



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 5/11/09

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SEND TO: LAVRA SMITH - RPS

LOCATION: for Anil Goel, M.D.

FAX NUMBER: 313-343-7323 **VERIFY BY CALLING SENDER**

FROM: (SENDER) Colleen Carol Casey

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1078

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MESSAGE

Please call me if you have questions.

Thanks,

Colleen Carol Casey

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 515-1078

CONVERSATION RECORD

ACTUALLY FAXED? YES.

TIME DATE
*Reached Laura Smith
6:41 pm CT
5/11/09*

May 11, 2009

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Laura T. Smith consultant for

Dr. Anil K. Goel

cell:586-215-5947,
Pager: 313-609-2038
Fax:313-343-7323

SUBJECT

License No.: 21-32683-01

Control No.: 317919

SUMMARY

We have reviewed your letter dated February 4, 2009, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

attached

Your letter did not contain all of the information requested in Appendix V to NUREG 1556, Vol. 9, Rev. 2. I could not form a clear understanding of specifically what you are requesting authorization for in terms of a mobile service.

Please submit a complete response based upon the requested information, as it pertains to your proposed program. You may exclude the sections that address mobile therapy service.

For future reference, please always include the fax number for the person designated as the point of contact for your licensing requests.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

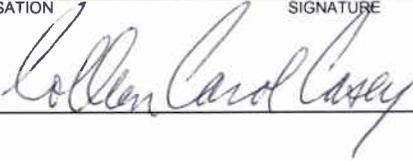
ACTION REQUIRED

As we cannot issue an amendment at this time we are voiding this request in order to enable you to prepare a quality application without time constraints. This is done without prejudice

to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA A WRITTEN RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS GENERALLY REGARDED AS A "GOOD THING."

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey		May 11, 2009

Guidance for Mobile Medical Services

With the implementation of the EPCRA, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, all the requirements for mobile medical services also apply to the mobile medical use of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Before submitting information to the NRC, review Section 5.2 of this document for guidance on identifying and protecting sensitive information. All security-related information in the application should be identified and properly marked.

Mobile medical service providers must comply with all applicable sections of 10 CFR Part 35 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 Subpart H of 10 CFR Part 35.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of byproduct material within a transport vehicle (e.g., in-van use). A second type is transportation of byproduct 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). As a result of the EPCRA, byproduct material now includes accelerator-produced radioactive materials and discrete sources of radium-226.

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 10 CFR 35.75 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 byproduct 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 byproduct material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the byproduct material use and patient treatments upon transfer of the byproduct material to the client's possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a), 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 byproduct 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 10 CFR 35.80(c) and 10 CFR 35.2080. Additionally, as required by 10 CFR 35.80(a)(4), the licensee must survey to ensure compliance with the requirements in 10 CFR Part 20 (e.g., ensure that all byproduct 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 a 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 10 CFR 30.33 and 10 CFR 35.12, applicants must submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 8.14 through 8.19 of this report. 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 10 CFR 20.1301. Include a diagram showing the location of the licensed material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226), 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 10 CFR 20.1201, "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 byproduct 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 byproduct material and radioactive waste if the van is disabled; and

- Byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226) 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 10 CFR 20.1301, "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 byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). 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 byproduct material services (e.g., in-van), the following additional facility information should be provided:

- For therapy treatments with byproduct 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 10 CFR 35.80(a), 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.

APPENDIX V

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 in accordance with Items 8.14 through 8.19 of this report. 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 10 CFR 20.1301. 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 10 CFR 35.80(a), that the mobile medical service licensee has full control of the treatment room during byproduct 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 10 CFR 35.633, 10 CFR 35.643, and 10 CFR 35.647.

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 byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). 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 byproduct 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 byproduct material for patient treatments. The responsibilities for supervising individuals who use the byproduct material, set forth in 10 CFR 35.27, 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 10 CFR 30.51, a formal record of the transfer of control of the byproduct 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 byproduct material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

In addition to the requirements in 10 CFR 19.12, 10 CFR 35.27 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 byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). Additionally, 10 CFR 35.27 requires the supervised individual to:

- Follow the instructions of the supervising AU for medical uses of byproduct material;
- Follow the instructions of the supervising ANP or supervising AU for preparation of byproduct material for medical uses;
- Follow the written radiation protection procedures and written directive procedures established by the licensee; and
- Comply with the provisions of 10 CFR Part 35 (e.g., 10 CFR 35.80 and 10 CFR 35.647 (if applicable)), and the license conditions with respect to the mobile medical use of byproduct 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 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (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 10 CFR 35.80, 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 Byproduct Material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226)

Byproduct 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 byproduct material ordered. Delivery of byproduct material to a van that is not occupied by the mobile medical service personnel will not be permitted.

Alternatively, licensees may pick up the byproduct 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 10 CFR 20.1101. 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 byproduct 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 numbers for NRC's Operation Center and all appropriate State radiological protection agencies;
- 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 byproduct 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 10 CFR 30.50, 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 (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226) 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 (this now includes waste containing accelerator-produced radioactive materials and discrete sources of radium-226)

If waste will be stored in vans, the vans must be properly secured and posted as byproduct material storage locations. Ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a byproduct material storage area.

Develop, document, and implement final waste disposal procedures in accordance with Section 8.28 of this report.

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 10 CFR 20.2003. 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 10 CFR 20.1201 and 20.1301, 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 10 CFR 35.643 and the additional spot checks required by 10 CFR 35.647 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 10 CFR 35.2647 and 10 CFR 35.2643, 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.

TRANSMISSION VERIFICATION REPORT

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4-2004



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
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SEND TO: LAURA SMITH - RRS

LOCATION: for Amir Guel, MD

FAX NUMBER: 313-343-7323 **VERIFY BY CALLING SENDER**

FROM: Colleen Carol Casey
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1078

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MESSAGE