From:	Sara Forster
To:	MARK PERNA
Cc:	sean.smith@wvumedicine.org
Subject:	Additional Information Request re Amendment to Camden-Clark Memorial Hospital Corporation, NRC License No. 47-09772-02, CN 636417
Date:	Friday, September 1, 2023 4:25:00 PM
Attachments:	02230.636417.47-09772-02 CamdenClark Memorial Hospital RFAI enclosure from NUREG 1556 Vol. 9 rev. 3 re HDR ML19256C219 sf 20230901.pdf

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Good afternoon, Mark:

As we discussed via telephone this afternoon, Friday, September 1, 2023, the U.S. Nuclear Regulatory Commission (NRC) has received and reviewed your amendment request to add a new model HDR and a new HDR facility to the above-referenced license. The review was completed in accordance with NRC's medical licensing guidance, NUREG 1556, Volume 9, revision 3, published in September 2019. As noted in our conversation, some additional items are needed to complete the review. For your convenience, the most applicable information from the NUREG 1556, Volume 9, revision 3, guidance volume are included in the Attachment to this email message.

1. Although the amendment request stated that a Model BRAVOS 232A HDR and source should be added to the license, it was unclear whether the maximum possession limits to be listed in Subitem No. 8.D., or maximum activity at time at medical use, in Subitem No. 9.D., should be updated.
   Please clarify whether both the maximum authorized per-source possession limit, and the maximum-authorized medical-use source strength should both remain at 12 curies, as current authorized on the license. If one or both of those values should be increased, please clarify those changes.

2. Although the request provided an overall facility diagram, drawn to scale, containing both the existing and proposed HDR facilities, no diagram specific to the new proposed area of use was included in the letter.
   Please refer to NUREG 1556, Volume 9, revision 3, pp. 8-45 to 8-51 and Appendix C, p. C-23 for specific details on information that should be included in the diagram for any new HDR area of use. If nothing about the facility is changing from your 2015 license application, please clarify that in your response. Please note that a shielding evaluation should be included with the request, specific to the maximum source activity to be permitted at medical use. The

3. Although the request committed the licensee to all the elements of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.643, 10 CFR 35.12(b)(2) requires that the spot-check procedure be submitted as part of the amendment request. No spot-check procedure was included in the application, and no statement was found indicating that the 2014 procedure submitted in 2015 would remain in effect.
   Please either confirm that the previously submitted HDR remote-afterloader unit spot-check procedure remains in effect, OR provide a copy of the spot-check procedure to be provided to authorized individuals, for use with the new BRAVOS 232A HDR device. Please refer to NUREG 1556, Volume 9, revision 3, pp. 8-55 to 8-57 and Appendix C, p. C-24 for specific details on

information that should be included in an updated spot-check procedure. Note that a Model Spot-Check procedure may be found in Appendix H to NUREG 1556, Volume 9, revision 3, pp. H-1 to H-4.

4. Although the request described some of the additional facility and equipment details required by 10 CFR 35.610 and 35.615, it was unclear whether any changes to previously authorized HDR facilities and equipment would be implemented.
   Please clarify how any previously submitted HDR remote-afterloader equipment and facility details, as required by 10 CFR 35.610 and 35.615, are being modified in conjunction with the new model HDR. Please refer to NUREG 1556, Volume 9, revision 3, pp. 8-57 to 8-60 and Appendix C, p. C-25 for additional information that should be provided for HDR facilities and equipment.

5. Although the request was for a model not included in previously submitted and required 10 CFR 35.610 emergency procedures, no updated emergency procedure for the Model BRAVOS 232A HDR was included in the application. Updated emergency procedures reflecting the new model are required, per 10 CFR 35.12(b)(2).
   Please provide a copy of the Model BRAVOS 232A HDR abnormal situation procedure, described in 10 CFR 35.610(a)(4) to be physically located at the new BRAVOS 232A HDR device console. Please refer to NUREG 1556, Volume 9, revision 3, pp. 8-74 to 8-76 and Appendix C, p. C-26 for specific details on information that should be included in an updated spot-check procedure.

Please provide the additional requested information as a signed and dated letter, as a pdf file attached to an email, within the next 14 days. If you are unable to provide the information by September 15, 2023, please indicate the date by which you will be able to respond to the request. Also, note that we understand that this is an expedited review request, and we will do our best to complete the amendment once the additional information is received. If you have any questions, please do not hesitate to call or email me.

Sincerely,

Sara

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8.9.1 Facility Diagram

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	
600	✓
1000	✓

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 30.33(a)(2), 10 CFR 35.12, 10 CFR 35.13, 10 CFR 35.14, 10 CFR 35.18(a)(3), 10 CFR 35.75, 10 CFR 35.315(a), 10 CFR 35.415, 10 CFR 35.615

Criteria: To issue a license, the NRC must find that facilities and equipment are adequate to protect health and minimize danger to life or property, as required under 10 CFR 30.33(a)(2) and 10 CFR 35.18(a)(3). In accordance with 10 CFR 20.1101, the licensee must design facilities to ensure occupational doses and doses to members of the public are ALARA.

Discussion: Applicants must describe the proposed facilities and equipment, as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. The facility diagram should include the room or rooms where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property. Because of the low energy of radionuclides used in nuclear medicine departments for diagnostic studies, a description of adjacent areas is unnecessary.

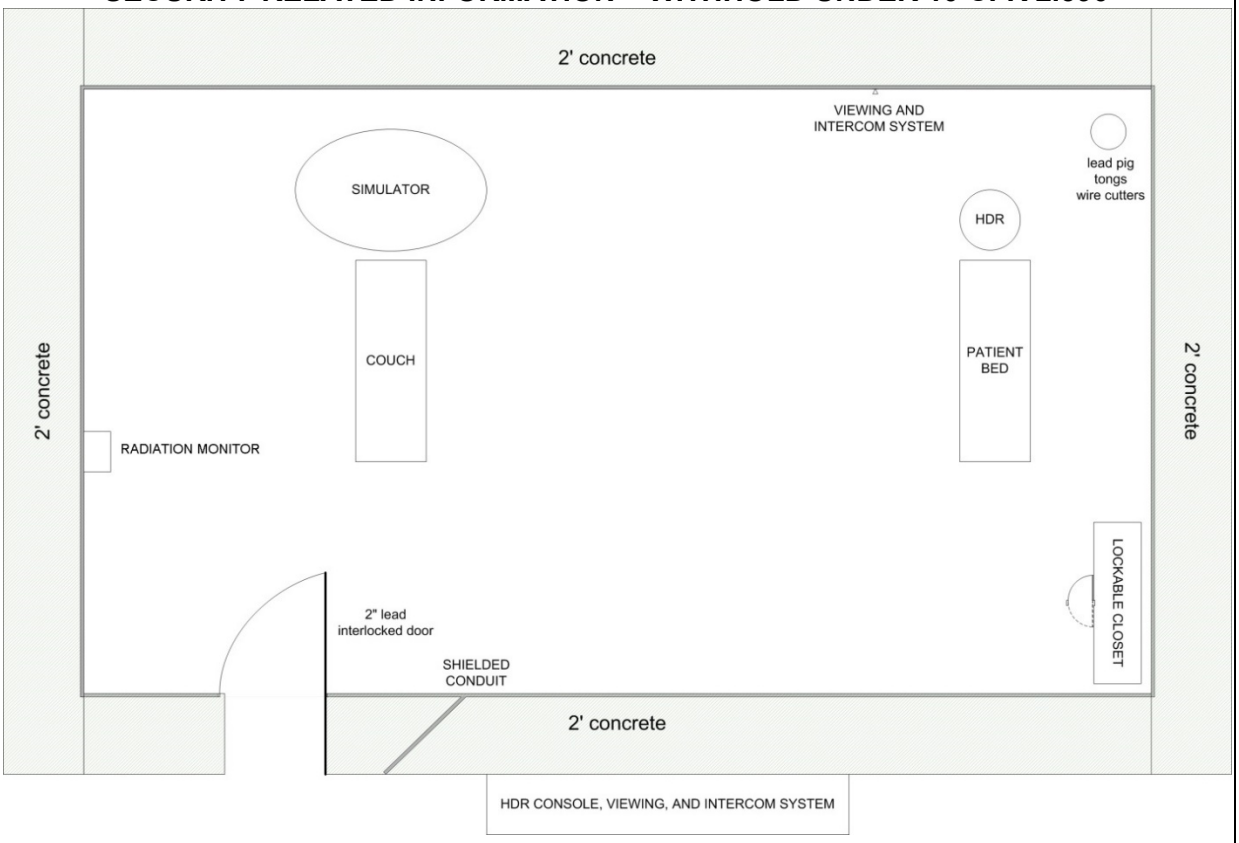
However, if PET radionuclides are used, a description of the specialized PET facilities should be provided. The description should include facility diagrams, the shielding installed, specialized handling equipment, and survey results to ensure that the regulatory limits in 10 CFR 20.1201, "Occupational dose limits for adults," and 10 CFR 20.1301, "Dose limits for individual members of the public," are not exceeded. The applicant should demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded and how access will be controlled in accordance with 10 CFR 20.1601 and 10 CFR 20.1602. If the facility descriptions or calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information – Withhold Under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information."

.... [OMITTED CONTENT IRRELEVANT TO HDR] ...

For types of use permitted by 10 CFR 35.600 and as required by 10 CFR 35.615, the applicant should provide a diagram and the shielding calculations for the facility. See Figure 8-5 for an example of a basic diagram. The applicant's diagram should be based on proposed room layout and shielding.

~~SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*~~



Iridium (Ir)-192 gamma constant from NCRP Report No. 49: 4.8 roentgen-cm^{2}h^{-1}mCi^{-1}
Ir-192 Tenth Value Layer from NCRP Report No. 49: 2 cm lead, 14.7 cm poured concrete
XX centimeters (cm) of lead† or XX cm of poured concrete† will be in doors, walls, ceiling, and floor.

~~SECURITY-RELATED INFORMATION—WITHHOLD UNDER 10 CFR 2.390*~~

*For the purpose of this NUREG, the facility diagram is marked appropriately for an application. This particular diagram does not contain real security-related sensitive information.

†NCRP report Numbers 49 and 151 provide guidance on determining appropriate thicknesses based on the assumed beam on-time, distances, and maximum loading to meet the regulatory requirements in 10 CFR 20.1301. Applicants should provide assumptions used in their calculations to determine these thicknesses.

Figure 8-5. Facility Diagram for HDR Suite

When preparing applications for use under 10 CFR 35.1000, applicants should review the guidance on the Medical Uses Licensee Toolkit Web page to determine the type of information appropriate to evaluate the adequacy of the facilities.

All limited, specific medical use licensees are required by 10 CFR 35.13, "License amendments," to obtain a license amendment before adding to or changing an area of use identified in the application or on the license. However, changes and additions to the 10 CFR 35.100 and 10 CFR 35.200 medical use areas located in the same address of use do not require a license amendment and can be made, provided the NRC is notified, as required by

10 CFR 35.14, within 30 days following the changes. The broad scope medical use licensee does not have to notify NRC of changes that do not require a license amendment.

Response from Applicant: All medical use applicants, including broad scope medical use applicants, are required to provide facility diagrams.

Provide the following:

- Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
- Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.
- Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET).
- Doors should be indicated, and specify which doors are access controlled (i.e., locked).
- Shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use, High Dose-Rate/Pulsed Dose Rate and Low-Dose Rate Remote Afterloaders, Teletherapy, and Gamma stereotactic radiosurgery (GSR). Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.
- For PET, radiopharmaceutical, and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

  ... [OMITTED CONTENT IRRELEVANT TO HDR] ...

Note: The applicant should follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if the response includes security-related sensitive information and needs to be marked accordingly.

References and Resources:

- National Council on Radiation Protection and Measurements (NCRP) Report No. 40, "Protection Against Radiation from Brachytherapy Sources," 1972.
- NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of XRays and Gamma Rays of Energies up to 10 MeV," 1976.
- NCRP Report No. 102, "Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)," 1989.
- NCRP Report No. 151 "Structural Shielding Design and Evaluation for Megavoltage and Gamma-Ray Radiotherapy Facilities," 2005.

8.9.4 Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use

Regulations: 10 CFR 30.33(a)(2), 10 CFR 35.12(c)(2), 10 CFR 35.432, 10 CFR 35.433, 10 CFR 35.630, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645, 10 CFR 35.652

Part 35	Applicability
100	
200	
300	
400	✓*
500	
600	✓*
1000	✓
*Special requirements re: brachytherapy and LDR afterloader sources and Sr-90 sources.	

Criteria: The above regulations contain NRC requirements for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For manual brachytherapy sources and low-dose rate (LDR) remote afterloader sources, licensees may use source activity or output determined by the manufacturer, provided that the manufacturer's measurements meet applicable requirements. Similar provisions are included in licensing guidance for certain therapy 10 CFR 35.1000 medical uses. See NRC's Medical Uses Licensee Toolkit Web page for specific information.

Discussion: Manual brachytherapy sources and LDR remote afterloader sources are often measured by the manufacturer for source output or activity. In accordance with 10 CFR 35.432, if the manual brachytherapy source output or activity is not determined by the manufacturer, the licensee must perform a calibration prior to medical use. Manual brachytherapy sources must be calibrated only initially, prior to use. For all other sealed sources used in a therapy unit, the licensee must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 10 CFR 35.630, "Dosimetry equipment." For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

Licensees must perform full calibrations before first medical use and at intervals as defined in 10 CFR 35.632, 10 CFR 35.633, and 10 CFR 35.635. In addition, licensees must perform full calibrations whenever one of the following conditions are met:

- spot-check measurements (if required) indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for decay
- following replacement of the sources or reinstallation of the unit in a new location not previously described in the license
- following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly

If the licensee seeks authorization for a medical use under 10 CFR 35.1000, the licensing guidance on NRC's Medical Uses Licensee Toolkit Web page should be reviewed to determine if calibration and use procedures need to be submitted for that 10 CFR 35.1000 medical use.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, American College of Radiology, ANSI). Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of Sr-90 sources. In accordance with 10 CFR 35.433, the licensee's AMP or ophthalmic physicist must calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic therapy. The calibration procedures for therapy sources should address, in part, the method used to determine the exposure rate (or activity) under specific criteria (e.g., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate).

In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645). These procedures must be submitted in accordance with 10 CFR 35.12(b)(2). Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. See Appendix H of this NUREG for model procedures for performing spot-checks of remote afterloader devices. In addition, AAPM Report No. 41, "Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41)," 1993, may also be helpful.

In accordance with 10 CFR 35.652, licensees must perform surveys around therapy devices to ensure that the maximum radiation levels and the average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed the levels stated in the SSD registry.

Response from Applicant: Provide the following:

- The applicant must provide the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.

- The applicant for a medical use under 10 CFR 35.1000 should provide the procedures required by 10 CFR 35.12(b)(2) that are described in the licensing guidance posted for that 10 CFR 35.1000 medical use on NRC's Medical Uses Licensee Toolkit Web page, or explain why the procedure is not provided.

References and Resources:

- AAPM Task Group No. 21, "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams," 1983.

- AAPM Report No. 46, "Comprehensive QA for Radiation Oncology, (Radiation Therapy Committee Task Group No. 40)," 1994.

- AAPM Report No. 54, "Stereotactic Radiosurgery," 1995.

- AAPM Report No. 59, "Code of Practice for Brachytherapy Physics, (Radiation Therapy Committee Task Group No. 56)," 1997.

- AAPM Report No. 61, "High Dose-Rate Brachytherapy Treatment Delivery, (Radiation Therapy Committee Task Group No. 59)," 1998.

- AAPM Report No. 67, "Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams, Medical Physics 26(9), pp. 1847-1870, (Radiation Therapy Committee Task Group No. 51)," September 1999.
- AAPM Report No. 68, "Permanent Prostate Seed Implant Brachytherapy, (Radiation Therapy Task Group No. 64)," October 1999.
- AAPM Report No. 84, "Update of AAPM Task Group No. 43 Report: A Revised AAPM Protocol for Brachytherapy Dose Calculations," February 2004.
- Erratum: "Supplement to the 2004 update of the AAPM Task Group No.43 Report," December 2004.
- AAPM Report No. 84S, "Supplement to the 2004 Update of the AAPM Task Group No. 43 Report," June 2007.
- NCRP Report No. 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," 1981.

8.9.5 Other Equipment and Facilities

Regulations: 10 CFR 20.1101, 10 CFR 20.1901, 10 CFR 20.1902, 10 CFR 30.33(a)(2), 10 CFR 35.12, 10 CFR 35.415, 10 CFR 35.610, 10 CFR 35.615

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Applicants must describe the proposed facilities and equipment, as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. The applicant should describe, in Item 9 of the application, any other proposed equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application. In accordance with 10 CFR 20.1901 and 10 CFR 20.1902, the applicant should ensure that the facilities include the appropriate caution signs and postings. For uses authorized by 10 CFR 35.400, 10 CFR 35.600, and 10 CFR 35.1000, as applicable, applicants are required to provide a description of emergency response equipment. In addition, the items below describe other necessary radiation safety equipment.

For PET radionuclide use: The applicant should focus on remote handling devices and storage containers that may be needed when handling and storing the higher energy emissions of these materials. AAPM Task Group 108, "PET and PET/CT Shielding Requirements," provides additional information on this topic, such as the use of tungsten syringe shields or automatic dispensing systems to reduce exposure.

For radiopharmaceutical therapy: The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations described in Section 8.9.1 (e.g., patient rooms). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., a fume hood) and consider the hazards from airborne I-131. Additionally, for both liquid and capsule form of I-131, applicants should

recognize the source of potential contamination from I-131 found in the patient's urine, perspiration, saliva, and other secretions.

For manual brachytherapy: The applicant should describe the emergency response equipment and its availability in accordance with 10 CFR 35.415.

For teletherapy, GSR, and remote afterloader (LDR, MDR, PDR, and HDR) facilities: The applicant should focus on facilities and equipment necessary to comply with 10 CFR 35.610 and 10 CFR 35.615:

- Appropriate radiation monitors to be used by any individual entering the treatment room to ensure that radiation levels have returned to ambient levels. One method of meeting this requirement is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source.

- Equipment or methods to be used to prevent dual operation of more than one radiation-producing device (e.g., linear accelerator, X-ray machine) in a treatment room, if applicable.

- Methods used to ensure that console keys will be inaccessible to unauthorized persons when the device is not in use or is unattended.

- Except for LDR remote afterloaders, a system for continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again.

- Except for LDR afterloaders, a system for communication with the patient in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

- An electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened. The interlock system must also prevent the operator from initiating a treatment cycle, unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the on-off control for the source(s) is reset at the console.

- ... [OMITTED CONTENT IRRELEVANT TO HDR] ...

If the alarm circuit is inoperative for any reason, licensees should prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Response from Applicant:

Provide the following, if applicable:

... [OMITTED CONTENT IRRELEVANT TO HDR] ...

For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

- warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room
- area radiation monitoring equipment
- viewing and intercom systems (except for LDR units)
- steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room
- methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons
- emergency response equipment

For 10 CFR 35.1000 medical uses, review the licensing guidance posted for that 10 CFR 35.1000 medical use on NRC's Medical Uses Licensee Toolkit Web page and provide the appropriate descriptions of other equipment and facilities.

***Note**:* Follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if the response to this section includes security-related sensitive information and needs to be marked accordingly.

Reference:

- NCRP Report No. 88 - Radiation Alarms and Access Control Systems, 1986

8.10.6 Emergency Procedures for Therapy Devices Containing Sealed Sources

Regulations: 10 CFR 35.12(c)(2), 10 CFR 35.610, 10 CFR 35.615

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

Criteria: Before using materials under 10 CFR 35.600, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit," the applicant must develop, document, implement, and submit written emergency procedures in accordance with 10 CFR 35.12(b)(2). Regulations in 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a GSR unit. The procedures needed to meet 10 CFR 35.610 must include

- instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions
- the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure
- the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally

A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

Regulations in 10 CFR 35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require the physical presence of certain individuals for therapy units to ensure that safety precautions are appropriately implemented. The following documents provide useful information regarding physical presence requirements:

- IN 2012-08, "High Dose-Rate Remote Afterloader (HDR) Physical Presence Requirements," April 10, 2012
- RIS 2005-23, "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments," October 7, 2005

When sources are placed within the patient's body, 10 CFR 35.615(e) requires that licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source.

... [OMITTED CONTENT IRRELEVANT TO HDR] ...

Discussion: The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. The licensee must provide instructions, initially and annually, to include responding to an abnormal situation described in 10 CFR 35.610(a)(4). Practice drills, using nonradioactive (dummy) sources when possible, must be practiced at least annually and may be conducted more frequently, as needed. Team practice is important for adequate emergency coordination. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators, if applicable, and emergency procedures for removing the patient from the radiation field. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.

- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing the safety of the patient.

- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.

- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.

- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).

- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.

- Specifying who is to be notified.

- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Response from Applicant: Provide procedures required by 10 CFR 35.610.

If appropriate, review 10 CFR 35.1000 medical use licensing guidance on NRC's Web site Medical Uses Licensee Toolkit Web page, and provide safety and emergency procedures requested for the particular 10 CFR 35.1000 medical use.

Model Procedures for Remote Afterloader Spot-Checks

This model provides acceptable procedures for performing spot-checks of Remote Afterloader units, equipment, and facilities as required in 10 CFR 35.643. This procedure applies to high dose-rate, medium dose-rate, pulsed dose-rate, or low dose-rate (LDR) remote afterloader units. Applicants may either adopt these model procedures or develop alternative procedures.

Periodic Spot-Checks for Remote Afterloader Units

Before the first use on a given day (or before each patient treatment for LDR remote afterloaders) and after each source installation, the following spot-checks will be performed:

- Electrical Interlocks at Each Room Entrance

Proper functioning of the treatment room door interlock will be performed using the remote afterloader source.

Expose the remote afterloader source inside the treatment room, open the treatment room door, and verify that the source retracts. The source should retract immediately, the area radiation monitor should alarm, and the control console should indicate that the door is open. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Source Exposure Indicator Lights

  — Treatment Console Indicators and Status Lamps

    Turn on the remote afterloader unit and verify that the indicator lights flash to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the treatment console are lit to indicate an exposed source.

  — Remote Afterloader Indicators and Status Lamps

    Turn on the remote afterloader unit and verify that the indicator lights flash on the remote afterloader to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the remote afterloader are lit to indicate an exposed source.

- Viewing and Intercom Systems

  — Viewing System

    Turn on the camera(s). Check that the camera(s) is (are) operable and that the treatment area can be viewed from the treatment console. Adjust, if necessary.

  — Intercom System

    Turn on the intercom system. The intercom system will be tested using a two-person method. One person will be at the treatment console while another

person is in the treatment room. Both individuals will speak and confirm that the other is heard.

- Emergency Response Equipment

  Verify the presence of the emergency equipment within the treatment room. This equipment includes but is not limited to a mobile lead container large enough to hold the largest applicator, long-handled forceps, wire cutter, flashlight, suture removal kit, and timer (timer located at unit console). If a portable radiation survey meter is included, verify the presence, current calibration of the meter and check the operability using a radioactive check source.

- Radiation Monitors Used to Indicate the Source Position

  Verify that the area radiation monitor located inside the treatment room is on with the indicator light flashing green. Expose the remote afterloader source inside the treatment room with the door closed and verify that the indicator light flashes red; indicating the presence of radiation. This test will be performed with the area radiation monitor on *A/C* power and on battery backup power.

- Timer Accuracy

  Expose the remote afterloader source inside the treatment room with the door closed. Immediately start a stopwatch when the control console indicates that the source is exposed. Stop the stopwatch when the control console indicates that the source is retracted. Compare the stopwatch measured time to the irradiation time indicated on the control console. Verify that the comparison is within 1 percent.

- Clock Date and Time in the Computer for the Remote Afterloader

  Verify clock date and time printed on the control console documentation of the pretreatment checks against the actual date and time. The date must be exact, and the time may be within 1 hour.

- Decayed Source Activity in the Computer for the Remote Afterloader

  Verify the source activity (or decay factor) displayed on the remote afterloader control console matches to within 0.5 percent of the manufacturer's provided decay table for today's date.

If the results of the above checks indicate the malfunction of any system, the control console shall be locked in the off position, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.643(e), and not used except as may be necessary to repair, replace, or check the malfunctioning system.

In addition, consideration will be given to testing the following before the first use of the remote afterloader unit on a given day:

- Treatment Interrupt Button

  Press the “Interrupt” button on the control console while source is exposed. Verify that the source retracts immediately, and the control console indicates an alarm. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Emergency Off Button

  Press the “Stop” button on the control console while the source is exposed. Verify that the source retracts immediately, and the control console indicates an alarm. Repeat the test for all wall-mounted “Stop” buttons. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Dual Use Switch

  An X-ray unit is also used in the remote afterloader treatment room, and a selector switch to limit operation to only one unit at a time is installed.

  With the key switch on the wall set to X-ray, attempt to expose the remote afterloader source. Verify that the area radiation monitor and the control console source indicator lights do not illuminate; indicating that the source did not expose. Switch the key to remote afterloader. Expose the remote afterloader source and confirm that the area radiation monitor illuminates. With the remote afterloader source still exposed, switch the key back to X-ray, and confirm that the remote afterloader source retracts and the area radiation monitor flashes green. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Misconnected or Missing Transfer Tube and/or Applicator

  Misconnect a transfer tube to the remote afterloader. This may either be performed by connecting the transfer tube to the wrong channel or by not fully inserting the transfer tube into the correct channel. Attempt to expose the remote afterloader source and verify that the source does not expose as indicated by the area radiation monitor. Additionally, verify that an error is indicated on the control console for the misconnection. Repeat the test with an applicator intentionally misconnected to a transfer tube that is correctly inserted into the remote afterloader.

- Mechanical Integrity of Applicators, Transfer Tubes, Connectors

  Perform a visual inspection of all applicators, transfer tubes, and connectors to be used for patient treatments that day. Check for any potential mechanical defects. Replace if a defect is noted.

- Position of Remote Afterloader Within the Treatment Room

  For some remote afterloader units located within minimally shielded rooms, the location of use within the room may have been specified in the application to ensure that the regulatory limits in 10 CFR 20.1301 will not be exceeded. If this is the case, verify that the positioning of the remote afterloader unit within the treatment room is in accordance with the commitments made in the application.

References and Resources:

AAPM Report No. 41, "Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41)," 1993