

<b>CONVERSATION RECORD</b>		TIME: 3:20 pm	DATE: 7/20/11
<b>TYPE</b> <input type="checkbox"/> VISIT <input type="checkbox"/> CONFERENCE <input checked="" type="checkbox"/> TELEPHONE <span style="margin-left: 300px;"><input type="checkbox"/> INCOMING</span> <span style="margin-left: 300px;"><input checked="" type="checkbox"/> OUTGOING</span>			
NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU <i>Amy Davis, NM tech</i>		ORGANIZATION (Office, dept., bureau, etc.) <i>Nuclear Medicine</i>	TELEPHONE NO. <i>260-435-7291</i>
<b>SUBJECT:</b> FDA communication about strontium breakthrough in rubidium generators			
<b>SUMMARY</b> <p>The inspector contacted the licensee to: (1) notify the licensee about the FDA's July 15, 2011, communication concerning strontium breakthrough in rubidium generators, (2) provide additional information if the licensee had not already received the information, and (3) discuss the FDA's recommendations concerning breakthrough testing for the generators.</p> <p><i>Had heard needed to do breakthrough daily. E-mailed FDA link.</i></p> <p>Licensee: <i>QHG of Indiana, Inc. / Lutheran Hospital</i></p> <p>License No.: <i>13-01535-01</i>                      Docket No.: <i>030-01594</i></p>			
<b>ACTION REQUIRED</b> None.			
NAME OF PERSON DOCUMENTING CONVERSATION <i>Geoffrey Warren</i>		SIGNATURE <i>GJ Warren</i>	DATE <i>7/20/11</i>
<b>ACTION TAKEN</b>			
SIGNATURE		TITLE	DATE