Licensing Experience
Interim Staff Guidance ISG-06

Licensing Process for Digital I&C Safety Systems

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Agenda

- **ISG-06 Pilot Project Background**

- **ISG-06 Process Review and Discussion**
  - ISG-6 Layout
  - Section C Process Overview
    - Tier Concept for graded approach
    - Phased Submittal process
    - Enclosure C process flowchart

- **Lessons Learned**
  - Concepts that have worked
  - Concepts that have not worked
  - Concepts that need more development
  - Potential New concepts

The ISG is not organized into a logical topical review area format.

ISG 6 Lay-out

- **A – Introduction**
- **B – Purpose**
- **C – Digital I&C Review Process**
- **D – Review Areas**
    1. **System Description**
    2. **Hardware Development Process**
    3. **Software Architecture**
    4. **Software Development Process**
    5. **Environmental Equipment Qualifications**
    6. **Diversity and Defense-In-Depth**
    7. **Communications**
    8. **System, Hardware, Software, and Methodology Modifications**
    9. **IEEE 603**
    10. **7-4.3.2**
    11. **Technical Specifications**
    12. **SDOE**

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    8. **System, Hardware, Software, and Methodology Modifications**
    9. **IEEE 603 (See SRP Appendix 7.1C)**
    10. **7-4.3.2 (See SRP Appendix 7.1D)**
    11. **Technical Specifications**
    12. **SDOE (See Reg. Guide 1.152 and IEEE 7-4.3.2)**

- **System Description**

- **System Development Process (See BTP 7-14)**
  Planning Processes (Refer to Section B.3.1 of BTP 7-14)
  Process Implementation (Refer to Section B.3.2 of BTP 7-14)
  Process Design Output (Refer to Section B.3.3 of BTP 7-14)

- **Diversity and Defense-In-Depth (Refer to BTP 7-19)**

- **Communications (Refer to ISG 04 until IEEE 7-4.3.2 is endorsed)**

- **Technical Specification Evaluation**

- **Equipment Environmental Qualifications**

IEEE 603 (See SRP Appendix 7.1C)

7-4.3.2 (See SRP Appendix 7.1D)

SDOE (See Reg. Guide 1.152 and IEEE 7-4.3.2)

There is no direct correlation between the information we require licensee's to provide and the evaluations we perform.

Planning Process Review

- **BTP 7-14 currently identifies 12 areas for Planning. They are**
  - **Management Plan**
  - **Development Plan**
  - **Quality Assurance Plan**
  - **Integration Plan**
  - **Installation Plan**
  - **Maintenance Plan**
  - **Training Plan**
  - **Operations Plan**
  - **Safety Plan**
  - **Verification and Validation Plan**
  - **Configuration Management Plan**
  - **Test Plan**

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Typical Evaluation write-up

Software Operations Plan (SOP)

The acceptance criteria for a SOP are contained in the SRP, BTP 7-14, Section B.3.1.8, "Software Operations Plan." This section states that the primary aspect is completeness; however, it adds that the operations plan needs to address the security of the system, and in particular, the means used to ensure that there are no unauthorized changes to hardware, software and system parameters, and that there is monitoring to detect penetration or attempted penetration of the system.

Because the operation of the system is a licensee, and not a vendor responsibility, there is no requirement for the vendor to have an operations plan and, therefore, no AREVA software operations plan has been reviewed for this safety evaluation. The operations planning activities are the responsibility of the licensee. The ONS SOP was not submitted as a part of the LAR. The SOP assessment is considered to be part of the NRC inspection. *

ISG-06 Processes

- **Useful principles**

    - **Enclosure B Tables and the ISG-06 Matrix**
        - **Cross Reference to body of ISG**

    - **Open Item List**
        - **RAI coordination**
        - **Facilitation of Conference Calls**

ISG-06 Issues

- **Ongoing Process Issues**
  - Duplicate and/or conflicting Guidance
  - Document Submittal Issues
  - Graded Approach
    - Tier Approach is OK but a way to grade the review effort based on Scope and Complexity of proposed modification is needed
  - Scope Definition Issues (Between vendors and licensee)
- **New Concepts being Considered**
  - Volatile Document Concept
  - Phase 2a submittal Concept
  - Conditional Letter of approval prior to FAT
  - Separate Guidance and Appendix B Matrix for TR Evaluations

Solutions Being Considered

– Volatile Document Concept

Some documents associated with software development are expected to be revised as system development activities progress. These are sometimes referred to as "living documents." Such documents should be classified as volatile. For such documents; a decision of what version of the document should be submitted and when (i.e. what phase) the document is to be submitted should be made during the acceptance review. It is not necessary for applicants to submit multiple versions of volatile documents to support the safety evaluation, however; the submitted volatile document should be sufficient to demonstrate conformance to all applicable regulatory requirements. In some cases it may also be necessary to provide accessibility to current versions of a volatile document for audit during a safety evaluation. Additional document specific guidance on document volatility is provided within Section D.

Solutions Being Considered

– Phase 2a

The initial Phase 2 document concept was that design output documents which might not be available for submittal at the time of LAR could be submitted at a later time as the system design was completed.

We have observed that some of these documents such as Summary Test Reports (D.4.4.2.4) are confirmatory in nature and can be distinguished from those which require detailed evaluation and assessment. Such confirmatory reports would not be subjected to the early submittal requirements of other Phase 2 documents.

Safety Evaluation Status Letter

- – We have received feedback from industry on several occasions that the SE should be completed using design information and should be independent of the factory test processes. FAT testing could then be verified by the staff on a confirmatory inspection basis.

- – *The NRC has resisted this idea for the following reasons:*
  - *Safety Evaluation conclusions cannot legally contain conditional requirements.*
  - *Experience has shown; significant design changes are often initiated as a result of test performance of the systems. Such changes have the potential of invalidating safety conclusions.*
  - *In absence of system test results or conditional requirements it is difficult to reach and provide basis for reasonable assurance safety findings . This places an undue burden of risk on the NRC staff.*

Safety Evaluation Status Letter

- – Add a Letter of regulatory conformance to the review process similar to what is currently being done in the Acceptance Reviews for License Amendments.

  - *No Safety Conclusions or approval of license amendment*
  - *Provides Status of safety evaluation activities at completion of design*
  - *Provides Pre-decisional Regulatory Compliance statement.*

- – *Would such a letter provide the level of confidence the industry is looking for to minimize Risk factors prior to expenditure of resources?*

Topical Report Guidance and Appendix B Tables

– Include regulator review guidance more applicable to Topical Reports.

– Add a new Appendix B table /Template for TR Reviews

Options for Adopting ISG as Permanent Guidance

- **Revise ISG**
  - **Shortest way to adopt changes**
  - **Leaves inconsistencies**
  - **Follow-up actions necessary to incorporate**
  - **Does not eliminate duplicate guidance**

- **Incorporate ISG into Standard Review Plan (Ch. 7)**
  - **Will take longest amount of time**
  - **Most technically correct**
  - **Will impact several sub-chapters**

- **Move to Branch Technical Position**
  - **Medium time to implement**
  - **@Will not likely apply to new reactors**

End of Presentation