

February 5, 2007

MEMORANDUM TO: License File No. 22-00057-61

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Materials Licensing Branch
Division of Nuclear Materials Safety

FROM: Colleen Carol Casey, Health Physicist */RA/*
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Division of Nuclear Materials Safety

SUBJECT: LICENSING SITE VISIT FOR 3M COMPANY PANORAMIC
IRRADIATOR, BROOKINGS, SOUTH DAKOTA

DATES OF VISIT: November 28 - 29, 2006

PURPOSE OF VISIT: TO OBSERVE PREOPERATIONAL TESTING REQUIRED BY
MANUAL CHAPTER 2815 "CONSTRUCTION AND
PREOPERATIONAL INSPECTION OF PANORAMIC, WET-SOURCE
STORAGE GAMMA IRRADIATORS" AND DISCUSS LICENSING
DEFICIENCIES

Representatives from Materials Licensing and Inspection Branches and the Division of Reactor Safety participated in this licensing site visit. This prelicensing site visit was conducted in accordance with NUREG 1556, Vol. 20, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Administrative Licensing Procedures," to evaluate the current status of system installation activities of a new panoramic irradiator under construction at the 3M facility in Brookings, South Dakota. The site visit focused on preoperational testing required by Manual Chapter 2815 "Construction and Preoperational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators" and included a discussion of the remaining licensing issues to be resolved in support of the license amendment.

Observations

The licensee submitted an amendment request application dated July 27, 2005, to build a new panoramic, wet-source storage irradiator on the site immediately adjacent to its existing panoramic, wet-source storage irradiator. The licensee's newly constructed MDS Nordion JS 10000 irradiator, referred to as the "S-10," will eventually replace the current JS 7500 irradiator, referred to as the "S-8." Construction of the S-10 irradiator began in the third quarter of 2005.

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The first loading of cobalt-60 sources into the S-10 irradiator was projected for September 2006. However, economic factors, construction issues, and irradiator system installation problems have delayed the initial source loading. The licensee currently projects source loading no earlier than March 2007. The license authorizes cobalt-60 to sterilize medical supplies, such as bandages, adhesives, and surgical drapes that are manufactured by 3M. The S-10 irradiator will assume this function upon source loading and commissioning in 2007. Regional participants in this site visit were Roger Lanksbury, Senior Project Manager, DRS; Geoffrey Warren, Radiation Specialist, DNMS-MIB, and Colleen Carol Casey, Health Physicist, DNMS - MLB.

Licensee participants were Jon Neff and Travis Mosley, S-8 and S-10 irradiator operators; Ronald Stangeland, Alternate Site Radiation Safety Officer; Ely Arcilla, Brookings Site Plant Manager; Kostas Kaounas, Site Radiation Safety Officer; and Frederick Entwistle, Manager, Corporate Health Physics.

NRC representatives met with the site RSO, Kostas Kaounas, toured the existing and operational S-8 irradiator and toured the S-10 irradiator, in the final stages of construction.

The NRC representatives also requested certain changes and corrections to be made to the testing protocol to conform with 10 CFR Part 36 and Manual Chapter 2815 criteria, as follows:

- (1) a test to verify that the water level control system operates properly - NRC questioned the number of inches for moving the float below floor level, resulting in a change from "11" to "10.25" and both "29" numbers to 26 1/8";
- (2) a test for access control pursuant to 10 CFR 36.23(e), requiring each radiation room at a panoramic irradiator to have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position - NRC noted that the requirement stated, in part, that the test should cause the source rack to return to the fully shielded position. The licensee added this to the definition of a successful test and this had been a previous comment that had not previously been reconciled;
- (3) a test for radiation monitors pursuant to 10 CFR 36.39(e), requiring the product conveyor to be designed to stop before a source on the product conveyor would cause a radiation overexposure to any person - NRC noted that the licensee deleted the section of the testing that verified the conveyors stopped. This was added back in.
- (4) a test of the fire protection system to verify the ability of heat and smoke detectors to detect a fire, activate alarms and cause the source rack to become fully shielded - NRC noted that the licensee had deleted the criteria for the source rack to become fully shielded, which was a required part of a successful test and had been in the test procedure in an earlier revision. The criteria were restored to the test procedure.

These changes and corrections were made and testing commenced on November 29, 2006. Most of the preoperational acceptance testing of the S-10 irradiator was conducted successfully, with the exception of several tests that were deferred to December 2006 and completed successfully on December 19, 2006.

Two S-10 trained operators conducted each of the tests, which were observed and verified by the regional participants and licensee representatives.

The acceptance testing, required by 10 CFR 36.41 to ensure compliance with 10 CFR 36.23, 36.29, 36.39 and 36.59, was conducted to demonstrate that "construction met design" criteria in the following areas: shielding, foundations, pool integrity and wiring.

Acceptance testing of the systems and equipment identified below was conducted to demonstrate reasonable assurance that each operational system functioned as required. Due to vendor installation problems and a frozen heat exchanger, all tests involving alarms sent to the guard desk, two radiation monitor tests, visual "flashing light" tests, and source protection deluge water system tests were deferred to December 19, 2006. All deferred tests have been completed and the results were provided to the NRC.

- water-handling system (including the water purification system, five tests performed);
- source- rack (including source return to safe position after simulated loss of off-site power, four tests performed and one test deferred to December 2006, for source rack lowering resulting in guard desk alarm);
- access control (including computer systems and security, ten tests performed and six tests deferred to December 2006, for visual source movement alarms and/or guard desk alarms, related to the personnel access door entry, the conveyor inlet access, the conveyor outlet access, the research loop and the source condition indicator reflecting movement from shielded to unshielded position);
- radiation monitors (one test performed, two deferred to December 2006, for visible and audible guard desk alarms, when the product conveyor stops and when the deionizer pump and chiller pump stop operating in response to check source "contamination" activation of the in-line water monitor);
- fire protection system (two tests deferred to December 2006, for guard desk alarms when a smoke detector fault illuminates on the control console in response to smoke can activation of smoke detector inlet pipe and when a high temperature fault illuminates on the control console in response to heat gun activation of the heat detector);
- tests of ozone entry delay timer (performed) and deluge water in source shroud (one test deferred to December 2006 for deluge water flow in source shroud).

At the conclusion of testing, NRC representatives met with licensee management representatives to discuss the remaining licensing deficiencies (see ADAMS ML070310226), to be addressed in order to complete the amendment to authorize the use of the new irradiator.

Conclusion

The NRC participants noted that observation of the actual testing was a valuable learning experience, which integrated critical components of the construction and licensing activities of this project. In addition, this site visit afforded NRC staff in MIB, MLB and DRS an opportunity to interact cooperatively, learn from each other, maintain continuity throughout the course of a lengthy construction project, and share joint responsibility under Manual Chapter 2815.

License No. 22-00057-61
 Docket No. 030-14999

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