TRIONIX
RESEARCH LABORATORY, INC.

1666 Enterprise Parkway
Twinsburg, Ohio 44087
216-425-9055

May 18, 1987

Ms. Patricia J. Whiston
Materials Licensing Section
Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Control Number - 83114

Dear Ms. Whiston:

Enclosed is our item-by-item response pertaining to your letter dated April 21, 1987, requesting additional information.

I thank you for your kind explanation and advice given in our response preparation for our NRC License Application in Nuclear Medicine Camera Calibration.

Sincerely,

Chun Bin Lim

Chun Bin Lim, Ph.D.
President

CBL:pct

Encl.

NRC
C.B. Lim
5/18/87

This is our item-by-item response to your letter dated April 21, 1987 for our NRC license: (Refer to Control Number 83114)

1. Materials

a. We limit our license request to the following gamma emitting isotopes.

Isotope Name	Gamma Ray Emitted keV	Manufacturer's Name	Model No.	Physical Form	Max Activity
Am-241	60	Amersham	AMC-62	Sealed	5 mCi
Ba-133	81,303,356	Amersham	BDC-801	Sealed	5 mCi
Cd-109	88	Amersham	CUC-13052	Sealed	5 mCi
Cs-137	662	Amersham	CDC-801	Sealed	1 mCi
Tc-99m	140	Syncor		Vial	200 mCi

Please note the following aspects in our usage.

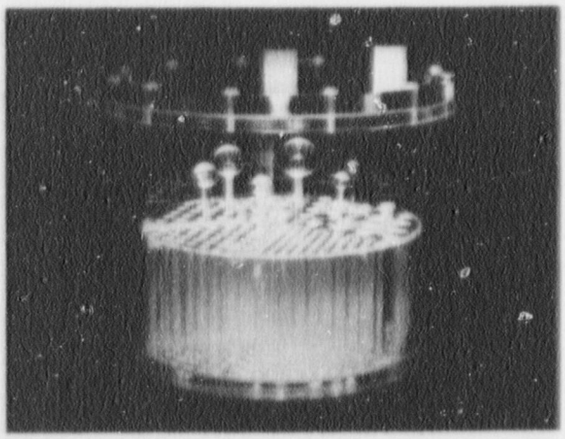
A. The first four sources are standard sealed sources by the manufacturer and will be used once every two months on an average for photopeak energy calibration of gamma cameras. Particularly note that I^{131} and Xe^{133} have been eliminated.

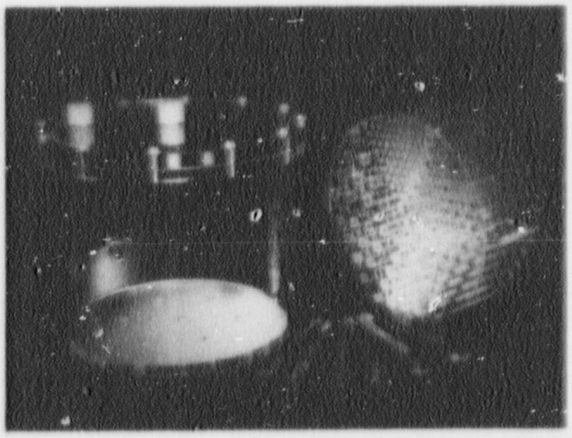
B. Tc^{99m} is a short lived isotope with 6 hours half life and will be available to us in liquid form in a vial. This isotope will be injected into a sealed lucite phantom using a syringe and will be used for gamma camera resolution calibration. Average activity per study is 10 mCi with maximum of no more than 25 mCi. This calibration will be done once every month on an average.

C. Tc^{99m} will be used in the resolution calibration test of Single Photon Emission Computed Tomography with a rotating gamma camera. The isotope is injected into either a circular or an elliptical shape Data Spectrum's SPECT phantom, which will be placed on the gamma camera's patient table during imaging period. During the calibration test study, the camera is covered by several mobile lead-lined x-ray barriers of area 75"H x 30"W for personal protection shielding.

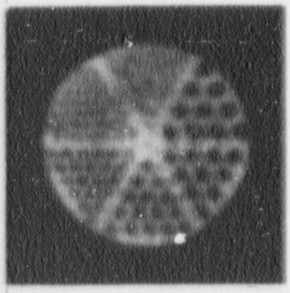
Data Spectrum's SPECT phantom is a standard SPECT calibration test phantom used for gamma cameras. The phantom is made of a lucite container of 22 cm diameter and 20 cm height and has several resolution test pattern inserts such as different size rods, pie pattern and spheres, etc. The detailed dimensions, construction method, usage purposes, and the resulting images are shown in the following three brochures of Data SPECTRUM.

Data Spectrum's SPECT Phantom

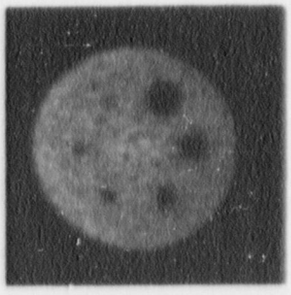




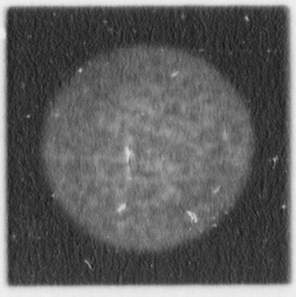
The **Original** Benchmark for determining **Total** ECT system performance.



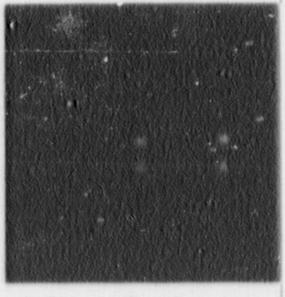
Rods



Spheres



Uniform



Line Sources

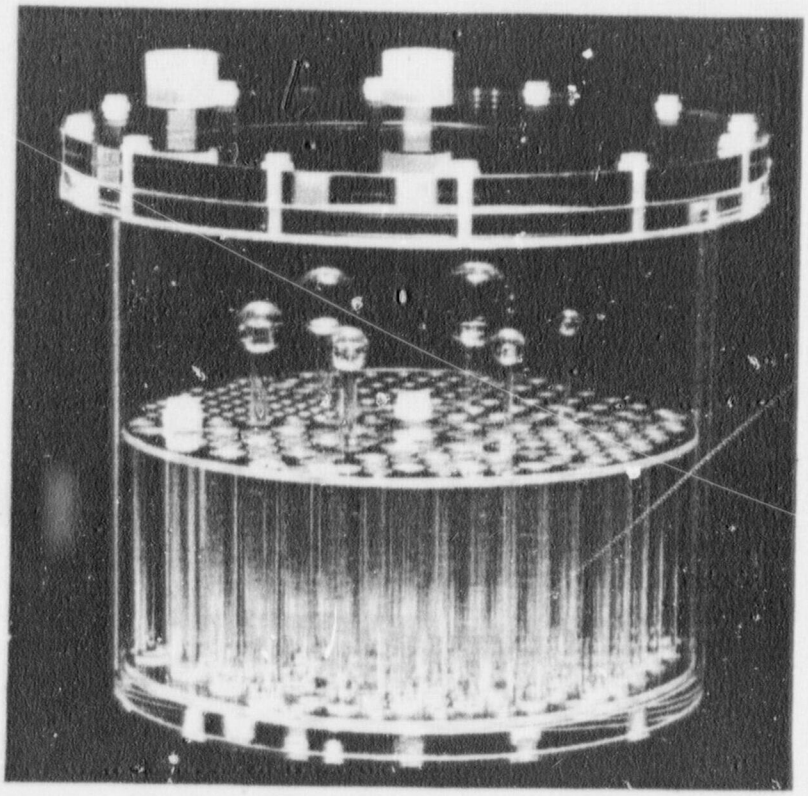
Evaluates: Resolution, sensitivity, % rms noise, S/N ratios, collimators and filters, variations with depth, effectiveness of flood and attenuation compensation, system alignment and calibration.

Optional Inserts: H ɔt Spot, Cardiac, Hollow Spheres, 3-D Plate.

Data Spectrum Corporation

2307 Honeysuckle Road
Chapel Hill, North Carolina 27514
(919) 942-6192 TELEX 499-5399

Data Spectrum's SPECT Phantoms



(Deluxe Model is shown)

Easily provides valuable and consistent information on the performance of any ECT camera... whether it's a SPECT or positron system.

Evaluates multiple performance characteristics of camera-based SPECT system from a single scan of the phantom, including:

- *System single-slice volume sensitivity.*
- *System total volume sensitivity.*
- *Effect of regional variations in intrinsic system response using uniform cylindrical portion of insert.*
- *Accuracy of attenuation compensation algorithm.*
- *Spatial resolution variations within field-of-view using portion of insert containing the array of variable sized rods.*
- *Lesion detectability using portion of insert.*
- *Effect of finite, spatial resolution and Compton scattering on image quality.*
- *Image contrast, %rms noise and signal-to-noise (S/N) measurements.*

On-axis, and off-axis transverse line spread function may be easily measured without the necessity of removing the cover plate. Hence, measurements of full-width-half (or tenth) maximum can be readily determined, either in air or in water.

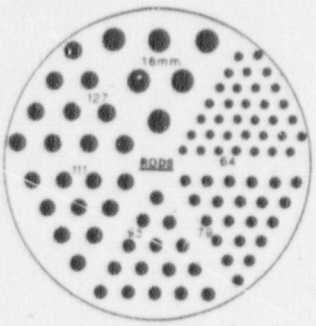
Inserts may be removed to permit additional test fixtures to be installed.

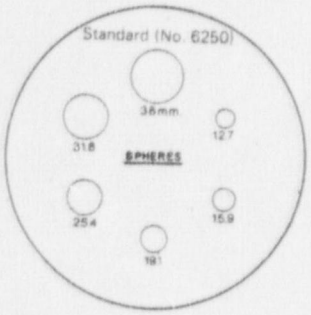
Four models available: The **Deluxe** Model for high quality SPECT cameras. The **Standard** Model for lower resolution systems. The **Benchmark** Model is recommended for routine Quality Control because of the large diameter of the rods. The **Elliptical** Model is suitable for non-circular or elliptical SPECT orbits.

Optional Inserts — see page 23.

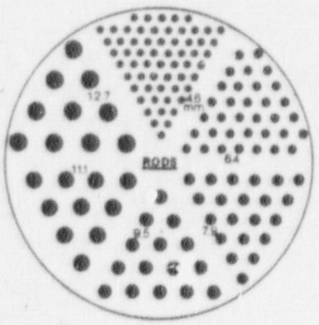
043-762	Standard SPECT Phantom	$1420.00
043-750	Deluxe SPECT Phantom	1620.00
043-770	Benchmark SPECT Phantom ...	1320.00
043-722	Elliptical SPECT Phantom	2420.00

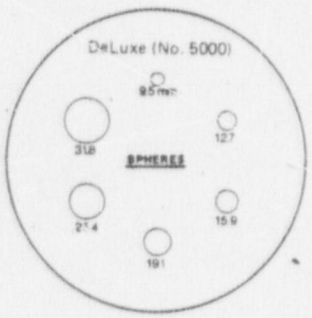
Standard SPECT Phantom



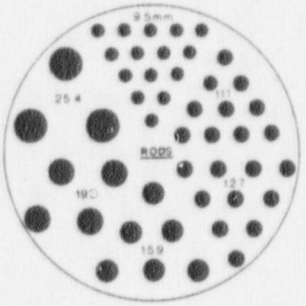


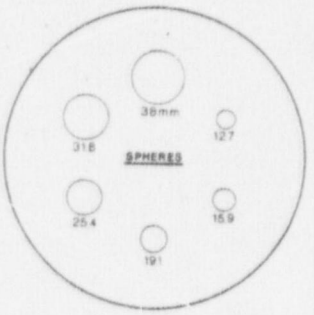
Deluxe SPECT Phantom



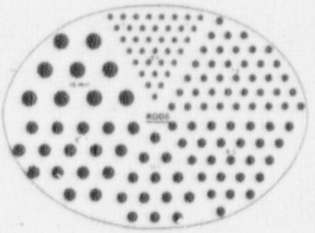


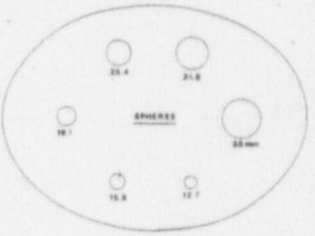
Benchmark SPECT Phantom



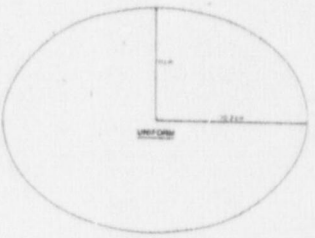


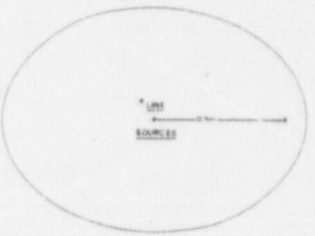
Elliptical SPECT Phantom





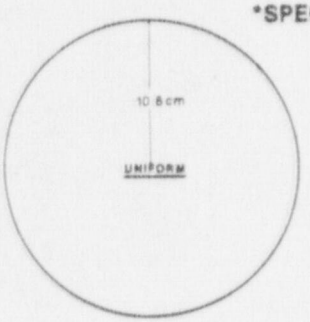
SPECIFICATIONS:

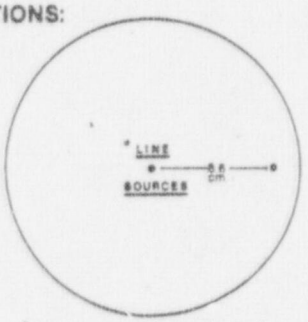




Inside Diameter of Major Axis: 30.5 cm
Inside Diameter of Minor Axis: 22 cm
Cylinder Inside Height: 18.6 cm
Six Solid Spheres: Each individually removable.
Diameters: 12.7, 15.9, 19.1, 25.4, 31.8, 38.1 mm.
Spheres are 12.7 cm above base plate.
Six Sets of Solid Rods: Insert Removable.
Diameters: 6.4, 7.9, 9.5, 11.1, 12.7, 15.9 mm.
Center-to-center spacing: Twice the rod diameter.
Height of Rods: 8.8 cm
**With user supplied capillary tubes.*
Glass Capillary Tubes: 12 cm (user supplied). Two tubes may be positioned without removing top cover as a result of a unique design of filler caps, one on-axis, one off-axis.
Construction: High quality custom machinery is used throughout, including the use of O-ring seals for the cover plate and filler caps. The top and bottom plates are made of ⅛" thick acrylic, and special high-strength fabrication methods are used in assembly.

*SPECIFICATIONS:





** With user supplied glass capillary tubes.*

SPECIFICATIONS:

Cylinder Inside Diameter: 21.6 cm
Cylinder Outside Diameter: 22.2 cm
Cylinder Inside Height: 18.6 cm

Six Spheres: Solid, each individually removable.
043-762 12.7 - 38.1 mm
043-750 9.5 - 38.1 mm
043-770 12.7 - 38.1 mm
Spheres are 12.7 cm above base plate.

Six Sets of Solid Rods: Insert Removable.
043-762 6.4 - 15.9 mm
043-750 4.8 - 12.7 mm
043-770 9.5 - 25.4 mm
Center-to-center spacing: Twice the rod diameter.
Height of Rods: 8.8 cm

Glass Capillary Tubes: 12 cm (user supplied). May be positioned without removing top cover plate as a result of unique design of filler caps, one on axis, one 8.8 cm from axis of rotation.

Construction: High quality custom machinery is used throughout, including the use of O-ring seals for the top cover plate and filler caps. The top and bottom plates are made of ⅛" thick acrylic plate, and special high-strength fabrication methods are used in assembly.

Specifications subject to change without notice.

The average activity used per study is approximately 10 mCi with maximum no more than 25 mCi. When the isotope is injected into the phantom, the phantom is labeled with the standard yellow radiation label and the caution reading "CAUTION - RADIOACTIVE MATERIAL". After the study, the phantom is stored in the 1" thick lead-lined vault (locked) for one week (7 x 24/6 = 28 half lifes) for activity decay to the neglible level before they are drained in a sink for disposal. Before drainage, the low activity level will be confirmed using G-M counter.

2. Users

A. Radioactive material handling experience of C.B. Lim:

Isotope	Activity Handled	Testing and Calibration	Dates	Where
Am-241	10 mCi	Multi-wire spark chamber testing and calibration	1968-72	Lawrence Berkeley Lab. Health Physics Dept., California
Cd-109	10 mCi	" " "	" "	" " "
Ce-141	40 mCi	" " "	" "	" " "
Cs-137	50 mCi	" " "	" "	" " "
Co-57	20 mCi	" " "	" "	" " "
I-131	50 mCi	" " "	" "	" " "
Fe-55	10 mCi	" " "	" "	" " "
Co-60	10 mCi	" " "	" "	" " "
Ge68/ Ga-68	30 mCi (unsealed)	MWPC positron camera development system testing and patient clinical study	1973-78	Univ. of California San Francisco, Nuclear Medicine Department
Na-22	10 mCi	" " "	" "	" " "
Cu-64	50 mCi (unsealed)	" " "	" "	" " "
Au-198	30 mCi	Gamma camera clinical patient study and system testing	1974-78	" " "
I-131	30 mCi (unsealed)	" " "	" "	" " "
Hg-197	30 mCi	" " "	" "	" " "

Tc-99m	300 mCi (unsealed)	" " "	" "	" " "
Ga-67	40 mCi (unsealed)	" " "	" "	" " "
Tl-201	20 mCi (unsealed)	" " "	" "	" " "
Xe-133	20 mCi	Gamma camera system calibration testing	1980-86	Technicare, Solon, Ohio
I-131	20 mCi	" " "	" "	" " "
Ce-141	20 mCi	" " "	" "	" " "

b. Additional users to our license:

Dan Gasparovich
Roger Kump

Their training and experience with radioactive materials are as follows:

Dan Gasparovich:

Isotope	Activity Handled	Testing and Calibration	Dates	Where
Tc-99m	200 mC (sealed)	Milking Tc-99m generator	1983-87	Technicare, Solon, Ohio
Tc-99m	Up to 30mC (sealed)	Extraction with syringe	1983-87	" " "
Tc-99m	Various (sealed)	Calculating Dosage	"	" " "
Tc-99m	Up to 30mC (unsealed)	Phantoms	"	" " "
Tc-99m	300 mC to 20 mC (sealed)	Calibration Vials	"	" " "
Ga-67	2 mC (sealed)	Calibration Vials	1985-86	" " "
Xe-133	5 mC	Calibration Vials	1985-86	" " "
Ce-141	1-3 mC	Calibration Vial	1977-80	" " "
Cesium 137	100 uC (sealed)	Calibration Button	1977-87	" " "

Co-57	500 uC (sealed)	Calibration Button	1977-87	"	"	"
I-131	1 mC	Calibration Vials	1983-87	"	"	"

Training - Technicare Corporation, from Barb McVey who was in charge of Technicare's Isotope Licensing and Safety Radiation Officer. Mrs. McVey was a former employee of the State of Ohio, Ohio Department of Health, Radiological Health Program. She conducted classes yearly on Safety and Preparation of Isotopes.

Roger Kump:

Isotope	Activity Handled	Testing and Calibration	Dates	Where
Co-57	100 uc to 5 mC (sealed)	Camera Testing	1970-86	Technicare, Solon, Ohio
Cs-137	100 uC to 500 uC (sealed)	" "	"	" " "
Tc-99m	100 uC to 200 mC (unsealed)	Extract from generator and dispense in vials and phantoms	"	" " "
I-131	100 uC to 5 mC (unsealed)	Extract from generator and dispense in vials and phantoms	"	" " "
Xe-133	20 uc (unsealed)		"	" " "
Ga-67	500 uc to 10 mC (unsealed)		"	" " "

Numerous company training sessions on rules and regulations of isotope handling, given by Technicare's Radiation Safety Officer.

3. Personnel Monitoring

a. Criteria used to determine extremity monitoring:

Each user who handles phantom preparation by injecting Tc-99m into it, will use the extremity monitoring device.

Dan Gasparovich and Roger Kump named above will be assigned to this duty and thus will have finger badges as well.

b. We have eliminated the licensing request for I-131 and Xe-133. Therefore, we will not need bioassay program in-house.

4. Facilities

We have removed our licensing request for I-131 and Xe-133. Currently, our facility is quite adequate for handling the isotopes specified in Section 1. Please note that the isotope usage frequency in our facility is approximately once a month and therefore we are not frequent users. We spend most of our time in developing the gamma camera's electronics and related softwares.

5. Calibration

a. We have two G-M survey meters and will be calibrated annually by an approved NRC group below.

b. Dose calibrator will be calibrated annually. The multichannel analyzer is not used for radiation safety purpose. Both the G-M survey meters and dose calibrator will be calibrated annually by an on-going contract with the following company:

Nuclear Medicine Associates
9726 Park Heights Avenue
Cleveland, Ohio 44125
NRC License Number: 34-16272-01

6. Surveys

On the average, our use of radioisotopes is once a month. Please note that we have reduced the number of radioisotopes to five, namely four standard energy calibration sourcees and Tc-99m.

Under this environment, our survey program will consist of:

1) routine area survey program at each use of radioisotope

2) comprehensive biannual survey

The surveyed area will be limited to the laboratory area only, where the isotope is used for camera calibration and phantom preparation.

Using the G-M counter, the routine area survey will be conducted in the camera laboratory area after each use. The level of background counting or contamination that we consider acceptable around the camera area is to be under .01 mR/hr. The general criteria that we use for special attention is the background G-M counter reading increase by a factor of two above the normal background level after storage of the isotopes in the storage vault. We will keep a log

book preserving the survey results (G-M counter reading) together with the data and the area surveyed information. This log book will be kept near the isotope storage vault.

The comprehensive bi-annual survey will be conducted by the following NRC-approved professional group, based on an ongoing open service contract with Trionix:

Nuclear Medicine Associates
9726 Park Heights Avenue
Cleveland, Ohio 44125
NRC License Number: 34-16272-01

The service work to be done by Nuclear Medicine Associates includes G-M counter and dose calibrator calibration, wipe test of all sources, area survey, and all other aspects related to compliance with NRC regulations.

7. Leak Test Procedures

Leak testing of all sealed sources will be conducted by the above-mentioned NRC-approved professionals of Nuclear Medicine Associates.

8. Waste Disposal Program

a. The long-lived sealed sources for gamma ray energy calibration will be sent back to the original manufacturer packed in the original container.

Realistically, the only waste that we generate is the Tc-99m liquid solution in the phantom and the disposable materials such as rubber gloves and absorbent papers used in the handling of the phantom preparation. The liquid-filled phantom will be stored in the storage vault for a week (28 half lives period) before they are drained in a sink. The disposable materials used in the phantom preparation will be kept in a special container for a week before they are moved to a regular garbage container. Before any of these disposal actions, both the phantom and the disposable materials should be surveyed for confirmation of negligible activity. The special container has radiation caution symbols and the words "CAUTION, RADIOACTIVE MATERIAL". The people responsible for phantom handling, waste collection, storage, and removal are: Dan Gasparovich and Roger Kump.

b. Radioactivity calculation of Tc-99m after a week:

Tc-99m: half life = 6 hours
1 week = 24 hours x 7 days = 168 hours = 28 half lifes
Decay factor after a week = 3.7×10^{-9}

Maximum phantom activity = 30 mCi
Phantom activity after a week = (30 mCi) x (3.7×10^{-9})
<1 uCi
Confirmatary survey before disposal.

9. Laboratory Rules

The following new Standard Procedure has been established specifically in order to implement your recommendation applicable in the Central System Test Laboratory area.

STANDARD PROCEDURES - 5

1.0 Purpose

This procedure states the rules that personnel is required to follow in handling radioactive materials in the laboratory area, such as sealed source use and phantom preparation, use, and storage for safety.

2.0 Scope

The scope of this procedure defines the authorized personnel and the rules for those employees handling radioactive materials in the laboratory area.

3.0 Authorized Personnel

3.1 Personnel using permanently sealed sources should be authorized by Radiation Safety Officer (RSO) according to the requirementss specified in SP-1. Approved person cannot handle more than 5 mCi at a time.

3.2 Personnel who handle phantom preparation, use, its storage and its related procedures will be limited to the NRC-licensed personnel. The radioactive quantity permitted to be used is the NRC-approved limit to Trionix.

4.0 Protective Clothing and Laboratory Apparel

4.1 The basic purpose of protective clothing is to avoid the direct contact with the radioactive material in case of contamination.

4.2 When using the low activity sealed sources, the user should minimize the direct contact. In this case, the protection rule to be followed is the shielding and the distance between the user and the source material.

4.3 The personnel who use and handle liquid filled phantoms should wear laboratory gown and safety rubber gloves. This requirement should be followed strictly from the phantom preparation through th safe storage of the phantom used and the confirmation survey of the area used.

4.4 When preparing the phantom, the phantom preparation working desk area should be covered by the plastic lined leak-proof paper to avoid potential contamination of the laboratory furniture. After phantom preparation, the materials used should be stored in a special container and should be kept there for one week before transfer to regular garbage after confirmation monitoring.

5.0 Area Limitation for Radioactive Usage

The usage and handling of radioactive materials will be strictly confined to the central system test laboratory area.

6.0 Routine Survey Monitoring and Procedure

6.1 Routine survey monitoring is to be done by the NRC-approved RSO only for consistency and meaningful interpretation of survey results against the normal background level.

6.2 Routine survey monitoring is to be done by the G-M counter.

6.3 Survey results is to be written down on the survey results log book.

6.4 In case of area contamination, the area is to be cleaned by the NRC-approved RSO under the supervision of Dr. Chun B. Lim, and the area should be marked with "radiation sign" until the activity level comes down to the normal background level in order to block people access.

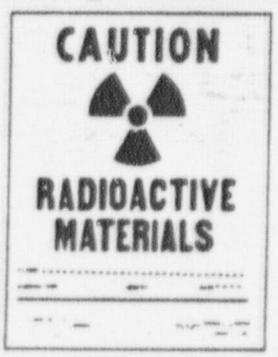
6.5 The material used in clean-up should be stored in the radioactive material storage vault for one week until their activity comes to normal background level before disposal.

7.0 Movement of Radioactive Materials

7.1 Movement of radioactive materials is confined to the central system test laboratory area, except incoming receipt of radioactive materials, which should be handled by NRC-approved personnel.

8.0 Storage Requirement and Radioactivity Labeling

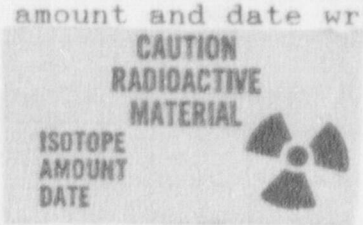
8.1 Radioactive Material Storage Vaults of 2' x 2' x 2' volume capacity lined with 1" thick lead is used for storage of radioactive materials. There are two vaults of this type; each vault has the following radiation sign on its cover door:



Each vault is located in the radioactive material handling area in the corner of the central system test laboratory area.

8.2 Each time a radioactive material is taken out, the user should write down in the log book, the date, time, the isotope name, the user's name, and the time it is returned to the Storage Vault.

8.3 When a Tc-99m filled phantom is prepared, the phantom should have the following radioactive material sign attached on it with the isotope amount and date written down on it:



9.0 Personnel Monitoring Device and Recording Procedure

9.1 Everyone working in the central system test area should have a monitoring device from the RSO according to Standard Procedure-2.

9.2 Everyone should turn the old film badge in and receive a new badge from the RSO at the beginning of each month for whole body exposure reading evaluation. Monthly exposure results will be posted on the bulletin board every month.

9.3 The personnel who handles phantom preparation should have additional extremity finger badge for arm and hand exposure monitoring with 1 month periodic evaluatin period. This personnel is limited to the NRC-approved users only.

10. Waste Disposal Procedure

10.1 Any radioactive waste material generated in the phantom preparation should be collected in a special waste container assigned for radioactive waste material collection, which has the radiation sign with the label "CAUTION, RADIOACTIVE MATERIAL".

10.2 The normal radioactive waste material should remain in that container for one week for activity decay to a safe negligible level and should be transferred to the regular garbage area after activity confirmation G-M reading check.

10.3 The special radioactive waste generated by spill in the phantom preparation should all be collected in a vinyl bag and should be stored in a storage vault for one week before they are handled as normal radioactive waste material.

11. Records To Be Kept

The following log books should be kept in the radioactive handling area:

1. Radioactive material check-out and turn-in log book
2. Area Survey Results Log Book
3. Waste Disposal, Date, Time, Activity Confirmation Log-Book

12. Contamination Control Procedure

To avoid potential contamination, no one should smoke, nor consume food and beverages near the radioactive material handling area while working on the phantom preparation.

13. Enforcement Rule

Everyone working in the Central System Test Lab area should have this copy as well as the other four standard procedures.