NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Karmanos Cancer Center REPORT NUMBER(S) 2011-001	2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S) 030-09376	4. LICENSE NUMBER(S) 21-04127-06	5. DATE(S) OF INSPECTION 1/31 – 2/4 with continuing review through 3/17/2011
5. INSPECTION PROCEDURES 87131 and 87132	7. INSPECTION FOCUS AREAS 03.01 – 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2310	2	Dr. Joseph Rakowski - RSO	313-745-1435

☒ Main Office Inspection Next Inspection Date: ___March 2013_____

☐ Field Office Inspection _____ ☐ Temporary Job Site Inspection

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PROGRAM SCOPE

The licensee is permitted to use licensed material in accordance with 10 CFR 35.400, 10 CFR 35.600 and 10 CFR 35.1000. The licensee possesses two teletherapy units containing Co-60 and a Gamma Knife also containing Co-60. The licensee also possesses an HDR unit. The licensee has not performed licensed activities permitted by 10 CFR 35.1000 since the last inspection. One of the teletherapy units is used for whole body irradiation; approximately 40-60 patients per year. The Gamma Knife unit patient load is approximately 20-40 patients per year. The second teletherapy unit is currently in storage and not being used for irradiation of patients or other activities. The HDR unit is used 3-5 times per week for the treatment of cancer. The licensee also has a permanent seed implant program using iodine-125 with 1-2 patients per month. The licensee had five authorized users and six authorized medical physicists. Licensed operations are normally Monday through Friday 7 am to 4-5 pm.

Observations and Findings

This was a routine safety inspection of the license which reviewed permitted activities of those noted above. The inspector observed licensed activities as they related to the preparation of licensed material, storage of licensed material, and demonstrations of radiological surveys; no regulatory issues were identified. The inspector interviewed licensee personnel and found they had adequate knowledge to ensure the safe use of licensed material. The inspector performed independent radiation measurements of areas where licensed material was used and did not identify any elevated radiation levels. The inspector made a comparison between NRC and licensee survey instrumentation and found radiation measurements were within +/-20% of one another. The inspector reviewed the licensee's therapy administration program, including written directives and supporting documentation; no regulatory issues were identified. The inspection was extended for continuing review of the licensee's program regarding the administration of therapeutic quantities of radiation to patients.

During the last NRC inspection, two Severity Level IV violations, which consisted of: 1) 10 CFR 35.41(a)(2) and (b)(2) – licensee's procedure for prostate seed implants did not provide high confidence that each administration was in accordance with the written directive; and 2) 10 CFR 30.3045 – failure to timely notify the NRC of a medical event. The inspector reviewed the licensee's corrective actions, which appeared to be adequate and did not identify any recurrent issues.