

From: Penny Lanzisera
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Subject: St. Luke's Hospital, LN 37-07939-01, Inspection No. 2005-001

Mr. Robinson,

On September 27, 2005, I discussed with the nuclear medicine technologist the method used for setting the dose calibrator for yttrium-90 sirsphere measurements. For a treatment conducted on July 26, 2005, this setting resulted in a measurement 20% different from the activity provided by the manufacturer, corrected for decay. This appears to be a large discrepancy. Please provide the following additional information:

- 1) manufacturer's procedures for determining the activity placed on the label
- 2) manufacturer's instructions (or expectations) for end-users verifying the initial activity and measuring aliquots of the activity (e.g., dose calibrator with the initial setting of the dose calibrator determined by...).
- 3) manufacturer's label information for all sirsphere treatments conducted by the facility (e.g., # GBq, calibrated for time/date)
- 4) Sirsphere Treatment Record, Written Directive, and Dose Calculation Sheet for all treatments conducted by the facility.
- 5) Explanation of reduction/increase in administered activity from methods (e.g., BSA) provided by the manufacturer. For example, during the inspection, licensee staff stated that patients tolerate treatment better when clinically reducing the administered activity by 20 to 50%.
- 6) Indication of whether treatments are on-going or on-hold and if on-going, whether any changes in the initial activity measurement technique were implemented.
- 7) Explanation of why the right lobe was treated (instead of the left lobe) for the 7-26-05 treatment, since the Dose Calculation Sheet indicates that 0% of the Right Lobe is occupied by the tumor.

Thanks in advance for your cooperation.

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