVIEW BY THE RADIATION SAFETY COMMITTEE.

IODINE-131 THERAPY PROGRESS NOTES
NUCLEAR MEDICINE DEPARTMENT
MERCY HOSPITAL- HAMILTON/FAIRFIELD

PATIENT: _____ ID# _____

PHYSICIAN: _____

INFORMATION FOR TREATMENT

TEST RESULTS: UPTAKE _____ % DATE _____

T3 _____ T4 _____ TSH _____ DATE _____

REASON FOR TREATMENT _____

AMT ORDERED: _____ mCi of NaI-131 to be given PO

ORDERED BY: _____ M.D. DATE _____

AMT. GIVEN _____ mCi VERIFIED BY _____ M.D.

DATE _____ TECH _____

INFORMATION AT TIME OF TREATMENT:

PATIENT'S WEIGHT _____ LBS PULSE _____ BPM

COMMENTS _____

ONE MONTH CHECK-UP DATE _____

WT. _____ LBS. PULSE _____ BPM COMMENTS _____

TWO MONTH CHECK-UP DATE _____

WT. _____ LBS. PULSE _____ BPM COMMENTS _____

FOUR MONTH CHECK-UP DATE _____

WT. _____ LBS. PULSE _____ BPM COMMENTS _____

ATTACH DOSE SLIP ON BACK

*** Please write oral directives
oral revisions and written
revisions on back.
Sign and Date.

THERAPY.PN/Disk3
REVISED 9/15/94 mb

QUALITY MANAGEMENT PROGRAM
REVIEW OF 100% OF PATIENTS

YEAR: _____

[illegible]

QUALITY MANAGEMENT PROGRAM

Procedure for Use of Therapeutic Radiopharmaceuticals other than I-125 and/or I-131

1. All orders for the therapeutic use of any radiopharmaceutical dosage other than Iodine 131 and/or Iodine 125 must have a prescription or worksheet filled out by an authorized user showing the DATE, SIGNATURE and ROUTE of ADMINISTRATION prior to administration.

This WRITTEN DIRECTIVE must include Radiopharmaceutical, Dosage and Route of Administration. This must be an order for a specific patient.

An oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record (on the therapy worksheet) and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

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(on the therapy worksheet) and a written directive is prepared within 24 hours of the oral directive.

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

2. Prior to the administration of a radiopharmaceutical dosage, verification of the patient must be established by at least two of the following methods: Ask patient's name and confirm by comparison with corresponding information to patient's record: (birthdate), (address), (social security number), (ID bracelet), (signature) (Driver's license), or (Medical Insurance Card). Confirm methods by listing on Q.C. check list and initialing.
3. Prior to administration of the radiopharmaceutical dosage, the radio-isotope is placed in the dose calibrator and dosage is verified with with the written prescription, the dosage read on the dose calibrator

is recorded on the dose slip, worksheet and the requisition, and a copy of the prescription is attached to the requisition. The dosage and route of administration is verified by an authorized user present prior to the administration of any dosage. The authorized user is to sign the worksheet stating that he verified this information

4. Administration of any therapeutic radiopharmaceutical other than Iodine 131 and/or Iodine 125 may be given only by an authorized user or a registered nuclear medicine technologists under the direct supervision of an authorized user. No procedure should be performed if any doubt or question is present as to the proper performance of that procedure. Contact the Chief Technologist or authorized user before the therapeutic administration of any radiopharmaceutical other than Iodine 131 and/or Iodine 125 if there are any questions.
5. After the administration of the radiopharmaceutical, the physician user will document the amount given, the date, and sign the patient consent form and the Progress Notes. He will also dictate a report for the attending physician. The nuclear medicine technologist will complete the Checklist for Therapy and Worksheet.
6. An audit will be performed at least annually to identify and evaluate any unintended deviation from a written directive. The records of all patients who received therapeutic radiopharmaceutical other than NaI I-125 or I-131 will be audited. The written directives will be reviewed to make sure that it includes order for a specific patient, has been dated and signed by an authorized user or a physician under the supervision of an authorized user, and contains the dosage to be administered and the route of administration.

If there has been an oral directive, verify that the oral directive was documented in the patient's record and a written directive was prepared within 24 hours of the oral directive.

If there has been an oral revision, verify that the oral revision was documented in the patient's record and a written directive was prepared within 48 hours of the oral revision.

Verify that the patient's identity was verified by more than one method.

Verify that the person administering the dose recorded the radiopharmaceutical, dose and route of administration.

For each patient case, comparison is to be made between Radiopharmaceutical, Dosage, and Route of Administration which was administered versus prescribed for in the written directive.

7. A summary of administration of these radiopharmaceuticals will be reviewed at least annually by the Radiation Safety Committee. The committee will determine if the radiopharmaceutical, dosage, and route of administration were in accordance with the written directive. For any deviation from the written directive, the committee will document cause of deviation and the action required to prevent recurrence. The action may include new revised policies, new revised procedures, additional training, or increased supervisory review of work. Any summary must be maintained for a minimum of three years.
8. Written directives and a record of each administered dosage will be retained for a minimum of three years after the date of administration.
9. This quality management program will be reviewed annually for its effectiveness and need for change.

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SUBJECT: BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM

ORIGIN & DATE: DEPARTMENT OF NUCLEAR MEDICINE (MRP,INC.)

APPROVED BY: _____ REVIEWS (INITIAL & DATE) _____

PURPOSE: To follow the procedures of a quality management program as required by the Nuclear Regulatory Commission and outlined in the Federal Register, Section 35.32 and 35.33.

POLICIES:

I. INTRODUCTION

Each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

II. Procedure

A. Prior to administration, a **written directive** will be prepared for any brachytherapy radiation dose which is dated and signed by an authorized user. No **oral directive** will be accepted except as noted in Item 'G'. The directive will contain the patient's name, radioisotope, number of sources and source strength. After implementation and prior to the completion of the procedure, documentation will be made of the treatment site, total source strength and exposure time (or, equivalently, the total dose). See attachment.

B. The identity of the patient named in the written directive will be verified by two (2) independent methods. The procedure used to confirm the name with the written directive will be through corresponding information in the patient's hospital record- birthdate, address, and social security number. Or, through positive identification by hospital I.D. bracelet.

C. Brachytherapy sources prepared for implantation according to the written directive will be verified by a second individual that the directive is being implemented correctly by the authorized user or his/her delegate. Appropriate verification methods will be:

- *verifying the serial number of the source(s) used
- *verifying the color-code of the source(s) used
- *verifying by utilizing a dose calibrator
- *verification via observation of the loading process

A second signature, recording the verification, will be in the Brachytherapy log.

D. All workers will seek guidance if they do not understand the written documentation **before** the procedure is done to prevent misunderstanding.

E. After insertion of a temporary or permanent implant utilizing brachytherapy sources, the authorized user will document the treatment in the patient's chart noting total number of

sources, source strength, placement and loading sequence if necessary.

F. The dose calculation will be checked before the total prescribed dose has been administered. An authorized user or qualified person under the supervision of an authorized user (e.g. radiation therapy physicist, radiation oncologist, dosimetrist or therapist), who whenever possible did not make the original calculation, will check the dose calculation and sign off on the plan. The authorized user will sign the final dosimetry treatment plan and revise the written directive if need be. Any changes to the original written directive will bear the signature of the authorized user prior to completion of the procedure.

G. All revisions to a written directive will be made prior to the administration of any brachytherapy dose. The NRC stipulates that if, because of a 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 to an existing written directive will be acceptable, provided that the patient record and a revised written directive is signed by the authorized user within forty-eight (48) hours of the oral revision. See attachment.

H. A log will be kept in the Hot Lab which will summarize the on-going activity associated with the Brachytherapy Quality Management Program. This log will also contain a copy of the written directive, source loading, final dosimetry, and total dose. It will provide notation for a recordable event or misadministration. All records will be kept a minimum of 3 years.

I. After discovery of a **Recordable Event**, the situation will be evaluated as required in 10 CFR 35.32(c), and respond within 30 days after discovery of any recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent reoccurrence and © retaining a record, in auditable form (see Item K) , for a minimum of three (3) years detailing the relevant facts and corrective action.

J. After discovery of a **Misadministration**, the situation will be evaluated according to 10 CFR 35.33 by : (a) notifying the NRC Operation Center by telephone within 24 hours after discovery, (b) notifying the referring physician and patient of the misadministration within 24 hours after discovery, unless referring physician personally informs licensee that either he/she will inform patient or base on medical judgement, telling the patient would be harmful, © submitting a written report to the NRC Regional Office within 15 days of such discovery that includes licensee name, Radiation Oncologist's name, description of event and why the event occurred, the effect on the patient, improvements needed to prevent recurrence and subsequent action taken to this effect, whether or not the patient (or patient's responsible relative or guardian) was notified, and what information was provided to the patient, (d) submitting a written report to the patient (if notified) within 15 days of such discovery as described in 10 CFR 35.33 (2) 4, and (e) retaining a record of each misadministration for a minimum of five (5) years.

K. An annual review of the Brachytherapy Quality Management Program will be performed by the Medical Radiation Physicist and reported to the Radiation Safety Committee. This annual report will include all patient administrations, any recordable events, any

misadministrations, and selected quality control indicators. See attached form. The current program will be evaluated annually to determine its effectiveness and if necessary, modifications will be made to better meet the objectives. A copy of the Annual Review as well as the evaluation will be included with the minutes of the Radiation Safety Committee.

L. Any modification made to the brachytherapy Quality Management Program will be evaluated via the Radiation Safety Committee and submitted to the Nuclear Regulatory Commission's Regional Office within 30 days after the modification has been approved.

M. Any modification made to the Treatment Planning Computer software or hardware that effects the programs which compute brachytherapy dosage and summation will be evaluated via the Quality Control Procedures recommended by the manufacturer to assure similar results as that of published data.

MERCY HOSPITAL- FAIRFIELD, OHIO
BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

PATIENT NAME: _____ DATE: _____

SS#: _____ DIAGNOSIS: _____

RADIATION ONCOLOGIST: _____ TREATMENT SITE: _____

REFERRING PHYSICIAN: _____

MODE OF TREATMENT:

☐ INTRACAVITARY

☐ INTERSTITIAL

☐ OTHER _____

RADIOACTIVE SOURCE :

☐ Cs-137

☐ Ir-192*

☐ Au-198*

☐ I-125*

☐ OTHER _____

*Isotopes requiring ordering through an outside manufacturer. Form A must be filled out by the Radiation Oncologist.

NUMBER OF SOURCES: _____ TOTAL SOURCE STRENGTH: _____

PRESCRIBED DOSE: _____

RADIATION ONCOLOGIST SIGNATURE: _____

IMPLANTATION DATE AND TIME: _____

REVISION OF PRESCRIBED DOSE: _____

RADIATION ONCOLOGIST SIGNATURE: _____

DATE AND TIME: _____

LOADING SCHEMATIC:

FINAL COMPLETION OF DOSIMETRY: _____

REMOVAL DATE & TIME: _____

TOTAL DOSE ADMINISTERED: _____

FORM A
RADIOACTIVE MATERIAL FORM

MERCY HOSPITAL - FAIRFIELD, OHIO
BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM

PATIENT NAME: _____

RADIATION ONCOLOGIST: _____

TREATMENT SITE: _____

DATE & TIME OF PROCEDURE: _____

RADIOACTIVE SOURCE*:
() Au-198 () Ir-192 () I-125 () OTHER _____

QUANTITY OF RADIATIVE MATERIAL: _____

ACTIVITY/SEED (if applicable): _____

SUPPLIER (Company) _____

P.O. NUMBER: _____

DATE OF SHIPMENT: _____

DATE RECEIVED: _____

RADIATION ONCOLOGIST SIGNATURE: _____

*DISPOSITION OF UNUSED OR RETURNED RADIOACTIVE MATERIALS:

DATE RETURNED: _____ TO: _____

QUANTITY OF RADIOACTIVE MATERIAL: _____

SHIPPER: _____

ADDITIONAL COMMENTS: _____

SIGNATURE: _____