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October 1, 2018

Ms. Kerri A. Kavanagh, Chief
Quality Assurance Vendor Inspection Branches 1 & 2
Division of Construction Inspection and Operational Programs
Office of New Reactors
M/S O-4A17M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Endorsement of ISO/IEC 17025: 2017, "General Requirements for the Competence of Testing and Calibration Laboratories"

Project Number: 689

Dear Ms. Kavanagh:

The United States Nuclear Regulatory Commission (NRC) endorsed the International Laboratory Accreditation Cooperation (ILAC) process through their endorsement of Nuclear Energy Institute[1] (NEI) 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services" on February 9, 2015. The ILAC process allows nuclear utilities and their suppliers to accept testing and calibration services (in lieu of a commercial grade survey) from laboratories that are accredited to ISO/IEC 17025:2005 by Accreditation Bodies (AB) that are signatories to the ILAC Mutual Recognition Agreement (MRA). Use of the ILAC process is contingent on meeting the conditions specified in NEI 14-05A; one of which is the laboratory must be accredited to ISO/IEC 17025:2005.

On November 30, 2017, ISO (International Organization for Standardization) published a new version of ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." In order for nuclear utilities and their suppliers to continue to utilize the ILAC process during commercial grade dedication of calibration and testing services, the nuclear industry must first gain the NRC's acceptance of ISO/IEC 17025:2017. The Nuclear Procurement Issues Corporation (NUPIC) in conjunction with NEI is seeking the NRC's endorsement of ISO/IEC 17025:2017.

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

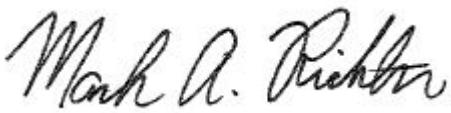
ISO/IEC 17025:2017 covers all laboratory activities, including testing, calibration and the sampling associated with subsequent calibration and testing. ISO/IEC 17025:2017 includes technical enhancements, definitions of key terms, and provisions for greater use of Information Technology (IT) techniques. The major changes are identified in Attachment 1 "ISO/IEC GAP Analysis Summary."

The NUPIC/NEI Committee performed a detailed review of the 2005 and 2017 versions of ISO/IEC 17025 to substantiate that the ISO/IEC 17025:2017 does not reduce technical commitments or quality requirements. This review verified that the major changes were essentially formatting and additions which enhance the ISO/IEC 17025 standard. A Requirements Traceability/Cross Reference Matrix (Attachment 2) was developed to perform this review. As a result, the NEI/NUPIC Committee concluded that the ISO/IEC 17025:2017 is equivalent to, or better than, ISO/IEC 17025:2005 in technical and quality requirements.

ISO has designated a three (3) year transition for the ISO/IEC 17025:2017. Since the standard was published on November 30, 2017, all re-accreditations and new accreditations to ISO/IEC 17025 must be made to ISO/IEC 17025:2017 by November 30, 2020. In order to meet this deadline, each AB that is a signatory to the ILAC MRA has developed a transition plan for accrediting their laboratories and prospective laboratories. To ensure successful transitions, some ABs have started the process of accrediting laboratories to ISO/IEC 17025:2017. To this end, ILAC/ISO issued a Joint Communication which stressed that during this transition period, ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are valid and equivalent for use. ILAC/ISO strongly recommends that governmental bodies and approval agencies recognize both versions until the 3-year transition period closes. The Joint Communication is attached (Attachment 3.) The NUPIC/NEI Committee is requesting endorsement of ISO/IEC 17025:2017 by the NRC on behalf of the nuclear industry during this transition period. This endorsement should recognize both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 during this transition period. A revision to NEI 14-05A will be subsequently provided to the NRC requesting endorsement of ISO/IEC 17025:2017 beyond the transition period.

Should you have any questions, please do not hesitate to contact me.

Sincerely,



Mark A. Richter

Attachments

Joint ILAC-ISO Communiqué on the recognition of ISO/IEC 17025 during a Three-Year Transition

Laboratories wishing to demonstrate their technical competence can do so via conformity with the international standard ISO/IEC 17025 '*General requirements for the competence of testing and calibration laboratories*'. Conformity with this standard also means that the laboratory generally operates a management system in accordance with the principles of ISO 9001.

In 2017, ISO published a revision to ISO/IEC 17025 (previously published in 2005) to ensure that requirements continue to meet the demands of the modern market place. As a consequence, it has been agreed that laboratories that demonstrate conformity through third-party accreditation will need to transition their processes to the new version within a defined timeframe. ILAC, in consultation with ISO, agreed that a three year period from the date of publication shall be allowed for this transition.

During this transition period, it is important to note that both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are equally valid and applicable. Formal accreditation to either standard granted by an accreditation body that is a signatory to the ILAC Arrangement should be recognised by the market place, and it is strongly recommended that specifiers equally recognise both versions until after the 3-year transition period has closed.

ILAC Chair

ISO/CASCO Chair

November 2017

ISO/IEC 17025: 2005 and 2017 Requirement Traceability/Cross Reference Matrix

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Scope	**Scope**	Section 1, Page 1 Clause 1.1, 1.2, 1.3, 1.4, 1.5, 1.6 , All Page 1	Section 1, Page 1	Equivalent
Normative References	**Normative References**	Section 2 , Page 2	Section 2, Page 1	Equivalent
Terms and Definitions	**Terms and Definitions**	Section 3, Page 2	Section 3, Pages 1-3	**ISO/IEC 17025:2017 improved this area. Key terms are defined.**
Management Requirements	**Management System Requirements**	Section 4, Page 2	Section 5, Page 4 Section 6, Page 5 Section 8, Page 19	Equivalent
Organization	**Structural Requirements**	Section 4.1, Page 2 Clause 4.1.1, Page 2 Clause 4.1.2, Page 2	Section 5, Page 4 Clause 5.1, Page 4 Clause 5.4, Page 4	Equivalent The requirement to appoint a deputy for each key managerial

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 4.1.3, Page 2 Clause 4.1.4, Page 2 Clause 4.1.5a, Page2 Clause 4.1.5b, Page 3 Clause 4.1.5c, Page 3 Clause 4.1.5d, Page 3 Clause 4.1.5e, Page 3 Clause 4.1.5f, Page 3 Clause 4.1.5g, Page 3 Clause 4.1.5h, Page 3 Clause 4.1.5i, Page 3	Clause 5.4, Page 4 Clause 4.1.4, Page 3 Clause 5.6a, 5.6b, 5.6c, Page 4 Clause 4.1.2, 4.1.3, Page 4 Clause 4.2, Pages 3-4 Clause 4.1.1, Page 3 Clause 6.2.1, Page 5 Clause 4.1.1, Page 3, Clause 5.5a, Page 4 Clause 4.1.1, Page 3 Clause 5.5b, Page 4 Clause 6.2.5d, Page 5 Clause 5.2, Page 4 Clause 5.2, Page 4 Clause 5.6d, 5.6e, Page 4	personnel (4.1.5j) was not carried over from ISO 17025:2005 to ISO 17025:2017. This does not present a problem because the new standard still requires a laboratory to have the personnel resources to manage and perform its laboratory activities.

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 4.1.5j, Page 3 Clause 4.1.5k, Page 3 Clause 4.1.6, Page 3	**No Equivalent Requirement – See Clause 6.1** Clause 6.2.3, Page 5, Clause 8.2.1, Page 20 Clause5.7a, Page 5	
Management Systems	**Management Systems Requirements**	Section 4.2, Page 3 Clause 4.2.1, Page 3 Clause 4.2.2a, Page 3 Clause 4.2.2b, Page 3 Clause 4.2.2C, Page 3 Clause 4.2.2d, Page 4	Section 8, Page 19 Clause 8.1.2 Clause 5.5c, Page 4 Clause 6.2.4, Page 5 Clause 8.2.1, Page 20 Clause 8.2.5, Page 20 Clause 8.9.2b, Page 23 Clause 8.2.1, Page 20 Clause 8.2.2, Page 20 **No Equivalent Requirement** **No Equivalent Requirement**	Equivalent An Annex B has been added to the 2017 Version. This Annex allows the option of using the Management System requirements specified in ISO/IEC 1702:2017 or implementing Management System requirements from ISO 9001:2015. In both cases, the Clauses of 4 to 7 (Technical

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 4.2.2e, Page 4 Clause 4.2.3, Page 4 Clause 4.2.4, Page 4 Clause 4.2.5, Page 4 Clause 4.2.6, Page 4 Clause 4.2.7, Page 4	Clause 5.6a Clause 5.6e, Page 4 Clause 5.7a, Page 5 Clause 8.2.3, Page 20 Clause 6.2.4, Page 5 Clause 8.2.4, Page 20 **No Equivalent Requirement** Clause 5.7b	Requirements) shall be met. In addition, ISO 17025:2017 does not include a requirement for having a Quality Manual. However, all of the requirements for implementation of a Management Systems are included through the standard including Clause5 (Structural Requirements) and Clause9 (Management System Requirements)
Document Control - - General - Document	**Control of Management System Documents**	Section 4.3, Page 4 Clause 4.3.1, Page 4 Clause 4.3.2, Page 4 Clause 4.3.2.1, Page 4	Clause 7.2.1.2, Page 10 Clause 8.1.2, Page 20 Clause 8.3.1, Page 20 Clause 7.11.5, Page 19 Clause 8.3.2a, Page 20	Equivalent ISO 17025:2017 does not include provisions for making amendments to documents by hand but the new standard

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Approval - and Issuance - - - - - - Document Changes		Clause 4.3.2.2a, Page 4 Clause 4.3.2.2b, Page 4 Clause 4.3.2.2c, Page 5 Clause 4.3.2.2d, Page 5 Clause 4.3.2.3, Page 5 Clause 4.3.3.1, Page 5 Clause 4.3.3.2, Page 5 Clause 4.3.3.3, Page 5 Clause 4.3.3.4, Page 5	Clause 8.3.2d, Page 21 Clause 8.3.2b, Page 21 Clause 8.3.2f, Page 21 Clause 8.3.2f, Page 21 Clause 8.3.2e, Page 21 Clause 8.3.2a, Page 20 Clause 8.3.2c, Page 21 **No Equivalent Requirement** **No equivalent Requirement**	still requires all changes to be approved by authorized personnel. ISO 17025:2017 does not include a provision for changing computerized document but does include provision for controlling changes to all documents and acknowledges that documents can be controlled in various formats including electronically.
Review of requests, tenders and contracts	**Review of requests, tenders and contracts**	Section 4.4, Page 5 Clause 4.4.1, Page 5	Section 7.1, Page 9 Clause 7.1.1, Page 9 Clause 7.1.4, Page 10	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 4.4.1a, Page 5 Clause 4.4.1b, Page 5 Clause 4.4.1c, Page 5 Clause 4.4.2, Page 5 Clause 4.4.3, Page 6 Clause 4.4.4, Page 6 Clause 4.4.5, Page 6	Clause 7.1.1a, Page 9 Clause 7.1.1b, Page 9 Clause 7.1.1d, Page 9 Clause 7.1.8, Page 10 Clause 7.1.1c, Page 9 Clause 7.1.5, Page 10 Clause 7.1.6, Page 10	
Subcontracting of tests and calibrations	**Externally Provided Products and Services**	Section 4.5, Page 6 Clause 4.5.1, Page 6 Clause 4.5.2, Page 6 Clause 4.5.3, Page 6 Clause 4.5.4, Page 6	Section 6.6, Page 8 Clause 6.6.1, Page 8 Clause 6.6.2b, Page 9 Clause 7.1.1c, Page 9 Clause 6.6.1b, Page 8 Clause 6.6.2d, Page 9 Clause 6.6.2 b& c, Page 9	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Purchasing services and supplies	**Externally Provided Products and Services**	Section 4.6, Page 6 Clause 4.6.1, Page 6 Clause 4.6.2, page 6 Clause 4.6.3, Page 6 Clause 4.6.4, Page 6	Section 6.6, Page 8 Clause 6.6.1a&c, Page 8 Clause 6.6.2b, Page 9 Clause 6.6.1, 6.61a, Page 8 Clause 6.6.2c, Page 9 Clause 6.6.3, Page 9 **No Equivalent Requirement**	Equivalent ISO 17025:2017 does not specifically state that approved sub-suppliers are to be listed, it does require only approved sub-supplier are used and records of their approval and acceptance of their items and services are required to be maintained.
Service to the customer	**Review of Requests, Tenders and Contracts** **And Improvements**	Section 4.7, Page 6 Clause 4.7.1, Page 6 Clause 4.7.2, Page 7	Section 7.1 Clause 7.1.7, Page 10 Clause 8.6.2, Page 22	Equivalent While ISO 17025:2017 does not include a section titled "Service to the Customer", the requirements in this area from ISO 17025:2005 are addressed in Clauses

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
				7.1.7 and 8.6.2 of ISO 17025:2017.
Complaints	**Complaints**	Section 4.8, Page 7	Section 7.9, Page 17 Clause 7.9.1, Page 17 Clause 7.9.2, Page 18 Clause 7.9.3a, b, c. Page 18 ***Clause 7.9.4, Page 18*** ***Clause 7.9.5, Page 18*** ***Clause 7.9.6, Page 18*** ***Clause 7.9.7, Page 18***	**ISO/IEC 17025:2017 improved this area. Additional requirements for addressing complaints have been added.**
Control of nonconforming testing and/or calibration work	**Nonconforming Work**	Section 4.9, Page 7 Clause 4.9.1 Clause 4.9.1a	Section 7.10, Page 18 Clause 7.11.3e, Page 19 Clause 7.10.1, Page 18 Clause 7.10.1a & b, Page 18	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 4.9.1b Clause 4.9.1c Clause 4.9.1d Clause 4.9.1.e Clause 4.9.2	Clause 7.10.1c, Page 18 Clause 7.10.1b & d, Page 18 Clause 8.7.1a Clause 7.10.1e, Page 18 Clause 7.10.1f, Page 18 Clause 7.10.3, Page 18	
Improvement	**Management System Requirements Option A Improvement**	Section 4.10, Page 7	Clause 8.1.2, Page 20 Section 8.6, Page 22 Clause 8.6.1, Page 22 Clause 8.6.2, Page 22	Equivalent
Corrective Actions -General - Cause analysis - Selection and implementation of	**Corrective Actions**	Section 4.11 Page 8, Clause 4.11.1, Page 8 Clause 4.11.2, Page 8 Clause 4.11.3, Page 8	Section 8.7, Page 22 Clause 7.11.3e, Page 19 Clause 8.7.1b, Page 22 Clause 8.7.1c & f, Page 22 Clause 8.7.2, Page 22	Equivalent While ISO 17025:2017 does not include a statement regarding performing additional internal audits as a result of corrective

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
corrective actions - Monitoring of corrective actions - Additional audits - 4.12		Clause 4.11.4, Page 8 Clause 4.11.5, Page 8	Clause 8.7.1d, Page 22 **No Equivalent Requirement**	actions in a given area, ISO 17025-2017 does require effectiveness reviews for corrective action taken and internal audits based on results of management reviews and management discretion.
Preventive action	**No Specific Section for Preventive action**	Section 4.12, Page 8 Clause 4.12.1, Page 8 Clause 4.12.2, Page 8	**No Equivalent Section** Clause 8.6.1, Page 22 **No Equivalent Requirement**	**Equivalent** The 2017 Version does not have a specific Section on Preventive Action. However, the basic requirements for corrective action and preventive action are addressed in the Corrective Action and Improvement Sections.

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Control of Records General	**Control of Records**	Section 4.13, Page 9 Clause 4.13.1.1, Page 9 Clause 4.13.1.2, Page 9 Clause 4.13.1.3, Page 9 Clause 4.13.1.4, Page 9	Section 8.4, Page 21 Clause 7.10.2, Page 18 Clause 8.1.2, Page 20 Clause 8.4.1, Page 21 Clause 8.7.3a & b, Page 22 Clause 7.11.3d, Page 19 Clause 8.4.1 & 2, Page 21 Clause 8.4.2, Page 21 Clause 7.11.3a, b, c, Page 19	Equivalent
Technical Records	**Technical Records**	Clause 4.13.2.1, Page 9 Clause 4.13.2.2, Page 9 Clause 4.13.2.3, Page 9	Clause 7.8.1.2, Page 14 Clause 7.5.1, Page 13 Clause 7.5.1, Page 13 Clause 7.5.2, Page 13	Equivalent
Internal audits	**Internal Audits**	Section 4.14, Page 9 Clause 4.14.1, Page 9	Section 8.8, Page 23 Clause 8.8.1,8.8.1a, Page 23	Equivalent ISO 17025:2017 does

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 4.14.2, Page 10 Clause 4.14.3, Page 10 Clause 4.14.4, Page 10	Clause 8.8.2a, b, c, Page 23 Clause 8.8.1b,8.8.2d, Page 23 Clause 8.8.2e, Page 23 **No Equivalent Requirement**	not specifically require follow-up audits to verify corrective action effectiveness, however, the corrective action process does require effectiveness reviews
Management reviews	**Management Reviews**	Section 4.15, Page 10 Clause 4.15.1, Page 10 Clause 4.15.1, Page 10	Section 8.9, Page 23 Clause 8.9.1, 8.9.2a-o, Page 23 Clause 8.9.3a-d, Page 24	Equivalent
Technical Requirements **General**	**Resource Requirements**	Section 5, Page 10 Clause 5.1.1, Page 10 Clause 5.1.2, Page 11	Section 6, Page 5 Section 6.1, Page 5 **No Equivalent Statement**	Equivalent ISO 17025:2017 does not have a single statement addressing Clause 5.1.2 from ISO 17025:2005, however, various sections such as Section 6.1,

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
				"General", Section 6.2, "Personnel", Section 6.3, "Facilities and Environmental Conditions", Section 6.4, "Equipment" collectively address this area.
Personnel	**Personnel**	Section 5.2, Page 11 Clause 5.2.1, Page 11 Clause 5.2.2, Page 11 Clause 5.2.3, Page 11 Clause 5.2.4, Page 11 Clause 5.2.5, Page 11	Section 6.2, Page 5 Clause 6.2.1, 6.2.2, 6.2.5a, f, Page 5 Clause 6.2.5b, c, f, Page 5 Clause 6.1, Page 5 Clause 6.2.1, 6.2.2, Page 5 Clause 6.2.2, Page 5 Clause 6.2.3, Page 5 Clause 6.2.5a, d, Page 5 Clause 6.2.6,a,b,c, Page 5 Clause 7.8.7.1, Page 17	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Accommodation and environmental conditions	**Facilities and Environment Conditions**	Section 5.3, Page 12 Clause 5.3.1, Page 12 Clause 5.3.2, Page 12 Clause 5.3.3, Page 12 Clause 5.3.4, Page 12 Clause 5.3.5, Page 12	Section 6.3, Page 6 Section 6.1, Page 5 Clause 6.3.1, 6.3.2, Page 6 Clause 6.3.5, Page 6 Clause 6.3.3, Page 6 Clause 6.3.4b, Page 6 Clause 6.3.4c, Page 6 Clause 6.3.4a, Page 6 **No Equivalent Requirement**	Equivalent While ISO 17025:2017 does not have a statement specifically addressing housekeeping of laboratory areas, Section 6.3 does address environmental controls and the suitability of the laboratory to prevent conditions that could adversely impact the validity of results including contamination.
Test and calibration methods and method	**Selection, Verification and Validation of Methods**	Section 5.4, Page 12 Clause 5.4.1, Page 12	Section 7.2, Page 10 Clause 6.4.3, Page 6 Clause 7.2.1.1, 7.2.1.2, Page 10 Clause 7.2.1.7, Page 11	Equivalent While ISO 17025:2017 does not have a section titled Non-standard Methods, Clause7.2.2, 'Verification of

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
validation **- General** - **Selection of methods** - **Laboratory-developed methods** **Non-standard methods** **Validation of methods** -	**Selection and Verification of Methods** **Selection and Verification of Methods** **Selection and Verification of Methods** **Validation of Methods**	Clause 5.4.2, Page 13 Clause 5.4.3, Page 13 Clause 5.4.4, Page 13 Clause 5.4.5, Page 14 Clause 5.4.5.1, Page 14 Clause 5.4.5.2, Page 14 Clause 5.4.5.3, Page 14	Clause 7.1.2, Page 9 Clause 7.1.4, Page 10 Clause 7.2.1.3, 7.2.1.4, Page 10 Clause 6.2.3, Page 5 Clause 6.2.5e, Page 5 Clause 6.2.6a, Page 5 Clause 7.2.1.6, Page 11 **No Equivalent Requirement** Clause 7.2.2, Page 11 Clause 3.8 & 3.9, Page 2-3 Clause 7.2.2.1 & 7.2.2.2, Page 11 Clause 7.2.2.4a,d,e, Page 11-12 Clause 7.2.1.6, Page 11 Clause 7.2.2.3, Page 11 Clause 7.2.2.4b,c, Page 11-12	Methods", includes controls for the verification of non-standard methods as well as laboratory developed and modified standard methods.

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Estimation of uncertainty of measurement -	**Evaluation of Measurement Uncertainty**	Clause 5.4.6, Page 14 Clause 5.4.6.1, Page 14 Clause 5.4.6.2, Page 14 Clause 5.4.6.3, Page 15	Section 7.6, Page 13 Clause 7.6.2, Page 13 Clause 7.6.1, Page 13 Clause 7.6.3, Page 13 Clause 7.6.1, Page 13	
Control of data	**Control of Data and Information Management**	Clause 5.4.7, Page 15 Clause 5.4.7.1, Page 15 Clause 5.4.7.2a, Page 15 Clause 5.4.7.2b, Page 15 Clause 5.4.7.2c, Page 15	Section 7.11, page 19 Clause 7.11.6, Page 19 Clause 7.11.2, Page 19 Clause 7.11.3a, Page 19 Clause 6.4.3, Page 6 Clause 6.4.12, Page 7 Clause 7.11.3b,c, Page 19	

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Equipment	**Equipment**	Section 5.5, Page 15 Clause 5.5.1, Page 15 Clause 5.5.2, Page 15 Clause 5.5.3, Page 16 Clause 5.5.4, Page 16 Clause 5.5.5a, Page 16 Clause 5.5.5b, Page 16 Clause 5.5.5c, Page 16 Clause 5.5.5d, page 16 Clause 5.5.5e, Page 16 Clause 5.5.5f, Page 16 Clause 5.5.5g, Page 16	Section 6.4, Page 6 Section 6.1, Page 4 Clause 6.4.1, 6.4.2, Page 6 Clause 6.4.1, 6.4.4, Page 6 Clause 6.4.5, 6.4.6, 6.4.7, Page 7 Clause 6.4.3, Page 6 Clause 6.4.8, 6.4.13a, Page 7 Clause 6.4.13a, Page 7 Clause 6.4.13b, Page 7 Clause 6.4.13c, Page 7 Clause 6.4.13d, Page 7 Clause 6.4.3, Page 6 Clause 6.4.13e, Page 7 Clause 6.4.13g, Page 8	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
		Clause 5.5.5h, Page 16 Clause 5.5.6, Page 16 Clause 5.5.7, Page 16 Clause 5.5.8, Page 16 Clause 5.5.9, Page 16 Clause 5.5.10, Page 16 Clause 5.5.11, Page 16 Clause 5.5.12, Page 16	Clause 6.4.13h, Page 8 Clause 6.4.3, Page 6 Clause 6.4.9, Page 7 Clause 6.4.8, Page 7 Clause 6.4.4, Page 6 Clause 6.4.10, page 7 Clause 6.4.11, Page 7 Clause 6.4.12, Page 7	
Measurement Traceability **General** - **Calibration**	**Metrological Traceability**	Section 5.6, Page 17 Clause 5.6.1, Page 17 Clause 5.6.2.1.1, Page 17 Clause 5.6.2.1.2, page 18	Section 6.5, Page 8 Clause 6.4.4, Page 6 Clause 6.4.6, 6.4.7, Page 7 Clause 6.5.1,6.5.2a,c, Page 8 Clause 6.5.3a,b, Page 8	Equivalent A new ANNEX A has been added to the 2017 version to provided additional information on the subject of Metrological Traceability See page 25-26

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Testing - **Reference standards** **Reference materials** **Intermediate Checks** **Transport and Storage**		Clause 5.6.2.2.1, Page 18 Clause 5.6.2.2.2, Page 18 Clause 5.6.3.1, Page 18 Clause 5.6.3.2, Page 18 Clause 5.6.3.3, Page 18 Clause 5.6.3.4, Page 18	Clause 7.7.2, Page 14 Clause 6.4.7, Page 7 Clause 6.5.3a,b, Page 8 Clause 6.4.7, Page 7 Clause 6.4.10, Page 7 Clause 6.4.10, Page 7 Clause 6.4.3, Page 6	
Sampling	**Sampling**	Section 5.7, Page 19 Clause 5.7.1, Page 19 Clause 5.7.2, Page 19 Clause 5.7.3, Page 19	Section 7.3, Page 12 Clause 7.3.1, 7.3.2a-c, Page 12 Clause 7.3.3c, h, Page 12 Clause 7.3.3a-h, Page 12	Equivalent
Handling of test	**Handling of Test**	Section 5.8, Page 19	Section 7.4, Page 12	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
and calibration items	**or Calibrated Items**	Clause 5.8.1, Page 19 Clause 5.8.2, Page 19 Clause 5.8.3, Page 19 Clause 5.8.4, Page 19	Clause 7.4.1,Page 12 Clause 7.4.2, Page 12 Clause 7.4.3, Page 13 Clause 7.4.1, Page 12 Clause 7.4.4, Page 13	
Assuring the Quality of Test and Calibration Results	**Ensuring the Validity of Results**	Clause 5.9, Page 20 Clause 5.9.1a-e, Page 20 Clause 5.9.2, Page 20	Clause 7.7, Page 13 Clause 7.7.1a-k, 7.7.2a-b, Page 13 Clause 7.7.3, Page 14	Equivalent
Reporting the Results **General** - **Test reports and calibration certificates** -	**Reporting the Results** **Common requirements for reports (test, calibration,, sampling)**	Section 5.10, Page 20 Clause 5.10.1, Page 20 Clause 5.10.2a-k, Page 20	Section 7.8, Page 14 Clause 7.8.1.2, 7.8.1.3, Page 14 Clause 7.8.1.1, Page 14 Clause 7.8.2.1a-p, Page 15	Equivalent

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
Test reports -	**Specific requirements for test reports**	Clause 5.10.3, Page 21 Clause 5.10.3.1a-e, Page 21 Clause 5.10.3.2a-f, Page 21	Clause 7.8.3, Page 15 Clause 7.8.2.1n, Page 15 Clause 7.8.3.1a-e, Page 15-16 Clause7 .8.6.2, Page 17 Clause 7.8.3.2, Page 16 Clause 7.8.5a-f, Page 17	
Calibration certificates	**Specific Requirements for Calibration Certificates**	Clause 5.10.4, Page 22 Clause 5.10.4.1a-c, Page 22 Clause 5.10.4.2, Page 22 Clause 5.10.4.3, Page 22 Clause 5.10.4.4, Page 22	Clause 7.8.4, Page 16 Clause 7.8.4.1a-f, Page 16 Clause 7.8.4.1e, Page 16 Clause 7.8.6.1, Page 17 Clause 7.8.6.2a,b, Page 17 Clause 7.8.4.1d, Page 16 Clause 7.8.4.3, Page 16 Clause 7.8.4.1f, Page 16	

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
- **Opinions and interpretations**	**Reporting Opinions and Interpretations**	Clause 5.10.5, Page 22	Clause 7.8.7, Page 17 Clause 7.8.7.1-7.8.7.3, Page 17	
- **Testing and calibration results obtained from subcontractors**	**Externally Provided Products and Services**	Clause 5.10.6, Page 23	Section 6.6, Page 8 Clause 6.6.1b, Page 8 Clause 7.8.2.1p, Page 15	
- **Electronic transmission of results**	**Control of Data and Information Management**	Clause 5.10.7, Page 23	Clause 7.11.2, Page 19	
- **Format of reports and certificates** -	**Reporting of Results**	Clause 5.10.8, Page 23	Section 7.8, Page 14 Clause 7.8.1.2, 7.8.1.3, Page 14	

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Amendments to test reports and calibration certificates	**Amendments to Reports**	Clause 5.10.9, Page 23	Clause 7.8.8, Page 17 Clause 7.8.8.1 – 7.8.8.3, Page 17	
Nominal cross-references to ISO 9001:2000	**There is no Equivalent Section**	Annex A, Page 24	No Equivalent Section	Different but no adverse impact. ISO 17025:2017 does not include an equivalent reference section; however this difference has no impact on acceptability of the 2017 version since it this was a reference section only.
Guidelines for establishing applications for	**There is no Equivalent Section**	Annex B, Page 26	No Equivalent Section	Different but no adverse impact. ISO 17025:2017 does

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
specific fields				not include an equivalent section addressing guidelines for establishing applications for specific fields; however this difference has no impact on acceptability of the 2017 version since this section provided additional guidance and not requirements.
			Additions to ISO/IEC 17025:2017	Comments
			New Additions to ISO/IEC implemented in the 17025:2017. **THE NUPIC/NEI team views these additions as enhancements to the**	

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
			standard. These clauses are listed below in bold and italicized print.	
			Impartiality ***Clause 4.1.4, 4.1.5, Page 3***	Enhancement
			Confidentiality ***Clause 4.2.1, Page 3*** ***Clause 4.2.2. Page 3*** ***Clause 4.2.3, Page 4*** ***Clause 4.2.4, Page 4***	Enhancement
			Structural Requirements ***Section 5.3, Page 4***	Enhancement This new clause requires laboratories to define and document the range of laboratory activities for which it conforms to ISO/IEC 17025:2017. The laboratory can only

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
				claim conformity with the standard for the specified range of activities which excludes externally provided activities on an ongoing basis.
			Resource Requirements ***Clause 6.2.5f, Page 5***	Enhancement
			Equipment ***Clause 6.4.7, Page 7*** ***Clause 6.4.8, Page 7*** ***Clause 6.4.11, Page 7*** ***Clause 6.4.13a, Page 7*** ***Clause 6.4.13f, Page 7***	Enhancement
			Metrological Traceability ***Clause 6.5.2b, Page 8***	Enhancement

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
			Externally Provided Products and Services ***Clause 6.6.2a, d, Page 9*** ***Clause 6.6.3b, c, d, Page 9***	Enhancement
			Review of Requests, Tenders and Contracts ***Clause 7.1.1c, Page 9*** ***Clause 7.1.3, Page 9***	Enhancement
			Selection, Verification and Validation of Methods ***Clause 7.2.1.5, Page 11***	Enhancement
			Sampling **Clause 7.3.3b, c, e, h, Page 12**	Enhancement
			Handling of Test or Calibration Items ***Clause 7.4.3, Page 13***	Enhancement
			Technical Records	Enhancement

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
			Clause 7.5.2, Page 13	
			Ensuring the Validity of Results ***Clause 7.7.2a, b, Page 14***	Enhancement
			Reporting the Results ***Clause 7.8.1.2, Page 14*** ***Clause 7.8.2.1j, Page 15*** ***Clause 7.8.2.2, Page 15*** ***Clause 7.8.4.2, Page 16*** ***Clause 7.8.5f, Page 17*** ***Clause 7.8.6, 7.8.6.1, 7.8.6.2, Page 17*** ***Clause 7.8.7.3, Page 17*** ***Clause 7.8.8.1, Page 17***	Enhancement
			Complaints ***Clause 7.9.2, Page 18***	Enhancement

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			Clause 7.9.3a, b, c, Page 18 ***Clause 7.9.4, 7.9.5, 7.9.6, 7.9.7, Page 18***	
			Nonconforming Work ***Clause 7.10.1b, c, Page 18*** ***Clause 7.10.2, Page 18***	Enhancement
			Control of Data and Information Management ***Clause 7.11.2, Page 19*** ***Clause 7.11.3e, Page 19*** ***Clause 7.11.4, Page 19***	Enhancement
			Management Systems Requirements ***Clause 8.1.1, Page 19***	Enhancement
			Actions to Address Risks and Opportunities ***Clause 8.5.1a, b, c, Page 21***	Enhancement

2005 Element - Description	2017 Element - Description	2005 Section # / Page #	2017 Section # / Page #	Comments
			Clause 8.5.2a, b, Page 21 ***Clause 8.5.3, Page 21***	
			Corrective Actions ***Clause 8.7.1e, Page 22***	Enhancement
			Internal Audits ***Clause 8.8.2a, b, page***	Enhancement
			Management Review ***Clause 8.9.2a, d, k, m, Page 23-24*** ***Clause 8.9.3a, b, c, d, Page 24***	Enhancement

ISO/IEC GAP Analysis Summary

The United States Nuclear Regulatory Commission (USNRC) previously endorsed the "ILAC" process through their endorsement of Nuclear Energy Institute (NEI) 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services". The International Laboratory Accreditation Cooperation (ILAC) process allows nuclear utilities and their suppliers to accept testing and calibration services (in lieu of a commercial grade survey) from laboratories that are accredited to ISO/IEC 17025:2005 by Accreditation Bodies (AB's) that are signatories to the ILAC Mutual Recognition Agreement (MRA). Use of the ILAC process is contingent on meeting the conditions specified in NEI 14-05A; one of which is the laboratory must be accredited to ISO/IEC 17025:2005.

On November 30, 2017, ISO (International Organization for Standardization) published a new version of ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories". In order for nuclear utilities and their suppliers to continue to utilize the ILAC process during commercial grade dedication of calibration and testing services, the nuclear industry must first gain the USNRC acceptance of the new version of ISO/IEC 17025 which is known as ISO/IEC 17025:2017. The Nuclear Procurement Issues Corporation (NUPIC) in conjunction NEI has undertaken the effort and is currently seeking the NRC's endorsement of ISO/IEC 17025:2017 version of the standard based on a review of the revision to ISO/IEC 17025 to verify that the new version is equivalent to the previous version.

ISO/IEC 17025:2017 covers all laboratory activities, including testing, calibration and the sampling associated with subsequent calibration and testing. ISO/IEC 17025:2017 includes technical enhancements, definitions of key terms, and provisions for greater use of Information Technology (IT) techniques. The major changes are as follows:

- A new structure has been adopted to align the standard with the other existing ISO/IEC conformity assessment standards such as the ISO/IEC 17000 series on conformity assessment.
- The process approach now matches that of newer standards such as ISO 9001:2015 (quality management), ISO 15189 (quality of medical laboratories) and the ISO/IEC 17000 series (standards for conformity assessment activities), putting the emphasis on the results of a process instead of the detailed description of its tasks and steps.
- The standard has a stronger focus on information technologies. In recognition of the fact that hard-copy manuals, records and reports are slowly being phased out in favor of electronic versions, it incorporates the use of computer systems, electronic records and the production of electronic results and reports.

- A new section has been added introducing the concept of risk-based thinking and describes the commonalities with the new version of ISO 9001:2015, Quality Management Systems Requirements.
- The terminology has been updated. Examples include changes to the International Vocabulary of Metrology (VIM) and alignment with ISO/IEC terminology, which has a set of common terms and definitions for all standards dedicated to conformity assessment.

The NUPIC/NEI Committee performed a detailed review of the 2005 and 2017 versions of ISO/IEC 17025 to substantiate that the ISO/IEC 17025:2017 does not reduce commitments in technical or quality requirements. This review was performed by verifying, via a line by line review, that all of the relevant technical and quality requirements specified in ISO/IEC 17025:2005 are included in ISO/IEC 17025:2017 and that the major changes were essentially formatting and additions which enhance the ISO/IEC 17025 standard. For example, additional restrictions have been added for subcontracting accredited tests or calibrations and the focus on technical competency has increased. A Requirements Traceability/Cross Reference Matrix was developed to perform this review. As a result, it was concluded that the ISO/IEC 17025:2017 is equal to or better than ISO/IEC 17025:2005 in both main areas: technical and quality requirements. The Requirements Traceability/Cross Reference Matrix is included as an attachment. In addition, it was verified that all of the technical and quality requirements specified in the NUPIC Calibration Survey Critical Characteristics Worksheet are appropriately addressed in ISO/IEC 17025:2017. It should be noted that the USNRC utilized the NUPIC Calibration Survey Critical Characteristics Worksheet as an aid during the NRC's original endorsement of the ISO/IEC 17025:2005 when it was concluded the accreditation process is equivalent to a NUPIC Commercial Grade Calibration Survey.

ISO has designated a three (3) year transition for the ISO/IEC 17025:2017. Since the standard was published on November 30, 2017, all re-accreditations and new accreditations to ISO/IEC 17025 must be to ISO/IEC 17025:2017 by November 30, 2020. In order to meet this deadline, each AB that is a signatory to the ILAC MRA has developed a transition plan for accrediting their laboratories and prospective laboratories. Due to the logistics involved with this massive workload and to ensure successful transitions, some AB's have started the process of accrediting laboratories to 17025:2017. To this end, ILAC/ISO issued a Joint Communication which stressed that during this transition period, both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are equally valid and applicable. Formal accreditation to either standard granted by an accreditation body that is a signatory to the ILAC Arrangement should be recognized by the market place. ILAC/ISO strongly recommended that governmental bodies and approval agencies equally recognize both versions until after the 3-year transition period has closed. The Joint Communication is attached to this document. It should be noted that the US Federal Communications Commission (FCC) and US Consumer Product Safety Commission (CPSC) have both endorsed ISO/IEC 17025:2017 during this transition period. The NUPIC/NEI is requesting a similar endorsement from the USNRC on behalf of the nuclear industry during this transition period. In addition, a revision to NEI 14-05A will be subsequently presented to the NRC requesting a permanent endorsement to ISO/IEC 17025:2017.