

APPENDIX P-9

MOBILE MEDICAL SERVICE

General Information

Radioactive Material Licensees who are authorized to perform mobile medical services must comply with the requirements of RH-8425 and RH-8647, as well as all other applicable regulations.

Applicants for licensure of mobile medical services must review other Items of this Licensing Guide for information to be submitted as part of their applications; many of the requirements in these sections are relevant to use of radioactive material by mobile medical service providers with details being dependent upon the scope of such programs. Mobile medical service licensees may transport radioactive material and equipment into a client's building, or may bring patients into the transport vehicle (e.g., van). In either case, the vehicle must be located on the client's property that is under the client's control.

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 Section 9. Before using a remote afterloader for this type of service, the device must 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 the 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 RH-8420 are met before releasing patients treated in their facilities.

Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of Section 9 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 paragraphs RH-8630 through RH-8670.

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).

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 their possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with RH-8425, 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 RH-8425 and RH-8711. Additionally, as required by RH-8425, the licensee must survey to ensure compliance with the requirements in RH-1300 (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 location of use for mobile medical services is 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 a medical institution, non-institutional medical practice, commercial facility, or mobile van. The Applicant must specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital).

As required by RH-404 and RH-8010, the Applicant must submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Item 16 of the Application. 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 RH-1208. A diagram showing the location of the licensed material, receipt, and use areas, and the identity of all areas adjacent to restricted areas, including areas above and below the restricted areas must be included. For storage locations within a van, the description of the van must address radiation levels in the van driver's compartment to demonstrate compliance with RH-1200.

- The Applicant 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.
- Perform required radiation surveys to show that exposure rates do not exceed 2 millirem in any one hour nor 100 millirem per year.

Client Site

For all types of radioactive material 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 Applicant must provide the following additional facility information:

- 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 RH-8425, 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 the Applicant will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, the Applicant must provide the following client facility information and commitment:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 16 of the Application. 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 RH-1208. The Applicant must 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 RH-8425 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 RH-8641, RH-8644, and RH-8647.

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, the Applicant must ensure the following:

- Each client is properly licensed for medical use of radioactive material. If applicable, the Applicant must 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 RH-8306, transfer to the client's Authorized Users 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 RH-600, 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 RH-2803, RH-8306 requires that the Applicant will instruct supervised individuals in your written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of radioactive material. Additionally, as required by RH-8306, the Applicant will require the supervised individual to:

- Follow the instructions of the supervising Authorized User for medical uses of radioactive material;
- Follow the instructions of the supervising Authorized Nuclear Pharmacists or supervising Authorized User 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 Section 9, [e.g., RH-8425 and RH-8647 (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 RH-2803, RH-8306, RH-8551, RH-8603, and RH-8633 (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 RH-8425, the Applicant must check instruments for proper operation before use at each address of use. You will check dosage measurement instruments 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, the Applicant 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 safety program required by RH-1004. The Applicant must indicate typical response times of the RSO and Authorized User in the event of an event 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 must cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous material-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 numbers for the Department;
- 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 Authorized Medical Physicist. 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 RH-1502, 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 phone contact for minor spills to prompt on-site 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 170B189. 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 radioactive material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. The Applicant will 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 will be properly secured and posted as radioactive material storage locations. The Applicant will 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 in accordance with Item 19 of the Application.

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 sewerage system, in accordance with RH-1402. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system. If restroom facilities are provided in the van for patient use, submit the following information for Department 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 RH-1200 and RH-1208, that the external surfaces of the van do not exceed 2 millirem/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, you will develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted on a remote afterloader device and facility. The procedure will include the periodic spot checks required by RH-8644 and the additional spot checks required by RH-8647 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.
- The Applicant must maintain records, as described in RH-8726 and RH-8724, showing the results of the above safety checks for Department 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 HDR 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.