

DATE RECEIVED:	08/27/2015
EVENT DATE:	July 31, 2015
REPORT DATE:	08/14/2015

NRC EVENT	51287
DOCKET	030-03249
LICENSE	40-12378-01

DNMS CONTROLLED CORRESPONDENCE ROUTING SLIP - MATERIALS LER

DNMS	Initials	Note to DNMS Staff
C:NMIB	G. MICHAEL VASQUEZ <i>for final review</i> <u>GMV</u>	WHEN LER ACTION IS COMPLETED: Return routing slip and completed LER evaluation to LER PROJECT MANAGER NOTE: Licensee report MUST be scanned into ADAMS.
Assigned to:	Janine Katanic	
Copy to:	LER Point of Contact: Jason Dykert	

This section is to be completed by a DNMS Branch Chief (or designee):

Circle appropriate response:	Yes	No	Indicate appropriate basis for LER:
REPORTABLE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Regulation(s): 35.3045(a)(1)
PN	<input type="checkbox"/>	<input type="checkbox"/>	License Condition:
ABNORMAL OCCURRENCE	<input type="checkbox"/>	<input type="checkbox"/>	For Abnormal Occurrence criteria see MD 8.1, Handbook 8.1, Part II
EVENT OF INTEREST	<input type="checkbox"/>	<input type="checkbox"/>	For Event of Interest guidelines see MD 8.1, Handbook 8.1, Part II
REACTIVE / SPECIAL INSPECTION REQUIRED	<input type="checkbox"/>	<input checked="" type="checkbox"/>	This event was reviewed against the criteria contained in IMCs 2800, 1301, 1302, etc., and it was determined that a reactive or special inspection was not necessary at this time.

Assigned Staff are to check (Y) ADAMS document availability below and to enter the following numbers, if applicable:

<input checked="" type="checkbox"/> Public	<input type="checkbox"/> Nonpublic	PNO-IV- <u>N/A</u>
<input type="checkbox"/> Sensitive	<input checked="" type="checkbox"/> Nonsensitive	NMED <u>150455</u>
<input checked="" type="checkbox"/> NRC Viewers Access Rights		NRC INSPECTION REPORT <u>N/A</u>

SUNSI Review Completed: Initials JPK

LICENSEE / NOTIFYING ENTITY: Sanford Health / Steven Moeckly

EVENT LOCATION: Sioux Falls, SD

ADAMS ML15224B358

COMMENTS: Need written report ML #

License report dated 8/14/15 ML15246A428

decision to not perform reactive inspection

LICENSEE EVENT REPORT EVALUATION FORM

EVENT CLASS: MED - MEDICAL EVENT

LICENSEE / REPORTING PARTY INFORMATION:

Licensee/Reporting party name:	Sanford Medical Center dba Sanford USD Medical Center		
License number :	40-12378-01		
Docket number :	030-03249		
Licensee's City of record :	Sioux Falls		
Licensees State of record :	SD		
NRC regulated?	Yes	If so, what Region?	RIV
Working under reciprocity?	No		

EVENT INFORMATION:

In what City and State did the event occur?	Sioux Falls
Event date :	7/30/2015
Discovery date :	8/4/2015
Report date :	8/4/2015
Agreement State reportable?	No
NRC reportable?	Yes
Reporting regulation :	10 CFR 35.3045(a)(1)(i)
NMED Item Number :	150445

RADIATION SOURCE INFORMATION:

Isotope :	Y-90
Activity :	37.03 mCi
Manufacturer :	Sirtex
Model number :	SIR-spheres
Serial number :	N/A

LICENSEE EVENT REPORT EVALUATION FORM

EVENT CLASS: MED - MEDICAL EVENT

ADDITIONAL INFORMATION REQUIRED:

Procedure administered?	Brachytherapy
Dose intended?	29.46 mCi
Dose administered?	37.03 mCi
Target organ?	Liver

NARRATIVE EVENT DESCRIPTION:

Because of the patient's lung shunt volume, the Authorized User (AU) had two numbers for activity on the written directive (WD); one that did not take into account the lung shunt volume "pre-reduction" and the other that took the lung shunt volume into account "post-reduction." The pre-reduction activity was 37.76 mCi and the post-reduction activity was 29.46 mCi. The nuclear medicine technologist used the pre-reduction activity instead of the post-reduction activity. The technologist drew up 40.0 mCi, which was administered to the patient on 7/31/2015. After the procedure, the remainder in the administration kit was assayed and it was determined that 37.03 mCi was the final administered amount.

During a routine audit on 8/4/2015, the licensee discovered this discrepancy and identified that a medical event occurred. This was reported to NRC on 8/4/2015 pursuant to 10 CFR 35.3045(a)(1)(i). The event was evaluated based on information provided by the licensee and it was determined that a reactive inspection was not warranted (ADAMS ML15224B358).

The licensee determined that the activity administered was approximately 26% greater than prescribed and resulted in a possible difference in effective dose equivalent to the patient of 68 rem to an organ (liver). The prescribing physician and the patient were notified by the licensee on 8/5/2015. The licensee does not expect any adverse outcomes to the patient as a result of this medical event.

The licensee's causal factors analysis determined that the event was due to the following contributing factors: (1) for WDs where there is a reduction due to a lung shunt, the activity was not always written in the same place on the WD by the AU; (2) the nuclear medicine technologists did not independently verify the activity used in the calculations; and (3) during the time-out period during the procedure, the AU was not shown the WD.

The Radiation Safety Officer (Head of Radiation Therapy Physics) performed an audit of over 50 procedures involving the administration of SIR-spheres and did not find any similar cases or additional medical events. The licensee also performs the procedure utilizing Thera-spheres and noted that the process used for those is different and that this type of situation would not manifest in this way for Thera-sphere procedures.

LICENSEE EVENT REPORT EVALUATION FORM

EVENT CLASS: MED - MEDICAL EVENT

CORRECTIVE ACTIONS:

As corrective actions, the licensee: (1) revised the WD form for this type of therapeutic procedure to clarify the prescribed dose; (2) initiated dual dose verification to allow for independent dose verification; (3) revised the SIR-spheres procedure to include the step of showing the AU the WD during the "time-out" period; and (4) provided training to the technologists with regard to the procedure revisions.

RECOMMENDED FOLLOWUP:

Was a reactive inspection conducted?	No	If so, inspection report number :	N/A
Is LER recommended for closure?	Yes		
Is this NMED Item Number recommended to reflect "complete"?	Yes		

LER Evaluator: <u>Janine F. Kataric, PhD, CHP</u>	Branch Chief or Designee Review:
Name: <u>Janine F. Kataric</u> Date: <u>12/7/15</u>	Name: <u>George J. Smith</u> Date: <u>12/21/15</u>