syncor

The National Pharmaceutical Service Network

July 22, 1988

A. Bert Davis
Regional Administrator
U.S.N.R.C., Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: License No. 34-18309-01MD

Dear Mr. Davis:

This refers to your letter of July 13, 1988 regarding the July 6, 7, 8, 1988 inspection of Syncor's Blue Ash, OH facility. As confirmed in the July 13, 1988 letter, please amend the above referenced license to include the following provisions.

1. The NRC-Region III office will be immediately notified upon discovery of 3 or more misadministrations resulting from mislabeled radiopharmaceuticals which were prepared and transferred from the Blue Ash facility in any single day.

2. Customers receiving mislabeled radiopharmaceuticals will be immediately notified upon discovery of a mislabeled radiopharmaceutical which was shipped from the Blue Ash facility.

3. Random test samples will be presented to supervised quality control technicians at Blue Ash for the purpose of assuring the adequacy of quality control. As a minimum two random test samples per month will be submitted and the results documented.

4. Quality control procedures in Blue Ash will be performed by an authorized user or a trained technician. If performed by a technician, the results will be verified by another trained individual.

Related to Item 4, Syncor is investigating a number of procedures to assure continuing quality of products. Those found most effective will be implemented in an ongoing effort to maintain the highest quality of products and services for Syncor customers.

Sincerely,

Monty Fu, Chairman

cc: Syncor Distribution

Syncor International Corporation
20001 Prairie Street
P.O. Box 2185
Chatsworth, California 91313-2185
Telephone (818) 886-7400
Telex 182527 Syncor CHATS

JLC 80721 A

MEMORANDUM

To: Jim Stone, Zone Director
Bill McHugh, Regional Manager
Michelle Loos, Manager

From: Monty Fu, Chairman

Date: July 21, 1988

Re: Modifying Order - Blue Ash

As a result of the serious deterioration of the regulatory program in the Blue Ash Center, the Radiation Safety Committee orders that operations in that facility be modified.

Effective immediately, you will take the following actions.

1. Immediately notify Region III of the NRC and the Corporate Radiation Safety Officer when you become aware of 3 or more misadministrations that resulted from mislabeled radiopharmaceuticals that were prepared and transferred from your facility in any single day.

2. Upon discovery of a mislabeled radiopharmaceutical, immediately notify any customer who is the recipient of the mislabeled radiopharmaceutical that was shipped from your facility.

3. Institute a program of random test samples to assure adequacy of quality control tests. Initially, a minimum of two random samples per week must be submitted to the QC technician and results documented. With satisfactory results this may be relaxed to two samples per month. The commitment to the NRC will be for a minimum of two samples per month.

4. Quality Control procedures will be performed by an authorized user or a trained technician. If performed by a technician, the results will be verified by another trained individual. Documentation of training in the Quality Control procedure must be available for inspection before individuals may perform QC procedures or verify the results of others.

5. Clearly identify quality control strips so the origin and

solvent front can be distinguished before and after the procedure. The identification can be done in a number of ways including:

- Use of CIS kits that have the origin clearly marked.

- Pencil markings or notching of the strips.

- Ink mark which will run with the solvent during the procedure.

6. Discontinue the use of "superkits". All kits will be prepared in the manufacturer's original vial.

7. Purchase and put into use lead glass vial shields for all prepared kits. Until these arrive all prepared kits should be verified by visual inspection of the manufacturer's vial inside the lead shield before dispensing. Purchase a supply of tongs for the safe inspection of the vials if needed. Notify Health Physics of the date of implementation of the lead glass vial shields so potential hand exposure differences can be evaluated.

8. Be prepared for monthly regulatory audits until satisfactory compliance is demonstrated in Blue Ash.

Items 1 through 4 are commitments which will be incorporated into the operating procedures as a license amendment. Items 5 through 8 are Radiation Safety Committee requirements and your compliance with these items will be discussed at the next meeting.

A full report of the progress should be prepared for presentation to the committee at the next meeting.

cc: Radiation Safety Committee Members

JLC 80722 A

MEMORANDUM

To: Cyncor Pharmacy Service Center Managers
Regional Operations Managers
Zone Directors

From: Monty Fu, Chairman

Date: July 22, 1988

Re: Disciplinary Actions Associated with Misadministrations

The importance of preventing misadministrations necessitates policy regarding disciplinary actions for those involved. Everyone associated with receiving orders, dispensing, packaging, and delivering products to our customers must be accountable for their actions. Persons who can impact this area include those who take phone prescription orders, input the orders into the computer, set up the orders for dispensing, dispense the doses, and those who package and deliver the doses.

Effective immediately, the following policy regarding misadministrations is in effect.

1. First occurrence - a recorded oral warning issued to responsible personnel.

2. Second occurrence - written warning.

3. Third occurrence - discipline up to and including termination.

4. Employee may appeal discipline at any time to a panel consisting of the Zone Director from the opposite zone, the Director of Professional Affairs and the Director of Human Resources.

Your compliance with this policy is required as part of our commitment to our customers to supply only the best products and services.

cc: Jim Harrington
Radiation Safety Committee Members

CONFIRMATORY ACTION LETTER CAL-RIII-88-0026

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

SEP 0 2 1988

Syncor International Corporation
ATTN: Mr. Monte Fu
Chairman of the Board
Post Office Box 2185
20001 Prairie Street
Chatsworth, CA 91313-2185

License No. 34-18309-01MD
EA 88-194

Gentlemen:

This refers to a telephone conversation between you, Ms. Michelle Loos, and Mr. C. E. Norelius of this office on September 2, 1988, regarding activities at your facility at Blue Ash, Ohio. The subject of this conversation related to numerous occurrences of improperly labeled compounds that have been distributed by the Blue Ash facility to local hospitals. The information discussed and agreed to during this conversation supersedes the requirements that were set forth in your letter to Mr. A. B. Davis dated July 22, 1988, and subsequently referenced in License Condition No. 23 of NRC License No. 34-18309-01MD.

Based on this conversation it is our understanding that you will implement the following actions:

A. Require that two individuals independently perform the following activities:

1. Verify the performance of all tests and assays of radiopharmaceuticals and labelling of products and product packages as required by your NRC license and as listed below in Item C;

2. Complete each verification prior to further distribution of material;

3. Document each verification by signature; and

4. Maintain documentation of each verification.

One of the individuals shall be listed on an NRC or Agreement State license, or shall possess equivalent qualifications, and shall not be currently affiliated with your Blue Ash facility.

B. Submit telephonically, to the NRC Region III office with written confirmation within 5 days, the name and qualifications of the individuals who will perform the verifications specified above. Approval of these individuals shall be obtained prior to further distribution of material.

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C. Additional activities to be verified:

1. Molybdenum breakthrough test;

2. Alumina breakthrough test;

3. Labeling efficiency test for technetium-99m prepared radiopharmaceuticals;

4. [illegible]ivity measurement; and

5. Proper product and product package label.

D. Within one week, inform all clients of the Blue Ash facility that misadministrations of NRC licensed materials must be reported by the hospital to the NRC.

If our understanding of the above is not correct please contact this office by telephone immediately. Issuance of this Confirmatory Action Letter does not preclude the issuance of an Order requiring implementation of the above commitments.

Sincerely,

A. Bert Davis
Regional Administrator

cc: Michelle Loos, Manager,
Blue Ash Facility
Frank Comer, Corporate RSO
DCD/DCB (RIDS)

TO: All Blue Ash Dispensers and Verifiers

A copy of the letter from the Nuclear Regulatory Commission is attached which describes the present dual verification which must be performed in the Blue Ash facility. Read thoroughly and ask questions if you need clarification on any part.

Also attached is an instruction sheet for verifiers and dispensers. Please read and understand these instructions before beginning to work under this dual verification system.

I have read the attached documents and understand my duties.

_____
Signature

_____
Initials to be used
in lieu of signature

_____
date

INSTRUCTIONS TO BLUE ASH DISPENSERS AND VERIFIERS

Under the provisions of the September 2, 1988 letter from NRC, a number of procedural changes will be necessary. The following procedures must be verified by an authorized user not currently affiliated with the Blue Ash facility.

1. Molybdenum breakthrough test
2. Alumina breakthrough test
3. Tagging efficiency for Tc-99m prepared radiopharmaceuticals
4. Activity measurement of each dose
5. Proper product (kit prep set up, kit prep, and vials entering drawing station)
6. Proper package label (unit dose pig label)

During this period you will work with many different people. It will be necessary to communicate, communicate, and then communicate more. Some verifiers may be able to help with calculations, etc. and actually speed up the dispensing process. Others may only be able to actually observe and verify numbers. In both cases it will be necessary to verbalize all activities such that the verifier knows what is going on at all times.

It is essential that you assure the verifier sees all steps of each procedure. The verifiers can not verify anything they have not personally seen. Specifically on the following procedures, the verifier must:

1. Moly breakthrough
   a. observe vial going into the Mo shield and into calibrator;
   b. observe proper calibrator setting;
   c. observe reading of Mo-99;
   d. initial recorded value of Mo-99 (verify multiplication by 3.5 factor);
   e. observe Tc-99m vial into calibrator;
   f. observe Tc-99m reading on calibrator;
   g. verify recorded data, and uCi of Mo-99 per mCi of Tc-99m;
   h. initial record.
2. Alumina breakthrough
   a. observe spotting of disk;
   b. observe results;
   c. initial record.

3. Quality Control

   a. observe spotting of strip;
   b. observe solvent front;
   c. observe cutting of strip;
   d. observe and verify counts of each strip;
   e. verify calculation of percent tag;
   f. initial results.

4. Activity measurement

   a. observe syringe into calibrator;
   b. observe proper calibrator setting;
   c. observe activity reading;
   d. verify reading versus required dose
   e. initial script.

5. Proper product (kit prep set up and dispensing)

   a. compare cold vial label with the vial shield label and compare products during set up;
   b. verify lot numbers of vials recorded on kit prep sheet for next day set up;
   c. pass the dispenser the proper vial from which to dispense required doses.

6. Product package label (unit dose pig label)

   a. observe script and pig with dose going out of drawing station;
   ~~b. observe script being attached to pig;~~
   c. verification on script (one set of initials for activity and label check).

Experience will dictate which procedure is most efficient for dispenser and verifier. Changes can be made at any time as long as the verification retained.

syncor

The National Pharmaceutical Service Network

September 26, 1988

A. Bert Davis
Regional Administrator
U.S.N.R.C., Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: Syncor Facilities in Region III: License Numbers 34-16654-01MD (Toledo,OH), 21-17189-01MD (Ferndale, MI), 34-18309-01MD (Blue Ash, OH), 34-18484-01MD (Columbus,OH), 34-19008-01MD (Akron, OH), 13-19229-01MD (Indianapolis, IN), 21-19219-01MD (Grand Rapids, MI), 13-19451-01MD (Dyer, IN), 34-19007-01MD (Dayton, OH), 21-21141-01MD (Flint, MI), 34-16405-01MD (Cleveland, OH), 24-16617-01MD (Kansas City, MO), 24-19360-01MD (St. Louis, MO), 22-19174-01MD (St. Paul, MN), 22-24309-01MD (Moorhead, MN), 48-17466-01MD (Wauwatosa, WI).

Dear Mr. Davis:

Recently NRC staff members have expressed concerns over the quality control procedures being performed at Syncor facilities in Region III. In response to these concerns please amend all Syncor licenses in Region III (referenced above) to include a quality control commitment for Tc-99m labeled radiopharmaceuticals. The quality control procedure used will be either the enclosed Syncor procedure or that of a commercially available quality control kit. We confirm that any changes made to these procedures will be equivalent or superior to those submitted.

The amendment fee of $3680.00 for the 16 license amendments is enclosed. If there are questions about this amendment request, please contact me.

Sincerely,

Jack L. Coffey

Jack L. Coffey, M.S., C.H.P.
Corporate Radiation Safety Officer

cc: Syncor Region III Facilities
Regional Managers
Zone Directors
Monty Fu
Bob Irwin
Kathy Seifert
Health Physics Staff

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20001 Prairie Street
P.O. Box 2185
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Telephone (818) 886-7400
Telex 18222 Syncor CHATS

11.0 RADIONUCLIDIC PURITY

11.1 PURPOSE

When Technetium-99m is eluted from a Molybdenum-99\Technetium-99m generator, Molybdenum-99 could be eluted along with the Technetium. This possible outcome is termed "Molybdenum breakthrough". The US Pharmacopeia XXI specifies that Technetium-99m radiopharmaceuticals contain no more than 0.15 microcurie of Molybdenum-99 per millicurie of Technetium-99m radiopharmaceutical at the time of patient administration. It is mandatory that every elution from a Molybdenum-99/Technetium-99m generator be tested for Molybdenum breakthrough and the expiration time for the Technetium-99m be determined. Under no circumstances will the expiration time exceed 12 hours from time of elution.

11.2 RATIONALE

Since Molybdenum-99 has a longer half life and produces higher energy beta emissions, the radiation dose to the patient would be significantly increased should the radiopharmaceutical contain more than the allowable amount of Molybdenum-99. Therefore, maximum levels for Molybdenum content are set by law.

11.3 EQUIPMENT

Dose Calibrator
Molybdenum Assay Shield (moly assay shield)

11.4 PROCEDURE

a. Using calibrated dose calibrator, select the "pre-set" Molybdenum-99 option or adjust the dose calibrator in order to assay Molybdenum-99 on the lowest or most sensitive radioactivity scale.

b. With the Molybdenum-99 assay shield in place, zero the dose calibrator, or record the displayed existing background radioactivity if applicable.

c. Working behind a lead shield and using a remote handling device, transfer the Technetium-99m pertechnetate eluate vial from the elution shield to the "Moly" assay shield.

d. Place the "Moly" assay shield containing the eluate vial into the dose calibrator's well and assay on the lowest or most sensitive scale.

e. Record and initial the total displayed activity in microcuries.

f. Subtract the background activity (Step b) from the total displayed radioactivity reading, and record net Mo-99 activity as measured in microcuries.

g. Remove the "Moly" assay shield containing the eluate vial from the well and transfer the eluate to a suitable shielded container.

h. Calculate the Molybdenum-99 content as follows:

Total Molybdenum-99 content= net 99 Mo activity (Step F) multiplied by the "Moly" assay shield's attenuation factor.

Note: The "Moly" assay shield attenuation factor is supplied by the manufacturer and can be found in the operation manual for the dose calibrator.

i. Enter the total 99 Mo content and the time of assay in the appropriate records.

j. Divide the total 99 Mo content (microcuries) by the 99m Tc radioactivity (millicuries) to obtain the ratio of microcuries of 99 Mo per millicurie of 99m Tc at calibration time.

11.5 SHELF LIFE OF 99m TECHNETIUM PERTECHNETATE ELUATE

Limits: The USP XXI specifies a limit of 0.15 microcuries of 99 Molybdenum per millicurie of 99m Technetium at the time of patient administration.

Note: The 99 Molybdenum/99m Technetium ratio may be acceptable at the time of elution but may become unacceptable at the actual time of patient administration. This is due t the fact that 99m Technetium (physical half life = 6 hours) decays more rapidly than 99 Molybdenum (physical half life = 67 hours).

a. Determine the initial ratio of microcuries (uCi) 99 Mo to millicuries (mCi) 99m Tc. This initial uCi 99 Mo/mCi 99m Tc is described as the eluate's N value.

$$N = \frac{\text{uCi 99 Mo}}{\text{mCi 99m Tc}}$$

b. Locate the eluate's N value in the following table and corresponding hourly expiration time interval.

SHELF LIFE OF TECHNETIUM

uCi Mo-99/mCi Tc-99m (N)	(hours)
.0425	12.0
.0472	11.0
.0524	10.0
.0582	9.0
.0647	8.0
.0719	6.0
.0827	5.0

Note: The maximum expiration time for Technetium-99m eluate is 12 hours from time of elution.

12.0 CHEMICAL PURITY OF ELUATE

12.1 Purpose

When a Molybdenum-99\Technetium-99m generator is eluted, it is possible to elute aluminum ion along with the Technetium-99m. This procedure uses a semi-quantitative colorometric test method to test for breakthrough of aluminium in a generator elution.

12.2 RATIONALE

This procedure is performed to ensure that the aluminum ion concentration in Technetium-99m eluates is within allowable limits of the U.S. Pharmacopeia XXI.

12.3 EQUIPMENT

Colorimeter Test Kit for Aluminum Ion.

12.4 PROCEDURE

12.4.1 Aluminum Ion Breakthrough Test

(Follow any additional manufacturer's directions on kit use)

a) Place one drop of standard solution on an indicator strip provided in the kit. This solution contains 10 mcg per ml aluminum ion.

b) Working behind a shielded work station, aseptically withdraw a small amount of eluate and place a drop of same on the indicator strip next to the standard solution spot.

c) Compare the color intensity of the two spots.

d) If the eluate spot is more intense than the standard solution spot, the Al^{+3} ion is excessive and the eluate should not be used.

Note: The U.S. Pharmacopeia XXI allows 10 micrograms of Al^{+3} ion per milliliter of Technetium-99m eluate from fission produced Molybdenum-99 generators.

e) Record and initial the results.

Note: Saline used in product preparation and dose dispensing should contain no benzyl alcohol (used as a preservative). If present, benzyl alcohol will inhibit/compromise the product's binding efficiency.

13.0 RADIOCHEMICAL PURITY

13.1 PURPOSE

When a radiopharmaceutical kit is prepared using Tc99m as the tagging agent, the Tc-99m becomes attached to a substrate molecule designed to localize in a specific organ system. An efficient radiopharmaceutical has most of the Tc-99m tagged to the substrate, leaving very little untagged or free Technetium-99m. Hydrolyzed reduced Technetium-99m may also be present and it will locate in organ systems differently than the radiopharmaceutical.

Both free Technetium-99m and hydrolyzed reduced Technetium-99m localizing in the organ systems of the patient can give artifacts on scanning that may mislead the clinician or make assessment of scans difficult. Unless the radiopharmaceutical is efficiently tagged, the accuracy of the resultant diagnosis can be compromised. Syncor has set minimum standards for tagging efficiency, and each vial of radiopharmaceutical prepared in a Syncor pharmacy must be tested for the parameters appropriate to the radiopharmaceutical. Procedures for each radiopharmaceutical can be found in Section 13.4.

13.2 RATIONALE

Radiochemical purity evaluations are essential because the agents tested are for human use in diagnostic evaluations. These agents are targeted to specific organ systems, and it is necessary to assure that the quality of the resulting diagnostic image is optimized, and that the radiation dose to nontarget organs is minimized.

13.3 EQUIPMENT AND SUPPLIES

Acetone
Saline (0.9%)
Saline (20%)
Pencil
ITLC-SG strips (see figure A)
ITLC-SA strips (see figure A)
Water (distilled)
Multichannel Analyzer/Scaler with scintillation well.

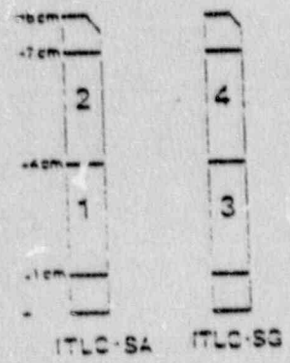

FIGURE A

To identify top from bottom, cut a small corner off the top of the strip.

13.4 PROCEDURES

13.4.1 General Guidelines

Quality Control for radiochemical purity must be performed on every vial of radiopharmaceutical tagged with Tc-99m and dispensed from a Syncor pharmacy for patient use. The table below lists radiopharmaceuticals, the appropriate test procedure as found in Section 13.4.2, the minimum acceptable purity, and the potential radiochemical contaminants.

Radiopharmaceuticals	Test Procedure	Minimum Acceptable Purity	Potential Radiochemical Contaminants
99m Tc-Pertechnetate	No. 1	*95%	99m TcO2-and other HR species
99m Tc-Sulfur Colloid	No. 2	*92%	99-m TcO4-
99m Tc-Albumin Colloid	No. 3	92%	99-m TcO4-
99m Tc-Macroaggregated Albumin	No. 2	*90%	99m TcO4-
99m Tc-Disofenin	No. 5	90%	99m TcO2-;
99m Tc-Mebrofenin	No. 5	90%	99m Tc-Sn Colloid; and 99m TcO4-
99m Tc-Medronate (MDP)	No. 3	*90%	99m TcO2-;
99m Tc-Oxidronate (HDP)	No. 3	*90%	99m TcO4- and
99m Tc-Pyrophosphate (PYP)	No. 3	*90%	99m Tc-Sn Colloid
99m Tc-Pentatate	No. 3	*90%	99m TcO2-;
99m Tc-Gluceptate	No. 3	*90%	99m TcO4-; and 99m Tc-Sn Colloid

* Acceptable Purity Requirement as Established, USP XXI

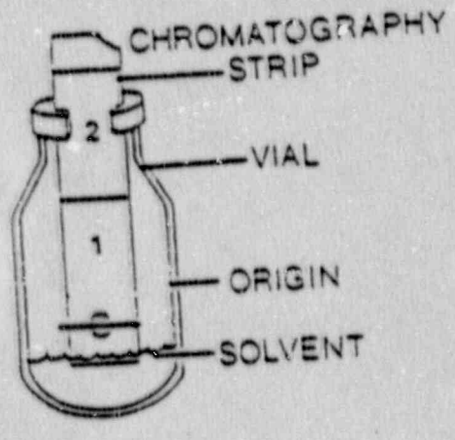

FIGURE B: Procedures 1,2,and 4

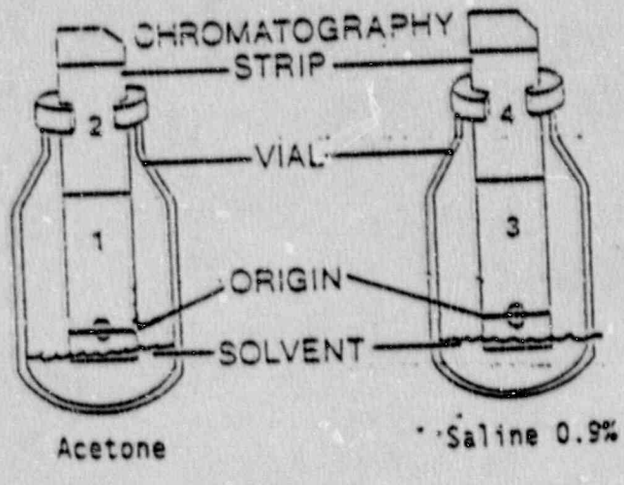

FIGURE C: Procedure 3

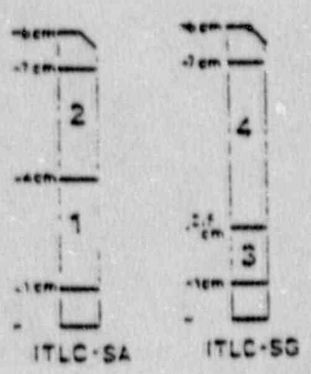

FIGURE D: Preparation of Chromatography strips for Procedure 5

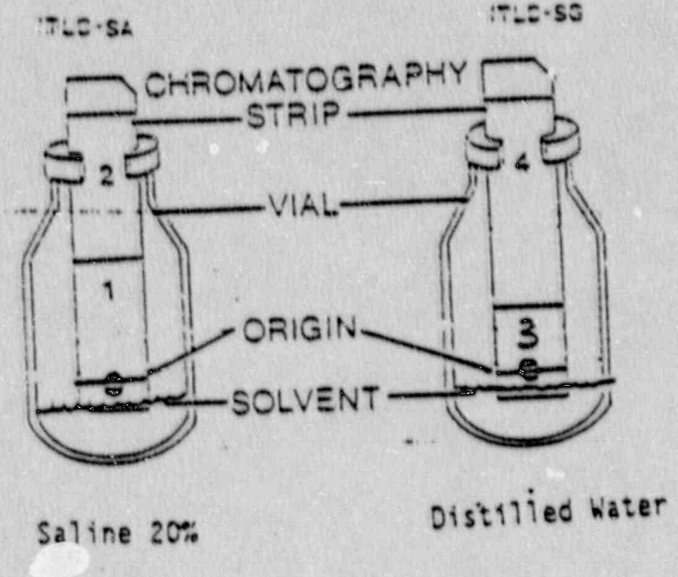

FIGURE E: Procedure 5

13.4.2 PROCEDURE 1

Detection of Tc-99m hydrolyzed reduced in sodium pertechnetate.

a. Place enough acetone in developing vial to just cover the bottom of the vial. (See figure B.)

b. Using a tuberculin syringe with a small needle, spot the sodium pertechnetate on the bottom pencil line of ITLC-SG Media strip.

c. Immediately develop the strip in acetone. Do not allow the solvent front to reach the end of the strip.

d. Cut strip at center pencil line producing sections 1 & 2 (See figure B).

e. Count each section in well counter on appropriate settings and record raw data results.

f. Using the following formula, calculate % free TcO_4

$$\frac{\text{(net activity of section 2)}}{\text{(net activity of sec. 1) + (net activity of sec. 2)}} \times 100$$

13.4.3 PROCEDURE 2

Detection of Free 99m Tc in Particulate Radiopharmaceuticals.

a. Place enough saline 0.9% in developing unit to just cover the bottom of the vial. (See figure B)

b. Using a tuberculin syringe with a small needle, spot the sodium pertechnetate on the bottom pencil line of ITLC-SG Media Strip.

c. Immediately place strip in vial and develop. Do not allow saline to reach the end of the strip.

d. Cut strip at center pencil line producing Sections 1 & 2. (See figure B)

e. Count each section in well counter on appropriate settings and record raw data results.

f. Using the following formula, calculate % of free TcO4.

$$\frac{\text{(net counts in section 2)}}{\text{(net counts in section 1) + (net counts in section 2)}} \times 100$$

g. % of 99m-Tc bound = 100 - % Free TcO4.

13.4.4 PROCEDURE 3

Detection of free TcO4 and Tc-Hydrolyzed reduced in water-soluble Tc-radiopharmaceuticals.

a. Place acetone in one developing vial and normal saline in another. Use just enough solvent to cover the bottom of each vial. (See figure C)

b. Spot radiopharmaceutical on bottom pencil lines of ITLC-SG media strips.

c. Immediately develop one strip ITLC-SG in acetone and the second strip in normal saline.

d. Cut strips at center pencil lines producing section 1, 2, 3, and 4 (See figure C).

e. Count each section in a well counter on appropriate settings and record raw data results.

f. % free TcO4 equals:

$$\frac{\text{(net activity of section 2)}}{\text{(net activity section 1) + (net activity section 2)}} \times 100$$

g. % HR-Tc equals:

$$\frac{\text{(net activity of section 3)}}{\text{(net activity section 3) + (net activity section 4)}} \times 100$$

h. % bound = 100 - (% Free TcO4 + % HR-Tc).

13.4.5 PROCEDURE 4

Detection of free TcO4

a. Follow Procedure No. 2; however, acetone should be used as the developing solvent.

13.4.6 PROCEDURE 5

Detection of free TcO4 and Tc-Hydrolyzed reduced in Tc-labeled IDA agents.

a. Place saline 20% in one developing vial and 2-4 mm distilled water in another developing vial. Use just enough solvent to cover the bottom of each vial. (see figure E).

b. Spot radiopharmaceutical on bottom pencil line of ITLC-SA and ITLC-SG chromatography strips.

c. Immediately develop the SA strip in Saline 20% and the SG strip in distilled water until solvents migrate to top pencil line.

d. Cut the SA strip at the center pencil line and the SG strip at 2 cm from origin producing sections 1, 2, 3, and 4 (see figure D).

e. Count each section in a well counter on appropriate settings. Record raw data results.

f. Free % TcO4 equals:

$$\frac{\text{(net activity of section 2)}}{\text{(net activity section 1) + (net activity section 2)}} \times 100$$

g. % HR-Tc equals:

$$\frac{\text{(net activity of section 3)}}{\text{(net activity section 3) + (net activity section 4)}} \times 100$$

h. % bound = 100 - (% TcO4 + % HR-Tc).

14.0 PARTICLE SIZING

14.1 PURPOSE

Prepared kits of particulate Technetium - 99m radiopharmaceuticals will be checked for particle size. Particle sizes must meet the specifications of the U.S. Pharmacopeia XXI.

14.2 RATIONALE

Appropriate particle size in particulate radiopharmaceuticals permit the desired biodistribution during human administration while minimizing patient risk.

14.3 EQUIPMENT

Microscope
Hemocytometer (50 micrometers per grid square)
Cover Slides
Glass Slides

14.4 PROCEDURE

14.4.1 Technetium-99m Lung Imaging Agents

a. Using safe radiation handling practices, place a sample containing not less than 100 particles on the hemocytometer grid. Place a cover slide over the hemocytometer.

b. Place the hemocytometer under the microscope, focus on the appropriate power resolution and observe particle sizes.

c. 90% or greater of all lung imaging particles should be from 10 to 90 micrometers in diameter with no particles greater than 150 micrometers.

d. Prepared kits that meet the specifications above may be used for unit and multidose prescriptions. Those exceeding the specifications must be removed from use.

Samples of Quality Control Data Collection Forms Follow

Quality Control Reminders

1. Always use fresh noncontaminated solvents.
2. Spot the strip on the origin line and assure the spot is not immersed in the solvent.
3. Secure the solvent vial in a rack or other configuration to prevent tipping over.
4. Frequently check tweezers, tongs, and scissors for contamination.
5. Use glass counting tubes so the identity of the strip can readily be determined.
6. Use a reproducible counting geometry which minimizes deadtime/coincidence counting losses.
7. Use a counting region of interest which is specific for Tc-99m.

DATE: _____

LOCATION: _____

FORMULAS:
A = D + E
B = C x 100 = F
C = D + E
G = B x 100 = H
100 - (F - F) = I

PRODUCTS	TIME	ACETONE/ITLC-SG				SALINE/ITLC-SG					
		ORIGIN COUNTS A	TOP COUNTS B	TOTAL COUNTS C	% FREE F	ORIGIN COUNTS D	TOP COUNTS E	TOTAL COUNTS G	% HYDROL H	% TAG I	INITIA
VDP #1											
VDP #2											
VDP #3											
VDP #4											
XDP #1											
ITPA #1											
ITPA #2											
ITPA #3											
ITPA #4											
ITPA #5											
DYP #1											
DYP #2											
DYP #3											
BLOOD #1											
		SALINE 20%/ITLC-SA				DISTILLED WATER/ITLC-SG					
HEP #1											
HEP #2											

QUALITY CONTROL DATA

DATE: _____

FORMULAS: $\frac{A - B = C}{B \div C \times 100 = F}$

$\frac{100 - F = T}{}$

SALINE/ITLC-SC

PRODUCT	TIME	PARTICLE SIZE	ORIGIN COUNTS A	TOP COUNTS B	TOTAL COUNTS C	% FREE F	% TAGGED T	INIT:
RBC #1								
RBC #2								
RBC #3								
PP #1								
PP #2								
PC #1								
PC #2								

FORMULAS: $\frac{A - B = C}{B \div C \times 100 = H}$

$\frac{100 - H = T}{}$

PRODUCT	TIME	SALINE 0.9% ITLC-SC N/A	ORIGIN COUNTS A	TOP COUNTS B	TOTAL COUNTS C	% HYDROL H	% TCSA T	INIT:
ELU #1								
ELU #2								
ELU #3								
ELU #4								
ELU #5								
ELU #6								
ELU #7								