DRAFT
NUPIC DOCUMENT NO. XX
SIL CERTIFICATION
ACCREDITATION BODY OVERSIGHT
REVISION 0
EFFECTIVE DATE:
APPROVED: DATE:
Mark Coren – NUPIC Chairman

I. PURPOSE

This document delineates the NUPIC's responsibilities, activities, and obligations for performing oversight of the Accreditation Bodies that provide certification of Safety Integrity Levels (SIL). The purpose of this directive is to describe the cooperation with Nuclear Energy Institute (NEI) to maintain the Nuclear Regulatory Commission's (NRC's) acceptance of the SIL Certification Process as described in NEI 17-06. This includes maintaining the commitments delineated in NEI 17-06, interfacing with the NEI, NRC, and the Accreditation Bodies to ensure the commitments specified in NEI 17-06 are maintained.

II. <u>SCOPE</u>

This procedure applies to those activities performed by the NUPIC in order to maintain the NRC's endorsement of NEI 17-06 including collaborating with NEI to maintain and revise NEI 17-06 as applicable, and to report the committee's activities to the NUPIC Steering Committee and General Membership.

III. REFERENCES

NEI 17-06,

NRC Final Safety Evaluation for Technical Report for NEI 17-06

ISO/IEC 17065, Conformity assessment – Requirements for bodies certifying products, processes, and services. First Edition 09-15-2012

ISO/IEC 17011-2017, "Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies", dated November 1, 2017

IEC 61508, Introduction to Functional Safety, March 2002

NUPIC - NEI Memorandum of Understanding, dated November 30, 2017 (To Be Determined)

IV. **DEFINITIONS**

- SIL Safety Integrity Level
- CAB Conformity Assessment Bodies are Laboratories Accredited to ISO/IEC 17025 or seeking accreditation to ISO/IEC 17025.
- ISO- International Standards Organization

V. **RESPONSIBILITIES**

- A. NUPIC "Safety Integrity Level (SIL) Chairperson is responsible for directing all business of the SIL Committee. The SIL Committee is responsible for the following:
 - Monitoring SIL activities to verify that requirements and procedures used in the SIL process relative to digital equipment and software service accreditation continue to be consistent with the NRC accepted practices and implementation conforms to the SIL standards/procedures which includes the following:
 - a) Performance of triennial observation of SIL peer evaluation
 - b) Conducting annual review of changes to SIL requirements/procedure
 - c) Retention of annual review and triennial observation summaries/conclusions
 - d) Participation in SIL standards committees and meeting attendance as necessary (*Not sure about this one yet*)
 - 2. Maintain interface with NEI per NUPIC NEI Memorandum of Understanding including collaborating on revisions to NEI 17-06.
 - 3. Reporting to the NUPIC Steering Committee and General Membership on all matters pertinent to NEI 17-06.

VI. INSTRUCTIONS

- A. NEI Interface
 - 1. Meet Regularly with NEI personnel assigned to support NEI 17-06.
 - 2. Verify the Status of NUPIC/NEI Membership with ILAC on an annual basis.
 - 3. Draft changes to NEI 17-06 as needed when revision to NEI 17-06 is required.
 - 4. Update NEI on SIL Committee activities including the need for NEI assistance as applicable.
- B. Perform Annual Review of SIL changes
 - Throughout each calendar year, the Committee will remain abreast of and review changes that are made to SIL requirements, processes, and procedure. The SIL Committee is privy to these changes through our NUPIC/NEI relationship.
 - 2. Such changes are reviewed to verify the changes do not adversely impact the robustness of the SIL process and the NRC's endorsement of the SIL process.
 - 3. Issue an annual report summarizing the changes and confirming that changes do not adverse impact the NRC's endorsement of the SIL process.

- 4. The report must be issued prior to December 31st each year.
- 5. The Report shall be posted on the NUPIC Website.
- 6. The Committee Chairman must maintain a copy of the report under the Committee Chair's utility 10CFR50, Appendix B program.
- 7. If changes are identified, which could impact the NRC's endorsement of the process, a Steering Committee Action Request (SCAR) should be initiated and the NRC contacted.
- C. Performance of Triennial Observation of SIL Evaluation
 - 1. Schedule and perform an Observation of an SIL Peer Evaluation once every three years.
 - 2. Invite the NRC to participate in the Peer Evaluation
 - Collaborate with NEI to schedule a Peer Evaluation of an Accreditation Body (AB) that is a signatory to the SIL process. The assessment should include observation of the selected AB undergoing a Peer Evaluation by other AB's that are signatories to the SIL process and observations of the AB performing assessments of Conformity Assessment Bodies.
 - 4. A report of the Observation must be generated and maintained on the NUPIC database and by the SIL Committee Chairs' QA record storage program.
 - 5. The report will be distributed to the NRC upon request.
- D. Participate in SIL Activities
 - 1. Consider attending SIL Meetings to gain additional understanding of the process and ongoing changes and improvements
 - 2. Consider attending SIL training including CAB assessor training and ISO/ 17011 Peer Evaluation training
- E. Interface with NUPIC Steering Committee and General Membership
 - 1. Keep Steering Committee and General Membership apprised of all major activities.
 - 2. Provide regular presentations during NUPIC General Membership Meetings.
 - 3. Provide regular presentations during NUPIC Vendor Meetings.
 - 4. Submit Articles to the NUPIC Newsletter as necessary to keep the user community updated on SIL related matters.
 - 5. Maintaining the pertinent SIL documents on the NUPIC website under the NUPIC SIL Documents tab under the Download Center Section on the NUPIC website.