LICENSEE EVENT REPORT EVALUATION FORM

EVENT CLASS: MED - MEDICAL EVENT

LICENSEE / REPORTING PARTY INFORMATION:

Licensee/Reporting party name:	The Queen's Medical Center		
License number :	53-16533-02		
Docket number :	030-14522		
Licensee's City of record :	Honolulu		
Licensees State of record :	Hawaii		
NRC regulated?	Yes	If so, what Region?	IV
Working under reciprocity?	No		

EVENT INFORMATION:

In what City and State did the event occur?	Honolulu, Oahu, Hawaii
Event date :	09/13/2011
Discovery date :	09/13/2011
Report date :	09/13/2011
Agreement State reportable?	No
NRC reportable?	Yes
Reporting regulation :	Reportable threshold in accordance with 10 CFR 35.3045(a)(2)
NMED Item Number :	Event #47263

ADDITIONAL PARTIES INVOLVED:

Name :	N/A
License number :	
City :	
State :	

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CONSULTANT INFORMATION (if any):

Consultant name :	Edward B. Silberstein, M.D.
Company :	Eugene L. and Sue R. Saenger Professor of Radiological Sciences
Who hired consultant?	NRC

DEVICE INFORMATION:

Manufacturer :	N/A
Model number :	
Serial number :	

RADIATION SOURCE INFORMATION:

Isotope :	Strontium-89
Activity :	1.59 millicuries
Manufacturer :	N/A
Model number :	N/A
Serial number :	N/A

ADDITIONAL INFORMATION REQUIRED:

Procedure administered?	whole body bone scan
Dose intended?	6.0 milliCuries of Octreotide
Dose administered?	1.59 milliCuries of Metastron
Target organ?	bone

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NARRATIVE EVENT DESCRIPTION:

On September 13, 2011, at approximately 1000 HST, a nuclear medicine technologist dosed a patient scheduled to receive an administration of 5 milliCuries (mCi) of In-111 for an imaging scan (Octreotide), but instead administered 1.55 mCi Sr-89 therapeutic injection (Metastron). The Sr-89 dose, originally 3.99 mCi, was expired from its intended assay and treatment administration date of July 6, 2011 with an expiration date of August 2, 2011 (89 days). The therapeutic dose was administered unintentionally due to human error. The RSO calculated that the red bone marrow would have received a dose of 63 Rem.

The patient was informed and is being monitored for changes in blood chemistry. The attending and prescribing physician were immediately informed.

The licensee discovered the mistake within minutes of the administration while entering dosing information into the licensee's Database.

Based on the dose assessment, although the whole body did not receive greater than 5 Rem exposure, the calculated dose to the patient's red bone marrow was approximately 65 Rem. Based on the attending physician's review, the most significant potential consequence of the Sr-89 dose would be a transient decrease in red blood cell counts due to its effects on the bone marrow; therefore, blood samples would need to be collected over several months post administration to then assess any transitory effects. The NRC's consulting physician requested any pre-administration blood work data that might be made available for a more accurate assessment. Although the whole body dose did not receive greater than 5 Rem, the target organ (bone/bone marrow) or tissue exceeded 50 Rem exposure (i.e. 63 Rem), therefore this event was reportable under 10 CFR 35.3045(a)(2).

CORRECTIVE ACTIONS:

The licensee informed the patient of the mistake, and the technician has been re-instructed on the extreme importance of checking all of the labels prior to delivering any radioisotope. The ordering physician was also notified of the event.

The licensee has implemented double-validation of all radiopharmaceutical doses; documentation of the double validation protocols; revised "Radiopharmaceutical Use Authorization" written procedures; provided additional training and competency validation for all high-risk isotope procedures; implemented additional core competency validation in the annual Nuclear Medicine Technologist performance evaluation program; contacted the nuclear pharmacies to request additional labels on the outside of the syringe pigs to identify the radioisotopes in large font.

RECOMMENDED FOLLOWUP:

Was a reactive inspection conducted?	Yes	If so, inspection report number :	03014522/2011-001 (open)
Is LER recommended for closure?	Yes		
Is this NMED Item Number recommended to reflect "complete"?	Yes		
LER Evaluator: Name: [signature] Date: 1/11/2012		Branch Chief or Designee Review: Name: [signature] Date: 1/11/2012	