



U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

**Process for Development of
Interim Staff Guidance (ISG)
in Support of Reviews of
Digital I&C Applications**

(ML072140211)

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1.0 INTRODUCTION

The use of digital devices in Instrumentation and Controls (I&C) systems of nuclear facilities has the potential to improve safety and operational performance. The NRC is committed to licensing digital technology in safety system applications, and is continuing efforts to find solutions for technical challenges that affect licensing of digital systems for both operating and new reactors and nuclear fuel cycle facilities.

To provide oversight and guidance to the NRC staff on key Digital I&C technical and regulatory issues and to interface with the industry, a Digital I&C Project was initiated. The basis for the Digital I&C project is the November 8, 2006, Commission meeting with the industry and the December 6, 2006, Staff Requirements Memorandum (SRM) (ADAMS Accession No. ML0640033). To execute the Digital I&C project, a Steering Committee was formed by a memorandum from the Executive Director of Operations (EDO) dated January 12, 2007 (ADAMS Accession No. ML063390606).

The Digital I&C Steering Committee has the overall responsibility of timely resolution of Digital I&C technical, regulatory, strategic, and policy issues, through implementation of the Digital I&C project plan. The Digital I&C Steering Committee provides oversight and guidance on key digital I&C technical and regulatory issues and interfaces with industry on those issues. The primary responsibilities of the Steering Committee are (1) to interface with industry representatives on plans for resolution of digital I&C issues, (2) to oversee and facilitate resolution of technical and regulatory issues related to the deployment of digital I&C, and (3) to ensure effective inter-office coordination on digital I&C issues. The Steering Committee will monitor the NRC line organizations' progress on Digital I&C Project Plan implementation and review specific goals and deliverables. The Steering Committee will approve the initial Digital I&C Project Plan and subsequent revisions to the plan. The Steering Committee will approve Interim Staff Guidance generated by the Task Working Groups.

The Digital I&C project plan (ML071900253) defines Digital I&C regulatory and technical issues identified by the NRC and industry stakeholders for which interim staff guidance (ISG) can be developed in time to support the review of anticipated licensing actions including digital upgrades at operating reactors and fuel cycle facilities, new reactor Combined License (COL) and Design Certification applications, and new fuel cycle facilities. The project plan is divided into near-term and long-term activities for the six key areas listed below:

1. Cyber Security
2. Diversity and Defense-in-Depth (D3)
3. Risk-Informed Digital I&C Reviews
4. Highly Integrated Control Rooms – Digital Communication Systems (HICR-C)
5. Highly Integrated Control Rooms – Human Factors (HICR-HF)
6. Digital I&C Licensing Process

The digital I&C Task Working Groups (TWGs) were established to include technical representation by NRC staff and industry counterparts to focus on six key areas. The TWGs interactions are designed to facilitate discussion of technical and regulatory issues and the development of recommendations to effectively address digital I&C issues. The TWG have been working with their industry counterparts in public meetings to resolve digital I&C issues identified in the project plan. Each TWG is responsible for developing ISG to refine and enhance digital I&C regulatory guidance. The ISG and its references serve as the primary sources of guidance to the staff for its review of Digital I&C applications.

The principal purpose of ISG is to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate Digital I&C applications. The document is also intended to make information about regulatory matters widely available, to enhance communication with interested members of the public and the nuclear power industry, and to improve the public's understanding of the staff review process. The individual sections of ISG addresses (1) who performs the review, (2) the matters that are reviewed, (3) the basis for review, (4) the way the review is accomplished, and (5) typical conclusions.

The development of ISG supports the Digital I&C review process by providing timely updated guidance to staff reviewers of Digital I&C applications, as well as information for stakeholders. Approved ISGs will be used by staff reviewers and be available to stakeholders for information until the subjects of the ISGs are further refined and incorporated, as appropriate, into future revisions of appropriate regulatory documents.

2.0 OBJECTIVES

This instruction ensures that Digital I&C ISGs reflecting new or revised guidance are properly evaluated, documented, and implemented. Further, this instruction establishes the responsibilities and authorities for the NRC staff in identifying needed changes to ISG using the Digital I&C ISG process.

This instruction provides NRC staff with the basic framework for processing Digital I&C ISGs. The goals of this instruction include the following:

- Helping provide reasonable assurance that the health and safety of the public are protected by supporting a rigorous and consistent Digital I&C review process
- Promoting openness in the Digital I&C application review process by making guidance to staff reviewers available to stakeholders
- Implementing a documented and controlled review process for Digital I&C guidance, so as to support effective and efficient NRC regulation

The ISGs will be developed to facilitate the Digital I&C application review process. It is expected that, during reviews of initial Digital I&C applications, guidance to staff reviewers reflected in ISG may be used to review Digital I&C applications. The ISGs will serve as a bridge until the interim guidance can be refined as necessary and appropriate regulatory documents can be revised.

3.0 Digital I&C ISG PROCESS

3.1 Overview

The staff, industry, or interested members of the public may comment on, raise issues regarding, or propose changes to information provided in ISG or its references. Each ISG will be refined as appropriate and will be incorporated, into future updates of appropriate regulatory documents.

Early communication with stakeholders, in accordance with applicable NRC directives and NRR Office Instructions is important when issues or potential issues are identified. The process is administered and controlled by the Digital I&C Steering Committee and its Task Working Groups (TWG).

The Digital I&C TWG Managers and the Digital I&C project managers (PMs) play vital roles in the overall review process. They are responsible for screening, documenting, planning, tracking, coordinating, and implementing resolutions of Digital I&C ISGs. Technical reviewers will be asked to support the development of each Digital I&C ISG, as needed.

3.2 Processing of Digital I&C ISGs

The basic activities involved in processing a Digital I&C ISG are as follows:

- Section 3.2.1 - Identification of the Need for ISG
- Section 3.2.2 - Development of Draft ISG and Availability to Stakeholders for Comments
- Section 3.2.3 - Discussion of Draft ISG with Stakeholders in Public Meetings
- Section 3.2.4 - Addressing Stakeholders Comments and Preparation of the ISG
- Section 3.2.5 - Review, Approval, and Issuance of the ISG
- Section 3.2.6 - Implementation of the Approved ISG
- Section 3.2.7 - Future Revisions of the Approved ISG

These basic activities are described in the sections below and are also shown graphically in the process flow chart in Appendix A of this instruction.

3.2.1 Identification of the Need for ISG

The six TWGs have been working with their industry counterparts in public meetings to resolve issues regarding the application of digital technology in operating reactors, new reactors, and nuclear fuel cycle facilities. Each TWG has identified the issues and the related ISGs to resolve them in the areas of Cyber Security, Diversity and Defense-in-Depth (D3), Risk-Informed Digital I&C Reviews, Highly Integrated Control Rooms – Digital Communication Systems (HICR-C), Highly Integrated Control Rooms – Human Factors (HICR-HF), and Digital I&C Licensing Process.

3.2.2 Development of Draft ISG and Availability to Stakeholders for Comments

The TWGs are responsible for developing the ISG which will serve as for additional source of guidance to the staff for its review of Digital I&C applications and as information for stakeholders. The TWGs have been working with their industry counterparts in public meetings to develop appropriate ISGs to resolve the issues related to Digital I&C applications. The TWGs will consider industry inputs or “white papers”, if available, in the development of the draft ISGs.

Each TWG will prepare a draft ISG and provide the draft ISG to other TWGs for peer review and comments. The draft ISG will be reviewed by the Steering Committee and subsequently posted in the Digital I&C public website.

The following provides guidance for the format and content that should be used for all Digital I&C ISGs:

- Issue Heading:

A short summary or description of the issue (one or two sentences). [Keyword searches in ADAMS could be generated from the summary, so it is beneficial to be specific.]

- Staff Position:

This section describes the Digital I&C ISG, which includes proposed resolutions.

- Rationale:

This section should provide a description of the issue in sufficient detail, such that an informed reader could understand the issue, its basis, significance, applicability, and ramifications. The staff will document its analysis of the Digital I&C ISG in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria.

- References:

List references mentioned in the Digital I&C ISG text. These could include NUREGs, other Digital I&C ISGs, applicable regulations, industry standards, and Regulatory Guides (RGs).

TWGs will address comments from other TWGs and the Steering Committee. TWGs will make the draft ISGs available to the public and stakeholders by posting on the Digital I&C public website. Digital I&C PMs will issue a public meeting notice with link to Digital I&C web site. Digital I&C PMs will publish draft ISGs on the Digital I&C web page with a minimum of 48 hours prior to the public meeting.

3.2.3 Discussion of Draft ISG with Stakeholders in Public Meetings

Each TWG will hold a public meeting with their industry counterparts to discuss the draft ISG and solicit stakeholders comments. NEI will be requested to provide industry's consolidated comments to the TWG Managers, within 10 working days.

3.2.4 Addressing Stakeholders Comments and Preparation of the ISG

The TWGs will consider industry's consolidated comments prior to the approval process for the ISG. If necessary and practical, the TWGs will hold public meetings to discuss staff resolution of the stakeholders comments.

The TWGs will update the ISG after addressing the industry comments, within 10 working days.

3.2.5 Review, Approval and Issuance of the ISG

After TWGs have updated ISGs conveying the staff's technical position and evaluation, the Digital I&C PMs will develop a cover letter to issue the ISG to stakeholders.

The draft cover letter and proposed ISG should be reviewed by the manager of the TWG supporting the Digital I&C ISG, any other involved TWGs, the cognizant Division Director, OGC, and the Digital I&C Steering Committee. Review and concurrence should ensure the quality and consistency of the proposed resolution of the issue.

The Digital I&C PMs will obtain the OGC's no legal objection (NLO) within 10 working days, in parallel with the Digital I&C Steering Committee's review and approval process. The Chairman of the Digital I&C Steering Committee will obtain concurrence from cognizant Steering Committee members. The Digital I&C PMs will provide copies of the approved ISG to ACRS and CRGR for information, and issue the approved ISG to interested stakeholders by letter.

The approved Digital I&C ISG will be published in ADAMS and updated on the NRC Digital I&C public web page for staff and industry use. Also, a link to the approved ISG will be placed on the NRC's Interim Staff Guidance public web page.

The Digital I&C ISG can then be referenced in a Digital I&C application for the regulatory review process. The Digital I&C ISG will be further refined as appropriate and recommended for incorporation into the next revision of the corresponding Digital I&C regulatory documents.

3.2.6 Implementation of the Approved Digital I&C ISG

Implementation affects both future and current applicants. Future Digital I&C applications will address the Digital I&C ISG (until it is reflected in a revision to the corresponding regulatory document). Current Digital I&C applicants may need to address the approved Digital I&C ISG by responding to an RAI, by addressing an open item in the draft SER, or by supplementing their application.

3.2.7 Future Revisions of the Approved ISG

Approved ISGs issued to facilitate the Digital I&C application review process are dynamic guidance documents. The NRC staff, industry, and other interested stakeholders may gain experience and develop lessons learned from the use of the ISGs. Therefore, it is expected that, as lessons are learned during the reviews of Digital I&C applications, these guidance documents may need to be modified to capture new insights or address emergent issues. These insights, lessons learned, and resolutions of emergent issues will be captured in the future revisions to the ISGs until the appropriate regulatory documents can be revised.

4.0 RESPONSIBILITIES AND AUTHORITIES

All NRC staff members who participate in the review of Digital I&C applications and inspections of related activities are responsible for reading, understanding, and applying the guidance provided in Digital I&C ISG.

4.1 Roles and Responsibilities for the Review of Digital I&C ISGs

- The Digital I&C Steering Committee (DI&C SC)

The Digital I&C Steering Committee is responsible for oversight of Digital I&C activities, process development activities, and implementation of the Digital I&C ISG program. The Steering Committee will also approve Interim Staff Guidance generated by the Task Working Groups.

- The Digital I&C Project Managers

The Digital I&C project managers have the overall project management responsibility for the Digital I&C project. The PMs are responsible for coordinating internal and external meetings, preparing and issuing meeting notices and meeting summaries, facilitating preparation and review of ISGs, transmitting draft ISGs to stakeholders for comments, posting ISGs on the NRC web pages, and issuing the ISGs to stakeholders.

- The Task Working Groups (TWGs)

The TWGs are responsible for coordinating with the stakeholders for resolution of the issues related to Digital I&C, and preparation, review, and issuance of ISGs. Staff involved with the review should be familiar with the requirements of the applicable regulation, the guidance provided in the applicable regulatory Guides, the ISG, and its references applicable to their areas of review responsibility.

- NRC Management

Division directors, program directors, and the regions will assist in resolving concerns relating to Digital I&C ISGs, including schedules, resources, priorities, and technical issues.

- The Office of the General Counsel (OGC)

The Office of the General Counsel reviews Digital I&C ISGs from a regulatory and legal perspective and provides legal and regulatory advice to NRC management.

6.0 PRIMARY CONTACTS

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7.0 RESPONSIBLE ORGANIZATION

The Digital I&C Steering Committee

8.0 EFFECTIVE DATE

August, 2007

ADAMS ACCESSION NO. ML072140211

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Appendix A: Process Flow

Task Working Group (TWG) Interim Staff Guidance for Digital I&C Reviews - Process Flow Chart

