

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NEW REACTORS
WASHINGTON, DC 20555-0001

November 20, 2015

NRC INFORMATION NOTICE 2015-12: UNACCOUNTED FOR ERROR TERMS
ASSOCIATED WITH THE IRRADIATION TESTING
AND ENVIRONMENTAL QUALIFICATION OF
IMPORTANT-TO-SAFETY COMPONENTS

ADDRESSEES

All holders of an operating license or construction permit for a nuclear power reactor issued under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of and applicants for a power reactor early site permit, combined license, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." All applicants for a standard design certification, including such applicants after initial issuance of a design certification rule.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of issues identified by the NRC staff concerning unaccounted for error terms associated with the irradiation testing and environmental qualification of important-to-safety components. The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to address the identified issues and avoid similar problems. No specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

The environmental qualification of nuclear components is performed by specialized test facilities that have the equipment necessary to simulate the conditions (i.e., temperature, pressure, humidity, chemical spray, etc.) that would be expected during a nuclear accident. While such facilities often have specialized environmental chambers for simulating nuclear accident environments, they rarely have the capability to perform the irradiation of nuclear components as required by the qualification process. The irradiation phase of the qualification process is typically performed before subjecting a component to the accident environment. As such, the large majority of nuclear component irradiations performed as part of nuclear equipment qualification programs is, and were, subcontracted out to a few specialized facilities. Steris Isomedix in Whippany, New Jersey, is one such facility where a large number of nuclear components were irradiated as part of an environmental qualification process.

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During an NRC vendor inspection conducted in April 2014, at Steris, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14128A117), the NRC identified that Steris had failed to ensure that the measuring and testing system (e.g., the dosimeters, associated procedures, and dosimetry reading equipment) used to determine the applied radiation dose to the nuclear components being tested was properly controlled. Specifically, Steris had not accounted for all variability in the irradiation process. The NRC identified that Steris had failed to account for the density of other products placed into the irradiation chamber, source decay, and location within the irradiation chamber. As a consequence, inspectors identified the actual radiation dose applied to nuclear components as potentially being less than what was reported on the irradiation certificates of conformance provided by Steris.

Subsequent to the NRC inspection, on June 18, 2014, Steris notified its customers under the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," that the actual radiation dose applied to components irradiated at the Steris Whippany facility might not have been achieved as certified by Steris. At the time the Part 21 notification was issued, the unaccounted for variability in the irradiation process was thought by Steris to be as much as 5.1 percent. This was in addition to a 6.5 percent measurement uncertainty associated with the Harwell Red 4034 Perspex dosimetry utilized by Steris to determine radiation dose, which may or may not have been considered and understood by Steris's customers. On July 14, 2014, Steris responded (ADAMS Accession No. ML14197A113) to the NRC inspection report and detailed its corrective actions, which were largely focused around ensuring the accurate communication of uncertainties in its process for any future work.

Subsequent to identification of this issue, and since Steris has been a service supplier for a large portion of irradiation services for nuclear safety-related components, an industry group was formed to work with Steris, as necessary, to determine the broad scope of the issue. On April 27, 2015, Steris released a position paper (ADAMS Accession No. ML15170A147) that more thoroughly examined the previously-identified issues and provided a refined estimate of the maximum error (radiation dose applied that was less than requested) for any previous components irradiated at the Steris Whippany facility. In that position paper, Steris stated that it had recalculated the overall potential variability in the irradiation process to be approximately 9.6 percent for most applications, and to be 11.8 percent for components processed at Steris in the ceiling location within their irradiation cell between October 19, 2007, and April 28, 2014. In June of 2015, the Nuclear Utility Group on Equipment Qualification, in collaboration with the Institute of Electrical and Electronics Engineers (IEEE), released an Industry Guidance Position Paper (ADAMS Accession No. ML15170A148), which provides an aid to utilities faced with responding to the subject issues. While the NRC has not performed a formal review of this document, it appears to provide useful supplemental information that could be used in response to this issue.

BACKGROUND

The regulations in 10 CFR 50.49, "Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants," state that each item in this category must be qualified either by type tests or a combination of type tests and analyses. NRC Regulatory Guide (RG) 1.89, Revision 1, "Environmental Qualification of Certain Electric Equipment Important to Safety for Nuclear Power Plants," dated June 1984, endorses IEEE 323-1974, "IEEE Standard for Qualifying Class IE Equipment for Nuclear Power Generating Stations," with some exceptions, as one method to comply with 10 CFR 50.49. Included within 10 CFR 50.49, and also

addressed by RG 1.89 and IEEE 323, is a consideration of the effects of radiation on the components being qualified. Specifically, 10 CFR 50.49 states, in part, that:

The radiation environment must be based on the type of radiation, the total dose expected during normal operation over the installed life of the equipment, and the radiation environment associated with the most severe design basis accident during or following which the equipment is required to remain functional, including the radiation resulting from recirculating fluids for equipment located near the recirculating lines and including dose-rate effects.

Consequently, for a component to be considered qualified for its application, licensees must evaluate the component's ability to perform after being subjected to a radiation dose commensurate to what the component would be expected to receive once installed in the reactor facility. In most cases, the radiation dose includes a dose related to normal and abnormal operations, as well as a dose related to an accident.

The regulations in 10 CFR 50.49 also require that margins be included to account for unquantified uncertainty in the qualification process, such as the effects of production variations between tested and production components, as well as inaccuracies in test instrumentation. RG 1.89, Revision 1, states that the suggested margin values in Section 6.3.1.5 of IEEE 323-1974—as applied to radiation dose—are acceptable for meeting the 10 CFR 50.49(e)(8) margin requirements.

In addition, Criterion 4, "Environmental and dynamic effects design bases," of the General Design Criteria contained in Appendix A to 10 CFR Part 50, requires that all structures, systems, and components important to safety be designed to accommodate the effects of and to be compatible with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. Consequently, the issues identified in this IN might also apply to some non-electrical equipment not covered under the scope of 10 CFR 50.49 (e.g., certain important-to-safety mechanical equipment, containment coatings, etc.).

DISCUSSION

The issues described above associated with the irradiation of nuclear components at Steris span many years, beginning since the opening of its Whippany facility in 1984. In most cases, Steris was not a direct service supplier to the nuclear utilities themselves, and nuclear utilities may not have been notified directly by their suppliers regarding the subject issues. While Steris notified its direct customers as required by 10 CFR Part 21, some of Steris's customers that were originally responsible for the qualification of the equipment and components in question are no longer in business or no longer maintain nuclear quality assurance programs.

Also, often times the radiation dose requirements provided by Steris's customers were not nuclear power plant specific; therefore, the effect of the errors in irradiation on each component's qualification is unknown. With respect to radiation, IEEE 323-1974 states that a margin of 10 percent of the accident dose should be used during the qualification process to account for uncertainties associated with variations in commercial production, inaccuracies in test equipment, and reasonable errors in defining satisfactory performance.

CONTACT

This IN requires no specific action or written response. Please direct any questions about this matter to the technical contact listed below or the appropriate Office of Nuclear Reactor Regulation (NRR) or Office of New Reactors (NRO) project manager.

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ADAMS Accession No.: ML15215A502

TAC MF6471

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