

Torres, RobertoJ

From: Tressa Fraker [tressaf@inlandcardiology.com]
Sent: Friday, August 21, 2009 3:45 PM
To: Torres, RobertoJ
Subject: RE: Request for additional information in support of license renewal
Attachments: Medical Events.doc

Roberto,

Here is my latest version of our "Medical Event" policy. I hope it is more what you are looking for. If anything needs added to it, please let me know.

As for Washington's changes, I'm not sure why a different phone number would be listed. We just had our inspection at two of our sites last week and the inspector told me that the number I have listed is the one to call still.

Have a great weekend!

Tressa Fraker, BS, CNMT

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From: Torres, RobertoJ [mailto:RobertoJ.Torres@nrc.gov]
Sent: Wed 8/12/2009 10:15 AM
To: Tressa Fraker
Subject: Request for additional information in support of license renewal

Tressa:

I just noticed that the State of Washington's, Medical use of radioactive material, regulations were changed to adopt NRC's 10 CFR Part 35 (meaning State of WA regulations = NRC's Part 35 regulations). The new State of WA regulations were renumbered (from 246-239-xxx to 246-240-xxx) and can be found at: <http://apps.leg.wa.gov/WAC/default.aspx?cite=246-240>. Even the State of WA telephone number for reporting events is different than what you have in your "Medical Event" procedure. This is FYI for you (you may have to revise your procedures to satisfy State of WA regulations - this is outside my jurisdiction).

Regarding the NRC's renewal process, the "Medical Event" procedure that you submitted does not reflect NRC's 10 CFR 35.3045 (nor WAC 246-240-651). Please modify this procedure to reflect 10 CFR 35.3045 and resubmit by email this procedure only.

Thank you.

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INLAND CARDIOLOGY ASSOCIATES, P.S.	REFERENCE #
SUBJECT: Medical Events	PAGE:
	EFFECTIVE: 10/2005
WRITTEN BY: Sherman Slater, CNMT	REVISED: 08/2009
APPROVED BY:	BY: Tressa Fraker, BS, CNMT, RSO

Medical Events

Medical Events are reportable under NRC's 10 CFR 35.3045

Reportable Events are defined as:

An event in which the administration of byproduct material or radiation from byproduct material results in:

1. A dose that differs from the prescribed dose by more than 5 rem effective dose equivalent, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin *and*:
 - The total dose delivered differs from the prescribed dose by 20% or more.
 - The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range.
 - The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
2. A dose that exceeds 5 rem effective dose equivalent, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin from any of the following:
 - An administration of a wrong radioactive drug containing byproduct material
 - An administration of a radioactive drug containing byproduct material by the wrong route of administration.
 - An administration of a dose or dosage to the wrong individual or human research subject.
 - An administration of a dose or dosage delivered by the wrong mode of treatment.
 - A leaking sealed source.
3. A dose to the skin, an organ, or tissue other than the treatment site that exceeds by 50 rem to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

An event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

If an error that may be a medical event is suspected:

1. Inform the RSO immediately.
2. Preserve all documentary and physical evidence, such as labels and the actual syringe and vial.
3. The RSO will determine if the incident is a misadministration or recordable event.

If the event is a reportable misadministration:

1. The Department of Health must be informed by telephone no later than the next calendar day at (206) 682-5327.
2. Inform the referring physician.
3. Inform the patient within 24 hours unless the referring physician agrees to inform the patient or advises that it is likely to be harmful to the patient.

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4. Written reports must be filed within 15 days. See NRC's 10 CFR.35.3045

Recordable Events

"Recordable Event" means the administration of:

- A radiopharmaceutical or radiation without a written directive where a written directive is required;
- A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record.
- A radiopharmaceutical dosage greater than 30 uCi. of either sodium iodide I125 or I131 when both: The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and the difference between the administered dosage and prescribed dosage exceeds 15 uCi.
- A therapeutic radiopharmaceutical dosage, other than sodium iodide I125 or I131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

Documentation of recordable events must be completed within 30 days and must include:

- A description of the circumstances,
- the consequences, and
- the corrective action taken.

Some events may not fit the definition of either medical event or recordable event, but action may be called for. *Diagnostic nuclear medicine mishaps rarely exceed the threshold for either medical events or recordable events.*

Patient radiation doses should be calculated in cases involving the diagnostic administration of the wrong drug, or the wrong patient, but the wrong route, or when the wrong study was performed. (Note that the regulations specify dose as *effective dose equivalent*, which is not the same as the "whole body" dose in the package insert or MIRD tables.) Contact Empiricos at (425) 259-3808 for health physics assistance.

Mislabeled drugs may be a violation of FDA regulations but not NRC regulations.

Radiopharmaceuticals and kit products that have unusual biodistribution, poor labeling efficiency or free pertechnetate are *not reportable or recordable* under the regulations. Problems with the radiopharmaceuticals may be reported through the USP/SNM drug product problem reporting program at (800) 638-6725.