

NOV 21 1994

ARMY, DEPARTMENT OF THE
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5001

ATTN: WILLIAM B. JOHNSON

RE: Docket Number: 030-01317
License Number: 08-01738-02

Dear Col. Johnson:

This letter acknowledges receipt of your letter dated November 1, 1994, in response to our letter which addressed deficiencies in your Quality Management Program (QMP). Your implementation of the QMP and its adequacy will be reviewed as part of the next NRC inspection. This inspection will include a review of your letter referenced above and any resulting changes to your QMP.

This QMP will not be incorporated into your license by condition. You have the flexibility to make changes to your quality management program without obtaining prior NRC approval. However, modifications to your program must be submitted to this Office within 30 days as required by 10 CFR 35.32(e).

Thank you for your cooperation in this matter; no reply is required in response to this letter.

Sincerely,

ORIGINAL SIGNED BY:

JENNY M. JOHANSEN

Jenny M. Johansen
Quality Management Program Coordinator
Region I

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 2
FOIA 2006-0238

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ML 10



DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5001



REPLY TO
ATTENTION OF:

1 November 1994

Health Physics Office

SUBJECT: Quality Management Program (QMP), Reference Docket
Number 030-01317, License Number 08-01738-02, QMP File Date of
27 January 1992, Region I

Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
ATTENTION: QMP Coordinator/Mr. James P. Dwyer
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Dwyer:

Your letter of 28 September 1994, subject as above, was received by the Health Physics Office, Walter Reed Army Medical Center, Washington, D.C. on 27 October 1994. The referenced letter requested that we immediately update the Quality Management Program (QMP), which was dated 27 January 1992, and submit the new QMP to the NRC, Region I.

Since the QMP dated 27 January 1992, the following revisions and actions of the QMP have taken place:

a. A memorandum, dated 2 June 1994, subject: Additional Information for Review of Renewal of USNRC License No. 08-01738-02, mail control number 117725, was submitted to USNRC Office, Region I. Enclosure 2 of this memorandum provided the QMP for the Nuclear Medicine Service, Walter Reed Army Medical Center (WRAMC), dated 22 March 1994. Also the QMP for brachytherapy from the Radiation Oncology Service, WRAMC, was provided.

b. A new Brachytherapy QMP was approved and became effective on 1 September 1994. The revised brachytherapy QMP was forwarded to USNRC, Region I, by memorandum dated 15 September 1994, subject: QMP Revision.

ML 10

NOV - 7 1994

Since the QMP has been completely revised from the document that was reviewed, request that the NRC review the current QMP for WRAMC to meet the objectives of 10 CFR 35.32. A copy of our current QMP is enclosed. The point of contact for questions regarding this submittal is the undersigned at 301 427-5104.

Enclosure
As Stated

William B. Johnson
WILLIAM B. JOHNSON
Colonel, U.S. Army
Chief, Health Physics Office &
Radiation Protection Officer

BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM SOP

I. Quality Management Program

- A. The five objectives which this program aims to achieve with high confidence are:
1. Written directive given prior to administration.
 2. Patient I.D. verified by more than one method.
 3. Final plan of treatment and dosimetry calculations are in accordance with the written directive.
 4. Source loading, prior to implantation, in accordance with written directive.
 5. Any unintended deviation from the written directive is identified, evaluated, and appropriate action taken.
- B. Periodic review of the QMP includes:
1. All misadministrations.
 2. All recordable events.
 3. All brachytherapy procedures.
 4. Frequency of review at least annually.
 5. Retain records for three years.

II. QMP for Brachytherapy

- A. Written Directive -- A written directive must be signed and dated by the authorized user prior to administration of the brachytherapy dose. This must include:
1. Name of patient.
 2. Radionuclide.
 3. Treatment site.
 4. Applicator.
 5. Cumulative dose and anatomical dose point.
- B. Oral Directives -- Oral directives will generally not be issued. However, if an oral directive is given to modify a written directive, then the recommendations for documentation as specified in NRC Guide 8.33 will be followed.
- C. Dosimetry Plan -- A (computer) dosimetry plan must be accepted by the authorized user prior to implantation. This plan must include:
1. Radiographic localization of sources (either actual or dummy) as the basis for verifying position of the sources and for calculating exposure time (or total dose).
 2. Listing of source information, including radionuclide, position, and strength.
 3. Dose or dose rate at selected anatomical points.
 4. Initials and date of the authorized user.

D. **Source Loading** -- The individual loading the sources into the applicator (before implantation) must document the exact distribution and identity of the sources in the applicator. He must also check for consistency of:

1. Physical loading of sources in applicator
2. Dosimetry plan, and
3. Written directive.

A single-page form (see attached) will be used for this purpose, i.e., for ensuring consistency of the written directive, the dosimetry plan, and the actual loading of the sources in the applicator. The form requires the signature of the physician both before and after implantation, as well as the individual who loads the sources into the applicator.

E. **Patient Identity** -- The user and/or his designee will verify the patient's identity by asking his name and confirming the name and at least one of the following with the patient's record:

1. Birth date
2. Social security number
3. Address
4. Signature
5. ID bracelet
6. Hospital ID card
7. Military ID card.

The method of secondary identification will be documented.

F. **Questions About Procedure** -- The worker (e.g., technologist, dosimetrist, physicist) shall be encouraged to ask questions if there is any confusion or uncertainty regarding the details of the procedure, and will be instructed to not proceed if any discrepancy is noted.

G. **Records** -- Records generated by the QMP's procedures will be retained for a period of five years.

III. Annual Review

A. **Methodology of review** -- A review of the QM program will be conducted at least annually and will include ALL brachytherapy procedures done during the review period. The annual review will be conducted by a committee or designated individual such that an authorized user reviews his/her own procedures. Specifically, the review will include verification of the following:

1. Prior to implantation:
 - a. Radionuclide
 - b. Number of sources
 - c. Source strengths
 - d. Treatment site

2. After implantation but prior to completion of procedure:

- a. Radionuclide
- b. Total source strength
- c. Treatment site
- d. Exposure time (or equivalently, total dose)

- B. Misadministrations -- The review will include all misadministrations and corrective actions taken.
- C. Recordable events -- The review will include all recordable events and corrective actions taken.
- D. Recommendations -- The existing QM program's policies and procedures will be reevaluated for effectiveness following the annual review. Actions which are required to make the program more effective will be identified in writing as part of the review.
- E. Revisions to the QMP -- Revisions to the QMP following the annual review will be submitted to the facility Radiation Safety Officer for subsequent submittal to the NRC regional office.
- F. Records of Annual Review -- Records of the annual review, misadministrations, and recordable events will be retained as required by 10 CFR Part 35. The Chief Medical Physicist will be responsible for maintaining these records in an auditable form.

Merle S. Sprague
MERLE S. SPRAGUE
LTC, MC
Chief, Radiation Oncology Service

Walter Reed Army Medical Center
Radiation Oncology Service

TANDEM & OVOIDS IMPLANT WITH CESIUM-137

PATIENT: _____ ID: _____ DATE: _____

To Be Completed By Dosimetrist Before Loading of Sources:

LOADING (actual source strengths)

Tandem: Tip: _____
 Ovoids: Rt/Lt: _____
 Caps: _____
 Total Number of Sources: _____ Total mg Ra eq: _____

Is this the loading used for the computer dosimetry plan? _____
 Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ ONCOLOGIST: _____
 DATE: _____ DATE: _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

	mg Ra eq	I.D.	Location	Color
Tandem:	_____	_____	_____	_____
	_____	_____	_____	_____
	_____	_____	_____	_____
Ovoids:	_____	_____	_____	_____
	_____	_____	_____	_____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ DATE: _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D Insertion date & time: _____
 I Treatment site: _____
 A Patient ID confirmed by: _____
 G Number of sources implanted: _____
 R Record loading sequence to left _____
 A Sources implanted as listed above? _____
 M Total number of hours (planned): _____
 Total mg x hours: _____
 Date & time for removal: _____

ADDITIONAL INSTRUCTIONS: _____

ONCOLOGIST: _____ DATE: _____

To Be Completed After Removal of Implant:

Date & time of actual removal: _____
 Number of sources removed: _____

INDIVIDUAL REMOVING SOURCES: _____ DATE: _____

Walter Reed Army Medical Center
Radiation Oncology Service

BRACHYTHERAPY TREATMENT WITH CESIUM-137

PATIENT: _____ ID: _____ DATE: _____

To Be Completed By Dosimetrist Before Loading of Sources:
(Based on Approved Computer Plan)

APPLICATOR: _____
SOURCE: _____
STRENGTH: _____
POSITION: _____

Total Number of Sources: _____
Total mg-Ra-eq: _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ ONCOLOGIST: _____
DATE: _____ DATE: _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

	mg Ra eq	I.O.	Location	Color
Tandem:	_____	_____	_____	_____
	_____	_____	_____	_____
	_____	_____	_____	_____
Ovoids:	_____	_____	_____	_____
	_____	_____	_____	_____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ DATE: _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D Insertion date & time: _____
I Treatment site: _____
A Patient ID confirmed by: _____
G Number of sources implanted: _____
R Record loading sequence to left _____
A Sources implanted as listed above? _____
A Total number of hours (planned): _____
M Total mg x hours: _____
Date & time for removal: _____

ADDITIONAL INSTRUCTIONS: _____
ONCOLOGIST: _____ DATE: _____

To Be Completed After Removal of Implant:

Date & time of actual removal: _____
Number of sources removed: _____

INDIVIDUAL REMOVING SOURCES: _____ DATE: _____

PERMANENT SEED IMPLANT WITH GOLD-198

PATIENT: _____ **ID:** _____ **DATE:** _____

To Be Completed By Dosimetrist Before Loading of Sources:

LOADING

Location of Implant: _____

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ **ONCOLOGIST:** _____
DATE: _____ **DATE:** _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ **DATE:** _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D	Insertion date & time:	_____
I	Treatment site:	_____
A	Patient ID confirmed by:	_____
G	Number of seeds implanted:	_____
R	Total activity implanted:	_____
A	Record loading sequence to left	_____
M	Seeds implanted as listed above?	_____

ADDITIONAL INSTRUCTIONS: _____

ONCOLOGIST: _____ **DATE:** _____

Walter Reed Army Medical Center
Radiation Oncology Service

PERMANENT SEED IMPLANT WITH IODINE-125

PATIENT: _____ **ID:** _____ **DATE:** _____

To Be Completed By Dosimetrist Before Loading of Sources:

LOADING

Location of Implant: _____

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ **ONCOLOGIST:** _____
DATE: _____ **DATE:** _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ **DATE:** _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D	Insertion date & time:	_____
I	Treatment site:	_____
A	Patient ID confirmed by:	_____
G	Number of seeds implanted:	_____
R	Total activity implanted:	_____
R	Record loading sequence to left	_____
A	Seeds implanted as listed above?	_____
M		

ADDITIONAL INSTRUCTIONS: _____

ONCOLOGIST: _____ **DATE:** _____

QUALITY MANAGEMENT

I. Quality Management Program, WRAMC Nuclear Medicine Service

A. The five objectives are:

1. Written directive given prior to administration.
2. Patient I.D. verified by more than one method.
3. Final plans of treatment and calculations are in accordance with written directives.
4. Each administration in accordance with written directives.
5. Any unintended deviation from written directives is I.D.'d, evaluated, and appropriate action is taken.

B. Develop procedures for and conduct a review of the QMP including:

1. All misadministration.
2. All recordable events.
3. A sampling of patient administrations... at intervals no greater than 12 months.
4. Retain records for three years.

II. Radiopharmaceutical QMP

C. For all Radiopharmaceutical Therapies and Diagnostic Iodine 131 & 125; Iodine MIBG & NP59; Strontium-89 Chloride, and Phosphorus-32 IV.

1. Authorized user - Sign and date written directive (Radiopharmaceutical, Dosage, Route of Administration) before administration. (Delays, oral directives and revisions OK under certain circumstances. 10 CFR 35.32(a)(1).).
2. User and/or Designee verify patient identity by more than one method:
 - a) Ask patient name, confirm, and,
 - b) Birth date, or
 - c) Social security number, or
 - d) Address, or
 - e) Signature, or
 - f) ID Bracelet, or
 - g) Hospital ID card, or
 - h) Military ID card.

II. Radiopharmaceutical QMP cont.

3. Person administering dose verify details of administration:
 - a) Radiopharmaceutical
 - b) Dose
 - c) Route of Administration
4. Encourage worker to ask questions.
5. User or supervised person date and sign/initial written record (chart).

****See enclosure Radiopharmaceutical Administration Checklist****

III. Annual Review

6. At least annually the QMP review will consist of:
 - a) Random Sample of therapies representative of the following patient administrations:

Lot size	Sample size	Acceptance No.
20	ALL	0
21 - 100	20	0
>100	20%	0

- b) All misadministration
- c) All recordable events.

For each patient case, compare administered vs. prescribed for

- a) Written directive complete
- b) Patient identity verified
- c) Radiopharmaceutical
- d) Dose
- e) Route of administration


ANA A. RODRIGUEZ
COL, MC
CHIEF, NUCLEAR MEDICINE SERVICE

SEP 28 1994

ARMY, DEPARTMENT OF THE
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5001

ATTN: LTC ARTHUR G. SAMILJAN,

RE: Docket Number: 030-01317
License Number: 08-01738-02
Plan File Date: 27-JAN-92
Region Number: 1

Dear Mr. Samiljan:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

Regarding Brachytherapy

- 1 A written QMP must be established and maintained for each Brachytherapy use as required in 10 CFR 35.32(f)(1). Please submit your QMP for your Brachytherapy program.
- 2 Please be advised that multiple misadministrations and other errors have occurred due to sources that are inaccurately placed or have moved. In addition, wrong organs have been irradiated as a result of unintentional and undetected movement of the source, once implanted. Each licensee should review their procedures to ensure that source positions are verified and frequently checked.

Regarding I-125 and /or I-131 > 30 microcuries

- 1 A written QMP must be established and maintained for each I-125 and /or I-131 > 30 microcuries use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your NaI I-125 or I-131 >30 microcuries.

Regarding Therapeutic Radiopharmaceutical other than I-125 and/or I-131

- 1 A written QMP must be established and maintained for use of Radiopharmaceuticals for therapy other than I-125 and I-131 as required in 10 CFR35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33(enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

Due to the apparent failure of your written QMP to meet the objectives in 10 CFR 35.32, you must immediately modify your written QMP to address the items listed above, and provide those modifications to your NRC regional office within 30 days of the date of this letter. NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be taken at that time for failure to meet the requirements of 10 CFR 35.32.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, You should submit any changes to your QMP to this Office within 30 days as required by 10 CFR 35.32(e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management. If you have any questions about this review, you may call me at (610)337-5309. Thank you for your cooperation in this matter.

Sincerely,

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated



DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5001



REPLY TO
ATTENTION OF:

September 15, 1994

Health Physics Office

SUBJECT: Quality Management Program (QMP) Revision

030-01317

Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
ATTENTION: QMP Coordinator
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear QMP Coordinator

Walter Reed Army Medical Center uses radioactive material authorized by US Nuclear Regulatory Commission Byproduct Material License Number 08-01738-02 with an expiration date of June 30, 1999. This a medical broadscope Type A license for human use and research.

The Radiation Oncology Service has just completed a comprehensive review and total revision of the Brachytherapy Quality Management Program SOP. The new Brachytherapy QMP was approved and became effective September 1, 1994. Please note that the Radiopharmaceutical QMP, dated 22 March 1994, has not been changed. This revision only effects the Brachytherapy QMP.

The Brachytherapy QMP and supporting forms are submitted as required by 10 CFR 35.32(e). If you have any questions regarding this submittal, please contact the undersigned at 301 427-5104.

Enclosures
as

WILLIAM B. JOHNSON
Lieutenant Colonel, U.S. Army
Chief, Health Physics Office

ML 10
SEP 23 1994

BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM SOP**I. Quality Management Program**

- A. The five objectives which this program aims to achieve with high confidence are:**
1. Written directive given prior to administration.
 2. Patient I.D. verified by more than one method.
 3. Final plan of treatment and dosimetry calculations are in accordance with the written directive.
 4. Source loading, prior to implantation, in accordance with written directive.
 5. Any unintended deviation from the written directive is identified, evaluated, and appropriate action taken.
- B. Periodic review of the QMP includes:**
1. All misadministrations.
 2. All recordable events.
 3. All brachytherapy procedures.
 4. Frequency of review at least annually.
 5. Retain records for three years.

II. QMP for Brachytherapy

- A. Written Directive -- A written directive must be signed and dated by the authorized user prior to administration of the brachytherapy dose. This must include:**
1. Name of patient.
 2. Radionuclide.
 3. Treatment site.
 4. Applicator.
 5. Cumulative dose and anatomical dose point.
- B. Oral Directives -- Oral directives will generally not be issued. However, if an oral directive is given to modify a written directive, then the recommendations for documentation as specified in NRC Guide 8.33 will be followed.**
- C. Dosimetry Plan -- A (computer) dosimetry plan must be accepted by the authorized user prior to implantation. This plan must include:**
1. Radiographic localization of sources (either actual or dummy) as the basis for verifying position of the sources and for calculating exposure time (or total dose).
 2. Listing of source information, including radionuclide, position, and strength.
 3. Dose or dose rate at selected anatomical points.
 4. Initials and date of the authorized user.

D. **Source Loading** -- The individual loading the sources into the applicator (before implantation) must document the exact distribution and identity of the sources in the applicator. He must also check for consistency of:

1. Physical loading of sources in applicator
2. Dosimetry plan, and
3. Written directive.

A single-page form (see attached) will be used for this purpose, i.e., for ensuring consistency of the written directive, the dosimetry plan, and the actual loading of the sources in the applicator. The form requires the signature of the physician both before and after implantation, as well as the individual who loads the sources into the applicator.

E. **Patient Identity** -- The user and/or his designee will verify the patient's identity by asking his name and confirming the name and at least one of the following with the patient's record:

1. Birth date
2. Social security number
3. Address
4. Signature
5. ID bracelet
6. Hospital ID card
7. Military ID card.

The method of secondary identification will be documented.

F. **Questions About Procedure** -- The worker (e.g., technologist, dosimetrist, physicist) shall be encouraged to ask questions if there is any confusion or uncertainty regarding the details of the procedure, and will be instructed to not proceed if any discrepancy is noted.

G. **Records** -- Records generated by the QMP's procedures will be retained for a period of five years.

III. Annual Review

A. **Methodology of review** -- A review of the QM program will be conducted at least annually and will include ALL brachytherapy procedures done during the review period. The annual review will be conducted by a committee or designated individual such that an authorized user reviews his/her own procedures. Specifically, the review will include verification of the following:

1. Prior to implantation:
 - a. Radionuclide
 - b. Number of sources
 - c. Source strengths
 - d. Treatment site

2. After implantation but prior to completion of procedure:

- a. Radionuclide
- b. Total source strength
- c. Treatment site
- d. Exposure time (or equivalently, total dose);

- B. Misadministrations -- The review will include all misadministrations and corrective actions taken.
- C. Recordable events -- The review will include all recordable events and corrective actions taken.
- D. Recommendations -- The existing QM program's policies and procedures will be reevaluated for effectiveness following the annual review. Actions which are required to make the program more effective will be identified in writing as part of the review.
- E. Revisions to the QMP -- Revisions to the QMP following the annual review will be submitted to the facility Radiation Safety Officer for subsequent submittal to the NRC regional office.
- F. Records of Annual Review -- Records of the annual review, misadministrations, and recordable events will be retained as required by 10 CFR Part 35. The Chief Medical Physicist will be responsible for maintaining these records in an auditable form.


MERLE S. SPRADLE
LTC, MC
Chief, Radiation Oncology Service

Walter Reed Army Medical Center
Radiation Oncology Service

TANDEM & OVOIDS IMPLANT WITH CESIUM-137

PATIENT: _____ **ID:** _____ **DATE:** _____

To Be Completed By Dosimetrist Before Loading of Sources:

LOADING (actual source strengths)

Tandem: **Tip:** _____
Ovoids: **Rt/Lt:** _____
Caps: _____
Total Number of Sources: _____ **Total mg Ra eq:** _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ **ONCOLOGIST:** _____
DATE: _____ **DATE:** _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

	<u>mg Ra eq</u>	<u>I.D.</u>	<u>Location</u>	<u>Color</u>
Tandem:	_____	_____	_____	_____
	_____	_____	_____	_____
	_____	_____	_____	_____
Ovoids:	_____	_____	_____	_____
	_____	_____	_____	_____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ **DATE:** _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D Insertion date & time: _____
I Treatment site: _____
A Patient ID confirmed by: _____
G Number of sources implanted: _____
R Record loading sequence to left _____
A Sources implanted as listed above? _____
N Total number of hours (planned): _____
Total mg x hours: _____
Date & time for removal: _____

ADDITIONAL INSTRUCTIONS: _____

ONCOLOGIST: _____ **DATE:** _____

To Be Completed After Removal of Implant:

Date & time of actual removal: _____
Number of sources removed: _____

INDIVIDUAL REMOVING SOURCES: _____ **DATE:** _____

Walter Reed Army Medical Center
Radiation Oncology Service

BRACHYTHERAPY TREATMENT WITH CESIUM-137

PATIENT: _____ ID: _____ DATE: _____

To Be Completed By Dosimetrist before Loading of Sources:
(Based on Approved Computer Plan)

APPLICATOR: _____
SOURCE: _____
STRENGTH: _____
POSITION: _____

Total Number of Sources: _____
Total mg-Ra-eq: _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ ONCOLOGIST: _____
DATE: _____ DATE: _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before
Implantation:

	mg Ra-eq	I.D.	Location	Color
Tandem:	_____	_____	_____	_____
	_____	_____	_____	_____
	_____	_____	_____	_____
Ovoids:	_____	_____	_____	_____
	_____	_____	_____	_____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ DATE: _____

To Be Completed By Oncologist After Implantation but Before Completion of
Procedure:

D Insertion date & time: _____
I Treatment site: _____
A Patient ID confirmed by: _____
G Number of sources implanted: _____
R Record loading sequence to left _____
A Sources implanted as listed above? _____
M Total number of hours (planned): _____
Total mg x hours: _____
Date & time for removal: _____

ADDITIONAL INSTRUCTIONS: _____
ONCOLOGIST: _____ DATE: _____

To Be Completed After Removal of Implant:

Date & time of actual removal: _____
Number of sources removed: _____

INDIVIDUAL REMOVING SOURCES: _____ DATE: _____

Walter Reed Army Medical Center
Radiation Oncology Service

PERMANENT SEED IMPLANT WITH GOLD-198

PATIENT: _____ **ID:** _____ **DATE:** _____

To Be Completed By Dosimetrist Before Loading of Sources:

LOADING

Location of Implant: _____

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ **ONCOLOGIST:** _____
DATE: _____ **DATE:** _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ **DATE:** _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D	Insertion date & time:	_____
I	Treatment site:	_____
A	Patient ID confirmed by:	_____
G	Number of seeds implanted:	_____
R	Total activity implanted:	_____
A	Record loading sequence to left	_____
M	Seeds implanted as listed above?	_____

ADDITIONAL INSTRUCTIONS: _____

ONCOLOGIST: _____ **DATE:** _____

Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10CFR35.2, must include: the radioisotope, number of sources, and source strengths; and after implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose). Your QMP must include a written policy/procedure which requires that any written directives for brachytherapy doses will include all treatment parameters prior to administration. Your QMP is missing procedures to require that the written directive include:

- (a) Order for a specific patient.
- (b) Dated and signature of authorized user
- (c) Prior to implantation:
- (d) the radioisotope,
- (e) number of sources,
- (f) source strengths;
- (g) After implantation, but prior to completion of the procedure:
- (h) the radioisotope,
- (i) treatment site,
- (j) total source strength and exposure time (or, equivalently, the total dose)

60. Documentation of oral revisions and oral directives: _ YES NO (18a)

a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

A footnote to 10 CFR 35.32(a)(1) provides that 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 written 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. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP _ YES NO (18b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

61. Revisions to written directives dated and signed by a.u. prior to administration of brachytherapy dose or next fraction of brachytherapy dose _ YES NO (22)

Revisions to written directives for brachytherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose or next fractional brachytherapy dose.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

62. Procedure to verify patient's identity by more than one method prior to administration _ YES NO (23d)

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed

in your QMP. Your QMP must include a policy/procedure to require that, prior to each Brachytherapy administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

63. For brachytherapy other than high-dose-rate remote afterloaders:
- a. a plan of treatment will be prepared in accordance with the respective written directive. YES NO (24a)
 - b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Dose calculations checked by 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 whenever possible did not make the original calculations. YES NO (24b)
 - c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources YES NO (24c)
 - d. performance of acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations YES NO (24d)

Your submittal does not include policies/procedures that ensure that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should require that:

- a. a plan of treatment will be prepared in accordance with the respective written directive.
- b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations) are prepared. Procedures for checking the dose calculations before administration of the prescribed brachytherapy dose. 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 whenever possible did not make the original calculations, should check the dose calculations.
- c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources, is accomplished
- d. acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations is performed.

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE
[10 CFR 35.32(a)(4)]

- 64a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. YES NO (29d)

Your submittal for brachytherapy does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10CFR35.32(a)(4). Please include such a provision in your QMP.

- 64b. The person administering the brachytherapy treatment should confirm the prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, total dose. YES NO (29e)
(*Reviewer, if any one item is missing, mark "no")

Your procedures should include a requirement for verification, before administering each brachytherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

- 64c. Prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record. YES NO (29a)

Your procedures should include a requirement for prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record.

65. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive YES NO (31)

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

66. A written directive and records of each administered Brachytherapy must be maintained for three years. YES NO (33)

Your QMP must include a commitment to retain each written directive and a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). Describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make, date, and sign or initial a written record. Your procedure should describe what this record will include.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

67. Policies/Procedures for identification and evaluation of unintended deviations from the written directive YES NO (34d)

Your QMP for Brachytherapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

- 68a. Institution of corrective actions to be taken after the deviation has been identified YES NO (35)

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

- 68b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. YES NO (1)

As required in 10 CFR 35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

69. Time intervals (intervals not to exceed 12 months) YES NO (36d)

Your submittal for Brachytherapy does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

70. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations YES NO (37)

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

71. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. YES NO (38)

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include this provision in your QMP.

72. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program YES NO (39)

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

73. Modifications to QM program submitted to NRC within 30 days after modification has been made

YES NO (40)

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32 (e).

74. Records of each review and evaluation to be maintained for 3 years

YES NO (41)

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS: _____

No brachy QMP

Quality Management Program for I-125 and/or I-131 > 30uCi

75. A written QMP for I-125 and/or I-131 > 30 uCi was provided. YES NO (3e)

A written QMP must be established and maintained for each I-125 and/or I-131 > uCi use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your NaI I-125 or I-131 > 30 microCi.

76. Written certification that QM program has been implemented YES NO (4)

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

- 77a. A written directive is prepared for administration of greater than 30 uCi of I-125 and/or I-131 YES NO (7)

The preparation of written directives prior to the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 is required by 10 CFR 35.32(a)(1). Your QMP must include a written policy that requires that such a written directive be prepared prior to each patient administration.

The QMP provides procedures to require that the written directive include:

- 77b. an order for a specific patient..... YES NO (8a)
 77c. date and signature of authorized user..... YES NO (8b)
 77d. dosage to be administered..... YES NO (8c)

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and, for any administration of quantities greater than 30 microcuries of either I-125 or I-131, the dosage. Your QMP is missing procedures to require that the written directive for I-125 and/or I-131 > 30 uCi:

- (a) be an order for a specific patient
- (b) is dated and signed by the authorized user
- (c) contains the dosage to be administered.

78. Documentation of oral revisions and oral directives: YES NO (18a)

- a. Documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

A footnote to 10 CFR 35.32(a)(1) provides that 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 written 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. Please include such a policy in your QMP.

- b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP
- _ YES _ NO (18b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

79. Revisions to written directives dated and signed by a.u. prior to administration of a radiopharmaceutical dosage
- _ YES _ NO (19)

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. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

80. Procedure to verify patient's identity by more than one method prior to administration
- _ YES _ NO (23e)

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each NaI I-125 or I-131 >30 microCi administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL ADMINISTRATION)

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

- 81a. Procedures to ensure, before administration, that each administration is in accordance with the written directive.
- _ YES _ NO (27a)

Your submittal for I-125 and/or I-131 > 30uCi administration does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive.

- 81b. For I-125 and/or I-131 > 30uCi:

Dosage measured in dose calibrator and results compared with the prescribed dosage in the written directive

_ YES _ NO (27b) 10.8-27

According to guidance provided by Regulatory Guide 8.33, the dosage, should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive, that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures in your QMP.

82. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive YES NO (31)

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

83. A written directive and records of each administered I-125 and/or I-131 >30 uCi must be maintained for three years. YES NO (32)

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

84. Policies/Procedures for identification and evaluation of unintended deviations from the written directive YES NO (34e)

Your QMP for NaI I-125 or I-131 >30 microCi must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

- 85a. Institution of corrective actions to be taken after the deviation has been identified YES NO (35)

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

- 85b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. YES NO (1)

As required in 10 CFR 35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE OM PROGRAM [10 CFR 35.32(b)]

86. Time intervals (intervals not to exceed 12 months) YES NO (36e)

Your submittal for NaI I-125 or I-131 >30 microCi does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

Walter Reed Army Medical Center
Radiation Oncology Service

PERMANENT SEED IMPLANT WITH IODINE-125

PATIENT: _____ **ID:** _____ **DATE:** _____

To Be Completed By Dosimetrist Before Loading of Sources:

LOADING

Location of Implant: _____

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Is this the loading used for the computer dosimetry plan? _____
Is this loading consistent with the written directive? _____

DOSIMETRIST: _____ **ONCOLOGIST:** _____
DATE: _____ **DATE:** _____

To Be Completed By Dosimetrist/Physicist After Loading Sources and Before Implantation:

Number of seeds: _____ **Activity per seed:** _____

Total activity: _____

Does this loading agree with the dosimetrist's plan above? _____

DOSIMETRIST/PHYSICIST: _____ **DATE:** _____

To Be Completed By Oncologist After Implantation But Before Completion of Procedure:

D	Insertion date & time:	_____
I	Treatment site:	_____
A	Patient ID confirmed by:	_____
G	Number of seeds implanted:	_____
R	Total activity implanted:	_____
A	Record loading sequence to left	_____
M	Seeds implanted as listed above?	_____

ADDITIONAL INSTRUCTIONS: _____

ONCOLOGIST: _____ **DATE:** _____

LICENSE NO. 08-01738-02

DOCKET NO. 030-01317

HSHL-XN

22 March 1994

QUALITY MANAGEMENT

I. Quality Management Program, WRAMC Nuclear Medicine Service

A. The five objectives are:

1. Written directive given prior to administration.
2. Patient I.D. verified by more than one method.
3. Final plans of treatment and calculations are in accordance with written directives.
4. Each administration in accordance with written directives.
5. Any unintended deviation from written directives is I.D.'d, evaluated, and appropriate action is taken.

B. Develop procedures for and conduct a review of the QMP including:

1. All misadministration.
2. All recordable events.
3. A sampling of patient administrations... at intervals no greater than 12 months.
4. Retain records for three years.

II. Radiopharmaceutical QMP

C. For all Radiopharmaceutical Therapies and Diagnostic Iodine 131 & 125; Iodine MIBG & NP59; Strontium-89 Chloride, and Phosphorus-32 IV.

1. Authorized user - Sign and date written directive (Radiopharmaceutical, Dosage, Route of Administration) before administration. (Delays, oral directives and revisions OK under certain circumstances. 10 CFR 35.32(a)(1).).
2. User and/or Designee verify patient identity by more than one method:
 - a) Ask patient name, confirm, and,
 - b) Birth date, or
 - c) Social security number, or
 - d) Address, or
 - e) Signature, or
 - f) ID Bracelet, or
 - g) Hospital ID card, or
 - h) Military ID card.

ML 10

Encl 2

JUN 06 1994

II. Radiopharmaceutical QMP cont.

3. Person administering dose verify details of administration:
 - a) Radiopharmaceutical
 - b) Dose
 - c) Route of Administration
4. Encourage worker to ask questions.
5. User or supervised person date and sign/initial written record (chart).

****See enclosure Radiopharmaceutical Administration Checklist****

III. Annual Review

6. At least annually the QMP review will consist of:

- a) Random Sample of therapies representative of the following patient administrations:

Lot size	Sample size	Acceptance No.
20	ALL	0
21 - 100	20	0
>100	20%	0

- b) All misadministration
- c) All recordable events.

For each patient case, compare administered vs. prescribed for

- a) Written directive complete
- b) Patient identity verified
- c) Radiopharmaceutical
- d) Dose
- e) Route of administration

Ana A. Rodriguez
ANA A. RODRIGUEZ
COL, MC
CHIEF, NUCLEAR MEDICINE SERVICE

RADIOPHARMACEUTICAL ADMINISTRATION CHECKLIST

(To be filled out by individuals administering a therapeutic dosage of any radiopharmaceutical other than sodium iodine I-125 or I-131 (SR-89 MIBG, NP-59, P-32), or any dosage greater than 30 microcuries of sodium iodide I-125 or I-131).

DIRECTIONS: Complete the items below in the order listed, and initial each item when completed. If you do not fully understand how to carry out the written directive (PRESCRIPTION/CONSENT FORM) for this administration, halt the procedure and contact the Chief, Nuclear Medicine Service, or other authorized user immediately.

PLACE RADIOPHARMACEUTICAL STICKER HERE

PART I - BEFORE ADMINISTRATION

Attach a copy of the written directive (PRESCRIPTION/CONSENT FORM) for the dosage prepared.

initials

The written directive (PRESCRIPTION/CONSENT FORM) is signed and dated by an authorized user.

initials

The patient's identity checked verbally and confirmed as the individual named in the written directive (PRESCRIPTION/CONSENT FORM) by comparison with corresponding information in the patient's record using at least one of the following means of identification.

initials

(Listed in order of preference. Check applicable means.)

- 1. Military ID card
2. Name on the patient's ID bracelet
3. Drivers license photo
4. Other (SSAN Birth date Address Signature)

The radiopharmaceutical to be administered is the same as that identified on the written directive (PRESCRIPTION/CONSENT FORM).

initials

Route of administration (circle): I.V. I.M. P.O. Other (what?)

The dosage to be administered is the same as that identified on the written directive (PRESCRIPTION/CONSENT FORM).

initials

Laboratory test results (Beta HCG, TSH, CBC, etc) have been reviewed.

initials

PART II - AFTER ADMINISTRATION

Date and time of dose administration: DATE TIME

Record, date, and initial the administered dosage on the patients's consult, and place in the Nuclear Medicine Folder.

initials

REVIEWED BY (AUTHORIZED USER):

SIGNATURE

DATE

QUALITY MANAGEMENT PROGRAM - BRACHYTHERAPY

The following is an extract from Chapter 3, the Radiation Oncology Service Policy and Procedure Manual, Walter Reed Army Medical Center.

3.2.7.11 Quality Management Program for WRAMC Radioactive Material Permit Program. The NRC has amended Part 35 of its regulations governing the therapeutic administration of radiation and radioactive material covered by the hospital's WRAMC Radioactive Materials Permit. A complete copy of the affected changes is located in Federal Register, Volume 56, Number 143, of 25 July 1991, pages 34120-34122. These changes affect brachytherapy procedures with Radiation Oncology. The changes effected are summarized here:

1. Definitions. In radiation oncology, MISADMINISTRATION means the administration of a brachytherapy radiation dose:
 - 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; or
 - d. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

RECORDABLE EVENT means the administration of:

- a. Radiation without a written directive (see definition below) where a written directive is required;
- b. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Extract of the Quality Management Program for Brachytherapy, Chapter 3, Policy & Procedure Manual, Radiation Oncology, WRAMC, September 1993

WRITTEN DIRECTIVE means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information:

- a. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
- b. For all other brachytherapy:
 - (1) Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - (2) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

ORAL DIRECTIVES AND REVISIONS TO WRITTEN DIRECTIVES:
A footnote to 10 CFR 35.32(a)(1) reads as follows:

"If, because of the patient's medical condition, a delay in order to provide a 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 a revised written directive is dated and signed by the authorized user within 48 hours of the oral directive.

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 prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next teletherapy fractional dose.

Extract of the Quality Management Program for Brachytherapy, Chapter 3, Policy & Procedure Manual, Radiation Oncology, WRAMC, September 1993

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 and 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."

3.2.7.12 QUALITY MANAGEMENT PROGRAM. Major aspects of the Brachytherapy Quality Management Program a WRAMC includes:

- a. A written directive is required for and must be written prior to any brachytherapy radiation dose.
- b. Prior to each administration the patient's identity must be verified by more than one method as the individual named in the written directive.
- c. All workers must seek guidance if they do not understand how to carry out the written directive.
- d. Final plans of treatment and related calculations for brachytherapy must be in accordance with the respective written directive.
- e. Each administration must be in accordance with the written directive.
- f. For temporary and permanent implants radiographs or other comparable images (e.g. CT) of the brachytherapy radioactive sources (or dummies) shall be obtained for verifying the position of the sources and calculation of dose. This may not be necessary for fixed geometry applicators (e.g., templates).

Extract of the Quality Management Program for Brachytherapy, Chapter 3, Policy & Procedure Manual, Radiation Oncology, WRAMC, September 1993

- g. The authorized user will promptly record in the patient's chart the actual loading sequence of the radioactive sources implanted.
- h. After insertion of the brachytherapy sources but prior to completion of the procedure, the authorized user will enter in the patient's record the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
- i. Within 24-hours of the implant or before the total prescribed brachytherapy dose has been administered, computer and manual calculation shall be checked.
- j. Any unintended deviation from the written directive must be identified and evaluated as a recordable event or misadministration. An investigation and evaluation with the division is required and recommendations for corrective action will be implemented. Appropriate action must be taken. A summary of evaluation will be presented to the quarterly meeting of the Radiation Control Committee. A copy of the evaluation of recordable events will be sent within thirty days to Health Services Command.
- k. A review of the quality management program must be conducted at intervals no greater than 12 months.

QUALITY MANAGEMENT (QM) PROGRAM CHECKLIST

1. *NAME OF LICENSEE: Department of Health Services / Medical Center / Long Beach Medical Center

Date QM Plan submitted to NRC 11/27/92

*License No.: 08-0172-2

*Docket No.: (7-1000)

Telephone No.: () _____

LLNL Authorization Reviewer# 16

Reviewer# 11 Reviewer Loc (UCSF or other) UCSF

2nd Reviewer# 54 Reviewer Loc (UCSF or other) UCSF

LLNL Reviewer# _____

Reviewer's Notes:

Start in 92

Send in UCSF with 52-92 and copy to usual dossier

NO QMP for SF-92

Reviewers: Cross out comments which are no longer relevant. Date and initial comments. This information will not be stored in database. These are comments to the tracking office.

*R.S.O. LT J. Thomas H. Smith (include title ,e.g. Dr., Mr., Ms., etc.)

*Department _____ (e.g., Nuclear Med., Radiation Oncology, etc.)

*Street or P.O. Box Wash. etc.

*City Washington State DC Zip Code 20001

*Reviewer: Take this information from license only.

- 2a. Authorized user for Teletherapy (35.600)..... YES NO U
- 2b. Authorized user for Gamma Stereotactic Radiosurgery..... YES NO U
- 2c. Authorized user for High-Dose-Rate Remote Afterloading Brachytherapy (HDR)..... YES NO U
- 2d. Authorized user for Brachytherapy (35.400)..... YES NO U
- 2e. Authorized user for I-125 and/or I-131 > 30 uCi
Any or all of 35.100, 35.200, 35.300, unless both I-125 and I-131 are excluded or not included in section 6 of license YES NO U
- 2f. Authorized user for Radiopharmaceutical Therapy other than I-125 and/or I-131 (35.300)..... YES NO U

Reviewer: U means that the licensee is authorized for this modality but has stated in a letter that the facility will not be using this modality in practice.

Quality Management Program for Brachytherapy

57. A written QMP for Brachytherapy was provided. _ YES NO (3d)

A written QMP must be established and maintained for each Brachytherapy use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your Brachytherapy program

58. Written certification that QM program has been implemented _ YES _ NO (4)

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented long with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

59a. A written directive is prepared for Brachytherapy, other than high-dose-rate: _ YES NO (11)

10 CFR 35.32(a)(1) requires that QMPs for brachytherapy include a procedure for the preparation of written directives prior to administration of any brachytherapy dose. The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared for each patient.

The QMP provides procedures to require that the written directive include: (12)

59b. Order for a specific patient..... _ YES NO (12a)

59c. Dated and signed by authorized user _ YES NO (12b)

Prior to implantation: (12c)

59d. the radioisotope, _ YES NO (12d)

59e. number of sources,..... _ YES NO (12e)

59f. source strengths;..... _ YES NO (12f)

After implantation, but prior to completion of the procedure: (12g)

59g. the radioisotope, _ YES NO (12g)

59h. treatment site, _ YES NO (12i)

59i. total source strength and exposure time (or, equivalently, the total dose)..... _ YES NO (12j)

87. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations. YES NO (37)

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

88. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. YES NO (38)

According to guidance provided by Regulatory Guide 8.33, your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

89. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program. YES NO (39)

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

90. Modifications to QM program submitted to NRC within 30 days after modification has been made YES NO (40)

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32(e).

91. Records of each review and evaluation to be maintained for 3 years YES NO (41)

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS: _____

No real plan submitted

Quality Management Program for Therapeutic Radiopharmaceutical other than I-125 or I-131

92. A written QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 was provided. _ YES NO (3f)

A written QMP must be established and maintained for Radiopharmaceutical use as required in 10 CFR 35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

93. Written certification that QM program has been implemented _ YES NO (4)

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32.f(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

94a. A written directive is prepared for administration of therapeutic radiopharmaceutical other than I-125 and/or I-131 _ YES NO (9)

10 CFR 35.32(a)(1) requires a QMP to include policies and procedures for the preparation of a written directive, prior to the administration of any therapeutic radiopharmaceutical, other than sodium iodide I-125 or I-131. Please provide such a policy in your QMP.

The QMP provides procedures to require that the written directive include:

- 94b. Radiopharmaceutical..... _ YES NO (10a)
- 94c. Dosage..... _ YES NO (10b)
- 94d. Route of administration..... _ YES NO (10c)
- 94e. Order for a specific patient..... _ YES NO (10d)
- 94f. Dated and signed by authorized user..... _ YES NO (10e)

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and, for a therapeutic use of a radiopharmaceutical other than I-125 or I-131, the radiopharmaceutical, dosage, and route of administration. Your QMP is missing procedures to require that the written directive for therapeutic radiopharmaceutical other than I-125 and/or I-131 include:

- (a) Radiopharmaceutical
- (b) Dosage
- (c) Route of administration
- (d) Order for a specific patient
- (e) Date and signed by authorized user

95. Documentation of oral revisions and oral directives:
- a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision YES NO (18a)

A footnote to 10 CFR 35.32(a)(1) provides that 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 written 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. Please include such a policy in your QMP.

- b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP. YES NO (18b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

96. Revisions to written directives dated and signed by a.u. prior to administration of a radiopharmaceutical dosage YES NO (19)

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. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

97. Procedure to verify patient's identity by more than one method prior to administration YES NO (23f)

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each Therapeutic Radiopharmaceutical other than I-125 or I-131 administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

- 98a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. YES NO (27c)

Your submittal for administration of therapeutic radiopharmaceutical other than I-125 or I-131 does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive.

- 98b. Confirm the radiopharmaceutical, dosage and route of administration

Dosage measured in dose calibrator and results compared with the prescribed dosage in the written directive YES NO (27d)

According to guidance provided by Regulatory Guide 8.33, the radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive, that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures in your QMP.

99. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive YES NO (31)

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

100. A written directive and records of each administered Therapeutic Radiopharmaceutical other than I-125 or I-131 must be maintained for three years. YES NO (32)

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d)(2). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

101. Policies/Procedures for identification and evaluation of unintended deviations from the written directive YES NO (34f)

Your QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

- 102a. Institution of corrective actions to be taken after the deviation has been identified YES NO (35)

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

- 102b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. YES NO (1)

As required in 10 CFR 35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

103. Time intervals (intervals not to exceed 12 months) YES NO (36f)
- Your submittal for Therapeutic Radiopharmaceutical other than I-125 or I-131 does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.
104. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations YES NO (37)

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

105. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. YES NO (38)

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

106. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program YES NO (39)

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

107. Modifications to QM program submitted to NRC within 30 days after modification has been made YES NO (40)

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32 (e)

108. Records of each review and evaluation to be maintained for 3 years YES NO (41)

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS: _____

No real plan here



DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307-5001



REPLY TO
ATTENTION OF:

January 10, 1992

Nuclear Medicine Service

030-01317
08-01738-02

United States Nuclear Regulatory
Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406

Gentlemen:

Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 35, Section 35.32(f)(2), we provide you with written certification that a Quality Management Program, or continuous Quality Improvement (CQI) Plan, is implemented at Walter Reed Army Medical Center.

Referenced in paragraph 1 of the CQI are the written policies and procedures which make up the plan (Enclosure). Also enclosed is a copy of the Nuclear Medicine Service Pharmacy Standing Operating Procedures (SOP) which contain the specific objectives as established in 10 CFR 35.

Sincerely,

Roy D. Quick, Jr.
Major, U.S. Army
Executive Officer

Enclosures

WR Dpt. of the Army
RSD HP Office
2681 Lindbergh
Silver Spring

14111 --

JAN 27 1992

NUCLEAR MEDICINE SERVICE
DEPARTMENT OF RADIOLOGY
WALTER REED ARMY MEDICAL CENTER

CONTINUOUS QUALITY IMPROVEMENT (CQI) PLAN (REV, 03/01/92)

1. References:

- a. AR-40-66
- b. WRAMC REG 40-60
- c. WRAMC REG 40-92
- d. JCAH MANUAL
- e. JCAH QUALITY REVIEW BULLETIN, SEP 1986
- f. QA PLAN, DEPT OF RADIOLOGY 1990
- g. WRAMC NUCLEAR MEDICINE SERVICE PHARMACY SOP
- h. U.S. NRC REGULATORY GUIDE 10.8, AUGUST 1987 (rev 2)
- i. WRAMC NUCLEAR MEDICINE IMAGING SOP

2. Responsibility: Colonel Jay H. Anderson, MC, Chief, Nuclear Medicine Service has been appointed the Quality Assurance Officer for the Nuclear Medicine Service. He shall be responsible for coordinating all monitoring and evaluation of the quality and appropriateness of care in the Nuclear Medicine Service.

3. Scope: The Nuclear Medicine Service provides diagnostic nuclear medicine procedures, both imaging and non-imaging, for in-patients and out-patients, interprets these studies and performs radionuclide therapy in accordance with appropriate standards of practice and governing regulations.

4. Important Aspects of Care:

(A). Assessing patient condition to determine special needs for supervision.

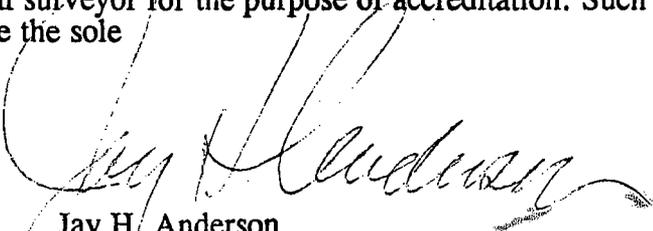
(B). Assessing risk factors in the following patient population:

- (1). Patients with fractures or limitation of motion.
- (2). Cardiac patients being tested by stress testing.
- (3). Pediatric patients.
- (4). Women during childbearing years.
- (5). Senile patients.
- (6). Disoriented or comatose patients.

(C). Staff performance during procedures:

- (1). Radiopharmaceutical dose preparation.
- (2). Administering radiopharmaceuticals.
- (3). Patient imaging
- (4). Computer analysis of studies.
- (5). Providing patient with specific instructions as to the risks, benefits and side affects of specific treatments.
- (6). Alievating patients fears about radioactivity.

5. Indicators: See attached appendix A.
6. Criteria: See attached appendix A.
7. Data Collection: See attached appendix A.
8. Problem Solving:
 - a. A monthly Nuclear Medicine Service CQI meeting will address ongoing indicators and identify new problems, which if validated will be entered into the tracking system.
 - b. Based on the nature of the problem, an individual or a group of individuals will be given responsibility to investigate the problem and recommend corrective action where necessary.
9. Reports: The minutes of the Nuclear Medicine Service CQI Committee will be forwarded to the CQI committee of the Dept of Radiology. A copy will be maintained by the NMS.
10. The CQI coordinator will be responsible for an annual review and update of the Total Quality Management plan (January), including the monthly Peer Review, and CQI minutes. The CQI Plan incorporates the recommendations published in the Federal Register (10CFR 35.32) on July 25 1991. Specific issues are addressed in the references cited at the top of this document.
11. The Nuclear Medicine Pharmacist will be responsible for maintaining optimal radiopharmacy practices, and will provide an annual review of the NMS SOP to include quality control and radiation safety which will be updated and modified to comply with federal regulations.
12. The Technical Director and the Imaging Supervisor will be responsible for an annual review and update of the Imaging SOP, monthly technologist peer review, and supervising the instrument quality control on a daily basis. A consulting physicist will review these procedures at least bi-annually.
13. The RIA Supervisory Technologist is responsible for maintenance of optimal practices and an annual review of the SOP.
14. Confidentiality: All Quality Assurance activities, all committee members and all personnel engaged in the Quality Assurance program will be bound by the confidentiality Policy.
15. Reports, minutes, and other findings may not be released to or discussed with any person or agency except those mandated by Chief, Nuclear Medicine Service. These activities may be reviewed by JCAHO or any professional surveyor for the purpose of accreditation. Such professional accreditation review will be the sole exception to the confidentiality policy.



Jay H. Anderson
COL, MC
Chief, Nuclear Medicine Service

**DEPARTMENT OF RADIOLOGY -- NUCLEAR MEDICINE SERVICE
ON-GOING QUALITY ASSURANCE MONITORING PROGRAM**

INDICATOR	CRITERIA	HOW MONITORED	WHO MONITORS	MONITORING FREQUENCY	RESULTS
Misadministration of radionuclides	No more than 3 per 12 months (< 3 / 10000)	Review of each administration by Health Physics Office	Radiopharmacist	Semiannually (Feb and Oct)	No misadministrations indentified during the past 12 months
Patient Waiting Times (appointment delays)	3 days inpatient 3 weeks outpatients	Weekly review of scheduling times	Receptionist and QA Coordinator	Semiannually (Mar and Sep)	
Patient satisfaction	< 5% dissatisfied	Review of patient survey questionnaires	NM QA Coordinator and service chief	Semiannually (Mar and Sep)	
Pathologic confirmation of thyroid malignancy prior to 131-I therapy	< 2 per year (2 / 10 to 12)		NM Staff physicians	Annually	
Monthly case (peer review) results	< 5% overall disagreement on an annualized basis	Independent monthly case review by all NM staff physicians and fellows	Assistant Chief, NM service	Annually (Jun)	Less than 1 case per 2 weeks (< 1/200) All identified reporting discrepencies corrected immediately
Weekly case conference	No reporting discrepencies	Joint weekly case review by NM staff physicians and fellows	NM Fellows and service chief	Monthly	
Instrument Down Time	Being Established	Monthly log	Tech Supervisor	Monthly	
Infiltrated Doses which require reinjection	< 1%	Pharmacy log	Radiopharmacy	Semiannually	

INTENT

THE INTENT OF THIS SOP IS TO PROVIDE GUIDANCE FOR THE OPERATION
OF THE NUCLEAR PHARMACY

SECTION I.

NUCLEAR PHARMACY SOP

TABLE OF CONTENTS

SOP TITLE	PAGE #
Purpose, Function, Duties and Qualifications of Nuclear Pharmacists	1
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SECTION II.

FORMULA RECORD WORKSHEETS

Tc-99m Sulfur Colloid
Tc-99m DTPA
Tc-99m HIDA
Tc-99m MDP
Tc-99m MA
Tc-99m GI
Tc-99m DMSA
Tc-99m PYRO
Tc-99m RBC (GI BLEED)
Tc-99m RBC (MUGA)
In-111 WBC
In-111 PLATELETS
Tc-99m HEAT DAMAGED RBC

SECTION III.

NUCLEAR MEDICINE SERVICE DIRECTIVES

NUCLEAR PHARMACY SOP

1. PURPOSE: The purpose of this SOP is to describe the procurement, compounding, quality control, and dispensing of radiopharmaceuticals to include investigational new agents.

2. FUNCTIONS OF NUCLEAR PHARMACIST:

a. Assure safety, effectiveness and correctness of radioactive drugs used in patients at WRAMC through biological, chemical, physical, and radiological testing and radioactive drug use surveillance.

b. Assists in clinical and laboratory investigations using radioactive drugs through consultation, drug formulation and safety testing, assisting principal investigators with the preparation of research protocols, and INDs and carrying out the portion of the Pharmacy Service's responsibility to the WRAMC investigational drug program that pertains to the use of radioactive drugs in humans.

c. Provides didactic and laboratory instruction and examination in nuclear pharmacy courses and programs in support of nuclear medicine, nuclear medicine technology, radiation health physics, and clinical nuclear pharmacy courses, programs, residencies, and clerkships.

d. Develops and evaluates new radiopharmaceuticals and new radiopharmaceutical compounding and testing procedures and evaluates those developed by other institutions and by manufacturers.

e. Provides nuclear pharmacy services within the WRAMC Nuclear Medicine Services:

(1) Maintains a continuous inventory of the best quality radiopharmaceuticals available at the least practical cost; includes commercial and in-house formulations.

(2) Prepares and dispenses quality control tested radiopharmaceuticals in precalibrated doses ready for patient administration.

(3) Orders, receives, assays and stores radioactive drugs IAW WRAMC, DA, and federal regulations.

(4) Maintains prescription, formulation, receipt, inventory, use and disposal records pertaining to approved and investigational radioactive drugs as required by military, federal, and WRAMC rules and regulations.

(5) Monitors and reduces laboratory radiation levels and surveys for and decontaminates spilled radioactive material in cooperation with WRAMC Health Physics Officer.

(6) Instructs Nuclear Medicine Service personnel in laboratory techniques for safe handling of radioactive materials.

(7) Conducts Nuclear Pharmacy laboratory training for nuclear medicine technologists and nuclear medicine residents.

3. QUALIFICATIONS AND DUTIES OF NUCLEAR PHARMACIST:

a. The nuclear pharmacist should be certified by the American Pharmaceutical Association, Board of Pharmaceutical Specialties as a Nuclear Pharmacist. As a minimum the radiopharmacist will be a registered pharmacist with training and experience in nuclear pharmacy, nuclear medical science, and radiation health physics.

b. Serves as a member of the WRAMC Radiation Control Committee.

c. Has operational control of nuclear medicine technologists and technicians working in the Nuclear Pharmacy laboratory.

d. Supervises radiation safety procedures, laboratory, and personnel radiation monitoring, radioactive waste handling and related health physics operations within the nuclear pharmacy in close cooperation with the WRAMC Health Physics officer.

e. Coordinates storage, preparation, use, disposal and records-keeping for human use, radioactive, investigational new drugs, with the Pharmacy Service, Nuclear Medicine Service, and Dept of Clinical Investigations.

SOP RP # 1

MANDATORY WORK RULES

1. Disposable gloves and lab coats will be worn as protective garments when working with radioactive materials.
2. Technetium-99m radiopharmaceutical solutions will be tested by radiochromatography and pH before dispensing individual doses.
3. Doses of radiopharmaceuticals will be within 10% of the prescribed radioactivity at the time of administration to patients.
4. All student prepared doses of radiopharmaceuticals will be checked for correctness by a staff member prior to dispensing. The staff member who checks a dose prepared by a student will initial the consultation and dose label. The staff member must observe the student while the dose is being prepared or the student must leave out for inspection all vials and paraphernalia needed to prepare the dose.
5. Records will be completed and doses of radiopharmaceuticals will be prepared and available for administration to patients by 0730 daily, when appropriate.
6. All appropriate labeling and record entries will be completed before workers leave the radiopharmaceutical laboratory area.
7. All radiopharmaceutical doses will have a dose label attached to the syringe for parenteral doses or dispensing vial for oral doses.
8. Work areas will be surveyed at close of business daily with an appropriate portable radiation detection instrument. Results will be recorded in the record book designated for this purpose.
9. Syringe and vial shields will be utilized for the preparation of radiopharmaceutical vials. Syringe shields will be utilized for administration of doses to patients except in circumstances where their use would compromise the patient's well being.
10. Workers will insure that radioactive materials are either secured or under supervision of clinic personnel at all times, and that non-clinic personnel are accompanied whenever they venture into controlled areas.
11. The clinic will be locked after duty hours.

12. For each dose prepared, review the consultation sheet and radiopharmacy order to insure that you understand it. Select the one correct radiopharmaceutical from the storage area and place it in the work area. Read the label. Prepare the dose consistent with the activity required for the study. Read the label. Replace the vial back into the storage area. Read the label. One and only one radiopharmaceutical will be in the work area at a time.

SOP RP # 2

PREPARING TECHNETIUM-99m RADIOPHARMACEUTICALS

1. Technetium-99m radiopharmaceuticals are prepared according to the directions given in WRAMC Nuclear Pharmacy Formula Record Worksheets.
2. Quality control tests will be initiated before preparing individual precalibrated doses and will be completed before dispensing doses for administration to patients. Radiochemical purity of products will comply with guidance given in the current United States Pharmacopeia (U.S.P.). In cases where no U.S.P. guidance exist, doses will not be dispensed if there is more than 10% of the radionuclide in an undesirable radiochemical form.

SOP RP # 3

MONITORING AND INITIAL RECORDS KEEPING
UPON RECEIPT OF RADIOACTIVE MATERIALS

1. Radiopharmaceuticals intended for use at Walter Reed AMC Nuclear Medicine Service may be received directly from a local centralized nuclear pharmacy during duty hours. They will be monitored, inspected, and wipe tested where appropriate. Radiopharmaceuticals ordered from a manufacturer will be received by Health Physics Office located at Forest Glen Section and subsequently delivered to Nuclear Medicine.
2. Follow the attached receipt procedure for initial log in of radiopharmaceuticals into the radiopharmacy record system.
3. The vial should be placed in the lead container and the radiopharmaceutical stored in the shielded radiopharmaceutical storage area.
4. If the radiopharmaceutical requires refrigeration, it should be placed in the shielded refrigerator designated for radioactive materials.
5. Upon receipt of RIA kits, the type, lot number, date of expiration, and control number will be assigned in the RIA log.

SOP RP # 4

RECORDS KEEPING

1. The purpose of these records is:

a. A history of each radioactive item received from date of receipt, through use, to final disposition as radioactive waste or as decayed to background radiation level.

b. A record of patients to whom radioactive materials are administered, including lot numbers of component ingredients.

c. A record of doses prescribed on the individual consultation sheet, individual worksheet, or daily batch worksheet.

d. Consent record for use of investigational or therapeutic radioactive drugs in all patients.

e. Record of calibration checks on radiation dose measuring devices.

f. Record of compounding radiolabeling kits.

2. Several records are kept from one Nuclear Regulatory Commission inspection to the next or for three years or longer, as appropriate. These records include:

a. A radiopharmaceutical stock record which documents the lot number, use, and disposition of radiopharmaceuticals and also gives individual radionuclide dose measurements for each dose of radioactive material administered to patients. (Stock Record Sheet)

b. A Nuclear Pharmacy laboratory record which gives a chronological record of radiation dose calibrator checks.

c. Patient consent forms are filed in the nuclear pharmacy.

3. Records of all misadministrations of radiopharmaceuticals shall be preserved until the Nuclear Regulatory Commission authorizes their disposition.

SOP RP # 5

RADIATION SAFETY

1. The WRAMC Health Physics Office has principal responsibility for formulating radiation safety procedures and for records keeping for WRAMC. These procedures, which are given in WRAMC Regulation 40-10, must be perused and followed by persons assigned to the Nuclear Pharmacy Service.

2. In addition to the directives and guides in WRAMC Reg 40-10, the following rules will be followed:

a. Latex gloves and lab coats will be worn when handling radioactive materials.

b. Work surfaces will be lined with absorbent paper before handling radioactive materials.

c. After handling radioactive materials, hands and immediate work areas should be checked with a radiation monitor before leaving the radiopharmacy laboratory.

d. All pharmacy personnel will wear a film badge, and a TLD ring when working in the Nuclear Pharmacy laboratory or with radioactive patients.

e. The Nuclear Pharmacy laboratory will be continuously monitored with radiation detectors. Monitoring should reveal improper storage of radioactive material and poor handling techniques of workers.

f. A radiation survey will be conducted in the Nuclear Pharmacy daily at close of business with an appropriate portable radiation detection instrument. Routine surveys of the radiopharmacy and dose room will include the areas indicated on the Health Physics Laboratory Survey Form (WRAMC 708) included as addendum one to this annex.

g. The procedure for handling spills of radioactive materials in the radiopharmacy is outlined in addendum to this SOP.

NUCLEAR MEDICINE SERVICE
DEPARTMENT OF RADIOLOGY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307-5001

HSHL-XN1

19 August 1987

RADIONUCLIDE ACCIDENT EMERGENCY PROCEDURES

A. Purpose: To define actions to be taken in event of an accident involving radioactive materials.

B. Minor Spills Involving No Radiation Hazard to Personnel:

1. Notify all other persons in the room at once.
2. Permit only the minimum number of persons necessary to deal with the spill into the area.
3. Confine the spill immediately.

Liquid spills:

Don protective gloves
Drop absorbent paper on spill

Dry Materials Contamination:

- Don protective gloves
Dampen thoroughly, taking care not to spread the contamination
4. Notify the Health Physics Office as soon as possible.
 5. Decontaminate.
 6. Monitor all persons involved in the spill and cleaning.
 7. Permit no person to resume work in the area until survey is made, and approval of the Health Physics Officer is secured.
 8. Prepare a complete history of the accident and subsequent activity relating thereto for the Health Physics Office.

C. Major Spills involving Radiation Hazard to Personnel:

1. Notify all persons involved in the spill to vacate the room at once.
2. If the spill is liquid, and the hands are protected, right the container.
3. If the spill is on the skin, flush thoroughly.
4. If the spill is on the clothing, discard outer or protective clothing at once.
5. Switch off all fans.
6. Vacate the room.
7. Notify the Health Physics Office as soon as possible.
8. Take immediate steps to decontaminate personnel involved as necessary.
9. Decontaminate the area. (Personnel involved in decontamination must be adequately protected).

SOP RP # 6

QUALITY CONTROL PROCEDURES

1. The purpose of quality control procedures is to insure that the correct radionuclide in the correct radiochemical form is administered in the correct dose of radioactivity.
2. Sterility and nonpyrogenicity, if appropriate, is assured by either the manufacturer or by compounding procedures given in SOP RP #8 (Compounding Radiopharmaceuticals).
3. The correct radiochemical form for drugs purchased in precalibrated final dose form is assured by the supplier. Spot checks may be done by the Nuclear Pharmacy if the radiochemical form usually has short stability or if the quality control procedures of the supplier are not considered adequate. Quality control tests for radiochemical form of technetium-99m compounds are given in SOP RP #2 (Preparing Technetium-99m Radiopharmaceuticals) and in SOP RP #8 (Compounding Radiopharmaceuticals).
4. Highly important quality control and radiation safety procedures are given in SOP RP #1 (Mandatory Work Rules).
5. Quality control tests for dose calibrators are performed IAW NRC Reg Guide 10.8, Appendix C.
6. Quality control tests for in-house compounded radiolabeling kits are described in SOP RP #8 (Compounding Radiopharmaceuticals).

**NUCLEAR MEDICINE
QUALITY ASSURANCE PROGRAM**

RADIOPHARMACY

The radiopharmacy receives, performs Q.C. and measurements, and dispenses all radiopharmaceutical doses for the Nuclear Medicine Service.

Ongoing indicators are related to instrumentation, radiation protection, and product quality control as well as dispensing and patient considerations. Special indicators and data searches are developed at the request of Nuc Med Svc QA committee.

<u>INDICATOR</u>	<u>THRESHOLD</u>	<u>FREQUENCY</u>
DOSE CALIBRATOR QC CONSTANCY LINEARITY ACCURACY GEOMETRY	1/MONTH 0 0 0	QUARTERLY " ANNUALLY AS NEEDED
RECEIPT OF ISOTOPES MONITOR WIPE TEST	PER DOT NMT 2000 DPM	SEMI-ANNUAL "
PRODUCT QC RADIOISOTOPE RADIOCHEMICAL CHEMICAL	< 1% REQUIRE RECOM- POUNDING	QUARTERLY " "
PATIENT DOSES MISADMINISTRATION DOCUMENT EACH MISAD RP DOSE TO PREGNANT PT ADVERSE RESPONSE TO RP MEASURED PRIOR TO ADMIN	0 ALL Extreme Conditions < 1 PER 1000 ALL	ANNUALLY " " " "
RADIATION PROTECTION UNTIMELY BIOASSAY ALARA BIOASSAY ALARA DOSIMETRY ROOM MONITOR	NMT 1 PER QUARTER NMT 1 PER YEAR NMT 1 PER YEAR 5000 CPM - 1 PER WEEK	QUARTERLY ANNUALLY ANNUALLY QUARTERLY

SOP RP # 7

RADIATION WASTE MANAGEMENT AND DISPOSAL

1. Records of radiopharmaceuticals transferred to "rad waste" are kept on the radiopharmaceutical stock record sheet.
2. Radioactive waste is separated into two lead-lined containers. One container contains needles, syringes, and other paraphernalia presenting a chemical or bio-hazard to waste handlers. Other radioactive waste is placed in the second container.
3. The waste containers are collected as needed on Wednesday afternoon by Health Physics.

SOP RP # 8

COMPOUNDING RADIOPHARMACEUTICALS

1. Radiolabeling kits will be compounded by a pharmacist who has satisfied the WRAMC Radiation Control Committee that he is competent to compound radiopharmaceuticals and to handle radioactive materials.

2. A record will be maintained of each lot of radiolabeling kits compounded. The record will show the ingredients and lot numbers, method of compounding and quality control test results.

3. The compounding of radiolabeling kits for investigational new drugs will require submission of a research protocol through the Radiation Control Committee and the Clinical Investigation Committee and final review by the OTSG Human Use Review Board as appropriate. Formulations for radiolabeling kits compounded for clinical use at WRAMC will be reviewed by the Human Use Subcommittee of the RCC with a recommendation to the plenary RCC.

4. Quality control procedures may include, as appropriate, testing for radionuclidic purity by spectrum analysis, radiochemical purity by radiochromatography, sterility and nonpyrogenicity by U.S.P. designated tests, particle size by microscopic examination, and pH by pH meter or pH paper.

Product: Tc-99m DMSA (Succimer Kit) by MPI May 1988

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during this preparation.
2. Hold the ampule of DMSA reagent in one hand and open it by applying pressure above the score line on the narrow part of the neck of the ampule.
3. Pull up 2 ml. of DMSA and inject into the shielded mixing vial and withdraw an equal volume of air.
4. Calculate the volume of pertechnetate needed for 20 mCi. of activity. Pull up this volume and if necessary add sufficient normal saline to make 2 ml. of pertechnetate solution. Print the appropriate subtraction and product tickets.
5. Aseptically inject the pertechnetate into the mixing vial and withdraw an equal volume of air. This will give a final volume of 4 ml. Mix the solution thoroughly.
6. Incubate the labeled product at room temperature for at least 10 minutes before dispensing.
7. Check the pH. and record (3.0 - 4.0)
8. Perform ITLC using silica gel (SG) paper with acetone as solvent. Do not use the product if less than 85% label.
9. **DO NOT USE THE PRODUCT MORE THAN TWO HOURS FROM THE TIME OF PREPARATION. REPEAT QC PRIOR TO EACH DOSE WHEN USED OVER 30 MINUTES FROM PREPARATION TIME.**

Jul 1987

TECHNETIUM Tc-99m PENTETATE KIT (MPI DTPA by Medi-Physics)

KIT PREPARATION INSTRUCTIONS

1. Waterproof gloves should be worn during the preparation procedure.
2. Remove the central plastic disc from the MPI DTPA vial and swab the tip of the vial closure with alcohol to sanitize the surface.
3. Place the vial in a suitable radiation shield.
4. Calculate the required amount of TcO_4 (range 15 to 250 mCi.) and draw this amount into a shielded syringe. If required, add sufficient normal saline to give a final volume of 4 ml. Place the syringe in the dose calibrator to measure the radioactivity and print the product ticket.
5. Slowly inject the TcO_4 into the vial which had been placed in the shield.
6. Prior to removing the needle, withdraw an equal volume of air as was injected into the vial.
7. Swirl the contents of the vial for one minute and let stand 1 or 2 minutes.
8. Determine pH of the product. (3.8 - 7.5)
9. Perform ITLC chromatography using Silica Gel (SG) paper with acetone for the solvent. The desired product will stay at the origin. Record the results. Do not use if chromatography indicates more than 10% free TcO_4 is present.
10. Examine vial contents for particulates prior to injection. If cloudy, do not use.
11. Use within eight hours of preparation.

Product: Tc-99m Gluceptate by Mallinckrodt May 1988

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation.
2. Calculate the required amount of TcO_4 to add to the vial. Usually add 80 mCi in a total of 2 ml..
3. Aseptically add the pertechnetate to the shielded reaction vial and remove an equal volume of air to maintain a negative pressure. Swirl for 30 seconds.
4. Assay and print the appropriate dose calibrator tickets to account of TcO_4 . Using proper shielding visually inspect to insure that the solution is clear and free of particulate matter. Do not use if either is present.
5. Check and record the pH. (5.5 - 7)
6. Perform ITLC chromatography using silica gel (SG) paper with acetone as solvent. Do not use if less than a 90% label.
7. Use within eight hours from time of preparation.

JUL 1987

Technetium-99m DISOFENIN (HEPATOLITE BY NEN)

KIT PREPARATION INSTRUCTIONS

1. Assemble the following items prior to preparation: 1 vial of Disofenin, vial shield, 3 ml syringe, normal saline without bacteriostatic agent.
2. Latex gloves should be worn during the preparation.
3. Remove the plastic disc from the vial, swab the top of the vial closure with alcohol and let the alcohol dry.
4. Place the vial in a suitable radiation shield.
5. With a sterile shielded syringe, aseptically obtain not more than 100mCi TcO_4 solution in 2 to 3 ml. THE GOAL IS 20mCi/ml.
6. Aseptically add the TcO_4 to the vial in the lead shield and withdraw an equal amount of air from the vial.
7. Swirl the contents of the vial for 1 minute and let stand 1 to 2 minutes
8. Print appropriate calibrator dose tickets to account for TcO_4 used and to create a product ticket for disofenin.
9. Examine vial contents for particulates prior to injection.
10. Check pH.
11. Perform ITLC chromatography using polysilicic acid gel (SA) paper with 20% saline as the solvent. Record the results. Do not use if less than 90% label.
12. Use within eight (8) hours from the time of preparation.

Product: Tc-99m Macroaggregated Albumin (MAA) (Pulmolite by NEN or MPI MAA by Medi-Physics) May 1988

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation.
2. Calculate the amount of TcO_4 to be added aseptically to the shielded vial. Recommend maximum of 60 mCi. (Usually use 60 mCi. TcO_4 and add sufficient normal saline U.S.P. to make 6 ml total volume. This gives a concentration of about 1 million particles per milliliter.) Draw this amount into the shielded syringe. Place the syringe in the dose calibrator to measure the radioactivity and print product and subtract ticket.
3. Add TcO_4 down the side of the vial and withdraw air from the vial to maintain negative pressure.
4. After addition of the pertechnetate, swirl for a few seconds and allow to stand for five (5) minutes. During the mixing process do not shake the product enough to cause foaming of the solution.
5. Determine the pH of the product. (3.8 - 8.0).
6. Perform ITLC chromatography using Silica Gel (SG) paper with normal saline as solvent. The desired product will stay at the origin. Do not use the product if less than a 90% label.
7. Prior to withdrawing a dose, the contents of the vial should be sufficiently agitated to effect homogenous suspension of the aggregated albumin.
8. Store the vial in the shield in the refrigerator at 2 to 8 degrees C.
9. Discard the solution after six(6) hours from time of preparation.
10. SPECIAL NOTE: DO NOT EXCEED 1 ML VOLUME PER SINGLE PATIENT DOSE.

Product: Tc99m Medronate (Tc-MDP by Medi-Physics Inc) May 88

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation procedure.
2. Remove the central plastic disc from the MPI MDP Kit vial and swab the top of the vial closure with alcohol to sanitize the surface.
3. Place the vial in a suitable radiation shield.
4. Calculate the required amount of TcO_4 (range 15 to 500 mCi.) and draw this amount into a shielded syringe. If required, add sufficient normal saline to give a final volume of 6 ml. Place the syringe in the dose calibrator to measure the radioactivity and print the product ticket.
5. Slowly inject the TcO_4 into the vial which had been placed in the shield.
6. Prior to removing the needle withdraw an equal volume air from the vial.
7. Swirl the contents of the vial for one minute and let stand 1 or 2 minutes.
8. Determine the product pH. (4.0-7.4)
9. Perform ITLC chromatography using Silica Gel (SG) paper with acetone for the solvent. The desired product will stay at the origin. Record the results. Do not use if more than 10% free TcO_4 is present.
10. Examine the vial contents for particulates prior to injection. If cloudy do not use.
11. Use within eight hours of preparation.

Product: Stannous Pyrophosphate for BLOOD POOL IMAGINE
TechnescanPYP by Mallinckrodt. May 1988

KIT PREPARATION INSTRUCTIONS

1. Reconstitute the PYP vial with 2.4 ml. of normal saline
2. Shake the reaction vial sufficiently to bring the lyophilized powder into solution. Allow to stand until all particles are dissolved and in solution. This is usually less than five minutes. The resulting solution should be clear and colorless. If not the vial should not be used.
3. Administer 1 ml. per patient dose by direct venepuncture.
4. Write the time and date of preparation on the vial. Store the vial at room temperature under the laminar flow hood and use within 6 hours after reconstitution.

Product: Technetium 99m pyrophosphate (Technescan PYP by Mallinckrodt) May 1988

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation.
2. Calculate the amount of pertechnetate solution required. (Use 60 mCi. in a total of 2 ml.). Pull up the required activity, make the dilution if needed, and assay the activity. Make the required subtraction and product tickets in the dose calibrator.
3. Aseptically add the pertechnetate solution to the shielded mixing vial and remove an equal volume of air.
4. Mix thoroughly and allow to stand at room temperature for 5 minutes.
5. Check the pH. (4.5 - 6.0)
6. Perform ITLC using silica gel (SG) paper and acetone. If the label is less than 90% do not use the product.
7. Store in the shielded vial at room temperature and use within 6 hours.

Product: Tc-99m Sulfur Colloid (Technecoll by Mallinckrodt) Jul 87

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation procedure
2. Assemble the following items prior to preparation: Technecoll kit from Mallinckrodt which contains a reaction vial (2 ml. of phosphoric acid, 100 mg.) syringe I (1.1 ml with 12 mg. gelatin and 9 mg. sodium chloride also 0.5 ml with 12 mg. sodium thiosulfate, and syringe II (0.6 ml. with 36 mg. gelatin and 9 mg of sodium chloride also 1.0 ml with 544 mg sodium acetate and 5 mg edetate disodium).
3. Start the water bath and heat water to boiling.
4. Calculate the required amount of TcO_4 (range 5mCi to 120 mCi in a maximum of 5 ml.) and draw this amount into the syringe noting the volume used. Place the syringe in the dose calibrator to measure the radioactivity and print product ticket. Note: There is 5 ml in the reaction vial and the 2 syringes.
5. Place the reaction vial into the shield and add the TcO_4 .
6. Immediately add syringe I.
7. Place the reaction vial in the boiling water for 8 minutes.
8. Remove the reaction vial from the water bath (solution will appear milky white) and using a 20 ml. syringe, vent the pressure from the reaction vial.
9. Add syringe II to the reaction vial.
10. Place the reaction vial in boiling water for 2 minutes.
11. Remove the reaction vial from the water bath and cool.
12. Determine the pH of the product (4.0 - 7.5).
13. Perform ITLC using SG paper with normal saline as the solvent. The desired product will stay at the origin. Record the results. Do not use if less than 92% label.
14. Use with 8 hours of preparation.

Product: Tc-99m Sulfur Colloid (TechneColl by Mallinckrodt) Jul 87

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation procedure
2. Assemble the following items prior to preparation: Technecoll kit from Mallinckrodt which contains a reaction vial (2 ml. of phosphoric acid, 100 mg.) syringe I (1.1 ml with 12 mg. gelatin and 9 mg. sodium chloride also 0.5 ml with 12 mg. sodium thiosulfate, and syringe II (0.6 ml. with 36 mg. gelatin and 9 mg of sodium chloride also 1.0 ml with 544 mg sodium acetate and 5 mg edetate disodium).
3. Start the water bath and heat water to boiling.
4. Calculate the required amount of TcO_4 (range 5mCi to 120 mCi in a maximum of 5 ml.) and draw this amount into the syringe noting the volume used. Place the syringe in the dose calibrator to measure the radioactivity and print product ticket. Note: There is 5 ml in the reaction vial and the 2 syringes.
5. Place the reaction vial into the shield and add the TcO_4 .
6. Immediately add syringe I.
7. Place the reaction vial in the boiling water for 8 minutes.
8. Remove the reaction vial from the water bath (solution will appear milky white) and using a 20 ml. syringe, vent the pressure from the reaction vial.
9. Add syringe II to the reaction vial.
10. Place the reaction vial in boiling water for 2 minutes.
11. Remove the reaction vial from the water bath and cool.
12. Determine the pH of the product (4.0 - 7.5).
13. Perform ITLC using SG paper with normal saline as the solvent. The desired product will stay at the origin. Record the results. Do not use if less than 92% label.
14. Use with 8 hours of preparation.

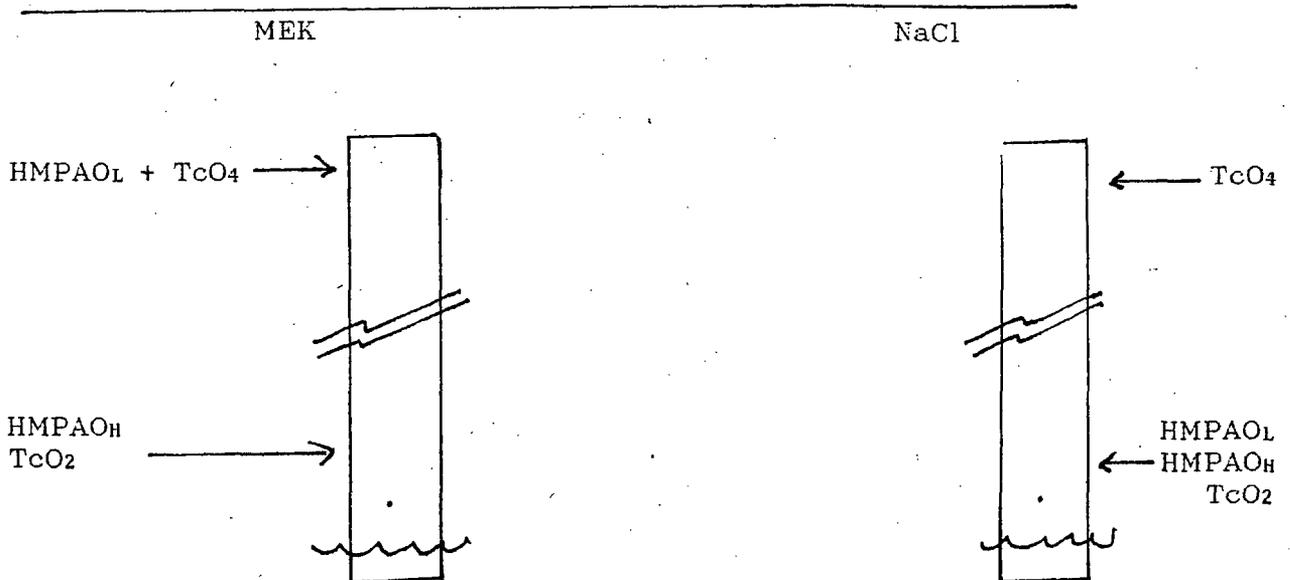
Product: Tc-99m HMPAO (Tc-Ceretec by Amersham Inc.)

KIT PREPARATION INSTRUCTIONS

1. Latex gloves should be worn during the preparation procedure.
2. Remove the center disc from the CERETEC vial and swab with alcohol.
3. Place the vial in a vial shield.
4. Using a 10 ml. shielded syringe prepare 30 mCi of TcO₄ in 5 ml. of normal saline.¹ Place the syringe in the dose calibrator and prepare a product ticket.
5. Inject the activity into the shielded vial and withdraw an equal volume of headspace.
6. Proceed with QC within 5 minutes of product preparation.
7. Use the product within 30 minutes of preparation time.

QUALITY CONTROL OF HMPAO

1. Prepare a vial with 0.5 cm of Methyl Ethyl Ketone (MEK) in it.
2. Use the normal saline QC flask for a second strip.
3. Use SG ITLC paper for both tests.
4. Place a drop of Tc-HMPAO about 1 cm from the bottom of each strip.
5. Allow the strips to run and cut them in half.
6. Lipophilic HMPAO (HMPAO_L) should be at least 80%
The distribution of the substituents are as follows:



$$\text{Percent HMPAO}_L = \% \text{HMPAO}_L + \text{TcO}_4 \text{ (MEK strip)} \\ \text{minus } - \% \text{TcO}_4 \text{ (NaCl strip)}$$

¹ Generator must have been eluted within TWO HOURS of preparation time of HMPAO

Technetium-Mertiatide (MAG3) by Mallinckrodt

KIT PREPARATION INSTRUCTIONS

1. Put on Latex Gloves
2. Swab the top of the vial rubber septum with isopropyl alcohol
3. Prepare a rolling water bath.
4.
 - a. Insert a filtered venting needle into the septum.
 - b. Inject **100 mCi. of TcO₄ in a volume of 4 ml** into the vial.
 - c. After adding the TcO₄ draw 2 ml of air back into the syringe.
5. Withdraw the venting needle and syringe from the vial; invert the vial several times to fully dissolve the powder.
6. Place the reaction vial into the boiling **water bath for 10 minutes.**
7.
 - a. Remove from bath and cool for 10 minutes.
 - b. Inspect the solution for clarity and particulate matter. If it is cloudy or if particulates are present do not use.
8. Label the vial and store at room temperature. Use within six hours.
9. Radiochemical purity must be checked prior to use. If the radiochemical purity is less than 90% do not use.

QUALITY CONTROL

PREPARATION OF SEP-PAK CARTRIDGE

- a. Using a 3 ml syringe, push 1 ml of ethanol thru the cartridge; discard the eluate.
- b. Push 1 ml of 0.001N HCl solution thru the cartridge; discard the eluate.
- c. Push 3 ml of air thru the cartridge; discard the eluate.

QUALITY CONTROL TESTING

- a. Using a 1 cc tuberculin syringe, withdraw a sample of MAG3 and insert 0.1 ml into the longer end of the cartridge.
- b. Slowly push (dropwise) 3 ml of 0.001N HCl solution thru the cartridge; collect the eluate in a test tube and assay. This eluate contains the hydrophilic (TcO₄) forms of radiochemical contaminant.
- c. Slowly push (dropwise) 3 ml of 1:1 ethanol/saline solution thru the cartridge; collect in a test tube and assay. This eluate contains the MAG3.
- d. Place the cartridge in a test tube and assay. This contains reduced-hydrolyzed technetium.

CALCULATIONS

$$\%Tc99m - MAG3 = \frac{(\text{Act of ethanol/saline})}{(\text{total Act})} \times 100$$

$$\%TcO_4 = \frac{(\text{Act of HCl elution})}{(\text{total Act})} \times 100$$

$$\%RH - Tc = \frac{(\text{Act on Cartridge})}{(\text{total Act})} \times 100$$

11 APR 91

TM

KIT PREPARATION INSTRUCTIONS

CARDIOLITE

1. Put on latex gloves
2. Place the reaction vial in a vial shield.
3. Swab the top of the rubber septum with isopropyl alcohol.
4. Using a syringe shield prepare **150 mCi. of TcO₄ in 3 ml of normal saline.**
5. Measure the activity in the syringe and prepare a product ticket.
6. Add the TcO₄ to the reaction vial and withdraw an equal volume headspace.
7. Swirl the vial several times.
8. Place the vial in a boiling water bath for **10 minutes.**
9. Remove the vial from the water bath, shield, and **cool for 15 minutes.**
10. Visually inspect the vial contents. It must be clear and colorless.
11. Use within 6 hours.

12. RADIOCHEMICAL QC

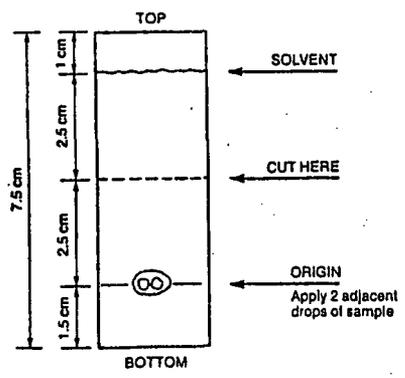
- a. Use Aluminum Oxide coated plastic TLC plate (Baker # 1 B-F)
- b. Apply 1 drop of ethanol 1.5 cm up the strip.
- c. Immediately add 2 drops of cardiolite side by side on the ethanol.
- d. Evaporate to dryness with compressed air line.
- e. Place the strip in a covered TLC tank containing ethanol.
- f. Develop the strip to within 1 cm. of the end of the strip.
- g. Calculate the % Cardiolite as follows:

$$\%Tc99m - Sestamibi = \left(\frac{(uCiTop)}{(uCiTop + Bottom)} \right) \times 100$$

13. Illustration of QC step:

$$\% Tc99m Sestamibi = \frac{\mu Ci \text{ Top Piece}}{\mu Ci \text{ Both Pieces}} \times 100$$

TLC Plate Diagram



JUL 1988

Technetium-99m MEBROFENIN (CHOLETEC BY SQUIBB)

DIRECTIONS FOR MANUFACTURE

1. Assemble the following items prior to preparation: 1 vial of mebrofenin, vial shield, 3 ml syringe, normal saline without bacteriostatic agent.
2. Latex gloves should be worn during the preparation.
3. Remove the plastic disc from the vial, swab the top of the vial closure with alcohol and let the alcohol dry.
4. Place the vial in a suitable radiation shield.
5. With a sterile shielded syringe, aseptically obtain not more than 100mCi TcO₂ solution in 2 to 5 ml. THE GOAL IS 20mCi/ml.
6. Print appropriate calibrator dose tickets to account for TcO₂ used and to create a product ticket for mebrofenin.
7. Aseptically add the TcO₂ to the vial in the lead shield and withdraw an equal amount of air from the vial.
8. Swirl the contents of the vial gently for 1 minute and **LET STAND FOR 15 MINUTES.**
9. Examine vial contents for particulates prior to injection.
10. Check pH. (range is 4.2 TO 5.7)
11. Perform ITLC chromatography using polysilicic acid gel (SA) paper with 20% saline as the solvent. Record the results. Do not use if less than 90% label.
12. **USE WITHIN EIGHTEEN (18) HOURS** from the time of preparation.

SOP RP # 9

Accountability of Sealed source Markers

1. Sealed source markers are used in nuclear medicine to establish anatomical position and size of underlying structures. Therefore, markers are maintained in the nuclear medicine clinic and must be readily available to imaging technologists.
2. In order to maintain control of these markers a log sheet is kept in the radiopharmacy. This log titled "SIGN OUT LOG FOR SEALED POINT & STRING SOURCES" (attached) identifies the technologist, source, and room where the source is used. Proper use of this log will identify the location of all sealed sources and will provide an indication of use for point and string sources.
3. The log described above must be completed in a timely manner. This means all sources must be returned to the radiopharmacy and log entries completed prior to the close of the business day.
4. The technologist who signs out the source is responsible for its return. However, when a source cannot be found the technologist working in the pharmacy or the nuclear pharmacist should be notified immediately.

FVI-PTP

Dr. Bruce H. Mock
Division of Nuclear Medicine
UH-P16
Indiana University Medical Center
926 West Michigan St
Indianapolis, IN 46223

Dear Sir;

We wish to produce ^{123}I -MIBG in-house especially to image children with neuroblastoma. I have read with interest your article in Appl. Radiat. Isot. (39:939-942, 1988). If possible could I obtain a copy of your current labelling method, information regarding your source of unlabeled MIBG and requesting an IND, and suggestions toward avoiding pitfalls with this procedure. Thank you for your time and assistance.

Sincerely,

Patrick J. Peller MD
Nuclear Medicine Fellow

Commander
Chief, Nuclear Medicine
ATTN: MAJ PELLER
Walter Reed AMC
Washington, DC 20307-5001

White Cell Separation and Labeling with In-111 Oxine

ALL PROCEDURES ARE DONE IN

THE VERTICAL HOOD

1. Collect 90ml. of venous blood in two 50-60 ml. syringes containing 1,000 units of heparin and 10 cc of 6% hetastarch (Hespan[®]) in each syringe (Note: If the patient has a WBC count of greater than 8×10^3 , one 50-60 ml. syringe of blood may be drawn.)
2. Place each syringe of blood into the ringstand mount at a 45° angle. Take care not to allow the blood to come into contact with the top of the syringe as additional contamination with RBC can result.
3. Allow the red blood cells to settle to the bottom of the syringe for at least one hour.
4. Remove supernatant (platelets, plasma and WBC's), and centrifuge the supernatant at 450g for five minutes.
5. Pour off the supernatant (platelets, and plasma also called platelet rich plasma or PRP) and save. Resuspend the WBC buttons with 3 ml. of normal saline using a sterile plastic pipette. Combine the two WBC suspensions in one tube and q.s. to 20 ml. with normal saline. Centrifuge at 450g for five minutes.
6. Centrifuge PRP at 1000g for twenty minutes. When finished, the supernatant is platelet poor plasma (PPP).
7. Remove supernatant and discard from step #5. Add 6 ml. of normal saline to the WBC button and resuspend with pipette.
8. Add In-111 Oxine to the WBC suspension and incubate at room temperature for twenty minutes. Gently agitate 3-4 times during incubation. (Note: The desired dose is 500 microcuries so add approximately 600-650 uCi. In-111 Oxine to the WBC suspension).
9. Add PPP to WBC suspension to bring volume up to 15 ml. and centrifuge at 450g for five minutes.
10. Pour off RADIOACTIVE supernatant and save for labeling efficiency. Resuspend WBC button with 8 ml. of fresh PPP. This is the final product for reinjection into the patient.
11. Do labeling yield calculations with labeled WBC and RADIOACTIVE supernatant.

IN-111 LABELED PLATELET PROCEDURE
WRAMC NUCLEAR MEDICINE SERVICE

1. Wipe down the laminar flow hood with alcohol and allow to evaporate. Set up the water bath at 37 C with a lead shield.
2. Put 10 cc of sterile normal saline in a sterile syringe and place int the hood. Draw 8 cc of acid-citrate dextrose solution A (ACD-A) into a 50 cc syringe.
3. Assemble stopcock, 50 cc syringe, one 30 cc syringe, tubing and needle. Withdraw atraumatically and aseptically 7 cc of blood and discard. Withdraw 42 cc of blood into the 50cc syringe, mixing the blood with the anticoagulant.
4. Transfer the blood to a sterile centrifuge tube directly from the syringe. Prepare a balance tube and centrifuge at 225 G (950 rpm) for 15 minutes.
5. Pipette platelet rich plasma (PRP) into a new centrifuge tube. If there is no clear separation between the PRP and red cells, risk using a few red blood cells (RBCs) and perform steps 6 and 7. Add 5 cc ACD-A solution/100 cc of PRP.

Steps 6 and 7 are optional. Perform only if significant RBC contamination of PRP is present.
6. Prepare balance tube and spin PRP at 225 G for 10 minutes.
7. Using a sterile plastic pipette, carefully withdraw the PRP into a new centrifuge tube. Take care not to transfer and RBCs.
8. Prepare the balance tube and centrifuge the PRP at 650 G (1600 rpm) for 10 minutes.
9. Separate the platelet poor plasma (PPP) with a new sterile plastic pipette and store in a sterile centrifuge tube at room temperature.
10. Add 2 cc of saline solution to the pellet. Place the tube aside and let stand at room temperature for 10 minutes. Thereafter, the button may be agitated gently, without frothing, to completely resuspend the cells.
11. When the pellet is completely resuspended, place the tube in the water bath, add 600 mCi of In-111 oxine and incubate at 37 C for an additional 5 minutes.
12. Prepare a balance tube and centrifuge the resuspended platelets at 190 g (850 rpm) for 15 minutes.
13. Decant radioactive supernatant (the empty balance tube may be used). Gently layer 2 cc of saline solution over the pellet

PROCEDURE FOR LABELING HEAT DAMAGED RBCs

1. Inject patient with 15 mg Sn-pyrophosphate
2. Wait 20 minutes
3. Withdraw 10ml. whole blood into a 20 ml. syringe which has been heparinized with with 100 units of sodium heparin.
4. Place 10 ml. of this whole blood into a sterile screw top tube.
5. Spin down the RBCs in a centrifuge for 5 minutes at a fast spin of 1000g (2000 rpm)
6. Using aseptic technique and a long spinal needle attached to a 10 ml. syringe, withdraw the plasma and buffy coat.
7. Add the sodium pertechnetate to the packed cells and vortex gently to resuspend the RBCs. Use 8 to 10 mCi to start and end with a final dose of 3 to 5 mCi
8. Incubate for 5 minutes using proper shielding.
9. Add normal saline to bring volume up to original volume and vortex gently to resuspend the RBCs.
10. Place this solution RBCs, $^{99m}\text{TcO}_4$, at original volume, in sealed screw top tube into a water bath with stirrer at 49 degrees C for 35 minutes. Make sure the level of the blood is below the water level.
11. To assure even heating, every 3 to 5 minutes lift the blood tube out of the water and invert several times and return it to the water bath.
12. Be sure to maintain the temperature below 50 degrees C. Use ice to cool off if necessary.
13. For shielding place a lead sheet around the water bath.
14. After 35 minutes spin down this mixture to wash off any unbound pertechnetate for 5 minutes at 2000 rpm.
15. Withdraw the plasma with a long spinal needle.
16. Add sufficient normal saline to bring back to original volume. Vortex gently to resuspend the RBCs. Use this suspension to reinject into the patient.

Quality control step: withdraw 1 ml. of final solution. Place in a small tube with stopper. Add 2 ml. of normal saline, vortex, spin down 5 minutes at 2000rpm, withdraw supernatant. Measure the supernatant in a dose calibrator; measure packed cells to determine tagging efficiency.

Tagging Efficiency:

$$\frac{A_r}{A_r + A_p} \times 100$$

A_r = activity in QC RBC sample

A_p = activity in QC plasma sample

PROCEDURE FOR LABELING RBC'S FOR GI BLEED

1. Inject patient with 15 mg of Sn-PYP(1 vial). Wait 20 minutes.
2. Withdraw 10 ml whole blood into a syringe heparinized with 100 units heparin.
3. Place 10 ml of this whole blood into a sterile screw top tube.
4. Spin down the RBC's in a centrifuge for 5 minutes at fastest speed. Using a long needle attached to a 10 ml syringe, withdraw plasma and buffy coat layer.
5. Add the TcO4 to the packed cells. For GI bleed using approximately 28 - 30 mCi. to start with. Final dose is 20 mCi. Vortex gently.
6. Incubate for 5 minutes using proper shielding.
7. Add normal saline to bring up to original volume and vortex gently to resuspend the RBC's.
8. Spin for 5 minutes at fastest speed to wash off unbound ^{99m}TcO4.
9. Withdraw plasma using a long spinal needle.
10. Add sufficient normal saline to bring up to original volume and vortex to resuspend the RBC's.
11. Quality Control: Withdraw about 0.5ml of final solution. Place in small tube with stopper and add 1.5ml of normal saline. Vortex then centrifuge for 5 minutes at fastest speed. Withdraw plasma, use for channel # 18, use packed cells for # 19. The desired tag is over 90%.

3/5/07

NUCLEAR MEDICINE TECHNOLOGIST COURSE

TRAINING IN NUCLEAR PHARMACY AT WALTER REED ARMY MEDICAL CENTER

Program Goal: To provide education, training, and laboratory experience in nuclear pharmacy to phase two nuclear medicine technology students.

Facility: The Nuclear Pharmacy is located in the Nuclear Medicine Service at Walter Reed Army Medical Center. The Nuclear Pharmacy provides individualized doses of diagnostic and therapeutic radiopharmaceuticals to the patient population served by the medical center. In a teaching role, the nuclear pharmacist instructs nuclear medicine residents, radiology residents, and nuclear medicine technologists in aspects of radiopharmacy appropriate for each group.

Instructor: TERRY R. MINTON R.Ph. BCNP
Major, United States Army, Medical Service Corp

Course Description:

In order to provide a course of instruction which satisfies both academic curiosity and practical application, the curriculum must accommodate both didactic and laboratory instruction concurrently.

The following outline identifies some of the major subject areas and breaks them into manageable blocks of instruction:

SECTION	TOPIC
1	SAFE USE AND HANDLING OF RADIOACTIVE MATERIALS
2	BASIC RADIATION PHYSICS alpha, beta, gamma radiation dosimetry and radiation dose
3	REGULATORY ASPECTS OF NUCLEAR PHARMACY NRC regulations NRC license example FDA regulations when should an IND be submitted IND form FD 1571 How to write an IND
4	EQUIPMENT NECESSARY IN A NUCLEAR PHARMACY dose calibrators (ion chambers) well counters (scintillation counting)

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-XN (385 Iik)

Pediatric Intravenous Access Policy

TO, Pediatric Clinic
WRAMC

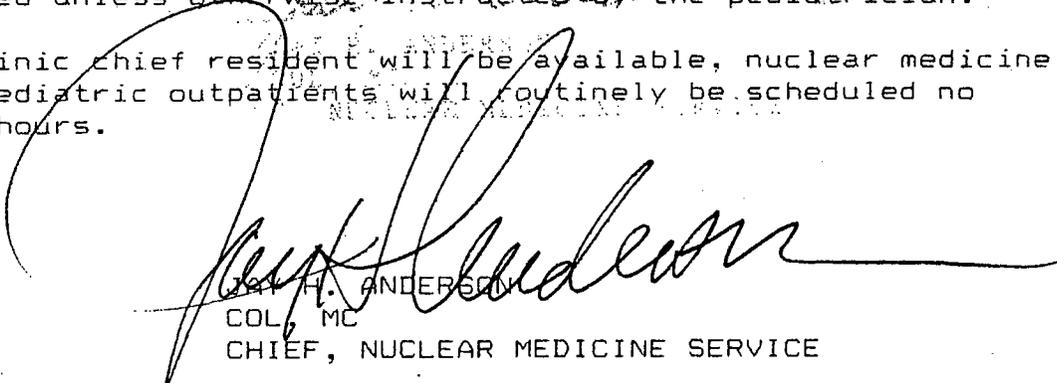
FROM C. Nuc Med Svc
WRAMC

DATE 29 Nov 88

CMT 1

Dr. Anderson/af/6-0176

1. Because of previous problems establishing intravenous access in some pediatric patients, the following policy has been established.
2. For pediatric inpatients, the current policy of their arriving with a running I.V. (not a heparin lock) will continue. After the completion of their injection(s), their I.V. will not be removed.
3. For pediatric outpatients, the nuclear medicine technologists and/or physicians will examine the patient upon arrival and determine if there are any special circumstances to address (e.g. patient with obvious problems with intravenous access due to previous chemotherapy, patient's parents make special request for pediatrician, etc). Under normal circumstances, the nuclear medicine service will make an attempt at intravenous access (usually two attempts). If this is unsuccessful or if special circumstances exist, the nuclear medicine service will call the pediatric clinic [phone numbers: 6-1101/1103/1112], and contact the clinic chief resident (a roster will be provided by the Pediatric Department so that Nuclear Medicine will have the name of the designated physician). If the clinic chief resident is unavailable, the pediatric clinic head nurse is an alternate point-of-contact.
4. The patient (with parents and/or attendants) will go to the pediatric clinic and a running I.V. (not a heparin lock) will be started by the pediatric clinic chief resident, head nurse, or their designee. This will normally be done and the patient returned to the Nuclear Medicine Clinic within 45 minutes of the call from Nuclear Medicine. If a delay (<60 mins) in establishing intravenous access is anticipated by the pediatric clinic, their representative will call the nuclear medicine clinic [phone numbers: 6-0168/0169/0170] so that consideration for special arrangements may be made. After the patient's need for intravenous access is over, the I.V. will be discontinued unless otherwise instructed by the pediatrician.
5. So that the clinic chief resident will be available, nuclear medicine appointments for pediatric outpatients will routinely be scheduled no earlier than 1000 hours.


J. H. ANDERSON
COL, MC
CHIEF, NUCLEAR MEDICINE SERVICE

HSHL-XN (340a)

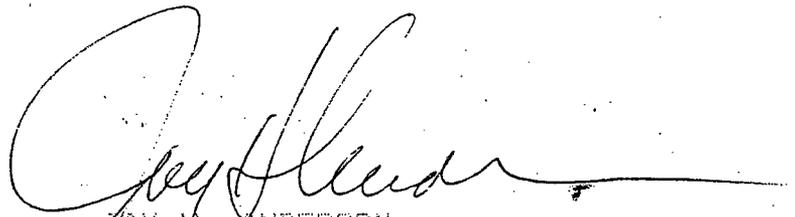
October 2, 1990

MEMORANDUM FOR: HEALTH PHYSICS OFFICER

SUBJECT: Receipt of Radiopharmaceuticals

The following personnel are hereby authorized to sign for radiopharmaceuticals:

MAJ TERRY MINTON
SSG ROBERT WARREN
SSG WAYNE DUNKLE
SGT ANGEL CUEVAS



JAY H. ANDERSON
COL, MC
Chief, Nuclear Med Svc

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-XN

Use of Syringe Shields in Nuclear Medicine

TO

FROM

DATE

CMT 1

All Nuclear Medicine
Personnel

C, Nuc Med Svc

9 Jan 89
Dr. Anderson/af/6 0176

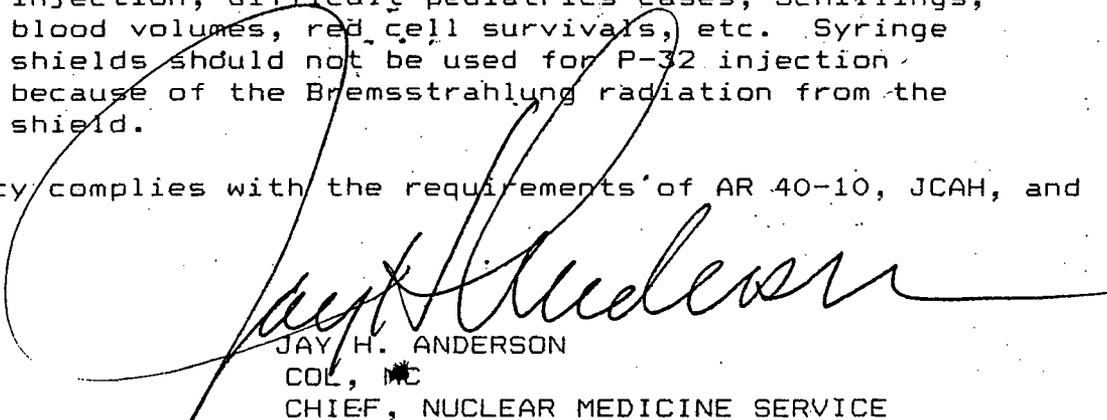
1. The following is the policy for the use of syringe shields in the Nuclear Medicine Clinic for the administration of radio-pharmaceuticals.

- a. Syringe shields are required for all administrations of radionuclides with exception noted above. Shields will be placed on syringes by the radiopharmacy. The syringe and shields will be placed inside the lead carrying pig. All other standard procedures are unchanged.

2. Exceptions are as noted below:

- a. If the syringe shields will compromise patient care, then the syringe shield may be removed. This decision lies within the physicians, radio-pharmacist, chief technologist, or imaging supervisor.
- b. Syringe shields are not required for a cisternogram, MAAAP study, direct jugular vein injection, difficult pediatrics cases, Schillings, blood volumes, red cell survivals, etc. Syringe shields should not be used for P-32 injection because of the Bremsstrahlung radiation from the shield.

3. This policy complies with the requirements of AR 40-10, JCAH, and NRC.


JAY H. ANDERSON
COL, MC
CHIEF, NUCLEAR MEDICINE SERVICE

SUBJECT 131I Treatment
TO: Endocrine staff

In order to allay what recently has been increasing confusion regarding patients who seemingly appearing unannounced to the Nuclear Medicine Service for treatment the following guidelines are being implemented.

1. Endocrine physician communicates personally with a Nuclear medicine service physician

- A. This is imperative so that points of contact and continuity for the treatment of this patient is established on both services.
- B. Joint discussion of treatment goals and projected dosage
- C. One physician from each service to serve as points of contact and who will manage the therapy.

2. Nuclear medicine worksheet generated (sample attached)

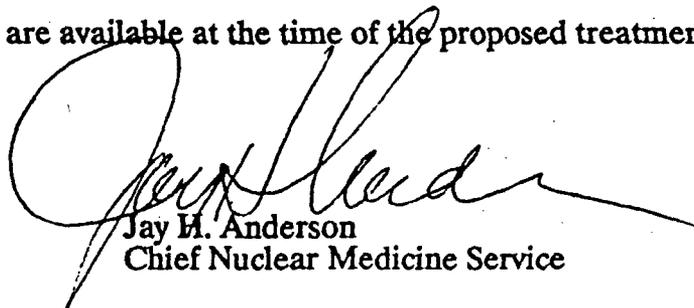
- A. This worksheet serves three purposes
 - 1. A check list of the necessary information necessary prior to treatment, particularly high dose inpatient treatment
 - 2. Provides a planning and scheduling document to insure that the Nuclear medicine service is prepared for the patient when he or she arrives
 - 3. A reference source for both the Endocrine and Nuclear medicine services
 - a. Documents the communication referred to in paragraph (1 above)
 - b. In the event the Nuclear medicine physician who initially discussed the case is not available will allow another physician to intelligently take over the treatment.
 - 4. These while be kept in a notebook in the reading room until the treatment has been completed

3. Pharmacy notified by only by NM physician

- A. Date of treatment and projected dose
- B. To insure that the necessary quantity of I131 is available when the patient presents him or herself for treatment.
- C. Endocrine and Nuclear Medicine physicians names attached to request to further ensure continuity of management.

4. Pharmacy arranges with Health Physics Office for inpatient Rx

- A. To insure that the room(s) are available at the time of the proposed treatment.



Jay H. Anderson
Chief Nuclear Medicine Service

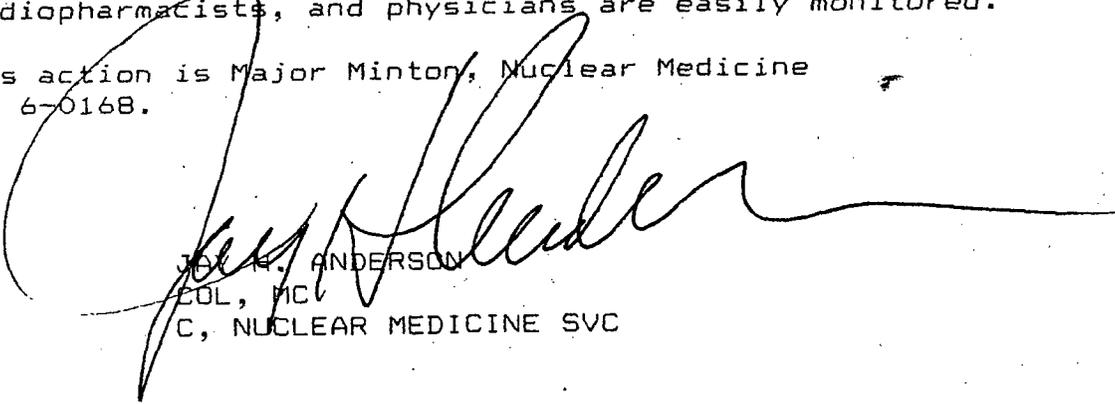
DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL	SUBJECT		
HSHL-XN	Radioisotopes Therapies		
TO Nuc Med Personnel WRAMC	FROM C, Nuc Med Svc WRAMC	DATE 9 Jan 89 Dr. Anderson/af/60176	CMT 1

1. Orders for therapeutic radiopharmaceutical doses must be initiated by the Nuclear Medicine physicians. All radioisotopic therapies, regardless of route of administration, will be performed by a physician. It is within the discretion of the physician to allow a technician or radiopharmacist to administer the dose under his immediate supervision, when the supervising physician believes (1) that in the interest of the patient, the administration would be better performed by the technician or radiopharmacist (i.e. intravenous), or (2) that it is in the interest of the physician to have a technician perform the administration in order to distribute occupational radiation exposure. The frequency of dosing by technicians, radiopharmacists, and physicians are easily monitored.

2. POC for this action is Major Minton, Nuclear Medicine Radiopharmacist 6-0168.


JOE G. ANDERSON
COL, MC
C, NUCLEAR MEDICINE SVC

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-XN

Nuclear Medicine Policy for TRH Studies

TO All Nuclear Medicine Personnel

FROM

Nuclear Medicine Service

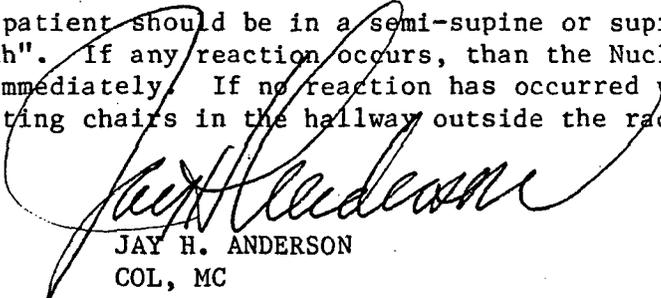
DATE

9 JAN 89

CMT 1

Dr. Anderson/af/60176

1. The Thyrotropin Releasing Hormone (TRH) stimulation test should be ordered on the Nuclear Medicine consult form or the standard consultation form 513. This must be signed by a physician and acts as the official request and prescription. (Technologist or Physician Assistant signatures must be co-signed.)
2. The consult does not have to be approved (or "OD") by a Nuclear Medicine physician.
3. Prior to the administration of the TRH, the Nuclear Medicine technologist will take the blood pressure in the semi-supine position. If the diastolic blood pressure is equal to or greater than 105, than the study is terminated. For these cases, the Nuclear Medicine technologist should write on the consult, that "the diastotic blood pressure was greater than or equal to 105 mm Hg. Because this is a relative contraindication, the test was cancelled. If any questions, please call laboratory. In all cases, the Nuclear Medicine technologist should write the blood pressure on the consult. The Nuclear Medicine technologist should also ask the patient if he/she has had any previous reaction to a TRH test. If the patient has had a reaction, then the technologist should contact the O.D. physician for a decision regarding whether to proceed or not.
4. See the Nuclear Medicine Clinic signature sheet in the Laboratory Book #1 for the list of physicians and technologists authorized to inject TRH.
5. For the TRH injection, the patient should be in a semi-supine or supine position in the appropriate blood drawing "couch". If any reaction occurs, than the Nuclear Medicine O.D. physician should be contacted immediately. If no reaction has occurred within five minutes, the patient may wait in the waiting chairs in the hallway outside the radioimmunoassay lab.


JAY H. ANDERSON

COL, MC

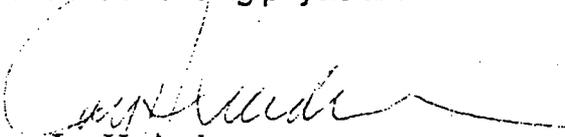
C, NUCLEAR MEDICINE SVC

WALTER REED ARMY MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
NUCLEAR MEDICINE SERVICE

1 October, 1990

STERILE PRECAUTIONS FOR VENIPUNCTURES

1. Disposable latex gloves will be worn by all personnel performing venipunctures.
2. Wash hands and change gloves each time before collecting blood from and/or injecting a radiopharmaceutical into a patient.
3. All new needles and syringes used on the Nuclear Medicine Service are sterile. When the protecting cover is removed from a new needle, the needle must not touch anything until it punctures the skin. If it should touch anything, discard it and use a new needle. Never use a needle with a broken seal.
4. Alcohol pads are used to cleanse the site of puncture. Alcohol itself may destroy some of the bacteria present, but it is the rubbing that is important. Rubbing with the pad removes many skin organisms. Do not touch the venipuncture site after cleansing.
5. If you did not enter a vein at one puncture site, replace the needle with a new one before attempting a second puncture. The first needle may have become contaminated and should not be used again.
6. Under no circumstances will a Hickman or Swan-Ganz catheter be entered without prior approval and knowledge of the patient's attending physician.



Jay H. Anderson
COL, MC
Chief, Nuclear Medicine Service

99Mo ASSAY PROCEDURE

SEP 90 14

1. PURPOSE: The purpose of the SOP is to describe the procedure to assay a low level contamination of Molybdenum-99 in solution with 99m Technetium.
2. DESCRIPTION: The assay kit consists of a lead canister of the proper dimension to accept a 30 milliliter vial and an insertion holder. The characteristics of the canister are such that the 99m Tc reading is reduced to less than 10^{-6} of the unshielded reading while the 99Mo reading is reduced by approximately 65%.

The NRC allowable level of 99Mo contamination in Technetium is NMT one part per thousand (NMT 1 uCi 99Mo/mCi 99mTc) nor more than 5 uCi 99Mo per patient dose.

The U.S.P. XX allowable limit 99Mo is not greater than 0.15 uCi per mCi of Technetium 99m per administered dose of the injection, at the time of administration.

NOTE: Because of the differences in half-lives of these two isotopes, the concentration of 99Mo will increase with time.

3. RESPONSIBILITIES: The Mo assay will be performed on every generator elution. In no case will 99mTc eluate be used if either limit of 99Mo contamination is exceeded. Furthermore, any 99Mo contamination level of 0.1 uCi 99Mo/mCi 99mTc will be reported immediately to the radiopharmacist or Chief of the Service for appropriate guidance.

4. ASSAY PROCEDURE: CRC-30 Dose Calibrators

- a. Be sure there are no other isotopes near the calibrator.
- b. Insert the CAPMAC pig (purple and yellow one) into the CAPMAC assembly. Lower the complete assembly into the well of the dose calibrator.
- c. Push "Mo Assay" + "Activity" buttons.
- d. Set Patient Dose wheels to 0000.
- e. Dial in sample # _____. Dial in sample volume.
- f. Turn key until EEEEE indicates data entry.
- g. Open the canister by holding the handle and rotating the level counterclockwise until it stops. Move the lever to the raised vertical position.
- h. Push "CAPMAC" and "Activity" buttons. Patient dose, sample #, and sample volume remain the same as in steps d, e, & f. Calibrator will display activity in mCi and then flash ----/mCi, ----/mCi.
- i. Turn the key to enter EEEE and push print (front side of dose ticket).
- j. Turn dose ticket over and enter (feed) into printer.
- k. Press "Mo Assay" and "Activity" and print.

HSHL-XN

September 1986

7/17

88 T9

SEN

90 PLM

NUCLEAR PHARMACY "ON-CALL" PROCEDURE

Before milking the generator, check if there is enough activity left in Elution #1, #2, or #3.

If Yes: Proceed with making the product desired.

If No: Milk the #2 generator and put it in the #2 pig. (Use 10 ml elution vial.)

A single dose ticket is needed for the generator.

1. Insert the CAPMAC pig (purple and yellow one) into the CAPMAC assembly. Lower the complete assembly into the well of the dose calibrator.

2. Set the SAMPLE VOLUME and the SAMPLE NUMBER on the appropriate thumbwheel switches. Sample volume on 10.00 and the sample number on 02. The PATIENT DOSE thumbwheel should be set on all zeroes.

3. Press the button labeled MO ASSAY and the button labeled ACT.

NOTE: The blinking display indicates that the operation is incomplete.

4. Rotate the ENTER KEY to register the activity.

5. Open the canister by holding the handle and rotating the lever counterclockwise until it stops. Move the lever to the raised vertical position.

6. Press the button labeled 99m Tc CAP MAC.

7. If no reading is observed, the canister is not open. Repeat step #5.

8. Rotate the ENTER KEY to register the reading. The display will stop blinking after the key is turned. Print this information on the front side of the ticket. Turn the ticket over to print on the back side.

9. Close the canister by lowering the lever to the horizontal position. Lock the canister to the base by holding the handle, pressing down and rotating the lever clockwise until it stops.

10. Remove the complete assembly from the well and remove the CAPMAC PIG from the holder.

11. Press the MO ASSAY button and the ACT button (the Patient Dose, Sample Number and the Sample Volume Buttons remain the same as in step #2).

12. PRINT on the back side of the ticket. This will give the Moly Assay.

SEP 90 94

PREPARING A PRODUCT: Example 99m Tc - MAA

- 1) Draw up in a syringe the 99m TcO₄ activity needed to prepare the product.
Prepare a subtract stock ticket (Page 1 of ticket) (NO CARBONS)

Press: and buttons

Set: Patient Dose dial in the mCi of 99mTc displayed on the calibrator, which is to be subtracted from elution vial #1, #2, or #3. sample number 01, 02, 03 depending upon the elution used. sample volume doesn't matter

TURN THE KEY to subtract this volume displayed on the calibrator from the appropriate elution. Make sure that E E E E's flash on the display to indicate entry of data.

Print this ticket will be the subtract stock ticket. This goes with the generator ticket.

- 2) Create a Product Ticket.
Place the completed product vial in the well of the calibrator in the plastic dipper.

To Transfer Molly Assay:

Press: button and ALL OTHER BUTTONS OUT

Set: Patient Dose depending on the elution # 00.01, 00.02, 00.03. Sample Number 08. Sample Volume dial in the total volume of final product

From Elution # used to Sample # of product prepared with total volume (ml) of product.

TURN THE KEY to transfer the MOLLY Assay. Make sure the E E E E's flash on the display to indicate entry of data.

Press: and buttons

The calibrator will flash ---/ mci, ----/ mCi, ----/ mCi to indicate it is waiting for the second entry.

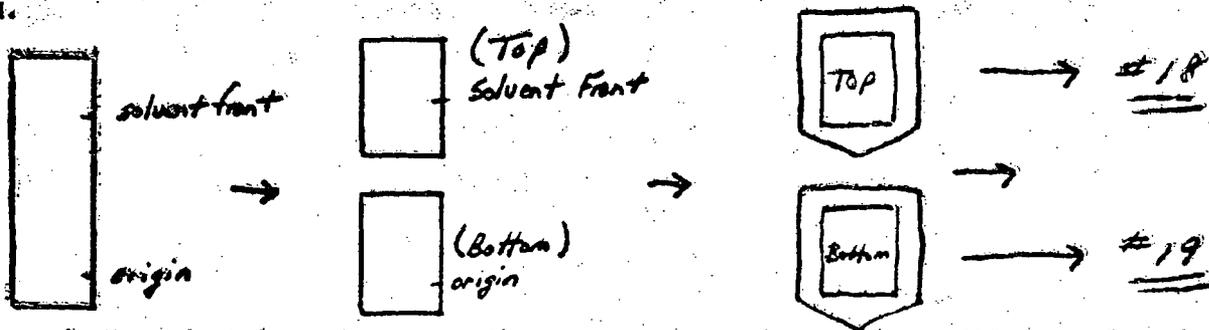
TURN THE KEY to complete the entry. Make sure E E E E's flash on display .

Print on page 2 of the ticket (no carbons) This is now your PRODUCT TICKET
Note: Please print the results of Quality Control chromatography on the reverse of this ticket.

FM SEP 90

NUCLEAR PHARMACY CHROMATOGRAPHY PROCEDURE USING CRC-30

1. Spot a small drop of product on ITLC (Instant thin layer chromatography paper). Place in developing tank containing appropriate solvent. Let solvent migrate two-thirds the way up the strip. Using tongs remove strip from tank, mark solvent front, using scissors cut strip one half way between origin of spot and solvent front. Place in chromatography strip holder tube marked for top and bottom.



2. Place product ticket in printer so that chromatography results will be printed on back of ticket.

3. Press: 99mTc & Q.C. buttons.

4. Dial setup:

00.08

19

doesn't matter

Patient Dose

Sample Number

Volume

use last two digits to indicate product number
ie: 00.08 for Tc MAA

Place Chromatography tube with bottom strip in the dose calibrator well, let the reading stabilize then Turn Key to enter. Note : Be sure you see EEEE displayed to indicate that the information was entered.

5. Remove the Bottom tube and replace with the Top tube, let the reading stabilize, change the sample number setting to 18, turn key to enter data.

6. Print ticket.

7. Note: Display on ticket
 19 indicates % tagged product
 18 indicates % free TcO₄⁻

PROCEDURE

NUCLEAR MEDICINE SERVICE DEPARTMENT OF RADIOLOGY WALTER REED ARMY MEDICAL CENTER

1. **PURPOSE:** The procedure describes the MANDATORY process by which a patient will be identified prior to injection of a radiopharmaceutical for diagnostic imaging purposes.

2. **METHOD OF IDENTIFICATION OF PATIENT:** All patients will be required to produce one of three forms of identification:

- a. Inpatients - hospital identification bracelet
- b. Outpatients - blue clinic card or
- military/dependent identification card

The name and social security number on the identification must be matched against the name and social security number on the consult and printed dose ticket.

3. **METHOD OF RADIOPHARMACEUTICAL IDENTIFICATION:** Each and every radiopharmaceutical is assigned a unique radiopharmacy number. This number is stamped on the patient's consult, the pharmacy dose ticket, and the individual dose. Once a positive patient identification is made, the radiopharmacy number must be verified on both of the dosing documents and on the syringe. In addition, the color coded pharmaceutical sticker on the syringe should be matched against the radiopharmaceutical ordered on the consult and printed on the dose ticket.

4. Once steps 1-3 above have been completed, the radiopharmaceutical may be injected. The technologist injecting/dosing the patient must sign both the consult and dose ticket and indicate the time of dose administration.

5. **PROCEDURE FOR PATIENT IDENTIFICATION FOR ADMINISTRATION OF IN VITRO LABELLED HUMAN BLOOD PRODUCTS:** Steps 1-4 must be completed and verified by two people, the radiopharmacist who labelled the blood product and the technologist administering the dose. Both individuals will sign off on the documents listed in step 4.

6. Failure to follow the procedure rigorously could result in an adverse impact on patient care and as such any lapse in this procedure will result in administrative corrective measures.

NUCLEAR PHARMACY DAILY CHECKLIST

JAN 87

1. Prepare elution & compounding vials & paperwork for the next day.
2. Integrate the 2nd copy of the dose tickets into the numerical prescription file.
3. Make up QC syringes for cameras.
4. Make up QC syringes for daily products
5. Close out products at the end of the day and do work count.
6. Check Radiopharmacy & RIA Log Book-make sure all entries have been completed.
7. Make up Chromotography Strips to have some on hand.
8. Survey work surfaces-record results in Survey Log Bk.
9. Restock needles, syringes, alcohol pads, etc, in RP preparation area.
10. Empty rad waste-deliver to 2nd floor dock to Health Physics Wednesday afternoons 1330-1430 hours.
11. Daily calibrator check.
12. Order supplies.
13. Prepare 10 Saline and 10 Heparin Syringes
14. Inventory R.P. and Kits on Mondays of stock level and expiration dates.
15. Check and record temperature of refers. in Nuclear Pharmacy.

NUCLEAR MEDICINE SERVICE
WALTER REED ARMY MEDICAL CENTER

PEDIATRIC DOSES

I. Radionuclide Studies

$$\text{PEDIATRIC DOSE} = \frac{\text{Surface Area of Child's Body}}{\text{Surface Area of Adult's Body}} \times \text{Adult Dose}$$

The body surface area may be estimated from the body weight to within $\pm 8\%$ s.d.:

$$\text{Body Surface area} = \frac{(\text{Body Weight (Kg)})^{0.7}}{11}$$

Schedule for calculation of pediatric doses:

Weight lb	Weight Kg	Fraction of Adult Dose	DOSE 20 mCi	DOSE 15 mCi	DOSE 10 mCi	DOSE 5 mCi
2.2	1 Kg	0.05	1.0	0.8	0.5	0.3
4.4	2 Kg	0.09	1.7	1.3	0.9	0.4
6.6	3 Kg	0.12	2.3	1.7	1.2	0.6
8.8	4 Kg	0.14	2.8	2.1	1.4	0.7
11	5 Kg	0.16	3.3	2.5	1.6	0.8
13.2	6 Kg	0.19	3.7	2.8	1.9	0.9
15.4	7 Kg	0.21	4.2	3.1	2.1	1.0
17.6	8 Kg	0.23	4.6	3.4	2.3	1.1
19.8	9 Kg	0.25	5.0	3.7	2.5	1.2
22	10 Kg	0.27	5.4	4.0	2.7	1.3
26	12 Kg	0.30	6.1	4.6	3.0	1.5
31	14 Kg	0.34	6.8	5.1	3.4	1.7
35	16 Kg	0.37	7.4	5.6	3.7	1.9
40	18 Kg	0.40	8.1	6.1	4.0	2.0
44	20 Kg	0.44	8.7	6.5	4.4	2.2
48	22 Kg	0.47	9.3	7.0	4.7	2.3
53	24 Kg	0.49	9.9	7.4	4.9	2.5
57	26 Kg	0.52	10.5	7.8	5.2	2.6
62	28 Kg	0.55	11.0	8.3	5.5	2.8
66	30 Kg	0.58	11.6	8.7	5.8	2.9
70	32 Kg	0.61	12.1	9.1	6.1	3.0
75	34 Kg	0.63	12.6	9.5	6.3	3.2
79	36 Kg	0.66	13.1	9.9	6.6	3.3
84	38 Kg	0.68	13.6	10.2	6.8	3.4
88	40 Kg	0.71	14.1	10.6	7.1	3.5
92	42 Kg	0.73	14.6	11.0	7.3	3.7
97	44 Kg	0.76	15.1	11.3	7.6	3.8
101	46 Kg	0.78	15.6	11.7	7.8	3.9
106	48 Kg	0.80	16.1	12.1	8.0	4.0
110	50 Kg	0.83	16.5	12.4	8.3	4.1
114	52 Kg	0.85	17.0	12.7	8.5	4.2
119	54 Kg	0.87	17.5	13.1	8.7	4.4
123	56 Kg	0.90	17.9	13.4	9.0	4.5
128	58 Kg	0.92	18.3	13.8	9.2	4.6
132	60 Kg	0.94	18.8	14.0	9.4	4.7
136	62 Kg	0.96	19.2	14.4	9.6	4.8
141	64 Kg	0.98	19.6	14.7	9.8	4.9
143	65 Kg	1.00	20	15	10	5.0

Adapted from: A.E. JAMES, H.N. WAGNER, & R.E. COOKE, Pediatric Nuclear Medicine, Saunders Company, 1974, p.92.

II. Potassium Perchlorate and other Non-radioactive medications use: YOUNG'S RULE

$$\text{PEDIATRIC DOSE} = \frac{\text{AGE}}{\text{AGE} + 12} \times \text{ADULT DOSE}$$

MINIMUM/MAXIMUM PEDIATRIC DOSES*

EXAM	ISOTOPE	DOSE uCi/kg	MIN	MAX
Brain	TcDTPA	250 uCi/kg	2 mCi	20 mCi.
Cisternogram	In-111 DTPA	15 uCi./kg	100 uCi.s	500 uCi.
Lung	133-Xe gas	100 uCi/kg	3 mCi.	20 mCi.
Cardiovascular	Muga TcO4	250 uCi/kg	3 mCi.	20 mCi.
Thyroid Scan	TcO4	150 uCi/kg	2 mCi.	10 mCi.
Liver/Spleen	Tc-sulfur col	50 uCi/kg	500 uCi.	5 mCi.
Hepatobiliary	Tc-Choletec	50 uCi/kg	1 mCi.	3 mCi.
Bone Scan	Tc MDP	250 uCi/kg	2 mCi.	20 mCi.
Kidney	Tc DTPA	150 uCi/kg	2 mCi	15 mCi.
	Tc DMSA	50 uCi/kg	300 uCi.	4 mCi.
Gallium-67	Ga Citr	50 uCi/kg	500 uCi.	3 mCi.
GE Reflux/ Aspiration	Tc-sulfur Col		---1000 uCi---	
<u>GI Bleed</u>	Tc-RBC	250 uCi/kg	2 mCi.	20 mCi.
	Tc-Sulf Col	100 uCi/kg	1 mCi.	5 mCi.
Cystogram	tc-DTPA or Tc-SC		1 mCi	
Meckles	TcO4	150 uCi/kg	2 mCi.	10 mCi.
Dacrocystogram	TcDTPA		100 uCi	
Testicular	TcO4	250 uCi/kg	2 mCi.	10 mCi.

*To age 18 or 120 lb.

Patients over 120 lb will receive an adult dose of technetium labeled radiopharmaceuticals. Radiopharmaceuticals labeled with other isotopes will be dosed BY WEIGHT.

Nuclear Medicine Procedures 4/17/91

NUCLEAR MEDICINE PROCEDURES							
CODE	STUDY NAME	AGENT 1	DOSE 1	ROUTE	AGENT 2	DOSE 2	ROUTE 2
Endocrine System 001-099		AGENT	DOSE	ROUTE	AGENT	DOSE	ROUTE
001	THYROID SCAN PERTECHNATE	TcO4	10 mCi	IV			
010	THYROID SCAN I123	I123	100 uCi	PO			
020	THYROID SCAN I131	I131	30 uCi	PO			
030	THYROID NECK AND CHEST I131	Dosed under #031					
031	THYROID NECK AND CHEST DOSING	I131	10 mCi				
032	THYROID DOSIMETRY	I131	5 mCi	PO			
034	THYROID NECK AND CHEST TI201	TI201	2.2 mCi	IV			
039	THYROID UPTAKE DOSING	I131	7uCi	PO			
040	THYROID UPTAKE	Dosed under #039					
041	PERCHLORATE DISCHARGE	I131	10 uCi	PO	KClO4	1 gm	PO
043	SUBSTERNAL GOITRE SCAN	I131	30 Uci	PO			
070	I131 Rx HYPERTHYROIDISM	I131	Varied				
072	I131 Rx METASTATIC THYROID CA	I131	Varied				
080	ADRENAL SCAN NP-59	Dosed under #081					
081	NP-59 DOSING	NP59	1-2 mCi				
085	ADRENAL MEDULLARY SCAN MIBG	Dosed under #086					
086	MIBG DOSING	MIBG	500 uCi				
090	PARATHYROID SCAN	TI201	2 mCi	IV	TcO4	2 MCi	IV
Hematopoietic System 100-173		AGENT	DOSE		AGENT	DOSE	
121	LYMPHSCINTOGRAPHY	TcSbSc	1.0 mCi x 2				
160	P32 INTRAVENOUS RX		Varied				
161	P32 INTRAPERITONEAL RX		Varied				
171	BLOOD AND/OR PLASMA VOLUME	Cr51	35 uCi	IV	I125HSA	10 uCi	IV

Nuclear Medicine Procedures 4/17/91

	Gastrointestinal System 200-299	AGENT	DOSE		AGENT	DOSE	
200	LIVER SPLEEN SCAN (PLANAR)	TcSc	5 mCi	IV			
203	HEMANGIOMA LIVER (TOMO)	SnPYP	15 mg	IV	TcO4	20 mCi	
210	HEPATOBIILIARY STUDY	TcChole	5 mCi	IV			
211	HEPATOBIILIARY IMAGING (PEDS-ATRESIA)	TcChole	5 mCi	IV			
213	GALLBLADDER EJECTION FRACTION	TcChole	5 mCi	IV	CCK	0.1 mg/kg	IV
220	SALIVARY GLAND IMAGING (PAROTID)	TcO4	5 mCi	IV			
230	MECKEL'S SCAN	TcO4	10 mCi	IV	Cimetadine		
240	GI BLEEDING STUDY (RBC)	SnPyp	15 mg	IV	TcO4	20 mCi	IV
241	GI BLEEDING STUDY (SULFUR COLLOID)	TcSc	10 mCi	IV			
250	ESOPHAGEAL CLEARANCE (CORNFLAKES)	TcDTPA	500 uCi	PO			
251	ESOPHAGEAL REFLUX STUDY	TcSc	1 mCi	PO			
252	MILK ASPIRATATION STUDY	TcSc	1 mCi	PO			
261	GASTRIC EMPTYING STUDY (SCAMBLED EGGS)	TcSc	500 uCi	PO			
280	SHILLING TEST	Co57B12	0.5 uCi	PO			

Nuclear Medicine Procedures 4/17/91

Musculo-skeletal System 300-399		AGENT	DOSE		AGENT	DOSE	
300	BONE SCAN (WHOLE BODY PLANAR)	TcMDP	20 mCi	IV			
310	BONE SCAN (PAIN PELVIS/LOWER EXTREMITY)	TcMDP	20 mCi	IV			
395	JOINT IMAGING	TcO4	10 mCi	IV			
Cardiovascular System 400-499		AGENT	DOSE		AGENT	DOSE	
400	REST MUGA	SnPyp	7.5 mg	IV	TcO4	25 mCi	IV
405	EXERCISE MUGA	SnPyp	7.5 mg	IV	TcO4	30 MCI	IV
410	REST FIRST PASS STUDY (RV EF)	SnPyp	7.5 mg	IV	TcO4	25 mCi	IV
415	EXERCISE FIRST PASS STUDY	SnPyp	7.5 mg	IV	TcO4	30 MCI	IV
420	REST THALLIUM (PLANAR)	Tl201	2.2 mCi	IV			
425	STRESS THALLIUM (PLANAR)	Tl201	3.0 mCi	IV	Tl201	1.0 MCI	IV
426	STRESS THALLIUM (TOMO)	Tl201	3.0 mCi	IV	Tl201	1.0 MCI	IV
430	CARDIAC SHUNT EVALUATION	TcO4	10 mCi	Jugular			
435	INFARCT AVID SCAN (PLANAR)	TcPYP	20 mCi	IV			
440	VENOGRAPHY	TcSe	7.5 mCi	IV	TcDTPA	7.5 MCI	IV
Respiratory System 500-599		AGENT	DOSE		AGENT	DOSE	
500	V/Q SCAN	Xe133	15-25mCi	Inhale	TcMAA	5 mCi	IV
510	PERFUSION SCAN ONLY	TcMAA	5 mCi	IV			
580	PREOPERATIVE LUNG EVALUATION	TcMAA	5 mCi	IV			
Central Nervous System 600-699		AGENT	DOSE		AGENT	DOSE	
600	BRAIN IMAGING (PLANAR)	TcDTPA	15 mCi	IV			
610	CISTERNOGRAPHY	In111DPTA	500 uCi	IT			
622	VENTRICULO-PERITIONEAL SHUNT	TcDTPA	10 uCi	Reservoir			
630	CSF LEAKAGE (PLEDGET STUDY)	In111DPTA	500 uCi	IT			
641	I123 IMP (TOMO)	I123IMP	3-5 MCI	IV			
644	HMPAO (TOMO)	TcHMPAO	20 mCi	IV			

Nuclear Medicine Procedures 4/17/91

Genitourinary System 700-799		AGENT	DOSE		AGENT	DOSE	
700	RENAL TX EVALUATION WITH HIPURAN	TcDTPA	15 mCi	IV	I131HIP	150 uCi	IV
710	RENAL IMAGING (DTPA)	TcDTPA	15 mCi	IV			
711	POST CAPTOPRIL RENAL IMAGING (DTPA)	TcDTPA	15 mCi	IV			
720	RENAL IMAGING (DMSA)	TcDMSA	4 mCi	IV			
721	RENAL IMAGING (DMSA -- TOMO)	TcDMSA	4 mCi	IV			
725	RENAL IMAGING (HIPURAN)	I131HIP	300 uCi	IV			
726	POST CAPTOPRIL RENAL IMAGING (HIPURAN)	I131HIP	300 uCi	IV			
730	LASIX RENAL SCAN	TcDTPA	15 mCi	IV			
750	VOIDING CYSTOGRAM	TcDTPA	1 mCi	Bladder			
760	TESTICULAR SCAN	TcO4	10 mCi	IV			
Miscellaneous 900-999		AGENT	DOSE		AGENT	DOSE	
900	GALLIUM SCAN	Dosed under #901					
901	GALLIUM DOSING	Ga67	10 mCi	IV			
910	WBC SCAN	In111WBC	500 uCi	IV			

RECEIPT OF RADIOPHARMACEUTICALS

Applies to packages received from the Roche or Syncor radiopharmacies

I. SURVEY OF PACKAGE:

1. Put on Latex Gloves
2. Inspect the package for signs of damage. If damage is noted, stop and call the RPO.
3. Measure the package at 1 meter and at the package surface. If it is greater than expected stop and notify the RPO.

LABEL REQUIRED	LIMITS OF RADIATION EXPOSURE	
	TI ¹	AT PACKAGE SURFACE
White-I	NA	≤ 0.5 mR/hr
Yellow-II	< 1 mR/hr	> 0.5 mR/hr but ≤ 50 mR/hr
Yellow-III	> 1 mR/hr	> 50 mR/hr

No package shall exceed 200 mR/hr at the surface nor 10 mR/hr at 1 meter.

II. WIPE TEST THE PACKAGE:

1. Wipe the exterior of the package with an absorbant paper. A minimum of 4X4 inch area must be wiped.
2. Place the wipe in the Victoreen Wipe Test Counter (model 05-578). Press the "count" button. A green light indicates the wipe has less activity than the allowable threshold activity. If a red fail light is displayed proceed to section III, ANALYSIS OF WIPE TEST RESULTS
3. Wipe the surface of the radiopharmaceutical containers as in step 1 above. Count the wipe as in step 2 above².

Remove the radiopharmaceuticals from the package and store them in their designated areas. Make sure the packing slip agrees with drugs received. Enter the survey and wipe test in the pharmacy computer system for each radiopharmaceutical received. When several radiopharmaceuticals are received in the same package the wipe test and survey results will be the same for each radiopharmaceutical.

¹ Transportation Index (TI) is the radiation level in mR/hr at 1 meter from the package surface

² NRC does not require wipe test of the interior of the package. However, it is good practice to determine if there is removable contamination on the products we receive.

III. ANALYSIS OF WIPE TEST RESULTS:

When a wipe test fails to pass as indicated by the wipe test counter use the following procedure to ascertain the isotope and activity.

1. When a wipe test has failed the red LED light will be glowing and a value in kilo-disintegrations per minute (KDPM) will be displayed.

2. Remove the wipe from the wipe test counter and place it in a glycine paper pouch. Place the pouch in the well counter attached to the thyroid probe in the thyroid room (7A08). Run the "calibration" procedure to identify the isotope by its emission peak(s).

3. The wipe test counter is set up to read out directly for Technetium-99m in KDPM. For other isotopes it is necessary to convert the displayed KDPM into actual KDPM by using a conversion factor for the isotope. Conversion factors (C.F.) for commonly used isotopes at WRAMC nuclear medicine are as follows:

ISOTOPE	C.F.
I-131	0.13
Tl-201	1.30
Ga-67	1.50
In-111	0.08

The threshold activity for all radiopharmaceuticals received at WRAMC is 2000 dpm/ 100 cm² removable contamination. The threshold activities for the above listed isotopes are:

I-131	15.3 KDPM
Tl-201	1.5
Ga-67	1.3
In-111	25.0

Press the "threshold" button and enter the isotope threshold value using the "change digit" keys. Press the "activity key" to put into memory. Count the wipe in the usual manner described in section II. A green PASS means the contamination is less than 2000 DPM for the isotope being counted. A FAIL displays a KDPM value which must be multiplied by the C.F. to get the actual KDPM value for the wipe. For wipes which result in a FAIL indication notify the RPO.

FIRE PLAN FOR BUILDING #2 (NEW MEDICAL TREATMENT FACILITY)

FIRE EMERGENCY PROCEDURE:

Procedures must include the following order of importance:

a. Rescue persons in immediate danger.

b. Report the fire immediately.

(1) Make the fire known to everyone in the immediate area.

(2) Call the Fire Department. Use the building fire alarm system. The fire alarm system will call the Fire Department and also let everyone in the building know there is a fire. The Fire Department should also be called by telephone (dial 63317).

(3) To sound the fire alarm in the building, locate one of the RED, metal boxes mounted on the wall in the hallway and near each stairway door and pull down on the handle on the front of the box.

c. Confine the fire. Close the door to the room where the fire is located.

d. Secure the area.

(1) Close all the doors in the area.

(2) Turn OFF oxygen and gas valves.

(3) Do not allow anyone to go back into the area.

e. Fight the fire with the proper extinguisher. Use extinguishers if fire is small, for example: when the fire is just getting started, a mattress is smoldering and there is just a little smoke, or a fire in a trash can. If the room is full of smoke, GET OUT and CLOSE THE DOOR.

f. Control employees, visitors and patients. There will be visitors, patients and employees from other areas of the building who will not know what to do when a fire takes place. Keep them calm and tell them how to leave the area.

g. Meet the Fire Department and direct them to the fire.

h. Evacuation.

(1) Remove patients from rooms to the hallway. From there go down the hallway until you go through the double doors dividing the hallway. Make sure these doors are closed and remain closed after everyone has been removed from area of the fire.

11 APR 88

WALTER REED ARMY MEDICAL CENTER
NUCLEAR MEDICINE SERVICE

PERSONNEL POLICY NO: HSHL-XN-1

SUPERSEDES: ALL OTHERS

SUBJECT: INFECTION CONTROL POLICY

1. PURPOSE: To establish guidelines for the Nuclear Medicine Service employees to minimize the risk of infection due to exposure, and prevent the transmission of infective agents to patients, co-workers and the community.

2. GENERAL:

- a. A system of barrier protection (i.e. rubber gloves, gown etc) must be used to prevent skin and mucous membrane exposure to biological fluids and/or wounds etc.
- b. All skin defects (cuts, abrasions etc) must be covered with protective bandages.
- c. Meticulous handwashing, even when gloves are used. If hands or other body surfaces become contaminated, they should be washed immediately with soap and water or Hibeclens (each room has been supplied with adequate amounts of Hibeclens).
- d. Gloves must be worn for contact with any patients' blood or body fluids. This includes routine phlebotomy, injecting radiopharmaceuticals, etc. Body fluids includes drainage of any type, saliva, sputum, urine etc.
- e. Gloves must be removed prior to the use of telephone, CRT's or other clean surfaces. Clean, fresh gloves may be worn.
- f. Consuming beverages or food, smoking and applying cosmetics are not permitted in the clinical work areas of Nuclear Medicine.
- g. All accidents should be reported immediately to your supervisor or Chief technologist. Appropriate forms will be filled out (see PPN HSHL-XN-2).
- h. Food and beverages will be stored in the refrigerator marked "Staff Only" in the conference room.

HSHL-NIC

11 JAN 89

MEMORANDUM FOR: All Generators of Infectious Waste at WRAMC

SUBJECT: Proper Packaging of Infectious Waste

1. All generators of infectious waste are reminded that proper packaging procedures must be followed if the waste is to be contained from the site of origin to final disposal.

2. The Infection Control Committee and the Preventive Medicine Service offer the following guidelines for packaging of infectious waste at WRAMC.

a. All infectious waste will either be in standard boxes or in plastic needle and syringe containers.

b. Boxes should be sealed with masking or strapping tape on both top and bottom middle seams and on all four open side seams.

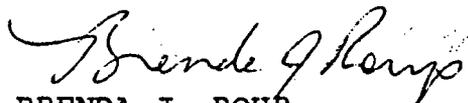
c. The LARGE needle and syringe containers must have the lids taped securely with either masking or strapping tape, since these large lids have a tendency to come open when the containers are transported.

d. The small needle and syringe containers can simply be securely closed. A "snap" is generally heard when they are closed correctly.

e. Each container or box must be labeled with WRAMC FORM 801, BURN TAG. The tag must contain the point of origin and a point of contact.

3. Housekeeping personnel are currently being trained not to pick up the boxes and containers if they are not properly sealed and labeled. Additionally, Infection Control personnel will be conducting unannounced environmental rounds with housekeeping supervisors to check on packaging procedures.

4. If there are any questions or comments, please call Infection Control at 64350/51.



BRENDA J. ROUP
LTC, AN
Chief, Infection Control

Distribution "A"

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μ Ci of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

** Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ± 5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ± 5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

DOSE CALIBRATOR CONSTANCY

1. A quality control test of the dose calibrator is required each day prior to its use to prepare radiopharmaceutical doses.
2. Use the computer generated "DOSE CALIBRATOR CONSTANCY" form to record the observations. Use the ^{137}Cs and ^{57}Co dose calibrator sources in the pharmacy and test each button normally used. For ^{137}Cs , ^{111}In , and ^{57}Co use the following "calibration" dial settings and the "other" button:

^{137}Cs	220
^{111}In	303
^{57}Co	112

For the "moly assay" button use the displayed reading times 3.5 for the observed activity.

3. In addition to the blanks provided on the form perform the following tests and adjust the dose calibrator as needed.

ZERO - With chamber empty, zero the chamber. (voltage offset control)

BACKGROUND - Acceptable range is +/- 0.1 uCi. Record this reading.

TEST - Checks the level of the high voltage battery (normal 151-152)

PART 35 • HUMAN USES OF BYPRODUCT MATERIAL

and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.33 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible

relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record as directed in § 35.33(d). The licensee shall also notify the referring physician and the appropriate NRC Office specified in § 30.6 of this part in writing on Form NRC-_____ within 15 days if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

(d) Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

(e) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Part 30 and §§ 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the

preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this

* The staff is developing this form and will make it available before the effective date of this regulation. A notice of its availability will be published in the Federal Register.

authorize departures from the manufacturer's instructions for eluting the generator or preparing the therapy kit.

Section 30.34 Terms and Conditions of Licenses

Commercial nuclear pharmacies are licensed pursuant to 10 CFR part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." These licensees are required by a license condition similar to § 35.200(b) to elute generators and prepare reagent kits in accordance with the manufacturer's instructions. The NRC believes that authorized users obtaining radiopharmaceuticals from commercial nuclear pharmacy licensees should not be bound by this restriction in the commercial nuclear pharmacy license. Therefore, the NRC is amending 10 CFR 30.34, "Terms and Conditions of Licenses," to permit actions within the scope of those permitted by the new § 35.200(c). For situations not within the scope of the amended § 30.34, a commercial nuclear pharmacy licensee may file an application to have its license amended to permit specific departures from the manufacturer's instructions for identified products.

Under the interim rule, commercial nuclear pharmacy licensees would no longer be bound by the requirement in their licenses to follow the manufacturer's instructions for a radiopharmaceutical for which the FDA has approved an NDA if they have a written directive made by an authorized user physician directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. As in § 35.200(c), there is an exception to the requirement for a written directive before preparing the radiopharmaceutical in an emergency situation if an authorized user physician determines that a delay in obtaining the written directive would jeopardize the patient's health. In this case, the commercial nuclear pharmacy licensee shall obtain the written directive from the authorized user physician within 3 working days of the prescribed departure. The directive must contain information regarding the emergency and all other required information. Licensees shall keep those records in an auditable form and available for inspection for 5 years.

These amendments to § 30.34 take precedence over the restrictive conditions (i.e., on eluting generators and preparing reagent kits for NDA radiopharmaceuticals) in the licenses of commercial nuclear pharmacies. Therefore, those parts of the license conditions no longer apply during the 3-year period when the interim rule is in effect. This interim rule does not address departures from IND generator elution instructions or IND protocol directions for reagent kit preparation, thus licensees shall continue to follow the IND instructions.

Continuing Applicability of Regulatory Requirements

The NRC notes that this interim rule does not relieve licensees from the requirements to comply with other applicable NRC, FDA, and other Federal or State regulations or NRC orders or license conditions concerning possession or use of byproduct material for medical use or other purposes as specified in 10 CFR parts 30, 32, 33, and 35. Moreover, if a radioactive biologic receives a product license approval (PLA), this interim rule does not authorize departures from the manufacturer's instructions for preparing the biologic. In addition, if a kit or generator for a radiopharmaceutical for therapy receives an approved NDA, this interim rule does not authorize departures from the manufacturer's instructions for eluting the generator or preparing the therapy kit. Neither of these approvals exists at this time and neither is authorized by current regulations.

Radiation Safety Responsibilities of Medical Use Licensees

NRC medical use licensees are required by § 35.21 to appoint a Radiation Safety Officer (RSO) responsible for implementing the licensee's radiation safety program. The licensee is required, through the RSO, to ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Nothing in this rulemaking relieves the licensee from complying with the requirements of § 35.21.

In accordance with 10 CFR 35.22, NRC medical institution licensees are required to establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. The duties of the RSC are specified in § 35.22(b) and include reviews, on the basis of safety, of numerous aspects of a licensee's use of byproduct material. Nothing in this rulemaking relieves the licensee from

complying with the requirements of § 35.22.

VI. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51 that these amendments are not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. This interim rule amends NRC regulations to permit licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions if those persons have a written directive made by an authorized user physician that requests a specific departure for a particular patient, or patients, or for a radiopharmaceutical. This directive must provide the specific nature of the departure, a precise description of the departure, and the reasons why the departure from the manufacturer's instructions would obtain medical results, diagnostic or therapeutic, not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The amendment does not address departures from IND generator elution instructions or IND protocol directions for reagent kit preparation. The NRC is also modifying its regulations to permit, if certain requirements are met, the therapeutic use of radiopharmaceuticals without following the package instructions regarding indications and method of administration. The interim rule does not affect the exemption in 10 CFR part 20 for the intentional exposure of patients to radiation for the purpose of medical diagnosis and therapy.

Although the rule may cause some patients to be exposed to higher or lower levels of radiation than otherwise expected, those exposures would be given to obtain medical results not otherwise attainable or to reduce other risks to the patient. It should be noted that current requirements do not limit the radiation dose prescribed by the authorized user physician for either diagnosis or therapy. The amendments would not relieve licensees from meeting the requirements in 10 CFR parts 20 and 35 that restrict radiation exposure to medical care personnel in the restricted area or to the general public in the unrestricted area, or radioactive effluent releases. It is expected that there would be no

MEMORANDUM FOR: Nuclear Medicine Service

5 Feb 91

Subject: Departure from FDA radiopharmaceutical kit preparation and use guidelines to satisfy NRC interim 10 CFR 35.200 requirements.

1. Radiopharmaceuticals will be used in pediatric patients if, in the opinion of the prescribing physician, the benefit of the procedure outweighs the risks from exposure to ionizing radiation. The radiopharmaceutical dose will be determined by the current clinic guideline for pediatric doses.
2. Technetium radiopharmaceutical kits (DTPA, MDP, Sulfur Colloid) prepared in the nuclear pharmacy may be used for an eight hour period from preparation time provided they meet USP radiochemical standards. Tc-DMSA may be used for two hours after preparation provided radiochemical QC is determined to meet USP standards for each dose prepared. The nuclear pharmacist will be responsible for periodically monitoring the radiochemical stability of radiopharmaceutical kits after normal expiration. Preparation of additional kits when the current drug remains useful is an unnecessary expense and exposes personnel to additional radiation.



JAY H. ANDERSON
COL, MC
Chief, Nuclear Medicine Svc

APPENDIX N

Model Procedure for Area Surveys (See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Stochastic Dose Rate Surveys

i. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
- d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

! Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

i. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

APPLICATION FOR AUTHORIZATION TO USE RADIOACTIVE MATERIAL - HUMAN USE

1. APPLICATION FOR: (Check and/or complete as appropriate)	<input type="checkbox"/> NEW AUTHORIZATION	<input checked="" type="checkbox"/> RENEWAL OF AUTHORIZATION NUMBER	<input type="checkbox"/> AMENDMENT TO AUTHORIZATION NUMBER
		H 274	

APPLICANT'S NAME (Principal User): <u>Andersen, Jay H. COL</u> NEUTZE, JANET A. M.D., MAJ, MC	3. APPLICANT'S MAILING ADDRESS (Include Organization): Asst Chief, Nuclear Medicine Svc HSHL-XN, WRAMC
TELEPHONE NUMBER 576-0168	

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

4. List all CO-WORKERS w/grade & org. Attach comp WRAMC Form 1643 if not on file with WRAMC HPO. Abreu, Sue, CPT, MC Norby, Eric, MAJ, MC <u>Van Nostrand, Douglas LTC</u> <u>Neutze, JANET A. MAJ</u> <u>Utz, Joseph, LTC, MC</u>	5. List all TRAINEES w/grade & org. Ghaed, Victor, COL. MC Kark, John A. COL, MC Radiology Residents Student Technicians Nagorski, Leonard, MAJ, MC Oswald, Stephen, MAJ, MC Fortenbery, Edwin, CPT, MC Jeinek, James, CPT, MC	6. List all TECHNICIANS who will work with RAD MAT under this Authorization. See attached sheet
--	--	--

7. LOCATION WHERE MATERIAL WILL BE USED:

Ex 2 **APPROVED BY** *Ex 2*

RCC *Ex 2* **10 FEB 1988**

10. Radioisotope	11. Chemical and/or Physical Form	12. Possession Limit	13. Excluded or Sealed Source
See attached listing of by product material, chemical and/or physical form possession limit date 26 Nov 84.			
OLD HUMAN USE AUTHORIZATION			
			21 JAN 1988
			This Application is given interim approval until the next meeting of the RCC which is scheduled for FEB 1988

15. CERTIFICATE

(This item must be completed by applicant)

I certify compliance with the provisions of AR 40-7 (Clinical Use of Investigational Drugs), AR 70-25 (Use of Volunteers as Subjects of Research), AR 40-37 (Radioisotope License Program-Human Use), All applicable WRAMC Regulations, and that all information contained herein, including any supplements attached hereto, is true and correct.

MEMORANDUM FOR: WRAMC Nuclear Medicine Professional and Technical Staff

SUBJECT: Time Period for cessation of Breast-Feeding after a Nuclear Medicine Procedure

International Council on Radiation Protection (ICRP) publication 52, Protection of the Patient in Nuclear Medicine, makes specific suggestions on the time period a nursing mother should cease breast-feeding after a nuclear medicine procedure. Three groups of radiopharmaceuticals used at WRAMC have been identified with different "stop nursing" times:

GROUP I - Stop nursing for at least 3 weeks¹

All ^{131}I - and ^{125}I -
radiopharmaceuticals except hippuran,

^{67}Ga , ^{201}Tl

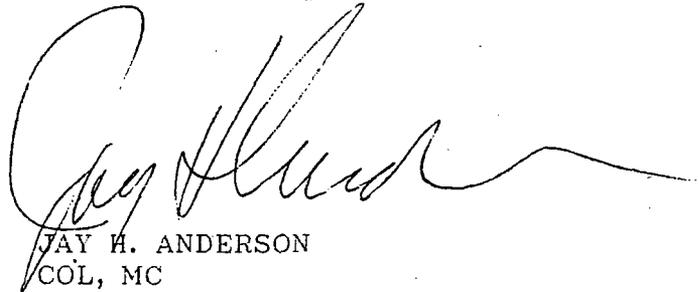
GROUP II - Stop nursing for at least 12 hours

^{131}I , ^{125}I , and ^{123}I hippuran

All $^{99\text{m}}\text{Tc}$ -compounds except
labelled -RBCs, -phosphonates, and
-DTPA

GROUP III - Stop nursing for at least 4 hours

All $^{99\text{m}}\text{Tc}$ -RBCs, -phosphonates, and
-DTPA



JAY H. ANDERSON
COL, MC

Chief, Nuclear Medicine Service

¹ This implies normally that nursing will have to be discontinued.

WALTER REED ARMY MEDICAL CENTER
NUCLEAR MEDICINE SERVICE

TO ALL FEMALE PATIENTS BETWEEN 12 AND 55 YEARS OF AGE:

Patient's Name (Please print)

Sponsor's Social Security #

Study Date:

Like many other x-ray procedures, Nuclear Medicine scans are not usually performed if you have a reasonable chance of being pregnant. To determine this, please answer the following questions.

YES

NO

- | | | |
|-------|-------|--|
| _____ | _____ | Are you breast feeding? |
| _____ | _____ | Are you post-menopausal (mensutral cycle)? |
| _____ | _____ | Was your last menses (period) within the last 10 days? |
| _____ | _____ | Have you had a tubal ligation (tubes tied)? |
| _____ | _____ | Have you had a hysterectomy (uterus removed)? |
| _____ | _____ | Are you on birth control pills (BCP)? |
| _____ | _____ | Do you used an IUD (intra-urine device)? |
| _____ | _____ | Are you pregnant? |

Patient's Signature

or

Physician Signature

After consultation with this patient, it is my impression that the likelihood of her being pregnant is small (less than or equal to the likelihood with BCPS/IUD) and does not warrant cancelling or rescheduling the study.

Physician's signature

I-131 CHEST SURVEY
PATIENT INFORMATION SHEET

Your Endocrinology or Nuclear Medicine physician has requested an I-131 chest survey which is to localize any remaining thyroid tissue in your neck or chest. This study requires significant preparation and time on your part which should be carefully adhered to for maximum results. This is described below and the total preparation time, scanning time, and if necessary, I-131 treatment time is two months.

1. Your I-131 chest survey is scheduled for _____ and if necessary, an I-131 treatment will be performed on the subsequent Monday of _____.
2. Your thyroid hormone (for example Synthroid or desicated thyroid USP) should be discontinued 5 weeks prior to the above date for your I-131 chest survey.
3. Upon discontinuation of the above medication, you should begin Cytomel 25 mcg orally twice daily. Your physician should give you a prescription for such and this should be discontinued 2 weeks prior to the above date for your I-131 chest survey. You will be on no thyroid medication for the last 2 weeks.
4. You should not have any x-ray contrast study (if in doubt ask physician), seafood, iodine containing drugs (SSKI, Lugol's Betadine) for two months prior to study. Your physician may want you to adhere to a low iodine diet during this time and this should be discussed with him.
5. Report to the Nuclear Medicine Clinic at the above appointed time which is usually Monday to have thyroid blood tests drawn and for the oral administration of radioactive iodine. This will take approximately 30 minutes to 1 hour.
6. Report to the Nuclear Medicine Clinic on (Date/Time) _____ for images of your chest and thyroid. This will require at least 1/2 to 3/4 of a day.
7. On the 6th day after you have received the radioactive iodine, report between 0900 and 1400 to the nursing station of the Kyle Metabolic Unit (Ward 47, 4th floor) for final thyroid blood tests.
8. A decision regarding radioactive iodine treatment will be made usually by the following Monday after the images and blood tests are obtained.
 - a. If treatment is not elected, you will have completed your evaluation. Follow-up I-131 chest survey in 6 months to 1 year should be scheduled before you go home. You should not wait to schedule this! You may begin your thyroid hormone according to the schedule recommended by your primary physician.
 - b. If low dose treatment is recommended, and if you elect such, then you will be treated at a time convenient to you, the Endocrinology staff and the Nuclear Medicine radiopharmacist. You may begin thyroid medication after the treatment according to the schedule recommended by your primary physician. Usually this is 2-3 days after treatment and may include a brief initial interval on Cytomel as well as thyroxine. In addition, you will be scheduled for a scan 7-10 days after the treatment dose.

Updated September 1985

I-131 DOSIMETRY/CHEST SURVEY/TREATMENT PROCEDURE

Your Endocrinologist and Nuclear Medicine physicians have requested a procedure to determine the "treatment dose" of radioactive iodine you should take to treat your thyroid cancer. The procedure estimates the largest dose we can give to destroy thyroid cancer without significantly increasing the risk of radioactive iodine to you. Because the procedure is very important for you and because it is time consuming and complex, it is very important that the procedure be performed as ideally as possible. This requires significant work on your part to assure the best results possible.

A schedule of events is listed on the attached sheet. The column on the left is what you need to do and the column on the right is what the technicians will do. Dates are all determined based on the day you receive your "small tracer dose" of radioactive iodine which is _____.

Updated September 1985

DATE	DAY	PATIENT	TECHNICIAN
	1+	Return to Nuclear Medicine Clinic at approximately 1000. Give technician urine bottle and pick up new urine bottle. You will have blood drawn and measurements of radioactivity in your body taken. Total time in the Nuclear Medicine Clinic should be less than one hour.	<ol style="list-style-type: none">1. Collect urine bottle #0, label as #0, and store in pharmacy.2. Give new urine bottle #1.3. Draw 4 cc of heparinized blood. Label tube with patient's name, date, and time and give to lab.
	2+	Same as day 1+.	Same as day 1+.
	3+	Same as day 1+, however, images of lung and body will be obtained. Anticipate approximately 3 hours.	Same as day 1+, however, perform I-131 chest survey as in routine procedure book.
	4+	Same as day 1+.	Same as day 1+.
	5+	Same as day 1+.	Same as day 1+.
	6+	Same as day 1+.	Same as day 1+.
	7+	Same as day 1+.	<ol style="list-style-type: none">1. Same as day 1+.2. Draw PBI-131. Label patient's name, date, and give to lab.

DATE DAY PATIENT TECHNICIAN

10+ After computer calculations Schedule patient at reception desk
to of data, a dose will be for a post-treatment I-131 chest
13+ determined and ordered. This survey 7-10 days after treatment.
time delay is necessary to Notify patient of time and day.
count blood and urine
specimens, calculate data,
make decisions, and order
the radioactive iodine. You
will then be admitted to the
hospital. Please read the
attached booklet "The Patient's
Guide to Iodine I-131 Therapy"

explaining treatment in the
hospital. Arrive in the AM of
the day of admission and plan on
staying 5 days. On the day of
discharge from the hospital,
begin regular diet and thyroid
hormone unless notified other-
wise. Thyroid hormone should be
started according to one of the
following schedules (circled),
unless notified otherwise:

REGULAR REPLACEMENT: Begin
taking the same dose each day
that you were on prior to this
study.

SLOW REPLACEMENT: Begin taking
.05 mg/day for 7 days. Then
increase dose to .10 mg/day for
7 more days. Continue to increase
dose each week by .05 mg/day until
you are taking the same dose you
were on prior to this study.

17+ The technician/physician will
to notify you of a time to return
23+ to the Nuclear Medicine Clinic
for further lung and body images
between the above days. Antici-
pate 2-3 hours. No injec-
tion or blood drawing will be done.

Updated September 1985

DATE	DAY	PATIENT	TECHNICIAN
-35		Stop thyroid medication you are on and begin Cytomel one tablet 2 times each day. The prescription is attached. For any other medication, check with your physician. Begin low iodine diet. See booklet of low iodine diet.	
-14		Stop Cytomel.	
-6 or -7		Come to Nuclear Medicine Clinic between 0800-1500 and have blood drawn.	Draw T3RU, T4, TSH and T3RIA (Lab slip attached)

Dose		<p>Come to Nuclear Medicine Clinic by 1000 to receive tracer dose of radioactive iodine. Plan to spend from 1000-1200 and from 1400 to 1600 in the Nuclear Medicine Clinic. You may eat a light breakfast.</p> <p>After you receive your dose, you must save <u>ALL</u> your urine. You will be given urine bottles to collect urine in, and you should collect all urine for each 24 hour period from noon until noon of the next day in one bottle. At noon the next day, you will turn in the urine bottle. Then begin collecting urine in the new bottle.</p> <p>In addition, you will be scheduled for a "post I-131 treatment" scan 7-10 days after treatment dose. This is highly recommended as it allows a chest survey to be performed after a large dose of radioactive iodine. One may be able to detect other remaining thyroid tissue which had not previously been noted.</p>	<ol style="list-style-type: none">1. Prepare I-131 radiopharmaceutical standard. See full procedure.2. Determine and record exact dose.3. Dose patient with 5 mCi noting exact time of administration. Give patient urine bottle labeled with name, #, date, and time.4. Perform uptake probe counts of whole body at time 0. See full procedure.5. Give 2 packages of lemon drops or equivalent to patient.6. 4 hours after dose, draw 5 ml of heparinized blood. Label tube with patient name, number, date, time and give to lab.7. Perform uptake probe counts at 4 hrs.

NECK AND CHEST SURVEY CHECKLIST

PRIOR TO DOSING THE PATIENT WITH I-131, THE FOLLOWING CHECKLIST
MUST BE COMPLETED.

_____ 1. Lab slip(s) prepared for the following
studies.

TSH
THYROGLOBULIN
BHCG
CBC

_____ 2. Patient to lab for blood drawing

_____ 3. Pathologist's report in patient's film
jacket verifying patient's malignancy and/or
extent of previous thyroid surgery. If uncertain,
check with O.D. physician.

_____ Technician initials completing checklist

_____ O.D. physician initials

IMPORTANT INFORMATION

DO NOT REFRIGERATE MPI KIDNEY REAGENT

(Stannous Dimercaptosuccinic acid)

Ampuls should be checked for discoloration and presence of particulate matter prior to labeling with sodium pertechnetate Tc 99m. Do not use if the solution is discolored or contains particulates.

Small quantities of hydrogen sulfide may be produced from the aqueous dimercaptosuccinic acid (DMSA), resulting in an unpleasant odor when the ampul is opened. These small quantities of hydrogen sulfide have not been associated with adverse reactions or alterations in the in vivo distribution of the labeled reagent.

For further information, or to notify Medi-Physics, Inc. of a discolored ampul or one containing particulates, use our toll-free numbers:

OUTSIDE CALIFORNIA: (800) 227-0483

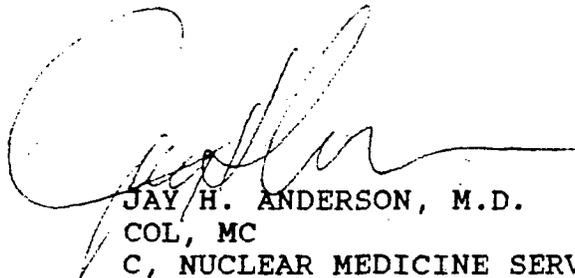
IN CALIFORNIA: (800) 772-2446

HSHL-XN (340a)

2 October 1990

SUBJECT: Procedure Manual

The procedures and related information contained in this manual have been reviewed and are found to be accurate and current as of 1 October 1990.



JAY H. ANDERSON, M.D.
COL, MC
C, NUCLEAR MEDICINE SERVICE

HSHL-XN (340a)

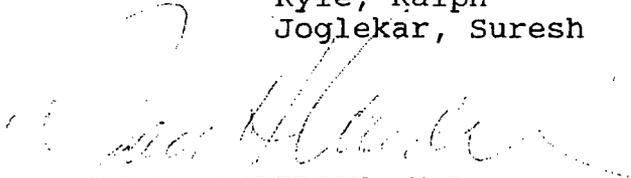
4 APR 91

SUBJECT: Injection of Radiopharmaceuticals

1. The following technologists are authorized to inject patients with radiopharmaceutical materials.

Alugbuo, Charles
Bautista, Simon
Cranston, Toni
Cain, Cheryl
Cross, Alberto
Cuevas, Angel
Dixon, Claudette
Dunkle, Wayne
Ferguson, Patricia
Goldsmith, Donald
Greenwood, Valerie
Hall, Sharon

Kennedy, Kevin
Lima-Brunn, Edith
Medina, Angel
Mullaney, John
Roberts, Harriet
Rumingan, Wilfredo
Warren, Robert
Peyton, Elaine
Turner, Lynette
Sandfer, David
Kyle, Ralph
Joglekar, Suresh


JAY H. ANDERSON, M.D.
COL. MC
C, NUCLEAR MEDICINE SVC

Nuclear Medicine Service

Chief, Nuclear Medicine Service

Dr. Jay H. Anderson

Technical Director

Mr. Kyle

NCOIC

SFC Bautista

Physician Staff

Pharmacy Section

Maj Minton

SPC Mullaney

Student Coord

Student Techs

Admin Staff

IMAGING SECTION

SSG Dunkle

Imaging Techs

RIA SECTION

Ms. Cranston

RIA Techs

Nuc Med Fellow

Pharmacy Tech

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL

SUBJECT

HSHL-XN (340a)

Authorized Areas for Eating/Smoking

THRU: C, Nuclear Med Svc

FROM: Technical Director

DATE

22 JUL 88

CMT 1

Mr. Kyle/af/6-0168

TO: All Nuclear Medicine Personnel

The following areas are designated smoking and/or eating areas as indicated:

<u>ROOM # AND AREA</u>	<u>Smoking</u>	<u>Eating</u>
# 1 File room (secretarial area only)	No	Yes
# 2 Dose room	No	No
	No	No
	No	Yes
# 5 Physics Lab	No	Yes
# 6 Fellows' Office	No	Yes
# 7 Staff Office	No	Yes
# 8 Staff Office	No	Yes
# 9 Camera Room	No	No
#10 Fellows' Office	No	Yes
#11 Fellows' Office	No	No
#12 Fluoro Room	No	Yes
#13 Camera Room	No	No
#14 Camera Room	No	No
#15 Computer Room	No	No
#16 Short Desk Room	No	Yes
#17 Camera Room	No	No
#18 Camera Room	No	No
#19 Camera Room	No	No
#20 Chief Tech's Office	No	Yes
#21 Technical Director's Office	No	Yes
#22 Conference Room	NO	Yes
#23 RIA Lab	No	No
#24 Secretary's Office	NO	Yes
#25 Long Desk Room	No	Yes
Court yard (weather permitting)	Yes	Yes


RALPH W. KYLE
Technical Director
Nuclear Medicine Service

EX 2

R. Kyle