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U.S. NRC Region I  
475 Allendale Road  
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K-8

Re: License No. 47-05322-02

03012570

Dear US NRC:

Thank you for your suggestions regarding additional information needed to complete action on our license amendment request to offer yttrium-90 (<sup>90</sup>Y) microspheres brachytherapy as a treatment for patients with liver tumors.

This electronic submission contains the following documents:

- **Contents.pdf** — *This is a point-by-point response to issues raised in an e-mail from Sandy Gabriel of the US NRC.*
- **SirTex Microspheres Training.pdf** — *Sec 25, pages 20-21 of the Schiffler Cancer Center Policy and Procedures Manual*
- **Sirtex Calc & Written Directive Lt.pdf and Sirtex Calc & Written Directive Rt.pdf** — *formsprinted from a spreadsheet that serves as a dose calculator and a pre- and post-administration written directive*
- **SirTex Microspheres Procedures.pdf** — *Section 23, pages 27 – 31 of the Schiffler Cancer Center Policy and Procedures Manual*
- **Reporting Medical Events.pdf** — *Section 22, pages 12 – 16 of the Schiffler Cancer Center Policy and Procedures Manual*

If you have any questions about this amendment request, please refer to our authorized medical physicist, Dr. Wayne Butler at 304-243-3983 or e-mail him at wbutler@wheelinghospital.org.

Best regards,

Ronald Violi  
Chief Executive Officer

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143229

## Contents

License No.: 47-05322-02  
Docket No.: 03012570  
Mail Control No.: 143229

This collection of documents is in response to an e-mail from Sandra Gabriel, dated March 13, 2009, regarding our license amendment request. The numbering below refers to points raised in her e-mail. Our responses are in italics.

1. Confirm that you will submit documentation to NRC Region I within 30 days after completing the 3 hands-on cases supervised in the presence of a manufacturer's representative.

*We have modified our Policy and Procedure Manual, Training Procedure for <sup>90</sup>Y (yttrium-90) Microspheres, to indicate that we will do this. The relevant statement is in C.2 on page I of the enclosed policy (SirTex Microspheres Training.pdf, Sec 25, pages 20-21 of our manual.)*

2. a. If stasis is to be considered an acceptable end-point for dose administration, the licensing guidance requires this to be included in both the pre-administration and post-administration portions of the written directive.

*A revised written directive and dose calculation worksheet is enclosed. These contain a qualifying statement after the numerical value of the prescribed activity: "or, the activity implanted at time of Stasis." The forms are attached as Sirtex Calc & Written Directive Lt.pdf and Sirtex Calc & Written Directive Rt.pdf.*

b. The licensing guidance requires the authorized user to sign and date the pre-administration written directive before the Y-90 microspheres are administered, and after completion to sign and date the post-administration written directive.

*The attached forms, Sirtex Calc & Written Directive Lt.pdf and Sirtex Calc & Written Directive Rt.pdf, indicate the revisions we have made to have the authorized user sign and date a pre- and post-administration written directive.*

3. Please confirm that you will implement the following items:

- a. You will label vials and vial shields with the radionuclide and form ..

*Our Policy and Procedure Manual dealing with Selective Internal Radiation Therapy (SIRT) involving Yttrium-90 (Y-90) microspheres, Section 23, pages 27 – 31, have been revised accordingly. The relevant statements are on the 2<sup>nd</sup> page of the enclosed pdf (SirTex Microspheres Procedures.pdf) as the 3<sup>rd</sup> and 4<sup>th</sup> bullet points under duties of the Medical Physicist/Nuclear Medicine Technologist.*

- b. You will comply with the medical event reporting and notification requirements as described in 10 CFR 30.3045(b)(g), ...

*Enclosed is a pdf (Reporting Medical Events.pdf) from our Policy and Procedure Manual on Reporting Medical Events (misadministrations Section 22, pages 12 – 16. The relevant statements on in items 1 – 4 on the first page.*

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**SUBJECT: Training Procedure for <sup>90</sup>Y (yttrium-90) microspheres**

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**Training Procedure for Staff Involved in <sup>90</sup>Y microspheres Treatments**

- A. All individuals involved in dose preparation, measurement, dosimetry calculations, and microsphere administration will receive manufacturer training in their areas of responsibility before first use of the SIR-Spheres delivery system..
13. Primary Personnel Training
1. Initial primary personnel, including the radiation oncologist (Authorized User), interventional radiologist, medical physicist, and nuclear medicine technologist, will receive device-specific training on at least three hands-on *in-vitro* simulated cases under guidance from representatives of the manufacturer, SirTex. These initial primary personnel will then be approved by the Radiation Safety Committee.
  2. The first three patient cases by each authorized user at Wheeling Hospital shall be hands-on and under the direct supervision of the manufacturer's representative.
  3. Future primary personnel must receive device-specific, manufacturer-equivalent training from primary personnel already approved by the Radiation Safety Committee, assist in three documented procedures, and be approved by the Radiation Safety Committee before serving as primary personnel during these procedures.
- C. Documentation of training
1. Documentation of training on the in-vitro simulated cases will be submitted to the US Nuclear regulatory Commission (NRC) with the application for a license amendment.
  2. Documentation of completion of the first three patient cases under the mentorship of an experienced user chosen by the manufacturer, SirTex, shall be submitted to the appropriate NRC Regional Office within 30 days of when these three patient cases have been completed.
- D. Ancillary Personnel Training
1. Initial ancillary personnel will receive device-specific training from the vendor.
  2. Future ancillary personnel will receive training from initial primary personnel, initial ancillary personnel, or the Radiation Safety Officer
- E. Individuals who are trained in the use of <sup>90</sup>Y microspheres and have practiced the emergency procedures will be on-site while the device is in use.
- F. **As** per federal and state regulations, the training will include (but not limited to):
- Hazards associated with radiation/radioactive materials;  
Size and appearance of radioactive sources;
  - Procedures to minimize exposure;
  - Procedures for visitor control;
  - Procedures for notification of appropriate personnel if patient has medical emergency or dies;
  - Appropriate response to unusual occurrence that may involve exposure to radiation or radioactive material; and

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**SUBJECT: Training Procedure for <sup>90</sup>Y (yttrium-90) microspheres**

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- Worker responsibility to report promptly any condition that may lead to unnecessary radiation exposure or violation of regulations
- G. The Radiation Safety Officer will maintain records of individuals receiving training, a description of the training (such as the lecture outline), the training date, and the name of the individual(s) providing the training.
- H. Before being released from inpatient care, the patient will be provided with instructions that will support efforts to maintain radiation exposure to household members and the public ALARA (as low as reasonable achievable).

**Written Directive for Liver SIRT**  
 Y-90 "SirSphere" Microspheres Interventional Radiology

**LEFT LOBE**

**Patient :** Wayne Butle  
**Hospital Number :** 09-666  
**Rad Onc Number :** 09-666

**Right Lobe Date :** 5-Mar-2009

**Tumor Volume (cc) :** 612  
**Total Vol = Liver+Tumor (cc) :** 2744  
**% Lung Shunting :** 2.0%  
**Liver/Tumor Ratio :** 3 : 1

**Patient Weight (lbs) :** 180

**Patient Height (ft) :** 5  
**(in) :** 9

**% Left Lobe :** 33  
**% Clinical Reduction RT :** 20

Clinical Reduction could be due to factors including:  
 Lung Shunting, Tumor Load, and Previous Chemotherapy

**Pre-Implant**

Initials

**Body Surface Area (BSA) Model:**

Patient Weight (kg) = 81.6  
 Patient Height (m) = 1.8

**BSA = 1.98 m<sup>2</sup>**

**Total Activity (Whole Liver) = 2.00 GBq**

**Left Lobe**  
 0.53 GBq or -->

**14.3 mCi** Recommended Y-90 Prescribed Activity (GBq)  
 or, the activity implanted at time of Stasis

**14.0 mCi**  
**0.3 mCi**

Activity going to Liver  
 Activity going to Lungs

**9.1 Gy**  
**0.5 Gy**  
**27.3 Gy**

Estimated Liver Dose (Lifetime Maximum Permissible Dose is 90 Gy)  
 Estimated Lung Dose (Lifetime Maximum Permissible Dose is 25 Gy)  
 Estimated Tumor Dose (Assuming stated Tumor/Liver Activity Density Ratio)

Radiation Oncologist :

Date :

**Post-Implant & Final Dose Report**

**134 mCi**  
**90.0%**

Drawn Activity (Drawn activity must be +/- 10% of Rx Activity)  
 % Activity Infused

Stasis Reached?  no

**12.1 mCi**  
**10%**

Actual Y-90 Activity Infused  
 % difference:

**8 Gy**  
**0 Gy**  
**23 Gy**

Final Dose to Liver (80 Gy max)  
 Final Dose to Lung (25 Gy max)  
 Final Dose to tumor

Radiation Oncologist :

Date :

**Radiation Safety**

Patient Survey @ surface

5.00 mR/hr

Patient reading @ 1 meter

0.50 mR/hr

Radwaste was properly accounted for and disposed of as per regulations. Operating/procedure room was cleaned and surveyed with calibrated and op-checked rad survey meter(s) and determined to be free of contamination following the end of the implantation procedure. The delivered activity and radiation doses to the patient conform to the written directive.

**Comments:**

Medical Physicist : \_\_\_\_\_

Date : \_\_\_\_\_

**Written Directive for Liver SIRT**  
 Y-90 "SirSphere" Microspheres Interventional Radiology

**RIGHT LOBE**

**Patient :** Wayne Butler  
**Hospital Number :** 09-666  
**Rad Onc Number :** 09-666  
**Tumor Volume (cc) :** 612  
**Total Vol = Liver+Tumor (cc) :** 2744  
**% Lung Shunting :** 2.0%  
**Liver/Tumor Ratio :** 3 :1  
**% Right Lob. :** 66  
**% Clinical Reduction RT :** 20

**Right Lobe Date :** 5-Mar-200  
**Patient Weight (lbs) :** 180  
**Patient Height (ft) :** 5  
**(in) :** 9  
 Clinical Reduction could be due to factors including:  
 Lung Shunting, Tumor Load, and Previous Chemotherapy

**Pre-Implant**

Initials

**Body Surface Area (BSA) Model:**  
 Patient Weight (kg) = 81.6  
 Patient Height (m) = 1.8

**BSA = 1.98 m<sup>2</sup>**

**Total Activity (Whole Liver) = 2.00 GBq**

**Recommended Y-90 Prescribed Activity** 28.5 mCi **Right Lobe** <-- or 1.05 GBq  
 or, the activity implanted at time of Stasis

|   |          |
|---|----------|
| Activity going to Liver   | 27.9 mCi |
| Activity going to Lungs   | 0.6 mCi  |
| (Lifetime Maximum Permissible Dose is 80 Gy) Estimated Liver Dose         | 18.2 Gy  |
| (Lifetime Maximum Permissible Dose is 25 Gy) Estimated Lung Dose          | 1.0 Gy   |
| (Assuming stated Tumor/Liver Activity Density Ratio) Estimated Tumor Dose | 54.5 Gy  |

Radiation Oncologist : \_\_\_\_\_ Date : \_\_\_\_\_

**Post-Implant & Final Dose Report**

(Drawn activity must be +/- 10% of Rx activity) **Drawn Activity :** 27.0 mCi  
**% Activity Infused :** 90.0%  
**Actual Y-90 Activity Infused :** 24.3 mCi  
**% Difference :** 10%

**Stasis Reached?**

|  |       |
|--|-------|
| <b>Final Dose to Liver (80 Gy max)</b> | 15 Gy |
| <b>Final Dose to Lung (25 Gy max)</b>  | 1 Gy  |
| <b>Final Dose to tumor</b>             | 46 Gy |

Radiation Oncologist : \_\_\_\_\_ Date : \_\_\_\_\_

**Radiation Safety**

**Patient Survey @ surface** 5.00 mR/hr  
**Patient reading @ 1 meter** 0.50 mR/hr

Radwaste was properly accounted for and disposed of as per regulations. Operating/procedure room was cleaned and surveyed with calibrated and op-checked rad survey meter(s) and determined to be free of contamination following the end of the implantation procedure.  
 The delivered activity and radiation doses to the patient conform to the written directive.

**Comments:**  
 \_\_\_\_\_  
 \_\_\_\_\_

Medical Physicist : \_\_\_\_\_ Date : \_\_\_\_\_

### Introduction.

The purpose of selective internal radiation therapy (SIRT) involving Yttrium-90 (Y-90) microspheres is to selectively target a very high radiation dose (typically 280-380 Gy) to all tumors within the liver, regardless of their cell of origin, number, size or location while at the same time maintaining a low radiation dose to the normal liver tissue (< 40 Gy).

### Commitment to Follow Regulatory Authority

Wheeling Hospital will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where the following licensing commitments provide regulatory relief:

- For Y-90 microspheres, "prescribed dose" means the total dose documented in the written directive.
- The written directive will include:
  1. before implantation: the treatment site, the radionuclide (including the **chemical/physical** form [Y-90 microspheres]), the manufacturer, the dose in Gray, and, if appropriate for the type of microsphere used, the statement "dose delivered at stasis"; and
  2. after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, treatment site, and the total dose to the treatment site. If the implantation was terminated because of stasis, then the total dose is the value of the total dose delivered when stasis occurred and the implantation was terminated.
- The written directive will specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (e.g. lung and gastrointestinal tract). The postimplantation written directive should specify the dose that will result to the specified site (or sites) due to shunting.
- The semiannual physical inventory of microspheres aggregates (e.g. vials) will include:
  1. the radionuclide and physical form,
  2. unique identification of each vial in which the microspheres are contained,
  3. the total activity of the vial(s), and
  4. the location of the vial(s).
- Procedures will describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75.

Microsphere brachytherapy treatment is usually conducted using a multidisciplinary team approach. The authorized user will consult, as necessary, with individuals with expertise in:

- Cancer management (e.g. radiation or medical oncology)
- Catheter placement
- Radiation dosimetry
- Safe handling of unsealed byproduct material

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One individual may satisfy more than one of the listed areas of expertise.

## **TRAINING**

All personnel providing care to a patient undergoing SIRT will receive appropriate radiation safety training detailed in Section 25 of this manual.

## **DESCRIPTION OF DUTIES**

### ***Radiation Oncologist/Interventional Radiologist/Nuclear Medicine Authorized User***

- Calculates required activity based on intended dose for specific patient.
- Completes written directive that includes prescribed dose.
- Prepares patient for dose delivery.
- Verifies patient's identification, dose prescription, and completes quality assurance form (QA checklist).
- Assembles microsphere delivery system.
- Ensures delivery system assembled correctly.
- Delivers microsphere dose.
- Ensures delivered dose is prescribed dose.
- Assists in disposal of delivery system.

### ***Special Procedures Radiologic Technologist***

- Prepares room for procedure.
- Retrieves sterile delivery system set from Nuclear Medicine.
- Assists interventional radiologist with assembly of delivery system.
- Ensures delivery system assembled correctly.

### ***Medical Physicist/Nuclear Medicine Technologist***

- Orders radioactive material from manufacturer
- Receives and processes package of radioactive material from manufacturer.
- If radioactive material is placed in vials or vial radiation shields not labeled by the manufacturer, the vials and shields will be labeled to indicate the radionuclide and its form; e.g., Y-90: microspheres.
- If radioactive material is placed in syringes or syringe radiation shields not labeled by the manufacturer, the syringes and shields will be labeled to indicate the radionuclide, form, and therapeutic procedure; e.g., Y-90, microspheres, brachytherapy.
- Provides sterile delivery system set to Special Procedures.
- Assays radioactive material in shipping vial.
- Prepares dose for delivery system.

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- Assays radioactive material and confirms dose is correct prior to patient delivery.
- Delivers dose to Special Procedures.
- Ensures delivery system assembled correctly.
- Ensures personnel wearing dosimeters.
- Ensures proper radiation monitoring equipment is available.
- Ensures container for waste disposal is available.
- Assists interventional radiologist in completing quality assurance form (QA checklist)
- Ensures proper shielding and safe handling procedures used during procedure.
- Monitors delivery system during dose delivery.
- Determines when maximum dose has been delivered.
- Performs final assay of remaining dose to determine amount delivered to patient.
- Measures exposure rate 1 meter from patient.
- Performs surveys of hands, feet, and clothing of all individuals leaving room.
- Identification and collects of all radioactive waste.
- Surveys room for contamination following removal of patient.
- Decontaminates contaminated areas.
- Collects and labels all radioactive waste.
- Logs all radioactive waste and places it in storage for decay.

#### **RADIATION SAFETY DURING DOSE DELIVERY**

- a. All personnel entering the treatment room will wear protective equipment as needed, including scrubs, disposable gown, hair net, face mask, gloves, shoe covers, and, during fluoroscopy, lead aprons and thyroid shields.
- b. All personnel will wear radiation dosimeters.
- c. The patient will be covered with large drapes and the floor next to the treatment table will be covered with plastic-backed absorbent paper.
- d. Radioactive waste will be disposed in a designated container. Regular waste should not be mixed with radioactive waste.

#### **POST-THERAPY RADIATION SAFETY**

- a. Following therapy, the exposure rate from the patient will be measured at one meter to assure it is below 2 mR/hour.
- b. Provided the patient exposure rate is less than 2 mR/hr at one meter, there are no restrictions if the patient is admitted to the hospital. However, pregnant staff will not provide patient care.
- c. If the patient is admitted to the hospital, his/her visitors are restricted to non-pregnant persons. Visitors should avoid close contact with the patient.

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- d. The patient will be provided with instructions regarding additional precautions to keep exposures to others ALARA.

### **RADIATION MONITORING INSTRUMENTS**

- a. An ionization chamber will be used to monitor radiation exposure during dose delivery and to monitor patient exposure at one meter prior to patient release.
- b. A directional survey meter may be used to monitor the source vial and lines during delivery.
- c. A pancake GM detector will be used for monitoring all equipment and personnel for contamination.

### **EMERGENCY PROCEDURES**

If the patient dies or undergoes a medical emergency following the dose delivery, the referring physician will be notified immediately. The Radiation Safety Officer will also be notified immediately.

### **SPILL PROCEDURES**

#### *Minor Spills*

- All individuals in area will be notified that spill has occurred.
- Spread of contamination will be prevented by covering spill with absorbent material and controlling movement of potentially contaminated individuals.
- Spill will be cleaned using absorbent material.
- All areas and potentially contaminated individuals will be surveyed with appropriate radiation detector such as pancake GM (with audio output).
- If spill is not contained to absorbent paper floor covering, contamination survey (i.e. wipe testing) of area in question will be completed to confirm that removable decontamination does not exceed 2000 dpm/cm<sup>2</sup>.
- The area and personnel will be decontaminated as necessary.
- All spills will be reported to the Radiation Safety Officer.

#### *Major Spills*

- All individuals in area will be notified that spill has occurred.
- Nonessential personnel in immediate area will be evacuated.
- Spread of contamination will be prevented by covering spill with absorbent material and controlling movement of potentially contaminated individuals.
- If possible (without increasing significantly spread of contamination), radiation source will be shielded.
- Entry to room will be prevented.
- All potentially contaminated individuals will be surveyed with appropriate radiation detector such as pancake GM (with audio output).

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- The area and personnel will be decontaminated as necessary.
- Radiation Safety Officer will be notified immediately
- Room will be decontaminated under direction of Radiation Safety Officer.
- Decontamination will continue until removable contamination, as confirmed by wipe testing, does not exceed 2000 dpm/cm<sup>2</sup>.
- Room will be released by Radiation Safety Officer once removable contamination less than 2000 dpm/cm<sup>2</sup>.

### WASTE DISPOSAL

- e. Because <sup>90</sup>Y has a half life of only 64 hours, radioactive waste from the procedure may be held for decay in storage until suitable for disposal as ordinary trash.
- f. Place contaminated material in the radioactive labeled sharps container in the fume hood in the hot cell room for decay in storage for at least 10 half-lives.
- g. After at least 30 days (11 half lives). survey the byproduct material at the surface to determine that its radioactivity cannot be distinguished from the background radiation level with a Geiger-Mueller detection survey meter set on its most sensitive scale and with no interposed shielding.
- h. If the survey indicates the material is indistinguishable from background, remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after release from decay storage.
- i. Dispose of the material as ordinary trash or biomedical waste as appropriate and complete the radioactive material disposal portion on the copy of the written directive held in the medical physics office.

### RECORDS AND REPORTS

#### *Records*

Radiation safety records associated with the delivery of the Y-90 microspheres may include (but are not limited to) records related to ordering, package receipts, training, written directives, dose assay and delivery, personnel monitoring results, area surveys, and spills.

#### *Reports*

Certain reports may be required if a Y-90 microsphere treatment results in a spill, recordable event, or misadministration. In all instances, the Radiation Safety Officer will be notified immediately and will take appropriate actions.

### CHANGES IN PROCEDURES

Wheeling Hospital may institute changes in its Y-90 microsphere procedures or its radiation safety program, provided the following conditions are met:

- a. the revision is in compliance with state and federal regulations;

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- b. the revision is based upon NRC's current guidance for SIR-Spheres@ Y-90 microspheres use posted on the NRC Web site or in 10 CFR 35.1000;
- c. the revision has been reviewed and approved by the Radiation Safety Officer and licensee's management;
- d. the affected individuals are instructed on the revised program before the change is implemented;
- e. the licensee will retain a record of each change for five years; and
- f. the record will include a reference to the appropriate NRC guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

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*SUBJECT:* **Reporting Medical Events (misadministrations)**

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**Definition of a medical event.**

- A. The Schiffler Cancer Center shall report any event, except for an event that results from patient intervention, in which the administration of radiation or radioactive material results in —
1. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
  2. A dose that differs from the prescribed dose (written directive) or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
    - a. The total dose delivered differs from the prescribed dose by 20 percent or more;
    - b. The total dosage (i.e. source activity or strength) delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
    - c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
  3. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following —
    - a. An administration of a wrong radioactive drug containing byproduct material;
    - b. An administration of a radioactive drug containing byproduct material or <sup>90</sup>Y microspheres by the wrong route of administration;
    - c. An administration of a dose or dosage to the wrong individual or human research subject;
    - d. An administration of a dose or dosage delivered by the wrong mode or treatment; or
    - e. A leaking sealed source.
  4. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the pre-administration portion of the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

**Reporting and notification of a medical event.**

- B. The Schiffler Cancer Center shall report any event resulting from intervention of a patient or human research subject in which the administration of radiation or radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

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SUBJECT: **Reporting Medical Events (misadministrations)**

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- C. The Schiffler Cancer Center shall notify by telephone either the NRC Operations Center or the West Virginia Department of Radiological Health as appropriate no later than the next calendar day after discovery of the medical event. The commercial telephone number of NRC Operations Center is (301) 816-5100. The Center will accept collect calls.
- D. The Schiffler Cancer Center shall submit a written report to either the appropriate NRC Regional Office or the West Virginia Department of Radiological Health within 15 days after discovery of the medical event.
1. The written report must include —
    - a. The licensee's name (Schiffler Cancer Center);
    - b. The name of the prescribing physician;
    - c. A brief description of the event;
    - d. Why the event occurred;
    - e. The effect, if any, on the individual(s) who received the administration;
    - f. What actions, if any, have been taken or are planned to prevent recurrence; and
    - g. Certification that the Schiffler Cancer Center notified the individual (or the individual's responsible relative or guardian), and if not, why not.
  2. The report may not contain the individual's name or any other information that could lead to identification of the individual.
- E. The Schiffler Cancer Center shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the Schiffler Cancer Center either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The Schiffler Cancer Center is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the Schiffler Cancer Center shall notify the individual as soon as possible thereafter. The Schiffler Cancer Center may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the Schiffler Cancer Center shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the Schiffler Cancer Center upon request. The Schiffler Cancer Center shall provide such a written description if requested.
- F. Aside from the notification requirement, nothing in this section affects any rights or duties of the Schiffler Cancer Center and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- G. The Schiffler Cancer Center shall:

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1. Annotate a copy of the report provided to the NRC with the:
  - a. Name of the individual who is the subject of the event; and
  - b. Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
2. Provide a copy of the annotated report to the referring physician, if other than the Schiffler Cancer Center, no later than 15 days after the discovery of the event.

**Report and notification of a dose to an embryo/fetus or a nursing child.**

- A. The Schiffler Cancer Center shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radiation or radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- H. The Schiffler Cancer Center shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that —
  1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or
  2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
    - a. The Schiffler Cancer Center shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (A) or (B) in this section. The commercial telephone number of NRC Operations Center is (301) 816-5100. The Center will accept collect calls.
    - b. The Schiffler Cancer Center shall submit a written report to the appropriate NRC Regional Office within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (A) or (B) in this section.
3. The written report must include —
  - a. The licensee's name (Schiffler Cancer Center);
  - b. The name of the prescribing physician;
  - c. A brief description of the event;
  - d. Why the event occurred;
  - e. The effect, if any, on the embryo/fetus or the nursing child;

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- f. What actions, if any, have been taken or are planned to prevent recurrence; and .
  - g. Certification that the Schiffler Cancer Center notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.
4. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

The Schiffler Cancer Center shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (A) or (B) of this section, unless the referring physician personally informs the Schiffler Cancer Center either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The Schiffler Cancer Center is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the Schiffler Cancer Center shall make the appropriate notifications as soon as possible thereafter. The Schiffler Cancer Center may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the Schiffler Cancer Center shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the Schiffler Cancer Center upon request. The Schiffler Cancer Center shall provide such a written description if requested.

## D. The Schiffler Cancer Center shall:

1. Annotate a copy of the report provided to the NRC with the:
  - a. Name of the pregnant individual or the nursing child who is the subject of the event; and
  - b. Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
2. Provide a copy of the annotated report to the referring physician, if other than the Schiffler Cancer Center, no later than 15 days after the discovery of the event.

**Report of a leaking source.**

The Schiffler Cancer Center shall file a report within 5 days if a leak test required by §35.67 reveals the presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

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