

AE 23-1

PDR

SUPPORTING DATA FOR THE PROPOSED RULE TO AMEND
10 CFR PARTS 30 AND 35, "DEPARTURES FROM
MANUFACTURE INSTRUCTIONS; ELIMINATION OF
RECORDKEEPING REQUIREMENTS"

(Vol. 1 of two volumes)

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PDR PR
30 57FR24763 PDR

APRIL 16, 1992 PRELIMINARY SUMMARY
DEPARTURES MADE UNDER THE INTERIM FINAL RULE

NRC inspectors have inspected 251 of NRC's 1881 non-broadscope medical licensees to collect data on the kinds of departures requested under the authority of the Interim Final rule and the frequency of those departures.

The preliminary data appears to show the following:

1. Community hospitals and individual doctors are not requesting departures.
2. The written directives requesting departures are usually form letters or adaptations of form letters prepared by commercial nuclear pharmacies and sent to the medical use licensees for signature.
3. The most common departures are to extend the "life span" of technetium radiopharmaceuticals from 6 to 12 hours.
4. The most common reasons provided for the extension of the "life span" appear to be economics, reduction of after hours calls to the pharmacy, and patient scheduling.
5. The second most frequent departure is to increase the activity of technetium-99m in cardiolite to get more doses per vial.

Enclosure I

U. S. Nuclear Regulatory Commission
 Licensee Inspection Results for
 Radiopharmaceutical Package Insert
 Departures Under Interim Final Rule
 (55 FR 34513)

April 29, 1992

Note: The inspection period varies for different licensees.

Inspection Results for Medical Licensees

<u>Total Licensees</u>	<u>Licensees Inspected</u>	<u>No. Request[*] Diagnostic Departures</u>	<u>No. Request Therapeutic Departures</u>	<u>Total** Departures</u>
1,781	255	25	1	4,867

** The total represents data from 3 of the 12 hospitals making in-house departures. For the remaining 9 hospitals, total departure numbers were not collected.

* Thirteen hospitals did not make in-house departures but requested the departures be made by a commercial nuclear pharmacy.

Inspection Results for Commercial Nuclear Pharmacies

<u>Total Licensees</u>	<u>Licensees Inspected</u>	<u>No. Making Diagnostic Departures</u>	<u>Total* Departures</u>
54	8	3	28,728

* Total represents data from 2 of the 3 pharmacies making departures. One pharmacy had 28,282 departures and the other had 466. These numbers may not include the departures requested by the 13 hospitals in the above table.

Note: no therapeutic departures were noted

Enclosure II

Summary of the Nature of Departures
from Radiopharmaceutical Package Inserts
Made by Medical Licensees

P-32 Used for indication which was not included in the package insert; indication defined as over production of blood platelets

Xenon-133 Dissolved in saline solution

Technetium-99m

Cardiolite Used activity greater than the package insert maximum for preparation

Volume greater than suggested in package insert

Ceretec Used for labeling leukocytes (not specified in the package insert)

DTPA Used for gastric emptying (not specified in the package insert)

Used activity greater than the package insert maximum for preparation

Extended expiration time beyond that indicated in the package insert

MDP Used activity greater than the package insert maximum for preparation

Added ascorbic acid

MAA Used activity greater than the package insert maximum for preparation

Extended expiration time beyond that indicated in the package insert

Oxidionate Extended expiration time beyond that indicated in the package insert

Summary of the Nature of Departures
from Radiopharmaceutical Package Inserts
Made by Medical Licensees

PYP	Used procedures not specified in the package insert: <ol style="list-style-type: none">1. Washed PYP labeled erythrocytes with saline solution and/or2. Heat damaged PYP labeled erythrocytes
Sodium Pertechnate	Extended expiration time beyond that indicated in the package insert
Sulfur Colloid	Filtered prior to use (not specified in the package insert) Extended expiration time beyond that indicated in the package insert Dosage greater than suggested in package insert

Representative Examples Providing
the Nature of Departures from
Radiopharmaceutical Package Inserts
Made by Commercial Nuclear Pharmacies

Enclosure III B

Syncor Kit Prep Guidelines

TABLE 1: Tc99m MACROAGGREGATED ALBUMIN

MANUFACTURER	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ³	Tc99m Volume	Time of Use ²
DuPont (3.6 - 6.5M Particles)	125 mCi	2-8 ml	12 hours	72 mCi	2-8 ml	6 hours
CIS (12 - 15M Particles)	340 mCi	3-5 ml	12 hours	240 mCi	3-5 ml	6 hours
Squibb (2 - 7M Particles)	115 mCi	1-3 ml	12 hours	40 mCi	1-3 ml	6 hours
Medi+Physics (1.5 - 2.5M Particles)	50 mCi	up to 3 ml	12 hours	80 mCi (4 - 8M Particles)	2-8 ml	6 hours
Mallinckrodt (4 - 12M Particles)	200 mCi	5-10 ml	12 hours	80 mCi	5-10 ml	discard vial after 8 hrs.

¹ Amounts used in November 1989 guidelines for MAA based on 200,000 particles per 5 mCi dose, and average number of particles per vial at time of preparation. These values may be increased to account for decay up to the time of calibration of the dispensed dose.

² Do not exceed the expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Activity is based on 200,000 particles per 4 mCi dose, and minimum number of particles per vial at time of preparation. Activity may be increased to account for decay up to the time of calibration of the first dispensed dose.

TABLE 2: Tc99m BONE IMAGING AGENTS

PRODUCT	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ¹	Tc99m Volume	Time of Use ²
Squibb MDP	400 mCi	0.5-5 ml	12 hours ³	150 mCi	0.5-5 ml	12 hours ³
Medi+Physics MDP	400 mCi	2-8 ml	12 hours	400 mCi ⁴	2-8 ml	6 hours
DuPont MDP	200 mCi	2-8 ml	6 hours	200 mCi ⁵	2-8 ml	6 hours
CIS MDP	200 mCi	1-8 ml	6 hours	200 mCi ⁶	1-8 ml	6 hours
Amersham MDP	100 mCi	1-8 ml	6 hours	100 mCi	1-8 ml	6 hours
Mallinckrodt HDP	150 mCi		6 hours	150 mCi ⁷	3-6 ml	6 hours ⁸
DuPont PYP	200 mCi	3-7 ml	6 hours	200 mCi	3-7 ml	6 hours
Squibb PYP	75 mCi	2-4 ml	6 hours	75 mCi	2-4 ml	6 hours
Mallinckrodt	100 mCi	1-10 ml	6 hours	100 mCi	1-10 ml	6 hours

¹ These activities are maximum amounts and lesser amounts should be used as experience dictates.

² Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Recommended time of use is not specified in the manufacturer's instructions.

⁴ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 400 mCi.

⁵ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 200 mCi.

⁶ The manufacturer specifies maximum activity of 300 mCi, but Syncor policy limits it to 200 mCi.

⁷ The manufacturer specifies maximum activity of 200 mCi, but Syncor policy limits it to 150 mCi.

⁸ Manufacturer's instructions recommend an 8 hour time of use, but Syncor policy limits it to 6 hours.

TABLE 3: Tc99m DTPA

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	Squibb	300 mCi	up to 5 ml	6 hours
Renal Scan	Squibb	300 mCi	up to 5 ml	4 hours ²
Ventilation Study	Squibb	300 mCi	up to 5 ml	6 hours
GFR Assessment ³	Squibb	50 mCi	2-5 ml	1 hour
Brain Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Renal Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Ventilation Study	Medi+Physics	300 mCi ²	2-8 ml	6 hours
GFR Assessment ³	Medi+Physics	50 mCi	2-8 ml	1 hour
Brain Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Renal Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Ventilation Study	CIS	100 mCi ²	2-3 ml	2 hours ²
GFR Assessment ³	CIS	50 mCi ²	2-3 ml	1 hour

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

³ Syncor experience shows that Medi+Physics DTPA is preferred for GFR assessment.

TABLE 4: Tc99m GLUCONEPTONATE

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	DuPont	150 mCi ²	3-7 ml	6 hours
Renal Scan	DuPont	150 mCi ²	3-7 ml	4 hours ²

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

TABLE 5: Tc99m HUMAN SERUM ALBUMIN

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

Procedure	Manufacturer	November 1989 Kit Prep Guidelines			Package Insert Recommendations		
		Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Multidose	Medi+Physics	200 mCi	3 ml	6 hours	100 mCi	3 ml	6 hours
Unit Dose	Medi+Physics	70 mCi	1.3 ml	6 hours	30 mCi	1.3 ml	3 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

TABLE 6: Tc99m HEPATOBILIARY AND LIVER AGENTS

Product	Manufacturer	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
		Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Cholotec	Squibb	200 mCi	2-5 ml	18 hours ²	100 mCi	1-5 ml	18 hours ²
Hepatology	DuPont	150 mCi	2-5 ml	8 hours	100 mCi	4-5 ml	6 hours
Microlite	DuPont	75 mCi	2-8 ml	6 hours	75 mCi	2-8 ml	6 hours
Sulfur Colloid	CIS	500 mCi	1-3 ml	12 hours	500 mCi	1-3 ml	6 hours
Sulfur Colloid	Mallinckrodt	400 mCi	0.1-5 ml	12 hours	400 mCi	0.1-5 ml	discard vial after 6 hrs.
Sulfur Colloid	Squibb	500 mCi	0.1-5 ml	12 hours	500 mCi ³	0.1-5 ml	6 hours
Sulfur	Hedi+Physics	400 mCi	0.5-5 ml	12 hours	400 mCi	0.5-5ml	6 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Preservative in formulation allows 18 hour expiration time specified in package insert. Tc99m must have Mo99 concentration within acceptable limits as of expiration time.

³ Manufacturer's instructions do not specify maximum activity. Syncor policy limits activity to 500 mCi.

TABLE 7: OTHER Tc99M IMAGING AGENTS

- November 1989 Kit Prep Guidelines/ - Package Insert Recommendations				
Product	Manufacturer	Activity	Tc99m Volume	Time of Use ¹
DMSA	Medi+Physics	44-88 mCi	2.2 - 4.4 ml 2.2 ml reagent	30 minutes
HM-PAO (Ceretek®)	Amergham	30 mCi ³	up to 5 ml	30 minutes

¹ Syncor Guidelines correspond to manufacturers' instructions.

² Do not exceed 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Sodium pertechnetate elution must be less than 2 hours old when used to prepare the kit.

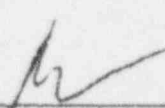
To: Kamal Amin, Syncor, Inc.
 Re: Preparation of Technetium 99m HMPAO--Labeled Leukocytes

Dear Mr. Amin:

This to authorize Syncor to prepare Technetium 99m HMPAO--labeled leukocytes for use by the Nuclear Medicine Service, Department of Radiology at Akron General Medical Center, Akron, Ohio.

These labeled leukocytes will be used for imaging patients with suspected infection, such as osteomyelitis. Use of this product is indicated as a substitute for 111-in leukocytes because of increased resolution of Technetium 99m and reduced radiation dose to the patient, particularly the spleen.

Use was approved at the Radiation Safety Committee meeting held in July, 1991. This authorization is made pursuant to CFR 35.200 (c)(1).



Dr. Richard Albright,
 Director, Department of Nuclear Medicine
 Akron General Medical Center

Post-It™ brand fax transmittal memo 7671		* of pages * 1
To: JAMES CAMPBELL	From: SYNCOR INC LCV	
Co: NRC	Co:	
Dept:	Phone: 216 753 0140	
Fax: 216 753 0140	Fax: 216 753 0140	

MALLINCKRODT
Nuclear Medicine

January 23, 1992

Mr. Robert Ellis
Nuclear Medicine Dept.
Lutheran Medical Center
2639 Miami St.
St. Louis MO 63118

Mallinckrodt Medical, Inc.
Diagnostic Imaging Services
1827 Bell Way Drive
St. Louis, Missouri 63114
Telephone (314) 427-1555
Facsimile (314) 427-3163

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original sent to
Mallinckrodt
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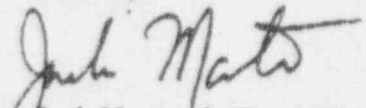
Dear Mr. Ellis,

Recently the NRC has become interested in the issue of nuclear pharmacists compounding Tc-99m technetium radiopharmaceutical kits using parameters other than those stated in the product's package insert. The NRC is allowing nuclear pharmacies to amend their licenses under 10 CFR Part 30.34 to deviate from the package insert guidelines only if it can be demonstrated that the product quality is not compromised. The Mallinckrodt DIS pharmacy currently prepares your radiopharmaceuticals slightly different than the conservative manufacturers' package insert guidelines. (For specific changes, see attached sheet.) These changes are consistent with current standards of nuclear pharmacy practice, and quality assurance procedures are performed daily. Until the necessary license amendment is submitted, the NRC is requesting that Mallinckrodt have on file at the nuclear pharmacy a signed authorization from the prescribing physician (M.D. authorized user) for radiopharmaceutical compounded outside the parameters stated in the package insert.

In order to remain in regulatory compliance with 10 CFR Part 35, we ask you to sign and return the attached authorization form indicating your approval for radiopharmaceutical kit preparation consistent with current standards of nuclear pharmacy practice. As always, Mallinckrodt is committed to excellence in nuclear medicine and the safety and well-being of your patients. Enclosed are two copies of the authorization form. Keep one copy for your records and return the other copy to Mallinckrodt in the enclosed self-addressed stamped envelope.

Please contact me if you have questions regarding this request or would like to discuss any portion of the current regulations.

Sincerely,


Jack Martin, R.Ph., BCNP

Facility Manager

Enclosures

MALLINCKRODT MEDICAL, INC.
ST. LOUIS DIS

RADIOPHARMACEUTICAL PREPARATION GUIDELINES						
RADIOPHARMACEUTICAL NAME	PACKAGE INSERT			MMI-DIS PHARMACY		
	Activity (mCi)	Expiration (hrs)	Kit	Activity (mCi)	Expiration (hrs)	Additional
Tc-99m SULFUR COLLOID	500	8	MMI	500	12	—
Tc-99m MAA	80	8	MMI	160	10	—
Tc-99m MDP	200	8	MMI	325	8	3mg ascorbic acid
Tc-99m DTPA	180	8	CTS	300	10	3mg ascorbic acid
Tc-99m GLUCAPTATE	300	8	MMI	300	8	—
Tc-99m PYP	100	8	MMI	300	7	—
Tc-99m HDP	200	8	MMI	285	8	—
Tc-99m MAG3	100	8	MMI	100	10	—
Tc-99m MSA	100	8	MPI	175	8	—
Tc-99m Na PERTECHNETATE	—	12	MMI	—	24	—

Note: All other radiopharmaceutical kits are prepared according to manufacturer package insert guidelines.

PHYSICIAN AUTHORIZATION

I hereby grant approval for Mallinckrodt pharmacists to exercise their professional judgement in the preparation of radiopharmaceutical kits consistent with the standards of practice of nuclear pharmacy as detailed under MMI-DIS pharmacy preparation guidelines on this page.

Hospital Name: LUTHERAN MEDICAL CENTER

Physician Signature: *William McCombs MD*

Date: JAN 28 1992

Departure Requests

Enclosure IV

DEPARTURE FROM MANUFACTURERS INSTRUCTIONS
TECHNETIUM 99m SESTAMIBI

The instructions for Cardiolite, the Technetium Sestamibi product of Dupont calls for the addition of 25-150 mCi of technetium to the supplied vial. After discussion with a number of centers using the Sestamibi agent, it is quite apparent that over 200 mCi of technetium can be instilled into the vial without degrading the tagging of the tracer.

The cost for Technetium Sestamibi per patient is determine by the number of patient doses obtained per vial. By increasing the technetium placed in the vial from 150 to 225 mCi and to a volume of 4 ccm, it is possible to cut the cost of the material substantially resulting in a health care benefit to the general population. Consequently, I am recommending a departure from the package insert with an allowance for up to 225 mCi and 4 cc of technetium to be instilled per vial of Sestamibi.

Paul Gowan
6-12-91

DEPARTURE FROM PACKAGE INSERT
P-32 THERAPY FOR THROMBOCYTOSIS

Intravenous aqueous P-32 has been shown repeatedly to be of benefit for patients with overproduction of blood cells by the bone marrow. It is one of the major treatments given for patients with polycythemia vera, for whom the other therapies include phlebotomy and chemotherapy.

In some patients the only overproduced element is the blood platelet. For these individuals phlebotomy is not a therapeutic option but P-32 has proven to be of great benefit. Consequently, as a principle user of therapeutic radionuclides at the Williamsport Hospital & Medical Center, I authorize the use of therapeutic aqueous P-32 for this indication.

W. R. Gaudin
6-12-64

WRITTEN DIRECTIVE FOR DEVIATION FROM MANUFACTURER'S
INSTRUCTIONS FOR A RADIOPHARMACEUTICAL

Date: January 3, 1992

Patient Name: SEE LIST

Patient SSN: SEE LIST

Specific Nature of the Departure:

This is a written directive to deviate from the manufacturer's instructions concerning the amount of activity that will be added to all Cardiolite kits.

Precise Description of the Departure:

When reconstituting Cardiolite kits, add a total activity of 300 mCi to each kit instead of the recommended 25-150 mCi. All other parameters including volume of reconstitution, expiration time, and method of quality control will be performed as instructed by the manufacturer.

Reason for the Departure:

This deviation will allow us to obtain more patient doses from one vial. Therefore, the benefit to the patient is in terms of cost savings. Since there are no effects on product quality, radiation dosimetry to the patient, or any other test parameters, additional risks to the patient as a result of this deviation are nonexistent.

Andrew Michaelson, Jr. M.D.
Authorized User Physician Signature

DOCUMENTATION OF DEVIATION FROM PRESCRIBED DOSE AS PER PACKAGE INSERT:

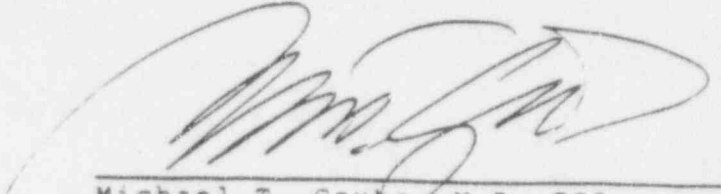
SCAN: Sigenoz
Vena cavaogram (Flow study)
PATIENT: [] PHYSICIAN: Yip T. L. DATE: 1-2-7

ADMINISTERED DOSE: 10 mCi Tl²⁰¹ -> T+subcut (injection (injection))

CLINICAL INDICATOR: R/O Obstructive Pnoedlogene CA - metastasis

DEVIATION FROM SUGGESTED DOSE:
PER THIS RADIOPHARMACEUTICAL
PACKAGE INSERT

+ 8 mCi uCi
- _____ mCi uCi Circle


Michael T. Czuba, M.D., RSO

7/01/91
Revised 8/01/91

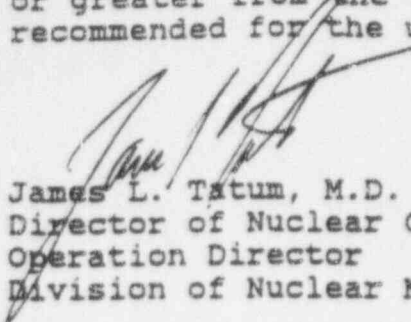
EXEMPTION TO PACKAGE INSERT FOR SAME DAY STUDIES USING TECHNETIUM
99M CARDIOLITE

Sestamibi (Cardiolite) is a new technetium based compound for myocardial perfusion imaging. Technetium energy and lack of significant redistribution make this an ideal perfusion imaging agent particularly for use with SPECT imaging. However, one of the major advantages of this new compound is that it allows first pass evaluation of left ventricular function both at rest and stress providing significant important prognostic and diagnostic information in addition to the perfusion image with the same injection of radiotracer at the same dosimetry. This is one of the major advantages leading to its utilization at the Medical College of Virginia and partially justifies its marked increase in expense. However, unlike Thallium-201, it does not redistribute and two injections of tracer are required either on the same day or on separate days. To perform quality, valid first pass studies the bolus must not exceed 0.5cc and the smaller the bolus, the better. In the case of two day studies adequate specific activity to allow this is not problematic; however, in the single day protocol preferred by both patients and referring physicians, a low dose (10mCi) rest study is followed by a high dose (30mCi) stress study performed several hours later.

The vendor permits six doses per vial with a shelf life of six hours following preparation; however, the package insert recommends 1 to 3 milliliters of volume containing 25 to 150mCi. In order to perform same day studies with first pass on three patients (6 injections) which is the minimum feasible number considering the cost, the recommendation is not cogent. A minimum of volume of 2ml is necessary to provide the six injections and to provide adequate activity for the 30mCi late doses at the shelf life projected by the vendor would require that the initial activity be 120mCi per milliliter. Therefore for same day studies with Cardiolite it is necessary to prepare kits with up to 250mCi in a vial with a volume not to exceed 2.5ml. With this exemption alterations in QC will be performed to ensure the stability of the compound before being injected. Although the initial QC will be performed as recommended a second QC will be performed prior to the late injections of the tracer (ie., the second stress high dose injections) and at the expiration of the kit.

The following exemption appears reasonable and in the best interest of providing quality patient care. Single day first pass rest/stress studies are optimal for providing the maximum information for the dose administered. It should be noted the patient dose has not been changed and is within the recommended guidelines of the package insert. There is no evidence to support that this change in kit preparation changes either the stability or binding efficiency of the compound in any way and that the limitations are primarily of commercial origin. We have observed

no problems with stability or binding in kit preparations in which doses have exceeded that suggested. In addition, QC will be strictly followed so as to detect any change in binding efficiency or stability and kits will not be used where the QC degrades by 5% or greater from the initial QC or if any of the QC's exceed that recommended for the utilization by the commercial vendor.



James L. Tatum, M.D.
Director of Nuclear Cardiology
Operation Director
Division of Nuclear Medicine



Hospital and Medical Center

2101 Mission Road
Denville, Michigan 48824-1111
(313) 481-2000

Date: January 22, 1992
To: Nuclear Medicine Personnel
From: Edward R. Powsner, M.D.
Subject: Preparation of Technetium-99m Sestamibi

NRC regulations require that radiopharmaceuticals be prepared according to the manufacturer's instructions except in those instances where the desired medical results would not be otherwise obtainable. Specifically, DuPont/NEN instructions for Cardiolite (sestamibi) recommend adding 25 to 150 mCi of sodium pertechnetate technetium-99m in 1 to 3 mL. The following change is authorized:

Technetium-99m sestamibi is to be prepared with up to 370 mCi of technetium-99m.

The purpose of this change is to allow the radiopharmacy to dispense the recommended 30 mCi per patient so as to complete the rest/stress study in one day instead of in two days. This reduces the length of stay for inpatients and eliminates the inconvenience of a two-day study for outpatients. Chromatography of the kit prepared this way has repeatedly confirmed that there is 95 to 98% radiochemical purity at 6 hours post-calibration.

A handwritten signature in cursive script, appearing to read "E. Powsner".

MEMORANDUM

TO: NUCLEAR MEDICINE PHYSICIAN STAFF

FROM: RADIOPHARMACIST

SUBJ: PREPARATION OF TC99M CARDIOLITE

I HAVE DETERMINED THAT ONE VIAL CAN "HOLD" UP TO 300 MILLICURIES OF TC99M AND MAINTAIN A TAG OF OVER 95% UP TO 5 HOURS POST PREPARATION. THE PACKAGE INSERT ONLY ALLOWS UP TO 150 MCI TO BE ADDED PER VIAL. THE NRC WILL HOLD US TO THAT LIMIT OF 150 MILLICURIES PER VIAL UNLESS WE STATE THE 1) SPECIFIC NATURE OF THE DEPARTURE FROM THE PACKAGE INSERT, 2) A PRECISE DESCRIPTION OF THE DEPARTURE AND 3) A BRIEF STATEMENT OF THE REASONS WHY THE DEPARTURE FROM THE PACKAGE INSERT PREPARATIONS INSTRUCTIONS WOULD OBTAIN MEDICAL RESULTS NOT OTHERWISE ATTAINABLE OR WOULD REDUCE MEDICAL RISKS TO PARTICULAR PATIENTS BECAUSE OF THEIR MEDICAL CONDITION.

ACCORDINGLY I WOULD LIKE TO HAVE THE STAFF PHYSICIANS SIGN OFF ON THE FOLLOWING STATEMENT. THE RADIOPHARMACY WILL KEEP A RECORD OF THESE PATIENTS FOR FIVE YEARS.

I AUTHORIZE THE ADDITION OF UP TO 300 MILLICURIES OF TC99M PER VIAL OF CARDIOLITE TO REDUCE THE COSTS OF UTILIZATION OF THIS RADIOPHARMACEUTICAL IN PLACE OF THALLIUM 201. THIS REDUCTION IN COST WILL ENABLE THIS MEDICAL CENTER TO USE THIS AGENT WHICH WOULD BE PROHIBITIVE UNDER CURRENT BUDGETARY RESTRAINTS.

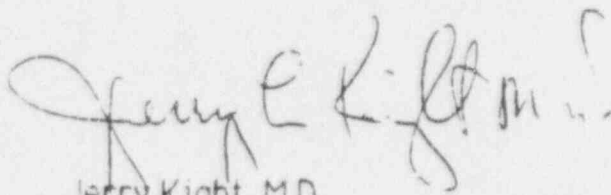
... ..
ever prepared from the manufacturer's suggested concentration.

agent (manufacturer)	suggested act (mCi)	clinical act (mCi)
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Tc-99m Cardiolite as Part 1	150	300
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The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



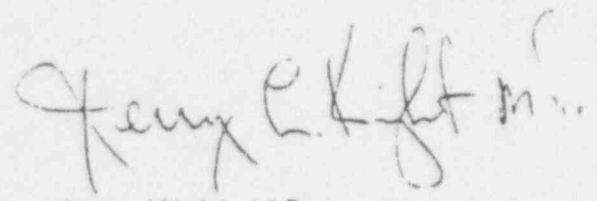
Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

The following radiopharmaceuticals are available in a concentration greater than the manufacturer's suggested activity:

agent (manufacturer)	suggested act. (mCi)	clinical act. (mCi)
Tc99m AN-DTPA (S-US)	160	300

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

The listed radiopharmaceutical is prepared at a radioactivity level greater than the manufacturer's suggested radioactivity level.

agent (manufacturer) suggested act (mCi) clinical act (mCi)


Tc-99m AN-MDP
(CIS-33)

300

400

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

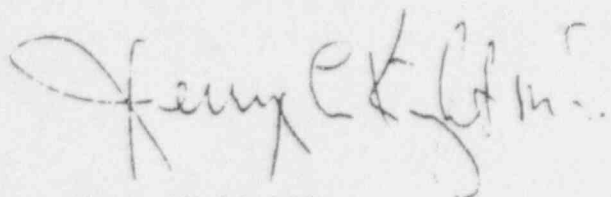
The following information is provided for the information of the user. The level of purity of the radiopharmaceutical is stated in the following table.

agent (manufacturer) suggested activity (mCi) clinical activity (mCi)

Tc-99m HSA (Medionvics)	30	45
----------------------------	----	----

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

MALLINCKRODT

INSTITUTE OF

RADIOLOGY

AT WASHINGTON UNIVERSITY MEDICAL CENTER

5 November 1990

To: Radiation Safety Officer
Nuclear Medicine Professional and Technical Staff

From: Barry A. Siegel, M.D.
Sally Schwarz, M.S., R.Ph.

Re: NRC Interim Final Rule on Radiopharmaceutical Preparation and Therapeutic Uses of Radiopharmaceuticals

An interim final rule issued by the NRC on 23 August 1990 modifies 10 CFR Parts 30 and 35 to permit (1) certain deviations from manufacturers' instructions for elution of generators and preparation of radiopharmaceuticals and (2) for deviations from therapeutic indications specified in the package insert. Such deviations are permitted at the instruction of an authorized user physician if they are expected to allow specific medical benefits. The rule also imposes the requirement for a written directive (i.e., a prescription) made by an authorized user directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes (1) the specific nature of the departure; (2) a precise description of the departure; and (3) a brief statement of the reasons 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 conditions. Ordinarily, such a written directive would be accomplished generically (see below) or specifically for a particular patient prior to the procedure. An oral directive is acceptable under emergency circumstances, but the rule requires that the written directive must be completed within three working days of the emergency administration. The rule also requires that we maintain records of such departures from manufacturers' instructions in an auditable form for a period of five years.

510 South Kingshighway Boulevard
St. Louis, Missouri 63110
(314) 362-2809

5 November 1990

Page 2

At the present time, we are not aware of deviations in the indications for therapeutic radiopharmaceutical administrations in the Division of Nuclear Medicine, since our sole therapeutic procedure is the administration of I-131 sodium iodide oral solution for treatment of hyperthyroidism.

Attached is a copy of a new "prescription" form to be used when departures from established procedures are requested by an authorized user. Completion of this form will be necessary only for those departures from established procedures that are not already codified in the Division's Clinical Procedure Manual and/or Radiopharmacy Procedure Manual (see below).

The following represent deviations from manufacturers' package labeling in the preparation of radiopharmaceuticals that are established procedures of the Division documented in the Clinical Procedure Manual and/or Radiopharmacy Procedure Manual, and already in effect as of 23 August 1990. This memorandum serves as formal notification to file and to the Radiation Safety Committee of deviations in radiopharmaceutical preparation. (Note that, for the sake of completeness, deviations involving non-byproduct material are included in this listing, although these are not subject to the NRC rule.) Tracking of the numbers of these "established deviations," as required by the NRC, will be simply accomplished by keeping track of the diagnostic codes for these procedures by way of the MIR accounting system.

A. Tc-99m Macroaggregated Albumin (Mallinckrodt)

1. Specific Nature of Departure: Removal of 1/2 of vial contents before compounding and increase the ratio of added Tc-99m pertechnetate to mass of macroaggregated albumin.
2. Description of Departure:
 - a. Withdraw 1/2 of vial contents after reconstituting lyophilized particles with 1 mL 0.9% NaCl, USP.
 - b. Add 60 mCi Tc-99m pertechnetate to vial.
 - c. Use kit within 3 hours (instead of 8 hours).

5 November 1990

Page 3

3. Rationale: Permits particle number of administered particles to be maintained in the range 2.6×10^5 to 4.7×10^5 per 4 or 5 mCi dose of Tc-99m MAA. This is necessary because of the large fraction of our patients with underlying severe parenchymal pulmonary disease or pulmonary hypertension.

B. Tc-99m Macroaggregated Albumin (DuPont)

1. Specific Nature of Departure: Add 80 mCi Tc-99m pertechnetate to vial (instead of 50 mCi).
2. Description of Departure:
 - a. Add 80 mCi Tc-99m pertechnetate to vial.
 - b. Dilute total vial to 8.0 mL using 0.9% NaCl.
 - c. Use kit within 3.5 hours (instead of 6 hours).
3. Rationale: Permits particle number of administered particles to be maintained in the range 2.6×10^5 to 4.7×10^5 per 4 or 5 mCi dose of Tc-99m MAA. This is necessary because of the large fraction of our patients with underlying severe parenchymal pulmonary disease or pulmonary hypertension.

C. Tc-99m Sulfur Colloid (Mallinckrodt)

1. Specific Nature of Departure: Pass 1 mL of Tc-99m Sulfur Colloid suspension through a $0.45 \mu\text{m}$ filter.
2. Description of Departure:
 - a. Prepare kit with 150 mCi Tc-99m pertechnetate.
 - b. Filter 1 mL through $0.45 \mu\text{m}$ filter.
 - c. Use final filtrate for injection.
3. Rationale: Filter allows retention of large colloidal particles. Small particles passing through filter are in the preferred size range for use in lymphoscintigraphy.

D. In-111 DTPA

1. Specific Nature of the Departure: Addition of 10% dextrose to the In-111 DTPA being used for injection.
2. Description of the Departure:
 - a. Draw volume required for 500 μCi In-111 DTPA dose into a syringe.

5 November 1990

Page 4

- b. Dilute volume 1:1 with 10% Dextrose, USP.
3. Rationale: Increases the flow rate of the radiopharmaceutical to the basal cisterns and decreases the "leakage" rate at the lumbar injection site during radionuclide cisternography.

E. **Pyrophosphate (PYP)**

1. Specific Nature of Departure: Washing of Tc-99m modified *in vivo* labeled red blood cells with 0.9% NaCl, USP.
2. Description of Departure:
 - a. Fifteen minutes after administering 1/2 to 1 vial PYP (vial reconstituted with 2 mL 0.9% NaCl USP), 3-5 mL whole blood is withdrawn into a 6 mL syringe containing 0.5-1.0 mL ACD (acid-citrate-dextrose) solution.
 - b. The whole blood is added to a sterile yellow-top Vacutainer tube (no additive).
 - c. Tc-99m pertechnetate (30 mCi adult; 0.25 mCi/kg pediatric + 25% additional) is added to the blood and incubated at room temperature for 10 minutes.
 - d. The whole blood is then centrifuged at full speed for 4 minutes.
 - e. The plasma is removed and the Tc-99m activity is measured.
 - f. The same volume of 0.9% NaCl, USP is added to the red cells remaining in the tube.
 - g. The tube is inverted several times, and then recentrifuged for 4 minutes at full speed.
 - h. The supernatant is withdrawn and the Tc-99m activity measured, in both supernatant and red cells.
 - i. If the supernatant contains > 10% of the total activity, the Tc-99m red cells are washed again (as in step f above).
 - j. The same volume (as supernatant removed) of 0.9% NaCl is added to the labeled red cells before reinjection.
3. Rationale: The washing step, by removing unbound Tc-99m pertechnetate or free reduced Tc-99m, reduces the likelihood that either gastric or urinary activity will interfere with the interpretation of gastrointestinal bleeding studies.

5 November 1990

Page 5

F. Pyrophosphate (PYP)

1. Specific Nature of Departure: Washing Tc-99m modified *in vivo* labeled red blood cells with 0.9% NaCl, USP, and then damaging labeled cells by heating at $49.5^{\circ} \pm 0.5^{\circ}$ C for 20 minutes.
2. Description of Departure:
 - a. Fifteen minutes after administering 1/2 to 1 vial PYP (vial reconstituted with 2 mL 0.9% NaCl USP), 3-5 mL whole blood is withdrawn into a 6 mL syringe containing 0.5-1.0 mL ACD (acid-citrate-dextrose) solution.
 - b. The whole blood is added to a sterile yellow-top Vacutainer tube (no additive).
 - c. Tc-99m pertechnetate (3-6 mCi) is added to the blood and incubated at room temperature for 10 minutes.
 - d. The whole blood is then centrifuged at full speed for 4 minutes.
 - e. The plasma is removed and the Tc-99m activity is measured.
 - f. The same volume of 0.9% NaCl, USP is added to the red cells remaining in the tube.
 - g. The tube is inverted several times, and then recentrifuged for 4 minutes at full speed.
 - h. The supernatant is withdrawn and the Tc-99m activity measured, in both supernatant and red cells.
 - i. If the supernatant contains > 10% of the total activity, the Tc-99m red cells are washed again (as in step f above).
 - j. The same volume (as supernatant removed) of 0.9% NaCl is added to the red cells before reinjection.
 - k. Heat the resuspended red cells in a water bath at $49.5^{\circ} \pm 0.5^{\circ}$ C for 20 minutes.
 - l. Centrifuge sample at full speed for 4 minutes.
 - m. Remove supernatant and measure activity in supernatant and red cells. Add a volume of 0.9% NaCl, USP equal to supernatant removed.
 - n. Repeat the wash step (step m above) if supernatant contains > 10% of the total activity.

MEMORANDUM FOR THE NUCLEAR REGULATORY COMMISSION

SUBJECT: Departure from the Manufacturer's package insert for the preparation of radiopharmaceuticals.

1. In response to the Federal Register, Vol. 55, No. 164, Thursday, August 23, 1990, pages 34513-18, an interim rule titled "Authorization to Prepare Radiopharmaceuticals Reagent Kits and Elute Radiopharmaceutical Generators; Use of Radiopharmaceuticals for Therapy". The interim rule allows licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions for elution and preparation in the package insert, provided the licensees meet certain conditions and limitations.

2. The following departures from the package insert are used within the Nuclear Medicine Service on either a daily basis or on a as needed basis for benefit of patient care and diagnostic studies.

a. On a daily basis, Methylene Diphosphonate (MDP) cold kits, by any manufacturer are compounded with an activity of 600 mCi of ^{99m}Tc Pertechnetate as a cost savings measure to the clinic. Most kits on the market are limited (by the package insert) to 200 mCi. Radiochemical purity is checked daily, using paper chromatography to insure the tagged compound is within the USP and NRC guidelines.

b. On a daily basis, Ascorbic Acid (3 mg) is added to the MDP kits to prevent any oxidation of the kit and resulting breakdown of the kit.

c. For V/Q scans on patients with a Right to Left shunt, or in patients with possible pulmonary hypertension, the Macroaggregated Albumin (MAA) kits are compounded with 100 mCi of ^{99m}Tc Pertechnetate. Double the amount stated in the package insert, in the effort to limit the number of particles injected during the study.

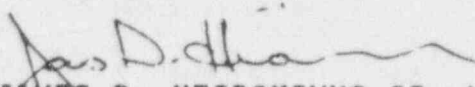
d. On a weekly basis, Xe-133 as a radiochemical is dissolved in saline and used for injection for burn lung and heart right ventricle "first pass" studies.

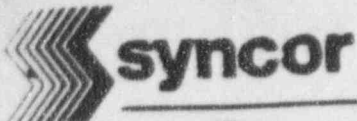
e. As needed, ^{99m}Tc Diethylenetriamine pentaacetic acid (DTPA) is used for gastric emptying studies.

f. As needed, ^{99m}Tc-exametazine white blood cells are labeled for detection of infection.

(L.R.T.C.)

3. The above uses, while not included in the package insert, are reported in current medical journals of nuclear medicine and are found to be useful and appropriate for medical care at this medical facility.


JAMES D. HEIRONIMUS II, M.D.
Lt. Col., USAF, MC
Chief, Nuclear Medicine Service



DELAWARE SPECT IMAGING CTR.
9-40 OMEGA DRIVE
NEWARK, DELAWARE 9713
302-777-6000

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA, and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturers' package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

John J. M. J.
3/3/91

To: Frank Ruddy, Pharmacy Manager
Megan McDonough, Pharmacy Representative

From: *JAMES H. LANIGELIS M.D.*

Department of Radiology 347
RE: Written Directive for Eluting Generators and Preparing
Radiopharmaceuticals

Dear Megan and Frank,

As we discussed on December 1, 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed a copy of the Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from the manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- * Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- * Times of use for Sulfur Colloid, MDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases. Time of use for TcO4 is extended to twenty four hours for the same reason.
- * Times of use for Sulfur Colloid, MDP, MAA, and TcO4 have been extended to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered in this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

James H. Lanigelis M.D.

January 10, 1991

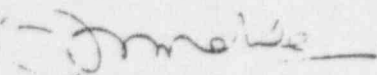
Syncor International Corp.
2208 West Central Ave.
Toledo, Ohio 43606

Dear Syncor:

I have reviewed the package insert for ^{99m}Tc Human Serum Albumin and the procedure used in lymphatic imaging with this agent. I understand that this procedure is a deviation from the approved uses.

Until further notice, please use ^{99m}Tc labeled HSA for lymphatic imaging in malignant melanoma. I wish to use the radiopharmaceutical that provides the lowest patient absorbed dose and most rapid diagnostic information. I believe that using ^{99m}Tc labeled HSA represents a significant clinical benefit warranting the use of this procedure for our patients.

Sincerely,


G. B. Mehta, M.D.
Chairman
Department of Radiology

GBM/sac

Att.

CONSULTING RADIOLOGISTS CORP.

RADIOLOGISTS

ST PINSKY, M.D.
RE MYERS, M.D.
RW SIDERS, M.D.
PM ROYEN, M.D.
SE GORDON, M.D.
MF FADELL, M.D.
DE HOOVER, M.D.
GB GLASSBERG, M.D.
RR DOERFLER, M.D.
SL MAYES, M.D.
TT LOH, M.D.
SS MANION, M.D.

X-RAY, ULTRASOUND AND NUCLEAR MEDICINE

Physicians and Surgeons Building
3100 W. Central Avenue
Toledo, Ohio 43606
(419) 535-7758

BUSINESS OFFICE

4351 Monroe Street
Toledo, Ohio 43606
(419) 473-3553

October 16, 1990

Syncor Inc.
2208 W. Central Ave.
Toledo, Oh. 43606

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc-99m Sulfur Colloid, MDP, MAA and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturers' package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

S. T. Pinsky, M. D.

STP/nk

Written Directive for exceeding recommended package insert dosage:

MDP- In my judgement, these departures from manufacturers instructions are justified for the following reason:

Adjusting the activity used for Bone scans to 27-30 mCi, to allow for SPECT imaging with greater count rates, and decreased scanning time. Also to increase scan quality and image resolution. *

Gunnell O Bruen
Authorized User Physician

*The patients health will not be affected by this change.

January 1, 1991

Written Directive for exceeding recommended package insert dosage:

201 Tl- In my judgement, these departures from manufacturers instructions are justified for the following reason:

Adjusting the dosage for Thallium 201 Chloride to 3.5-3.8 mCi to decrease imaging time and to increase image quality and resolution, while performing SPECT Thallium studies.

The patients health will not be affected by this change.

Bussell O. Brown
Authorized User Physician

January 1, 1991

Written Directive for exceeding recommended package insert dosage:

DTPA- We will be using ^{99m}Tc DTPA Aerosol in place of ^{133}Xe gas for Ventilation lung imaging. In my judgement, these departures from manufacturers instructions are justified for the following reasons:

The availability of ^{99m}Tc DTPA and the reduction in cost, greatly exceeds that of ^{133}Xe gas.

Aerosol studies are preferred over gaseous studies (in this institution) because all views of the lung may be obtained with aerosol imaging, which provides a better mechanism for comparison with the perfusion images.

No need for negative air flow in imaging rooms which requires monitoring twice yearly to comply with NRC specifications.

The patients health will not be affected by this change.

Russell O Brown
Authorized User Physician

January 1, 1991



Hendricks County Hospital
1000 East Main Street
P.O. Box 409
Danville, Indiana 46122
(317) 745-4451

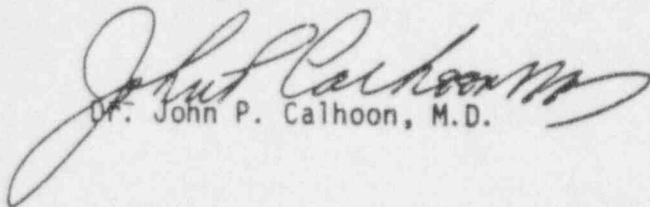
October 17, 1990

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals. I hereby direct you to compound and dispense Tc-99m sulfur Colloid, MDP, MAA, and other Tc-99m radiopharmaceuticals in accordance with Syncor Kit Prep Guidelines. I recognize that the manufacturer's packages inserts for these products specify 6 hour time of use, but my experience in their use has demonstrated that they may in fact be used safely and effectively for up to 12 hours. The twelve hour time of use is needed so that the scheduling of the use of products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,


Dr. John P. Calhoon, M.D.

TO: Syncor Pharmacy Manager

FROM: Authorized User Physician

RE: Written Directive for Eluting Generators and Preparing Radiopharmaceuticals

As we discussed on 17 December, 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed the copy of Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- o Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- o Times of use for Sulfur Colloid, MDP and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases.
- o Times of use for Sulfur Colloid, MDP and MAA are extended to twelve hours, to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered by this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

NOTE: Follow Package Insert Requirements for DTPA-Renal Exp Time
This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

T. H. JANISON

T. H. JANISON, MD

William S. Community Hospital
Williamstown, Vt 05498 23125



Floyd
Memorial
Hospital

January 11, 1991

Mike Wyant, Pharmacy Manager
Syncor International
Pharmacy Service Center
831 South 6th Street
Louisville, KY 40203

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA, and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturer's package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

A handwritten signature in black ink, appearing to read 'William R. Fortner'.

William R. Fortner, M.D.
Radiation Safety Officer

WRF:kmb

VHA.

Member of Voluntary Hospitals of America, Inc.

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFII

FROM: J. Lynch
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-15462-01 for St. Lawrence Hospital (licensee's name)
was inspected on 3/27/92. Radiopharmaceutical departure records were
inspected for the period ~~10/90~~ ^{10/90} to 3/92 with the following results:

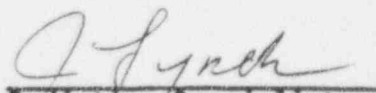
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain): _____


Radiation Specialist
(Signature and Date)

Attachment: As stated

Post-It brand

Fax Transmittal Memo

7672

No. of Pages 1

Today's Date 3-27-92

Time 16:20

To James L. Lynch

From Debra Mellentine RT(N)

Company United States N.R.C.

Company St. Lawrence Hospital

Location 799 Roosevelt Rd, Glen Ellyn IL 60137

Dept. of Origin Nuclear Medicine

Fax # 708-790-5665

Telephone # 708-790-5500

Fax # 517-377-0382

Telephone # 517 377 0448

Comments

Original Disposition: Destroy Return Call for pickup



St. Lawrence
Hospital & Healthcare Services

March 27, 1992

James L. Lynch, Radiation Specialist
United States Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Isotope Variance
Interim Rule Parts 30 & 35

St. Lawrence Hospital Nuclear Medicine Department found it necessary to utilize 99m Technetium materials after the 12 hour expiration time on thirty (30) occasions between the dates of October 17, 1990 and March 26, 1992. Listed below are the type of exams performed, material used, and medical reason for these exams.

1. 99m Technetium Aggregated Albumin for Perfusion Lung Scans
25 cases Indications - Sudden onset chest pain, shortness of breathe, low PO2. Some cases were post operative cases as well. Diagnosis - Question Pulmonary Embolism.
2. 99m Technetium - DTPA for Renal Flow / Scan.
1 case Indication - Elevated lab values.
Diagnosis - Question Renal Thrombosis.
3. 99m Technetium Pertechnetate for Testicular Scan.
1 case Indication - sudden onset painful testes.
Diagnosis - Possible Testicular Torsion.
4. 99m Technetium Pertechnetate for Gastrointestinal Bleed Scan.
3 cases Indication - active rectal bleeding, localize site.
Diagnosis - Question GI Bleed.

The above exams were performed as indicated. They were deemed necessary as medical emergencies because delay could be detrimental to the patient's care.

Debra H. Mellentine, RT-N, CNMT
Lead Nuclear Medicine Technologist

*Y. Lynch
L. were not
the 11:00 dep
the 11:00
provided the
beginning
L. H.*

NUCLEAR MEDICINE
ISOTOPE VARIANCE REQUEST

Patient Name: _____ Date of Birth: _____

Date of Exam: _____ Exam Time: _____

Product: _____ Expiration Time: _____

The Nuclear Medicine Department of St. Lawrence Hospital is directed to utilize the above isotope for the performance of a _____ scan even though the expiration time as indicated on the dose has expired. I deem that the patient's history of _____ raises significant suspicion for the possibility of _____ warranting this utilization of the isotope as a medical emergency because delay could be detrimental to the patient's care.

WRITTEN DIRECTIVE FOR DEVIATION FROM MANUFACTURER'S
INSTRUCTIONS FOR A RADIOPHARMACEUTICAL

Date: January 3, 1992

Patient Name: SEE LIST

Patient SSN: SEE LIST

Specific Nature of the Departure:

This is a written directive to deviate from the manufacturer's instructions concerning the amount of activity that will be added to all Cardiolite kits.

Precise Description of the Departure:

When reconstituting Cardiolite kits, add a total activity of 300 mCi to each kit instead of the recommended 25-150 mCi. All other parameters including volume of reconstitution, expiration time, and method of quality control will be performed as instructed by the manufacturer.

Reason for the Departure:

This deviation will allow us to obtain more patient doses from one vial. Therefore, the benefit to the patient is in terms of cost savings. Since there are no effects on product quality, radiation dosimetry to the patient, or any other test parameters, additional risks to the patient as a result of this deviation are nonexistent.

Andrew J. Melchioro, Jr. M.D.
Authorized User Physician Signature

HOSPITAL VA Medical Center

PHARMACY VA Medical Center

WRITTEN DEPARTURE
REQUEST PRESENT

DATE SIGNED

ALL DEPARTURE
ELEMENTS PRESENT

yes () no

11/21/82

yes () no

<u>Departures</u>									
<u>Date</u>									
<u>7/2/82</u>	36								
<u>7/2/82</u>	19								
<u>11/21/82</u>	82								
<u>11/21/82</u>	36								
Total	245								

Key

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: FREDERICK LEEBMAN
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-02615-01 for NEWTEN W'ELLSLEY HSP (licensee's name)
was inspected on DEC 5, 1991. Radiopharmaceutical departure records were
inspected for the period 11/88 to 12/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

F. M. Leebman
Radiation Specialist
(Signature and Date)

Attachment: As stated

DEPARTURE FROM PACKAGE INSERT
P-32 THERAPY FOR THROMBOCYTOSIS

Intravenous aqueous P-32 has been shown repeatedly to be of benefit for patients with overproduction of blood cells by the bone marrow. It is one of the major treatments given for patients with polycythemia vera, for whom the other therapies include phlebotomy and chemotherapy.

In some patients the only overproduced element is the blood platelet. For these individuals phlebotomy is not a therapeutic option but P-32 has proven to be of great benefit. Consequently, as a principle user of therapeutic radionuclides at the Williamsport Hospital & Medical Center, I authorize the use of therapeutic aqueous P-32 for this indication.

Mark Gaudin
6-12-67

DEPARTURE FROM MANUFACTURERS INSTRUCTIONS
TECHNETIUM 99m SESTAMIBI

The instructions for Cardiolite, the Technetium Sestamibi product of Dupont calls for the addition of 25-150 mCi of technetium to the supplied vial. After discussion with a number of centers using the Sestamibi agent, it is quite apparent that over 200 mCi of technetium can be instilled into the vial without degrading the tagging of the tracer.

The cost for Technetium Sestamibi per patient is determine by the number of patient doses obtained per vial. By increasing the technetium placed in the vial from 150 to 225 mCi and to a volume of 4 ccm, it is possible to cut the cost of the material substantially resulting in a health care benefit to the general population. Consequently, I am recommending a departure from the package insert with an allowance for up to 225 mCi and 4 cc of technetium to be instilled per vial of Sestamibi.

Jack Gordin
6-12-91

DEPARTURE FROM MANUFACTURERS INSTRUCTIONS
TECHNETIUM 99m SESTAMIBI

The instructions for Cardiolite, the Technetium Sestamibi product of Dupont calls for the addition of 25-150 mCi of technetium to the supplied vial. After discussion with a number of centers using the Sestamibi agent, it is quite apparent that over 200 mCi of technetium can be instilled into the vial without degrading the tagging of the tracer.

The cost for Technetium Sestamibi per patient is determine by the number of patient doses obtained per vial. By increasing the technetium placed in the vial from 150 to 225 mCi and to a volume of 4 ccm, it is possible to cut the cost of the material substantially resulting in a health care benefit to the general population. Consequently, I am recommending a departure from the package insert with an allowance for up to 225 mCi and 4 cc of technetium to be instilled per vial of Sestamibi.

Paul Gordon
6-12-91

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-15121-01 for GREENE COUNTY MEMORIAL HOSPITAL (licensee's name)
was inspected on 12-4-91. Radiopharmaceutical departure records were
inspected for the period 12-91 to 12-88 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Walter E. Davis 12-22-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

DOCUMENTATION OF DEVIATION FROM PRESCRIBED DOSE AS PER PACKAGE INSERT:

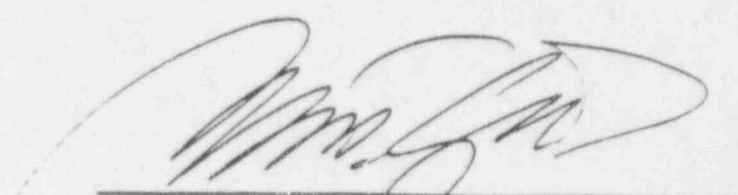
SCAN: Supenor
Vena cavaogram (Flow study)
PATIENT: [] PHYSICIAN: John T. ... DATE: 1-2-7

ADMINISTERED DOSE: 10 mCi Tc^{99m} Tc-sulfur colloid (Intraven. Colloid)

CLINICAL INDICATOR: ^{R/O} Obstructive Pnoecephalopathy CA = hemorrhage

DEVIATION FROM SUGGESTED DOSE:
PER THIS RADIOPHARMACEUTICAL
PACKAGE INSERT

8 mCi uCi Circle
- mCi uCi


Michael T. Czuba, M.D., RSO

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-00048-17 for Va Commonwealth (licensee's name) was inspected on 2/3 & 2/4/92. Radiopharmaceutical departure records were inspected for the period 1991 to 1991 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to (records of info available but not easily retrieved) (another NRC licensee or an Agreement State licensee) to actually make the departure.
- Other reason (explain).

Carol Conwell 2/4/92
Radiation Specialist (Signature and Date)

Attachment: As stated

D-7 T-3

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

a. Last inspection date: 1/10 & 11/91

b. Current inspection date: 2/3 & 4/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

a. Licensee directed diagnostic departures Y () N

If "Yes," answer the following:

b. Departures were made by the licensee () Y () N

(1) Written directive on file [35.200(c)(1)] Y () N

(2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure Y () N

(b) Description of the departure Y () N

(c) Reasons why departure was needed Y () N

(3) Records of number of departure administrations are on file [35.200(c)(2)] Y () N

c. Departures were made by a different licensee () Y N

(1) Name & location of other facility _____

approved by committee
9/19/91

7/01/91
Revised 8/01/91

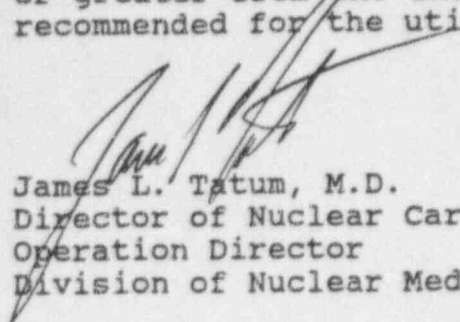
EXEMPTION TO PACKAGE INSERT FOR SAME DAY STUDIES USING TECHNETIUM 99M CARDIOLITE

Sestamibi (Cardiolite) is a new technetium based compound for myocardial perfusion imaging. Technetium energy and lack of significant redistribution make this an ideal perfusion imaging agent particularly for use with SPECT imaging. However, one of the major advantages of this new compound is that it allows first pass evaluation of left ventricular function both at rest and stress providing significant important prognostic and diagnostic information in addition to the perfusion image with the same injection of radiotracer at the same dosimetry. This is one of the major advantages leading to its utilization at the Medical College of Virginia and partially justifies its marked increase in expense. However, unlike Thallium-201, it does not redistribute and two injections of tracer are required either on the same day or on separate days. To perform quality, valid first pass studies the bolus must not exceed 0.5cc and the smaller the bolus, the better. In the case of two day studies adequate specific activity to allow this is not problematic; however, in the single day protocol preferred by both patients and referring physicians, a low dose (10mCi) rest study is followed by a high dose (30mCi) stress study performed several hours later.

The vendor permits six doses per vial with a shelf life of six hours following preparation; however, the package insert recommends 1 to 3 milliliters of volume containing 25 to 150mCi. In order to perform same day studies with first pass on three patients (6 injections) which is the minimum feasible number considering the cost, the recommendation is not cogent. A minimum of volume of 2ml is necessary to provide the six injections and to provide adequate activity for the 30mCi late doses at the shelf life projected by the vendor would require that the initial activity be 120mCi per milliliter. Therefore for same day studies with Cardiolite it is necessary to prepare kits with up to 250mCi in a vial with a volume not to exceed 2.5ml. With this exemption alterations in QC will be performed to ensure the stability of the compound before being injected. Although the initial QC will be performed as recommended a second QC will be performed prior to the late injections of the tracer (ie., the second stress high dose injections) and at the expiration of the kit.

The following exemption appears reasonable and in the best interest of providing quality patient care. Single day first pass rest/stress studies are optimal for providing the maximum information for the dose administered. It should be noted the patient dose has not been changed and is within the recommended guidelines of the package insert. There is no evidence to support that this change in kit preparation changes either the stability or binding efficiency of the compound in any way and that the limitations are primarily of commercial origin. We have observed

no problems with stability or binding in kit preparations in which doses have exceeded that suggested. In addition, QC will be strictly followed so as to detect any change in binding efficiency or stability and kits will not be used where the QC degrades by 5% or greater from the initial QC or if any of the QC's exceed that recommended for the utilization by the commercial vendor.



James L. Tatum, M.D.
Director of Nuclear Cardiology
Operation Director
Division of Nuclear Medicine



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MEMORANDUM FOR: Donna-Beth Howe
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

THROUGH: Jenny M. Johansen, Chief
Nuclear Materials Safety Section D
Division of Radiation Safety and Safeguards
Region I

FROM: Keith D. Brown, Health Physicist
Nuclear Materials Safety Section D
Division of Radiation Safety and Safeguards
Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-18461-01MD for Syncor Corporation, Folcroft, Pennsylvania was inspected on November 14, 1991. Radiopharmaceutical departure records were inspected for the period August 9, 1990 to November 14, 1991 with the following results:

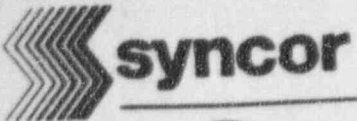
Diagnostic departures were requested by Delaware Spect Imaging Center, but not made. A copy of the request is attached.

License No. 06-19661-01MD for Syncor Corporation, Hartford, Connecticut was inspected on November 15, 1991. Radiopharmaceutical departure records were inspected for the period January 30, 1991 to November 15, 1991 with the following results:

Departures were requested by a number of the licensee's clients and were made. Copies of all cover letters requesting departures are attached. Copies of tables 1 through 7 were attached to each cover letter. Since, like the cover letters, the attached tables were identical, I have attached only one copy of these tables. Also attached are records of departure requests which were filled.

It is clear from these records that Syncor Corporation is actively soliciting requests for radiopharmaceutical departures from its customers. This allows them, in effect, to make pharmacy-directed departures so long as they get the cooperation of their clients. Since headquarters has recently directed a temporary stop on amendments to authorize pharmacy-directed departures, we would like to be advised if headquarters finds these practices acceptable.

Keith D. Brown
Health Physicist



DELAWARE SPECT IMAGING CTR.
6-40 OMEGA DRIVE
NEWARK, DELAWARE 9713
(302) 737-1400

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA, and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturers' package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

John J. ...
3/3/91

TABLE 1: Tc99m MACROAGGREGATED ALBUMIN

MANUFACTURER	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ³	Tc99m Volume	Time of Use ²
DuPont (3.6 - 6.5M Particles)	125 mCi	2-8 ml	12 hours	72 mCi	2-8 ml	6 hours
CIS (12 - 15M Particles)	340 mCi	3-5 ml	12 hours	240 mCi	3-5 ml	6 hours
Squibb (2 - 7M Particles)	115 mCi	1-3 ml	12 hours	40 mCi	1-3 ml	6 hours
Medi+Physics (1.5 - 2.5M Particles)	50 mCi	up to 3 ml	12 hours	80 mCi (4 - 8M Particles)	2-8 ml	6 hours
Mallinckrodt (4 - 12M Particles)	200 mCi	5-10 ml	12 hours	80 mCi	5-10 ml	discard vial after 8 hrs.

¹ Amounts used in November 1989 guidelines for MAA based on 200,000 particles per 5 mCi dose, and average number of particles per vial at time of preparation. These values may be increased to account for decay up to the time of calibration of the dispensed dose.

² Do not exceed the expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Activity is based on 200,000 particles per 4 mCi dose, and minimum number of particles per vial at time of preparation. Activity may be increased to account for decay up to the time of calibration of the first dispensed dose.

TABLE 2 : Tc 99 m BONE IMAGING AGENTS

PRODUCT	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ¹	Tc99m Volume	Time of Use
Squibb MDP	400 mCi	0.5-5 ml	12 hours ³	150 mCi	0.5-5 ml	12 hours ³
Medi+Physics MDP	400 mCi	2-8 ml	12 hours	400 mCi ⁴	2-8 ml	6 hours
DuPont MDP	200 mCi	2-8 ml	6 hours	200 mCi ⁵	2-8 ml	6 hours
CIS MDP	200 mCi	1-8 ml	6 hours	200 mCi ⁶	1-8 ml	6 hours
Amersham MDP	100 mCi	1-8 ml	6 hours	100 mCi	1-8 ml	6 hours
Mallinckrodt HDP	150 mCi		6 hours	150 mCi ⁷	3-6 ml	6 hours ⁸
DuPont PYP	200 mCi	3-7 ml	6 hours	200 mCi	3-7 ml	6 hours
Squibb PYP	75 mCi	2-4 ml	6 hours	75 mCi	2-4 ml	6 hours
Mallinckrodt	100 mCi	1-10 ml	6 hours	100 mCi	1-10 ml	6 hours

¹ These activities are maximum amounts and lesser amounts should be used as experience dictates.

² Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Recommended time of use is not specified in the manufacturer's instructions.

⁴ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 400 mCi.

⁵ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 200 mCi.

⁶ The manufacturer specifies maximum activity of 300 mCi, but Syncor policy limits it to 200 mCi.

⁷ The manufacturer specifies maximum activity of 200 mCi, but Syncor policy limits it to 150 mCi.

⁸ Manufacturer's instructions recommend an 8 hour time of use, but Syncor policy limits it to 6 hours.

TABLE 3: Tc99m DTPA

- November 1989 Kit Prep Guidelines/
- Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	Squibb	300 mCi	up to 5 ml	6 hours
Renal Scan	Squibb	300 mCi	up to 5 ml	4 hours ²
Ventilation Study	Squibb	300 mCi	up to 5 ml	6 hours
GFR Assessment ³	Squibb	50 mCi	2-5 ml	1 hour
Brain Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Renal Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Ventilation Study	Medi+Physics	300 mCi ²	2-8 ml	6 hours
GFR Assessment ³	Medi+Physics	50 mCi	2-8 ml	1 hour
Brain Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Renal Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Ventilation Study	CIS	100 mCi ²	2-3 ml	2 hours ²
GFR Assessment ³	CIS	50 mCi ²	2-3 ml	1 hour

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

³ Syncor experience shows that Medi+Physics DTPA is preferred for GFR assessment.

TABLE 4 : Tc 99 m G L U C O H E P T O N A T E

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	DuPont	150 mCi ²	3-7 ml	6 hours
Renal Scan	DuPont	150 mCi ²	3-7 ml	4 hours ²

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

=====

TABLE 5 : T c 9 9 m H U M A N S E R U M A L B U M I N

Procedure	Manufacturer	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
		Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Multidose	Medi+Physics	200 mCi	3 ml	6 hours	100 mCi	3 ml	6 hours
Unit Dose	Medi+Physics	70 mCi	1.3 ml	6 hours	30 mCi	1.3 ml	3 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

TABLE 6: Tc99m HEPATOBIILIARY AND LIVER AGENTS

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

Product	Manufacturer	Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Cholotec	Squibb	200 mCi	2-5 ml	18 hours ²	100 mCi	1-5 ml	18 hours ²
Hepatolite	DuPont	150 mCi	2-5 ml	8 hours	100 mCi	4-5 ml	6 hours
Microlite	DuPont	75 mCi	2-8 ml	6 hours	75 mCi	2-8 ml	6 hours
Sulfur Colloid	CIS	500 mCi	1-3 ml	12 hours	500 mCi	1-3 ml	6 hours
Sulfur Colloid	Mallinckrodt	400 mCi	0.1-5 ml	12 hours	400 mCi	0.1-5 ml	discard vial after 6 hrs.
Sulfur Colloid	Squibb	500 mCi	0.1-5 ml	12 hours	500 mCi ³	0.1-5 ml	6 hours
Sulfur	Medi+Physics	400 mCi	0.5-5 ml	12 hours	400 mCi	0.5-5ml	6 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Preservative in formulation allows 18 hour expiration time specified in package insert. Tc99m must have Mo99 concentration within acceptable limits as of expiration time.

³ Manufacturer's instructions do not specify maximum activity. Syncor policy limits activity to 500 mCi.

T A B L E 7 : O T H E R T c 9 9 M I M A G I N G A G E N T S

Product	Manufacturer	Activity	- November 1989 Kit Prep Guidelines/ - Package Insert Recommendations	
			Tc99m Volume	Time of Use ²
DMSA	Medi+Physics	44-88 mCi	2.2 - 4.4 ml 2.2 ml reagent	30 minutes
HM-PAO (Ceretek [®])	Amersham	30 mCi ³	up to 5 ml	30 minutes

¹ Syncor Guidelines correspond to manufacturers' instructions.

² Do not exceed 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Sodium pertechnetate elution must be less than 2 hours old when used to prepare the kit.

64

received
1/22/91

To: Frank Buddy, Pharmacy Manager
Megan McDonough, Pharmacy Representative

From: *JAMES H. DANIGELIS M.D.*

Department Chairman

RE: Written Directive for Eluting Generators and Preparing Radiopharmaceuticals

Dear Megan and Frank,

As we discussed on December , 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed a copy of the Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from the manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- * Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- * Times of use for Sulfur Colloid, MDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases. Time of use for TcO4 is extended to twenty four hours for the same reason.
- * Times of use for Sulfur Colloid, MDP, MAA, and TcO4 have been extended to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered in this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

James H. Danigelis M.D.

TC(3.5)
Date 11/01/91

Smcor Corp # 010
VARIANCE SUMMARY LIST

PAGE: 1
Run Time 09:00

Customer: 3072 Rockville General

For Dates: 10/01/91 thru 10/31/91

Line	Rx/Ord	Prod Desc.	Prod ID	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
122/91	677013	Sulf Col Tc99m	TC9920	6.00	Dose		0.00		X1407	Liver Imaging	Per Phys Order		7
123/91	677679	Sulf Col Tc99m	TC9920	6.00	Dose		0.00		X1407	Liver Imaging	Per Phys Order		7

Units For Each Product

TC9920 2

TC(3.5)
Run Date 06/01/91

Synacor Corp # 013
VARIANCE SUMMARY LIST

Customer: 3075 St. Mary's Hospital

For Dates: 05/01/91 thru 05/31/91

Date	Rx/Ord	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
05/13/91	639647	MCA Tc99m	TC9930	5.00	Dose		0.00		055013	Pulmonary Perfusion	Per Phys Order	Billed	Y

Units For Each Product

TC9930 1

SD-6 T-0 (17)

SIC(3.5)
in Date 06/01/91

Synacor Corp # 011
VARIANCE SUMMARY LIST

PAGE: 1
Run Time 02:27

Address: 3071 Westwood Imaging

For Dates: 5/01/91 thru 05/31/91

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
5/02/91	637395 MDP TC99m	TC9950	20.00	Dose	0.00			0032	Bone Imaging	Per Phys Order	Billed	Y

Units For Each Product

TC9950 1

20-5 T-0 (??)

received
1/9/91

To: Frank Ruddy, Pharmacy Manager
Megan McDonough, Pharmacy Representative

From: *Statenuey Hospital*

RE: Written Directive for Eluting Generators and Preparing Radiopharmaceuticals

Dear Megan and Frank,

As we discussed on December 23 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed a copy of the Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from the manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- * Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- * Times of use for Sulfur Colloid, MDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases. Time of use for TcO4 is extended to twenty four hours for the same reason.
- * Times of use for Sulfur Colloid, MDP, MAA, and TcO4 have been extended to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered in this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

Donald P. Bergman

TABLE 1: Tc99m MACROAGGREGATED ALBUMIN

Gmberg

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

MANUFACTURER

MANUFACTURER	November 1989 Kit Prep Guidelines			Package Insert Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ³	Tc99m Volume	Time of Use ²
DuPont (3.6 - 6.5M Particles)	125 mCi	2-8 ml	12 hours	72 mCi	2-8 ml	6 hours
CIS (12 - 15M Particles)	340 mCi	3-5 ml	12 hours	240 mCi	3-5 ml	6 hours
Squibb (2 - 7M Particles)	115 mCi	1-3 ml	12 hours	40 mCi	1-3 ml	6 hours
Medi+Physics (1.5 - 2.5M Particles)	50 mCi	up to 3 ml	12 hours	80 mCi	2-8 ml (4 - 8M Particles)	6 hours
Mallinckrodt (4 - 12M Particles)	200 mCi	5-10 ml	12 hours	80 mCi	5-10 ml	discard vial after 8 hrs.

¹ Amounts used in November 1989 guidelines for MAA based on 200,000 particles per 5 mCi dose, and average number of particles per vial at time of preparation. These values may be increased to account for decay up to the time of calibration of the dispensed dose.

² Do not exceed the expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Activity is based on 200,000 particles per 4 mCi dose, and minimum number of particles per vial at time of preparation. Activity may be increased to account for decay up to the time of calibration of the first dispensed dose.

10/03/91

3095 Waterbury Hosp Health Ctr

For Dates: 09/01/91 thru 09/30/91

Ord #	Date	Prod Desc.	Prod Id.	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
43	09/25/91	Sulf Col Tc99m	TC9920	6.00	Dose	0.00	21751			Liver Imaging	Per Phys Order	Billed	Y
Total For Each Product:													

TC9920

09/25/91

013.5)

Syncor Corp

013

PAGE: 1

n Date 06/04/91

VARIANCE SUMMARY LIST

Run Time 02:27

omer: 3095 Waterbury Hosp Health Ctr

For Dates: 05/01/91 thru 05/31/91

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
02/91	637382 MAE Tc99m	TC9930	6.00	Dose	0.00			21751	Pulmonary Perfusion	Per Phys Order	Billed	Y

ts For Each Product

TC9930 1

Rec'd from Bustell Hosp.
2/5/91

February 1, 1991

To: Frank Ruddy, Pharmacy Manager
Megan McDonough, Pharmacy Representative
FROM: Edward F. Fox, M.D., Chairman
Department of Diagnostic Imaging/Nuclear Medicine

RE: Written Directive for Eluting Generators and Preparing
Radiopharmaceuticals

Dear Megan and Frank,

As we discussed on December 17, 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed a copy of the Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from the manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- Times of use for Sulfur Colloid, NDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases. Time of use for TcO4 is extended to twenty four hours for the same reason.
- Times of use for Sulfur Colloid, NDP, MAA, and TcO4 have been extended to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered in this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

Edward F. Fox, M.D.

D-2 T-0 871

TC(3.5)

Syncor Corp

013

PAGE: 1

Run Time 02:27

Date 06/04/91

VARIANCE SUMMARY LIST

For Dates: 05/01/91 thru 05/31/91

Order: 3008 Bristol Hospital

	Rx/Ord	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
02/91	637376	MVA Tc99m	TC9930	4.00	Dose	0.00			4280	Pulmonary Perfusion	Per Phys Order	Billed	Y
07/91	636054	SN-DTPA Tc99m	TC9943	33.00	Dose	0.00			4280	Inhalation Study	Per Phys Order	Billed	Y
07/91	638988	Sulf Col Tc99m	TC9920	5.00	Dose	0.00			4280	Liver Imaging	Per Phys Order	Billed	Y
13/91	639639	MVA Tc99m	TC9930	4.00	Dose	0.00			4280	Pulmonary Perfusion	Per Phys Order	Billed	Y
20/91	640991	Sulf Col Tc99m	TC9920	5.00	Dose	0.00			4280	Liver Imaging	Per Phys Order	Billed	Y

Units For Each Product

- TC9930 2
- TC9943 1
- TC9920 2

STC(3.5)
Date 10/03/91

Syner Corp # 013
VARIANCE SUMMARY LIST

PAGE: 1
Run Time 18:58

Customer: 3008 Bristol Hospital
For Dates: 09/01/91 thru 09/30/91

Ord	Date	Prod Desc	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
45691	09/04/91	Sulf Col Tc99m	TC9920	5.00	Dose	0.00	117105			Liver Imaging	Per Phys Order	Billed	Y
45989	09/05/91	Sulf Col Tc99m	TC9920	5.00	Dose	0.00	117105			Liver Imaging	Per Phys Order	Billed	Y
67737	09/19/91	SH-DTPA Tc99m	TC9943	30.00	Dose	0.00	117105			Inhalation Study	Per Phys Order	Billed	Y

Units For Each Product

TC9920 2
TC9943 1

*received
1/9/91*

To: Frank Ruddy, Pharmacy Manager
Megan McDonough, Pharmacy Representative
From:

*Gerald R. Berg MD
~~Diagnostic Radiology~~ Radiology*

RE: Written Directive for Eluting Generators and Preparing Radiopharmaceuticals

Dear Megan and Frank,

As we discussed on December 13, 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed a copy of the Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from the manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- * Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- * Times of use for Sulfur Colloid, MDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases. Time of use for TcO4 is extended to twenty four hours for the same reason.
- * Times of use for Sulfur Colloid, MDP, MAA, and TcO4 have been extended to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered in this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

Gerald R. Berg MD

1STC(3.5)

Erncor Corp # 013

PAGE: 1

Date 09/01/91

VARIANCE SUMMARY LIST

Run Time 07:47

Customer: 3020 Diab. Radiology Assoc.

For Dates: 08/01/91 thru 08/31/91

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
8/05/91	658629 Sulf Col Tc99m	TC9920	6.00	Dose				0.00	Liver Imaging	Per Phys Order	Billed	Y
8/29/91	664569 Sulf Col Tc99m	TC9920	6.00	Dose				0.00	Liver Imaging	Per Phys Order	Billed	Y

Totals For Each Product

TC9920 2

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 DWFH

FROM: COLLEEN C. CASEY
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-03210-01 for ST. JOHN HOSPITAL (licensee's name)

was inspected on 2/27/92. Radiopharmaceutical departure records were inspected for the period 9/25/90 to 2/27/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- b 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- R 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached. SUMMARY.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

 The medical licensee did not make them in writing.

 The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

 Other reason (explain).

Colleen C. Casey
Radiation Specialist
(Signature and Date)

Attachment: As stated

VIOLATION SUBSTANTIATION

1. What was the requirement?

10 CFR 20.201 and 20.106 require, in sum, that licensees evaluate hazards incident to production, use, disposal, etc. of beam to show compliance with all of Pt. 20. 20.106 limits the release to unrestricted areas of airborne concentrations of rad.

2. How and when was the requirement violated?

(9/25/90) Since previous inspection, licensee hasn't evaluated its release of airborne iodine-131 from its radiopharmacy fume hood to demonstrate compliance with 20.201 and 20.106.

3. What was the root cause/contributing factor(s) for the violation and who identified the violation, the licensee or the NRC inspector?

Licensee was unaware of requirement for its iodine-131; it complies with reqs for Xe-133 (but doesn't make -133 anymore.)

4. Did the violation have any special safety significance? If yes, describe. Describe the inspector's "evaluation of the hazard," if applicable.

Licensee pipets open radioiodine therapy solution routinely 401-104. Typically with treatments per year. They order - 2l iodine solution therapies > 30mCi from manufacturer and only vent those in hood prior to administration. No significant spills have occurred in hood. Typically 25-50mCi solution in hood, up to 250-300mCi. Bioassays are performed at least every 2 weeks and no uptakes greater than ALARA level I observed. Hood negative pressure checks were adequate + hood pressure was operating during inspection.

5. What corrective actions, if any, were taken and when? Is the violation a repeat problem? Explain, if it is.

Not a repeat. Licensee agreed to evaluate its release of radioiodine per 20.106 and 20.201.

6. Is the violation an NCV or "no-response" violation? If an NCV, verify that the criteria in either 10 CFR 2 Appendix C, Section VA, Notice of Violation or Section VG, Exercise of Discretion have been met. No.

Also. License reviewer John Jones, who is working on St. John renewal now, is going to obtain procedures and commitments for air monitoring for I-131.

Ⓢ including occasional therapies > 30mCi.

F A X

D A T E
T O
F R O M

4/7/92

Susanne Woods, Mailstop 6H3

NUCLEAR MEDICINE DEPARTMENT

IN CASE OF A PROBLEM WITH THIS TRANSMISSION, PLEASE CALL Michele AT 343-3560.

COMMENTS: _____

NUMBER OF PAGES INCLUDING THIS COVER SHEET.

Michele M. Beaumont R.Ph.

SIGNATURE



Hospital and Medical Center

221st Michigan Road
Detroit, Michigan 48206-2171
313-343-4000

Michele M. Beauvais R.Ph., BCNP
Nuclear Medicine Department

Colleen Carol Casey
Nuclear Regulatory Commission
Region III

Dear Colleen,

This letter is a follow-up pursuant to our conversation February 27, 1992 regarding the number of patients who have received doses of Dupont Cardiolite whose preparation departed from the manufacturer's instructions. 361 patients have received doses of 30 mCi of Cardiolite. The physician directive and the number of prescriptions dispensed under the departure will be kept in an auditable form for 5 years and be available for inspection.

Sincerely,

Michele M. Beauvais R.Ph. BCNP

Michele M. Beauvais R.Ph., BCNP

sent 2/28/92

03/31/92 0120 (D) FAX COVER LETTER

FAX COVER LETTER

St. John Hospital
Department of Radiation Therapy
22101 Moross Road
Detroit, Mich. 48236

Date: March 13, 1992 Time: 12:20

To: Name: SUSAN WOODS
Company: N.R.C. MAIL STOP (6H3)
FAX # 1-313-504-2260

From: Name: WALTER NIKESCH, PH.D.
FAX #: 313-343-7831

Comments:

INFORMATION REQUESTED FOLLOWS

Total # of Pages Including Cover Letter 2

If you did not receive all of these pages, call 343-3750



Hospital and Medical Center

2701 Morris Ford
Detroit, Michigan 48226-1112
(313) 343-4000

Date: January 22, 1992
To: Nuclear Medicine Personnel
From: Edward R. Powsner, M.D.
Subject: Preparation of Technetium-99m Sestamibi

NRC regulations require that radiopharmaceuticals be prepared according to the manufacturer's instructions except in those instances where the desired medical results would not be otherwise obtainable. Specifically, DuPont/NEN instructions for Cardiolite (sestamibi) recommend adding 25 to 150 mCi of sodium pertechnetate technetium-99m in 1 to 3 mL. The following change is authorized:

Technetium-99m sestamibi is to be prepared with up to 370 mCi of technetium-99m.

The purpose of this change is to allow the radiopharmacy to dispense the recommended 30 mCi per patient so as to complete the rest/stress study in one day instead of in two days. This reduces the length of stay for inpatients and eliminates the inconvenience of a two-day study for outpatients. Chromatography of the kit prepared this way has repeatedly confirmed that there is 95 to 98% radiochemical purity at 6 hours post-calibration.

A handwritten signature in cursive script, appearing to read "E. Powsner".

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 ODFW

FROM: COLLEEN C. CASEY
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-00144-05 for VAMC-ST. LOUIS, MO. (licensee's name)
was inspected on 1/30-3/1/92. Radiopharmaceutical departure records were
inspected for the period 8/30-9/12/90 to 1/30-3/1/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain). VOLUME OF PATIENTS WAS GREAT AND
TOTALS NOT TRACKED. ONLY 1 DEPARTURE
MADE-DIAGNOSTIC ONLY.

Colleen C. Casey 2/6/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

1/31/92 All of our physicians (Nuclear Med)
have signed this letter.

Lynn R. Henderson

MEMORANDUM

TO: NUCLEAR MEDICINE PHYSICIAN STAFF

FROM: RADIOPHARMACIST

SUBJ: PREPARATION OF TC99M CARDIOLITE

I HAVE DETERMINED THAT ONE VIAL CAN "HOLD" UP TO 300 MILLICURIES OF TC99M AND MAINTAIN A TAG OF OVER 95% UP TO 5 HOURS POST PREPARATION. THE PACKAGE INSERT ONLY ALLOWS UP TO 150 MCI TO BE ADDED PER VIAL. THE NRC WILL HOLD US TO THAT LIMIT OF 150 MILLICURIES PER VIAL UNLESS WE STATE THE 1) SPECIFIC NATURE OF THE DEPARTURE FROM THE PACKAGE INSERT, 2) A PRECISE DESCRIPTION OF THE DEPARTURE AND 3) A BRIEF STATEMENT OF THE REASONS WHY THE DEPARTURE FROM THE PACKAGE INSERT PREPARATIONS INSTRUCTIONS WOULD OBTAIN MEDICAL RESULTS NOT OTHERWISE ATTAINABLE OR WOULD REDUCE MEDICAL RISKS TO PARTICULAR PATIENTS BECAUSE OF THEIR MEDICAL CONDITION.

ACCORDINGLY I WOULD LIKE TO HAVE THE STAFF PHYSICIANS SIGN OFF ON THE FOLLOWING STATEMENT. THE RADIOPHARMACY WILL KEEP A RECORD OF THESE PATIENTS FOR FIVE YEARS.

I AUTHORIZE THE ADDITION OF UP TO 300 MILLICURIES OF TC99M PER VIAL OF CARDIOLITE TO REDUCE THE COSTS OF UTILIZATION OF THIS RADIOPHARMACEUTICAL IN PLACE OF THALLIUM 201. THIS REDUCTION IN COST WILL ENABLE THIS MEDICAL CENTER TO USE THIS AGENT WHICH WOULD BE PROHIBITIVE UNDER CURRENT BUDGETARY RESTRAINTS.

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-67063-01 for Methodist Hospital (licensee's name)
was inspected on 11/19/91. Radiopharmaceutical departure records were
inspected for the period 3/6/90 to 11/19/91 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

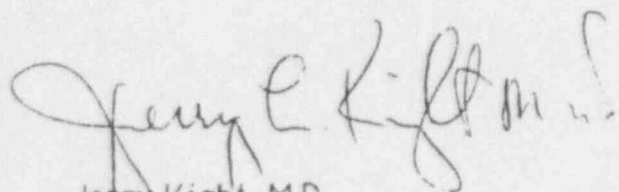
Attachment: As stated

The following radiopharmaceuticals is prepared at a total radioactivity level greater than the manufacturer's suggested loading value.

agent (manufacturer)	suggested act.(mCi)	clinical act (mCi)
Tc99m Cardiolite (du Pont)	150	360

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



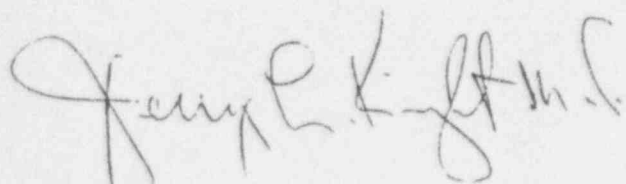
Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

The following radiopharmaceutical is prepared at a total radioactivity level greater than the manufacturer's suggested loading value

agent (manufacturer)	suggested act.(mCi)	clinical act (mCi)
Tc99m AN-MDP (CIS-US)	300	400

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



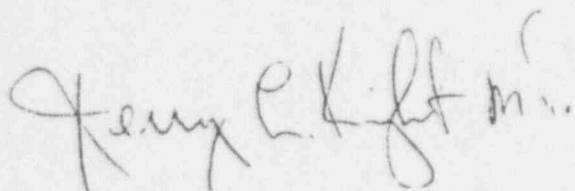
Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

The following radiopharmaceutical is prepared at a total radioactivity level greater than the manufacturer's suggested loading value

agent (manufacturer)	suggested act. (mCi)	clinical act. (mCi)
Tc99m AN-DTPA (CIS-US)	160	300

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



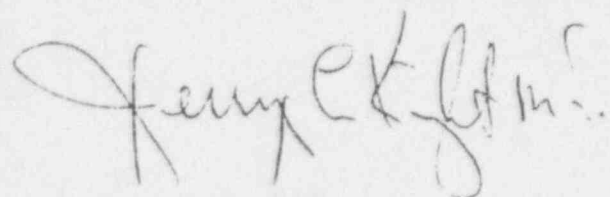
Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

The following radiopharmaceutical is prepared at a total radioactivity level greater than the manufacturer's suggested loading value

agent (manufacturer)	suggested act.(mCi)	clinical act (mCi)
Tc99m HSA (Medipysics)	30	45

The listed radiopharmaceutical has passed radiochemical quality control, historically with labeling efficiencies of 95-99% (reference the daily pharmaceutical quality control sheets).

The agent is prepared at high concentrations because bolus injections of this compound is required for the majority of the clinical studies that use it. Injected volumes of less than 0.5 mL containing 15-20 mCi are needed for statistically adequate images.



Jerry Kight, M.D.
Director, Nuclear Medicine
Methodist Hospital of Indiana
Indianapolis, IN

~~ATTACHMENT A~~

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: BRYAN A. PARKER + COLLEEN C. CASEY
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-00167-11 for WASHINGTON UNIVERSITY (licensee's name)
was inspected on AUGUST 12-16, 1991. Radiopharmaceutical departure records were
inspected for the period AUGUST 23, 1991 to PRESENT with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
~~and/or records of therapeutic departures~~ are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (~~or prescriptions dispensed~~) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

ATTACHMENT A - WRITTEN DIRECTIVES FOR
GIRLS AND CHILDREN HOSPITALS

ATTACHMENT B - WRITTEN DIRECTIVES FOR
JEWISH HOSPITAL

ATTACHMENT C - TABLE OF # OF PTS
TREATED UNDER DEPARTURES

Attachment: As stated

Bryan A. Parker Colleen C. Casey
Radiation Specialist
(Signature and Date) Aug. 22, 1991

MAIL - 3506
SUPPLY - 2
PAPER - 206
OR SERVICE - 1000

Attachment A, 2800/23

AWJ

Issue Date: 2XX1XX/XX

MALLINCKRODT INSTITUTE OF RADIOLOGY
DIVISION OF NUCLEAR MEDICINE
AUTHORIZATION FOR DEPARTURE FROM ESTABLISHED PROCEDURE

Date of Departure: _____ Patient Name: _____

Patient Birthdate: _____ Requisition Number: _____

Radiopharmaceutical: _____ Control No.: _____

1. Specific Nature of Departure:

2. Precise Description of Departure:

3. Brief explanation describing why departure from manufacturer's instructions (or from established Division of Nuclear Medicine procedure) is needed to achieve desired medical benefit. If the authorization for the departure originally was given orally (because the authorized user was not immediately available to execute a written directive), also provide the reasoning for an emergency departure necessitating lack of a prior written directive.

Physician Signature: _____

Date: _____

ATTACHMENT B

December 1, 1990

To: Radiation Safety Officer
Nuclear Medicine Professional and Technical Staff

From: Keith C. Fischer, M.D.
Director, DIVISION OF NUCLEAR MEDICINE THE JEWISH HOSP OF ST. LOUIS

Re: NRC Interim Final Rule on Radiopharmaceutical Preparation and
Therapeutic Uses of Radiopharmaceuticals

An interim final rule issued by the NRC on August 23, 1990 modifies 10 CFR Parts 30 and 35 to permit (1) certain deviations from manufacturers' instructions for elution of generators and preparation of radiopharmaceuticals and (2) for deviations from therapeutic indications specified in the package insert. Such deviations are permitted at the instruction of an authorized user physician if they are expected to allow specific medical benefits. The rule also imposes the requirement for a written directive (i.e., a prescription) made by an authorized user directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes (1) the specific nature of the departure; (2) a precise description of the departure; and (3) a brief statement of the reasons 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 conditions. Ordinarily, such a written directive would be accomplished generically (see below) or specifically for a particular patient prior to the procedure. An oral directive is acceptable under emergency circumstances, but the rule requires that the written directive must be completed within three working days of the emergency administration. The rule also requires that we maintain records of such departures from manufacturer's instructions in an auditable form for a period of five years.

At the present time, we are not aware of deviations in the indications for therapeutic radiopharmaceutical administrations in the Division of Nuclear Medicine, since our sole therapeutic procedures are the administration of I-131 sodium iodide oral solution for treatment of hyperthyroidism and thyroid cancer.

Attached is a copy of a new "prescription" form to be used when departures from established procedures are requested by an authorized user. Completion of this form will be necessary only for those departures from established procedures that are not already codified in the Division's Clinical Procedure Manual and/or Radiopharmacy Procedure Manual (see below).

JEWISH HOSPITAL

December 1, 1990

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The following represent deviations from manufacturers' package labeling in the preparation of radiopharmaceuticals that are established procedures of the Division documented in the Clinical Procedure Manual and/or Radiopharmacy Procedure Manual, and already in effect as of August 23, 1990. This memorandum serves as formal notification to file and to the Radiation Safety Committee of deviations in radiopharmaceutical preparation. (Note that, for the sake of completeness, deviations involving non-byproduct material are included in this listing, although these are not subject to the NRC rule).

Tracking of the numbers of these "established deviations" as required by the NRC, will be accomplished by keeping track of the diagnostic codes for these procedures by way of the Division of Nuclear Medicine's computer management system.

A. Tc-99m Macroaggregated Albumin (Mallinckrodt)

1. Specific Nature of Departure: Removal of 1/2 of vial contents before compounding and increase the ratio of added Tc-99m pertechnetate to mass of macroaggregated albumin.
2. Description of Departure:
 - a. Withdraw 1/2 of vial contents after reconstituting lyophilized particles with 1 mL 0.9% NaCl, USP.
 - b. Add 60 mCi Tc-99m pertechnetate to vial.
 - c. Use kit within 3 hours (instead of 8 hours)
3. Rationale: Permits particle number of administered particles to be maintained in the range of 2.6×10^5 to 4.7×10^5 per 4 or 5 mCi dose of Tc-99m MAA. This is necessary because of the large fraction of our patients with an underlying severe parenchymal pulmonary disease or pulmonary hypertension.

JEWISH HOSPITAL

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B. Tc-99m Macroaggregated Albumin (Dupont)

1. Specific Nature of Departure: Add 80 mCi Tc-99m pertechnetate to vial (instead of 50 mCi)
2. Description of Departure:
 - a. Add 80 mCi Tc-99m pertechnetate to vial.
 - b. Dilute total vial to 8.0 mL using 0.9% NaCl.
 - c. Use kit within 3.5 hours (instead of 6 hours)
3. Rationale: Permits particle number of administered particles to be maintained in the range of 2.6×10^5 per 4 or 5 mCi dose of Tc-99m MAA. This is necessary because of the large fraction of our patients with underlying severe parenchymal pulmonary disease or pulmonary hypertension.

C. PYROPHOSPHATE (PYP)

1. Specific Nature of Departure: Washing of Tc-99m modified in vivo labeled red blood cells with 0.9% NaCl, USP.
2. Description of Departure:
 - a. Fifteen minutes after administering 1/2 to 1 vial PYP (vial reconstituted with 2 mL 0.9% NaCl USP), 3.5 mL whole blood is withdrawn into a 6 mL syringe containing 0.5-1.0 mL ACD (acid-citrate-dextrose) solution.
 - b. The whole blood is added to a sterile yellow-top Vacutainer tube (no additive).
 - c. Tc-99m pertechnetate (30 mCi adult; 0.25 mCi/kg pediatric + 25% additional) is added to the blood and incubated at room temperature for 10 minutes.

JEWISH HOSPITAL

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Page four

- d. The whole blood is then centrifuged at full speed for 4 minutes.
 - e. The plasma is removed and the Tc-99m activity is measured.
 - f. The same volume of 0.9% NaCl, USP is added to the red cells remaining in the tube.
 - g. The tube is inverted several times, and then recentrifuged for 4 minutes at full speed.
 - h. The supernatant is withdrawn and the Tc-99m activity measured, in both supernatant and red cells.
 - i. If the supernatant contains > 10% of the total activity the Tc-99m red cells are washed again (as in step f above).
 - j. The same volume (as supernatant removed) of 0.9% NaCl is added to the labeled red cells before reinjection.
3. Rationale: The washing step, by removing unbound Tc-99m pertechnetate or free reduced Tc-99m, reduces the likelihood that either gastric or urinary activity will interfere with the interpretation of gastrointestinal bleeding studies.
- D. PYROPHOSPHATE (PYP)
1. Specific Nature of Departure: Washing Tc-99m modified in vivo labeled red blood cells with 0.9% NaCl, USP, and then damaging labeled cells by heating at 49.5 degrees \pm 0.5 degrees C for 20 minutes.
 2. Description of Departure:

JEWISH HOSPITAL

December 1, 1990

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- a. Fifteen minutes after administering 1/2 to 1 vial PYP (vial reconstituted with 2 mL 0.9% NaCl USP), 3-5 mL whole blood is withdrawn into a 6 mL syringe containing 0.5-1.0mL ACD (acid-citrate-dextrose) solution.
 - b. The whole blood is added to a sterile yellow-top Vacutainer tube (no additive).
 - c. Tc-99m pertechnetate (3-6 mCi) is added to the blood and incubated at room temperature for 10 minutes.
 - d. The whole blood is then centrifuged at full speed for 4 minutes.
 - e. The plasma is removed and the Tc-99m activity is measured.
 - f. The same volume of 0.9% NaCl, USP is added to the red cells remaining in the tube.
 - g. The tube is inverted several times, and then recentrifuged for 4 minutes at full speed.
 - h. The supernatant is withdrawn and the Tc-99m activity measured, in both supernatant and red cells.
 - i. If the supernatant contains > 10% of the total activity the Tc-99m red cells are washed again (as in step f above).
 - j. The same volume (as supernatant removed) of 0.9% NaCl is added to the red cells before reinjection.
 - k. Heat the resuspended red cells in a water bath at 49.5 degrees \pm 0.5 degrees C for 20 minutes.
 - l. Centrifuge sample at full speed for 4 minutes.
 - m. Remove supernatant and measure activity in supernatant and red cells. Add a volume of 0.9% NaCl, USP equal to supernatant removed.
 - n. Repeat the wash step (step m above) if supernatant contains > 10% of the total activity.
3. Rationale: The use of heat-damaged red blood cells is necessary for specific imaging of splenic tissue in such circumstances as evaluation of suspected asplenia/polysplenia, detection of accessory splenic tissue, or detection of splenosis.

E. Tc-99m Sulfur Colloid (Mallinckrodt)

1. Specific Nature of Departure: Extension of prepared vial expiration time to 12 hours.
2. Description of Departure:
 1. Prepare kit with up to 400mCi Tc-99m pertechnetate.
 2. Use kit within 12 hours (instead of 6 hours).
3. Rationale: Prohibits the need of additional sulfur colloid. Kit preparation for add on doses needed up to 12 hours after kit preparation.

F. Tc-99m Macroaggregated Albumin (Mallinckrodt)

1. Specific Nature of Departure: Extension of prepared kit expiration time to 14 hours.
2. Description of Departure:
 1. Add greater than 40 mCi and up to 100 ml of Tc-99m pertechnetate.
 2. Use kit within 14 hours (instead of 6 hours).
 3. Rationale: Prohibits the need of additional MAA kit preparation for add-on doses needed up to 14 hours after kit preparation.

G. Tc-99m Sulfur Colloid (Mallinckrodt; Squibb)

1. Specific Nature of Departure: Pass 10ml of Tc-99m Sulfur Colloid through a 0.22um filter.
2. Description of Departure:
 1. Prepare kit with 100 mcl Tc-99m pertechnetate and dilute to final volume of 10 ml.
 2. Filter 10 ml through 0.22 um filter.
 3. Use final filtrate for injection.
3. Rationale: Filter allows retention of large colloidal particles. Small particles passing through filter are preferred size range for use in bone marrow imaging.

H. Tc-99m Oxidronate (Mallinckrodt)

1. Specific Nature of Departure: Extension of maximum amount of Tc-99m pertechnetate required to prepare kit.
2. Description of Departure:
 - a. Prepare kit with 220 mCi Tc-99m pertechnetate.
3. Rationale: Allows an extra dose to be pulled from the kit eliminating the need to prepare a second kit.

JEWISH HOSPITAL DIVISION OF NUCLEAR MEDICINE
AUTHORIZATION FOR DEPARTURE FROM ESTABLISHED PROCEDURE

Date of Departure: _____ Patient Name: _____
Patient Birthdate: _____ Requisition Number _____
Radiopharmaceutical: _____ Control Number _____

1. Specific Nature of Departure:
2. Precise Description of Departure
3. Brief explanation describing why departure from manufacturer's instructions (or from established Division of Nuclear Medicine procedure) is needed to achieve desired medical benefit. If the authorization for the departure originally was given orally (because the authorized user was not immediately available to execute a written directive), also provide the reasoning for an emergency departure necessitating lack of a prior written directive.

Physician Signature: _____
Date: _____

jka
radsafty

ATTACHMENT C

DEPARTURE # OF PATIENTS TREATED SINCE AUGUST 23, 1990

Barnes and Childrens Hospitals

A and B (combined)	2787
C	2
D	15
E	142 - GI blood loss studies 59 - MUGA/RVG studies
F	3

Jewish Hospital

A	0
B	452
C	2
D	0
E	0
F	67
G	0
H	1080

MALLINCKRODT

INSTITUTE OF

RADIOLOGY

AT WASHINGTON UNIVERSITY MEDICAL CENTER

5 November 1990

To: Radiation Safety Officer
Nuclear Medicine Professional and Technical Staff

From: Barry A. Siegel, M.D.
Sally Schwarz, M.S., R.Ph.

Re: NRC Interim Final Rule on Radiopharmaceutical Preparation and Therapeutic
Uses of Radiopharmaceuticals

An interim final rule issued by the NRC on 23 August 1990 modifies 10 CFR Parts 30 and 35 to permit (1) certain deviations from manufacturers' instructions for elution of generators and preparation of radiopharmaceuticals and (2) for deviations from therapeutic indications specified in the package insert. Such deviations are permitted at the instruction of an authorized user physician if they are expected to allow specific medical benefits. The rule also imposes the requirement for a written directive (i.e., a prescription) made by an authorized user directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes (1) the specific nature of the departure; (2) a precise description of the departure; and (3) a brief statement of the reasons 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 conditions. Ordinarily, such a written directive would be accomplished generically (see below) or specifically for a particular patient prior to the procedure. An oral directive is acceptable under emergency circumstances, but the rule requires that the written directive must be completed within three working days of the emergency administration. The rule also requires that we maintain records of such departures from manufacturers' instructions in an auditable form for a period of five years.

510 South Kingshighway Boulevard
St. Louis, Missouri 63110
(314) 362-2809

5 November 1990

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At the present time, we are not aware of deviations in the indications for therapeutic radiopharmaceutical administrations in the Division of Nuclear Medicine, since our sole therapeutic procedure is the administration of I-131 sodium iodide oral solution for treatment of hyperthyroidism.

Attached is a copy of a new "prescription" form to be used when departures from established procedures are requested by an authorized user. Completion of this form will be necessary only for those departures from established procedures that are not already codified in the Division's Clinical Procedure Manual and/or Radiopharmacy Procedure Manual (see below).

The following represent deviations from manufacturers' package labeling in the preparation of radiopharmaceuticals that are established procedures of the Division documented in the Clinical Procedure Manual and/or Radiopharmacy Procedure Manual, and already in effect as of 23 August 1990. This memorandum serves as formal notification to file and to the Radiation Safety Committee of deviations in radiopharmaceutical preparation. (Note that, for the sake of completeness, deviations involving non-byproduct material are included in this listing, although these are not subject to the NRC rule.) Tracking of the numbers of these "established deviations," as required by the NRC, will be simply accomplished by keeping track of the diagnostic codes for these procedures by way of the MIR accounting system.

A. Tc-99m Macroaggregated Albumin (Mallinckrodt)

1. Specific Nature of Departure: Removal of 1/2 of vial contents before compounding and increase the ratio of added Tc-99m pertechnetate to mass of macroaggregated albumin.
2. Description of Departure:
 - a. Withdraw 1/2 of vial contents after reconstituting lyophilized particles with 1 mL 0.9% NaCl, USP.
 - b. Add 60 mCi Tc-99m pertechnetate to vial.
 - c. Use kit within 3 hours (instead of 8 hours).

5 November 1990

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3. Rationale: Permits particle number of administered particles to be maintained in the range 2.6×10^5 to 4.7×10^5 per 4 or 5 mCi dose of Tc-99m MAA. This is necessary because of the large fraction of our patients with underlying severe parenchymal pulmonary disease or pulmonary hypertension.

B. Tc-99m Macroaggregated Albumin (DuPont)

1. Specific Nature of Departure: Add 80 mCi Tc-99m pertechnetate to vial (instead of 50 mCi).
2. Description of Departure:
 - a. Add 80 mCi Tc-99m pertechnetate to vial.
 - b. Dilute total vial to 8.0 mL using 0.9% NaCl.
 - c. Use kit within 3.5 hours (instead of 6 hours).
3. Rationale: Permits particle number of administered particles to be maintained in the range 2.6×10^5 to 4.7×10^5 per 4 or 5 mCi dose of Tc-99m MAA. This is necessary because of the large fraction of our patients with underlying severe parenchymal pulmonary disease or pulmonary hypertension.

C. Tc-99m Sulfur Colloid (Mallinckrodt)

1. Specific Nature of Departure: Pass 1 mL of Tc-99m Sulfur Colloid suspension through a $0.45 \mu\text{m}$ filter.
2. Description of Departure:
 - a. Prepare kit with 150 mCi Tc-99m pertechnetate.
 - b. Filter 1 mL through $0.45 \mu\text{m}$ filter.
 - c. Use final filtrate for injection.
3. Rationale: Filter allows retention of large colloidal particles. Small particles passing through filter are in the preferred size range for use in lymphoscintigraphy.

D. In-111 DTPA

1. Specific Nature of the Departure: Addition of 10% dextrose to the In-111 DTPA being used for injection.
2. Description of the Departure:
 - a. Draw volume required for 500 μCi In-111 DTPA dose into a syringe.

5 November 1990

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- b. Dilute volume 1:1 with 10% Dextrose, USP.
3. Rationale: Increases the flow rate of the radiopharmaceutical to the basal cisterns and decreases the "leakage" rate at the lumbar injection site during radionuclide cisternography.

E. Pyrophosphate (PYP)

1. Specific Nature of Departure: Washing of Tc-99m modified *in vivo* labeled red blood cells with 0.9% NaCl, USP.
2. Description of Departure:
 - a. Fifteen minutes after administering 1/2 to 1 vial PYP (vial reconstituted with 2 mL 0.9% NaCl USP), 3-5 mL whole blood is withdrawn into a 6 mL syringe containing 0.5-1.0 mL ACD (acid-citrate-dextrose) solution.
 - b. The whole blood is added to a sterile yellow-top Vacutainer tube (no additive).
 - c. Tc-99m pertechnetate (30 mCi adult; 0.25 mCi/kg pediatric + 25% additional) is added to the blood and incubated at room temperature for 10 minutes.
 - d. The whole blood is then centrifuged at full speed for 4 minutes.
 - e. The plasma is removed and the Tc-99m activity is measured.
 - f. The same volume of 0.9% NaCl, USP is added to the red cells remaining in the tube.
 - g. The tube is inverted several times, and then recentrifuged for 4 minutes at full speed.
 - h. The supernatant is withdrawn and the Tc-99m activity measured, in both supernatant and red cells.
 - i. If the supernatant contains > 10% of the total activity, the Tc-99m red cells are washed again (as in step f above).
 - j. The same volume (as supernatant removed) of 0.9% NaCl is added to the labeled red cells before reinjection.
3. Rationale: The washing step, by removing unbound Tc-99m pertechnetate or free reduced Tc-99m, reduces the likelihood that either gastric or urinary activity will interfere with the interpretation of gastrointestinal bleeding studies.

5 November 1990

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F. Pyrophosphate (PYP)

1. Specific Nature of Departure: Washing Tc-99m modified *in vivo* labeled red blood cells with 0.9% NaCl, USP, and then damaging labeled cells by heating at $49.5^{\circ} \pm 0.5^{\circ}$ C for 20 minutes.
2. Description of Departure:
 - a. Fifteen minutes after administering 1/2 to 1 vial PYP (vial reconstituted with 2 mL 0.9% NaCl USP), 3-5 mL whole blood is withdrawn into a 6 mL syringe containing 0.5-1.0 mL ACD (acid-citrate-dextrose) solution.
 - b. The whole blood is added to a sterile yellow-top Vacutainer tube (no additive).
 - c. Tc-99m pertechnetate (3-6 mCi) is added to the blood and incubated at room temperature for 10 minutes.
 - d. The whole blood is then centrifuged at full speed for 4 minutes.
 - e. The plasma is removed and the Tc-99m activity is measured.
 - f. The same volume of 0.9% NaCl, USP is added to the red cells remaining in the tube.
 - g. The tube is inverted several times, and then recentrifuged for 4 minutes at full speed.
 - h. The supernatant is withdrawn and the Tc-99m activity measured, in both supernatant and red cells.
 - i. If the supernatant contains > 10% of the total activity, the Tc-99m red cells are washed again (as in step f above).
 - j. The same volume (as supernatant removed) of 0.9% NaCl is added to the red cells before reinjection.
 - k. Heat the resuspended red cells in a water bath at $49.5^{\circ} \pm 0.5^{\circ}$ C for 20 minutes.
 - l. Centrifuge sample at full speed for 4 minutes.
 - m. Remove supernatant and measure activity in supernatant and red cells. Add a volume of 0.9% NaCl, USP equal to supernatant removed.
 - n. Repeat the wash step (step m above) if supernatant contains > 10% of the total activity.

5 November 1990

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3. Rationale: The use of heat-damaged red blood cells is necessary for specific imaging of splenic tissue in such circumstances as evaluation of suspected asplenia/polysplenia, detection of accessory splenic tissue, or detection of splenosis.

~~Attachment B, 2802129~~

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: OCTOBER 30, 1990
- b. Current inspection date: AUGUST 12-16, 1991

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee Y () N

- (1) Written directive on file [35.200(c)(1)] Y () N

- (2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure Y () N
(b) Description of the departure Y () N
(c) Reasons why departure was needed Y () N

- (3) Records of number of departure administrations are on file [35.200(c)(2)] Y () N

- c. Departures were made by a different licensee Y N

- (1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: Y N
- (1) Written directive on file [35.200(c)(1)] Y N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] Y N
- (3) Written directive includes notation of emergency [35.200(c)(1)] Y N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures Y N
If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] Y N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure Y N
- (2) Reasons why departure was needed Y N
- d. Record of therapeutic departure made with in three working days after administration [35.300(b)(2)] Y N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] Y N

Remarks:

~~CONFIDENTIAL~~

INTERIM RULE FIELD NOTES FOR RADIOPHARMACY LICENSEES

1. GENERAL

- a. Last inspection date: N/A
- b. Current inspection date: _____

[Inspection should cover all departures made since the last inspection.]

2. RADIOPHARMACY DEPARTURES

- a. Radiopharmacy received diagnostic departure orders () Y () N
- If "Yes," answer the following:
- b. Written directive on file [30.34(i)(1)(i)]? () Y () N
- c. Written directive includes [30.34(i)(1)(i)]:
- (1) Nature of the departure () Y () N
 - (2) Description of the departure () Y () N
 - (3) Reasons why departure was needed () Y () N
- d. Records of number of departure prescriptions dispensed are on file [30.34(i)(1)(i)] () Y () N
- e. Radiopharmacy made emergency departures: () Y () N
- (1) Written directive obtained within three working days after emergency [30.34(i)(1)(ii)] () Y () N
 - (2) Written directive includes notation of emergency [30.34(i)(1)(ii)] () Y () N

Remarks:

N/A

[NOTE - Radiopharmacy licensees are not involved in therapeutic departures, so all of the above items apply to diagnostic departures made by the radiopharmacy.]

~~CONFIDENTIAL~~

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Radiopharmaceutical Departure Data

FROM: Linda L. Kasner
Senior Radiation Specialist, RIV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

LICENSEE: Department of the Army
Brooke Army Medical Center
Fort Sam Houston, TX.

LICENSE/DOCKET: 42-01368-01 / 30-03258

In lieu of the standard radiopharmaceutical departure data transmittal form, I have enclosed a copy of an inspection report (NRC Inspection Report No. 30-03258/91-01) recently issued to the captioned licensee which documents the findings of our inspection conducted on November 20-22, 1991. For your reference, I have also attached all radiopharmaceutical departure documents available at the time of the inspection (licensee memos dated November 11, 1990, and February 6, 1991). Section 8.b of the enclosed report provides a description of the nature of the departures identified during the inspection as well as discussion of the associated violation of NRC requirements. Please note that at the time of the inspection, the licensee was unable to provide information regarding the number of radiopharmaceutical administrations performed under either the documented departures or those which were not documented at that time.

In addition to the brief descriptions of radiopharmaceutical departures provided in the licensee's memos, I have included documentation on several radiopharmaceutical formulations routinely compounded by the licensee. As was noted in the report, the licensee had been compounding radiopharmaceuticals for a period of years, although the specific formulations had not been formally reviewed by the radiation safety committee for some time. In fact, our previous inspections had not identified this practice. In this particular case, the nuclear pharmacist was responsible for preparing the compounds; however, the hospital pharmacy retained responsibility for completing the necessary sterility and pyrogen tests and also maintained all associated records.

Subsequent to this inspection, I have been informed by several army pharmacists that there is continued interest in discontinuing the use of commercially prepared radiopharmaceutical kits in favor of the use of in-house preparations. Similar comments were also received from army pharmacists working under a specific medical license, although I am not aware that any facility has violated the conditions of its NRC license.

cc:
CL Cain

D-3 T-0

JAN 13 1992

Docket Nos. 30-03258
30-00504
License Nos. 42-01368-01
42-01368-02

Department of the Army
Brooke Army Medical Center (BAMC)
ATTN: Col. Thomas P. Hamilton II, M.D.
Deputy Commander for Clinical Services
Ft. Sam Houston, Texas 78234

Gentlemen:

SUBJECT: NRC INSPECTION REPORT NOS. 30-03258/91-01 AND 30-00504/91-01
(NOTICE OF VIOLATION)

This refers to the routine, unannounced radiation safety inspection conducted by Meses. L. L. Kasner and M. L. McLean of this office on November 20-22, 1991, of the activities authorized by NRC Byproduct Material License Nos. 42-01368-01 and 42-01368-02, and to the discussion of our findings held by the inspectors with Colonel L. E. Waldman, M.D., and Major J. E. Tucker at the conclusion of the inspection. The enclosed inspection report also serves to document the actions taken by BAMC in response to our concerns regarding the ventilation system located within the nuclear medicine department. This issue was discussed during a telephone conversation between Ms. Kasner and Major Tucker on November 26, 1991, in which Major Tucker reported that BAMC had suspended the use of xenon-133 gas within the nuclear medicine imaging and radiopharmacy areas until improvements to existing air supply and exhaust systems are completed.

The inspection was an examination of the activities conducted under both the broad scope medical and teletherapy licenses as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observations by the inspectors.

Please note that no violations were identified regarding the activities conducted under NRC License No. 42-01368-02.

With regard to NRC License No. 42-01368-01, certain of your activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter in writing, in accordance with the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter. In preparing your response, please refer to the instructions contained in the enclosed Notice.

RIV:NMIS *JK*
LLKasner *L*
1/10/92

NMIS *JK*
MLMcLean
1/10/92

C:NMIS *JK*
CLCain *JK*
01/03/92

D:DRSS *JK*
CLJCallan
1/10/92

JK
1/10/92

IE-07

The inspectors also reviewed the actions you had taken with respect to the violations observed during our previous inspection of the broad scope medical and teletherapy programs in July 1990. They verified that corrective actions for the violations associated with each license had been implemented as described in your correspondence dated October 12 and November 30, 1990.

The inspection revealed several weaknesses in the management oversight of the broad scope radiation safety program. These issues included, but were not limited to: (1) the failure to review user protocols annually as required; (2) the approval of individual users for the possession of quantities of radioactive materials which collectively could have exceeded the limits identified in the license; and (3) the failure to fully evaluate the use of xenon-133 gas within certain areas of the facility. These areas were later found without proper ventilation in that the air exhausted from restricted areas within the nuclear medicine department was recirculated to other unrestricted areas in the department. Further, the radiation safety officer (RSO) had not been informed of specific physician and pharmacy directives regarding the use of certain radiopharmaceuticals. These issues are discussed in greater detail in the enclosed inspection report.

Although the issues noted above did not result in any significant incident during this inspection period, they are nonetheless a concern because each had existed over a substantial period of time. Furthermore, the ventilation problems identified during this inspection could have resulted in a radioactive gas being directly vented to unrestricted areas had a spill occurred within the nuclear medicine imaging or radiopharmacy areas. Additionally, the findings of this inspection indicate that radiation safety audits warrant further improvement with respect to the detail of program reviews and the areas examined by the health physics staff.

Consequently, in your reply to this letter, you should describe those specific actions planned or taken to improve the effectiveness of the management control of your licensed operations, with particular emphasis on measures currently being taken to prevent further violations. Your response to this matter should address the broad concern regarding the program oversight afforded by the radiation safety committee and the RSO in addition to the specific actions taken to correct the violations discussed in the enclosed Notice.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,

ORIGINAL SIGNED BY:
LJ. CALLAN

L. J. Callan, Director
Division of Radiation Safety
and Safeguards

Enclosures:

1. Appendix A - Notice of Violation
2. Appendix B - NRC Inspection Report
30-03258/91-01

cc w/Enclosures:

Texas Radiation Control Program Director

bcc:

DMB - Original (IE-07)
RDMartin
LJCallan
JPJaudon
MRodriguez, OC/LFDCB (4503)
*WLFisher
*CLCain
*LLKasner
*MLMcLean
*NMIS
*MIS System
*RIV Files (2)
*RSTS Operator
*REHall, URFO

*W/IFS Form

APPENDIX A
NOTICE OF VIOLATION

Department of the Army
Brooke Army Medical Center
Ft. Sam. Houston, Texas

Docket No. 30-03258
License No. 42-01368-01

During an NRC inspection conducted on November 20-22, 1991, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991), the violations are listed below:

- A. 10 CFR 35.205(b) requires that a licensee administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

Contrary to the above, from July 1990 to November 20, 1991, the licensee administered radioactive xenon-133 gas in Rooms 31N, 34, and 35N of the nuclear medicine department. These rooms were not at negative pressure compared to surrounding rooms.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on November 20-22, 1991, licensed material consisting of microcurie quantities of iodine-125, carbon-14, and other radionuclides, located in a refrigerator and in a freezer in Room 7 of the Institute of Surgical Research, an unrestricted area, was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

This is a Severity Level IV violation (Supplement IV).

- C. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of November 22, 1991, the licensee did not make surveys to determine that individuals were not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103.

Specifically, the licensee had failed to evaluate airborne concentrations of xenon-133 within certain areas of the nuclear medicine department during patient examination involving the administration of xenon-133 without the use of a gas collection system.

This is a Severity Level IV violation (Supplement IV).

- D. 10 CFR 35.70(a) requires that a licensee survey with radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on numerous occasions from July 1990 to November 22, 1991, the licensee did not survey with a radiation detection instrument at the end of the day in Room 555 of the main hospital, an area where radiopharmaceuticals were routinely administered.

This is a Severity Level IV violation (Supplement VI).

- E. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity at least quarterly over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries

Contrary to the above, the licensee did not test a dose calibrator (Serial No. 30742) for linearity over a range of activity as low as 10 microcuries during the first and fourth quarters of 1991. The linearity tests performed during these quarters included only activities as low as 16.2 and 14.9 microcuries respectively. Additionally, the licensee did not test a second dose calibrator (Serial No. 30743) for linearity over a range of activity as low as 10 microcuries during the first, second, and third quarters of 1991. The linearity tests performed for this dose calibrator during these periods included only activities as low as 18, 15.5, and 16.3 microcuries respectively. A third dose calibrator was also not tested for linearity over a range of activity as low as 10 microcuries during the third quarter of 1991. This test included activities only as low as 12.6 microcuries.

This is a Severity Level IV violation (Supplement VI).

- F. 10 CFR 35.200(c)(1) specifies, in part, that a licensee may depart from the manufacturer's instructions for preparing reagent kits for which FDA has approved an NDA provided that the licensee has a written directive made by an authorized user physician which includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition.
10 CFR 35.200(c)(2) requires, in part, that a licensee keep the written directive and a record of the number of patient administrations under the departure in an auditable form and available for inspection.

Contrary to the above, as of November 22, 1991, the licensee had: (1) departed from manufacturers' instructions for preparing reagent kits for certain technetium-99m sestamibi, sulphur colloid, and diethylethylamine penta-acetic acid (DTPA) preparations without having a written directive made by an authorized user physician; (2) failed to include in some written departures a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition; and (3) failed to keep a record of the number of patient administrations under certain departures for the period July 1990 to November 1991.

This is a Severity Level IV violation (Supplement VI).

- G. License Condition 26 states, in part, that except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 4, 1984, including any enclosures.

1. Paragraph 11 of the Radiation Protection Program (BAMC Memo 40-72) enclosed with the application specifies, in part, that a physical inventory will be conducted under the supervision of the Health Physics Office personnel. Additionally, a written report detailing the amount of radioactive material received, used, disposed, and on hand will be submitted to the Health Physics Officer (HPO) at the end of each quarter.

Contrary to the above, the nuclear pharmacy inventory records submitted to the HPO, for the period from July 1990 to November 20, 1991, did not document the quantity of material disposed of for any radionuclide, nor did they include the quantity of technetium-99m currently on hand at the time the inventory was completed. The nuclear pharmacy inventory of technetium-99m did not account for the total quantity used, disposed of, or remaining in inventory.

This is a Severity Level IV violation (Supplement VI).

2. Paragraph 18 of the Radiation Protection Program (BAMC Memo 40-72), enclosed with the application states, in part, that the rules in Appendix G, NRC Regulatory Guide 10.8 (RG 10.8), will be followed as general rules for safe use of radioactive materials.

Appendix G of RG 10.8, "General Rules for Safe Use of Radioactive Materials," states, in part, that workers are not to eat, smoke, drink, or apply makeup in any area where radioactive material is used or stored.

Contrary to the above, on November 20 and 21, 1991, the inspectors observed an individual drinking coffee within a restricted area of the nuclear medicine department and an individual eating candy within

a research laboratory where radioactive materials were in use at the time.

This is a Severity Level IV violation (Supplement VI).

3. Paragraph 17(e) of the Radiation Safety Program (BAMC Memo 40-72), enclosed with the application states, in part, that the Health Physics Officer (HPO) will review current authorizations at least once a year.

Contrary to the above, as of November 22, 1991, the HPO had failed to review user authorizations for the use of specific radioactive materials for a period of several years. This has resulted in the failure to revise user certificates to correctly document the materials possessed and used by physician users.

This is a Severity Level IV violation (Supplement VI).

4. Paragraph 17(c)(1) of the Radiation Safety Program (BAMC Memo 40-72) enclosed with the application states, in part, the procedures for obtaining authorization from the Radiation Control Committee to use ionizing radiation. For human use, the principal user will prepare in final form, and provide to the Health Physics Officer (HPO) a protocol for nonroutine human use of radioactive materials. Specifically, the use of radiopharmaceuticals not listed in Appendix E, AR 40-37, of the Radiation Safety Program (BAMC 40-72) require a protocol submission to the Health Physics Officer (HPO).

Contrary to the above, as of November 22, 1991, a principal user failed to submit protocols for three radiopharmaceuticals not listed in Appendix E, AR 40-37 of the Radiation Safety Program (BAMC Memo 40-72).

This is a Severity Level IV violation (Supplement VI).

- H. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area be instructed in the health protection problems associated with exposure to radioactive materials or radiation and in precautions or procedures to minimize exposures.

Contrary to the above, as of November 22, 1991, the licensee failed to provide instruction to one group of individuals, a group of contract workers providing housekeeping services to the medical complex. Their work required that they perform their duties in some restricted areas without supervision by the technical staff or authorized users.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, the Department of the Army is hereby required to submit a written statement or explanation to the Regional Administrator, Region IV, with a copy to the U.S. Nuclear Regulatory

Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 13th day of January, 1992

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report No. 30-03258/91-01

License No. 42-01368-01

Licensee: Department of the Army
Brooke Army Medical Center
Ft. Sam Houston, Texas

Facility Name: Brooke Army Medical Center

Inspection At: Ft. Sam Houston

Inspection Conducted: November 20-22, 1991

Inspectors: Linda L. Kasner, Senior Radiation Specialist
Nuclear Materials Inspection Section

M. Linda McLean, Radiation Specialist
Nuclear Materials Inspection Section

Approved:

Charles L. Cain
Charles L. Cain, Chief, Nuclear Materials
Inspection Section

1/10/92
Date

Inspection Summary

Inspection Conducted November 20-22, 1991 (Report No. 30-03258/91-01)

Areas Inspected: This was a routine, unannounced radiation safety inspection of a broad scope byproduct material program authorizing the use of licensed materials for medical research and clinical diagnostic procedures, and the use of licensed radiopharmaceuticals and sealed sources in therapeutic procedures. The inspection included the review of facilities, instrumentation and calibrations, byproduct material receipt and use, inventory control, waste disposal, radiation surveys and evaluations, and management oversight and organization.

Results: Several violations of written commitments made in the license application and NRC regulations were identified. While none of the violations independently posed a significant safety risk, collectively the violations were considered notable because they had existed over a substantial period of time.

Of particular concern was a problem involving inadequate ventilation in areas where radioactive gases were used and stored. This issue was associated with the use and storage of curie quantities of xenon-133 and the administration of xenon-133 gas to patients without the use of a gas collection system. The inspection revealed that had a spill occurred in the specific areas of use,

radioactive gas would have been directly vented to other unrestricted areas of the facility. Furthermore, the licensee's evaluation of xenon-133 gas concentrations within the respective areas of use had not taken into consideration the failure to use a xenon-133 gas collection system for certain patient examinations.

Although several improvements were noted in the radiation safety program, the inspection findings involved a number of issues which indicate that internal program audits warrant further improvement with regard to the detail of program reviews. Specifically, the radiation safety officer (RSO) was either not informed or was unaware of certain practices within the medical facility. The inspection findings indicate a need for improvement in the management oversight of licensed operations.

Within this inspection, the following violations were identified:

Facilities

1. Administration of xenon-133 gas within rooms which were not at negative pressure relative to surrounding areas. (Section 4)
2. Failure to maintain constant surveillance or to otherwise secure licensed material stored in an unrestricted area. (Section 4)

Instrumentation and Calibrations

3. Failure to perform dose calibrator linearity tests over a range of activities that included values as low as 10 microcuries. (Section 5)
(Section 5)

Byproduct Material Receipt, Use, and Inventory Control

4. Failure of a user to submit to the RSO all required information for quarterly inventory reports. (Section 6)
5. Failure to observe restrictions against the consumption of food or beverage within restricted areas. (Section 6)

Radiation Surveys and Evaluations

6. Failure to evaluate airborne concentrations of xenon-133 gas under certain conditions associated with patient examinations. (Section 7)
7. Failure to survey with a radiation detection survey instrument at the end of each day of use certain areas where radiopharmaceuticals were administered. (Section 7)

Management Oversight

8. Failure to perform an annual review of protocols authorized by the radiation safety committee (RSC). (Section 8)

9. Failure to submit new protocols for review by the RSC. (Section 8)
10. Failure to document physician and pharmacy directed radiopharmaceutical departures. (Section 8)
11. Failure to provide training to contractor staff working within restricted areas. (Section 8)

One additional violation was identified but was not cited in accordance with Section V.G.1 of the NRC's Enforcement Policy (10 CFR Part 2, Appendix C). This violation is described in Section 8.

DETAILS

1. Individuals Contacted

*Col. L.E. Waldman, Asst. Deputy Commander for Clinical Services
*Maj. J.E. Tucker, Radiation Safety Officer (RSO)
Lt. Col. J.D. Heironimus II, M.D., Chief, Nuclear Medicine Service
MSgt. Rook, Health Physics Office
Sgt. Kalinowski
Maj. M.D. Berndt, R.Ph., Nuclear Pharmacist
Wanda Brown, Area Radiation Protection Officer, Institute of Surgical
Research (ARPO/ISR)
Dr. Gerald Merrill, Researcher, ISR
John Green, Pharmacy Assistant
Sgt. Dave Jackson, CNMT, Chief Technologist

*Indicates those individuals present during the exit briefing conducted on
November 22, 1991.

2. Followup on Previous Violations

(Closed) Violation of 10 CFR 20.201(b) (30-03258/90-01): Failure to
Evaluate the Occupational Exposure Received by Certain Individuals While
Participating in Licensed Activities. The licensee had completed the
required dose evaluations and had issued personal radiation monitoring
devices to all required personnel.

(Closed) Violation of 10 CFR 35.205(c) (30-03258/90-01): Failure to
Calculate Spilled Gas Clearance Times for Areas Where Xenon-133 was Used:
The licensee had completed the necessary calculations.

(Closed) Violation of 10 CFR 71.5(a) (30-03258/90-01): Failure to
Maintain on File the Performance Testing Records for DOT Type A
Specification 7A Packages Routinely Used for Transporting Radioactive
Materials. The licensee had obtained the required performance test
records.

3. Program Overview

This broad scope byproduct material program includes the use of medical
products for diagnostic and therapeutic procedures, as well as limited
research activities conducted under the specific approval of the radiation
safety committee (RSC).

Routine diagnostic and therapeutic procedures involving the use of
radiopharmaceuticals had been performed under the supervision of several
authorized user physicians, although the chief of nuclear medicine had
provided management oversight of the nuclear medicine service. The chief
of nuclear medicine had also served as the RSC chairman for several years.
The technical staff in the nuclear medicine department was comprised of

4-5 technologists and a nuclear pharmacist. This staff was responsible for completing 200-400 procedures per month, and patient examinations were routinely scheduled in three areas of the medical facility. During this inspection period, therapeutic procedures involving the use of brachytherapy sources were performed under the oversight of the radiation therapy department.

The research activities at this facility had declined during this inspection period, and several users had either departed from the research group or had discontinued their use of radioactive materials. At the time of this inspection, the remaining active research projects primarily involved radioimmunoassays (RIA) and labeling techniques involving microcurie quantities of carbon-14, iodine-125, and hydrogen-3.

Throughout this inspection period, the number of authorized users had remained a relatively small group which had submitted few petitions to the RSC for new protocol authorizations. The RSO had been designated to serve in the position since the previous inspection conducted in July 1990. Additionally, a new staff member had joined the health physics office during this inspection period and a senior staff member was preparing for reassignment elsewhere at the time of the inspection.

4. Facilities

As noted above, several areas of the medical complex were involved in the use of radioactive materials. Brachytherapy sources were stored and distributed for patient use from the radiation therapy department located in the main hospital (Building 1000), a separate structure from the primary nuclear medicine department. These sources were under the control of the licensee's teletherapy physicist and therapy technical staff who were responsible for transporting sources to and from patient rooms within the main hospital, inventory control, and periodic surveys of the storage area. The records associated with these tasks were reviewed and found to be complete in content. Exposure rate surveys of the source storage room and adjacent areas revealed that radiation levels were well within acceptable limits and the area was found to be adequately secured from unintended entrance.

Research activities were primarily conducted in a building designated as the Institute of Surgical Research (ISR). Within the ISR, several labs were identified as areas where radioactive materials were used and stored. A group of laboratories were selected for inspection tours based on the active use of materials at the time of the inspection. Of the four labs toured, all but one had provided adequate security for the areas where licensed material was stored.

The exception, designated as Room 7, was an area shared by a research lab and the ISR pathology department. Additionally, the room was also used as an entrance to the ISR building since it had both internal and external doorways. The material stored in Room 7 included microcurie quantities of radiochemicals which were stored within a refrigerator, and the

radioactive waste generated throughout the ISR which was stored in a freezer. At the time of this inspection, neither entrance to the room was secured. The staff explained that the purpose in leaving the doors unsecured was to provide a "shortcut" for other staff members who required access to administrative offices nearby. Likewise, the refrigerator and freezer were not secured, despite the fact that locks had been provided at some time in the past. When questioned regarding the lack of security for the storage locations, staff members working in this area explained that securing the refrigerator with each use required too much time and therefore, they had elected to leave it unsecured. They also acknowledged that since their work required that they attend to duties in other rooms, this unrestricted area had not remained under constant attendance by an authorized user or designate. This was identified as a violation of 10 CFR 20.207(a), which requires that licensed material stored in an unrestricted area be secured from unauthorized removal.

The principle area of use for the nuclear medicine service was a contiguous suite of rooms (Nos. 27-35) located on the ground floor of Building 2397 (Beach Pavilion). Additionally, the nuclear medicine service had routinely used Room 555 of the main hospital to perform clinical studies for intensive care patients. The cardiology department was likewise used for certain cardiac procedures. Although the aforementioned areas were noted to have adequate restriction and security for the use and storage of licensed materials, a concern was raised regarding the ventilation system serving the primary nuclear medicine department.

The nuclear medicine department was located adjacent to a patient registration area and included several offices and an employee breakroom as well as imaging areas and the nuclear pharmacy. Entrance to the area was provided via an open hallway and two exterior doors. The imaging rooms and main hallway entrance were without doors, although the remaining offices, breakroom, dictation area, and pharmacy had entrances equipped with doors.

Ventilation to this area was provided by several means, including an air exchange system for the entire area, a fume hood with separate exhaust located in the nuclear pharmacy, and independent floor vents located in each imaging cubicle. Although engineering diagrams were not available for the inspectors' review, examination of the ventilation diagrams which were available revealed several items of concern.

First, the primary air exchange for the area was via the general air exchange unit. This unit served as the air supply for each room as well as the principle means of exhaust. However, the air exhaust noted in the licensee's evaluations (also submitted with the license application) was determined to be air that was recirculated within all areas of the department, including certain unrestricted areas such as offices and the employee breakroom. Additionally, the air volume within the nuclear medicine area was found to communicate with the airspace above the suspended ceiling in this area as well as into the general hallway

adjacent to the department. Furthermore, the imaging areas where xenon-133 was routinely administered to patients were each found to be at positive pressure relative to the adjacent rooms. In examining this problem, the RSO stated that the licensee had, in the past, treated the entire area as a unit for the purpose of demonstrating a negative pressure gradient necessary for the use of xenon-133 rather than evaluating the individual rooms. This issue was identified as a violation of 10 CFR 35.205(b) which requires that a licensee limit the use of radioactive gases to rooms which are at negative pressure relative to surrounding rooms.

The inspectors also discussed their concern that although the ventilation rates in the nuclear medicine department had been measured at 6-month intervals as required, the evaluations performed prior to the inspection were inadequate to determine airflow patterns within the area since air was recirculated rather than directly vented to the outside and the rooms in which xenon-133 was administered were not enclosed.

In response to the concerns raised during the inspection, the RSO completed further evaluations of the ventilation system in the nuclear medicine department during the week following the inspection. These evaluations confirmed that air from the restricted areas (where xenon-133 was administered) was recirculated to unrestricted areas of the department. These findings were reported telephonically to the NRC Region IV office on November 26, 1991. After subsequent discussion with NRC staff and the RSO, the licensee elected to discontinue the use of xenon-133 in this area until improvements were made to the ventilation system and changes to create a confined space from an existing imaging area were complete. The RSO explained that the licensee's proposed corrective measures would limit the future use of xenon-133 to an enclosed room.

Two violations were identified.

5. Instrumentation and Calibrations

a. Dose Calibrators

Three dose calibrators were available for use by the nuclear medicine and pharmacy staffs. Each had been tested daily for constancy when in use and geometry and annual accuracy tests were performed as required. The licensee had tested each dose calibrator for linearity quarterly as required; however, the test had not been conducted over a range of activity that included values as low as 10 microcuries for each test performed during this inspection period. This issue involved: (1) a dose calibrator (Serial No. 30742) which was tested to values as low as 16.2 and 14.9 microcuries during the first and fourth quarters of 1991; (2) a dose calibrator (Serial No. 30743) which was tested to values as low as 18, 15.5, and 16.3 microcuries during the first, second, and third quarters of 1991; and (3) a dose calibrator (Serial No. 30163) which was tested to 12.6 microcuries

during the third quarter of 1991. This issue was identified as a violation of 10 CFR 35.50(b)(3) which requires that a linearity test be conducted over a range of activity from the highest dosage administered to a patient to 10 microcuries.

b. Survey Instruments

The licensee possessed an adequate number and type of survey instruments for the radioactive materials used at its facility. Each instrument had been calibrated at the required annual frequency in accordance with the procedures submitted in the license application. For those instruments used to analyze removable contamination survey samples, counting efficiency factors had been determined for the appropriate radionuclides. The licensee's records associated with survey instrument calibrations were found complete in content and no problems with this aspect of the program were identified.

c. Xenon-133 Gas Collection Systems

The licensee had used a Pulmonex gas collection system for certain ventilation lung studies. As was previously noted, this system was not used for all examinations requiring the administration of xenon-133. The system had been checked monthly for trap efficiency according to a protocol developed by the RSO. Although the licensee's test conformed to accepted industry standards and the licensee had determined the activity collected in trap effluent during a single patient study, the RSO had not yet established an action level for determining when trap filters were saturated and in need of replacement.

A review of the recorded efficiency test results for this inspection period revealed that trapping efficiency had fluctuated on several occasions. Test data indicated increased quantities of xenon-133 in the trap effluent for several tests, with some measurements evidencing emission of greater than 1 percent of the patient dose administered for an examination. This issue was discussed with the RSO, and it was noted that the procedure should be revised to establish an action level for filter replacement in the xenon-133 collection system.

One violation was identified.

6. Byproduct Material Receipt, Inventory Control and Waste Disposal

a. Byproduct Material Receipt, Use, and Inventory Control

Byproduct material had been received at several locations within the medical complex. In accordance with the license application, each authorized user was responsible to monitor his or her inventory to assure that individual possession limits were not exceeded where assigned. (Possession limits were not assigned to all users. This

matter is also discussed in Section 8). Inventory records for several users were reviewed and noted to have sufficient detail to assess the quantities of material currently on hand and the dates of use, transfer, or disposal.

The RSD was designated as the responsible individual for monitoring the byproduct material inventory for the medical complex as a whole. This was accomplished by periodic review of users' records during lab audits as well as through review of quarterly inventory reports submitted by each user to the health physics office. Item 11 of the licensee's radiation protection program manual describes individual responsibilities for inventory control, including a requirement for each user to submit a written report detailing the materials received, used, disposed, and currently on inventory at the end of each calendar quarter. A selection of reports submitted by active users were reviewed and with the exception of one group, all were found adequate to meet this license requirement.

The issue noted above involved inventory records for the nuclear pharmacy. Although the pharmacy had submitted inventory records quarterly as required, the records did not document the quantity of material disposed of for any radionuclide, nor did they include the quantity of technetium-99m currently on hand at the time the inventory was completed. The pharmacy had instead documented only the total activity of technetium-99m administered to patients, which did not account for the total quantity used, disposed of, or remaining in inventory. In discussions with pharmacy personnel, this oversight was attributed to the fact that the pharmacy's computer data base, which was used to complete the inventory, did not include software subroutines that would permit the generation of a report that included integrated data for all technetium-99m products used and disposed of during a given period. As a result, the staff had to tabulate the data by hand and had focused primarily on the quantities administered in patient dosages. This item was identified as a violation of License Condition 26, which references the license application and its enclosures. The licensee's radiation protection program manual (BAMC Memo 40-72), which describes specific inventory requirements, was enclosed with the application.

b. Byproduct Material Use

A review of the activities conducted within several areas of the medical complex and under the direction of a number of authorized users revealed that generally, the use of byproduct material was done in accordance with specific protocols approved by the RSC. With the exception of two instances during the inspection, the majority of the staff were observed conducting activities in compliance with the licensee's general safety rules.

The licensee had adopted the guidance provided in Appendix G of Regulatory Guide 10.8 (Revision 1) for its rules regarding the safe

use of radioactive material. Among other directives, Appendix G includes restrictions against eating or drinking in areas where radioactive materials are used or stored. The exceptions referenced above included observation of an individual drinking coffee within a restricted area of the nuclear medicine department and an individual eating candy within a research laboratory where radioactive materials were in use at the time. This was identified as a violation of License Condition 26, which references the licensee's radiation protection program. Item 18 of the program manual stated that the rules in Appendix G of Regulatory Guide 10.8 would be followed.

c. Waste Disposal

Throughout this inspection period, the health physics office had maintained responsibility for collecting waste material from the various areas of use, segregating the material, and arranging for its eventual transfer or disposal. Records associated with this activity were reviewed and found complete in content. Individual researchers had retained responsibility for evaluating and documenting the quantities of radioactive materials disposed of via the sanitary sewerage system. These records were also found to be adequate and the methods used to determine the activity disposed of in this manner were generally consistent among the research staff. No concerns were identified with the licensee's waste disposal procedures.

Two violations were identified.

7. Radiation Surveys and Evaluations

a. Area Surveys

The health physics staff was responsible for completing periodic surveys including weekly exposure rate and removable contamination surveys within areas designated for sealed source storage or routine medical use, as well as monthly and quarterly surveys performed in research and certain unrestricted areas. Survey records for this inspection period appeared adequate and contained all required information.

The technical staff in the nuclear medicine department was responsible for the daily surveys required under 10 CFR 35.70(a). Areas subject to this requirement included the nuclear pharmacy, the primary nuclear medicine department and on occasion, cardiology and Room 555 of the main hospital. The licensee had complied with this requirement and had maintained the required records for all areas except Room 555. In discussions with several staff members, the inspectors were informed that this area was used an average of one day per week for nuclear medicine studies involving intensive care patients. The staff confirmed that the use of this room included radiopharmaceutical dosage administration, but they were unable to confirm that Room 555 had been surveyed on each day of use throughout

this inspection period. Additionally, a member of the health physics staff acknowledged that with exception of the weekly surveys performed by the health physics office, no other survey records had been located in this area. This was identified as a violation of 10 CFR 35.70(a) which requires, in part, that areas where radiopharmaceuticals are administered be surveyed at the end of each day of use.

b. Radiological Evaluations

The licensee had completed a number of evaluations associated with the use of radioactive materials. Some of these were associated with the submission of its application for renewal of the license and others were performed in association with changing conditions within certain areas. In reviewing these evaluations, one area of deficiency was noted.

The licensee's evaluations for airborne concentrations of xenon-133 did not fully address the current use of the material. Specifically, when the licensee had last performed an evaluation to demonstrate that room air concentrations would be maintained below the limits identified in 10 CFR Part 20, it had failed to take into consideration examinations where xenon-133 was administered without the use of a gas collection system. The RSO had last completed this evaluation on July 11, 1991, using an estimated (atmosphere) release factor normally associated with the use a gas collection system for a patient study. Based on discussions with the RSO, the oversight was attributed to the fact that he was not fully familiar with the practice of administering xenon-133 without the use of a closed collection system. This was identified as a violation of 10 CFR 20.201(b), which requires that a licensee perform the surveys or evaluations necessary to demonstrate compliance with the requirements of 10 CFR Part 20.

c. Personnel Exposures

A review of dosimetry records for this inspection period revealed that personnel exposures were well within the occupational limits prescribed under 10 CFR Part 20. Likewise, exposures for both the technical and research staffs were typically within the Level I limits (125 and 1875 millirems per quarter for the whole body and extremities respectively) of licensee's ALARA program. Whole body exposures were typically within the range of 20-40 millirems per month throughout this inspection period. The nuclear pharmacy staff evidenced the highest extremity exposures, with a range of 200-800 millirems per month.

One individual assigned to work in the nuclear pharmacy had exceeded the licensee's Level II limit (5.26 rems) with a quarterly extremity exposure of 6.04 rems. The matter was promptly investigated by the RSO and RSC, and thereafter duties involving the preparation of

radiopharmaceuticals were more evenly distributed among the pharmacy staff, which served to reduce any single individual's exposure. Although this distribution of duties was later disrupted due to a loss in personnel, the inspectors noted that the nuclear pharmacist who was handling the majority of the radiopharmaceuticals at the time of the inspection had continued to maintain his exposures below the licensee's investigational levels.

d. Bioassays

At the time of the inspection, only one group of workers was subject to the requirements of the licensee's bioassay program. This group included members of the nuclear medicine technical and physician staffs who participated in the administration of therapeutic dosages of iodine-131. The staff had administered 10 dosages of radioiodine-131 in quantities of approximately 100 millicuries or greater during the previous year. In each case, bioassays were performed within the required time period for those staff members directly involved in handling or administering the dose.

Although no violation of the licensee's bioassay program was observed, one concern was identified. This issue involved the manner in which the staff determined the minimum detectable activity (MDA) for the detection system and procedure used to perform bioassays. The licensee's procedure involved taking a count over the mid-thigh area of the bioassay subject to determine the MDA rather than using a known "blank" count, such as a phantom, for the background count used to calculate the MDA. This issue was discussed with the RSO who acknowledged his concern regarding this aspect of the procedure, although it had not yet been revised. The RSO was encouraged to complete his review of the procedure and make revisions as he believed appropriate.

Two violations were identified.

8. Management Oversight

As was noted in Section 2 of this report, the RSO was appointed to serve in this position since the previous inspection. Subsequent to his appointment, he had initiated efforts to correct some oversights which had existed in the past. These included improvements in the licensee's survey and waste disposal program, as well as improved documentation for the protocols submitted for the RSC's review during this inspection period. With the exception of the RSO, the licensee's RSC membership had remained stable and was found to include an appropriate representation of users supervising activities at the facility. Although some improvement was noted with regard to program oversight, several deficiencies regarding user authorizations, the associated documentation, and periodic reviews were identified. These issues are discussed below.

a. User Authorization

The licensee's radiation protection program manual (BAMC Memo 40-72) describes several levels of review for both authorized users and their protocols, as well as for the radiation safety program as a whole. Petitions for user authorization or additions to current user certificates were required prior to project implementation. Additionally, each user certificate (a document describing the approved materials and uses for a specific individual) was to be reviewed annually by the RSO to determine if the authorization was to be renewed, amended, or rescinded with appropriate recommendations provided to the RSC.

Item 17 of the program refers to the steps required to receive the RSC's authorization to use licensed materials. These requirements include submission of a petition from each user to the RSC for approval for the use of specific radioactive materials, including descriptions of the protocols or procedures associated with specific uses. For medical uses, the user was not required to submit a protocol if the radiopharmaceutical and intended use was considered routine or was included in a document identified as AR-37, which was enclosed with the program manual. For nonroutine medical procedures, submission of a protocol was required.

A review of user authorizations revealed that with exception of 2-3 protocols which had been issued during this inspection period, user authorizations had not been reviewed or revised in several years. This had resulted in the failure to revise user certificates to correctly document the materials possessed and used by physician users. This was identified as a violation of License Condition 26, Item 17(e) of the radiation protection program, which specifies that current user authorizations would be reviewed annually by the RSO.

Associated with the issue discussed above was the failure to submit each protocol involving nonroutine human use for review by the RSC. This item involved the use of radiopharmaceuticals classified by the Food and Drug Administration (FDA) as investigational new drugs (IND). At the time of the inspection, three IND products were used as prescribed by the chief of nuclear medicine. Although the IND protocols had been reviewed by the BAMC human use subcommittee and the institutional review board (according to the chief of nuclear medicine and the nuclear pharmacist), the RSO was unable to locate documentation authorizing use of the products by the RSC. This was later reviewed again with the chief of nuclear medicine, also the RSC chairman, who acknowledged his belief that approval from the RSC was overlooked when the projects were initiated. This issue was identified as a violation of License Condition 26, Item 17(c)(1) of the radiation protection program, which specifies that for human use, the petitioning principal user must prepare and submit to the RSO and RSC a protocol describing the radiopharmaceutical or material to be used and the specific procedures to be followed if a proposed medical

procedure is considered nonroutine. This violation was attributed, in part, to the failure of a former RSO to submit the documentation to the RSC for review.

Additionally, a review of physician user authorizations for the nuclear medicine service revealed that possession limits had been assigned for only a few radionuclides rather than for each radionuclide identified on the user certificate. For those radionuclides associated with specific possession limits, such as iodine-131, it was noted that although the individual authorizations did not exceed the limit identified in the license, collectively the quantity approved for three users would have exceeded the license limit for iodine-131 by a factor of 3. This was noted as an item worthy of further review in order to ensure that adequate controls were in place to prevent any group of users from exceeding the possession limits identified in the license.

b. Physician Directed Departures

The chief of nuclear medicine and the nuclear pharmacist had documented several departures for radiopharmaceutical preparations and their use during 1990-1991. Additionally, the pharmacy had compounded radiopharmaceutical preparations rather than using a commercial preparation for some radiopharmaceuticals. This practice had existed over a period spanning several years, and had been approved by the RSC at some time in the past. (The practice of compounding radiopharmaceuticals was in existence prior to the current nuclear pharmacist's assignment at BAMC.) At the time of this inspection, the procedures for compounding radiopharmaceuticals had not been reviewed by the RSC in some time, and the RSO was unaware of this practice. Also, the nuclear pharmacist explained that with the exception of pyrophosphate, sulphur colloid and diethylenetriamine penta-acetic acid (DTPA), that he had not compounded radiopharmaceutical preparations during recent months because of a shortage in the pharmacy staff. The pharmacy had instead used commercial preparations during this period.

The departures documented by the licensee were reviewed and found deficient in several respects. These observations included the failure to document certain departures involving: (1) the use of activities in excess of those stated in the package insert for technetium-99m sestamibi (Cardiolite); (2) the use of sulphur colloid preparations beyond the expiration period specified by the manufacturer; and (3) the addition of ascorbic acid to DTPA preparations for certain examinations. Additionally, the licensee did not clearly document the reason for each departure and for some departures, documentation indicated that the reason for the departure was based on a cost savings for the nuclear medicine clinic. Likewise, the licensee had not maintained a record of the number of patient administrations under each departure. (It should be noted that the documented departures were for groups of patients rather

than a specific individual.) This was identified as a violation of 10 CFR 35.200(c)(1) and (2).

c. ALARA Program Oversight

The licensee had established an ALARA program for activities conducted at its facility. The program addressed many areas of concern, including personnel exposures and review, specific audits to be performed by the RSC and RSO, and requirements to submit documentation of associated safety procedures with petitions for specific protocol reviews. Although some of the protocols approved by the RSC included documentation regarding technical safety concerns, such as the need for bioassays or certain survey instrumentation, many did not include references to safety procedures. This issue was discussed with the RSO and noted as a concern in that it could have resulted in an oversight of certain technical issues associated with the use of radioactive materials. The RSO was encouraged to include full documentation of specific safety requirements with protocols that were approved and returned to the petitioning authorized user.

A review of the RSO's ALARA program audits revealed that quarterly exposure reviews had been performed as required with results reported to the RSC on a quarterly basis. However, the annual review required under the licensee's program (also a requirement of 10 CFR Part 35 for medical licensees) had not been conducted during the calendar year 1990. The RSO had conducted a program review in June 1991 for activities conducted in 1990, but as he acknowledged, the findings of his review were inconsistent with several of the findings of this inspection. Since the RSO had recognized this oversight and took efforts to correct it and prevent its recurrence, in accordance with 10 CFR Part 2, Appendix C, Section V.G.1, it was not cited as a violation.

This oversight was attributed, in part, to the fact that the RSO was appointed to his current position during the latter part of 1990 and had not received a detailed orientation regarding his incumbent duties. The RSO noted this as a problem as well, and further noted that his work at BAMC was his first experience with a medical program.

d. Training

The licensee had developed and initiated a training program for all personnel working in areas that were restricted due to the presence of radioactive materials. This program included instruction to authorized users and their staffs, as well as nursing personnel caring for patients who received therapeutic dosages of radiopharmaceuticals or brachytherapy treatments. Refresher training was provided on an annual basis in addition to the initial training given during employee orientation.

The licensee had complied with its approved training program; however, it had failed to provide instruction in accordance with 10 CFR 19.12 for one group of individuals. This problem involved a group of contract workers providing housekeeping services to the medical complex. Although their work was completed in the presence of authorized individuals in some restricted areas, the nature of their work required that they perform their duties in some restricted areas without supervision by the technical staff or authorized users. The health physics staff had recognized this oversight prior to the inspection, but had not yet corrected the problem at the time of the inspection. This issue was identified as a violation of 10 CFR 19.12 which requires that all individuals working in or frequenting any portion of a restricted area be informed of precautions or procedures to minimize their exposure to radiation.

Four violations were identified.

9. Exit Briefing

At the conclusion of the inspection, the inspectors met with the individuals noted in Section 1 to review the findings of the inspection as presented in this report. As noted elsewhere in this report, the concerns regarding facility ventilation were later discussed during a telephone conversation between the RSO and one of the inspectors on November 26, 1991.

6 Feb 1991

MEMORANDUM FOR THE NUCLEAR REGULATORY COMMISSION

SUBJECT: Departure from the Manufacturer's package insert for the preparation of radiopharmaceuticals.

1. In response to the Federal Register, Vol. 55, No. 164, Thursday, August 23, 1990, pages 34513-18, an interim rule titled "Authorization to Prepare Radiopharmaceuticals Reagent Kits and Elute Radiopharmaceutical Generators; Use of Radiopharmaceuticals for Therapy". The interim rule allows licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions for elution and preparation in the package insert, provided the licensees meet certain conditions and limitations.

2. The following departures from the package insert are used within the Nuclear Medicine Service on either a daily basis or on a as needed basis for benefit of patient care and diagnostic studies.

a. On a daily basis, Methylene Diphosphonate (MDP) cold kits, by any manufacturer are compounded with an activity of 600 mCi of ^{99m}Tc Pertechnetate as a cost savings measure to the clinic. Most kits on the market are limited (by the package insert) to 200 mCi. Radiochemical purity is checked daily, using paper chromatography to insure the tagged compound is within the USP and NRC guidelines.

b. On a daily basis, Ascorbic Acid (3 mg) is added to the MDP kits to prevent any oxidation of the kit and resulting breakdown of the kit.

c. For V/Q scans on patients with a Right to Left shunt, or in patients with possible pulmonary hypertension, the Macroaggregated Albumin (MAA) kits are compounded with 100 mCi of ^{99m}Tc Pertechnetate. Double the amount stated in the package insert, in the effort to limit the number of particles injected during the study.

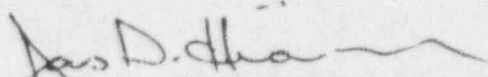
d. On a weekly basis, Xe-133 as a radiochemical is dissolved in saline and used for injection for burn lung and heart right ventricle "first pass" studies.

e. As needed, ^{99m}Tc Diethylenetriamine pentaacetic acid (DTPA) is used for gastric emptying studies.

f. As needed, ^{99m}Tc-exametazine white blood cells are labeled for detection of infection.

(LIROTEC)

3. The above uses, while not included in the package insert, are reported in current medical journals of nuclear medicine and are found to be useful and appropriate for medical care at this medical facility.



JAMES D. HEIRONIMUS II, M.D.
Lt. Col., USAF, MC
Chief, Nuclear Medicine Service

11 Nov 1990

MEMORANDUM FOR THE NUCLEAR REGULATORY COMMISSION

SUBJECT: Departure from the Manufacturer's package insert for the preparation of radiopharmaceuticals.

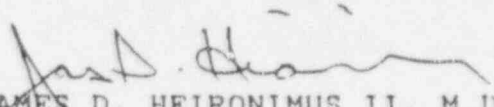
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2. The following departures from the package insert are used within the Nuclear Medicine Service on either a daily basis or on a as needed basis for benefit of patient care and diagnostic studies.

a. On a daily basis, Methylene Diphosphonate (MDP) cold kits, by any manufacturer are compounded with an activity of 500 mCi of ^{99m}Tc Pertechnetate as a cost savings measure to the clinic. Most kits on the market are limited (by the package insert) to 200 mCi. Radiochemical purity is checked daily, using paper chromatography to insure the tagged compound is within the USP and NRC guidelines.

b. On a daily basis, Ascorbic Acid (3 mg) is added to the MDP kits produced by Amersham, due to the lack of an anti-oxidant in the commercial formulation.

c. For V/Q scans on patients with a Right to Left shunt, or in patients with possible pulmonary hypertension, the Macroaggregated Albumin (MAA) kits are compounded with 100 mCi of ^{99m}Tc Pertechnetate. Double the amount stated in the package insert, in the effort to limit the number of particles injected during the study.


JAMES D. HEIRONIMUS II, M.D.
Lt. Col., USAF, MC
Chief, Nuclear Medicine Service

HOW SUPPLIED: Du Pont's **CARDIOLITE**[®] Kit for the preparation of Technetium Tc99m Sestamibi is supplied as a 5ml vial in kits of two (2) vials (5) and thirty (30) vials - sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at room temperature (15-30°C) before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each thirty (30) vial kit is one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material identified in 35.100 and 35.200 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

USA
E. I. du Pont de Nemours & Co.
331 Treble Cove Road
Billerica, Massachusetts USA 01862

CARDIOLITE[®]

Kit for the preparation of
Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5ml vial contains a sterile, non-pyrogenic, lyophilized mixture of:

Tetrakis (2-methoxy isobutyl isonitrile) Copper (II) tetrafluoroborate - 1.0mg
Sodium Citrate Dihydrate - 2.6mg
L-Cysteine Hydrochloride Monohydrate - 1.0mg
Mannitol - 20mg
Stannous Chloride Dihydrate - minimum (SnCl₂·2H₂O) - 0.025mg
Stannous Chloride, Dihydrate (SnCl₂·2H₂O) - 0.075mg
Tin Chloride (Stannous and Stannic) Dihydrate - minimum (as SnCl₂·2H₂O) - 0.086mg

Prior to lyophilization the pH is 5.3 to 5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m injection. The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is Tc99m(MIBI)₃⁺ where MIBI is 2-methoxy isobutyl isonitrile.

PHYSICAL CHARACTERISTICS

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.02 hours. Photons that are useful for detection and imaging studies are listed in Table 1.

Table 1. Principle Radiation Emission Data

Radiation	Mean γ / Disintegration	Mean Energy (keV)
Gamma-2	89.07	140.5

*Kocher, David C. Radioactive Decay Data Tables, DOE/TIC-11026, 108 (1981)

EXTERNAL RADIATION

The specific gamma ray constant for Tc99m is 5.4 microcuries/kg MBq hr (0.78R/mCi hr) at 1cm. The first half value layer is 0.017cm of Pb. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. To facilitate control of the radiation exposure from Mega becquerel (millicurie) amounts of this radionuclide, the use of a 0.25cm thickness of Pb will attenuate the radiation emitted by a factor of 1,000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.017	0.5
0.08	10 ⁻¹
0.16	10 ⁻²
0.25	10 ⁻³
0.33	10 ⁻⁴

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in Table 3.

Table 3. Physical Decay Chart, Tc99m Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	6	398
1	89.1	9	355
2	79.4	10	316
3	70.8	11	282
4	63.1	12	251
5	56.2		
6	50.1		
7	44.7		

* Calibration Time



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plex which has been found to accumulate in viable myocardial tissue in a manner analogous to that of Thallous Chloride Tl-201. Scintigraphic images obtained in animals and man after the intravenous administration of the drug have been comparable to those obtained with Thallous Chloride Tl-201 in normal and abnormal myocardial tissue.

The major pathway for clearance of Tc-99m Sestamibi is the hepatobiliary system. Activity from the gall bladder appears in the intestines within one hour of injection. Twenty-seven percent of the injected dose is excreted in the urine, and approximately thirty-three percent of the injected dose is cleared through the feces in 48 hours. The agent is excreted without any evidence of metabolism.

Pulmonary activity is negligible even immediately after injection. Blood clearance studies indicate that the fast clearing component clears with a $T_{1/2}$ of 4.3 minutes at rest. At five minutes post injection about 8% of the injected dose remains in circulation. There is less than 1% protein binding of Technetium Tc-99m Sestamibi in plasma. The myocardial biological half-life is approximately six hours after a rest injection. The biological half-life for the liver is approximately 30 minutes after a rest injection. The effective half-life of clearance (which includes both the biological half-life and radionuclide decay) for the heart is approximately 3 hours, and for the liver is approximately 28 minutes, after a rest injection. The ideal imaging time reflects the best compromise between heart count rate and surrounding organ uptake.

A study in a dog myocardial ischemia model reported that Technetium Tc-99m Sestamibi undergoes myocardial distribution (redistribution), although more slowly and less completely than Thallous Chloride Tl-201. A study in a dog myocardial infarction model reported that the drug showed no redistribution of any consequence. Definitive human studies to demonstrate possible redistribution have not been reported. In patients with documented myocardial infarction, imaging revealed the infarct up to four hours post dose.

Animal studies have shown that myocardial uptake is not blocked when the sodium pump mechanism is inhibited. Myocardial uptake which is coronary flow dependent is 1.2% of the injected dose. The following table illustrates the biological clearance as well as effective clearance (which includes biological clearance and radionuclide decay) of Tc-99m Sestamibi from the heart and liver.

[Organ concentrations expressed as percentage of injected dose; data based on an average of 5 subjects.]

Time	Heart		Liver	
	Biological	Effective	Biological	Effective
5 mins	1.2	1.2	20	20
30 mins	1.1	1.0	12	11.3
1 hour	1.0	0.9	5.6	5.0
2 hours	1.0	0.8	2.2	1.7
4 hours	0.8	0.5	0.7	0.4

INDICATIONS AND USAGE: CARDIOLITE™ Kit for the preparation of Technetium Tc-99m Sestamibi is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality in patients with suspected myocardial infarction.

CARDIOLITE™ Kit for the preparation of Technetium Tc-99m Sestamibi is also useful in the evaluation of myocardial function using the first pass technique.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure.

PRECAUTIONS:

GENERAL:

The contents of the vial are intended only for use in the preparation of Technetium Tc-99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc-99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc-99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc-99m Injection containing oxidants should not be used.

Technetium Tc-99m Sestamibi should not be used more than six hours after preparation.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In comparison with most other diagnostic technetium labeled radiopharma-

ceuticals, (ALARA) is necessary in written or (childbearing) (x) (Dosemetry subsection in DOSAGE AND ADMINISTRATION) (see).

The active intermediate, [Tc-99m]BF₄⁻, was evaluated for genotoxic potential using a battery of five tests. No genotoxic activity was observed in the Ames CHO/Hprt and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations ($\geq 20 \mu\text{g/ml}$), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. [Tc-99m]BF₄⁻ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, 600 X maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc-99m Sestamibi. It is also not known whether Technetium Tc-99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc-99m Sestamibi should be given in a pregnant woman only if clearly needed.

Infertility examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers:

Technetium Tc-99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc-99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use:

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient metallic or bitter taste immediately after the injection of Technetium Tc-99m Sestamibi. A few cases of transient headache, flushing and non-itching rash have also been attributed to administration of the agent. One patient demonstrated signs and symptoms consistent with seizure 6 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc-99m Sestamibi have been reported.

DOSAGE AND ADMINISTRATION: The suggested dose range for IV administration to be employed in the average patient (70kg) is:

$$370 \text{ (1110MBq) (10 30mCi)}$$

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (See also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at room temperature (15-30°C) before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70 kg) per 1110MBq (30mCi) of Technetium Tc-99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc-99m Sestamibi

Organ	Estimated Radiation Absorbed Dose			
	RFST		RFST	
	2.0 hour yield rad/30mCi	mSv/1110MBq	4.8 hour yield rad/30mCi	mSv/1110MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.1	55.5	5.1	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	5.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8

Slahin M., July 1990. Oak Ridge Associated Universities, P. O. Box 117, Oak Ridge, TN 37831. (615) 576-3449.

PREPARATION FOR THE PREPARATION OF TECHNETIUM Tc-99m SESTAMIBI: Preparation of the Technetium Tc-99m Sestamibi from the kit for the preparation of Technetium Tc-99m Sestamibi is done by the following aseptic procedure:

- Prior to adding the Sodium Pertechnetate Tc-99m Injection to the vial, affix a radiation symbol and attach it to the neck of the vial.
- Waterproof gloves should be worn during the preparation procedure. Remove the plastic disc from the vial and swab the top of the vial closure with alcohol to sanitize the surface.
- Place the vial in a suitable radiation shield with a fitted radiation cap.
- With a sterile shielded syringe, aseptically obtain additive-free, sterile non-pyrogenic Sodium Pertechnetate Tc-99m Injection (925-5550MBq (25.150mCi)) in approximately 1 to 3ml.
- Aseptically add the Sodium Pertechnetate Tc-99m Injection to the vial in the lead shield. Without withdrawing the needle, remove an equal volume of headspace to maintain atmospheric pressure within the vial.
- Swirl the contents of the vial for a few seconds.
- Remove the vial from the lead shield and place upright in a hoting water bath for 10 minutes. Timing for 10 minutes is begun as soon as the water comes to full boil.
- Remove the vial from the water bath, place in the lead container and allow to cool for fifteen minutes.
- Using proper shielding, the vial contents should be visually inspected. Use only if the solution is clear and free of particulate matter and discoloration.
- Assay the reaction vial using a suitable radioactivity calibration system. Record the Technetium Tc-99m concentration, total volume, assay date and date, expiration time and lot number on the vial steel label and affix the label to the vial.
- Store the reaction vial containing the Technetium Tc-99m Sestamibi at room temperature (15-30°C) until use. At such time the product should be aseptically withdrawn. Technetium Tc-99m Sestamibi should be used within six hours of preparation. The vial contains no preservative.

Note: Adherence to the above product reconstitution instructions is recommended.

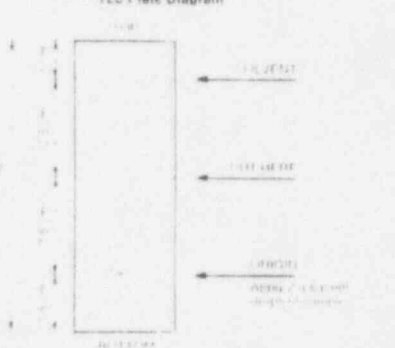
Product should be used within 6 hours after preparation. Final product with radiochemical purity of at least 90% was used in the clinical trials that established safety and effectiveness. The radiochemical purity was determined by the following method:

DETERMINATION OF RADIOCHEMICAL PURITY IN Technetium Tc-99m Sestamibi

- Obtain a Baker Flex Aluminum Oxide coated, plastic TLC plate (#1 R F, #8 x 10 x 2.5cm x 7.5cm).
- Dry the plate or plates at 100°C for 1 hour and store in a desiccator. Remove pre-dried plate from the desiccator just prior to use.
- Apply 1 drop of ethanol using a 1ml syringe with a 22-26 gauge needle, 1.5cm from the bottom of the plate. THE SPOT SHOULD BE LEFT ALLOWED TO DRY.
- Add 2 drops of Technetium Tc-99m Sestamibi solution, side by side on top of the ethanol spot. Return the plate to a desiccator and allow the sample spot to dry (typically 15 minutes).
- The TLC tank is prepared by pouring ethanol to a depth of 3-4mm. Cover the tank and let it equilibrate for 30 minutes.
- Develop the plate in the prepared TLC tank in ethanol to a distance of 5cm from the point of application.
- Put the TLC plate 4cm from the bottom and measure the Tc-99m activity in each piece by appropriate radiation detector.
- Calculate the % Tc-99m Sestamibi as:

$$\% \text{ Tc-99m Sestamibi} = \frac{A_{\text{Top Piece}}}{A_{\text{Top Piece}} + A_{\text{Bottom Piece}}} \times 100$$

TLC Plate Diagram



The standards used in this procedure should be 90% or greater in radiochemical purity. Vials should contain at least 100µCi of activity. The plate should be developed in ethanol to a distance of 5cm from the point of application.

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT Sulfur Colloid Compounding Sol. LOT # _____

COMPOUNDER _____ DATE _____

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ Sodium Thiosulfate	2 g		
2. Gelatin USP Type B 100 bloom	1.8 g		
3. Water for injection q.s.a.d.	100 ml		
4.			
5.			
6.			
7.			
8.			
9.			

DIRECTIONS FOR MANUFACTURE:

- Sod. Thiosulfate and gelatin into 250 ml beaker or flask (or larger)
- Add 100 ml cold water for injection and stir well (room temperature water)
- Heat to gentle boil with stirring for 3-4 min
- Coll and q.s.a.d. 100 ml with water for injection
- Membrane filter thru 0.22 micron filter (if using small filter may have to heat solution because of viscosity)
- Divide into vials (20 ml stock vials or 0.5 ml into $\text{Tc}^{99\text{m}}$ compounding vials)

Quality Control

pH _____

Particle Size _____

% radiolabeling _____

Sterility _____

Pyrogen Test _____

:

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT ^{99m}Tc Pyrophosphate Kit LOT # _____

COMPOUNDER DATE _____

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. Na ₄ P ₂ O ₇ ·10H ₂ O Sod. Pyrophosphate	1.5 g		
2. SnCl ₂ ·2H ₂ O	200 mg		
3. Conc HCl	1 ml		
4. 1 N NaOH			
5. SWFI qs ad	100 ml		
6.			
7.			
8.			
9.			

DIRECTIONS FOR MANUFACTURE: (100 vials)

1. Place pyrophosphate into 250 ml beaker with stirring bar
2. Add 60 mls SWFI
3. Dissolve pyrophosphate with heat, then cool, N₂ flush
4. Add Sn/HCl solution
5. Adjust pH to 5-5.5 with 1 N NaOH.
6. Qs ad 100 ml with SWFI
7. Continue N₂ flush
8. Dispense 1 ml aliquots into sterile 10 ml vials
9. Lyophilize
10. Store at room temperature.

pH _____

Sterility _____

Pyrogen Test _____

ITLC in acetone _____

ITLC in 0.9% NaCl _____

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT Sn MAA Kit LOT # _____

COMPOUNDER _____ DATE _____

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. Water for injection WFI)	21.8 ml		
2. Sn/HCl Soln 100 mg/ml	.2 ml		
3. Human Serum Albumin 25%	.8 ml		
4. Sod. Acetate Soln. 2mEq/ml	3.0 ml		
5. N ₂ gas			
6. 1" magnetic stirring bar	1		
7. Vial 30 ml (sterile)	1		
8. Vials 10 ml (sterile)	25		
9.			

DIRECTIONS FOR MANUFACTURE:

1. Start water bath with 300 ml H₂O in 1000 ml beaker (82-84c).
2. N₂ flush WFI and Sod. Scetate.
3. Add 0.2 ml HSA to 30 ml vial with magnetic stirring bar.
4. Add 0.8 ml WFI to vial.
5. Add 3 ml Sod. Acetate Soln (let stand for 2 min).
6. Add 5 ml WFI (let stand 5 min).
7. Add 0.2 ml Sn/HCl sol to empty amp and dilute with 1.8 ml WFI.
8. Add 0.35 ml diluted stannous soln to 30 ml vial (let stand for 2 min).
9. Add 16 ml WFI.
10. Replace stopper and reseal vial.
11. Submerge bottom 1/5 of vial in water bath and heat while stirring at maximum speed for 20 minutes.
12. Cool vial in tap water. Filter thru micro-syringe filter holder with filter support screen. (152 micron pore size.)
13. Withdraw 1 ml and perform Q.C.
14. Add 0.6 ml HSA to vial and divide into 1 ml aliquots.
15. Lyophilize and store in the refrigerator.

Particle Size _____

Sterility _____

ITLC in 0.9 NaCl _____

Pyrogen test _____

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT Bicarbonate Buffer Solution LOT # _____
 COMPOUNDER _____ DATE _____

INGREDIENTS	AMOUNT	MFCR LOT #	MFCR NAME
1. Sod. Bicarbonate inj. USP	2.8 g (37.3 ml)		
2. Sod. Carbonate (Na ₂ CO ₃)	0.6 g		
3. Sterile Water for Injection, q.s.a.d.	100 ml		
4.			
5.			
6.			
7.			
8.			
9.			

RECTIONS FOR MANUFACTURE:

1. Dissolve Na₂CO₃ in 50 mls of SWFI
2. Add NaHCO₃ inj USP to Na₂CO₃ solution
3. With SWFI q.s.a.d. 100 mls
4. Membrane filter into 30 ml sterile vials

pH _____

NUCLEAR PHARMACY FORMULATION RECORD, BANC

PRODUCT ^{99m}Tc-RBC Kit LOT # _____
 COMPOUNDER DATE _____

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. SnCl ₂ ·2H ₂ O	36 mg		
2. Conc. Hcl	1 ml		
3. Trisodium Citrate	1.5 g		
4. Dextrose anhydrous	2.25 g		
5. Sterile Water for Inj	209 ml		
6. 1 N NaOH			
7. Heparin, 10,000 units	2 ml		
8.			
9.			

DIRECTIONS FOR MANUFACTURE: Wash SnCl₂·2H₂O quickly with SWFI.

Solution A - Dissolve Stannous Chloride in Conc HCl q.s.a.d. 10 ml with SWFI. Flush with N₂

Diluent - Dissolve Sod. Citrate and Dextrose in SWFI q.s.a.d. 200 ml. Flush N₂

Solution B - To 30 ml of diluent, add 2 ml of soln. A dropwise. Adjust pH of soln. to pH 5-7 with 1 N NaOH. q.s.a.d. 50 ml with diluent soln. Adjust final pH to 7.5.

Solution C - Add 20,000 units of Heparin to 4 ml of soln. B and q.s.a.d. 100 ml with diluent. N₂ flush, filter with .22 millipore filter.

Dispense 0.5 ml aliquots into 10 ml vials.

QUALITY CONTROL

Take 0.5 ml aliquot of labeled RBC susp. dilute with 1.5 ml NaCl 0.9%. Centrifuge 5 min. Assay supernatant and determine label yield.

Sterility _____ Pyrogen _____

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT Methylene Diphosphonate Kit LOT # _____

COMPOUNDER _____ DATE _____

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. Methylene diphosphonate	1.2 g		
2. SnCl ₂ ·2H ₂ O	.120 g		
3. Conc. HCl	1.2 ml		
4. NaOH 1N			
5. SWFI qs ad	100 ml		
6.			
7.			
8.			
9.			

DIRECTIONS FOR MANUFACTURE: (100 vials)

Dissolve MDP in 75 ml SWFI (N₂ purged).
 Dissolve SnCl₂·2H₂O in HCl and add to MDP solution.

Adjust ph to 5 with 1N NaOH.
 Membrane filter with 0.22 micron filter.
 Place 1 ml aliquots into 10 ml vials.
 Lyophilize.

ITLC: Acetone _____ % reduced.
 Saline _____ % hydrolyzed

pH _____

Pyrogen Test _____

Sterility Test _____

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT Sn-DTPA Kits LOT # _____

COMPOUNDER _____ DATE _____

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. DTPA	554 mg		
2. SnCl ₂ ·2H ₂ O	60 mg		
3. Conc HCl	.6 ml		
4. 1 N NaOH	11 ml		
5. SWFI qs ad	100 ml		
6.			
7.			
8.			
9.			

DIRECTIONS FOR MANUFACTURE: (100 vials)

Dissolve DTPA in SWFI, heat if necessary. (75 ml)
N₂ purge.

Add dropwise SnCl₂·2H₂O/HCl or 1 N NaOH.
QS ad to 100 ml with SWFI
Membrane filter with 0.22 micron.
Aliquot 1 ml into 10 ml sterile/pyrogen free vials.
Lyophilize

Sterility _____

Pyrogen Test _____

pH _____

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT IN HCl LOT #
 COMPOUNDER DATE

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. Conc. HCl	10 ml		
2. SWFI q.s.a.d.	100 ml		
3.			
4.			
5.			
6.			
7.			
8.			
9.			

DIRECTIONS FOR MANUFACTURE:

1. Add the conc. HCl to SWFI
2. Mix well by swirling
3. Filter product into vacuum bottles using 0.22 micron filter.

NUCLEAR PHARMACY FORMULATION RECORD, BAMC

PRODUCT Phosphate Buffer Solution

LOT #

COMPOUNDER

DATE

INGREDIENTS	AMOUNT	MFGR LOT #	MFGR NAME
1. Sod. Phosphate Dibasic $\text{Na}_2\text{HPO}_4 \cdot 7\text{H}_2\text{O}$	45.84 g		
2. Sod. Phosphate Monobasic $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$	6.0 g		
3. SWFI	300 ml		
4. Falcon Filter 0.22 micron	2		
5.			
6.			
7.			
8.			
9.			

DIRECTIONS FOR MANUFACTURE: (12 x 25ml vials)

1. Remove rubber stopper from 250 ml SWFI.
2. Add Sod Phosphate Dibasic, replace stopper and dissolve using hot tap water bath.
3. Add Sod Phosphate monobasic and dissolve.
4. Filter and aliquote 25 mls into sterile vials.
5. Autoclave 30 minutes at 120° C.

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-16654-01MD for SYNCOB CORPORATION (licensee's name)
was inspected on 9/24/91. Radiopharmaceutical departure records were
inspected for the period to with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain). TOO MANY TO COPY
SAMPLE OF LABEL AND VARIATION PROCEDURES
ATTACHED

W.P. REICHMOLD
Radiation Specialist
(Signature and Date)

Attachment: As stated

VARIANCE



Syncor Corp
Pharmacy Service Center
6156 Trust Drive Ste B
Molland OH 43528
419/867-1077

RT #01 RUN # 1

Customer HARDIN MEMORIAL
921 E. FRANKLIN STREET
KENTON OH 43326
Doctor CHERUKURI Date 23 SEP 91

Radionuclide Tc99m

Pharmaceutical MAA DUP

Procedure Pulmonary Perfusion

Lot # TC9930-26604 Expires 2100 092391

Assay 4.742 mCi/ml as of 20:30

Qty Ordered 5.00 mCi 185.00 MBq

Dispensed 5.5 mCi

Vol. Dispensed 1.05 ml Rx # [redacted] Use as directed by physician

Patient: Per Phys Order
Tc99 (0.15 uCi/mCi Tc99m @ 21:00 09/23/91

Administer Intravenously

Product Of Fission Mo99

Comment: ***SHAKE WELL***

Revised - 11/84

TABLE 1: Tc99m MACROAGGREGATED ALBUMIN

MANUFACTURER	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ³	Tc99m Volume	Time of Use ²
DuPont (3.6 - 6.5M Particles)	125 mCi	2-8 ml	12 hours	72 mCi	2-8 ml	6 hours
CIS (12 - 15M Particles)	340 mCi	3-5 ml	12 hours	240 mCi	3-5 ml	6 hours
Squibb (2 - 7M Particles)	115 mCi	1-3 ml	12 hours	40 mCi	1-3 ml	6 hours
Medi+Physics (1.5 - 2.5M Particles)	50 mCi	up to 3 ml	12 hours	80 mCi (4 - 8M Particles)	2-8 ml	6 hours
Mallinckrodt (4 - 12M Particles)	200 mCi	5-10 ml	12 hours	80 mCi	5-10 ml	discard vial after 8 hrs.

¹ Amounts used in November 1989 guidelines for MAA based on 200,000 particles per 5 mCi dose, and average number of particles per vial at time of preparation. These values may be increased to account for decay up to the time of calibration of the dispensed dose.

² Do not exceed the expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Activity is based on 200,000 particles per 4 mCi dose, and minimum number of particles per vial at time of preparation. Activity may be increased to account for decay up to the time of calibration of the first dispensed dose.

TABLE 2 : Tc 99m BONE IMAGING AGENTS

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

PRODUCT	Activity ¹	Tc99m Volume	Time of Use ²	Activity ¹	Tc99m Volume	Time of Use ²
Squibb MDP	400 mCi	0.5-5 ml	12 hours ³	150 mCi	0.5-5 ml	12 hours ³
Medi+Physics MDP	400 mCi	2-8 ml	12 hours	400 mCi ⁴	2-8 ml	6 hours
DuPont MDP	200 mCi	2-8 ml	6 hours	200 mCi ⁵	2-8 ml	6 hours
CIS MDP	200 mCi	1-8 ml	6 hours	200 mCi ⁶	1-8 ml	6 hours
Amersham MDP	100 mCi	1-8 ml	6 hours	100 mCi	1-8 ml	6 hours
Mallinckrodt HDP	150 mCi		6 hours	150 mCi ⁷	3-6 ml	6 hours ⁸
DuPont PYP	200 mCi	3-7 ml	6 hours	200 mCi	3-7 ml	6 hours
Squibb PYP	75 mCi	2-4 ml	6 hours	75 mCi	2-4 ml	6 hours
Mallinckrodt	100 mCi	1-10 ml	6 hours	100 mCi	1-10 ml	6 hours

¹ These activities are maximum amounts and lesser amounts should be used as experience dictates.

² Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Recommended time of use is not specified in the manufacturer's instructions.

⁴ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 400 mCi.

⁵ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 200 mCi.

⁶ The manufacturer specifies maximum activity of 300 mCi, but Syncor policy limits it to 200 mCi.

⁷ The manufacturer specifies maximum activity of 200 mCi, but Syncor policy limits it to 150 mCi.

⁸ Manufacturer's instructions recommend an 8 hour time of use, but Syncor policy limits it to 6 hours.

T A B L E 3 : T c 9 9 m D T P A

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	Squibb	300 mCi	up to 5 ml	6 hours
Renal Scan	Squibb	300 mCi	up to 5 ml	4 hours ²
Ventilation Study	Squibb	300 mCi	up to 5 ml	6 hours
GFR Assessment ³	Squibb	50 mCi	2-5 ml	1 hour
Brain Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Renal Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Ventilation Study	Medi+Physics	300 mCi ²	2-8 ml	6 hours
GFR Assessment ³	Medi+Physics	50 mCi	2-8 ml	1 hour
Brain Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Renal Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Ventilation Study	CIS	100 mCi ²	2-3 ml	2 hours ²
GFR Assessment ³	CIS	50 mCi ²	2-3 ml	1 hour

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

³ Syncor experience shows that Medi+Physics DTPA is preferred for GFR assessment.

T A B L E 4 : T c 9 9 m G L U C O H E P T O N A T E

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	DuPont	150 mCi ²	3-7 ml	6 hours
Renal Scan	DuPont	150 mCi ²	3-7 ml	4 hours ²

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

=====

T A B L E 5 : T c 9 9 m H U M A N S E R U M A L B U M I N

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

Procedure	Manufacturer	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
		Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Multidose	Medi+Physics	200 mCi	3 ml	6 hours	100 mCi	3 ml	6 hours
Unit Dose	Medi+Physics	70 mCi	1.3 ml	6 hours	30 mCi	1.3 ml	3 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

T A B L E 6 : T c 9 9 m H E P A T O B I L I A R Y A N D L I V E R A G E N T S

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

Product	Manufacturer	Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Cholotec	Squibb	200 mCi	2-5 ml	18 hours ²	100 mCi	1-5 ml	18 hours ²
Hepatology	DuPont	150 mCi	2-5 ml	8 hours	100 mCi	4-5 ml	6 hours
Microlite	DuPont	75 mCi	2-8 ml	6 hours	75 mCi	2-8 ml	6 hours
Sulfur Colloid	CIS	500 mCi	1-3 ml	12 hours	500 mCi	1-3 ml	6 hours
Sulfur Colloid	Mallinckrodt	400 mCi	0.1-5 ml	12 hours	400 mCi	0.1-5 ml	discard vial after 6 hrs.
Sulfur Colloid	Squibb	500 mCi	0.1-5 ml	12 hours	500 mCi ³	0.1-5 ml	6 hours
Sulfur	Medi+Physics	400 mCi	0.5-5 ml	12 hours	400 mCi	0.5-5ml	6 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Preservative in formulation allows 18 hour expiration time specified in package insert. Tc99m must have Mo99 concentration within acceptable limits as of expiration time.

³ Manufacturer's instructions do not specify maximum activity. Syncor policy limits activity to 500 mCi.

TABLE 7: OTHER Tc99M IMAGING AGENTS

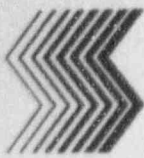
- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Product	Manufacturer	Activity	Tc99m Volume	Time of Use ²
DMSA	Medi+Physics	44-88 mCi	2.2 - 4.4 ml 2.2 ml reagent	30 minutes
HM-PAO (Ceretek®)	Amersham	30 mCi ³	up to 5 ml	30 minutes

¹ Syncor Guidelines correspond to manufacturers' instructions.

² Do not exceed 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Sodium pertechnetate elution must be less than 2 hours old when used to prepare the kit.



syncor

PLEASE SEND TO
DANA-HEALTHCARE PI
HARRINGTON COOKING ST, NILES
MICH ST 614-5 JAMES

January 13, 1992

United States Regulatory Commission
Attn: Bill Reichhold
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: License No. 34-16654-01MD
Number of Variance Prescriptions 1991

Dear Mr. Reichhold:

This letter is in reply to your request for the number of variance prescriptions dispensed from our pharmacy in 1991.

The total number of variance prescriptions dispensed from January 1, 1991 through December 31, 1991 was 28,282. Although this number represents dispensed variance prescriptions, it may not accurately represent the number of patient variance doses.

We placed 12 hour expiration times on these prescriptions consistent with the doctors' recommendations and signed authorization. Many times the doctor may have exercised his professional judgement to use these prescriptions well within their package insert recommended expiration time.

Our prescription labels show a 12 hour expiration time but we have no way of monitoring when these prescriptions are actually used.

If you have any questions, please feel free to contact me.

Sincerely,

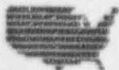
SYNCOR INTERNATIONAL CORPORATION
MEDICAL SERVICES GROUP

Stacy Demski

Stacy Demski, R.Ph.
Manager

*Not per M.F.
- inf required in DC -*

cc: Frank Comer



Innovators in high-tech pharmacy services

JAN 15 1992

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Mark R. Shaffer
Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 35-19583-01MD for Synacor - Tulsa, OK (licensee's name) was inspected on March 24, 1992. Radiopharmaceutical departure records were inspected for the period Aug. 1990 to Feb. 28, 1992 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

4... 22, 1992 *4... patients per...* *4... instructions...* *3/31/92*
Radiation Specialist (Signature and Date)

Attachment: As stated *As stated in report...*

HOSPITAL VA. Medical Center
Muskogee, Oklahoma

PHARMACY Syncor-Tulsa, OK

WRITTEN DEPARTURE
REQUEST PRESENT

DATE SIGNED
May 16, 1991

ALL DEPARTURE
ELEMENTS PRESENT

yes () no

yes () no

Departures									
	Tc 9950								
Date									
May 1-28, 91	37 →								
June 3-28, 91	38								
July 1-31, 91	57								
Aug. 1-30, 91	54								
Sept. 3-30, 91	48								
Oct. 1-31, 91	53								
Nov. 1-29, 91	40								
Dec. 2-31, 91	50								
Jan 2-31, 92	64								
Feb. 3-28, 92	57								
	466								
Total	16								

Key Tc 9950 = Tc ^{99m} - MDP

* Although VA submitted letter to Syncor for departures on several other kit preps, thus far Syncor has only dispensed Bone Kits (MDP) following the departure request.

Customer: 3204 Veterans Admin Med Ctr

Period Ending: 02/27/92

SCHEDULED PRODUCTS
 FOR PURCHASE ORDER# : 623A21937

Px/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Ext	Chg	Ord P.O. #	Procedure	Patient	Notation	Val
277460	02/03/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277461	02/03/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277462	02/03/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277463	02/03/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277464	02/03/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277505	02/04/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277506	02/04/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277507	02/04/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277508	02/04/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277509	02/04/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277600	02/04/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277601	02/04/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277675	02/05/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277676	02/05/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277680	02/05/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277686	02/06/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277687	02/06/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277688	02/06/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277689	02/06/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277701	02/06/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277702	02/06/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277718	02/07/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277719	02/07/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277721	02/07/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
277722	02/07/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
277723	02/07/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278049	02/10/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278053	02/10/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278172	02/11/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278173	02/11/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278174	02/11/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278176	02/11/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278177	02/11/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278178	02/11/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278302	02/12/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278303	02/12/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278304	02/12/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278306	02/12/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278415	02/13/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278416	02/13/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278417	02/13/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278420	02/13/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278421	02/13/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N
278507	02/14/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278508	02/14/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278510	02/14/92	HDP TC99m	TC9950	1.00	Dose	0.00		623A21937	Bone Imaging	Per Phys Order		Y
278511	02/14/92	Tc99 Kit Prep	TC9405	1.00	Dose	0.00		623A21937	Kit Preparation	Per Phys Order		N

Customer: 0001 Veterans Admin Med Ctr

Period Ending: 01/92

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# 623A21379

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Ext	Chg	Cd	P.O. #	Procedure	Patient	Notation
276401	01/21/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276402	01/21/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276403	01/21/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276404	01/21/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276405	01/21/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276500	01/22/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276500	01/22/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276501	01/22/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276641	01/23/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276642	01/23/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276643	01/23/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276644	01/23/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276646	01/23/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276750	01/24/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276750	01/24/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276760	01/24/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276761	01/24/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276762	01/24/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276763	01/24/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276764	01/24/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276856	01/27/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276857	01/27/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276858	01/27/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276859	01/27/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276860	01/27/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276861	01/27/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276862	01/27/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
276900	01/28/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
276999	01/28/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277000	01/28/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277001	01/28/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277002	01/28/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277003	01/28/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277004	01/28/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277106	01/29/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277107	01/29/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277108	01/29/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277109	01/29/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277110	01/29/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277111	01/29/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277112	01/29/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277240	01/30/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277241	01/30/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277242	01/30/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277243	01/30/92	MDF TC99m	TC9950	1.00	Dose	0.00			623A21379	Bone Imaging	Per Phys Order	
277244	01/30/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	
277245	01/30/92	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A21379	Kit Preparation	Per Phys Order	

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ITEMIZED BILLING LIST BY PURCHASE ORDER

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Customer: 0004 Veterans Admin Med Ctr

Period Ending: 01

SCHEDULED PRODUCTS
FOR PURCHASE ORDER # 000A21079

Day/Order #	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Ord P.O. #	Procedure	Patient	Notation
277046	01/01/92	TLO4 Kit Prep	TCC405	1.00	Dose	0.00		000A21079	Kit Preparation	Per Phys Order	
277045	01/01/92	MRF TCC0m	TCC050	1.00	Dose	0.00		000A21079	Bone Imaging	Per Phys Order	
277046	01/01/92	MRF TCC0m	TCC050	1.00	Dose	0.00		000A21079	Bone Imaging	Per Phys Order	
277047	01/01/92	MRF TCC0m	TCC050	1.00	Dose	0.00		000A21079	Bone Imaging	Per Phys Order	
277048	01/01/92	MRF TCC0m	TCC050	1.00	Dose	0.00		000A21079	Bone Imaging	Per Phys Order	
277049	01/01/92	TLO4 Kit Prep	TCC405	1.00	Dose	0.00		000A21079	Kit Preparation	Per Phys Order	
277050	01/01/92	TLO4 Kit Prep	TCC405	1.00	Dose	0.00		000A21079	Kit Preparation	Per Phys Order	
277051	01/01/92	TLO4 Kit Prep	TCC405	1.00	Dose	0.00		000A21079	Kit Preparation	Per Phys Order	

TOTAL: 102

MRF TCC0m	64
TLO4 Kit Prep	38

Customer: 3284 Veterans Admin Med Ctr

Period Ending: 12/31/

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A20893

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
272491	12/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
272492	12/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
272493	12/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
272494	12/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
272586	12/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
272588	12/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
272589	12/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
272590	12/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
272701	12/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
272703	12/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
272809	12/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
272810	12/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
272811	12/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
272814	12/05/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
272938	12/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
272939	12/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
272943	12/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273060	12/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273061	12/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
273062	12/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
273063	12/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273066	12/09/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273194	12/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273195	12/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
273196	12/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		N
273197	12/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273199	12/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273312	12/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273313	12/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273314	12/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273315	12/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273316	12/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273318	12/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273435	12/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273436	12/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273438	12/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273441	12/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273565	12/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273566	12/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273569	12/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273692	12/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273693	12/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273695	12/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273696	12/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273792	12/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273793	12/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273794	12/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y

Customer: 3284 Veterans Admin Med Ctr

Period Ending: 12/31

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A20893

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Val
273797	12/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
273913	12/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273914	12/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
273915	12/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274030	12/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274032	12/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274034	12/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
274149	12/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274150	12/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274151	12/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274152	12/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274153	12/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
274249	12/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274251	12/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274252	12/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274254	12/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
274365	12/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
274429	12/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274431	12/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274533	12/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274534	12/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
274629	12/30/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20893	Kit Preparation	Per Phys Order		N
274736	12/31/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y
274738	12/31/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20893	Bone Imaging	Per Phys Order		Y

TOTAL: 71

MDP TC99m 50
Tc04 Kit Prep 21

Customer: 3204 Veterans Admin Med Ctr

Period Ending: 11/30/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A20466

Rt/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
270333	11/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		N
270334	11/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		N
270338	11/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
270433	11/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270436	11/04/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
270656	11/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270657	11/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270657	11/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270662	11/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
270760	11/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270762	11/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270763	11/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
270848	11/08/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271180	11/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271181	11/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271182	11/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271185	11/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271201	11/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271282	11/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271283	11/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271284	11/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271285	11/14/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271374	11/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271375	11/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271376	11/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271376	11/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271377	11/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271378	11/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271379	11/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271400	11/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271476	11/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271477	11/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271500	11/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271595	11/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271596	11/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271597	11/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271598	11/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271601	11/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271717	11/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271718	11/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271719	11/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271720	11/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271721	11/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271722	11/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271723	11/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271822	11/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271823	11/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271825	11/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y

Customer: 3204 Veterans Admin Med Ctr

Period Ending: 11/30/91

SCHEDULED PRODUCTS
 FOR PURCHASE ORDER# : 623-20466

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
271026	11/21/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
271936	11/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
271938	11/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
272039	11/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		N
272040	11/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
272042	11/25/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272043	11/25/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272186	11/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		N
272189	11/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		Y
272191	11/26/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272299	11/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20466	Bone Imaging	Per Phys Order		N
272302	11/27/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272303	11/27/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272304	11/27/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272400	11/29/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N
272401	11/29/91	Tc04 Kit Prep	TCD405	1.00	Dose	0.00			623A20466	Kit Preparation	Per Phys Order		N

TOTAL: 63

MDP TC99m 40
 Tc04 Kit Prep 23

Customer: 3284 Veterans Admin Med Ctr

Period Ending: 10/31/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER #: 623A20011

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
267659	10/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267661	10/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267665	10/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
267766	10/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267769	10/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267877	10/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267878	10/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267879	10/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267880	10/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
267881	10/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
267999	10/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268000	10/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268001	10/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268098	10/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268099	10/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268104	10/07/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268207	10/08/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268321	10/09/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268322	10/09/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268423	10/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268424	10/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268428	10/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268529	10/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268530	10/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268533	10/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268765	10/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268766	10/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268767	10/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268768	10/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268769	10/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
268893	10/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268894	10/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268895	10/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
268898	10/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269006	10/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269007	10/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269008	10/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269009	10/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269012	10/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269128	10/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269129	10/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269130	10/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269131	10/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269231	10/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269232	10/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269235	10/21/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269237	10/21/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N

Customer: 3284 Veterans Admin Med Ctr

Period Ends: 10/31/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A20011

/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
269362	10/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269364	10/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269367	10/22/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269496	10/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269497	10/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269500	10/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269606	10/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269607	10/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269607	10/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269709	10/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269711	10/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269713	10/25/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269815	10/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269816	10/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269819	10/28/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
269943	10/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269944	10/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269945	10/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269946	10/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
269947	10/29/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
270080	10/30/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
270085	10/30/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
270086	10/30/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N
270194	10/31/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
270196	10/31/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
270197	10/31/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A20011	Bone Imaging	Per Phys Order		Y
270200	10/31/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A20011	Kit Preparation	Per Phys Order		N

TOTAL: 74

MDP TC99m	53
Tc04 Kit Prep	21

Customer: 3234 Veterans Admin Med Ctr

Period Ending: 09/30/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A14928

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
265417	09/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		N
265418	09/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		N
265419	09/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		N
265420	09/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		N
265422	09/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265477	09/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265528	09/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265529	09/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265530	09/04/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265531	09/04/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265639	09/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265640	09/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265641	09/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265642	09/05/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265644	09/05/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265768	09/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265770	09/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265771	09/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265772	09/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
265882	09/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
265886	09/09/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266015	09/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266018	09/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266019	09/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266020	09/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266123	09/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266126	09/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266238	09/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266239	09/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266240	09/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266346	09/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266347	09/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266348	09/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266350	09/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266448	09/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266450	09/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266451	09/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266564	09/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266565	09/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266567	09/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266569	09/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266570	09/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266678	09/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266679	09/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266680	09/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266681	09/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266682	09/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N

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Period Ends: 09/30/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A14928

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
266683	09/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266684	09/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266792	09/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266793	09/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266794	09/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266795	09/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266796	09/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266797	09/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266798	09/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
266887	09/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
266892	09/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267008	09/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267010	09/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267011	09/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267012	09/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267116	09/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267118	09/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267119	09/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267120	09/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267121	09/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267122	09/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267226	09/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267227	09/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267228	09/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267230	09/25/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267337	09/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267338	09/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267339	09/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267342	09/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267438	09/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267441	09/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267548	09/30/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267549	09/30/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267550	09/30/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14928	Bone Imaging	Per Phys Order		Y
267551	09/30/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N
267553	09/30/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14928	Kit Preparation	Per Phys Order		N

TOTAL: 83

MDP TC99m	48
Tc04 Kit Prep	35

ITEMIZED BILLING LIST

Customer: 3284 Veterans Admin Med Ctr

Period Ending:

SCHEDULED PRODUCTS

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation
262998	08/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
262999	08/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263001	08/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263002	08/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263004	08/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263121	08/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263122	08/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263124	08/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263125	08/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263127	08/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263222	08/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263223	08/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263224	08/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263226	08/05/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263356	08/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263357	08/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263358	08/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263360	08/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263477	08/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263571	08/08/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263574	08/08/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263577	08/08/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263658	08/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263659	08/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263748	08/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263749	08/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263750	08/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263751	08/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263752	08/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263895	08/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263896	08/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
263898	08/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263899	08/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
263900	08/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264037	08/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
264038	08/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
264039	08/14/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264040	08/14/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264041	08/14/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264133	08/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264187	08/15/91	SN-DTPA Tc99m	TC9940	1.00	Dose	0.00			623A14585	Brain Imasins	Per Phys Order	
264227	08/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264228	08/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264229	08/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	
264330	08/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
264331	08/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
264332	08/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imasins	Per Phys Order	
264333	08/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	

ITEMIZED BILLING LIST

Customer: 3284 Veterans Admin Med Ctr

Period Ends: 08/3

SCHEDULED PRODUCTS

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Va
264335	08/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
264465	08/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264467	08/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264468	08/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264469	08/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
264602	08/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264603	08/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264605	08/21/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
264606	08/21/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
264712	08/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264713	08/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264714	08/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264715	08/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264838	08/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264839	08/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264840	08/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264841	08/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264842	08/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	Returned	N
264843	08/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order	Returned	N
264844	08/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
264943	08/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264945	08/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264946	08/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
264947	08/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
264948	08/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
265062	08/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265063	08/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265066	08/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
265067	08/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
265068	08/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
265149	08/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265150	08/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265151	08/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265152	08/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265155	08/28/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
265255	08/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265256	08/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265257	08/29/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14585	Bone Imaging	Per Phys Order		Y
265260	08/29/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14585	Kit Preparation	Per Phys Order		N
265339	08/30/91	MDP TC99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
265340	08/30/91	MDP TC99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
265341	08/30/91	MDP TC99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y

TOTAL: 90

SN-DTPA Tc99m 1
 MDP TC99m 54
 Tc04 Kit Prep 35

Customer: 3284 Veterans Admin Med Ctr

Period Ending: 07/31/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A14113

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
260558	07/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260559	07/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260560	07/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260561	07/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260563	07/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260564	07/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260697	07/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260698	07/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260699	07/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260700	07/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260701	07/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260702	07/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260703	07/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260815	07/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260816	07/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260817	07/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260818	07/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260819	07/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260905	07/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260906	07/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260909	07/05/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260911	07/05/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
260989	07/08/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260991	07/08/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
260994	07/08/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261087	07/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261088	07/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261089	07/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261090	07/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261092	07/09/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261227	07/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261229	07/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261230	07/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261231	07/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261337	07/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261338	07/11/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261340	07/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261341	07/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261445	07/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261446	07/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261447	07/12/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261540	07/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261543	07/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-
261544	07/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261545	07/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261546	07/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order	N	
261681	07/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order	Y	-

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Period Ending: 07/31/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A14113

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
261682	07/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261684	07/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261685	07/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
261686	07/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
261687	07/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
261801	07/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261803	07/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261804	07/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
261900	07/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261901	07/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261902	07/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261903	07/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
261904	07/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
261905	07/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
261906	07/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262014	07/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262016	07/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262017	07/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262018	07/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262019	07/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262020	07/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262102	07/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262104	07/22/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262105	07/22/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262106	07/22/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262212	07/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262215	07/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262217	07/23/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262312	07/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262313	07/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262314	07/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262315	07/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262316	07/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262317	07/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262318	07/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262430	07/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262433	07/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262434	07/25/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262435	07/25/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262436	07/25/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262535	07/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262536	07/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262537	07/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262538	07/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A14113	Bone Imaging	Per Phys Order		Y -
262539	07/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262540	07/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N
262541	07/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A14113	Kit Preparation	Per Phys Order		N

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Period Ending: 07/31/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A14113

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Che	Cd	P.O. #	Procedure	Patient	Notation	Var
262636	07/29/91	MDP TC99m	TC9950	1.00	Dose		0.00		623A14113	Bone Imaging	Per Phys Order		Y -
262638	07/29/91	MDP TC99m	TC9950	1.00	Dose		0.00		623A14113	Bone Imaging	Per Phys Order		Y -
262640	07/29/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00		623A14113	Kit Preparation	Per Phys Order		N
262756	07/30/91	MDP TC99m	TC9950	1.00	Dose		0.00		623A14113	Bone Imaging	Per Phys Order		Y -
262757	07/30/91	MDP TC99m	TC9950	1.00	Dose		0.00		623A14113	Bone Imaging	Per Phys Order		Y -
262758	07/30/91	MDP TC99m	TC9950	1.00	Dose		0.00		623A14113	Bone Imaging	Per Phys Order		Y -
262760	07/30/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00		623A14113	Kit Preparation	Per Phys Order		N
262876	07/31/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00		623A14113	Kit Preparation	Per Phys Order		N
262878	07/31/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00		623A14113	Kit Preparation	Per Phys Order		N

TOTAL: 103

MDP TC99m	57	✓
Tc04 Kit Prep	46	

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Period Ends: 06/30/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A13829

Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
258502	06/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258504	06/03/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258506	06/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
258507	06/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
258508	06/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
258590	06/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258591	06/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258592	06/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258593	06/04/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258685	06/05/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258785	06/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258786	06/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258790	06/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
258886	06/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258887	06/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
258890	06/07/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
258997	06/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259119	06/11/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259218	06/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259219	06/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259221	06/12/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259312	06/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259313	06/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259315	06/13/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259434	06/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259435	06/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259437	06/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259439	06/14/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259503	06/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259504	06/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259505	06/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259506	06/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259507	06/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259508	06/17/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259622	06/18/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259626	06/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259628	06/18/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259725	06/19/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259730	06/19/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259813	06/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259814	06/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259817	06/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
259891	06/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259892	06/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
259896	06/21/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order	N	
260066	06/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-
260117	06/25/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order	Y	-

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SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A13829

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
260120	06/25/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order		N
260266	06/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260267	06/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260268	06/26/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260271	06/26/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order		N
260377	06/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260379	06/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260380	06/27/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260381	06/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order		N
260382	06/27/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order		N
260470	06/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13829	Bone Imaging	Per Phys Order		Y -
260472	06/28/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order		N
260473	06/28/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13829	Kit Preparation	Per Phys Order		N

TOTAL: 60

MDP TC99m	38	✓
Tc04 Kit Prep	22	

Customer: 3284 Veterans Admin Med Ctr

Period Ends: 05/31/91

SCHEDULED PRODUCTS
 FOR PURCHASE ORDER# : 623A13459

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
256408	05/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256411	05/01/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256414	05/01/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256498	05/02/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256503	05/02/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256592	05/03/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256685	05/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256686	05/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256687	05/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256688	05/06/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256690	05/06/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256794	05/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256795	05/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256797	05/07/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256798	05/07/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256799	05/07/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256868	05/08/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256870	05/08/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256871	05/08/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256872	05/08/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
256958	05/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256960	05/09/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
256963	05/09/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257043	05/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257044	05/10/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257046	05/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257047	05/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257048	05/10/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257151	05/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257152	05/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257154	05/13/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257250	05/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257251	05/14/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257256	05/14/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257337	05/15/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257340	05/15/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257439	05/16/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257440	05/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257441	05/16/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257539	05/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257540	05/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257541	05/17/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257621	05/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257623	05/20/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N
257625	05/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257627	05/20/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257708	05/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imaging	Per Phys Order		N

RLSTP(3.6)

Syncor Corp # 017
ITEMIZED BILLING LIST BY PURCHASE ORDER

Page: 2

Customer: 3284 Veterans Admin Med Ctr

Period Ending: 05/31/91

SCHEDULED PRODUCTS
FOR PURCHASE ORDER# : 623A13459

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
257709	05/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		N
257710	05/21/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		N
257712	05/21/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257797	05/22/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		N
257801	05/22/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
257900	05/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		Y
257901	05/23/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		Y
258019	05/24/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		Y
258020	05/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
258022	05/24/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
258091	05/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		Y
258092	05/28/91	MDP TC99m	TC9950	1.00	Dose	0.00			623A13459	Bone Imasins	Per Phys Order		Y
258094	05/28/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N
258095	05/28/91	Tc04 Kit Prep	TC0405	1.00	Dose	0.00			623A13459	Kit Preparation	Per Phys Order		N

TOTAL: 61

MDP TC99m
Tc04 Kit Prep

(37) 5 dep... (copy... that requires set... 5-3-91)
24



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011

DATE/TIME: Apr. 20, 1992
1:30 pm.

PRIORITY:
Immediately _____
1 Hour _____
2-4 Hours ✓

MESSAGE TO: Susanne Wood (OH3)

MESSAGE FROM: Mark R. Shaffer

NUMBER OF PAGES: 8 PLUS TRANSMITTAL SHEET

TELECOPY NUMBER: 301-504-2260 VERIFICATION NUMBER: _____

CONTACT: Susanne Wood ; FTS 964-2009

SPECIAL INSTRUCTIONS/ATTACHMENTS(S):

Susanne,

AS per our conversation, this is
the written directive from the
VA. Muskogee Medical Center.

Mark R. Shaffer

Transmitted & Verified by:

NAME DATE

DISPOSITION:
Return to Originator _____
Place in Mail _____
Other _____

TO: Brian Maxey, Manager
7212 East 38th Street
Tulsa, Oklahoma 74145

FROM: Dr. V. Agarwal, M.D.
Director of Nuclear Medicine
Veteran's Administration
Honor Heights Station
Muskogee, Oklahoma

As we discussed, I request that Syncor International Corporation prepare and dispense radiopharmaceuticals according to the attached Kit Preparation Guidelines dated November 1989. I have initialed the copy of Guidelines attached to indicate our review.

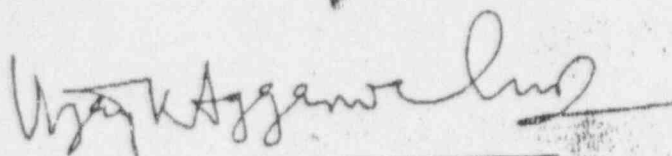
The Attached guidelines satisfy the requirement of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, the departures from manufacturer's instructions are justified for the following reasons:

- : Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- : Times of use for DTPA, Sulfur Colloid, MDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases thus, benefiting the patient in that he would no longer be required to wait in an emergency situation.
- : Times of use for DTPA, Sulfur Colloid, MDP and MAA are extended to twelve hours to allow for a practical delivery schedule from the Pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered by this department. Furthermore, we believe that the specialized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.
- : Use of technetium labeled white blood cells for lower radiation dose to the patient and quicker turnaround time to diagnosis.

8 1 31 36 12

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.



VIJAY K. AGGARWAL, M.D.
Chief, Nuclear Medicine Service
VA Medical Center, Muskogee, OK

5/16/91

DATED

WA

B Y N C O R

Guidelines for Compounding Tc-99m Radiopharmaceuticals

November, 1989

MAA

9/89

SYNCOR GUIDELINES FOR RADIOPHARMACEUTICAL KIT PREPARATION

TAB. 1. TECHNETIUM-99M MACROAGGREGATED ALBUMIN (MAA)

<u>Manufacturer</u>	<u>Activity(mCi)(1)</u>	<u>Tc-99m Volume(ml)</u>	<u>Expiration(2)</u>
DuPont (3.6-6.5M particles)	125 mCi	2-8 ml	12 hours
CIS 12-15M particles	340 mCi	3-5 ml	12 hours
Squibb 2-7M particles	115 mCi	1-3 ml	12 hours
Medi+Physics 1.5-2.5M particles	50 mCi	up to 3 ml	12 hours
Mallinckrodt 4-12M particles	200 mCi	5-10 ml	12 hours

1. Amounts used for MAA based on 200,000 particles and 5 mCi per dose, average number of particles per vial at time of preparation. These values may be increased to account for decay up to the time of calibration of the dispensed doses. For example, Dupont MAA which is to be used 4 hours after preparation could be compounded with 200 mCi of Tc-99m.

2. Not to exceed the 12 hour expiration of the Tc-99m elution.

WA

9/89

SYNCOR GUIDELINES FOR RADIOPHARMACEUTICAL KIT PREPARATION

TABLE 2. TECHNETIUM-99M BONE IMAGING AGENTS

<u>Product</u>	<u>Manufacturer</u>	<u>Maximum¹ Activity(mCi)</u>	<u>Tc-99m Volume(ml)</u>	<u>Expiration</u>
MDP	Squibb	400 mCi	0.5 - 5 ml	12 hours
MDP	Medi+Physics	400 mCi	2 - 8 ml	12 hours
MDP	DuPont	200 mCi	2 - 8 ml	6 hours
MDP	CIS	200 mCi	1 - 8 ml	6 hours
MDP	Amersham	100 mCi	1 - 8 ml	6 hours
HDP	Mallinckrodt	150 mCi		6 hours
PYP	DuPont	200 mCi	3 - 7 ml	6 hours
PYP	Squibb	75 mCi	2 - 4 ml	6 hours
PYP	Mallinckrodt	100 mCi	1 - 10 ml	6 hours

1. These activities are maximums and lesser amounts should be used where experience dictates.

WNA

Revised 11/89

SYNCOR GUIDELINES FOR RADIOPHARMACEUTICAL KIT PREPARATION

TABLE 3. TECHNETIUM-99M DTPA

Procedure	Manufacturer	Activity(mCi)	Tc-99m Volume(ml)	Expiration
Brain Scan	Squibb	300 mCi	up to 5 ml	6 hours
Renal Scan	Squibb	300 mCi	up to 5 ml	4 hours
Aerosol	Squibb	300 mCi	up to 5 ml	6 hours
Assess GFR	Squibb ¹	50 mCi	2 - 5 ml	1 hour
Brain Scan	Medi+Physics	300 mCi	2 - 8 ml	6 hours
Renal Scan	Medi+Physics	300 mCi	2 - 8 ml	4 hours
Aerosol	Medi+Physics	300 mCi	2 - 8 ml	6 hours
Assess GFR	Medi+Physics	50 mCi	2 - 8 ml	1 hour
Brain Scan	CIS	100 mCi	2 - 3 ml	2 hours
Renal Scan	CIS	100 mCi	2 - 3 ml	2 hours
Aerosol	CIS	100 mCi	2 - 3 ml	2 hours
Assess GFR	CIS ¹	50 mCi	2 - 3 ml	1 hour

1. Syncor experience shows Medi+Physics DTPA (Na-DTPA) is the drug of choice for GFR.

TABLE 4. TECHNETIUM-99M GLUCOHEPTONATE

Procedure	Manufacturer	Activity(mCi)	Tc-99m Volume(ml)	Expiration
Brain Scan	DuPont	150 mCi	3 - 7 ml	6 hours
Renal Scan	Dupont	150 mCi	3 - 7 ml	4 hours

WA

9/89

SYNCOR GUIDELINES FOR RADIOPHARMACEUTICAL KIT PREPARATION

TABLE 5. TECHNETIUM-99M HEPATOBILIARY IMAGING AGENTS

Product	Manufacturer	Activity(mCi)	Tc-99m Volume(ml)	Expiration
Choletec	Squibb	200 mCi	2 - 5 ml	18 hours (Note 1)
Hepatolite	Dupont	150 mCi	2 - 5 ml	8 hours

1. Preservative in formulation allows 18 hour expiration. Tc-99m must have Mo-99 concentration within limits at time of expiration.

TABLE 6. TECHNETIUM-99M LIVER IMAGING AGENTS

Product	Manufacturer	Activity(mCi)	Tc-99m Volume(ml)	Expiration
Sulfur Colloid	CIS	500 mCi	1 - 3 ml	12 hours
Sulfur Colloid	Mallinckrodt	400 mCi	0.1 - 5 ml	12 hours
Sulfur Colloid	Squibb	500 mCi	0.1 - 5 ml	12 hours
Sulfur Colloid	Medi+Physics	400 mCi	0.5 - 5 ml	12 hours
Microlite	DuPont	75 mCi	2 - 8 ml	6 hours

WA

9/89

SYNCOR GUIDELINES FOR RADIOPHARMACEUTICAL KIT PREPARATION

TABLE 7. TECHNETIUM-99M HUMAN SERUM ALBUMIN (HSA)

<u>Product</u>	<u>Manufacturer</u>	<u>Activity(mCi)</u>	<u>Tc-99m Volume(ml)</u>	<u>Expiration</u>
Multidose	Medi+Physics	200 mCi	3 ml	6 hours
Unitdose	Medi+Physics	70 mCi	1.3 ml	6 hours

TABLE 8. TECHNETIUM-99M DMSA

<u>Product</u>	<u>Manufacturer</u>	<u>Activity(mCi)</u>	<u>Tc-99m Volume(ml)</u>	<u>Expiration</u>
DMSA	Medi+Physics	44 - 88 mCi	2.2 ml reagent 2.2 -4.4 ml Tc-99m	30 minutes

TABLE 9. TECHNETIUM-99M HMPAO (Ceretek)

<u>Product</u>	<u>Manufacturer</u>	<u>Activity(mCi)</u>	<u>Tc-99m Volume(ml)</u>	<u>Expiration</u>
HMPAO	Amersham	30 mCi	up to 5 ml.	30 minutes

< TRANSACTION REPORT >

04-20-1992(MON) 13:39

[RECEIVE]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
1520	4-20	13:31	9410437	9	0'08'32"	NORMAL	OK
				9	0'08'32"		

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 35-03176-01 for Oklahoma Health Sciences Center (licensee's name) was inspected on March 11-13, 1992. Radiopharmaceutical departure records were inspected for the period July 1990 to March 11, 1992 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain). *Did not request copies.*

M. L. McLean March 16, 1992
Radiation Specialist (Signature and Date)

Attachment: As stated

*per attached. HMF's in possession of ...
↓
Brain Imaging Department*

D-1 T-

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFII

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-17835-01 for Richmond Hts General Hosp (licensee's name)
was inspected on 3/25/92. Radiopharmaceutical departure ^{information was} ~~records were~~
^{discussed} inspected for the period 1991 to 3/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ✓ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

 The medical licensee did not make them in writing.

 The medical licensee sent the written diagnostic directive to M. J. Smith (NRC licensee)
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

✓ Other reason (explain). Blanket authorization given by licensee to radiopharmaceutical supplier (ie. Mallinckrodt) regarding product expiration date and addition of cobalt and to certain products

W. A. Blain 3/31/92
Radiation Specialist
(Signature and Date)

Attachment: (As stated)

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFI

FROM: James Cameron
 Radiation Specialist, Region II


SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-02128-03 for St Francis Hosp (licensee's name)
 was inspected on 2/20/92. Radiopharmaceutical departure records were
 inspected for the period ~~2/1/92~~ 2/1/92 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
 (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
 (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
 and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
 administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
 records of therapeutic departures, or records or number of patient
 administrations (or prescriptions dispensed) were not available.
 Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
 to Syncor Pharmacy - Indianapolis
 (another NRC licensee or an Agreement State licensee)
 to actually make the departure.
- Other reason (explain).


 Radiation Specialist
 (Signature and Date) 3/10/92

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFn

FROM: Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-15249-01 for CHIPPENHAM HOSPITAL (licensee's name) was inspected on 2/7/92. Radiopharmaceutical departure records were inspected for the period 3/90 to 2/92 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to Syner, Richmond, Va.
(another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain).

Carl Cornell 2/7/92
Radiation Specialist (Signature and Date)

Attachment: As stated

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: 3/13/90
- b. Current inspection date: 2/7/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee Y () N

- (1) Written directive on file [35.200(c)(1)] Y () N

- (2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure Y () N
- (b) Description of the departure Y () N
- (c) Reasons why departure was needed Y () N

- (3) Records of number of departure administrations are on file [35.200(c)(2)] () Y N

- c. Departures were made by a different licensee Y () N

- (1) Name & location of other facility Lawson
Rehoboth, Va.

d. Licensee made emergency diagnostic departures:

() Y () N

(1) Written directive on file [35.200(c)(1)]

() Y () N

(2) Written directive made within three working days after emergency [35.200(c)(1)]

() Y () N

(3) Written directive includes notation of emergency [35.200(c)(1)]

() Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

a. Licensee had therapeutic departures

() Y () N

If "Yes," answer the following:

b. Record of therapeutic departure on file [35.300(b)(1)]

() Y () N

c. Record of therapeutic departure includes [35.300(b)(1)]:

(1) Nature of the departure

{ } Y { } N

(2) Reasons why departure was needed

{ } Y { } N

d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)]

() Y () N

e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)]

() Y () N

Remarks:

Written Directive for exceeding recommended package insert dosage:

MDP- In my judgement, these departures from manufacturers instructions are justified for the following reason:

Adjusting the activity used for Bone scans to 27-30 mCi, to allow for SPECT imaging with greater count rates, and decreased scanning time. Also to increase scan quality and image resolution. *

Samuel O Bruen
Authorized User Physician

*The patients health will not be affected by this change.

January 1, 1991

Written Directive for exceeding recommended package insert dosage:

DTPA- We will be using 99mTc DTPA Aerosol in place of 133Xe gas for Ventilation lung imaging. In my judgement, these departures from manufacturers instructions are justified for the following reasons:

The availability of 99mTc DTPA and the reduction in cost, greatly exceeds that of 133Xe gas.

Aerosol studies are preferred over gaseous studies (in this institution) because all views of the lung may be obtained with aerosol imaging, which provides a better mechanism for comparison with the perfusion images.

No need for negative air flow in imaging rooms which requires monitoring twice yearly to comply with NRC specifications.

The patients health will not be affected by this change.

Bunell O Bnare
Authorized User Physician

January 1, 1991

ALL INFORMATION CONTAINED
HEREIN IS UNCLASSIFIED

Written Directive for exceeding recommended package insert dosage:

201 Tl- In my judgement, these departures from manufacturers instructions are justified for the following reason:

Adjusting the dosage for Thallium 201 Chloride to 3.5-3.8 mCi to decrease imaging time and to increase image quality and resolution, while performing SPECT Thallium studies.

The patients health will not be affected by this change.

Burwell O. Knorr
Authorized User Physician

January 1, 1991

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-04010-01 for Lutheran Medical Center (licensee's name)
was inspected on 2/6/92. Radiopharmaceutical departure records were
inspected for the period 1/90 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Ken Lambert 2/12/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

MALLINCKRODT
Nuclear Medicine

January 23, 1992

Mr. Robert Ellis
Nuclear Medicine Dept.
Lutheran Medical Center
2639 Miami St.
St. Louis MO 63118

Mallinckrodt Medical, Inc.
Diagnostic Imaging Services
1827 Bell Way Drive
St. Louis, Missouri 63114
Telephone (314) 427-1555
Facsimile (314) 427-3163

Copy
1-28-92
Original sent to
Mallinckrodt
on 1-21-92
B2

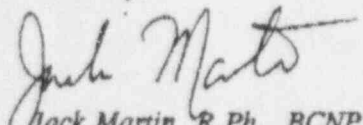
Dear Mr. Ellis,

Recently the NRC has become interested in the issue of nuclear pharmacists compounding Tc-99m technetium radiopharmaceutical kits using parameters other than those stated in the product's package insert. The NRC is allowing nuclear pharmacies to amend their licenses under 10 CFR Part 30.34 to deviate from the package insert guidelines only if it can be demonstrated that the product quality is not compromised. The Mallinckrodt DIS pharmacy currently prepares your radiopharmaceuticals slightly different than the conservative manufacturers' package insert guidelines. (For specific changes, see attached sheet.) These changes are consistent with current standards of nuclear pharmacy practice, and quality assurance procedures are performed daily. Until the necessary license amendment is submitted, the NRC is requesting that Mallinckrodt have on file at the nuclear pharmacy a signed authorization from the prescribing physician (M.D. authorized user) for radiopharmaceutical compounded outside the parameters stated in the package insert.

In order to remain in regulatory compliance with 10 CFR Part 35, we ask you to sign and return the attached authorization form indicating your approval for radiopharmaceutical kit preparation consistent with current standards of nuclear pharmacy practice. As always, Mallinckrodt is committed to excellence in nuclear medicine and the safety and well-being of your patients. Enclosed are two copies of the authorization form. Keep one copy for your records and return the other copy to Mallinckrodt in the enclosed self-addressed stamped envelope.

Please contact me if you have questions regarding this request or would like to discuss any portion of the current regulations.

Sincerely,


Jack Martin, R.Ph., BCNP
Facility Manager

Enclosures

10 12 13 92

MALLINCKRODT MEDICAL, INC.
ST. LOUIS DIS

RADIOPHARMACEUTICAL PREPARATION GUIDELINES						
RADIOPHARMACEUTICAL NAME	PACKAGE INSERT			MMI-DIS PHARMACY		
	maximum activity (mCi)	expiration (hr)	mg	maximum activity (mCi)	expiration (hr)	stabilizers
Tc-99m SULFUR COLLOID	500	6	MMI	500	12	--
Tc-99m MAA	60	8	MMI	150	10	--
Tc-99m MDP	200	6	MMI	325	8	3mg ascorbic acid
Tc-99m DTPA	180	6	CIS	300	10	3mg ascorbic acid
Tc-99m GLUCAPTATE	300	6	MMI	300	8	--
Tc-99m PYP	100	6	MMI	300	7	--
Tc-99m HDP	200	8	MMI	285	9	--
Tc-99m MAG3	100	6	MMI	100	10	--
Tc-99m HSA	100	6	MPI	175	8	--
Tc-99m Na PERTECHNETATE	--	12	MMI	--	24	--

Note: All other radiopharmaceutical kits are prepared according to manufacturer package insert guidelines.

PHYSICIAN AUTHORIZATION

I hereby grant approval for Mallinckrodt pharmacists to exercise their professional judgement in the preparation of radiopharmaceutical kits consistent with the standards of practice of nuclear pharmacy as detailed under MMI-DIS pharmacy preparation guidelines on this page.

Hospital Name: LUTHERAN MEDICAL CENTER

Physician Signature: *William Mc Connors MD*

Date: JAN 28 1992

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-16209-02 for WILLIAMSBURG COMMUNITY HOSPITAL (licensee's name)
 was inspected on 2/4/92. Radiopharmaceutical departure records were
 inspected for the period 3/90 to 2/92 with the following results:
 [NOTE: The transmittal memorandum is for inspections at both medical and
 radiopharmacy licensees. It does not apply to pharmacy-directed departures
 specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to someone in Richmond, Va.
 (another NRC licensee or an Agreement State licensee)
 to actually make the departure.
- Other reason (explain).

Carl Cornell 2-6-92
 Radiation Specialist (Signature and Date)

Attachment: As stated

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

a. Last inspection date: 3/15/90

b. Current inspection date: 2/16/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

a. Licensee directed diagnostic departures Y () N

If "Yes," answer the following:

b. Departures were made by the licensee Y () N

(1) Written directive on file [35.200(c)(1)] Y () N

(2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure Y () N

(b) Description of the departure Y () N

(c) Reasons why departure was needed Y () N

(3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

c. Departures were made by a different licensee Y () N

(1) Name & location of other facility Seymour
Richmond, Va.

*A number of
contaminating
that this
is kept by
showing*

- d. Licensee made emergency diagnostic departures: () Y () N
- (1) Written directive on file [35.200(c)(1)] () Y () N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] () Y () N
- (3) Written directive includes notation of emergency [35.200(c)(1)] () Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures () Y () N
 If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] () Y () N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure () Y () N
- (2) Reasons why departure was needed () Y () N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] () Y () N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] () Y () N

Remarks:

TO: Syncor Pharmacy Manager

FROM: Authorized User Physician

RE: Written Directive for Eluting Generators and Preparing Radiopharmaceuticals

As we discussed on 17 December, 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed the copy of Guidelines attached to indicate our review.

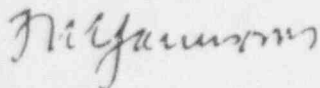
The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- o Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- o Times of use for Sulfur Colloid, MDP and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases.
- o Times of use for Sulfur Colloid, MDP and MAA are extended to twelve hours, to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered by this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

NOTE: Follow Package Insert Requirements for DTPA-Renal Exp Time
This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,



T. H. JANISON, MD

Williamson Community Hospital
Williamson, Virginia 23175

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: WADE T. LOO
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-09413-06 for V.A. MEDICAL CENTER - RICHMOND, VA (licensee's name) was inspected on 12/16-. Radiopharmaceutical departure records were inspected for the period 9/91 to 12/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (another NRC licensee or an Agreement State licensee) to actually make the departure.
- Other reason (explain).

Wade T. Loo 12/20/91
Radiation Specialist (Signature and Date)

Attachment: As stated

TABLE 7: OTHER Tc99m IMAGING AGENTS

3-15-91

- November 1989 Kit Prep Guidelines/
Package Insert Recommendations

Product	Manufacturer	Activity	Tc99m Volume	Time of Use ²
DMSA	Medi+Physics	44-88 mCi	2.2 - 4.4 ml 2.2 ml reagent	30 minutes
HM-PAO (Ceretek [®])	Amersham	30 mCi ³	up to 5 ml	30 minutes

¹ Syncor Guidelines correspond to manufacturers' instructions.

² Do not exceed 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Sodium pertechnetate elution must be less than 2 hours old when used to prepare the kit.

TABLE 6: Tc99m HEPATOBIILIARY AND LIVER AGENTS

Handwritten: JB
3-15-9

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

Product	Manufacturer	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
		Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Cholotec	Squibb	200 mCi	2-5 ml	18 hours ²	100 mCi	1-5 ml	18 hours ²
Hepatolite	↖ DuPont	150 mCi	2-5 ml	8 hours	100 mCi	4-5 ml	6 hours
Microlite	DuPont	75 mCi	2-8 ml	6 hours	75 mCi	2-8 ml	6 hours
Sulfur colloid	↖ CIS	500 mCi	1-3 ml	12 hours	500 mCi	1-3 ml	6 hours
Sulfur Colloid	↖ Mallinckrodt	400 mCi	0.1-5 ml	12 hours	400 mCi	0.1-5 ml	discard vial after 6 hrs.
Sulfur Colloid	Squibb	500 mCi	0.1-5 ml	12 hours	500 mCi ³	0.1-5 ml	6 hours
Sulfur	Medi+Physics	400 mCi	0.5-5 ml	12 hours	400 mCi	0.5-5ml	6 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Preservative in formulation allows 18 hour expiration time specified in package insert. Tc99m must have Mo99 concentration within acceptable limits as of expiration time.

³ Manufacturer's instructions do not specify maximum activity. Syncor policy limits activity to 500 mCi.

T A B L E 4 : T c 9 9 m G L U C O H E P T O N A T E

JS 3-15-91

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	DuPont	150 mCi ²	3-7 ml	6 hours
Renal Scan	DuPont	150 mCi ²	3-7 ml	4 hours ²

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

T A B L E 5 : T c 9 9 m H U M A N S E R U M A L B U M I N

Procedure	Manufacturer	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
		Activity	Tc99m Volume	Time of Use	Activity	Tc99m Volume	Time of Use
Multidose	Medi+Physics	200 mCi	3 ml	6 hours	100 mCi	3 ml	6 hours
Unit Dose	Medi+Physics	70 mCi	1.3 ml	6 hours	30 mCi	1.3 ml	3 hours

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

TABLE 3: Tc99m DTPA

Handwritten: 3-15-91

- November 1989 Kit Prep Guidelines/ -
Package Insert Recommendations

Procedure	Manufacturer	Activity	Tc99m Volume	Time of Use
Brain Scan	Squibb	300 mCi	up to 5 ml	6 hours
Renal Scan	Squibb	300 mCi	up to 5 ml	4 hours ²
Ventilation Study	Squibb	300 mCi	up to 5 ml	6 hours
GFR Assessment ³	Squibb	50 mCi	2-5 ml	1 hour
Brain Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Renal Scan	Medi+Physics	300 mCi ²	2-8 ml	6 hours
Ventilation Study	Medi+Physics	300 mCi ²	2-8 ml	6 hours
GFR Assessment ³	Medi+Physics	50 mCi	2-8 ml	1 hour
Brain Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Renal Scan	CIS	100 mCi ²	2-3 ml	2 hours ²
Ventilation Study	CIS	100 mCi ²	2-3 ml	2 hours ²
GFR Assessment ³	CIS	50 mCi ²	2-3 ml	1 hour

¹ Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Syncor guidelines are more restrictive than manufacturers' instructions.

³ Syncor experience shows that Medi+Physics DTPA is preferred for GFR assessment.

TABLE 2: Tc99m BONE IMAGING AGENTS

AS
3-15-91

----- November 1989 -----
Kit Prep Guidelines

----- Package Insert -----
Recommendations

PRODUCT	Activity ¹	Tc99m Volume	Time of Use ²	Activity ¹	Tc99m Volume	Time of Use ²
Squibb MDP	400 mCi	0.5-5 ml	12 hours ³	150 mCi	0.5-5 ml	12 hours ³
Medi+Physics MDP	400 mCi	2-8 ml	12 hours	400 mCi ⁴	2-8 ml	6 hours
DuPont MDP	200 mCi	2-8 ml	6 hours	200 mCi ⁵	2-8 ml	6 hours
CIS MDP	200 mCi	1-8 ml	6 hours	200 mCi ⁶	1-8 ml	6 hours
Amersham MDP	100 mCi	1-8 ml	6 hours	100 mCi	1-8 ml	6 hours
Mallinckrodt HDP	150 mCi		6 hours	150 mCi ⁷	3-6 ml	6 hours ⁸
DuPont PYP	200 mCi	3-7 ml	6 hours	200 mCi	3-7 ml	6 hours
Squibb PYP	75 mCi	2-4 ml	6 hours	75 mCi	2-4 ml	6 hours
Mallinckrodt	100 mCi	1-10 ml	6 hours	100 mCi	1-10 ml	6 hours

¹ These activities are maximum amounts and lesser amounts should be used as experience dictates.

Do not exceed the 12 hour expiration time of the sodium pertechnetate elution used to prepare the kit.

² Recommended time of use is not specified in the manufacturer's instructions.

⁴ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 400 mCi.

⁵ Maximum activity is not specified by the manufacturer. Syncor policy limits activity to 200 mCi.

⁶ The manufacturer specifies maximum activity of 300 mCi, but Syncor policy limits it to 200 mCi.

⁷ The manufacturer specifies maximum activity of 200 mCi, but Syncor policy limits it to 150 mCi.

⁸ Manufacturer's instructions recommend an 8 hour time of use, but Syncor policy limits it to 6 hours.

TABLE 1: Tc99m MACROAGGREGATED ALBUMIN

Handwritten: 3-15-91

MANUFACTURER	----- November 1989 ----- Kit Prep Guidelines			----- Package Insert ----- Recommendations		
	Activity ¹	Tc99m Volume	Time of Use ²	Activity ³	Tc99m Volume	Time of Use ²
DuPont (3.6 - 6.5M Particles)	125 mCi	2-8 ml	12 hours	72 mCi	2-8 ml	6 hours
CIS (12 - 15M Particles)	340 mCi	3-5 ml	12 hours	240 mCi	3-5 ml	6 hours
Amersham (4 - 7M Particles)	115 mCi	1-3 ml	12 hours	40 mCi	1-3 ml	6 hours
Medi+Physics (1.5 - 2.5M Particles)	50 mCi	up to 3 ml	12 hours	80 mCi (4 - 8M Particles)	2-8 ml	6 hours
Mallinckrodt (4 - 12M Particles)	200 mCi	5-10 ml	12 hours	80 mCi	5-10 ml	discard vial after 8 hrs.

¹ Amounts used in November 1989 guidelines for MAA based on 200,000 particles per 5 mCi dose, and average number of particles per vial at time of preparation. These values may be increased to account for decay up to the time of calibration of the dispensed dose.

² Do not exceed the expiration time of the sodium pertechnetate elution used to prepare the kit.

³ Activity is based on 200,000 particles per 4 mCi dose, and minimum number of particles per vial at time of preparation. Activity may be increased to account for decay up to the time of calibration of the first dispensed dose.

Interim Rule

ILST (2.6)

Synco International, Corp # 004
ITEMIZED BILLING LIST

PAGE: 1

Customer: 2361 MCGUIRE VA HOSPITAL

Period Ending: 11.7.91

SCHEDULED PRODUCTS

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	F.O. #	Procedure	Patient	Notation	Y/N
70756	11/01/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
470757	11/01/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
470829	11/02/91	MAA Tc99m	TC9932	1.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
470830	11/02/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
470852	11/03/91	MAA Tc99m	TC9932	1.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
470853	11/03/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
470990	11/04/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
470991	11/04/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471165	11/05/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471166	11/05/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471236	11/01/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471237	11/01/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471238	11/01/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471240	11/01/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471241	11/01/91	SN-DTPA Tc99m	TC9941	1.00	Dose	0.00				Renal Imaging	Per Phys Order		N
471322	11/06/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471323	11/06/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471431	11/04/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471432	11/04/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471433	11/04/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471434	11/04/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471436	11/04/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471437	11/04/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471438	11/04/91	MAA Tc99m	TC9930	1.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
471522	11/04/91	Tc04 Meckel's	TC0407	1.00	Dose	0.00				Meckel's Scan	Per Phys Order		N
471573	11/05/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471574	11/05/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471575	11/05/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
471577	11/05/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471578	11/05/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471579	11/05/91	MAA Tc99m	TC9930	1.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
471635	11/07/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471636	11/07/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471689	11/08/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471690	11/08/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471760	11/06/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471761	11/06/91	Tc04 Muga	TC0406	1.00	Dose	0.00				MUGA Study	Per Phys Order		N
471838	11/06/91	Sulf Col Tc99m	TC9920	1.00	Dose	0.00				Liver Study (CIS)	Per Phys Order		Y
471850	11/09/91	MAA Tc99m	TC9930	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471851	11/09/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471874	11/10/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471875	11/10/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
471909	11/11/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	No Charge	Y
471909	11/11/91	Tc04 Kit Pref	TC0405	1.00	Dose	0.00	9			UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472026	11/07/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
472027	11/07/91	MDF Tc99m	TC9950	1.00	Dose	0.00				Bone Imaging	Per Phys Order		Y
472028	11/07/91	SN-DTPA Tc99m	TC9941	1.00	Dose	0.00				Renal Imaging	Per Phys Order		N
472029	11/07/91	Sulf Col Tc99m	TC9920	1.00	Dose	0.00				Liver Study (CIS)	Per Phys Order		Y

Customer: 2361 McGUIRE VA HOSPITAL

Period Ending: 11/30/91

SCHEDULED PRODUCTS

Rx/Ord#	Date	Prod Desc.	Prod Id	Dlv. Unit	Extr	Chg Cd	P.O. #	Procedure	Patient	Notation	Var
72053	11/12/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472054	11/12/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472147	11/08/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472148	11/08/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472150	11/08/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472213	11/13/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472214	11/13/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472254	11/08/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472339	11/11/91	MAA Tc99m	TC9930	1.00	Dose	0.00		Lung Perfusion	Per Phys Order		Y
472385	11/12/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472386	11/12/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472387	11/12/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472388	11/12/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472389	11/12/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472405	11/14/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472406	11/14/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472519	11/12/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472534	11/15/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472535	11/15/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472634	11/16/91	MAA Tc99m	TC9932	1.00	Dose	0.00		Lung Perfusion	Per Phys Order		Y
472635	11/16/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472657	11/17/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472658	11/17/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472675	11/12/91	SN-DTPA Tc99m	TC9941	1.00	Dose	0.00		Renal Imaging	Per Phys Order		N
472682	11/12/91	Tc04-GI Bleed	TCD408	1.00	Dose	0.00		BLEEDING (GI) STUDY	Per Phys Order		N
472719	11/13/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472720	11/13/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472721	11/13/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472767	11/18/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472768	11/18/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472846	11/14/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472847	11/14/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472848	11/14/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
472850	11/14/91	SN-DTPA Tc99m	TC9941	1.00	Dose	0.00		Renal Imaging	Per Phys Order		N
472894	11/14/91	MAA Tc99m	TC9930	1.00	Dose	0.00		Lung Perfusion	Per Phys Order		Y
472895	11/14/91	MAA Tc99m	TC9930	1.00	Dose	0.00		Lung Perfusion	Per Phys Order		Y
472896	11/14/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
472926	11/19/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
472927	11/19/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
472974	11/14/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
473047	11/14/91	MAA Tc99m	TC9930	1.00	Dose	0.00		Lung Perfusion	Per Phys Order		Y
473063	11/15/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
473064	11/15/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
473065	11/15/91	Tc04 Muga	TCD406	1.00	Dose	0.00		MUGA Study	Per Phys Order		N
473110	11/20/91	MAA Tc99m	TC9932	1.00	Dose	0.00	9	Lung Perfusion	Per Phys Order	No Charge	Y
473111	11/20/91	Tc04 Kit Pref	TCD405	1.00	Dose	0.00	9	UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
473239	11/18/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y
473240	11/18/91	MDF TC99m	TC9950	1.00	Dose	0.00		Bone Imaging	Per Phys Order		Y

Customer: 2361 McGUIRE VA HOSPITAL

Period Ending: 11/30/91

SCHEDULED PRODUCTS

Rx/Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	F.O. #	Procedure	Patient	Notation	Var
3241	11/18/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3242	11/18/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
473243	11/18/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
3244	11/18/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
3245	11/18/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
473339	11/19/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3340	11/19/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3341	11/19/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
473342	11/19/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
473343	11/19/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
3344	11/19/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
3345	11/19/91	Sulf Col Tc99m	TC9924	1.00	Dose		0.00			EMERGENCY GASTRIC	Per Phys Order		Y
473346	11/19/91	SN-DTPA Tc99m	TC9941	1.00	Dose		0.00			Renal Imaging	Per Phys Order		N
3349	11/18/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
3377	11/19/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
173436	11/21/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
3499	11/21/91	TcD4 Kit Pref	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
3499	11/22/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
173500	11/22/91	TcD4 Kit Pref	TC0405	1.00	Dose		0.00			UNIT DOSE KIT PREP	Per Phys Order		N
173558	11/23/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
3559	11/23/91	TcD4 Kit Pref	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
3582	11/24/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
173584	11/24/91	TcD4 Kit Pref	TC0405	1.00	Dose		0.00			UNIT DOSE KIT PREP	Per Phys Order		N
3689	11/20/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3690	11/20/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3691	11/20/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3692	11/20/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3693	11/20/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
3694	11/20/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
3695	11/20/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
3753	11/25/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
3754	11/25/91	TcD4 Kit Pref	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
3896	11/21/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3897	11/21/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3898	11/21/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3899	11/21/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
3901	11/21/91	SN-DTPA Tc99m	TC9941	1.00	Dose		0.00			Renal Imaging	Per Phys Order		N
3929	11/26/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
3940	11/26/91	TcD4 Kit Pref	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
4017	11/22/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
4018	11/22/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
4019	11/22/91	MDF TC99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
4020	11/22/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
4021	11/22/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
4022	11/22/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
4023	11/22/91	TcD4 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
4024	11/22/91	SN-DTPA Tc99m	TC9941	1.00	Dose		0.00			Renal Imaging	Per Phys Order		N
4025	11/22/91	SN-DTPA Tc99m	TC9941	1.00	Dose		0.00			Renal Imaging	Per Phys Order		N

Customer: 236: McDUIRE VA HOSPITAL

Period Ending: 11/30/95

SCHEDULED PRODUCTS

Ord#	Date	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Co	F.C. #	Procedure	Patient	Notation	Var
474053	11/22/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474105	11/27/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
474106	11/27/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
474164	11/28/91	MAA Tc99m	TC9932	1.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	No Charge	Y
474165	11/28/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
474200	11/29/91	MAA Tc99m	TC9932	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
474207	11/29/91	Tc04 Kit Prep	TC0405	1.00	Dose		0.00	9		UNIT DOSE KIT PREP	Per Phys Order	No Charge	N
474210	11/29/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474311	11/25/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474312	11/25/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474313	11/25/91	Tc04 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
474315	11/25/91	Tc04 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
474316	11/25/91	Tc04 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
474317	11/25/91	Sulf Col Tc99m	TC9920	1.00	Dose		0.00			Liver Study (CIS)	Per Phys Order		Y
474387	11/25/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
474416	11/26/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474417	11/26/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474418	11/26/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474419	11/26/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474420	11/26/91	Tc04 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
474422	11/26/91	SN-DTPA Tc99m	TC9941	1.00	Dose		0.00			Renal Imaging	Per Phys Order		N
474423	11/26/91	SN-DTPA Tc99m	TC9941	1.00	Dose		0.00			Renal Imaging	Per Phys Order		N
474476	11/26/91	Tc04 Muga	TC0406	1.00	Dose		0.00			MUGA Study	Per Phys Order		N
474506	11/26/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
474535	11/26/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
474577	11/27/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474578	11/27/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474579	11/27/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474580	11/27/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474583	11/27/91	MAA Tc99m	TC9930	1.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
474584	11/29/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474585	11/29/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474586	11/29/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
474587	11/29/91	MDF Tc99m	TC9950	1.00	Dose		0.00			Bone Imaging	Per Phys Order		Y

TOTAL: 126

Sulf Col Tc99m	3
Sulf Col Tc99m	1
MAA Tc99m	13
MAA Tc99m	4
SN-DTPA Tc99m	10
MDF Tc99m	55
Tc04 Kit Prep	2
Tc04 Muga	36
Tc04 Meckel's	1
Tc04-GI Bleed	1

Customer: 2361 MCGUIRE VA HOSPITAL

Period Ending: 11/30/9

NON-SCHEDULED PRODUCTS

Order#	Date	Prod Desc.	Prod Id	Qty	Unit	Extr	Chg	Cd	F.C. #	Procedure	Patient	Notation	Var
73688	11/20/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
73707	11/20/91	Cardiolit Tc99m	TC99L0	1.00	Dose	0.00				Cardiac Study-DUPONT	Per Phys Order		N
473708	11/20/91	Cardiolit Tc99m	TC99L0	1.00	Dose	0.00				Cardiac Study-DUPONT	Per Phys Order		N
473715	11/20/91	Tc99m Ceretec	TC99C0	1.00	Dose	0.00				Brain Imaging	Per Phys Order		N
73886	11/21/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
473887	11/21/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
473888	11/21/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
73889	11/21/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
73990	11/21/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
473991	11/21/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
73900	11/21/91	Cardiolit Tc99m	TC99L0	1.00	Dose	0.00				Cardiac Study-DUPONT	Per Phys Order		N
73904	11/21/91	Cardiolit Tc99m	TC99L0	1.00	Dose	0.00				Cardiac Study-DUPONT	Per Phys Order		N
473905	11/21/91	Cardiolit Tc99m	TC99L0	1.00	Dose	0.00				Cardiac Study-DUPONT	Per Phys Order		N
473906	11/21/91	Cardiolit Tc99m	TC99L0	1.00	Dose	0.00				Cardiac Study-DUPONT	Per Phys Order		N
74007	11/22/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74008	11/22/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
474009	11/22/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74010	11/22/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74011	11/22/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
474012	11/22/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74013	11/22/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74014	11/22/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74015	11/22/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74016	11/22/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74153	11/22/91	DisofeninTc99m	TC9970	1.00	Dose	0.00				Biliary Imaging	Per Phys Order		Y
74208	11/29/91	Xe133 10 mCi	XE1331	2.00	Vial	0.00				Ventilation Stv-DUP	Per Phys Order		N
74300	11/25/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74301	11/25/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74302	11/25/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74303	11/25/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74304	11/25/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74305	11/25/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74306	11/25/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74307	11/25/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74308	11/25/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74309	11/25/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74318	11/25/91	Tc99m Ceretec	TC99C0	1.00	Dose	0.00				Brain Imaging	Per Phys Order		N
74319	11/25/91	Tc99m Ceretec	TC99C0	1.00	Dose	0.00				Brain Imaging	Per Phys Order		N
74383	11/25/91	Disofenin(DUP)	100070	5.00	Vial	0.00				Disofenin Prev.	Per Phys Order		N
74398	11/25/91	Ga67 Ct. (DUP)	GA6720	6.00	mCi	0.00				Soft Tissue Study	Per Phys Order		N
74407	11/26/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74408	11/26/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74409	11/26/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74410	11/26/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74411	11/26/91	Tl201 DUF	TL2011	2.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74412	11/26/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74413	11/26/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N
74414	11/26/91	Tl201 DUF	TL2011	1.00	mCi	0.00				Cardiac Study	Per Phys Order		N

Customer: 2351 McGUIRE VA HOSPITAL

For Dates: 11/01/91 thru 11/30/91

Date	Rx/Ord	Prod Desc.	Prod Id	Qty.	Unit	Ext	Chg	Co	F.C. #	Procedure	Patient	Notation	Var
11/29/91	474206	MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order	Billed	Y
	474841	MDF TC99m	TC9950	22.00	Dose	0.00				Bone Imaging	Per Phys Order	Billed	Y
	474842	MDF TC99m	TC9950	22.00	Dose	0.00				Bone Imaging	Per Phys Order	Billed	Y
	474843	MDF TC99m	TC9950	22.00	Dose	0.00				Bone Imaging	Per Phys Order	Billed	Y
	474844	MDF TC99m	TC9950	22.00	Dose	0.00				Bone Imaging	Per Phys Order	Billed	Y
11/30/91	474631	MAA Tc99m	TC9932	4.00	Dose	0.00	9			Lung Perfusion	Per Phys Order	Billed	Y
	474980	DisofeninTc99m	TC9970	15.00	Dose	0.00				Biliary Imaging	Per Phys Order	Billed	Y

Totals For Each Product

TC9932	2
TC9950	4
TC9970	1

Customer: 2361 McDUIRE VA HOSPITAL

For Dates: 10/01/91 thru 10/31/91

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Co	F.O. #	Procedure	Patient	Notation	Var
10/01/91	466546 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	467094 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467095 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467096 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467097 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/02/91	466816 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	467331 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467332 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467333 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/03/91	466996 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	467494 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467495 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467496 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467497 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/04/91	467165 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	467627 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467628 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467629 Sulf Col Tc99m	TC9924	0.50	Dose	0.00				EMERGENCY GASTRIC	Per Phys Order		Y
10/05/91	467220 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
10/06/91	467243 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
10/07/91	467400 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	467777 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467778 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/08/91	467532 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	467919 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467920 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	467921 MAA Tc99m	TC9930	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	468074 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/09/91	467697 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	468114 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468115 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/10/91	467861 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	468327 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
10/11/91	468015 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	468508 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468509 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468510 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468523 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468592 MAA Tc99m	TC9930	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
10/12/91	468166 MAA Tc99m	TC9932	4.00	Dose	0.00	9			Lung Perfusion	Per Phys Order		Y
10/13/91	468189 MAA Tc99m	TC9932	4.00	Dose	0.00	9			Lung Perfusion	Per Phys Order		Y
10/14/91	468223 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
10/15/91	468386 MAA Tc99m	TC9932	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y
	468716 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468717 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468718 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468719 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468720 MDP TC99m	TC9950	22.00	Dose	0.00				Bone Imasine	Per Phys Order		Y
	468724 MAA Tc99m	TC9930	4.00	Dose	0.00				Lung Perfusion	Per Phys Order		Y

Customer: 2361 McDUIRE VA HOSPITAL

For Dates: 10/01/91 thru 10/31/91

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chs	Cd	P.O. #	Procedure	Patient	Notation	Var
10/15/91	468984 MAA Tc99m	TC9930	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	468985 MAA Tc99m	TC9930	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/16/91	468551 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	469045 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469046 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469072 MAA Tc99m	TC9930	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/17/91	468789 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	469186 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469187 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469188 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469248 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/18/91	468872 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	469368 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469369 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469370 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469371 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/19/91	468928 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/20/91	468951 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/21/91	469111 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	469549 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469550 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469551 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469552 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469557 MAA Tc99m	TC9930	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/22/91	469276 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	469743 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469744 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469745 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469746 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/23/91	469431 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	469889 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469890 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469891 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	469892 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/24/91	469689 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	470100 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470101 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/25/91	469806 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	470301 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470302 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470303 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470304 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/26/91	469984 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/27/91	470007 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
10/28/91	470164 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	470498 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470499 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470500 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/29/91	470327 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y

BLSTC(3.5)
Run Date 11/01/91

Synco International Corp # 004
VARIANCE SUMMARY LIST

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Customer: 2361 McGUIRE VA HOSPITAL

For Dates: 10/01/91 thru 10/31/91

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
10/29/91	470681 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470682 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470683 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470684 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470686 DisofeninTc99m	TC9970	5.00	Dose		0.00			Biliary Imaging	Per Phys Order		Y
10/30/91	470380 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	470945 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	470946 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/31/91	470576 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	471111 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	471112 MDF TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y

Totals For Each Product

TC9932 31
TC9950 69
TC9924 1
TC9930 7
TC9970 1

Customer: 2361 McGUIRE WA HOSPITAL

For Dates: 00/00/00 thru 99/99/99

Date	Rx/Ord Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.D. #	Procedure	Patient	Notation	Var
09/26/91	466318 MAA Tc99m	TC9932	4.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	Billed	Y
09/29/91	466344 MAA Tc99m	TC9932	4.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	Billed	Y
09/30/91	466523 MAA Tc99m	TC9932	4.00	Dose		0.00	9		Lung Perfusion	Per Phys Order	Billed	Y
	466898 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order	Billed	Y
	466899 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order	Billed	Y
	466904 Sulf Col Tc99m	TC9920	8.00	Dose		0.00			Liver Study (CIS)	Per Phys Order	Billed	Y
	466921 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order	Billed	Y
	466968 MAA Tc99m	TC9930	4.00	Dose		0.00			Lung Perfusion	Per Phys Order	Billed	Y
	467040 MAA Tc99m	TC9930	4.00	Dose		0.00			Lung Perfusion	Per Phys Order	Billed	Y
10/01/91	466646 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	467094 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	467095 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	467096 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	467097 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
10/02/91	466816 MAA Tc99m	TC9932	4.00	Dose		0.00			Lung Perfusion	Per Phys Order		Y
	467331 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	467332 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y
	467333 MDP TC99m	TC9950	22.00	Dose		0.00			Bone Imaging	Per Phys Order		Y

Totals For Each Product

TC9932	5
TC9950	10
TC9920	1
TC9930	2



DEPARTMENT OF VETERANS AFFAIRS
Hunter Holmes McGuire Medical Center
1201 Broad Rock Boulevard
Richmond VA 23249

March 14, 1991

In Reply Refer To

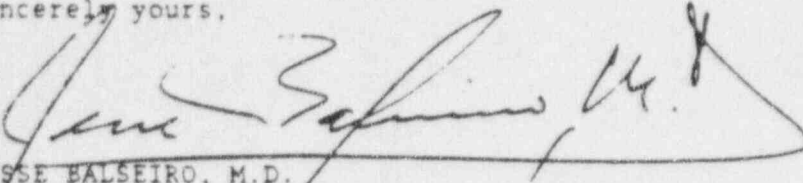
* Syncor International Corporation
Medical Services Group
2085 Dabney Road
Richmond, Virginia 23230

SUBJ: Written Directive for Eluting Generators and Preparing
Radiopharmaceuticals

1. As was discussed on 2/14/91, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed the copy of Guidelines attached to indicate our review.
2. The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.
3. In my judgement, these departures from manufacturer's instructions are justified for the following reasons:
 - a. Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
 - b. Times of use for Sulfur Colloid, MDP and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases.
 - c. Times of use for Sulfur Colloid, MDP and MAA are extended to twelve hours, to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered by this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.
 - d. NOTE: Follow Package Insert Requirements for DTPA-Renal Exp Time

4. This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jesse Balseiro, M.D.", with a large, sweeping flourish at the end.

JESSE BALSEIRO, M.D.
CHIEF, NUCLEAR MEDICINE SERVICE

Attachments

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-26286-01 for Medical Consultants Imaging Co (licensee's name)

was inspected on 2/28/92. Radiopharmaceutical departure records were
inspected for the period 10/91 to present with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

Correction → The medical licensee sent the written diagnostic directive to Erin Howell (another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain). Blanket departure authorization provided by licensee to Radiopharmacy for extending product expiration time and addition of ascorbic acid to certain products

W. Howell 3/10/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

56
①

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: JAMES L. CAMERON
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-03362-02 for AKRON GENERAL MED CTR. (licensee's name)
was inspected on 12/13/91. Radiopharmaceutical departure records were
inspected for the period 7/89 to 11/91 with the following results:

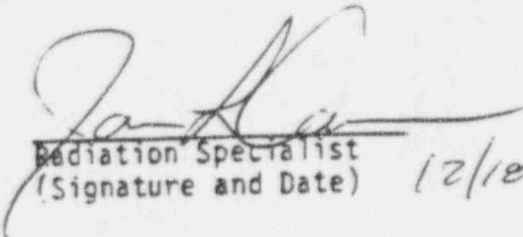
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of ~~therapeutic departures~~ are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to Surv
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

12/12/91

Attachment: As stated

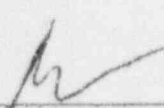
To: Kamal Amin, Syncor, Inc.
 Re: Preparation of Technetium 99m HMPAO--Labeled Leukocytes

Dear Mr. Amin:

This to authorize Syncor to prepare Technetium 99m HMPAO--labeled leukocytes for use by the Nuclear Medicine Service, Department of Radiology at Akron General Medical Center, Akron, Ohio.

These labeled leukocytes will be used for imaging patients with suspected infection, such as osteomyelitis. Use of this product is indicated as a substitute for 111-in leukocytes because of increased resolution of Technetium 99m and reduced radiation dose to the patient, particularly the spleen.

Use was approved at the Radiation Safety Committee meeting held in July, 1991. This authorization is made pursuant to CFR 35.200 (c)(1).



Dr. Richard Albright,
 Director, Department of Nuclear Medicine
 Akron General Medical Center

Post-It™ brand fax transmittal memo 7671		# of pages = 1
To: JAMES CAMERON	From: S-WALSH 1022 GED	
Co. NBC	Co.	
Dept.	Phone # 216 753	
Fax # 753-790-5665	Fax # 216 753 9480	

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM:

James Cameron
Radiation Specialist, Region III

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-17082-01 for Hendricks Community Hs (licensee's name)
was inspected on 11/22/91 Radiopharmaceutical departure records were
inspected for the period 3/10/89 to 11/22/91 with the following results.

[NOTE. The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to Sygar (another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain).

James Cameron
Radiation Specialist
(Signature and Date) 11/25/91

Attachment: As stated



Hendricks County Hospital
1000 East Main Street
P.O. Box 409
Danville, Indiana 46122
(317) 745-4451

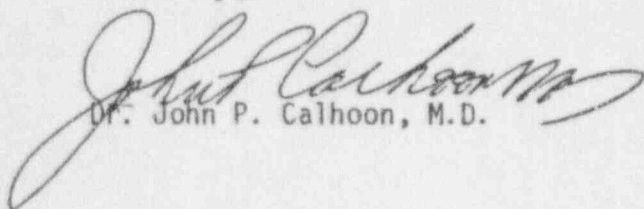
October 17, 1990

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals. I hereby direct you to compound and dispense Tc-99m sulfur Colloid, MDP, MAA, and other Tc-99m radiopharmaceuticals in accordance with Syncor Kit Prep Guidelines. I recognize that the manufacturer's packages inserts for these products specify 6 hour time of use, but my experience in their use has demonstrated that they may in fact be used safely and effectively for up to 12 hours. The twelve hour time of use is needed so that the scheduling of the use of products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,


Dr. John P. Calhoon, M.D.

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 DWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-00305-03 for MERCY HOSPITAL (licensee's name)
was inspected on 25 SEPTEMBER 1991. Radiopharmaceutical departure records were
inspected for the period — to — with the following results:
SEE ATTACHED.

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain). - TOO MANY RECORDS TO COPY. ATTACHED IS SAMPLE OF RECORDS.

W. P. REICHHOLD
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

A-1

Issue Date: XX/XX/XX

October 12, 1990

Randy A. Asmus, R.Ph., Manager
Syncor International Corporation
2208 West Central Avenue
Toledo, Ohio 43606

Dear Mr. Asmus:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA, and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturers' package inserts for these products specify a 6-hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12-hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility nor to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

G. B. Mehta, M.D., Chairman
Department of Radiology

GBM/sac



MERCY HOSPITAL • 2200 JEFFERSON AVENUE • TOLEDO, OHIO • 43624-0088 • 419 259-1500

October 30, 1990

Syncor International Corp.
2208 West Central Avenue
Toledo, Ohio 43606


Dear Syncor:

I have reviewed the attached Syncor procedure for labeling leukocytes with Ceretec (Technetium Tc99m exametazime injection). I understand that this procedure varies from the approved method of preparation for Ceretec, and I have initialed your labeling procedure worksheet to indicate my approval.

Until further notice, please use Ceretec for labeling leukocyte studies when ordered by the Nuclear Medicine Department at Mercy Hospital. When we perform labeled leukocyte studies, I wish to use the radiopharmaceutical that provides the lowest patient absorbed dose possible. I also believe that the more rapid diagnostic information and superior image quality provided by Ceretec-labeled leukocytes represents a significant clinical benefit warranting the use of this procedure for our patients.

We will verbally notify you of any exceptions to this request at the time we call you to place the prescription order for the study.

Sincerely,


G. B. Mehta, M.D., Chairman
Department of Radiology

GBM/sac

Attachment: Syncor Leukocyte Labeling Worksheet

Rx/Ord	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
	770101 MAA Tc99m	TC9930	6.00	Dose		0.00		664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
91	770027 MAA Tc99m	TC9930	4.00	Dose		0.00		664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	770270 MAA Tc99m	TC9930	6.00	Dose		50.00	3	664141	Pulmonary Perfusion	Per Phys Order		Y
	770272 MAA Tc99m	TC9930	6.00	Dose		0.00		664141	Pulmonary Perfusion	Per Phys Order		Y

For Each Product

930 47
 C9950 50
 920 5

Order: 2114 MERCY HOSPITAL

For Dates: 08/01/91 thru 08/31/91

	Ri/Ord	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
11/91	764168	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	764169	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	764304	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
12/91	764433	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	764434	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	764549	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	764550	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
13/91	764651	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	764683	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	764924	MAA Tc99m	TC9930	4.00	Dose	50.00	3		664141	Pulmonary Perfusion	Per Phys Order		Y
	764925	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
15/91	764703	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	764704	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	764987	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	764988	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
	765244	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	765245	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
18/91	765481	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	765800	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	765814	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
19/91	765723	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	765724	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	766090	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	766092	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	766106	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
	765971	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	766229	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
1/91	766003	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
2/91	766023	MAA Tc99m	TC9930	6.00	Dose	0.00	9		664141	Pulmonary Perfusion	Per Phys Order	Returned	Y
	766024	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	766134	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	766218	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	766413	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	766333	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	766334	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	766474	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
	766647	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
14/91	766585	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	766586	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
	766748	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
	766905	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
15/91	766844	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	766845	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767079	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	767080	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767303	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767437	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767445	MDF TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
17/91	767314	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y

Number: 2114 MERCY HOSPITAL

For Dates: 08/01/91 thru 08/31/91

Le	Rx/Ord	Prod Desc.	Prod Id	Qty.	Unit	Extr	Chg	Cd	P.O. #	Procedure	Patient	Notation	Var
18/91	767346	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
19/91	767366	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	767367	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767461	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767462	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767463	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767737	Sulf Col Tc99m	TC9920	6.00	Dose	0.00			664141	Liver Imaging	Per Phys Order	CR Return	Y
20/91	767676	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	767775	Sulf Col Tc99m	TC9920	6.00	Dose	0.00			664141	Liver Imaging	Per Phys Order		Y
	767776	Sulf Col Tc99m	TC9920	6.00	Dose	0.00			664141	Liver Imaging	Per Phys Order	CR Return	Y
	767777	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	767778	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
	768001	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	768040	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	768242	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
21/91	767942	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	767943	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768033	Sulf Col Tc99m	TC9920	6.00	Dose	0.00			664141	Liver Imaging	Per Phys Order		Y
	768034	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768035	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768036	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768059	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768213	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
22/91	768152	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	768276	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
23/91	768411	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	768412	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768514	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768515	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768579	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768580	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order	CR Return	Y
24/91	768662	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
25/91	768694	MAA Tc99m	TC9930	4.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
26/91	768714	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	768715	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	768937	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
27/91	769007	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	769008	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	769361	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
28/91	769280	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y
	769281	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	769463	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	769605	Sulf Col Tc99m	TC9920	6.00	Dose	0.00			664141	Liver Imaging	Per Phys Order		Y
29/91	769527	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
30/91	769779	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order	CR Return	Y
	769780	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	769881	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	770081	MDP TC99m	TC9950	25.00	Dose	0.00			664141	Bone Imaging	Per Phys Order		Y
	770084	MAA Tc99m	TC9930	6.00	Dose	0.00			664141	Pulmonary Perfusion	Per Phys Order		Y

January 10, 1991

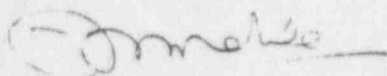
Syncor International Corp.
2208 West Central Ave.
Toledo, Ohio 43606

Dear Syncor:

I have reviewed the package insert for ^{99m}Tc Human Serum Albumin and the procedure used in lymphatic imaging with this agent. I understand that this procedure is a deviation from the approved uses.

Until further notice, please use ^{99m}Tc labeled HSA for lymphatic imaging in malignant melanoma. I wish to use the radiopharmaceutical that provides the lowest patient absorbed dose and most rapid diagnostic information. I believe that using ^{99m}Tc labeled HSA represents a significant clinical benefit warranting the use of this procedure for our patients.

Sincerely,



G. B. Mehta, M.D.
Chairman
Department of Radiology

GBM/sac

Att.

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-17518-01 for CONSULTING RADIOLOGISTS CORPORATION (licensee's name)
was inspected on 9/27/91. Radiopharmaceutical departure records were
inspected for the period — to — with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to —
(— another NRC licensee or — an Agreement State licensee)
to actually make the departure.

Other reason (explain).— TOO MANY - ATTACHED SAMPLE RECORDS!

W.P. REICHHOLD
Radiation Specialist
(Signature and Date)

Attachment: As stated

CONSULTING RADIOLOGISTS CORP.

RADIOLOGISTS

ST PINSKY, M.D.
RE MYERS, M.D.
RW SIDERS, M.D.
PM ROYEN, M.D.
SE GORDON, M.D.
MF FADELL, M.D.
DE HOOVER, M.D.
GB GLASSBERG, M.D.
RB DOERFLER, M.D.
SL MAYES, M.D.
TT LOH, M.D.
SS MANION, M.D.

X-RAY, ULTRASOUND AND NUCLEAR MEDICINE

Physicians and Surgeons Building
3100 W. Central Avenue
Toledo, Ohio 43606
(419) 535-7758

BUSINESS OFFICE

4351 Monroe Street
Toledo, Ohio 43606
(419) 473-3553

October 16, 1990

Syncor Inc.
2208 W. Central Ave.
Toledo, Oh. 43606

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturers' package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

S. T. Pinsky, M. D.

STP/nk

syncor[®]

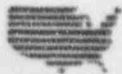
TO: NUCLEAR MEDICINE CUSTOMERS
FROM: SYNCOR INTERNATIONAL CORPORATION
RE: VARIANCE SUMMARY LIST
DATE: FEBRUARY 5, 1991

Enclosed you will find a copy of the Variance Summary List. This report lists the doses your department received over the past month which were variants from the manufacturers package insert.

This report will be sent to your department at the beginning of each month. We will be keeping a copy for our records to file with the variance letter signed by your authorized user physician in case of a NRC inspection.

If you have any questions, please feel free to call.

Thank you.



Innovators in high-tech pharmacy services

TC(3.5)
Date 03/02/91

Vendor Code: # 001
VARIANCE SUMMARY LIST

PAGE: 1
Run Time 05:19

Account: 2124 CONSULTING RADIOLOGIST

For Dates: 02/01/91 thru 02/28/91

Date	Ac/Ord	Prod Desc.	Prod Id	Qty.	Unit	Entr	Line	Ch	P.O. #	Procedure	Patient	NOTATION
01/91	729935	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
04/91	730273	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
06/91	730789	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
03/91	732230	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
05/91	732667	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
01/91	732971	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
	732972	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
09/91	733269	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
	733486	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
01/91	733869	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
02/91	734020	Sulf Col TC99m	TC9920	3.00	Dose	0.00				Liver Imaging	Per Phys Order	
	734021	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
02/91	734356	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
	734372	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
06/91	734606	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
	734805	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	
07/91	734874	Sulf Col TC99m	TC9920	3.00	Dose	0.00				Liver Imaging	Per Phys Order	
	734875	MDP TC99m	TC9950	20.00	Dose	0.00				Bone Imaging	Per Phys Order	

Sales For Each Product

TC9950 16
TC9920 2

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region 11

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-12371-d for FLOYD MEMORIAL HOSPITAL (licensee's name)

was inspected on AUGUST 20, 1991. Radiopharmaceutical departure records were inspected for the period 11-89 to 8-10-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to SYNCOM INTERNATIONAL
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).

SYNCOM INT.
201-206-32 KY LICENSE NO.

D.R. Gibbons 8-26-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: NOVEMBER 25, 1989
- b. Current inspection date: AUGUST 20, 1991

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

a. Licensee directed diagnostic departures Y N

If "Yes," answer the following:

b. Departures were made by the licensee Y N

(1) Written directive on file [35.200(c)(1)] Y N

(2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure Y N
- (b) Description of the departure Y N
- (c) Reasons why departure was needed Y N

(3) Records of number of departure administrations are on file [35.200(c)(2)] Y N

c. Departures were made by a different licensee Y N

- (1) Name & location of other facility _____
- _____
- _____
- _____

There were no records that indicated that the directive had been used. There were some emergency calls in that required ~~the~~ delivery during times that were close to the six hour limit, but none that appeared to exceed that limit. The directive was written to their vendor to aid in extreme emergency.

- d. Licensee made emergency diagnostic departures: () Y () N
- (1) Written directive on file [35.200(c)(1)] () Y () N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] () Y () N
- (3) Written directive includes notation of emergency [35.200(c)(1)] () Y () N

Remarks: *There were no records to indicate that call ins exceeded the six hour package insert limit.*

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures () Y () N
- If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] () Y () N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure () Y () N
- (2) Reasons why departure was needed () Y () N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] () Y () N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] () Y () N

Remarks:

ATTACHMENT C

INTERIM RULE FIELD NOTES FOR RADIOPHARMACY LICENSEES

1. GENERAL

a. Last inspection date: _____

b. Current inspection date: NA RADIOPHARMACY WAS NOT INSPECTED

[Inspection should cover all departures made since the last inspection.]

2. RADIOPHARMACY DEPARTURES

a. Radiopharmacy received diagnostic departure orders

Y () N

If "Yes," answer the following:

b. Written directive on file [30.34(i)(1)(i)]
SIX ATTACHED DIRECTIVE

Y () N

c. Written directive includes [30.34(i)(1)(i)]:

(1) Nature of the departure

Y () N

(2) Description of the departure

Y () N

(3) Reasons why departure was needed

Y () N

d. Records of number of departure prescriptions dispensed are on file [30.34(i)(1)(i)]

() Y () N

e. Radiopharmacy made emergency departures:

() Y () N

(1) Written directive obtained within three working days after emergency [30.34(i)(1)(ii)]

() Y () N

(2) Written directive includes notation of emergency [30.34(i)(1)(ii)]

() Y () N

Remarks:

[NOTE - Radiopharmacy licensees are not involved in therapeutic departures, so all of the above items apply to diagnostic departures made by the radiopharmacy.]



Floyd
Memorial
Hospital

January 11, 1991

Mike Wyant, Pharmacy Manager
Syncor International
Pharmacy Service Center
831 South 6th Street
Louisville, KY 40203

Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA, and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturer's package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

William R. Fortner, M.D.
Radiation Safety Officer

WRF:kmb

VHA.

Member of Voluntary Hospitals of America, Inc.

AE23-1

~~SECRET~~

PDR

SUPPORTING DATA FOR THE PROPOSED RULE TO
AMEND 10 CFR PARTS 30 and 35, "DEPARTURES
FROM MANUFACTURER'S INSTRUCTIONS;
ELIMINATION OF RECORDKEEPING REQUIREMENTS"

(Vol. 2 of two volumes)

No Departures

Carlisle Hosp. D-55 T-33
 Johnson Memorial Hosp. D-56 T-34
 Community Hosp. of Lancaster D-57 T-35
 Windham Community Men. Hosp. D-58 T-36
(** See "Departure Cahn" as well
 Rockville General Hosp. SD-59 T-36 (**)
 Clarion Hospital D-60 T-37
 Southwestern Health Center D-61 T-38
 SYRACUSE FOLLETT D-62 T-38
 Suburban Philadelphia Imaging Partners D-63 T-39

Departures

← note: lic. wasn't insp; Syracor, Hartford was insp.
 ← effective T-0

No Departures

Springfield Diagnostics	D-28 T-17
Beverly Hospital	D-29 T-17
Hodley Memorial Hospital	D-30 T-17
Paul H. Persner, M.D.	D-31 T-17
Medical Diagnostics & Therapeutics, P.C.	D-32 T-18
Hazleton General Hosp.	D-33 T-18
Wilkes-Barre Gen. Hosp.	D-34 T-19
Muhlenberg Hospital	D-35 T-20
Sharon Hospital	D-36 T-21
Norwalk Hospital	D-37 T-22
Boston City Hospital	D-38 T-23
Consultants in Cardiology, P.A.	D-39 T-23
Union County Cardiology Center, P.C.	D-40 T-23
Jordan Hospital, Inc.	D-41 T-23
St. Francis Hosp.	D-42 T-24
Christ. Hosp.	D-43 T-25
Veterans Medical Ctr., Fort Howard	D-44 T-25
Veterans Medical Ctr., Perry Pt.	D-45 T-25
Eric Nuclear Cardiology Ctr.	D-46 T-26
Holy Redeemer Hosp.	D-47 T-27
Spaulding Rehabilitation Hosp.	D-48 T-27
Life Signs/Boston Inc.	D-49 T-27
Divine Providence	D-50 T-28
Anna Jaques Hosp.	D-51 T-29
Bayshore Community Hosp.	D-52 T-30
St. Joseph Hosp.	D-53 T-31
Thack Nguyen, M.D.	D-54 T-32

Departures

NO DEPARTURES

SOLDIERS & SAILORS MEMOR HOSP	D-1	T-0
MILTON MED CENTR	D-2	T-1
SALEM HOSPITAL	D-3	T-2
ATLANTICARE MED CTR	D-4	T-3
BERSEY CITY Med CTR	D-5	T-4
THE HOSP CTR AT ORANGE	D-6	T-5
DOVER GEN Hosp & med CTR	D-7	T-6
CHILTON MEM HOSP	D-8	T-7
CONEMOUGH VALLEY MEM HOSP	D-9	T-7
MINERS HOSPITAL OF NORTH GAMBRIA	D-10	T-8
WALTHAM WESTON Hosp & med CTR	D-11	T-8
SAINTE VINCENT HOSPITAL, INC	D-12	T-9
THE MED CTR OF EAST MASS-MEMORIAL	D-13	T-10
MEMORIAL HOSPITAL	D-14	T-10
GOOD SAMARITAN Regional Med Ctr.	D-15	T-11
WING MEM. HOSP CORP	D-16	T-11
HARRINGTON MEM HOSP	D-17	T-11
LEFRANS Admin Med Ctr	D-18	T-11
MEDICAL IMAGING CTR, PC	D-19	T-11
SHORE MEMORIAL HOSP	D-20	T-12
Med. Ctr of OCEAN COUNTY	D-21	T-13
COMMUNITY Med Cent.	D-22	T-14
NUCLEAR Imaging Systems, INC	D-23	T-14
CARDIAC FITNESS KENNEDY OF ERIE INC	D-24	T-14
CLAYFIELD HOSPITAL	D-25	T-15
DILL CITY AREA HEALTH CTR	D-26	T-16
NEAR VILLE MEDICAL CTR	D-27	T-17

Departures

Diagnostic Radiology Association *	SD-1	T-0	(2?)
Bristol Hospital *	SD-1	T-0	(8?)
Waterbury Hospital Health Center *	SD-1	T-0	(2?)
Rockville General Hospital (**)*	SD-1	T-0	(2?)
Westwood Imaging *	SD-1	T-0	(1?)
St. Mary's Hospital *	SD-1	T-0	(1?)
Greene County Memorial	D-2	T-0	(1)
Williamsport Hospital	D-3	T-1	()
Newton - Wrursley Hospital (taken as at least 1 day dep.)	(D-4)	T-?	()

Info from Sign-out
* limited time period
represented; number goes
(or) See Dep. Column as well

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtenuche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-28563-01 for Suburban Philadelphia Imaging Partners Inc (licensee's name)
was inspected on 4/22/92. Radiopharmaceutical departure records were
inspected for the period 12/90 to 4/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Steven R. Courtenuche 4/23/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

12-01 T-39



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MEMORANDUM FOR: Donna-Beth Howe
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

THROUGH: Jenny M. Johansen, Chief
Nuclear Materials Safety Section D
Division of Radiation Safety and Safeguards
Region I

FROM: Keith D. Brown, Health Physicist
Nuclear Materials Safety Section D
Division of Radiation Safety and Safeguards
Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-18461-01MD for Syncor Corporation, Folcroft, Pennsylvania was inspected on November 14, 1991. Radiopharmaceutical departure records were inspected for the period August 9, 1990 to November 14, 1991 with the following results:

Diagnostic departures were requested by Delaware Spect Imaging Center, but not made. A copy of the request is attached.

License No. 06-19661-01MD for Syncor Corporation, Hartford, Connecticut was inspected on November 15, 1991. Radiopharmaceutical departure records were inspected for the period January 30, 1991 to November 15, 1991 with the following results:

Departures were requested by a number of the licensee's clients and were made. Copies of all cover letters requesting departures are attached. Copies of tables 1 through 7 were attached to each cover letter. Since, like the cover letters, the attached tables were identical, I have attached only one copy of these tables. Also attached are records of departure requests which were filled.

It is clear from these records that Syncor Corporation is actively soliciting requests for radiopharmaceutical departures from its customers. This allows them, in effect, to make pharmacy-directed departures so long as they get the cooperation of their clients. Since headquarters has recently directed a temporary stop on amendments to authorize pharmacy-directed departures, we would like to be advised if headquarters finds these practices acceptable.

Keith D. Brown
Health Physicist

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: FREDERICK URBAN
Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-18201-01 for SOUTHWESTERN HEALTH CENTER
030-14664 (licensee's name)
was inspected on 2/6/92. Radiopharmaceutical departure records were
inspected for the period 9/90 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

F. W. Urban 2/26/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Frederick Green
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-17215-01 for CLARION HOSPITAL (licensee's name)
was inspected on ~~7/5/92~~ 3/5/92. Radiopharmaceutical departure records were
inspected for the period 9/90 to 3/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Frederick Green 3/27/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 06-13001-02 for Rockville General Hospital (licensee's name)
was inspected on 3-13-92. Radiopharmaceutical departure records were
inspected for the period 3-27-89 to 3-13-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were ~~not~~ requested ^{but not} made.
(Applicable to both medical licensees and/or radiopharmacies.)
(copy of request attached)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- ___ The medical licensee did not make them in writing.
- ___ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- ___ Other reason (explain).

Penny Nessen, 3-13-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

To: Frank Ruddy, Pharmacy Manager
Megan McDonough, Pharmacy Representative
From: *JAMES A. DANIGELIS M.D.*

RE: Written Directive for Eluting Generators and Preparing
Radiopharmaceuticals

Dear Megan and Frank,

As we discussed on December 11, 1990, I request that Syncor International Corporation prepare and dispense Radiopharmaceuticals according to the attached Kit Preparation Guidelines, dated November 1989. I have initialed a copy of the Guidelines attached to indicate our review.

The attached guidelines satisfy the requirements of 10 CFR Part 35.200 that I provide a written directive with the nature and precise description of departures from the manufacturer's instructions in eluting generators and preparing diagnostic reagent kits.

In my judgement, these departures from manufacturer's instructions are justified for the following reasons:

- * Adjusting the activity used in reconstituting MAA is necessary for patient safety. Failure to make this compensation could result in administration of an improper number of particles to the patient, posing a significant risk to the patient in the event of pulmonary embolus.
- * Times of use for Sulfur Colloid, MDP, and MAA are extended to twelve hours to facilitate patient scheduling during the day, and to allow overnight use of doses for emergency cases. Time of use for TcO4 is extended to twenty four hours for the same reason.
- * Times of use for Sulfur Colloid, MDP, MAA, and TcO4 have been extended to allow for a practical delivery schedule from the pharmacy. Without the option of using the services of a radiopharmacy, this department would be forced to elute generators and prepare radiopharmaceuticals in-house. Because of the widespread shortage of qualified Nuclear Medicine Technologists, the time diverted to these activities would result in a reduction in the quality and quantity of patient care delivered in this department. Further, we believe that using a centralized radiopharmacy allows this institution to take advantage of the experience and expertise of a licensed radiopharmacist which we would not otherwise have.

This directive applies to all orders placed by this institution for these radiopharmaceuticals, unless you are specifically instructed otherwise at the time the order is placed, or until this directive is cancelled or replaced.

Sincerely yours,

James A. Danigelis M.D.

MALLINCKRODT MEDICAL, INC.
West Haven D.I.S.

RADIOPHARMACEUTICAL PREPARATION GUIDELINES						
Radio-pharmaceutical Name (^{99m} Tc -)	PACKAGE INSERT			MMI-DIS PHARMACY		
	max.act (mCi)	expiration (hr.)	mfg.	max.act. (mCi)	expira. (hr.)	stabilizers
Sulfur Colloid	500	6	MMI	500	12	---
MAA	60	8	MMI	100	10	---
MDP	200	6	MMI	300	9	3 mg ascorbic acid
DTPA	160	6	CIS	300	10	3 mg ascorbic acid
Glucaptate	300	6	MMI	300	8	---
PYP	100	6	MMI	125	7	---
HDP	200	8	MMI	265	9	---
MAG3	100	6	MMI	100	12	---
Na Pertechnatate	---	12	MMI	---	24	---
Cardiolite	150	6	Dupont	450	8	---
Sulfur Colloid	500	6	CIS	500	12	---

Note: All other radiopharmaceutical kits are prepared according to manufacturer package insert guidelines.

PHYSICIAN AUTHORIZATION

I hereby grant approval for Mallinckrodt pharmacists to exercise their professional judgement in the preparation of radiopharmaceutical kits consistent with the standards of practice of nuclear pharmacy as detailed under MMI-DIS pharmacy preparation guidelines on this page.

Hospital Name: Rockville General Hospital

Physician Signature: James M. [Signature] Date: 2/10/92

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 06-15203-01 for Wincham Community Mem. Hosp. (licensee's name)
was inspected on 3-12-92. Radiopharmaceutical departure records were
inspected for the period 3-28-89 to 3-13-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were ~~not~~ requested ^{but not} made. *Written directive*
(Applicable to both medical licensees and/or radiopharmacies.) *attached.*
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Penny Nessen 3-13-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-58 T-2



syncor[®]

April 19, 1991

Windham Hospital
112 Mansfield Avenue
Williamantic, CT 06226
Attn: Celeste Maynard, CNMT

Dear Celeste,

This letter is written in response to your hospital's inquiry concerning the time of use for radiopharmaceuticals.

As you are aware, it is up to the individual institution as to whether they wish to follow package insert guidelines or adhere to Syncor's guidelines regarding the expiration time. This choice gives the physician the flexibility needed for scheduling patients as well as for performing emergency procedures. The expiration time is not on prescriptions due to this variance.

On the conservative side, most of your radiopharmaceuticals have an expiration time of 11:00am for first run and 6:00pm for second run. Dr. Daly has signed a written directive requesting Syncor's guidelines on prepared doses as well as requesting a twenty four hour time of use for 99mTechnetium. Because of this, the majority of your doses have an extended time of use.

If you are concerned about a specific dose (ie one past calibration time) please feel free, as always, to call the pharmacy.

Sincerely,

Megan R. McDonough
Pharmacy Services Representative

Frank Ruddy
Pharmacy Manager

cc: Stuart Korchin, Health Physicist



Innovators in high-tech pharmacy services



Dear Syncor:

In accordance with the August 23, 1990 Interim Final Rule issued by the Nuclear Regulatory Commission concerning the compounding and use of radiopharmaceuticals, I hereby direct you to compound and dispense Tc99m Sulfur Colloid, MDP, MAA, and other Tc-99 radiopharmaceuticals in accordance with the Syncor prep guidelines. I recognize that the manufacturers' package inserts for these products specify a 6 hour time of use, but my experience in their use has demonstrated that they may in fact be safely and effectively used for up to 12 hours. The 12 hour time of use is needed so that the scheduling of the use of these products is neither inconvenient for this facility or to its patients.

This directive applies to all orders for the mentioned radiopharmaceuticals unless you are informed otherwise.

Sincerely,

Robert D. [unclear]
4/23/91

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Radiation Specialist, Region 1

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-12495-01 for Cover Hosp. of Lancaster (licensee's name)
was inspected on 3-11-92. Radiopharmaceutical departure records were
inspected for the period 2-89 to 3-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

William Davidson 3-14-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 06-16624-01 for Johnson Memorial Hospital (licensee's name)
was inspected on 3-11-92. Radiopharmaceutical departure records were
inspected for the period 3-23-89 to 3-11-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Penny Nessen 3-12-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM:

Radiation Specialist, Region 1

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-02335-02 for Carlisle Hosp. (licensee's name)
was inspected on 3-10-92. Radiopharmaceutical departure records were
inspected for the period 2-89 to 3-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- / 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- / 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to — another NRC licensee or — an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

William E. Davidson 3-14-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFII

FROM:

Radiation Specialist, Region 1

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-02763-01 for ST. JOSEPH HOSPITAL (licensee's name)
was inspected on 2-28-92. Radiopharmaceutical departure records were
inspected for the period 2-90 to 2-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Walter Davidson 3-2-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

ATTACHMENT A

MEMOPANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Radiation Specialist, Region +

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-15175-01 for Bayshore Comm Hosp (licensee's name)
was inspected on 2/25/92. Radiopharmaceutical departure records were
inspected for the period 1989 to present with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Mary Cahill
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-13391-01 for Anna Jaques Hospital (licensee's name)
was inspected on 2-25-92. Radiopharmaceutical departure records were
inspected for the period 1-27-89 to 2-25-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Penny Nessen, 2-26-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-51 T-07

ATTACHMENT A

MEMOPANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFK

FROM:

Radiation Specialist, Region I

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-16101-02 for DIVINE PROVIDENCE (licensee's name)
was inspected on 2-25-92. Radiopharmaceutical departure records were
inspected for the period 2-90 to 2-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to another NRC licensee or an Agreement State licensee to actually make the departure.
 - Other reason (explain).

Vicki E Davidson 3-4-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-28032-01 for Life Signs/Boston, Inc. (licensee's name)
was inspected on 2-24-92. Radiopharmaceutical departure records were
inspected for the period 2-12-88 to 2-24-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the ~~written~~ diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

 The medical licensee did not make them in writing.

 The medical licensee sent the written diagnostic directive
to _____
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

 Other reason (explain).

Penny Nessen 2-24-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-20615-01 for Spaulding Rehabilitation Hosp. (licensee's name)
was inspected on 2-13-92. Radiopharmaceutical departure records were
inspected for the period 3-10-89 to 2-13-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Penny Nessen, 2-21-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-48 T-27

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Thomas Thompson
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-05089-01 for [redacted] (licensee's name)
was inspected on 2/10/92. Radiopharmaceutical departure records were
inspected for the period 12/91 to 1/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Thomas K. Thompson
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-49 T-21

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

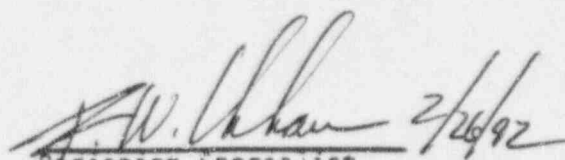
FROM: ~~Frederick L. Cohen~~
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-21489-01 for ERIE NUCLEAR RADIOLOGY CTR. (licensee's name)
was inspected on 2/4/92. Radiopharmaceutical departure records were
inspected for the period 9/90 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 19-00975-01 for Veterans Administration Med Ctr (licensee's name)
was inspected on 1-24-92. Radiopharmaceutical departure records were
inspected for the period 2-9-89 to 1-24-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Penny Nessen, 2-4-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-65 T-25

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 19-07187-01 for VA Medical Center (licensee's name)
was inspected on 1-23-92. Radiopharmaceutical departure records were
inspected for the period 2-10-89 to 1-23-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Penny Nessen, 2-3-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 DWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-12664-01 for Christ Hospital (licensee's name)
was inspected on 2/5 and 6/92. Radiopharmaceutical departure records were
inspected for the period 3/89 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Steven R. Courtemanche 2/12/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-43 T-25

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-12885-01 for St. Francis Hospital (licensee's name)
was inspected on 2/5/92. Radiopharmaceutical departure records were
inspected for the period 3/89 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Steven R. Courtemanche 2/10/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-10-T-4

Issue Date: XX/XX/XX

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-13556-01 for JORDAN HOSPITAL, INC. (licensee's name)
was inspected on 1/17/92. Radiopharmaceutical departure records were
inspected for the period 8/90 to 1/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Steven R. Courtemanche 1/21/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-4-102

ATTACHMENT A

MEMOPANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Mary Cahill
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-28419-01 for Wayne County, North Carolina (licensee's name) Center, P.C.
was inspected on 01/14/92. Radiopharmaceutical departure records were
inspected for the period 12/1/91 to 1/14/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Mary Cahill 1/21/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

A-1

D-40 T-02

Issue Date: XX/XX/XX

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 ODFW

FROM: Mary Cahill
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-28408-01 for Consultants in Cardiology, P.A. (Licensee's name)
was inspected on January 16, 1992 Radiopharmaceutical departure records were
inspected for the period 3/89 to 1/16/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to another NRC licensee or an Agreement State licensee to actually make the departure.
 - Other reason (explain).

Mary Cahill 2/3/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-00275-08 for BOSTON CITY HOSPITAL (licensee's name)
was inspected on 1/16/92. Radiopharmaceutical departure records were
inspected for the period 8/90 to 1/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Steven R. Courtemanche 1/21/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-33 T-23

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region L

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 06-00941-01 for NORWALK Hospital (licensee's name)
was inspected on 1-10-92. Radiopharmaceutical departure records were
inspected for the period present to 8-88 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Walter C. Davis
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-37 T-22

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN


FROM: Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 06-08020-02 for SHARON HOSPITAL (licensee's name)
was inspected on 1-8-92. Radiopharmaceutical departure records were
inspected for the period Present to 8-88 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-02575-C1 for Muhlenberg Hospital (licensee's name)
was inspected on January 7 and 9, 1992. Radiopharmaceutical departure records were
inspected for the period January, 1990 to January, 1992 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Mary Cahill January 13, 1992
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-16170-01 for LIVINGS-BARR? 65N HESD (licensee's name)
was inspected on 11-20-91. Radiopharmaceutical departure records were
inspected for the period 11-83 to 11-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Will Davidson 1-2-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWRN

FROM: William Davidson
Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-27899-01 for HAZLETON GEN. HOSP. (licensee's name)
was inspected on 11-19-91. Radiopharmaceutical departure records were
inspected for the period 11-91 to 11-88 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- NA 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

William E Davidson 11-25-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-3: T-V



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

30 License No. 08-16752-01 for Hadley Memorial Hospital was inspected on December 9, 1991. Radiopharmaceutical departure records were inspected for the period October 26, 1988 to December 9, 1991 with the following results:

Diagnostic departures were not requested or made.

31 License No. 08-19896-01 for Paul H. Pevsner, M.D. was inspected on December 10, 1991. Radiopharmaceutical departure records were inspected for the period August 29, 1991 to December 10, 1991 with the following results:

Diagnostic departures were not requested or made.

32 License No. 08-20991-01 for Medical Diagnostics and Therapeutics, P.C. was inspected on December 10, 1991. Radiopharmaceutical departure records were inspected for the period June 27, 1991 to December 10, 1991 with the following results:

33 Diagnostic departures were not requested or made.

34 Therapeutic departures were not made.

Keith D. Brown, Ph.D.
Health Physicist

Concept by: D-33 T-33
D-33 T-33
D-33 T-33

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 ODFW

FROM: FREDERICK URBAN
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-02039-01 for BEVERLY HOSP. (licensee's name)
was inspected on 12/5 AND 6/91. Radiopharmaceutical departure records were
inspected for the period 10/88 to 12/91 with the following results:

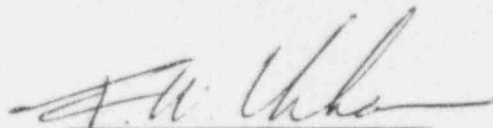
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date) 12/12/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *Keith D. Brown, Ph.D.*
~~Radiation Specialist~~, Region I
Health Physicist

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-20820-01 for Springfield Diagnostek (licensee's name)
was inspected on November 7, 1991. Radiopharmaceutical departure records were
inspected for the period March 1991 to November 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Keith D. Brown
~~Radiation Specialist~~ *Health Physicist*
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-02847-01 for Mendocino Medical Center (licensee's name)
was inspected on 10/24/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- X 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- _____ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- _____ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- _____ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

_____ The medical licensee did not make them in writing.

_____ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

_____ Other reason (explain).

Steven R. Courtemanche 10/30/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-10599-01 for C. I. City Area Health Center (licensee's name)
was inspected on 10/23/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Steven R. Courtemanche 10/30/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-12893-01 for Clearfield Hospital (licensee's name)
was inspected on 10/26/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Steven R. Courtemanche 10/31/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 DWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-2846 C1 for Cardiac Fitness Center (FECIE, Inc.) (licensee's name)
was inspected on 10/21/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Steven R. Courtemanche
Radiation Specialist
(Signature and Date)

10/30/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-28453-01 for Nuclear Imaging Systems, Inc. (licensee's name)
was inspected on 10-18-91. Radiopharmaceutical departure records were
inspected for the period 3-8-91 to 10-18-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Penny Nessen, 10-28-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-09806-03 for Community Medical Center was inspected on September 18, 1991. Radiopharmaceutical departure records were inspected for the period September 22, 1988 to September 18, 1991 with the following results:

Diagnostic departures were not requested or made.

Therapeutic departures were not made.

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-20690-01 for The Medical Center of Ocean County, Incorporated was inspected on September 17, 1991. Radiopharmaceutical departure records were inspected for the period June 29, 1988 to September 17, 1991 with the following results:

Diagnostic departures were not requested or made.

Therapeutic departures were not made.

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-11642-01 for Shore Memorial Hospital, was inspected on September 16, 1991. Radiopharmaceutical departure records were inspected for the period July 1, 1988 to September 16, 1991 with the following results:

Diagnostic departures were not requested or made.

Therapeutic departures were not made.

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 06-21317-01 for Medical Imaging Center, PC (licensee's name)
was inspected on 10-10-91. Radiopharmaceutical departure records were
inspected for the period 4-14-87 to 10-10-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- NA 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- _____ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- _____ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- _____ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- _____ The medical licensee did not make them in writing.
- _____ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- _____ Other reason (explain).

Penny Nessen, 10-16-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-20621-01 for Veterans Administration Med Ctr. (licensee's name)
was inspected on 10-9-91. Radiopharmaceutical departure records were
inspected for the period 8-31-88 to 10-9-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- _____ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- _____ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- _____ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- _____ The medical licensee did not make them in writing.
- _____ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- _____ Other reason (explain).

Penny Nessen, 10-9-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-14868-01 for Harrington Memorial Hospital (licensee's name)
was inspected on 10-9-91. Radiopharmaceutical departure records were
inspected for the period 9-22-88 to 10-9-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- ___ The medical licensee did not make them in writing.
- ___ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- ___ Other reason (explain).

Penny Nessen, 10-16-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-15280-01 for Wing Memorial Hospital Corp. (licensee's name)
was inspected on 10-8-91. Radiopharmaceutical departure records were
inspected for the period 9-1-88 to 10-8-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- NA 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- _____ 3. Departures were made. All of the written diagnostic directives
&/or records of therapeutic departures are attached.
- _____ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- _____ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- _____ The medical licensee did not make them in writing.
- _____ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- _____ Other reason (explain).

Penny Nessen, 10-16-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-15480-01 for Good Samaritan Regional Medical Center was inspected on September 5, 1991. Radiopharmaceutical departure records were inspected for the period February 25, 1988 to September 5, 1991 with the following results:

1. Diagnostic departures were not requested or made.
2. Therapeutic departures were not made.

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-14987-01 for Memorial Hospital was inspected on September 4, 1991. Radiopharmaceutical departure records were inspected for the period October 6, 1988 to September 4, 1991 with the following results:

Diagnostic departures were not requested or made.

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-02452-01 for The Medical Center of Central (licensee's name)
Massachusetts - Memorial
was inspected on 9-25-91. Radiopharmaceutical departure records were
inspected for the period 11-23-88 to 9-25-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Penny Nessen, 9-25-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-4-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-12869-01 for Saint Vincent Hospital, Inc. (licensee's name)
was inspected on 9-24-91. Radiopharmaceutical departure records were
inspected for the period 6-27-90 to 9-24-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Penny Nessen 9-24-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-13486-01 for Waltham Weston Hosp. + Med. Center (licensee's name)
was inspected on 9-23-91. Radiopharmaceutical departure records were
inspected for the period 3-10-89 to 9-23-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- NA 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- ___ The medical licensee did not make them in writing.
- ___ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- ___ Other reason (explain).

Penny Nessen, 9-23-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-28388-01 for Miner's Hospital of Northern Colorado (licensee's name)
was inspected on 9-19-91. Radiopharmaceutical departure records were
inspected for the period 11-7-90 to 9-19-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 The medical licensee did not make them in writing.
 The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 Other reason (explain).

Penny Nessen, 9-19-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-01873-01 for Conemaugh Valley Mem. Hospital (licensee's name)
was inspected on 9-18-91. Radiopharmaceutical departure records were
inspected for the period 8-10-88 to 9-18-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Penny Nessen 9-18-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-17074-C1 for Chilton Memorial Hospital (licensee's name)
was inspected on 9/20/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 9/20/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Steven R. Courtemanche 9/26/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-13740-01 for Dover General Hospital & Medical Center (licensee's name)
was inspected on 9/19/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 9/19/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Steven R. Courtemanche 9/26/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 27-0303E-01 for The Hospital Corp of Orange (licensee's name)
was inspected on 9/16/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 9/16/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Steven R. Courtemanche 9/26/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Steven R. Courtemanche
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 29-01663-03 for Jersey City Medical Center (licensee's name)
was inspected on 9/16-17/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 4/7/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Steven R. Courtemanche 9/26/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-10784-02 for Atlanticare Medical Center (licensee's name)
was inspected on 9-6-91. Radiopharmaceutical departure records were
inspected for the period 7-90 to 9-6-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
Program Active from 7-90 to 9-6-91.
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Penny Nessen 9-12-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Fenny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-00083-02 for Salem Hospital (licensee's name)
was inspected on 9-5-91. Radiopharmaceutical departure records were
inspected for the period 8-30-88 to 9-5-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Fenny Nessen 9-11-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Penny Nessen
Radiation Specialist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-15614-01 for Milton Medical Center (licensee's name)
was inspected on 9-3-91. Radiopharmaceutical departure records were
inspected for the period 7-7-88 to 9-3-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Penny Nessen 9-11-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Keith D. Brown, Ph.D.
Health Physicist, Region I

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 37-16602-01 for Soldiers and Sailors Memorial Hospital, was inspected on September 4, 1991. Radiopharmaceutical departure records were inspected for the period October 13, 1988 to September 4, 1991 with the following results:

Diagnostic departures were not requested or made.

NO DEPARTUULL

KETCHIKAN General Hospital	D-1 T-1
Silas Hays Army Community Hospital	D-2 T-1
Pali Momi Medical Center	D-3 T-2
Kuakini Medical Center	D-4 T-3
G. N. Wilcox Hospital	D-5 T-4

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Radiation Specialist, Region

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 53-15737-01 for G.N. Wilcox Hospital (licensee's name) was inspected on 1/14/92. Radiopharmaceutical departure records were inspected for the period _____ to _____ with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Donna-Beth Howe 1/14/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: 5/5/89
- b. Current inspection date: 1/10/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee () Y () N

(1) Written directive on file [35.200(c)(1)] () Y () N

(2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure () Y () N
- (b) Description of the departure () Y () N
- (c) Reasons why departure was needed () Y () N

(3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

- c. Departures were made by a different licensee () Y () N

(1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: () Y () N
- (1) Written directive on file [35.200(c)(1)] () Y () N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] () Y () N
- (3) Written directive includes notation of emergency [35.200(c)(1)] () Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures () Y () N
- If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] () Y () N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure () Y () N
- (2) Reasons why departure was needed () Y () N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] () Y () N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] () Y () N

Remarks:

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Radiation Specialist, Region V

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 53-17797-01 for Kuakini Med. Ctr. (licensee's name) was inspected on JAN E-9, 1992. Radiopharmaceutical departure records were inspected for the period _____ to _____ with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Donna-Beth Howe 1/14/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: February 6 and 10, 1990
b. Current inspection date: Jan 8-9, 1992

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee () Y () N

- (1) Written directive on file [35.200(c)(1)] () Y () N

- (2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure () Y () N
(b) Description of the departure () Y () N
(c) Reasons why departure was needed () Y () N

- (3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

- c. Departures were made by a different licensee () Y () N

- (1) Name & location of other facility _____

d. Licensee made emergency diagnostic departures:

() Y () N

(1) Written directive on file [35.200(c)(1)]

() Y () N

(2) Written directive made within three working days after emergency [35.200(c)(1)]

() Y () N

(3) Written directive includes notation of emergency [35.200(c)(1)]

() Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

a. Licensee had therapeutic departures

() Y () N

If "Yes," answer the following:

b. Record of therapeutic departure on file [35.300(b)(1)]

() Y () N

c. Record of therapeutic departure includes [35.300(b)(1)]:

(1) Nature of the departure

() Y () N

(2) Reasons why departure was needed

() Y () N

d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)]

() Y () N

e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)]

() Y () N

Remarks:

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region V

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 53-23297-c1 for Pali Momi Med (Tr.) (licensee's name) was inspected on January 6-7, 1992 Radiopharmaceutical departure records were inspected for the period _____ to _____ with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Donna-Beth Howe 1/14/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

a. Last inspection date: 2/8/90

b. Current inspection date: 1/6-7/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

b. Departures were made by the licensee () Y () N

(1) Written directive on file [35.200(c)(1)] () Y () N

(2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure () Y () N

(b) Description of the departure () Y () N

(c) Reasons why departure was needed () Y () N

(3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

c. Departures were made by a different licensee () Y () N

(1) Name & location of other facility _____

- d. Licensee made emer_gency diagnostic departures: () Y () N
- (1) Written directive on file [35.200(c)(1)] () Y () N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] () Y () N
- (3) Written directive includes notation of emergency [35.200(c)(1)] () Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures () Y () N
- If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] () Y () N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure () Y () N
- (2) Reasons why departure was needed () Y () N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] () Y () N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] () Y () N

Remarks:

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region V

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 04-12727-02 for Department of Army
Silas Hays Army Community Hospital
Ft Ord, California (licensee's name)
was inspected on November 7-8, 1991 Radiopharmaceutical departure records were
inspected for the period 7/89 to 11/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Donna-Beth Howe 11/22/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: July 26-27, 1989
b. Current inspection date: November 14-15, 1991

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee () Y () N

- (1) Written directive on file [35.200(c)(1)] () Y () N

- (2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure *N/A* () Y () N
(b) Description of the departure () Y () N
(c) Reasons why departure was needed () Y () N

- (3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

- c. Departures were made by a different licensee () Y () N

- (1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: () Y () N
- (1) Written directive on file [35.200(c)(1)] () Y () N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] *N/A* () Y () N
- (3) Written directive includes notation of emergency [35.200(c)(1)] () Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures () Y () N
- If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] *N/A* () Y () N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure () Y () N
- (2) Reasons why departure was needed () Y () N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] () Y () N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] () Y () N

Remarks:

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 5

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 50-19913-01 for Ketchikan GENERAL LICENSE (licensee's name)
was inspected on 10/10/91. Radiopharmaceutical departure records were
inspected for the period 9/98 to 10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

James J. Montgomery 10/18/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: 8/17-18/88
- b. Current inspection date: 10/10/91

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures Y N

If "Yes," answer the following:

- b. Departures were made by the licensee Y N

(1) Written directive on file [35.200(c)(1)] Y N

(2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure Y N
- (b) Description of the departure Y N
- (c) Reasons why departure was needed Y N

(3) Records of number of departure administrations are on file [35.200(c)(2)] Y N

- c. Departures were made by a different licensee Y N

(1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: Y N
- (1) Written directive on file [35.200(c)(1)] Y N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] Y N
- (3) Written directive includes notation of emergency [35.200(c)(1)] Y N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departure: Y N
If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] Y N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure Y N
- (2) Reasons why departure was needed Y N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] Y N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] Y N

Remarks:

No. Department

Days

VA Med Center, Lasernorth

D-2 T-3

VA Med Center, Tampa

D-32 T-24

VA Med Center, Denver

D-24 T-24

Dept. of Army

D-35 T-24

T-24 all long

NO DEPARTURES

Valley View Regional Hosp	D-1 T-1
McAlester Regional Health Ctr	D-2 T-2
Fulda Health Center Inc	D-3 T-3
Tahlequah City Hosp	D-4 T-4
McMurry Reg. Med. Ctr of N. Okla. Inc.	D-5 T-5
Wagon Wheel Hosp	D-6 T-5
Wichita Falls Hosp	D-7 T-6
Wichita Falls Hosp	D-8 T-7
Wichita Falls County Hospital	D-9 T-7
Wichita Falls County General Hospital	D-10 T-8
Wichita Falls General Hospital	D-11 T-8
Wichita Falls Hosp	D-12 T-9
Wichita Falls Hosp	D-13 T-10
Wichita Falls Hosp	D-14 T-10
Wichita Falls Hosp	D-15 T-10
Wichita Falls Hosp	D-16 T-10
Wichita Falls Hosp	D-17 T-10
Wichita Falls Hosp	D-18 T-10
Wichita Falls Hosp	D-19 T-10
Wichita Falls Hosp	D-20 T-10
Wichita Falls Hosp	D-21 T-10
Wichita Falls Hosp	D-22 T-10
Wichita Falls Hosp	D-23 T-10
Wichita Falls Hosp	D-24 T-10
Wichita Falls Hosp	D-25 T-10
Wichita Falls Hosp	D-26 T-10
Wichita Falls Hosp	D-27 T-10
Wichita Falls Hosp	D-28 T-10
Wichita Falls Hosp	D-29 T-10
Wichita Falls Hosp	D-30 T-10
Wichita Falls Hosp	D-31 T-10

Depart.

(Bracketed)

Oklahoma Home Service Center	D-1 T-?	()
Sydney, Tulsa	D-2 T-0	(466)
Beane Army Med. Ctr.	D-3 T-0	()
V.A. Medical Center, Albuquerque	D-4 T-5	()

Should also record 0: 11. Therap. Dep. note

effect. 10 T-3

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: ROBERT A. BROWN
SR. Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 05-00046-13 for Dept. of the Army (licensee's name)
was inspected on 12/18/91. Radiopharmaceutical departure records were
inspected for the period 8/90 to 12/19/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Robert A. Brown
Radiation Specialist (Signature and Date)

Attachment: As stated

12/27/91

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: ROBERT A. BROWN
SR Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. OS-01401-02 for Veterin. Admin. Dep. 110 (licensee's name) was inspected on 12/17/91. Radiopharmaceutical departure records were inspected for the period 8/24/90 to 12/17/91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

 12/27/91
Radiation Specialist (Signature and Date)

Attachment: As stated

D-20 T-04

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *[Handwritten Name]*
Radiation Specialist, Region 10

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 15-0000000000 for T. J. [Handwritten Name] (licensee's name) was inspected on 12-15-73. Radiopharmaceutical departure records were inspected for the period 12-15-73 to 12-15-73 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to [Handwritten Name] (another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain).

[Handwritten Signature]
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *[Handwritten Signature]*
Radiation Specialist, Region 11

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 15-127151 for *[Handwritten Name]* (licensee's name)
was inspected on *[Handwritten Date]*. Radiopharmaceutical departure records were
inspected for the period *[Handwritten Dates]* to *[Handwritten Date]* with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to *[Handwritten Name]* (another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain).

[Handwritten Signature]
Radiation Specialist (Signature and Date)

Attachment: As stated

[Handwritten] D-32 T-20

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Robert Brown
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 42-10737-05 for VA Temple (licensee's name)
was inspected on 3-24-92. Radiopharmaceutical departure records were
inspected for the period 1-26-92 to 3-24-92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
() another NRC licensee or () an Agreement State licensee
to actually make the departure.

Other reason (explain).

Robert L. Brown 3/31/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Robert L. Brown
Radiation Specialist, Region Ib

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 42-19113-01 for Dept. of the Army (licensee's name)
was inspected on 11/24/90 Radiopharmaceutical departure records were
inspected for the period 11/24/90 to 3/23/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
() another NRC licensee or () an Agreement State licensee
to actually make the departure.

Other reason (explain).

Robert L. Brown 3/31/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Robert L. Bue
Si Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 35-17654-01 for Clement Reg. Hosp. (licensee's name)
was inspected on 7/16/92. Radiopharmaceutical departure records were
inspected for the period 1/92 to 7/16/92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Robert L. Bue 3/7/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: R. B. T. A. B. e.
S. Radiation Specialist, Region iv

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 55-21269-01 for Woodland Hospital (licensee's name)
was inspected on 3/18/92. Radiopharmaceutical departure records were
inspected for the period 1/25/92 to 3/10/92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

 The medical licensee did not make them in writing.

 The medical licensee sent the written diagnostic directive to another NRC licensee or an Agreement State licensee) to actually make the departure.

 Other reason (explain).

Robert L. Brown 3/17/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Robert Brown
Sr. Radiation Specialist, Region TU

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 17-01322-07 for VAAC-New Orleans (licensee's name) was inspected on 2/20/92. Radiopharmaceutical departure records were inspected for the period 11/2/90 to 2/20/92 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State Licensee) to actually make the departure.

Other reason (explain).

Robert Brown 2/24/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Robert Brown
Sr. Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 17-09273-01 for VA-Alexandria, LA (licensee's name)
was inspected on 2/18+2/15/92 Radiopharmaceutical departure records were
inspected for the period 2/14/92 to 2/18/92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Robert A. Brown 2/24/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: R. A. Leonard
Radiation Specialist, Region LV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 35-18025-01 for Cardiovascular Professional Corp. (licensee's name)
was inspected on 2-7-92. ~~Radiopharmaceutical~~ Departure records were
inspected for the period 3/88 to 1/92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain).

R. A. Leonard . 2-13-92
Radiation Specialist (Signature and Date)

Attachment: As stated

D-23 T-17

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *R. O. Leonard*
Radiation Specialist, Region 14

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 35-14145-02 for Norman Regional Hospital (licensee's name) was inspected on 2-6-92. Radiopharmaceutical departure records were inspected for the period 1990 to 1991 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

R. O. Leonard 2/6/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Mark R. Shaffer
Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 15-08114-01 for VA Leavenworth, KS (licensee's name) was inspected on 12/10/91. Radiopharmaceutical departure records were inspected for the period 3/90 to 12/91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
- Other reason (explain).

Mark R. Shaffer 11/13/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Robert A. Bean
Sr. Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 26-00138-10 for VAMC (licensee's name) was inspected on 11/19/92. Radiopharmaceutical departure records were inspected for the period 8/90 to 1/7/92 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
- Other reason (explain).

Robert A. Bean
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *Mark R. Shaffer*
Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

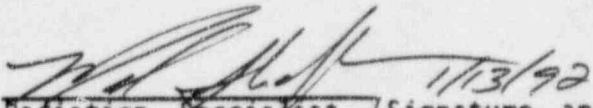
License No. 15-10940 for J.A. Topoka, KS (licensee's name)
was inspected on 12/11/91. Radiopharmaceutical departure records were
inspected for the period 3/90 to 12/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable
to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to
radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *Robert A. Bean*
Sr. Radiation Specialist, Region *14*

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. *25-17823-01* for *Marcus Daly Mem. Hospital* (licensee's name)
was inspected on *11/21/91*. Radiopharmaceutical departure records were
inspected for the period *1/90* to *11/21/91* with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
- Other reason (explain).

Robert A. Bean 11/25/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFN

FROM: Mark R. Shaffer
 Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 410-2619-1 for [redacted] (licensee's name) was inspected on [redacted]. Radiopharmaceutical departure records were inspected for the period [redacted] to [redacted] with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- X 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to [redacted] (another NRC licensee or an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Mark R. Shaffer 12/3/91
 Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *[Handwritten Signature]*
Radiation Specialist, Region 1A

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24162 for [Handwritten Name] (licensee's name)
was inspected on [Handwritten Date]. Radiopharmaceutical departure records were
inspected for the period [Handwritten Period] to [Handwritten Date] with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to [Handwritten Name] (another NRC licensee or an Agreement State licensee) to actually make the departure.
- Other reason (explain).

[Handwritten Signature] 12/3/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *Ronald H. ...*
SR Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 2502502-01 for H. G. ... Hospital (licensee's name)
was inspected on Radiopharmaceutical departure records were
inspected for the period ... to 1981 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to ... (another NRC licensee or an Agreement State licensee) to actually make the departure.

Other reason (explain).

Ronald H. ...
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Mark R. Shaffer
Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

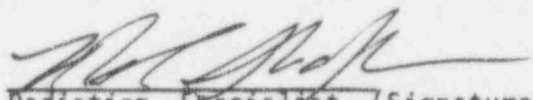
License No. 35-14046-02 for St. Joseph Regional Medical Center of North Oklahoma, Inc. (licensee's name) was inspected on 10-23-91. Radiopharmaceutical departure records were inspected for the period 9/89 to 10/91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records of number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

 10-23-91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *Mark R. Shaffer*
Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 35-15626-01 for Tahlequah City Hospital (licensee's name)
was inspected on 10-22-91. Radiopharmaceutical departure records were
inspected for the period 1/90 to 10/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable
to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to
radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Mark R. Shaffer 10-22-91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region _____

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 55 14042-01 for Valley View Regional Hospital (licensee's name)
was inspected on Oct 16-17, 1971. Radiopharmaceutical departure records were
inspected for the period 1969 to 1971 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- _____ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- _____ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- _____ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

_____ The medical licensee did not make them in writing.

_____ The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

_____ Other reason (explain).

Donna Kasper 3-NOV-71
Radiation Specialist (Signature and Date)

Attachment: As stated

No Departures

Diagnostic Photo Corp.	D-1	T-1
Warfolk Community Hospital	D-2	T-2
Central Norfolk General Hospital	D-3	T-3
Norfolk General Hospital	D-4	T-4
Maryview Hospital	D-5	T-5
Virginia Heart Institute	D-6	T-6
V.A. Medical Center, ...	D-7	T-7
Selpepper Memorial Hospital	D-8	T-8
V.A. (Dept. of Vet. Affairs), Lake City	D-9	T-9
V.A. Medical Center, Gainesville	D-10	T-10
V.A. - James A. Haley	D-11	T-11
St. Luke's Episcopal Hospital	D-12	T-12
Twins County Community Hospital	D-13	T-13
Palast. Community Hospital	D-14	T-13
V.A. Baptist Hospital	D-15	T-14
V.A. Medical Center, Murfreesboro	D-16	T-15
Army, Ft. Jackson	D-17	T-16
V.A. Hospital, Columbia	D-18	T-17
Dr. Jose T. Medina	D-19	T-18

T-19
* V.A. Commonwealth (Trans. not made)

Made Departures

V.A. Medical Center - ...	D-1	T-0	1/2
Williamsburg Community Hospital	D-2	T-0	1/2
Chippendale Hospital	D-3	T-0	1/2
* Virg. Commonwealth Univ.	D-4	T-0	
* noted as Dep. Trans. - fact as Ther. dep. not made.			

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D,
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 DWFN

FROM:

Hector Bermudez

Radiation Specialist, Region II

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 52-14931 for Dr. Jose T. Medina (licensee's name) was inspected on 2/4/92. Radiopharmaceutical departure records were inspected for the period 2/88 to 2/92 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made, (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made, (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Hector Bermudez 2/15/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Hector Bermudez

Radiation Specialist, Region II

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 39-09703-01 for V.A. Hospital/Columbia^{SC.} (licensee's name) was inspected on 1/29-30/92. Radiopharmaceutical departure records were inspected for the period 6/90 to 1/92 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- ~~1.~~ Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- ~~2.~~ Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

___ The medical licensee did not make them in writing.

___ The medical licensee sent the written diagnostic directive to
(___ another NRC licensee or ___ an Agreement State licensee)
to actually make the departure.

___ Other reason (explain).

Hector Bermudez 2/7/92
Radiation Specialist (Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Hector Bermudez
Radiation Specialist, Region II

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 39-14873-01 for Army, Ft. Jackson, S.C. (licensee's name) was inspected on 1/27/92. Radiopharmaceutical departure records were inspected for the period 6/90 to 1/92 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Hector Bermudez 2/7/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFM

FROM: Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 41-16374-01 for V.A. Medical Center (licensee's name)
was inspected on 1/22/92. Radiopharmaceutical departure records were
inspected for the period 2/22/90 to 1/22/92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Carl Conall 1/22/92
Radiation Specialist (Signature and Date)

Attachment: As stated

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: 2/22/90
- b. Current inspection date: 1/22/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee () Y () N

- (1) Written directive on file [35.200(c)(1)] () Y () N

- (2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure () Y () N
- (b) Description of the departure () Y () N
- (c) Reasons why departure was needed () Y () N

- (3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

- c. Departures were made by a different licensee () Y () N

- (1) Name & location of other facility _____

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Michael L. Fuller
Radiation Specialist, Region II

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-10542-01 for VA Baptist Hospital (licensee's name)
was inspected on 1-15-92. Radiopharmaceutical departure records were
inspected for the period 9-13-89 to 1-15-92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

 1-22-92
Radiation Specialist (Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Michael L. Fuller
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

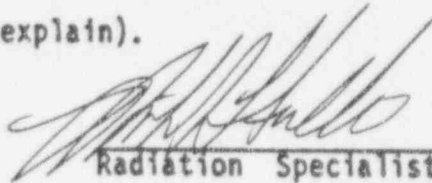
License No. 45-21206-01 for Pulaski Community Hospital (licensee's name) was inspected on 12-2-91. Radiopharmaceutical departure records were inspected for the period 3-70 to 12-91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- ~~X~~ 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- ~~NA~~ 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

___ The medical licensee did not make them in writing.

___ The medical licensee sent the written diagnostic directive to ___ (___ another NRC licensee or ___ an Agreement State licensee) to actually make the departure.

___ Other reason (explain).

 12-12-91
Radiation Specialist (Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Michael L. Fuller
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-18398-01 for Trish County Community Hosp (licensee's name) was inspected on 12-11-91. Radiopharmaceutical departure records were inspected for the period 8/89 to 11/91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Michael L. Fuller 12-11-91
Radiation Specialist (Signature and Date)

Attachment: As stated

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES1. GENERALa. Last inspection date: 8-17-89b. Current inspection date: 12-11-91

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURESa. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

b. Departures were made by the licensee () Y () N

(1) Written directive on file [35.200(c)(1)] () Y () N

(2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure { } Y { } N

(b) Description of the departure { } Y { } N

(c) Reasons why departure was needed { } Y { } N

(3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

c. Departures were made by a different licensee () Y () N(1) Name & location of other facility _____

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

a. Last inspection date: 1/17/91

b. Current inspection date: 12/4/91

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

b. Departures were made by the licensee () Y () N

(1) Written directive on file [35.200(c)(1)] () Y () N

(2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure () Y () N

(b) Description of the departure () Y () N

(c) Reasons why departure was needed () Y () N

(3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

c. Departures were made by a different licensee () Y () N

(1) Name & location of other facility _____

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: _____
- b. Current inspection date: 12/3/91 (initial)

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures () Y () N

If "Yes," answer the following:

- b. Departures were made by the licensee () Y () N

- (1) Written directive on file [35.200(c)(1)] () Y () N

- (2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure () Y () N

(b) Description of the departure () Y () N

(c) Reasons why departure was needed () Y () N

- (3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

- c. Departures were made by a different licensee () Y () N

- (1) Name & location of other facility _____

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: WADE T. LDO
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-23040-01 for CULPEPPER MEMORIAL HOSPITAL (licensee's name)
was inspected on 11/5/91. Radiopharmaceutical departure records were
inspected for the period 4/90 to 11/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made. (Applicable
to both medical licensees and/or radiopharmacies.)
- X 2. Therapeutic departures were not made. (Not applicable to
radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

___ The medical licensee did not make them in writing.

___ The medical licensee sent the written diagnostic directive
to _____
(___ another NRC licensee or ___ an Agreement State licensee)
to actually make the departure.

___ Other reason (explain).

Wade T. LDO 1/3/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: WADE T. Loo
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-16909-01 for CHESAPEAKE GENERAL HOSPITAL (licensee's name)
was inspected on 12/5/91. Radiopharmaceutical departure records were
inspected for the period 2/90 to 12/91 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Wade T. Loo 12/11/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: WADE T. LOO
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-00131-02 for SENTARA NORFOLK GENERAL HOSPITALS (licensee's name) was inspected on 12/3-12/4/91. Radiopharmaceutical departure records were inspected for the period 12/88 to 12/91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
- Other reason (explain).

Wade T. Loo 12/11/91
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: WADE T. LOO
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-12760-01 for NORFOLK COMMUNITY HOSPITAL (licensee's name) was inspected on 12/2-12/3/91. Radiopharmaceutical departure records were inspected for the period 2/28/90 to 12/2/91 with the following results: [NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- X 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

___ The medical licensee did not make them in writing.

___ The medical licensee sent the written diagnostic directive to _____ (___ another NRC licensee or ___ an Agreement State licensee) to actually make the departure.

___ Other reason (explain).

Wade T. Loo 12/11/91
Radiation Specialist (Signature and Date)

Attachment: As stated

REGION III RUNNING TOTAL

NO DEPARTURES		MADE DEPARTURES	
Va Medical Center Des Moines	D-1 T-0	Washington Univ	D-1 T-0
St. Blaise Mem. Hosp. Ia	D-2 T-0	FLOYD MEM HOSP	D-2 T-0
US ARMS FT LEONARD WOOD	D-3 T-1	SYNCOB CORP	D-3 T-0
OAKWOOD UNITED HOSP	D-4 T-2	MERCY HOSP	D-4 T-0
OAKWOOD HOSPITAL	D-5 T-3	CONSULTING RADIOL. CORP	D-5 T-0
ROBERT S. STOMEL DO	D-6 T-4		
ST JOSEPH'S HOSPITAL	D-7 T-4		
MEMORIAL HOSPITAL & HEALTH CENTER	D-8 T-4		
NORTH CLARK COMM HOSP	D-9 T-0	V.A. Medical Center, Sioux Falls	D-9 T-0
CHILDREN'S HOSP OF MI.	D-10 T-5	Luther Medical Center	D-10 T-0
MELING GENERAL HOSP	D-11 T-6	Medical Consultants, Irving Co.	D-11 T-0
BUMERWORTH HOSPITAL	D-12 T-6	St. John's Hospital	D-12 T-0 (361)
WATSON'S HOSPITAL	D-13 T-7	St. Francis Hospital	D-13 T-0
MARFETTE MEM HOSP	D-14 T-8	St. Lawrence Hospital	D-14 T-0 (30)
THEODORE CLARK REG HOSP	D-15 T-9	Ridgely Hts. General Hosp.	D-15 T-0 ?
NORTH MEM MED. CENTR	D-16 T-9		
JINDRA MEM HOSP	D-17 T-10		
DEALONSS HOSP	D-18 T-10		
ST FRANCIS REG MED CSR	D-19 T-11		
ANDERSEN CLINIC	D-20 T-12		
ACRED HEART HOSPITAL	D-21 T-13		
ORAIN COMMUNITY HOSP	D-22 T-14		
ROBERT HOSP	D-23 T-15		
MARSS HOSPITAL	D-24 T-16		
ANDERSON MEM HOSP	D-25 T-16		
W. MED CTR - IOWA CITY IOWA	D-26 T-17		

11/2 Departures

Departures

01/21/86 - Sacramento Med. Center D-112 T-80
Veterans Admin. Med. Center, Sacramento D-113 T-80
Hosp. 11 U- T-80
11/21/86 J- T-80

Dispositions

Departments

Deaconess Hospital (Addition)	D-86	T-60
Baptist Medical Center	D-87	T-62
Madison Memorial Hospital	D-88	T-64
Sisters Memorial Hospital	D-89	T-65
St. Francis Medical Center	D-90	T-66
Providence Hospital	D-91	T-67
Missouri Delta Medical Center	D-92	T-68
Central General Hosp.	D-93	T-69
Deaconess Hospital	D-94	T-70
Washington Health Center	D-95	T-71
St. Joseph's Medical Ctr.	D-96	T-72
Carroll Hospital	D-97	T-73
Sanitar Hospital	D-98	T-74
Graves Community Hosp.	D-99	T-75
Mary Hospital	D-100	T-76
St. Vincent Hosp.	D-101	T-77
Central General Hospital	D-102	T-78
St. Alexis Hospital	D-103	T-79
St. Joseph's Hospital	D-104	T-80
St. Joseph's Hospital	D-105	T-81
Tulipac Memorial Hospital	D-106	T-82
Pharos Medical Group	D-107	T-83
Saline Community Hosp.	D-108	T-84
St. Mary's Med. Ctr.	D-109	T-85
Lansing General Hospital	D-110	T-86
Providence Regional Hospital	D-111	T-87

Day

St. Louis Medical Center	D-60	T-40
St. Louis Children's Hospital	D-61	T-41
St. Louis University Hospital	D-62	T-42
St. Louis University Hospital	D-63	T-43
St. Louis University Hospital	D-64	T-44
St. Louis University Hospital	D-65	T-45
St. Louis University Hospital	D-66	T-46
St. Louis University Hospital	D-67	T-47
St. Louis University Hospital	D-68	T-48
Garden City Hospital	D-69	T-50
University Hospital of Iowa Co.	D-70	T-50
St. Louis University Hospital	D-71	T-51
St. Louis University Hospital	D-72	T-52
St. Louis University Hospital	D-73	T-53
St. Louis University Children's Hospital	D-74	T-53
St. Louis University Hospital	D-75	T-54
St. Louis University Hospital	D-76	T-54
St. Louis University Hospital	D-77	T-55
St. Louis University Hospital	D-78	T-56
St. Louis University Hospital	D-79	T-57
St. Louis University Hospital	D-80	T-57
St. Louis University Hospital	D-81	T-57
St. Louis University Hospital	D-82	T-58
St. Louis University Hospital	D-83	T-58
St. Louis University Hospital	D-84	T-58
St. Louis University Hospital	D-85	T-58

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM:

S. J. MURPHY
Radiation Specialist, Region 3

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-18585-01 for FAY MEDICAL CTR (licensee's name)
was inspected on 3/25/92. Radiopharmaceutical departure records were
inspected for the period — to — with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to —
(— another NRC licensee or — an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 31-26314-01 for Amherst Hosp (licensee's name)
was inspected on 3/24/92. Radiopharmaceutical departure records were
inspected for the period program inception to 3/24/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain): _____

W. Slawant 3/30/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: ROBERT A. BROWN
SR. Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 25-15463-01 for Kalispell Regional Hospital (licensee's name)
was inspected on 4-6-92. Radiopharmaceutical departure records were
inspected for the period 4-12-90 to 4-6-92 with the following results:
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made. (Applicable
to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made. (Not applicable to
radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

Robert A. Brown 4/13/92
Radiation Specialist (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Jim Lynch
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-04073-01 for Lansing Genl Hospital (licensee's name)
was inspected on 3/26/92. Radiopharmaceutical departure records were
inspected for the period 12/89 to 3/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason: (explain) _____

Jim Lynch 4/6/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: S. J. MURPHY
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-03646-03 for St. Mary's Med Ctr (licensee's name)
was inspected on 3/26/92. Radiopharmaceutical departure records were
inspected for the period to with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).

S. J. Murphy 3/31/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-16317-01 for Delaware Community Hosp (licensee's name)
was inspected on 3/25/92. Radiopharmaceutical departure records were
inspected for the period 6/27/89 to 3/25/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain). _____

Donna B. Howe
Radiation Specialist
(Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-10140-01 for Metro Medical Group (licensee's name)
was inspected on 3/24/92. Radiopharmaceutical departure records were
inspected for the period 8/22/89 to 3/24/92 with the following results:

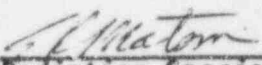
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFI

FROM: S. J. MULAY
 Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-18892-01 for TOLPAC MORGAN HOSP. (licensee's name)
 was inspected on 3/23/92. Radiopharmaceutical departure records were
 inspected for the period to with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
 (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
 (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
 and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
 administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
 records of therapeutic departures, or records or number of patient
 administrations (or prescriptions dispensed) were not available.
 Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
 to _____
 (_____ another NRC licensee or _____ an Agreement State licensee)
 to actually make the departure.

Other reason (explain): _____


 Radiation Specialist
 (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Michael F. Weber
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-05432-04 for Marquette General Hospital (licensee's name)
was inspected on 3/10/92. Radiopharmaceutical departure records were
inspected for the period 6/91 to 3/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason: (explain).

Michael F. Weber 3/20/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-05582-01 for St. Alexis Hospital (licensee's name)
was inspected on 3/3/92. Radiopharmaceutical departure records were
inspected for the period 1/90 to 3/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- ___ 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

___ The medical licensee did not make them in writing.

___ The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

___ Other reason (explain).

J. K. Sermonas 3/3/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-03364-02 for COMMUNITY MEMORIAL HOSPITAL (licensee's name)
was inspected on JANUARY 29, 1982, Radiopharmaceutical departure records were
inspected for the period JULY 1981 to 1-29-82 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NPC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

J. P. Sullivan 2-3-82
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFN

FROM: Samuel Cameron
 Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-08615-04 for St. Elizabeth Hosp. (licensee's name)
 was inspected on 2/27/92. Radiopharmaceutical departure records were
 inspected for the period 7/89 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
 radiopharmacy licensees. It does not apply to pharmacy-directed departures
 specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
 (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
 (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
 and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
 administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
 records of therapeutic departures, or records or number of patient
 administrations (or prescriptions dispensed) were not available.
 Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
 to _____
 (_____ another NRC licensee or _____ an Agreement State licensee)
 to actually make the departure.

Other reason (explain).

Samuel Cameron
 Radiation Specialist
 (Signature and Date) 3/9/92

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-02187-01 for Mercy Hospital (licensee's name)
was inspected on 12-26-91. Radiopharmaceutical departure records were
inspected for the period 12-89 to 12-91 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

 12/91
Radiation Specialist
(Signature and Date)
M. MITCHELL

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

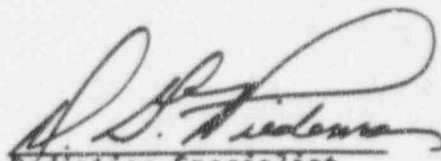
FROM: D. W. Edeman
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-03429-04 for Gratiot Community Hospital (licensee's name)
was inspected on 2/25/92. Radiopharmaceutical departure records were
inspected for the period 1990 to 1992 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain): _____


Radiation Specialist
(Signature and Date) 2/26/92

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-18591-01 for Lamaritan Hospital (licensee's name)
was inspected on Feb 25, 1992. Radiopharmaceutical departure records were
inspected for the period 2-24-92 to 2-25-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain): _____

Lamaritan 2-25-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region 1

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. for (licensee's name)
was inspected on . Radiopharmaceutical departure records were
inspected for the period to with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.

Other reason (explain).

M. K. H. 3/14/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 2

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-16-52-11 for Dr. [Name] (licensee's name)
was inspected on 2/1/52. Radiopharmaceutical departure records were
inspected for the period 12/29 to 2/1/52 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain): _____

DB Howe 2/1/52
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-03835-01 for Michigan Health Ctr. (licensee's name)
was inspected on 2/14/92. Radiopharmaceutical departure records were
inspected for the period 1989 to 1992 with the following results:

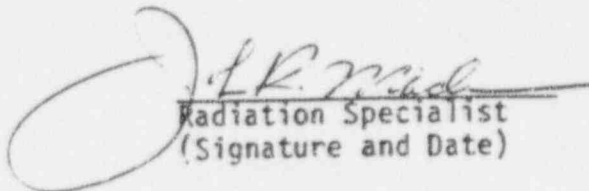
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTMENT DATA TRANSMITTAL

License No. 24-18627-01 for DEXTER McMONIGAN ^{HOSPITAL} (licensee's name)
was inspected on 2/14/92. Radiopharmaceutical departure records were
inspected for the period 7-14-89 to 2-14-92 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain): _____



Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-11494-01 for Oakland General Hosp. (licensee's name)
was inspected on 2/13/92. Radiopharmaceutical departure records were
inspected for the period 1989 to 1992 with the following results:

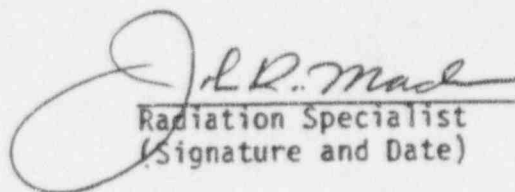
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

 2/20/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: 8/22/89
- b. Current inspection date: 2/13/92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures Y N
If "Yes," answer the following:
- b. Departures were made by the licensee Y N
- (1) Written directive on file [35.200(c)(1)] Y N
- (2) Written directive includes [35.200(c)(1)]:
- (a) Nature of the departure Y N
- (b) Description of the departure Y N
- (c) Reasons why departure was needed Y N
- (3) Records of number of departure administrations are on file [35.200(c)(2)] Y N
- c. Departures were made by a different licensee Y N
- (1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: Y N
- (1) Written directive on file [35.200(c)(1)] Y N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] Y N
- (3) Written directive includes notation of emergency [35.200(c)(1)] Y N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures Y N
- If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] Y N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure Y N
- (2) Reasons why departure was needed Y N
- d. Record of therapeutic departure made with in three working days after administration [35.300(b)(2)] Y N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] Y N

Remarks:

ATTACHMENT C

INTERIM RULE FIELD NOTES FOR RADIOPHARMACY LICENSEES

1. GENERAL

- a. Last inspection date: _____
- b. Current inspection date: _____

[Inspection should cover all departures made since the last inspection.]

2. RADIOPHARMACY DEPARTURES

- a. Radiopharmacy received diagnostic departure orders *N/A* () Y () N

If "Yes," answer the following:

- b. Written directive on file [30.34(i)(1)(i)] () Y () N

- c. Written directive includes [30.34(i)(1)(i)]:

- (1) Nature of the departure () Y () N
- (2) Description of the departure () Y () N
- (3) Reasons why departure was needed () Y () N

- d. Records of number of departure prescriptions dispensed are on file [30.34(i)(1)(i)] () Y () N

- e. Radiopharmacy made emergency departures: () Y () N

- (1) Written directive obtained within three working days after emergency [30.34(i)(1)(i)] () Y () N

- (2) Written directive includes notation of emergency [30.34(i)(1)(i)] () Y () N

Remarks:

[NOTE - Radiopharmacy licensees are not involved in therapeutic departures, so all of the above items apply to diagnostic departures made by the radiopharmacy.]

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-12876-62 for Missouri Delta Medical Center (licensee's name)
was inspected on 2-13-92. Radiopharmaceutical departure records were
inspected for the period 1-17-90 to 2-13-92 with the following results:

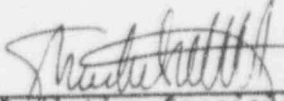
[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

 2/13/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

A-1

D-9-T-68
Issue Date: XX/XX/XX

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-02802-03 for Providence Hospital (licensee's name)
was inspected on 2/12/92. Radiopharmaceutical departure records were
inspected for the period 1989 to 1992 with the following results:

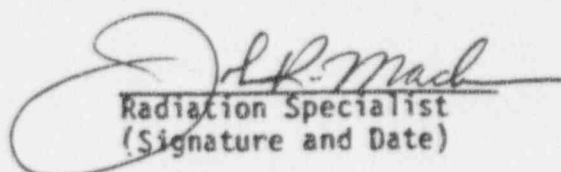
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

 2/19/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN


FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-00158-13 for St. Francis Medical Center (licensee's name)
was inspected on 2-12-92. Radiopharmaceutical departure records were
inspected for the period 7-18-89 to 2-12-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain): _____



Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-00128-03 for SOUTH-EAST ANTONOVSKI HOSPITAL (licensee's name)
was inspected on 2-11-92. Radiopharmaceutical departure records were
inspected for the period 1-18-90 to 2-12-92 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NFC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

 2/26/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-16564-01 for Madison Memorial ^{Hospital} (licensee's name)
was inspected on 2-10-92. Radiopharmaceutical departure records were
inspected for the period 7/28/88 to 2-10-92 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM RULE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

a. Last inspection date: 7-28-88

b. Current inspection date: 2-10-92

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

a. Licensee directed diagnostic departures () Y (X) N

If "Yes," answer the following:

b. Departures were made by the licensee () Y () N

(1) Written directive on file [35.200(c)(1)] () Y () N

(2) Written directive includes [35.200(c)(1)]:

(a) Nature of the departure () Y () N

(b) Description of the departure () Y () N

(c) Reasons why departure was needed () Y () N

(3) Records of number of departure administrations are on file [35.200(c)(2)] () Y () N

c. Departures were made by a different licensee () Y () N

(1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: () Y () N
- (1) Written directive on file [35.200(c)(1)] () Y () N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] () Y () N
- (3) Written directive includes notation of emergency [35.200(c)(1)] () Y () N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures () Y N
 If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] () Y () N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure () Y () N
- (2) Reasons why departure was needed () Y () N
- d. Record of therapeutic departure made with in three working days after administration [35.300(b)(2)] () Y () N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] () Y () N

Remarks:

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-CCSCF-01 for For Profit Medical Center (licensee's name)
was inspected on 2/16/92. Radiopharmaceutical departure records were
inspected for the period 1/9/90 to 2/16/92 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

D-86 T-62

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-00752-01 for Deaconess Hospital (licensee's name)
was inspected on 2/4/92. Radiopharmaceutical departure records were
inspected for the period 8/90 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

*The radiopharmacies supplying doses requested
departures, but the licensee did not authorize
them to do so.*

Donna-Beth Howe 2/12/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region _____

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-20036-01 for East Ohio Regional Hospital (licensee's name)

was inspected on 1/28/92. Radiopharmaceutical departure records were inspected for the period 1990 to 1992 with the following results:

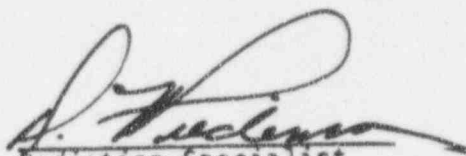
[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date) 1/30/92

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

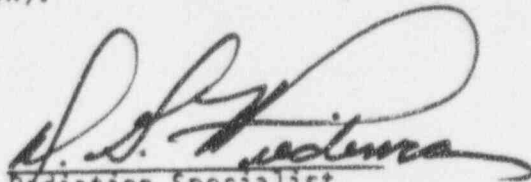
SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-16710-01 for Bethesda Hospital (licensee's name)

was inspected on 1/28-29/92. Radiopharmaceutical departure records were inspected for the period 1990 to 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NFC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date) 4/30/92

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Mike Kurth
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-01914-02 for United Hospital (licensee's name)
was inspected on 1/15/92. Radiopharmaceutical departure records were
inspected for the period 6/27/89 to 2/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

M Kurth 2/5/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-02491-03 for Midway Hospital (licensee's name)
was inspected on 1/16/92. Radiopharmaceutical departure records were
inspected for the period 02/89 to 01/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

M. Keith 2/6/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

KUSE -
COPY

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-11232-02 for LAKE Hospital Systems (licensee's name) West

was inspected on 1/30/92. Radiopharmaceutical departure records were inspected for the period _____ to _____ with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)

2. Therapeutic departures were not made. N.A.
(Not applicable to radiopharmacies.)

___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.

___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.

___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

___ The medical licensee did not make them in writing.

___ The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

___ Other reason (explain).

W.P. Richmond
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

D-11-53

Issue Date: XX/XX/XX

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: COLLEEN C. CASEY
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-24578-01 for St. Louis Regional Med. Center (licensee's name)
was inspected on 1/29/92. Radiopharmaceutical departure records were
inspected for the period 12/18/89 to 1/29/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 0 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - ___ The medical licensee did not make them in writing.
 - ___ The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - ___ Other reason (explain).

Colleen C. Casey 2/5/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN


FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-1275-02 for Bongers Hospital (licensee's name)
was inspected on 1-16-92. Radiopharmaceutical departure records were
inspected for the period 1-16-91 to 1-16-92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

 1/27/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Mike Kurth
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-01519-02 for Methodist Hospital (licensee's name)
was inspected on January 30, 1992. Radiopharmaceutical departure records were
inspected for the period 06/89 to 01/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

M Kurth 2/4/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFH

FROM: S. MULLAY / B. HAMRICK
 Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-26241-01 for MID-AMERICA ISOTOPES (licensee's name)
 was inspected on 1/30/92. Radiopharmaceutical departure records were
 inspected for the period 1/91 to 1/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
 radiopharmacy licensees. It does not apply to pharmacy-directed departures
 specifically authorized by license conditions.]

- N 1. Diagnostic departures were not requested or made.
 (Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
 (Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives
 and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient
 administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives,
 records of therapeutic departures, or records or number of patient
 administrations (or prescriptions dispensed) were not available.
 Those not available were lacking because:
 - ___ The medical licensee did not make them in writing.
 - ___ The medical licensee sent the written diagnostic directive
 to _____
 (_____ another NRC licensee or _____ an Agreement State licensee)
 to actually make the departure.
 - ___ Other reason (explain).

S. Mullay / B. Hamrick
 Radiation Specialist 2/4/92
 (Signature and Date)

Attachment: As stated

D-75 T54

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-10258-01 for ST. CLOUD HOSPITAL (licensee's name)

was inspected on JAN. 30, 1992. Radiopharmaceutical departure records were inspected for the period JUN 1989 to JAN. 30, 1992 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
- Other reason (explain).

D. R. Hibbons /- 30-92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Mike Kurth
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-20499-01 for Minneapolis Children's Medical Center (licensee's name)
was inspected on 01/21/92. Radiopharmaceutical departure records were
inspected for the period 07/88 to 01/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- NA 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Mike Kurth 2/4/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-15151-01 for La Porte Hospital. (licensee's name)
was inspected on 12-17-91. Radiopharmaceutical departure records were
inspected for the period 11-14-89 to 12-17-91 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date)

M. MITCHELL

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Wojciech Slawinski
Sr. Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-13100-02 for Wilson Memorial Hosp. (licensee's name)
was inspected on 1/31/92. Radiopharmaceutical departure ~~records were~~ ^{information was}
~~inspected~~ ^{discussed} for the period 1989 to 1/30/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NFC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: *Wagne* *Slawinski*
Sr Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-06123-01 for Stouder Memorial Hosp. (licensee's name)
was inspected on 1/31/92. Radiopharmaceutical departure ^{records} ~~records~~ were
^{discussed} inspected for the period 1989 to 1/31/92 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were ~~not requested or made~~ ^{reportedly made by the pharmacy without licensee direction or consent (Refer to Attach B)}.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NFC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

W. J. Slawinski 2/6/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 ODFW

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-17386-01 for Memorial Hosp. of Univ. Co. (licensee's name)
was inspected on 1/8/92. Radiopharmaceutical departure records were
inspected for the period _____ to _____ with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NFC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

W. REICHOLD 1/15/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: James Mullauer, M.H.S.
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-04072-01 for Gardner City Hosp. (licensee's name)
was inspected on 1/16/92. Radiopharmaceutical departure records were
inspected for the period 1989 to 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-20338-01 for WOODLAWN HOSPITAL (licensee's name)
was inspected on 12/17/91. Radiopharmaceutical departure records were
inspected for the period _____ to N.A. with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

W. P. REICHARD 12/27/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-11651-C1 for St. Joseph's Mercy Hospital (licensee's name)
was inspected on 12/17/91. Radiopharmaceutical departure records were
inspected for the period July 25, 1987 to December 17, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

AKH 1/8/92
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-00217-02 for Portico General Hospital (licensee's name)

was inspected on December 16, 1991. Radiopharmaceutical departure records were

inspected for the period June 15, 1989 to December 18, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

TH Kuntz 12/26/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-24584-01 for Avon Diagnostic Center (licensee's name)
was inspected on December 19, 1991. Radiopharmaceutical departure records were
inspected for the period 12/16/91 to 12/18/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Michael R. Kurtz 12/27/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-26098-C1 for Mad Shave, Troy, Diagnostic (licensee's name)
was inspected on 12/19/91. Radiopharmaceutical departure records were
inspected for the period 05/90 to 12/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

Michael O. Knuth 12/21/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-17971-01 for Muskegon General Hospital (licensee's name)
was inspected on 12-27-91. Radiopharmaceutical departure records were
inspected for the period 11/89 to 12/91 with the following results:


[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

 12/31/91
Radiation Specialist
(Signature and Date)

M. MITCHELL

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

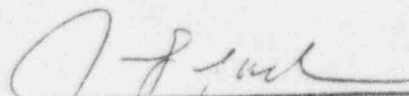
FROM: J. L. Lynch
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-26244-01 for Lakeview Memorial Hosp. (licensee's name)
was inspected on 12/20/91. Radiopharmaceutical departure records were
inspected for the period 9/90 to 11/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 The medical licensee did not make them in writing.
 The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

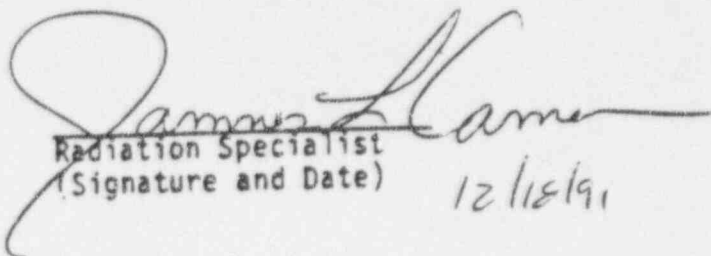
FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-01922-02 for Barberton Citizen (licensee's name)
was inspected on 12/11/91. Radiopharmaceutical departure records were
inspected for the period 8/89 to 12/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 The medical licensee did not make them in writing.
 The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 Other reason (explain).


Radiation Specialist
(Signature and Date) 12/11/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-09759-01 for MERIDA HILLCREST Hosp (licensee's name)
was inspected on 12/5/91. Radiopharmaceutical departure records were
inspected for the period 1990 to 12/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 The medical licensee did not make them in writing.
 The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 Other reason (explain).

T.L. Simmons
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-17073-01 for Porter Memorial Hospital (licensee's name)
was inspected on 12/5/91. Radiopharmaceutical departure records were
inspected for the period to with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to
(another NRC licensee or an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

W.P. Reynolds
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: T.L. Simmons
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-05382-D for MARYMOUNT HOSPITAL (licensee's name)
was inspected on 12/8/91. Radiopharmaceutical departure records were
inspected for the period 6/89 to 12/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

T.L. Simmons
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-01859-01 for VA Medical Center (licensee's name)

was inspected on 11/26/91. Radiopharmaceutical departure records were

inspected for the period 6/90 to 11/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

J Lynch 12/9/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: J. Lynch
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-00015-02 for Fairview Southdale Hospital (licensee's name)
was inspected on 11/25/91. Radiopharmaceutical departure records were
inspected for the period 4/89 to 11/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
- Other reason (explain).

J. Lynch 12/23/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Lolleen C. Casey
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-00607-04 for Saginaw General Hospital (licensee's name)
was inspected on 11/24/91. Radiopharmaceutical departure records were
inspected for the period 12/89 to 4/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- X 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- X 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - ___ The medical licensee did not make them in writing.
 - ___ The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - ___ Other reason (explain).

Lolleen Casey
Radiation Specialist
(Signature and Date) 12/6/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

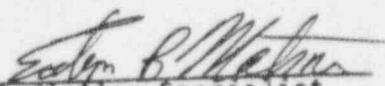
FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-20116-01 for Ingram Diagnostics (licensee's name)
was inspected on 11/22/91. Radiopharmaceutical departure records were
inspected for the period 9/5/87 to 11/22/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Jamies Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-17793-01 for St. John's Healthcare (licensee's name)
was inspected on 11/21/91. Radiopharmaceutical departure records were
inspected for the period 6/99 to 11/21/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Jamies Cameron
Radiation Specialist
(Signature and Date) 11/26/91

Attachment: As stated

2) Dix secured
1/10/91

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Colleen C. Casey
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTMENT DATA TRANSMITTAL

License No. 21-25815 for VAMC - Saginaw, MI (licensee's name)
was inspected on 11/24/91. Radiopharmaceutical departure records were
inspected for the period 1989 to 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licenses. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licenses and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records of number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____ another NRC licensee or _____ an Agreement State licensee
to actually make the departure.
 - Other reason (explain).

Colleen C. Casey
Radiation Specialist
(Signature and Date) 12/6/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFR

FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-26260-01 for Indian Heart Physicians (licensee's name)
was inspected on 11/20/91. Radiopharmaceutical departure records were
inspected for the period 2/5/91 to 11/20/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

James Cameron
Radiation Specialist
(Signature and Date) 11/25/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFi

FROM:

Janner Cameron
Radiation Specialist, Region III

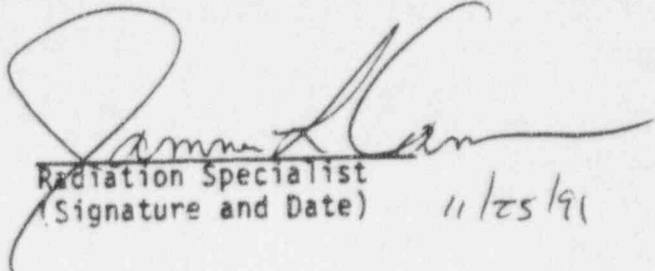
SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-26245-01 for Clinton City Hospital (licensee's name)
was inspected on 11/10/91. Radiopharmaceutical departure records were
inspected for the period 11/90 to 11/10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).


Radiation Specialist
(Signature and Date) 11/25/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: J. Lynch
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-26170-01 for Bloomfield Cardiology (licensee's name)
was inspected on 11/15/91. Radiopharmaceutical departure records were
inspected for the period 5/90 to 11/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

J. Lynch 11/20/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWH

FROM: Jim Lynch
 Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-26202-01 for Metro Diagnostic (licensee's name)
 was inspected on 11/12/91. Radiopharmaceutical departure records were
 inspected for the period 7/90 to 11/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
 (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
 (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
 and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
 administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
 records of therapeutic departures, or records or number of patient
 administrations (or prescriptions dispensed) were not available.
 Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
 to _____
 (_____ another NRC licensee or _____ an Agreement State licensee)
 to actually make the departure.
- Other reason (explain): _____

Jim Lynch 11/20/91
 Radiation Specialist
 (Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

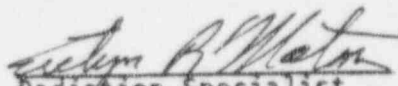
FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-20071-01 for Michigan Cardiology Assoc (licensee's name)
was inspected on 11/7/91. Radiopharmaceutical departure records were
inspected for the period 1/89 to 11/7/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-09649-02 for TERRE-HAUTE REGIONAL HOSPITAL (licensee's name)
was inspected on OCT. 29 AND 31, 1991. Radiopharmaceutical departure records were
inspected for the period AUGUST 1989 to OCT 31, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain): _____

D. P. Helton. 11-4-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-00293-02 for OHIO STATE UNIVERSITY (licensee's name)
was inspected on 10/28/91. Radiopharmaceutical departure records were
inspected for the period — to — with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

RADIOPHARMACEUTICAL
NO DEPARTURES

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to —
(— another NRC licensee or — an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

W. P. REICHOLD
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-00142-02 for DEACONS HOSPITAL (licensee's name)
was inspected on 10-1-91. Radiopharmaceutical departure records were
inspected for the period 8-30-89 to 11-1-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-03826-04 for ST. MARY'S MEDICAL CENTER (licensee's name)

was inspected on OCTOBER 30, 1991. Radiopharmaceutical departure records were

inspected for the period AUGUST 1989 to OCT. 30, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

D. R. Sullivan 10-30-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-01787-01 for GOOD SAMARITAN HOSP. (licensee's name)

was inspected on 007, 29, 1991. Radiopharmaceutical departure records were

inspected for the period 2-12-91 to 10-29-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region ____

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-26246-01 ^{MD} for RADIOPHARMACY INC. (licensee's name)

was inspected on Oct 28, 1991. Radiopharmaceutical departure records were inspected for the period Dec. 1990 to Oct 28, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFI

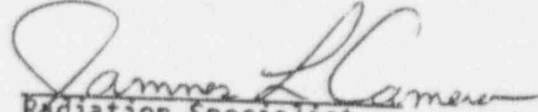
FROM: James Cameron
Radiation Specialist, Region IV

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-0213-00 for VA Med Ctr - Milwaukee (licensee's name)
was inspected on _____ . Radiopharmaceutical departure records were
inspected for the period 2/90 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records of number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).


Radiation Specialist
(Signature and Date) 10/3/91

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

Colleen Casey
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 24-04206-10M for Mattenskind & Medical, Inc. (licensee's name)
was inspected on 9/27/91. Radiopharmaceutical departure records were
inspected for the period _____ to _____ with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain): _____

Colleen Casey 10/23/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

Attachment A, 2800/23

A-1

Issue Date: XX/XX/XX

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTMENT DATA TRANSMITTAL

License No. 34-00179-02 for THE FREDERICK SMITH CLINIC (licensee's name)

was inspected on 9/26/91. Radiopharmaceutical departure records were inspected for the period to with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made. (Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made. (Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to (another NRC licensee or an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

W.P. REICHOLD
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-26091-01 for NORTHWEST OHIO CARDIOLOGY (licensee's name)
was inspected on 9/25/91. Radiopharmaceutical departure records were
inspected for the period _____ to _____ with the following results: N.A.

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

W. P. REICHMUND
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWEN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTMENTURE DATA TRANSMITTAL

License No. 34-01197-01 for Lakewood Hospital (licensee's name)
was inspected on 9/18/91. Radiopharmaceutical departure records were
inspected for the period 4/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records of number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

James L. Carneiro
Radiation Specialist
(Signature and Date) 10/3/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 31-09457-02 for Orange Hospital (licensee's name)
was inspected on 9/17/91. Radiopharmaceutical departure records were
inspected for the period 1/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records of number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

James Cameron
Radiation Specialist
(Signature and Date)

9/17/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-17967-01 for Deaconess Hospital (licensee's name)
was inspected on 9/16/91. Radiopharmaceutical departure records were
inspected for the period 1/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)

2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)

3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.


4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.

5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).


Radiation Specialist
(Signature and Date) 9/16/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

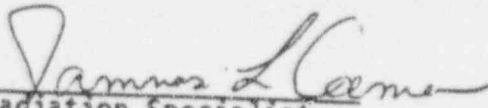
FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-00398-08 for St Luke's Hospital (licensee's name)
was inspected on 9/16/91. Radiopharmaceutical departure records were
inspected for the period 4/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: D. R. GIBBONS
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-24533-01 for COMPUTERIZED MEDICAL (licensee's name)
EMERGO
was inspected on SEPT. 10, 1991. Radiopharmaceutical departure records were
inspected for the period JAN. 24, 1989 to 9-10-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

Westview Osteopathic

License No. 13-18543-01 for Medical Hospital (licensee's name)
was inspected on 9/6/91. Radiopharmaceutical departure records were
inspected for the period 3/9/89 to 9/4/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

W.H. Schultzy / for
K.L. LAMBERT
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

CHECK
ATTACHMENT C
CALL IF NEEDED

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-26239-01MD for MPI PHARMACY SERVICES ^{INC.} (licensee's name)
was inspected on 9/4/91. Radiopharmaceutical departure records were
inspected for the period _____ to _____ with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

W.P. REICHARD 9/23/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

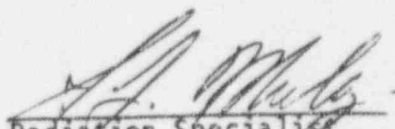
FROM: S. J. MURPHY
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-04125-01 for HACKLEY HOSPITAL (licensee's name)
was inspected on 8/21/91. Radiopharmaceutical departure records were
inspected for the period Aug 22 90 to 8/21/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

 - 10/1/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT B

INTERIM FILE FIELD NOTES FOR MEDICAL LICENSEES

1. GENERAL

- a. Last inspection date: 11/30/89
- b. Current inspection date: 8/21/91

[Inspection should cover all departures made since the last inspection.]

2. DIAGNOSTIC DEPARTURES

- a. Licensee directed diagnostic departures Y N

If "Yes," answer the following:

- b. Departures were made by the licensee Y N

(1) Written directive on file [35.200(c)(1)] Y N

(2) Written directive includes [35.200(c)(1)]:

- (a) Nature of the departure Y N
- (b) Description of the departure Y N
- (c) Reasons why departure was needed Y N

(3) Records of number of departure administrations are on file [35.200(c)(2)] Y N

- c. Departures were made by a different licensee Y N

(1) Name & location of other facility _____

- d. Licensee made emergency diagnostic departures: Y N
- (1) Written directive on file [35.200(c)(1)] Y N
- (2) Written directive made within three working days after emergency [35.200(c)(1)] Y N
- (3) Written directive includes notation of emergency [35.200(c)(1)] Y N

Remarks:

3. THERAPEUTIC DEPARTURES

- a. Licensee had therapeutic departures Y N
- If "Yes," answer the following:
- b. Record of therapeutic departure on file [35.300(b)(1)] Y N
- c. Record of therapeutic departure includes [35.300(b)(1)]:
- (1) Nature of the departure Y N
- (2) Reasons why departure was needed Y N
- d. Record of therapeutic departure made within three working days after administration [35.300(b)(2)] Y N
- e. Records of number of therapeutic departure administrations are on file [35.300(b)(2)] Y N

Remarks:

ATTACHMENT C

INTERIM RULE FIELD NOTES FOR RADIOPHARMACY LICENSEES

1. GENERAL

- a. Last inspection date: _____
- b. Current inspection date: _____

[Inspection should cover all departures made since the last inspection.]

2. RADIOPHARMACY DEPARTURES

- a. Radiopharmacy received diagnostic departure orders Y N
- If "Yes," answer the following:
- b. Written directive on file [30.34(i)(1)(i)]? Y N
- c. Written directive includes [30.34(i)(1)(i)]:
- (1) Nature of the departure Y N
- (2) Description of the departure Y N
- (3) Reasons why departure was needed Y N
- d. Records of number of departure prescriptions dispensed are on file [30.34(i)(1)(i)] Y N
- e. Radiopharmacy made emergency departures: Y N
- (1) Written directive obtained within three working days after emergency [30.34(i)(1)(ii)] Y N
- (2) Written directive includes notation of emergency [30.34(i)(1)(ii)] Y N

Remarks:

[NOTE - Radiopharmacy licensees are not involved in therapeutic departures, so all of the above items apply to diagnostic departures made by the radiopharmacy.]

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Radiation Specialist, Region ____

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 14-00822-01 for VIA MEDICAL CENTER (licensee's name)
IOWA CITY, IOWA
was inspected on AUG. 8-9, 1991. Radiopharmaceutical departure records were
inspected for the period JAN. 1990 to AUG 9, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

D.R. Gibson August 12, 1991
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN


FROM: James Cameron
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-16838-01 for Fl. Atkinson-Monroe (licensee's name)
was inspected on 9/27/91. Radiopharmaceutical departure records were
inspected for the period 5/88 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).


Radiation Specialist
(Signature and Date) 10/2/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-00919-03 for St. Mary's Hosp. (licensee's name)
was inspected on 9/27/91. Radiopharmaceutical departure records were
inspected for the period 2/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

James L. Cameron
Radiation Specialist
(Signature and Date) 9/27/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN


FROM: Radiation Specialist, Region ___

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-00537-03 for St. Joseph Hosp (licensee's name)
was inspected on 9/26/91. Radiopharmaceutical departure records were
inspected for the period 5/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- ___ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- ___ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- ___ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- ___ The medical licensee did not make them in writing.
- ___ The medical licensee sent the written diagnostic directive to
(___ another NRC licensee or ___ an Agreement State licensee)
to actually make the departure.
- ___ Other reason (explain).


Radiation Specialist
(Signature and Date) 10/2/91

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: James Cameron
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-17796-01 for Lorain Community Hosp (licensee's name)
was inspected on 9/20/91. Radiopharmaceutical departure records were
inspected for the period 4/89 to 9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

James Cameron 9/20/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-03116-01 for SACRED HEART HOSPITAL (licensee's name)

was inspected on SEPT. 12, 1991. Radiopharmaceutical departure records were inspected for the period SEPT. 2 1991 to SEPT. 12 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.

Other reason (explain).

D. R. Gilliam
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: D.R. Gibbons
Radiation Specialist, Region II

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 45-01277-01 for GUNDARSEN CLINIC (licensee's name)

was inspected on SEPT. 11, 1991. Radiopharmaceutical departure records were inspected for the period JULY 1988 to 9-11-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.

Other reason (explain).

D.R. Gibbons
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFII

FROM: Gary Shear
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 20-15538-01 for St. Francis Regional Med Ctr. (licensee's name)
was inspected on 9/9/91. Radiopharmaceutical departure records were
inspected for the period 8/23/90 to 9/9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records of number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain): _____

Gary L. Shear 9/26/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-03509-02 for DEACONES HOSPITAL (licensee's name)
was inspected on 9/6/91. Radiopharmaceutical departure records were
inspected for the period NA to NA with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
- Other reason (explain).

W. P. REICHARD 16 SEPTEMBER 1991
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Gary Shear
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 22-05792-01 for North Memorial Med Ctr. (licensee's name)
was inspected on 4/9/91. Radiopharmaceutical departure records were
inspected for the period 8/23/90 to 9/9/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Gary L Shear 9/27/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWH

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 48-09494-01 for THEDA CLARK REGIONAL Hosp (licensee's name)

was inspected on SEP. 5, 1991. Radiopharmaceutical departure records were inspected for the period Nov. 1988 to 9-5-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-12541-01 for MARGETTA MEMORCA FOSALTA (licensee's name)

was inspected on 4 August 1991. Radiopharmaceutical departure records were
~~inspected~~ ^{INSPECTED} for the period N.A. to N.A. with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

W. P. REICHHOLD
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

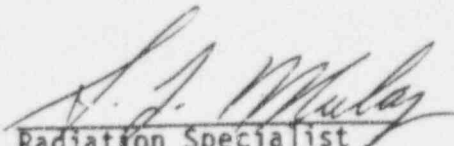
FROM: S. J. MULAY
Radiation Specialist, Region 3

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-16277-01 for West Shore Hospital (licensee's name)
was inspected on 8/22/91. Radiopharmaceutical departure records were
inspected for the period 10/90 to 8/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain): _____


Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region ___

SUBJECT: RADIOPHARMACEUTICAL DEPARTMENT DEPARTURE DATA TRANSMITTAL

License No. 21-0027-06 for BUTTENWORTH Hospital (licensee's name)
was inspected on 8/20/91. Radiopharmaceutical departure records were
inspected for the period Dec 1988 to July 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

inspection date
Aug 20 1991

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

A. J. Maly 8/29/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM:

James Cameron
Radiation Specialist, Region III

SUBJECT:

RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 34-16411-C1 for Medina General Hospital (licensee's name)
was inspected on 8/27/91. Radiopharmaceutical departure records were
inspected for the period 10/90 to 8/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

James Cameron 9/5/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFH

FROM: Garry L. Shear
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-03298-05 for Quincy Hos. A III (licensee's name)
was inspected on 8/23/91. Radiopharmaceutical departure records were
inspected for the period 8/23/90 to 8/23/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Garry L. Shear 8/30/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-23665-D for NORTH CLARK COMMUNITY HOSPITAL (licensee's name)

was inspected on AUGUST 22, 1991. Radiopharmaceutical departure records were inspected for the period JUN 1987 to AUGUST 15, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

D.R. Allison 8-26-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region _____

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-09274-03 for MEMORIAL HOSPITAL AND HEALTH CARE CENTER (licensee's name)

was inspected on August 21, 1991. Radiopharmaceutical departure records were inspected for the period JAN 1989 to 8-20-91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- N/A 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- _____ 3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
- _____ 4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
- _____ 5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - _____ The medical licensee did not make them in writing.
 - _____ The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - _____ Other reason (explain).

D.R. Halpin 8-26-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWRN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 13-18677-01 for ST. JOSEPH'S HOSPITAL (licensee's name)
was inspected on AUGUST 21-22, 1991. Radiopharmaceutical departure records were
inspected for the period JAN. 19, 1989 to AUGUST 21, 1989 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
radiopharmacy licensees. It does not apply to pharmacy-directed departures
specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 The medical licensee did not make them in writing.
 The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 Other reason (explain).

D.R. Gibson 8-26-91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Cary L. Shear
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-25964-01 for B Robert J. Stomel, R.D. (licensee's name)
was inspected on August 20, 1991. Radiopharmaceutical departure records were
inspected for the period 8/23/90 to 8/20/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive to _____ (_____ another NRC licensee or _____ an Agreement State licensee) to actually make the departure.
 - Other reason (explain).

Cary L. Shear 8/20/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-04515-21 for Cathwood Hospital (licensee's name)
was inspected on 8/20/91. Radiopharmaceutical departure records were
inspected for the period 8/23/90 to 8/20/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

- 1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
- 2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
- 3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
- 4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
- 5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 - The medical licensee did not make them in writing.
 - The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 - Other reason (explain).

[Signature] 8/28/91
Radiation Specialist
(Signature and Date)

Attachment: As stated

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
 Headquarters Coordinator, NMSS
 Mail Stop 6-H-3 OWFN

FROM: Gary Shear
 Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 21-17789-C1 for Columbia United Hospital (licensee's name)
 was inspected on August 19, 1991. Radiopharmaceutical departure records were
 inspected for the period 8/23/90 to 8/10/91 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and
 radiopharmacy licensees. It does not apply to pharmacy-directed departures
 specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
 (Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
 (Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
 and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
 administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
 records of therapeutic departures, or records or number of patient
 administrations (or prescriptions dispensed) were not available.
 Those not available were lacking because:

The medical licensee did not make them in writing.

The medical licensee sent the written diagnostic directive
 to _____
 (_____ another NRC licensee or _____ an Agreement State licensee)
 to actually make the departure.

Other reason (explain).

Gary Shear 8/27/91
 Radiation Specialist
 (Signature and Date)

Attachment: As stated

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: Evelyn R. Matson
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA

Licensee: Department of the Army
General Leonard Wood Army Community Hospital
Ft. Leonard Wood, Missouri

License No.: 24-15095-01

Inspection Date: August 16, 1991

Radiopharmaceutical departure records were inspected for the period August 1988 through August 1991 with the following results:

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and radiopharm.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives and records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patients administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives, records of therapeutic departures, or records or number of patient administrations (or prescriptions dispensed) were not available. Those not available were lacking because:
- The medical licensee did not make them in writing.
- The medical licensee sent the written diagnostic directive to _____ (____ another NRC licensee or ____ an Agreement State licensee) to actually make the departure.
- Other reason (explain)

Attachment: As stated

Attachment A, 2800/23

Evelyn R. Matson 8/19/91
signature and date

ATTACHMENT A

MEMORANDUM FOR: Donna-Beth Howe, Ph.D.
Headquarters Coordinator, NMSS
Mail Stop 6-H-3 OWFN

FROM: D.R. GIBBONS
Radiation Specialist, Region III

SUBJECT: RADIOPHARMACEUTICAL DEPARTURE DATA TRANSMITTAL

License No. 14-03523-02 for V.A. MEDICAL CENTER (licensee's name)
DES MOINES, IOWA 50210
was inspected on AUGUST 7, 1991. Radiopharmaceutical departure records were
inspected for the period JANUARY 9, 1990 to AUGUST 7, 1991 with the following results:

[NOTE: The transmittal memorandum is for inspections at both medical and radiopharmacy licensees. It does not apply to pharmacy-directed departures specifically authorized by license conditions.]

1. Diagnostic departures were not requested or made.
(Applicable to both medical licensees and/or radiopharmacies.)
2. Therapeutic departures were not made.
(Not applicable to radiopharmacies.)
3. Departures were made. All of the written diagnostic directives
and/or records of therapeutic departures are attached.
4. Departures were made. All of the records of the number of patient
administrations (or prescriptions dispensed) are attached.
5. Departures were made. All of the written diagnostic directives,
records of therapeutic departures, or records or number of patient
administrations (or prescriptions dispensed) were not available.
Those not available were lacking because:
 The medical licensee did not make them in writing.
 The medical licensee sent the written diagnostic directive
to _____
(_____ another NRC licensee or _____ an Agreement State licensee)
to actually make the departure.
 Other reason (explain).

D.R. Gibbons August 7, 1991
Radiation Specialist
(Signature and Date)

Attachment: As stated

D-1 T-0