

RI - DNMS Licensee Event Report Disposition

Licensee:	MedStar Georgetown University Hospital				
Event Description:	Violation of Written Directive				
License No:	OK30577-01	Docket No:	UP3035409	MLER-RI:	2016-009
Event Date:	05/19/16	Report Date:	07/28/16	HQ Ops Event #:	2

1. REPORTING REQUIREMENT

<input type="checkbox"/> 10 CFR 20.1906 Package Contamination <input type="checkbox"/> 10 CFR 20.2201 Theft or Loss <input type="checkbox"/> 10 CFR 20.2203 30 Day Report <input checked="" type="checkbox"/> Other <i>2LG 7/18/2016</i>	<input type="checkbox"/> 10 CFR 30.50 Report <input checked="" type="checkbox"/> 10 CFR 35.3045 Medical Event <input type="checkbox"/> License Condition
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2. REGION I RESPONSE

<input type="checkbox"/> Immediate Site Inspection <input checked="" type="checkbox"/> Special Inspection <i>Sensitive in July 2016</i> <input type="checkbox"/> Telephone Inquiry <input type="checkbox"/> Preliminary Notification/Report <input type="checkbox"/> Information Entered in RI Log <input type="checkbox"/> Report Referred To:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Inspector/Date</td><td> </td></tr> <tr><td>Inspector/Date</td><td> </td></tr> <tr><td>Inspector/Date</td><td> </td></tr> <tr><td> </td><td>Daily Report</td></tr> <tr><td> </td><td>Review at Next Inspection</td></tr> </table>	Inspector/Date		Inspector/Date		Inspector/Date			Daily Report		Review at Next Inspection
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3. REPORT EVALUATION

<input checked="" type="checkbox"/> Description of Event <input checked="" type="checkbox"/> Levels of RAM Involved <input checked="" type="checkbox"/> Cause of Event	<input checked="" type="checkbox"/> Corrective Actions <input checked="" type="checkbox"/> Calculations Adequate <input checked="" type="checkbox"/> Additional Information Requested from Licensee
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4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/> Release w/Exposure > Limits <input type="checkbox"/> Repeated Inadequate Control <input type="checkbox"/> Exposure 5x Limits <input type="checkbox"/> Potential Fatality	<input type="checkbox"/> Deliberate Misuse w/Exposure > Limits <input type="checkbox"/> Pkging Failure > 10 rads/hr or Contamination > 1000x Limits <input type="checkbox"/> Large# Indivs w/Exp > Limits or Medical Deterministic Effects <input type="checkbox"/> Unique Circumstances or Safeguards Concerns
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If any of the above are involved:

<input type="checkbox"/> Considered Need for IIT NA	<input type="checkbox"/> Considered Need for AIT NA
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Decision/Made By/Date: *Dwyer 6/30/2016*

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

<input type="checkbox"/> Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose) <input type="checkbox"/> Medical Consultant Used-Name of Consultant/Date of Report: _____ <input type="checkbox"/> Medical Consultant Determined Event Directly Contributed to Fatality <input type="checkbox"/> Device Failure with Possible Adverse Generic Implications <input type="checkbox"/> HQ or Contractor Support Required to Evaluate Consequences
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6. SPECIAL INSTRUCTIONS OR COMMENTS

Follow up to determine if event constitutes a medical event

<input type="checkbox"/> Non-Public <input checked="" type="checkbox"/> Public-SUNSI REVIEW COMPLETE	Inspector Signature: _____ Branch Chief Initials: _____	Date: _____ Date: <u><i>7/1/2016</i></u>
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7/18/16