Georgetown University Hospital

MedStar Health

J-9

July 19, 2010

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Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

03035409

Reference: License #08-30577-01 Renewal Application Additional Information

Dear Sir/Madam,

The Medstar Georgetown Medical Center, Inc. (MGMC) submitted a license renewal application on May 27, 2010. It has since come to our attention that information provided in the application is not consistent with current practices at our facility and proposed changes are documented below in Items A-L:

A. Section 7: D. Staffing of the MGMC Radiation Safety Program should be replaced with the following:

The RSO is supported and assisted in carrying out the duties and responsibilities by:
Deputy RSO
1 Health Physics Technician
1 part-time Dosimetry Clerk

MGMC proposes to have Auroba Al-Samaraee, M.Sc. serve as the Interim RSO for this program. Her resume is in Attachment 7D. The proposed Interim RSO for this facility has a Masters Degree in Medical Radiation Physics with post graduate certificate in Radiation Safety with more than 25 years of experience in both Health Physics and Diagnostic Medical Physics. Her experience in radiation health physics meets the requirements in 10 CFR 35.50 and 10 CFR 35.57.

The Radiation Safety Committee may appoint Deputy Radiation Safety Officer(s) who would be responsible for assuring continued compliance with U.S. Nuclear Regulatory Commission requirements during short absences of the Radiation Safety Officer and who would be delegated authority to sign records and reports as required by the regulations. These individuals would be directly responsible to the RSO and to the RSC. All required records and reports will be reviewed and certified by the RSO upon his/her return.

B. Section 9: Facilities and Equipment

MGMC Hospital Campus: Bles Building

1. Remove #1.

2. Lower Level Radiation Medicine Departments: Storage of materials for prostate seed brachytherapy and other sealed sources in the area marked "Hot Lab".

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NMSS/RGN1 MATERIALS-002

C. Section 10.1 B. Radiation Safety Officer and Staff Audits

The title should be changed to B. Radiation Safety Officer and Staff Audits, Inspection and Surveys

Monthly Audits should be changed to Monthly Inspections, and Surveys

D. Section 10.3 Material Receipt and Accountability

Section B. Radiation Medicine should be replaced with the following content:

1. An authorized staff member (e.g., medical physicist or dosimetrist) will order radioactive materials within the possession quantities authorized by the license.

2. An established system for ordering and receiving radioactive material is maintained by the Radiation Medicine Department. Records will be maintained that identify the isotope, type of sealed source, activity, and supplier. Examples of deliveries include, but are not limited to sealed sources of Iridium-192 for the HDR unit, and brachytherapy sources. Required package surveys and source tests must be performed by RSOS Staff and the record of receipts and checks maintained for review.

3. For deliveries during normal working hours, the Medical Physicist or Dosimetrist will tell venders to ship radioactive packages directly to the Department of Radiation Safety so they can be secured.

For deliveries during off-duty hours, the package will be placed in a secure area (Department of Radiation Safety) by the delivery driver from the contracted vendor. Access to this area is controlled via a locked room. The RSO's contact information is posted on the office door and available to the driver and other staff personnel if required.

Section D Transfer of Radioactive Materials second paragraph should be replaced with the following:

A record of the transfer is made to update all appropriate RAM inventory records. Nuclear Medicine may not return unit doses to the radiopharmacy without notifying RSOS.

E. Section10.4 Occupational Dose

A. Surveys

The first paragraph should be replaced with the following paragraph:

For the clinical use of radiopharmaceuticals, such as those used in the Nuclear Medicine Department and sealed source use areas of the Radiation Medicine Department, MGMC has established and implemented the model procedure for area surveys published in Appendix R of NUREG 1556, Volume 9, Revision 2.

For the medical radiopharmaceuticals, MGMC will follow Table R.2 "Surface Contamination Levels in Restricted Areas" and Table R.3 "Surface Contamination Levels in Unrestricted Areas".

For the research nuclides, MGMC will follow the guidelines in the table below

Action Levels for Surface Contamination in Research Laboratories		
	Alpha Emitters	**Beta, Gamma or X-ray Emitters**
Unrestricted Areas, personal clothing	20 dpm/100 cm^2	200 dpm/100 cm^2
Restricted areas, protective clothing used only in restricted areas, skin	200 dpm/100 cm^2	2,000 dpm/100 cm^2

F. Section 10.7 Surveys and Leak Tests

Sealed Sources: Paragraph 6 should be replaced with the following paragraph:

The leak test will be capable of detecting the presence of 0.005 microcuries (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcuries (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. NRC in accordance with 10 CFR 30.50(c)(2) and in 10 CFR 35.3067 for those sealed sources used in medicine. The source will be removed immediately from service and decontaminated, repaired, or disposed of in accordance with NRC requirements.

G. Appendix A: FC86-4 Information Required for Licensing Remote After Loading Devices

References to Varying in Appendix A should be replaced with Varian.

V. Facilities

A. Treatment Room should read HDR Treatment Room, LL Bles Building

H. MGMC Quality Management Program for HDR Brachytherapy

The existing MGMC Quality Management Program for HDR Brachytherapy should be replaced with the content in the Revised MGMC Quality Management Program for HDR Brachytherapy.

I. HDR Brachytherapy

Paragraph 5 Safe Operating Procedures first sentence should reference 10 CFR 35.643(d) as indicated below:

Safe Operating Procedures
Before each day of use, safety checks developed by the AMP will be performed by authorized staff. This day-of-use check is meant to fulfill the requirements of 10 CFR 35.643 (d), since treatments are performed at least weekly.

J. Permanent Implant Brachytherapy

The existing Permanent Implant Brachytherapy should be replaced with the content in the Revised Permanent Implant Brachytherapy.

K. Permanent Implant Brachytherapy Procedures Radiation Medicine Department MGMC

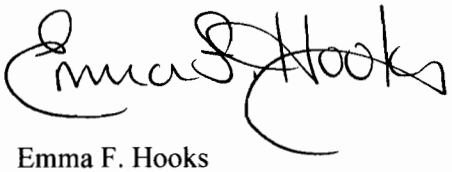
The existing Permanent Implant Brachytherapy Procedures Radiation Medicine Department MGMC should be replaced with the content in the Revised Permanent Implant Brachytherapy Procedures Radiation Medicine Department MGMC

L. Appendix C of the license renewal application.

A revised Appendix C is attached and should replace the version that was sent in the initial renewal application.

Thank you for your attention regarding this matter. Please contact me at (202) 444-4657 should you have any questions.

Sincerely,



Emma F. Hooks
Executive Administration Representative to the Radiation Safety Committee
Assistant Vice-President, Safety Management & Environmental Quality

Attachments

MGMC
Quality Management Program for HDR Brachytherapy
Revised 7/19/2010

Purpose: The policies and procedures described in this document refer to the administration radiation for therapeutic purposes utilizing the High Dose Rate (HDR) brachytherapy remote afterloader and have been developed in compliance with the established regulations described in 10 CFR Part 35.

Written Directive:

Prior to the administration of HDR Brachytherapy treatment, an authorized user or physician under the supervision of an authorized user will sign and date a prescription or written directive.

This written directive will include the treatment site, the radioisotope and the total prescribed dose.

If, because of the emergent nature of the patient's condition, a delay in the order to provide a written directive would jeopardize the patient's health, an oral directive or an oral revision to an existing written directive may be given, provided that the oral revision or directive is immediately documented in the patient's record and that a confirming written directive is prepared, signed and dated by the authorized user within 24 hours of the oral directive or revision.

A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the HDR dose.

Verification of Patient Information:

Prior to the administration, a member of the treatment staff (therapist, nurse, Authorized User or physicist/dosimetrist) will verify by more than one method the identity of the patient as the individual in the written directive The procedure used to identify the patient should be to ask the patient's name and confirm that name by comparing with corresponding information in the patients record such as: birth date, address, social security number, signature, or printed name on any identification card e.g., driver's license or medical insurance card, photograph of the patient's face or hospital ID bracelet.

Treatment Planning for HDR Brachytherapy and Verification of Administration

The location and position of the "dummy" sources will be verified by radiography or other suitable method. The image will be reviewed and approved by the Authorized User and medical physics representative as the basis for treatment planning. After dose distribution has been calculated, medical physics personnel will verify that the correct data for the patient was entered into the treatment planning computer. The channel number, source positions and treatment times from the planning computer to operating console will be verified. After administration, the Authorized User will verify that the proper dose was delivered in the proper time to the proper treatment site, within 20% of the Written Directive. An HDR source will only be used if it has been leak tested within the previous six months to prevent the possibility of placing a leaking source in a patient.

Program Review:

An ongoing review by staff and/or outside consultants shall be performed to assure compliance with written directives. Any unintended deviations discovered shall be immediately brought to the attention of the Radiation Safety Officer for further action and any further required report. Use of HDR

brachytherapy may be suspended by the RSO until resolution of the particular situation has been obtained through corrective actions, e.g., revised policy/procedure.

The Quality Management Program will be reviewed periodically and as part of the annual audit. All patient administrations, all recordable events, and all medical events will be included in the review. The following items will be verified for correspondence between what was ordered and what was given: the treatment site and the prescribed dose. Deviations must be identified, and the cause and actions taken to prevent recurrence documented. All documented administrations will be reviewed. When feasible, persons conducting the review will not review their own work. When this is not possible, the RSO and an authorized medical physicist or an authorized user will work together as a team to conduct the review. Program review results will be documented and maintained for regulatory inspections.

The effectiveness of the Quality Management Program shall include an ongoing assessment to the goals of the program: 1) to provide high confidence that HDR brachytherapy will be administered as directed by the authorized user; (2) that the program will contain written policies and procedures to help assure its success; (3) that necessary records are available for review; and (4) that periodic reviews are performed to document the program's success.

If indicated, the RSO will propose any necessary changes. To obtain the maximum results from the lessons learned from each review, the program review report will be distributed to each individual who is involved in the patient care process. Corrective action for a deficient condition will be implemented promptly after identification of the deficiency. Any modifications that are indicated and adopted will be furnished to the appropriate regulatory office within 30 days. Records of each review, including the evaluations and findings of the review will be maintained in an auditable form for three years.

Medical Event:

MGMC will follow the procedures for report and notification of a Medical Event in accordance with 10 CFR 35.3045.

Training

The licensee will provide training during the orientation period and upon changes to this program for individuals participating in the administration of HDR Brachytherapy in accordance with the Quality Management Program. This training will consist, in part, of the procedures for reviewing and performing an administration according to the written directive as described in the QMP. Individuals will have an opportunity to ask questions regarding any part of this procedure. Personnel who participate in the operation of the HDR Brachytherapy device will be trained by the manufacturer prior to first use and trained annually in the emergency procedures for the device by the Authorized Medical Physicist or the manufacturer. Documentation of this training will be maintained for review by regulatory personnel.

Release of Patients

Patients who receive HDR Brachytherapy treatments may be released without restrictions after the exit survey from the treatment room has shown that the source has returned to its shielded position inside the device. The patient survey will be performed prior to leaving the treatment room to confirm that there are no sources remaining in the patient.

Permanent Implant Brachytherapy Revised 7/19/2010

Permanent Implant Brachytherapy includes, but is not limited to:

I-125 seeds, Pd -103 seeds, Cs-131, and Y-90 Sirspheres

Facilities:
The permanent implant sources will be stored in a shielded container prior to transport to the Operating Room (OR). Radioactive sources or containers of radioactive sources may not be left unsecured or unattended. Sources will be locked in the designated storage room attended by radiation safety personnel or a medical physicist.

Training:
Patient-care personnel attending those individuals who have temporary implants shall receive initial and annual refresher training in accordance with the safety instructions outline in 10 CFR 35.410. MGMC will follow the outline specified in NUREG 1556, Vol. 9, Revision 2, Appendix J, page J-1, Section "Training for Individuals Involved in the Medical Usage of Byproduct Material".

Monitoring:
Staff assigned to care for the patient will be supplied with a pocket ionization chamber for the treatment.

Operating Room Procedures:
Only those persons needed for medical, safety, or training purposes will be present during the implant procedure in the OR.

Prior to removal of the radioactive source from the shielded container, the medical physicist or radiation safety will post each entrance to the area:

"Caution Radioactive Material Use" - for beta and gamma radiation

Prior to removing sealed or unsealed radioactive sources from the shielded, transport container, nonessential personnel will leave the posted area. Essential personnel are normally- the Cardiologist, the Radiation Oncologist and/or the certified radiation physicist, the representative from radiation safety and other personnel who have been approved by the Radiation Safety Officer.

After completion of the procedure, the patient and OR will be surveyed to ensure that no sources have been misplaced.

Recovery Room Procedures:
The patient will be briefed on radiation safety procedures for confinement to the room during recovery, visitor control, and other items as applicable, consistent with good medical care.

Visitors will not be restricted since the dose rate from the patient would permit him to be released in accordance with 10 CFR 35.75.

A survey of surrounding contiguous areas will not be necessary since the dose rate at one meter from the patient complies with the dose limits of 10 CFR 20 and is further reduced by shielding and distance from the patient.

Release from the Hospital:

Patients with permanent implants will not be released from the facility unless they meet the criteria in Appendix U, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials" in NUREG 1556, Volume 9, Revision 2.

Permanent Implant Brachytherapy Procedure
Radiation Medicine Department
MGMC
Revised 7/19/2010

Implants must be performed by, or under the direct supervision of Authorized Users AU) for manual brachytherapy that are approved by the Georgetown University Hospital (GUH) Radiation Safety Committee (RSC). Residents may assist in performing manual brachytherapy and this assistance is under the direct supervision of the AU.

Physics activities must be performed by, or under the direct supervision of an Authorized Medical Physicist (AMP) and/or an Authorized User (AU) for manual brachytherapy that is approved by the Georgetown University Hospital (GUH) Radiation Safety Committee (RSC). Other Physicists may assist in manual brachytherapy activities and this assistance is under the direct supervision of the AMP.

After completion of the procedure, the patient and OR will be surveyed to ensure that no sources have been misplaced.

Staff assigned to care for the patient in the recovery room will be briefed on radiation safety precautions. Nursing staff will also be trained annually in accordance with 10 CFR 35.410.

The patient will be briefed on radiation safety procedures for confinement to the room during recovery, visitor control, and other items as applicable, consistent with good medical care.

Only those persons needed for medical, safety, or training purposes will be present during the implant procedure in the OR

Visitors will not be restricted since the dose rate from the patient would permit him to be released in accordance with 10 CFR 35.75.

A survey of surrounding contiguous areas will not be necessary since the dose rate at one meter from the patient complies with the dose limits of 10 CFR 20 and is further reduced by shielding and distance from the patient.

Nursing staff instructions will be posted as necessary in t he patient's chart.

Emergency Contact Notification Numbers:

1.	Radiation Safety Officer	4-4049 (Office).....(202) 405-3445
2.	Dr. Dalong Pang	4-4069 (Office).....(202) 405-3899
3.	Dr. Anatoly Dritschilo	4-4068 (Office).....(202) 405-2231

Appendix C of MGMC License Renewal Package
Revised 7/19/2010

Iodine Therapy Program
Out-Patient Procedures

Patients undergoing I-131 therapy treatment may be released from the facility provided the guidance as outlined in Appendix U, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials" in NUREG 1556, Volume 9, Revision 2 is followed and documented.

Iodine Therapy Program
In-House Procedures

Facilities:
The patient's room shall be a private room with private sanitary facilities, and shall not be carpeted. MGMC uses 3 dedicated rooms on the 3rd Floor, Bles Building: Rooms 3015, 3016 and 3017 for patients who receive radioiodine therapy. The room the patient resides in will have a "Caution Radioactive Materials" sign posted on the door.

The floor, doorknobs, tables, chairs and equipment to be used by the patient should be covered with absorbent paper or plastic. A linen bag and a box for trash will be placed in the therapy room.

The following supplies should be readily available for those attending the patient: disposable booties, gloves and gowns and appropriate Caution Radioactive Materials labeling supplies and tape.

Training:
Patient-care personnel must have received specific radiation safety training per 10 CFR 35.310 prior to their involvement with patients who are undergoing I-131 therapies requiring hospitalization. Annual refresher training will be provided to these individuals.

Monitoring:
Everyone in the room during the therapy administration shall be monitored for contamination as they exit the room.

Safety precautions for patient-care staff will be provided by the RSOS staff advising them of the precautions to be taken specific to the amount of I-131 administered.

Exposure rate measurements are made at bedside, one meter from the patient and at the doorway. These dose rates and locations shall be recorded in mrem/hr on the survey form. The type and serial number of the instrument used to measure the dose rates will be recorded.

Exposure rates will not be measured in contiguous areas if documentation from previous therapies is on file verifying that for the activity being used, the exposure rates at one foot from the wall in those areas are such that no member of the general public would receive greater than 2 mrem in any one hour or 100 mrem in a year. If the exposure rate measured in an adjacent room is greater than 2 mrem/hr at 30 centimeters from the wall, that room shall remain vacant and will be posted as a Restricted Area until the dose rate no longer exceeds 2 mrem/hr at 30 centimeters from the wall.

No visitors are permitted inside of the therapy patient's room unless they have received approval and special instructions from the RSO or RSOS staff. If visitors are permitted, a visitor's "Safe line" will be marked on the floor in the therapy room. The exposure rate at this line will be measured and recorded on the survey form along with the time that the visitor may remain in the room. The stay time for visitors will be posted on the door or in the patient's chart.

Release of patients from Radiation Safety Isolation Procedures:
Patients placed under isolation precautions within the facility may be released using the guidance as outlined in Appendix U, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials" in NUREG 1556, Volume 9, Revision 2.

The patient's personal belongings and any items removed from the patient's room will be surveyed before they are removed or they will be handled as radioactive waste.

Before releasing the room, a survey will be performed to measure ambient dose rates and removable contamination. Contamination levels will not exceed 200 DPM per 100 square centimeters. The "Caution Radioactive Material" sign will be removed from the therapy room door.

Personnel who administer or prepare I-131 in liquid form will have a bioassay performed as per the bioassay section of this renewal application. Bioassays will not be performed for I-131 handled in capsule form.