

SOUTHEASTERN IMAGING

MEDICAL IMAGING SERVICES

319 HOSPITAL DRIVE, SUITE 208
P. O. BOX 1322
MARTINSVILLE, VA 24114
TELEPHONE (703) 634-5115

October 22, 1993

To: Earl Wright
Senior License Reviewer
USNRC, Region II
101 Marietta Street, Suite 2900
Atlanta, Georgia 30323

From: Kathy H. Pillis
Director, SEI

Subject: Information Request (Reference: 255522; 030-33303)

Dear Mr. Wright:

This refers to your request for additional information and/or clarification for the following:

1. We will obtain a letter from each client to meet the requirements of 10 CFR 35.29 (b) or (c), as appropriate and will maintain these letters on file for inspection by the NRC. I have made arrangements with my pharmacy supplier that they will only deliver materials to the unit and/or SEI personnel. I have instructed the clients that they can not accept delivery of any licensed radioactive material.

2. Name/address of dosimetry service:

Landauer, Inc.
2 Science Road
Glenwood, Illinois 60425-1586

Certificate of Accreditation and initial order enclosed.

3. Technetium 99m Aerosols

Item 10.13.2- Worker Dose from aerosols

We will collect spent aerosol in a shielded trap and, for reuseable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.

We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix O.1 to Regulatory Guide 10.8, Revision 2.

Item 10.13.3- Public Dose from Airborne Effluent

We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.

Control # 255522

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Page 2

In addition, I am confirming that our services will be limited to materials identified in 10 CFR 35.100 and 35.200 and Xenon gas will not be used. In addition, licensed materials will not be used unless an authorized physician user named on our license is physically present at the site.

If any additional information is needed I may be contacted at 703-634-5115.
Thank you for your consideration.

Respectfully submitted,

Kathy H. Pillis

Kathy H. Pillis

control 255522

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MEDICAL IMAGING SERVICES

319 HOSPITAL DRIVE, SUITE 208

P. O. BOX 1322

MARTINSVILLE, VA 24114

TELEPHONE (703) 634-5115

To: RJReynoldsPatrick County Memorial Hospital
John Phillips, Chief Technologist, Radiology

From: Kathy H. Pillis
Director, SEI

Re: Radioactive Materials Deliveries

This notification is to verify that under no circumstances any hospital employees can accept delivery of any radioactive material intended for SEI.

This issue was addressed to the Radiology personell during the inservice on October 19, 1993.

United States Department of Commerce
National Institute of Standards and Technology



Certificate of Accreditation

LANDAUER, INC.
GLENWOOD, IL

*is recognized under the National Voluntary Laboratory Accreditation Program
for satisfactory compliance with criteria established in Title 15, Part 7 Code of Federal Regulations.
Accreditation is awarded for specific services, listed on the Scope of Accreditation, for:*

PERSONNEL RADIATION DOSIMETRY

January 1, 1994

Effective until



A handwritten signature in cursive script, reading 'Albert D. Phalen', is written over a horizontal line.

For the National Institute of Standards and Technology

ACCT. NO.	SERIES	EXPOSURE PERIOD	BADGE DATE
139230		QUARTERLY	101593

Landauer®

Landauer, Inc.
2 Science Road Glenwood, Illinois 60425-1586
Telephone: (708) 755-7000 Facsimile: (708) 755-7016

SOUTH EASTERN IMAGING
ATTN KALYANI BHATT
319 HOSPITAL DRIVE
SUITE 208
MARTINSVILLE VA 24112

USE THIS SIDE FOR DELETIONS
PLACE "D" IN DELETE COLUMN

USE REVERSE SIDE FOR ADDITIONS
AND OTHER CHANGES.

SERVICE CHANGE ORDER

[illegible]

IMPORTANT: WHEN REQUESTING ANY CHANGES, ADDITIONS, OR DELETIONS, PLEASE MAKE THEM ON THIS FORM.
CHANGES TO BE EFFECTIVE FOR YOUR NEXT WEAR DATE
MUST REACH THE GLENWOOD OFFICE NO LATER THAN 12/21/93
PLEASE DO NOT DUPLICATE CHANGES REQUESTED DURING PRECEDING 20 DAYS.

12/21/93

DO NOT RETURN CHANGE REQUESTS WITH YOUR DOSIMETERS SINCE THIS DELAYS HANDLING

ONE HOLDER IS LOANED AT NO CHARGE FOR EACH BADGE IN SERVICE AND MUST BE RETURNED AT TERMINATION OF CONTRACT. EXTRA HOLDERS MAY BE PURCHASED ON REQUEST. WITH THIS SHIPMENT OUR RECORDS INDICATE THE FOLLOWING LOANED BADGE HOLDERS IN YOUR POSSESSION

SINCE THIS DELAYS HANDLING.			
G (REGULAR)	H (THERMAL)	B (NEUTRAK 144)	OTHER

PACKING LIST

Landauer, Inc.
2 Science Road, Glenwood, Illinois 60425-1586

AL
ED
RE
IN
MU

10/7/93

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

Earl G. Wright

OFFICE/ADDRESS

PHONE NUMBER

EXT

PERSON CALLED

Kathy Pillis

OFFICE/ADDRESS

Southeastern Imaging

PHONE NUMBER

EXT

703-634-5115

CONVERSATION

SUBJECT

Control # ~~255522~~ 255522 Mobile Nuclear Med. License

SUMMARY

1. Clarify licensed material to be possessed. 10CFR 35.100, 35.200 including Tc^{99m} aerosols but excluding Xenon gas
2. Licensee will use only unit doses obtained from licensed Nuclear Pharmacy
3. Licensee will obtain + keep on file letters of agreement called for in 10CFR 35.29
4. Dosimetry svc will be Landauer
5. Ordering/receiving. licensee's mobile Van has a lock box to accept orders from pharmacy when licensee's personnel are not available.

ECW

Check Items

[Y] [N] Decomi
[Y] [N] Facility R
[Y] [N] Qual. Mg
[Y] [N] Continge
[Y] [N] Decay-In
[Y] [N] SRP/RG
[Y] [N]
[Y] [N]

REFERRED TO:

ACTION REQUESTED

ACTION TAKEN

☐ ADVISE MI
ACTION T/

INITIALS

DATE

INITIALS

DATE

TELEPHONE DEFICIENCY

Southeastern Imaging
ATTN: Ms. Kathy H. Pillis, Director
P.O. Box 1322
319 Hospital Drive, Suite 208
Martinsville, Virginia 24114

Dear MS. Pillis:

SUBJECT: REQUEST FOR MORE INFORMATION ABOUT A MATERIALS LICENSE APPLICATION (REFERENCE: 255522; 030-33303)

This refers to your application dated August 25, 1993 requesting a license for a Mobile Nuclear Medicine Unit to perform nuclear medicine services at client hospital facilities through out the state of Virginia.

We have reviewed your request and as discussed in our telephone conversation of October 15, 1993, we need additional information and/or clarification as follows:

1. Conformation that you will obtain a letter meeting the requirements of 10 CFR 35.29(b) or (c), as appropriate, from each client and will maintain these letters on file for inspection by NRC. Also, please confirm that you will make arrangements with your pharmacy supplier that they will never deliver licensed material directly to your client. In addition, please confirm that you will instruct your client to never accept delivery of licensed material.
2. The name and address of your dosimetry service and/or confirmation that the service you will use is accredited pursuant to 10 CFR 20.202(c).
3. If you wish to use technetium 99m aerosols, you must provide information specified in section 10.13, paragraphs 2 and 3 of RG 10.8 (REV 2) for our review (see also Appendix O, RG 10.8 for additional instructions).

Furthermore, we understand from our telephone conversation, that your services will be limited to materials identified in 10 CFR 35.100 and 35.200 only and that xenon gas will not be used. In addition, licensed materials will not be used in your mobile facilities unless one of the authorized physician users named on your license is physically present.

If you have questions about this letter, please call me at 404-331-5617.

Sincerely,

EGW 10/18/93
EARL G. WRIGHT
Senior License Reviewer
Materials Licensing Section

ENCL
● RG 10-8 (Rev 2)

APPENDIX O

FROM RG 10.8 (REV 2)
Aug. 1987

Model Procedure for Monitoring, Calculating, and Controlling
Air Concentrations

(See §§ 20.103, 20.106, 20.201, 35.90, and 35.205.)

WORKER DOSE FROM NOBLE GASES (Item 10.13.1)

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix O.3 to Regulatory Guide 10.8, Revision 2."

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for NRC review during inspections.) If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item 10.13.1 by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix O.1 to Regulatory Guide 10.8, Revision 2."

If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.103, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as ATT 10.13.1," and append your procedure for monitoring worker dose from noble gases.

✓ WORKER DOSE FROM AEROSOLS (Item 10.13.2)

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the monitor manufacturer's instructions for checking for accuracy and constancy, you may respond to Item 10.13.2 by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for NRC

review during inspections.) If you will follow the model procedure below for calculating worker dose from aerosols, you may respond to Item 10.13.2 by saying, "We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix O.1 to Regulatory Guide 10.8, Revision 2."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.103, 20.106, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring worker dose due to aerosol concentrations that is appended as ATT 10.13.2," and append your procedure for monitoring worker dose from aerosols.

O.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:
 - a. Estimated number of studies per week;
 - b. Activity to be administered per study;
 - c. Estimated activity lost to the work areas per study (you may assume 20 percent loss);
 - d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);
 - e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);
 - f. Measured airflow exhaust at the storage site (e.g., a fume hood); and
 - g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} $\mu\text{Ci}/\text{m}^3$ in restricted areas and 3×10^{-7} $\mu\text{Ci}/\text{m}^3$ in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 4×10^{-5} $\mu\text{Ci}/\text{m}^3$ in restricted areas and 1×10^{-6} $\mu\text{Ci}/\text{m}^3$ in unrestricted areas. For other gases or aerosols, see Appendix B to 10 CFR Part 20.
2. The following calculations must be made:
 - a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
 - b. The estimated average concentration in restricted areas.
 - (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.

- (2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

0.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.
2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

0.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.
2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.
3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.
4. Follow the trap manufacturer's instructions for replacing the trap.

PUBLIC DOSE FROM AIRBORNE EFFLUENT (ITEM 10.13.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Table II of Appendix B to 10 CFR Part 20.

If you are not directly venting aerosols and gases to the atmosphere, you may respond to item 10.13.3 by saying, "We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit

the calculations with your application, but you should keep them for NRC review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond to Item 10.13.3 by saying, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix 0.2 to Regulatory Guide 10.8, Revision 2."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.106, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as ATT 10.13.3," and append your procedure for monitoring airborne effluent concentration.

SPILLED GAS CLEARANCE TIME (Item 10.13.4)

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix 0.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 10.13.4 by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of § 35.205. Say on your application, "We have developed a procedure for calculating spilled gas clearance times that is appended as ATT 10.13.4," and append your procedure.

0.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

- a. A, the highest activity of gas in a single container, in microcuries;
- b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;
- c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;
- d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} $\mu\text{Ci/ml}$ in restricted areas and 3×10^{-7} $\mu\text{Ci/ml}$ in unrestricted areas. For other gases, see Appendix B to 10 CFR Part 20; and
- e. V, the volume of the room in milliliters.

2. For each room make the following calculations:

- a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
- b. The evacuation time $t = \frac{-V}{Q} \times \ln (C \times V/A)$.

DATE
10/7/93

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

Earl G. Wright

OFFICE/ADDRESS

PHONE NUMBER EXTENSION

PERSON CALLED

Kathy Pillis

OFFICE/ADDRESS

Southeastern Imaging

PHONE NUMBER EXTENSION

703-634-5115

CONVERSATION

SUBJECT

Control # ~~25522~~ 255522 Mobile Nuclear Med. License

SUMMARY

1. Clarify licensed material to be possessed. 10CFR 35.100, 35.200 including Tc^{99m} aerosols but excluding Xenon gases
2. Licensee will use only unit doses obtained from licensed Nuclear Pharmacy
3. Licensee will obtain + keep on file letters of agreement called for in 10CFR 35.29
4. Dosimetry svc will be Landauer
5. Ordering/receiving. Licensee's mobile Van has a lock box to accept orders from pharmacy when licensee's personnel are not available.

EGW

Check Items

[Y] [N] Decommissioning
[Y] [N] Facility Requirements
[Y] [N] Quality Management
[Y] [N] Contingency Planning
[Y] [N] Decay-In-Storage
[Y] [N] SRP/Regulatory
[Y] [N] _____
[Y] [N] _____

REFERRED TO:

ACTION REQUESTED

ACTION TAKEN

☐ ADVISE ME OF ACTION TAKEN

INITIALS

DATE

INITIALS

DATE