

Industry Concerns with the Current Digital Licensing Process

The purpose of this list is to facilitate NRC public meeting discussions related to a revised digital license amendment process. The list was developed from solicited stakeholder input from various utilities, OEMs, consultants, etc. This list is not intended to be an exhaustive or definitive list but rather a high-level list of industry concerns with the current digital licensing review guidance contained in Digital I&C-ISG-06, *Licensing Process*, Revision 1.

1. Under the ISG-06 process, the SER is not issued until after the FAT is complete. As illustrated in the attached diagram, the safety determination can be made after system design is complete, and audits/inspections can be used to confirm the licensee's compliance with the NRC approved design. Such an approach is more appropriate for several reasons:
 - It would significantly reduce a licensee's regulatory uncertainty, and therefore risk, with respect to project cost and schedule, thereby increasing the likelihood that digital I&C projects will be undertaken to improve plant safety and reliability.
 - It would be more consistent with the licensing process for modifications involving other engineering disciplines (e.g., electrical, mechanical, etc.).
 - It would improve consistency between the licensing processes for existing plants and new plants.
 - Properly timed NRC audit/inspection activities would still provide ample opportunity to identify and correct improper licensee HW/SW design, implementation, and testing prior to system commissioning.
2. The current ISG-06 graded approach is based solely on approved platform status, and since most changes require some modification to the approval platform, this essentially eliminates the Tier 1 approval. It is not graded with respect to system importance or project size.
3. The current ISG process is not agile or scalable with respect to more important project parameters. Reviews are not based on system safety-significance and complexity, making it difficult to scale back to smaller, less complex, digital licensing changes that require NRC prior approval. It is primarily geared towards complete replacements of the reactor protection system.

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4. The ISG has a very large number of documents recommended for submittal (27 categories for the initial submittal and an additional 18 categories to be submitted within 12 months of SER approval) with no apparent need to support of the safety case (many are rarely referenced in final SER). This is out of sync with other NRC reviews in mechanical, civil, electrical, or nuclear codes and standards that require a similar level of detail review but much less documents are submitted.
 - Many of the 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.
 - There is significant cost in creating these documents that do not provide value often with both proprietary and nonproprietary versions.
 - Many documents are required to be submitted multiple times as RAIs are incorporated.
 - Many documents change during the software lifecycle, and are required to be submitted multiple times.
5. The primary technical basis, behind the review methodology embodied in the ISG approval process (as derived from BTP 7-14), needs to be revised or replaced. For example, there are a lot of planning documents that are driven by conventional processes that are either not unique to nuclear and not needed to make a safety determination or already addressed in other regulatory guidance. Project management is certainly not unique (outline the plan, risk assessment, division of responsibility, schedule, cost, required training, etc.). The licensee's QA Topical that was reviewed by the NRC should identify the high-level process applied (e.g., ASME NQA-1 for many) and there should be an allowance for crediting that process as being sufficient assurance in the QA realm.
6. The original SRM (found at <https://www.nrc.gov/about-nrc/regulatory/research/digital/public-meetings/2006/> for November 8, 2006 meeting) that established the need for regulatory reform that resulted in the ISGs (including ISG-06) was not followed to completion. The original intent was to develop a risk informed review process that allow licensees to forward-fit digital enhancements without unnecessary regulatory burden. DI&C-ISG-06 was not developed to be efficient or effective; instead, it was a fast track to provide conservative guidance to guide a digital equipment LAR.
7. The ISG has no mechanism to identify key threads needed for evidence of quality from the ISG prior to submittal, The ISG should provide guidance on the appropriate threads (deep slice) a to provide reasonable assurance of safety (e.g., a thread audit through a response time requirement). Because there is no guidance, often the process uses a broad independent review of many details that are not directly associated with any real impact on safety.
8. Elements of the NRC required documentation result in repeated evaluations of similar materials. A prime example of the duplicated work is the required duplicate sub-clause by sub-clause compliance matrices required for each of IEEE Stds. 603 and 7-4.3.2. A unified evaluation of the parallel sub-clauses for both standards would eliminate duplicative effort in both preparation and review.

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9. Recommendations for Topical Report guidance in support of the I&C LAR process: Guidance on application of older approved topical reports with newer regulatory guidance is needed. This guidance should allow for endorsement of a historical TR relative to newer regulatory guidance (as Tier 2 permitted “deviations”) if it can be demonstrated and justified explicitly in the LAR that the technical basis and criteria for SER for the TR has not been compromised. An example for consideration is that rather than re-submitting the TR or a supplement, instead the relevant differences in the regulatory guidance and a basis for acceptance of the later guidance could be included in the LAR. The ISG-06 guidance should explicitly include acknowledgment that any change to hardware/software module revision level is not a change to the topical report as long as the basic functional requirements are aligned and deviations have been justified in the LAR. This approach appears to be consistent with the approach discussed in Tier 2 relative to “deviations.”

Please note that work on this document is ongoing and an updated copy will be provided at the April 13 NRC public meeting. Thank you.