



**NORTH DAKOTA  
DEPARTMENT OF HEALTH**

**Division of Air Quality**

**RADIOACTIVE MATERIAL  
LICENSING GUIDE**

Guide for Medical Licensees  
Using Mobile Positron Emission  
Tomography (PET) Service Providers

Revised February 2, 2006

## INTRODUCTION

This licensing guide describes the type and extent of information needed before mobile positron emission tomography (PET) service providers may be used under an existing North Dakota Radioactive Material License. Please carefully study the North Dakota Radiological Health Rules, the standard licensing guide for medical use of radioactive material and this licensing guide. Submit all information requested.

## APPLICATION TO USE MOBILE PET SERVICE

Please address the following items in your application to use a mobile service company for PET imaging:

1. The transmission and calibration source(s) carried on the mobile PET scanning vehicle must be added to your license even if you choose not to use the sources in conjunction with your studies. Provide information about the sources (manufacturer, model number, radioactive material, activity, Sealed Source and Device Registry Number, number of sources and total activity to be possessed).
2. Before using a mobile PET service provider, your existing license must be amended to include the PET scanning vehicle as a use location. The vehicle must be parked on licensee property. Submit a map of your facility identifying the location of the PET scanning vehicle and adjacent restricted and unrestricted areas. Show the location of the restroom to be used by PET patients between the time of injection and the time of imaging. Show the location of the patient injection area, and patient holding rooms or waiting areas to be used by PET patients after administration.
3. Your radiation safety responsibilities and those of the mobile PET service must be thoroughly spelled out, including responsibilities for package receipt, dose preparation, patient injection, on-board holding areas, patient waiting or holding areas at the medical facility, restroom facilities for PET patients, area surveys, wipe tests, camera operation, patient release, waste disposal, source accountability, security of radioactive material, spill clean-up, emergency procedures and a final survey of the PET scanning vehicle before it leaves the location described in item 2 above.

This is intended to eliminate confusion that may arise over responsibilities for use and control of radioactive material. Generally, the facility is held responsible for complying with all radiation safety requirements while the mobile PET service is under their direction. The camera operator will be considered under contract to the facility if performing injections and is to follow the licensee's procedures in regard to all uses of F-18, including waste disposal.

4. Before the mobile service may perform PET scans at a facility, the mobile service's radioactive material license must be amended to authorize the fixed facility as a location of use. The mobile PET service company's license must authorize transportation of the sealed source(s) to temporary job sites. Confirm to the Department that the mobile PET service company's license has these authorizations.

In addition, the mobile PET service needs to have a letter of authorization from each medical facility where service is to be provided. Confirm to the Department that you will provide them with a letter of authorization.

5. According to one study, radiation fields around a patient injected with 10 mCi of F-18 are about 6 millirem/hr at 1 meter. Also, at one meter from some of the transmission or calibration sources or phantoms, the dose rate may exceed 2 millirem/hour. Therefore, there is a potential that the public dose limit of 2 millirem in any one hour and 100 millirem per year may be exceeded (particularly outside the PET scanning vehicle, and within and outside of patient waiting areas used by PET patients). Discuss how you will ensure that the dose to the public limits of 2 millirem in any one hour and 100 millirem per year will not be exceeded.

Discuss potential radiological exposures to other patients and staff; and potential effects on PET camera image quality. Discuss how you will survey areas adjacent to the PET scanning vehicle, patient waiting areas, and restrooms. How will you restrict those areas if a member of the public may be exposed to more than 2 millirem in any one hour or 100 millirem in a year? Discuss your consideration of a separate patient injection/holding room with a private restroom to reduce public/personnel exposures.

Discuss area surveys, area monitoring, and wipe tests of areas including the PET scanning vehicle, areas adjacent to the vehicle, dose preparation areas, injection areas, patient waiting and holding areas, and restroom facilities.

6. Describe all shielding in the PET scanning vehicle for on-board dose storage, temporary waste receptacles, dose calibrator, dose preparation area, patient waiting area, lavatory holding tank, PET syringe shields, etc.

Describe all shielding at your facility that will be used in PET procedures including shielding of the package receipt area, storage areas, waste handling areas, dose calibrator and dose preparation areas, syringes (with PET syringe shields), injection areas, restroom facilities, and PET patient holding or waiting areas.

Discuss remote handling of the PET radiopharmaceuticals and the use of automated injection systems. Discuss the use of beta or plastic pre-shielding.

7. Provide updated general safety procedures that address PET use. Emergency procedures, including procedures for handling spills should be provided.
8. Describe the radiation safety training for the technologists who will be handling PET radiopharmaceuticals, performing the injections, and operating the camera. State who will perform these duties.

Additional radiation safety training is necessary for technologists prior to handling PET radiopharmaceuticals (two days at a similar or larger operation handling high energy radiopharmaceuticals plus manufacturer's training for the camera). All technologists involved in PET work must be CNMT, R.T.(N)(ARRT), or equivalent.

If the scanner is not a U.S. Department of Transportation (DOT) approved container for the transmission and calibration sources, the sources will have to be transferred between the scanner and the DOT approved containers - if this is the case, describe the procedures that will be followed and describe the training that technologists will receive prior to performing any source installation, removal, or handling.

9. Authorized users must demonstrate a minimum of 24 hours of supervised PET work experience and 10 cases of clinical PET experience. Provide information on the training and experience of any physicians on your license that you would like to have authorized for PET. Form RCP-18, "Preceptor Statement" may be used to document experience. See Attachment A for more information.

10. Confirm that the authorized user is aware of and will fulfill his/her responsibility with respect to the use location. If the mobile service company provides a technologist, the authorized user must supervise the technologist. Also, the authorized user must ensure that the recommended scanner QA/QC is performed and reviewed before any patient studies are performed.
11. Provide procedures for dose calibrator checks and tests and PET camera QA/QC. Equipment QA/QC, checks, and tests must be performed daily at each location of use before administering the PET radiopharmaceuticals.
12. A permanent in-state location for records retention must be provided - either at your facility or at the mobile PET service's permanent in-state office, if they have one. Access to records for inspection must be readily available during all normal business hours. Alternatively, complete records may be kept in the mobile scanning vehicle and no permanent in-state location would be required if the Department is provided a "24/7" location schedule with 48 hour advance notification for deviations or changes to the schedule. The required records must include: location log, number of studies performed, source inventory, survey meter calibration, dose calibrator checks and calibration, PET camera QA/QC, contamination surveys, radiological surveys, personnel dosimetry, patient release, waste disposal, personnel training records, personnel qualifications, shipping papers (to be kept accessible to the driver per transportation regulations). State where the records will be maintained.
13. Confirm that you will inventory all sources on the PET scanning vehicle upon arrival and again prior to departure. The sources may include PET transmission and calibration sources and phantoms, dose calibrator reference sources, and survey instrument check sources.
14. Describe how you will provide for the security of radioactive sources on the PET scanning vehicle if it is left unattended. Request specific authorization to permanently store sealed sources overnight and on weekends in the PET scanning vehicle, if this will be done at your facility. Provide a description of security procedures and restricted access.
15. Your facility must be responsible for radiopharmaceutical ordering, receipt, use, and disposal. Doses should be delivered directly to your facility's nuclear medicine department and secured pending use. Doses may be delivered directly to the PET scanning vehicle, if that is the intended injection location and if personnel are present to receive the shipment. No radioactively contaminated waste (injection paraphernalia or consumed decontamination supplies) may be stored on the PET scanning vehicle, but must be returned to your facility for pharmacy pickup or decay in storage. Address these issues in your application. Also, if you plan to administer radiopharmaceuticals on the PET scanning vehicle, describe in detail how you will receive, transport and dispose of radiopharmaceuticals that are administered on the vehicle.
16. Confirm that your Radiation Safety Officer will perform periodic radiation safety audits of PET operations including staff safety practices, timely record keeping, adequate posting (signs), and assess security of restricted areas. The RSO should also determine that contamination surveys and public dose surveys of the PET scanning vehicle, patient waiting and holding areas, and restroom facilities are properly performed and documented.
17. Describe final survey procedure and documentation prior to departure of the PET scanning vehicle from your facility. Discuss actions in the event contamination is identified including emptying and rinsing of lavatory holding tank(s). Discuss how you will ensure that the PET scanning vehicle is free of radioactive contamination before releasing the PET scanning vehicle from your custody. No radioactively contaminated patient waste shall remain on the PET scanning vehicle when it leaves your facility.
18. Confirm that you will use only unit doses of PET radiopharmaceuticals.

## AMENDING THE LICENSE

Applications for license amendments may be filed either on an application form or in letter form. The request should identify the license by number and should clearly describe the exact nature of the changes, additions or deletions. References to previously submitted information should identify the pertinent information by date, page and paragraph.

Amendment applications must be signed and dated. The original copy of the application should be submitted to the Department of Health and a copy should be maintained for your records.

License amendments must be accompanied by the appropriate license amendment fee as described in Chapter 33-10-11 of the North Dakota Radiological Health Rules. The amendment fee for this type of amendment is \$150; the annual fee is \$2500, check or money order made payable to the North Dakota Department of Health.

## ATTACHMENT A

### **Additional Information Regarding Authorized User Training**

To become an authorized PET user, a formal training course is not required. However physicians must demonstrate a minimum of 24 hours of supervised PET work experience and 10 cases of clinical PET experience (notice the word is "clinical", not "didactic" - clinical experience involves direct observation of a patient). The required 10 clinical cases involve more than just image interpretation.

Form RCP-18, "Preceptor Statement" (<http://www.health.state.nd.us/AQ/RAD/forms/forms.htm>) includes entry blanks for the number of cases and total hours of positron emission tomography experience involving fluorine-18. The preceptor physician overseeing the training must be an authorized PET user. A formal letter from the preceptor describing the accomplishments of the physician during the preceptorship may also be used to document experience in lieu of form RCP-18.

The required hours of supervised work experience (under the supervision of an authorized PET user) may include the following activities:

1. Ordering, receiving, and unpacking positron-emitting radioactive materials safely and performing the related radiation surveys;
2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
3. Calculating and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving positron-emitting radioactive material;
5. Using procedures to contain spilled positron-emitting radioactive material safely and using proper decontamination procedures;
6. Examining patients or human research subjects and reviewing their case histories to determine their suitability for positron-emitting radioisotope diagnosis, limitations, or contraindications;
7. Selecting the suitable positron-emitting radiopharmaceuticals and calculating and measuring the dosages;
8. Administering dosages to patients or human research subjects and using syringe radiation shields;
9. Collaborating with the authorized user in the interpretation of positron-emitting radioisotope test results; and
10. Patient or human research subject follow-up.

In addition to the current authorized PET physicians in N.D., it may also be possible to arrange a preceptorship at other locations listed in the Directory of PET Centers at [http://www.snidd.org/pet\\_toc.htm](http://www.snidd.org/pet_toc.htm).