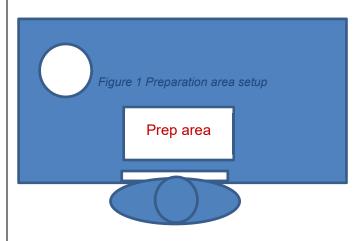
Title: Investigation - Skin Contamination Event of 19 May 2022Pharmalogic Puerto RicoPage 1 of 3

Date o	f Spill	Time	e of Spill	Area of Spill		Spill Involvement	
<b>19 May 2022</b> 01:50		01:50	SPER Restricted area, Compounding area,			<ul> <li>✓ Facility</li> <li>✓ Equipment</li> <li>✓ Personnel</li> </ul>	
Radionuclide			Ac	tivity in mCi		Chem. & Physical Form	
Tc99m			3 Ci		TcO4 <sup>-</sup> , liquid		
Description: Process:				al kits within biological s ained from Mo99 gener			
dose calib	orator's cham	ber. The v	vial fell outsid	e the chamber and onto	the su	from the vial shield into the urface of the biological safety and fell on top of the vial and	
shattered b) The skin o contamin containin mL was b	it, resulting contaminatio ation was lik g a solution o roken inside	in contam n was dete ely from a of Tc-99m the biolog	ination of a sr ected at appro small droplet pertechnetato ical safety cab	nall area limited to 50 c oximately 02:00 while m deposited on the opera	m2 of nonitor ator's g imate	the operator's left arm. ring the operator. The gowning after a vial concentration of 520 mCi per	
decontan most of tl decontan	ninated using ne contamina nination, the g a Ludlum m	a scrubbin ation, with dose rate	ng sponge and only a small a from residual	amount remaining non- skin contamination was	contam remov s meas	n the skin was nination efforts removed able contamination. After sured at 7 mR/h = 24,000 dlum model 44-9 pancake	
d) Other cor	ntaminated in	nanimate a	areas included	1:			
i) Le	i) Left side of the biological safety cabinet interior.						
-	ii) Stainless steel cart immediately in front of the biological safety cabinet, including computer monitor.						
iii) Flo	oor 2 feet im	mediately	in front of th	e biological safety cabin	et.		
	Initial fixed contamination readings were over 200 mRh <sup>-1,</sup> and no decontamination was performed. All these areas were shielded, and access was restricted to their immediacy.						
	The area was released for use on Monday, May 23, 2022, after allowing for decay and background levels were achieved.						
	) Only one person was contaminated in the event, and other adjacent areas were not cross- contaminated.						

Root cause:



There are two failure modes: the vial fell outside the well, and the shielding slipped the operator's hand falling on top of the vial below.

The operator attempted to drop a vial containing material into the well for activity reading using the vial shielding. Reading of the vial's content is performed regularly to accurately measure the vial's activity in performing dilutions and during molly breakthrough testing.

Since the well is located to the rear and the left of the biological safety cabinet, the operator needs to extend his right hand over the preparation area to deposit vials into the well. The left-hand raises the well's dipper and then lowers it into the well. In general, the latter has effects: it increases the distance required to deposit the vial and overextends the arm beyond a more stable position for more control.

Trying to deposit the vial from the left side using the left hand is not feasible for two reasons: most operators are right-handed, the approach toward the well needs to occur from the sides, and there is not enough space on the left side of the well.

Corrective Actions:

- Replaced vial shield with a top-loading shield instead of a bottom-loading shield. The latter will allow for the glass vial to be handled from the top and withing the shielding using long forceps.
- Instructed operators to use long forceps to manipulate the vial to deposit it into the dose calibrator's well. This change will provide more reach while avoiding the manipulation of the shield using overextension of the arm, and second, it will prevent the shielding from falling onto the vial.

## Conclusion:

An assessment of the dose received to the operator's skin was performed, see attachment. The dose to the skin was determined to be lower than the max extremity dose measured at the finger rings, and hence the reportable dose will be maintained as the one measured by the max extremity ring dose.

Because the dosimeter used during the event and during May was sent 10 days before the end of the month, and the dosimeters scheduled for June were used during the last days of May, a table using a normalized ratio between the dose measured at the rings and the activity handled by the operator was created.

Page 3 of 3

Month 2022	Kit Prep Activity	Chest mRem	Left Finger mRem	The left-hand dose ratio	Right Finger mRem	The right- hand dose ratio
January	78,813	20	1,692	2.1E-02	1,206	1.5E-02
February	83,915	26	2,410	2.9E-02	2,150	2.6E-02
March	117,570	36	1,946	1.7E-02	1,718	1.5E-02
April	111,897	39	2,618	2.3E-02	3,434	3.1E-02
May <sup>*</sup>	82,721	26	1,851	2.2E-02	2,817	3.4E-02
June	105,339	32	2,562	2.4E-02	1,932	1.8E-02
			Average	2.3E-02		2.3E-02

The table showed an increase in the dose ratio during May when the event occurred. The increase is noted in the right finger dosimeter. Using a range between the highest ratio of 3.1 and the average, we may conclude that the event may have provided an additional dose between 25 to 91 mRem to the right ring dosimeter.

The frequency of the event is low. This is the first time the event has been recorded to have happened. The corrective actions are expected to reduce the two failure modes identified as the cause of the event.

Rolando Garcia	18-Aug-2022
Performed By	Date