

Japan Atomic Energy Agency (JAEA)

Licensing Topical Report on Quality Assurance Program Description for Floating Seismic Isolation System (FSIS) Design Activities

Information Needs

- 1. Regulatory Basis:** Appendix B to 10 CFR Part 50, Criterion VII, requires measures to ensure that purchased material, equipment, and services meet established requirements. When laboratory accreditation is used in lieu of commercial-grade surveys for procurement of calibration or testing services, the applicable regulatory requirements include implementation of all conditions necessary for accreditation to provide sufficient assurance of quality for safety-related applications. Nuclear Energy Institute (NEI) 14-05A, Revision 1, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20135H229), as endorsed by the NRC Safety Evaluation (SE) ML20322A019, describes the staff-accepted method for using International Standard Organization/International Electrotechnical Commission (ISO/IEC) 17025:2017 laboratory accreditation under the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing commercial-grade surveys. The SE also imposes limitations and conditions on the use of accreditation, including restrictions on the use of remote accreditation assessments, prohibition of subcontracting of accredited services, validation that work is performed within the accredited scope, performance of technical evaluations, and an explicit restriction prohibiting the use of ILAC accreditation for acceptance of nondestructive examination or nondestructive testing (NDE/NDT) services.

Issue: JAEA/IHI’s Quality Assurance Program Description (QAPD) §7.2 permits acceptance of calibration and testing laboratories accredited under ISO/IEC 17025 and the ILAC MRA. However, the QAPD does not describe how accreditation-based acceptance meets all applicable requirements of Criterion VII nor does it incorporate all limitations and conditions established in NEI 14-05A, Revision 1 and NRC SE ML20322A019. Specifically, QAPD §7.2 does not address required conditions including: use of ISO/IEC 17025:2017; verification that accreditation is based on an onsite assessment within the past 48 months; prohibition on use of two consecutive remote accreditation assessments; prohibition of subcontracting accredited calibration or testing services; purchase-order controls requiring notification of accreditation or scope changes; technical evaluation requirements ensuring the correct technical and quality requirements are specified; and receipt-based validation confirming that the services were performed under the accredited program and within accredited scope. In addition, QAPD §7.2 does not incorporate the SE-mandated prohibition on using ILAC accreditation for acceptance of NDE or NDT services, because ISO/IEC 17025 accreditation does not address personnel qualification requirements necessary for safety-related NDE/NDT activities. Without inclusion of these controls and limitations, the QAPD does not demonstrate how accreditation-based acceptance provides assurance equivalent to a

commercial-grade survey as required by Criterion VII.

Information Need: As a nonlicensee applicant submitting a QA topical report, please demonstrate how calibration and testing services used in safety-related applications will be accepted under Appendix B Criterion VII. Specifically, either (1) describe how JAEA/IHI will perform supplier qualification or commercial-grade surveys consistent with Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 6 (ML23177A002) when accreditation-based acceptance is not used, or (2) commit to implementing NEI 14-05A, Revision 1 in full, as endorsed by NRC SE ML20322A019, including all conditions and limitations required for use of ILAC MRA accreditation in lieu of commercial-grade surveys. The description must address how accreditation-based acceptance will ensure procured services meet applicable technical and quality requirements, including: ISO/IEC 17025:2017 accreditation; onsite accreditation assessment within the past 48 months; prohibition of two consecutive remote assessments; prohibition of subcontracting accredited services; purchase-order requirements including notification of changes to accreditation or scope; performance of a documented technical evaluation; and receipt-validation confirming work was performed under the accredited program and within accredited scope. In addition, please describe how QAPD §7.2 will incorporate the SE-required prohibition on using ILAC accreditation to accept NDE/NDT services in lieu of performing a commercial-grade survey.

2. **Regulatory Basis:** Standard Review Plan (SRP) Section 17.5 (ML15037A441), Paragraph II.V, calls for applicants to establish QA program commitments and to maintain them consistent with current NRC positions. The JAEA/IHI QAPD Part IV currently cites RG 1.29, "Seismic Design Classification for Nuclear Power Plants," Revision 4 (March 2007).

Issue: The QAPD's commitment list is not up to date with respect to RG 1.29 (it references Revision 4 instead of Revision 6), creating a mismatch with current staff-endorsed guidance used in comparable accepted programs.

Information Need: Please update QAPD Part IV to replace RG 1.29, Revision 4 with RG 1.29, Revision 6 (ML21155A003), and identify any conformance statements or exceptions associated with the updated regulatory position. If JAEA/IHI intends to retain Revision 4, provide a justification for continued applicability and explain how the QAPD will remain aligned with current NRC guidance for seismic design classification.