"Michele Burgess"
<MLB5@nrc.gov>
06/15/2005 11:00 AM

To <Thomas.Smith@inl.gov>, "Ashley Tull" <amt1@nrc.gov>, "Gregory Morell" <GKM@nrc.gov>, "Lydia Chang" <LWC1@nrc.gov>
cc <Dante.Huntsman@inl.gov>, <Robert.Sant@inl.gov>, "Cynthia Flannery" <CMF@nrc.gov>, "Donna-Beth Howe" <DBH@nrc.gov>, "Ivelisse Cabrera" <IMC1@nrc.gov>,
bcc

Subject Medical Team determination on event at Edward W. Sparrow Regional Center (EN41763)

This is the retracted medical event we had been discussing. Please see the attached from the Medical Team determining that this is a medical event. Based on the Medical Team's evaluation, I am directing INL to mark the NMED record as reportable per Ron's email (this will result in it being counted against the Medical Event metric).

If further discussions indicate the need for NMED coding other than that, let me know and we can discuss.

Thanks.

!!!! THIS EVENT HAS BEEN RETRACTED. THIS EVENT HAS BEEN RETRACTED !!!!!
Hospital
Event Number: 41763
Rep Org: EDWARD W. SPARROW REGIONAL CENTER
Licensee: EDWARD W. SPARROW REGIONAL CENTER
Region: 3
City: LANSING State: MI

----- Message from "Cynthia Flannery" <CMF@nrc.gov> on Wed, 15 Jun 2005 12:28:50 -0400 -----

To: "Michele Burgess" <MLB5@nrc.gov>

Subject: Re: Fwd: Event Notice: 06/10/2005

Michele,

The Medical Radiation Safety Team is in agreement with Ron's statement and feel that this qualifies as a medical event.

Cindy

----- Message from "Ronald Zelac" <REZ@nrc.gov> on Wed, 15 Jun 2005 10:55:39 -0400 -----

To: "Lydia Chang" <LWC1.twf4_po.TWFN_DO@nrc.gov>

cc: "Cynthia Flannery" <CMF@nrc.gov>, "Donna-Beth Howe" <DBH.twf4_po.TWFN_DO@nrc.gov>

Subject: Re: Fwd: Event Notice: 06/10/2005

Per your request. See the following.

Reflecting MRST member discussions yesterday and today, MRST believes that this event meets the criteria for a medical event. Specifically, the event exceeds the threshold for reporting in 10 CFR 35.3045(a)(1)(ii).

The licensee administered 50% of the dosage called for in the written directive and then released the patient, unaware that the patient had been underdosed. The thyroid dose reduction resulting from the reduced dosage would exceed the 0.5 Sv (50 rem) to an organ threshold that appears in 10 CFR 35.3045(a). The fact that the licensee subsequently became aware of the underdosing, through contact from its supplier nuclear pharmacy, and corrected the underdosing the next day does not disqualify this occurrence from being classified as a medical event. Further, the licensee acknowledged that there had been a problem (with administration of a therapeutic dosage requiring, per 10 CFR 35.40(a), a written directive) and indicated that its procedures were being revised to prevent recurrence.

>>> Lydia Chang 06/14/05 02:58PM >>>
Perhaps, we should let the medical team determine whether it is or is not. I think we all agree that there is absolutely no health impact associated in administering the second capsule the next day. The question is whether the prescription is intended to be administered at once or in phases. Based on the information provided in the event report, it does appear that it may be a medical event during the period when the patient took the first capsule and the next day when the patient took the second capsule. During that period, only ~50% of the dosage was administered. Since this is a typerthyroid treatment, a 10 mci of I-131 could potentially give ~4 to 5 rem of effective dose and more than 10,000 rem to the thyroid. We all agree that the licensee took immediate action in contacting the patient and administering the second capsule. In addition, we all agree that the corrective action proposed by the licensee should prevent future occurrences. I think the medical team should take a look at this event and other similar events and make a determination.

>>> Gregory Morell 06/14/05 12:58PM >>>
Michele, Let me see if I can help.

As you know, it's up to the licensee to evaluate and then make a determination based on 35.3045. Of course we can tell them they are in violation of the reporting requirements if we have enough information to support the conclusion. Based on the biological half life, intake/uptake retention and the short interval in between the dose(s) and the improbable reality that the patient, because of the interval between doses, did not receive the intended dose, there's most likely no way this would meet 3045 (a)(1). If you go through the reqt, there's that "and" clause, specifically (a)(1)(i), (ii). Neither the total dose delivered in the licensee's opinion did not differ from prescribed outside the 20% criterion nor did the dosage delivered from prescribed did not fall outside the prescribed range.

I spoke with the region this a.m. and confirmed what I alluded to above. In addition, the licensee was coaxed to report more specifically why this "reported" event was retracted.

I don't think the thought process and the outcome was based on opinion, it's based on what was originally provided and subsequent information. On Friday, I questioned why this was reported because there was not enough information to conclude that it was reportable. Therein lies the reason for the discussion w/ the region and further follow-up.

I thought I understood the licensee had a nuc pharmacy, but I don't know for sure. I will follow-up on your question. I don't understand the 20.2201 issue. Please explain as this was not a loss of material.

I hope this helps!

Greg

>>> Michele Burgess 06/14/05 12:12PM >>>
There was not enough info in the EN for me to see why it is not a medical event, however I understand that there have been some other info exchange with the Region so maybe I'm missing something. Please let me know so we can make sure there is sufficient information in NMED so that it is clear.

Also, I had only seen the Reg Coord people on the emails going around. What is the Medical Team's opinion?

Another question I had:
Where is the radiopharmacy located? Is this a 20.2201 issue?

>>> Richard Correia 06/14/2005 8:21:18 AM >>>
I just talked with John Madera/R III abut this issue. I do not believe it is a medical event, John agrees. Does anyone have a different view/opinion?

>>> Gregory Morell 06/13/05 08:27AM >>>
In the last sentence of my response regarding Tom's question, I stated that "It appears that from the info we have that this issue clearly does constitute 35.3045 (a)(1) report," which was a typo. The sentence should have said does not constitute a 35.3045(a)(1) report.

>>> Thomas Essig 06/10/05 04:10PM >>>
Two 10 mCi I-131 capsules were supposed to be given at the same time, but ended up 1.5 hr apart, after the error was discovered. Can someone share with me what makes this reportable.....the fact that the capsules were separated in time by 1.5 hr??

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EN TEXT BEGIN
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!!!!! THIS EVENT HAS BEEN RETRACTED. THIS EVENT HAS BEEN RETRACTED !!!!!
Hospital
Event Number: 41763
Rep Org: EDWARD W. SPARROW REGIONAL CENTER
Licensee: EDWARD W. SPARROW REGIONAL CENTER
Region: 3
City: LANSING State: MI
County:
License #: 21-01430-01
Agreement: N
Docket:
NRC Notified By: TRACY MAUDRIE
HQ OPS Officer: JOHN KNOKE Notification Date: 06/10/2005
Notification Time: 14:07 [ET]
Event Date: 06/10/2005
Event Time: [EDT]
Last Update Date: 06/13/2005
Emergency Class: NON EMERGENCY
10 CFR Section:
35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE
Person (Organization):
JULIO LARA (R3)
TOM ESSIG (NMSS)

Event Text

FRACTIONAL DOSE DELIVERED DIFFERED FROM THE PRESCRIBED DOSE

"A hyperthyroid therapy patient received one of the intended two Nal-131 capsules sent by the radio pharmacy for the therapy. The patient received 10.2 mCi in one capsule instead of the intended 20.6 mCi in two capsules. Both capsules were received in one plastic vial inside of a lead shield. The entire vial was assayed and the assay of 20.6 mCi was within 10% of the prescribed dose of 20.0 mCi. The technologist failed to notice that there were two capsules in the vial because a desiccant inside the vial blocked the view of the second capsule and prevented the second capsule from leaving the vial. Normally, hyperthyroid therapy doses are received in one capsule. Therefore, the technologist was not expecting a second capsule.

"The radio pharmacy discovered the second capsule when the package was returned to the pharmacy the next day, June 10, 2005. They called the Nuclear Medicine department at 8:30 am on June 10, 2005. The prescribing physician was called and he requested that the patient receive the second capsule. The patient returned to the Nuclear Medicine department at 10:00 am on June 10, 2005 and received the second capsule, which assayed at 9.74 mCi at that time. The total dose the patient received was 19.94 mCi.

"Why the event occurred: Hyperthyroid therapy doses are normally received in one capsule. The technologist was not expecting a second capsule. The desiccant placed in the vial by the radio pharmacy obscured the second capsule from the technologist's sight. The desiccant also prevented the second capsule from coming out of the vial when the first capsule came out of the vial. car Greg

>>> Michele

"Effect on the patient: The prescribing physician does not believe this event will have a negative effect on the patient as she received the remainder of the dose within 24 hours.

"To prevent recurrence of this action the licensee will assay all applicable capsule vials after the patient has received their dose, but before the patient leaves the department. This will ensure that no capsules remain in the vial.

"Certification that the licensee notified the individual: The patient was notified by telephone on June 10, 2005 and the patient returned to the hospital to receive the second capsule of 9.74 mCi Nal-131."

* * * RETRACTION ON 06/13/05 AT 1720 BY MARTY JOHNSON TO CHAUNCEY GOULD * * *

Based on a re-reading of Part 35 and a conversation with Region 3 Materials Inspection and Materials Licensing Branches it was determined that this is not a medical event and should be retracted.

Notified Reg 3 RDO (Patrick Louden) and NMSS (Patricia Holahan)