MOBILE MEDICAL SERVICE GUIDANCE

Regulations:
391-3-17-.05(2), (8), (13), (38), (79), (97), (112)
391-3-17-.06(5), (4)(c-e), (22), (23)
391-3-17-.02(20)
49 CFR Parts 171-178

Criteria:
In addition to the requirements in 391-3-17-.05(9) and (79), as applicable, mobile medical service licensees must comply with all other applicable regulations.

Discussion:
Applicants for licensure of mobile medical services should review Part 2 (Items 7 through 13) of the Georgia Radioactive Material Program's Medical Licensing Guide for information to be submitted as part of their applications; many of the requirements in these sections are relevant to the use of ***radioactive materials*** by mobile medical service providers, with details being dependent upon the scope of such programs. **"Temporary job site"** means a location, other than the specific location(s) of use authorized on the license, where mobile medical services are conducted. Mobile medical service licensees may transport licensed material and equipment into a client's building, or may bring patients into the transport (e.g., van). In either case, the van should be located on the client's property that is under the client's control. Mobile PET medical service licensees must consider a "quiet room" as an area of use if the patients in the "quiet room" cannot be released under the provisions of 391-3-17-.05(37). A self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client's site. Companies providing transportation only will not be licensed for medical use under 391-3-17-.05. Before using a remote afterloader for this type of service, the device should be installed in an appropriately shielded treatment room.

The general types of services provided as mobile medical services are:

Mobile medical services (radioactive material, trained personnel, and facility) that provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the client site. These mobile medical service providers are responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).
Mobile medical service providers (radioactive material and trained personnel) that provide transportation to and use of the radioactive material within the client's facility. These mobile medical service providers are also responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).

Mobile medical service licensees must ensure that the criteria in 391-3-17-.05(37) are met before releasing patients treated in their facilities.

Refer to the attached Appendix N for additional guidance on information to provide in applications.

APPENDIX N

Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of 391-3-17-.05 as well as DOT regulations with regard to approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, mobile medical service providers offering remote afterloaders must comply with 391-3-17-.05(67) through (84).

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of radioactive material within a transport vehicle (e.g., in-van use). A second type is transportation of radioactive material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

Whether a PET mobile medical service provider that uses a "quiet room" in the client's facility is authorized for "in-van use" or " transport and use" depends on whether the PET patients meet the criteria for release in 391-3-17-.05(37) while they are in the "quiet room." If they do not, then the "quiet room" is an area of use for the mobile service licensee.

For the first and second types, which include use by the service provider, the service provider should apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the radioactive material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the radioactive material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the radioactive material use and patient treatments upon transfer of the radioactive material to the client's possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with 391-3-17-.05(9), which states that the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by 391-3-17-.05(97). Additionally, as required by 391-3-17-.05(38)(f), the licensee must survey to ensure compliance with the requirements in 391-3-17-.03 (e.g., ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes, have been removed) before leaving a client's address.

The locations of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in

medical institution, noninstitutional medical practice, commercial facility, or mobile van. Applicants should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (nonlicensee) located within a licensed medical institution (e.g., hospital). As required by 391-3-17-.02(8) and 391-3-17-.05(8), applicants must submit a description and diagram(s) of the proposed base facility and associated equipment. The description and diagram of the proposed facility should demonstrate that the building (or van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 391-3-17-.03(5). Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van, the description of the van should address radiation levels in the van driver's compartment to demonstrate compliance with 391-3-17-.03(5), "Occupational dose limits for adults."

Applicants may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.

Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the radioactive material storage, provide for the following:
—Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
—Secured storage facilities available for storage of radioactive material and radioactive waste if the van is disabled; and
—Radioactive material delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.

If a base facility is located in a residential area, provide the following information:
—Justification of the need for a private residence location rather than for a commercial location.
—Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
—A description of the program demonstrating compliance with 391-3-17-.03(5), "Dose limits for individual members of the public."
—Verification that restricted areas do not contain residential quarters.

Perform surveys necessary to show that exposure rates do not exceed 2 mrem in any 1 hour nor 100 mrem per year.

Client Site

This section applies only to therapeutic uses of radioactive material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained radioactive material services (e.g., in-van), the following additional facility information should be provided:

For therapy treatments with radioactive material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;

A signed agreement, as delineated in the letter required by 391-3-17-.05(9), that location of the device/vehicle will be on client-owned or controlled property;

The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.

A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If transportable services will be provided to the client's site for use within the client's facility by the mobile medical service's employees, the following client facility information and commitment should be provided:

A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 391-3-17-.03(5). Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.

A commitment, as delineated in the letter required by 391-3-17-.05(9), that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.

The initial installation records and function checks of a remote afterloader device for each site of use, as required by 391-3-17-.05(74), (77) & (79). For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, ensure the following:

Each client is properly licensed for medical use of radioactive material. If applicable, licensees should ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.

No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of radioactive material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the radioactive material for patient treatments. The responsibilities for supervising individuals who use the radioactive material, set forth in 391-3-17-.05(18), transfer to the client's AUs upon transfer of the device to the client by the mobile medical service provider.

The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).

As required by 391-3-17-.01(4), a formal record of the transfer of control of the radioactive material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of radioactive material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

In addition to the requirements in 391-3-17-.07(3), 391-3-17-.05(18) requires that instructions be given to supervised individuals in written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of radioactive material. Additionally, 391-3-17-.05(18) requires the supervised individual to:

Follow the instructions of the supervising AU for medical uses of radioactive material;

Follow the instructions of the supervising ANP or supervising AU for preparation of radioactive material for medical uses;

Follow the written radiation protection procedures and written directive procedures established by the licensee; and

Comply with the provisions of 391-3-17-.05 (e.g., 391-3-17-.05(9) and (79) (if applicable)), and the license conditions with respect to the mobile medical use of radioactive material.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of 391-3-17-.07(3), 391-3-17-.05(18), 391-3-17-.05(49), 391-3-17-.05(58), and 391-3-17-.05(70) (as applicable). The training for these individuals will include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by 391-3-17-.05(9), instruments should be checked for proper operation before use at each address of use. Dosage measurement instruments should be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Radioactive material

Radioactive material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. Delivery of radioactive material to a van that is not occupied by the mobile medical service personnel will not be permitted. Alternatively, licensees may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with the Radiation Protection Program required by 391-3-17-.03(4). Indicate typical response times of the RSO and AU in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as wind, water, or fire, that results in damage to exterior or interior portions of the vehicle or the radioactive material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous-material (HAZMAT)-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel;

The emergency contact number for State of Georgia Radioactive Material Program;

Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;

Procedures for retrieving and securing any radioactive material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers;

Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios;

Preplanned decontamination procedures, including ready access to all necessary materials;

A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys;

Security of the transport vehicle against unauthorized access, including the driver's compartment; and

Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 391-3-17-.05(115) through (118), will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

Note:
The type of response should be consistent with the level of the incident. The response may range from telephone contact for minor spills to prompt onsite response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following takes place:

Radioactive material is transported in accordance with 49 CFR Parts 170–189. Procedures will include:
—Use of approved packages,
—Use of approved labeling,
—Conduct of proper surveys,
—Complete and accurate shipping papers,
—Bracing of packages,
—Security provisions, and
—Written emergency instructions.

Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.

Licensed material is secured during transport and use at the client's facilities.

Radioactive waste is handled properly during transport. Describe the method of storage and final disposal.

The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note:
The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT

Type 7A packaging may be compromised, and the device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management

If waste will be stored in vans, the vans must be properly secured and posted as radioactive material storage locations. Ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a radioactive material storage area.
Develop, document, and implement final waste disposal procedures.
Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewer system, in accordance with 391-3-17-.03(13c). However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewer system. If restroom facilities are provided in the van for patient use, submit the following information for NRC review:

A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van, and the driver of the van; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any I-131 will be held in the tank.

A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 391-3-17-.03(5), that the external surfaces of the van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.

A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services With Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

Conduct safety checks on a remote afterloader device and facility. The procedure will include the periodic spot checks required by 391-3-17-.05(77) and the additional spot checks required by (79) before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly.

The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.

Such tests should be performed in accordance with written procedures.

As required by 391-3-17-.05(110) and (112), records showing the results of the above safety checks must be maintained for NRC inspection and review for a period of 3 years.

Perform surveys of the source housing and areas adjacent to the treatment room following relocation of a high dose-rate unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

Reciprocity for Out-of-State Users of Radioactive Materials

The State of Georgia recognizes radioactive materials licenses issued by either the U.S. Nuclear Regulatory Commission (www.nrc.gov) or other Agreement States. A person may conduct activities within the State of Georgia for up to 180 days per calendar year under reciprocity. Once reciprocity is granted, you MUST notify the Radioactive Materials Program a minimum of three (3) days prior to beginning work in the state, each time you will be performing work in Georgia.

The following information will be needed before granting reciprocity:

1. Mail/Fax/Email a letter requesting reciprocity including a current copy of your Agreement State or NRC license to :

   Georgia Department of Natural Resources
   Environmental Protection Division, Air Protection Branch
   4244 International Parkway, Suite 120
   Atlanta, GA 30354
   Telephone: (404) 362-2675
   Fax: (404) 363-7100
   Email: rad.reciprocity@dnr.state.ga.us

2. Submit the appropriate reciprocity fee. The fee schedule can be found in section **391-3-17-.10 – Administration. Amended** – of the Georgia Rules & Regulations at the following link: http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=GEORGIA DEPARTMENT OF NATURAL RESOURCES%2FENVIRONMENTAL PROTECTION%2FRADIOACTIVE MATERIALS%2Findex.html&d=1. There are nominal annual, small entity and lower tier fee options that can be found in the fee rule section. If your company qualifies for either of the latter two options, please submit supporting documentation with your application. Appropriate documentation for the letter two options would be: (1) a profit-loss statement for the most recent year, or (2) a copy of the most recent year's tax filing. The documentation must show that the gross revenue was less than $3.5 million ($1 million private practice physician) for small entity, or less than $250,000 for lower tier.

   The fee must be submitted prior to: 1) issuance of reciprocal approval by the State of Georgia, and 2) any licensed activities being initiated by a prospective reciprocal licensee in the State of Georgia.

Once the request and appropriate fee have been received by the Program, you will receive the following:

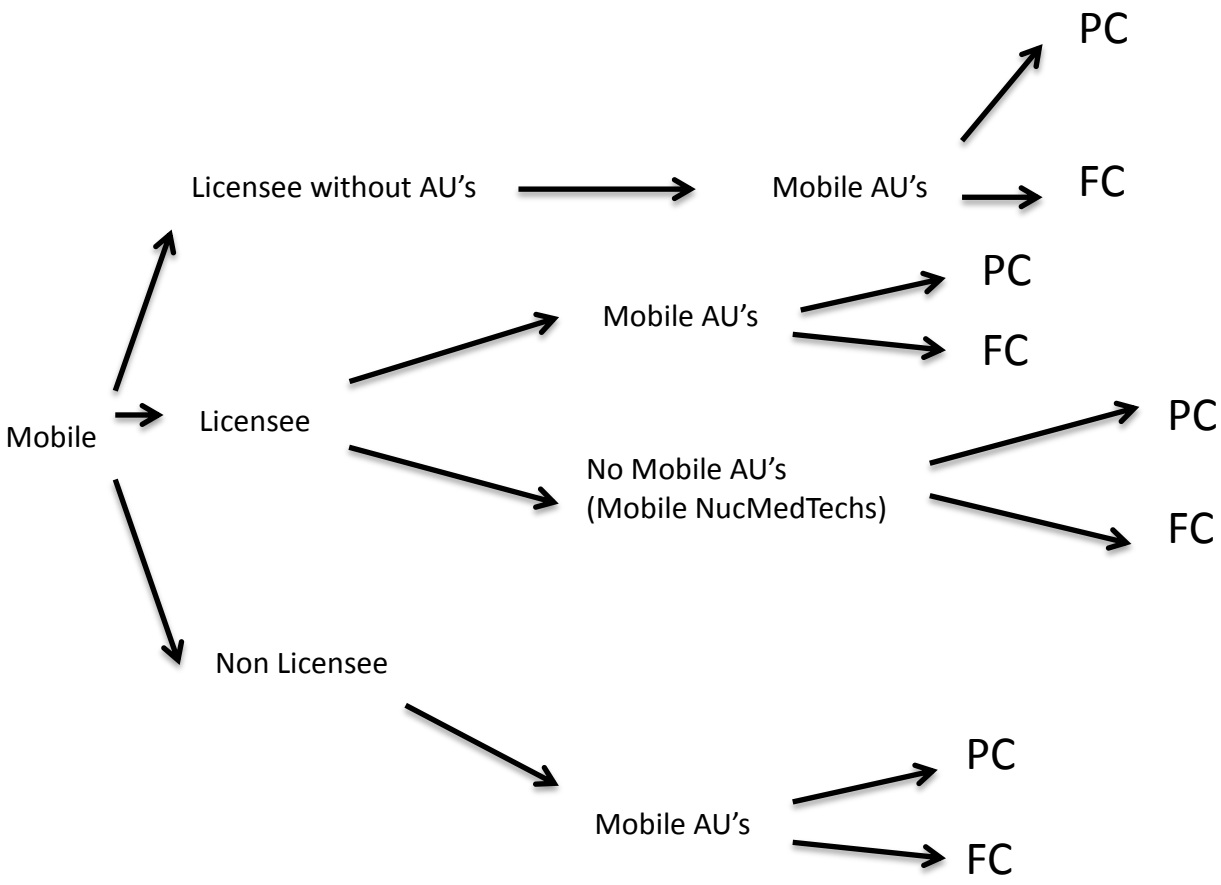
1. A letter granting you reciprocity
2. A Notice to Employee form
3. The program's Emergency Telephone Numbers

These items are required to be in your possession **at all times** when working in the State of Georgia under reciprocity. Reciprocity notification forms should be received in our office within three (3) days prior to performing work in the State of Georgia, each time you will be performing work in Georgia.

Note to Radiographers!

The State of Georgia requires a certified two-person crew for radiography.

Possibilities



PC = Portable Camera
FC = Fixed Camera
AU = Authorized User

GEORGIA MOBILE MEDICAL SERVICE RULES

Chapter 391-3-17-.05
(9) Mobile Medical Service Administrative Requirements

(a) The Department shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the clinic's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

(c) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(d) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with Rule .05(97).

(f) A mobile medical service licensee shall maintain on each mobile unit:

1. The current operating and emergency procedures;
2. A copy of the license;
3. Copies of the letter required by .05(9)(b);
4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

(g) A mobile medical service licensee shall maintain records required by Rules .03 and .05 of this Chapter at a location within the Department's jurisdiction that is:

1. A single address of use:

(i) Identified as the records retention location; and

(ii) Staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Department.

Chapter 391-3-17-.05

(38) Mobile Medical Service Technical Requirements. A licensee providing mobile medical service shall:

(a) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

(b) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

(d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

(e) Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Rule .03 of this Chapter;

(g) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and,

(h) Retain a record of each survey required by Rule .05(38)(f) in accordance with Rule .05(97)(b).

Chapter 391-3-17-.05

(97) Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by Rule .05(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by Rule .05(38)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.