

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Elkhart General Hospital REPORT 2006/001		2. NRC/REGIONAL OFFICE Region III	
3. DOCKET NUMBER(S) 030-17305	4. LICENSE NUMBER(S) 13-18879-01	5. DATE(S) OF INSPECTION 03/ 20 /06	
6. INSPECTION PROCEDURES 87131, 87132		7. INSPECTION FOCUS AREAS 03.01 - 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 2240	2. PRIORITY 2	3. LICENSEE CONTACT Sun-Shing Steven Leung, PhD	4. TELEPHONE NUMBER 574-523-7875
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: 03/08	
<input type="checkbox"/> Field			
<input type="checkbox"/> Temporary			

PROGRAM SCOPE

The licensee is a 300-bed medical facility located in Elkhart, IN, and it served the surrounding counties between Indiana and Michigan. The licensee is authorized to use byproduct materials per 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and as well 10 CFR 35.1000. At this facility, the licensee's oncology department operates a Varian's GammaMed Model-232 HDR unit.

The licensee's organizational structure is as stated on the license and it had not changed since the last inspection. However, according to the latest amendment, the licensee hired a new Physicist, Steven Leung, Ph.D., he is also the current RSO for both Nuclear Medicine and the Oncology Department. Currently, the licensee's authorized 29 users (MDs), a department manager, and a crew of dosimetrists. In 2005, the licensee performed approximately six HDR treatments of multiple fractions. The licensee oncology department also performed permanent prostate implants using I-125 seeds, and performed low dose LDR brachytherapies using Cs-137 tubes.

The Nuclear Medicine department performed 15 diagnostic studies per day, and radiopharmaceutical therapies. Specifically, the licensee's staff administered 25 hyperthyroid therapies per year using I-131 capsules with doses greater than 3 mCi, and approximately less than five ablation therapies per year with capsules containing 100 and 200 mCi of I-131. The licensee order unit doses from a radiopharmacy. The licensee employed six technologists for the NM department.

Performance Observations

During the inspection, the licensee's nuclear medicine staff demonstrated: (1) a daily radiation survey; (2) a weekly removable contamination survey; (3) a survey of a package; and (4) a daily dose calibrator constancy check. The inspector observed a diagnostic administration and the HDR daily QA tests during the inspection. The inspector reviewed written directives for iodine-131, HDR treatments and ~~small~~ permanent seed implants using palladium-103 seeds. No violations were identified during the inspections of the facilities. The records indicated that the licensee had conducted multiple fractions of gynecological therapies with the HDR unit. To improve utilization time of the HDR, The HDR unit was stored in a dedicated HDR room, known as the Nelco room. The HDR unit maintenance record was also reviewed during the inspection, and no safety problem was identified during the quarterly preventive maintenance. The inspector noted that the room contains all the safety systems, and it is located within the department as indicated in the license. The licensee secured the Nelco room by two padlocks and a heavy gauge of steel chain.