



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 11, 2009

MEMORANDUM TO: Lois M. James, Chief
Plant Licensing Branch III-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

FROM: G. Edward Miller, Project Manager
Plant Licensing Branch I-2
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

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SUBJECT: SUMMARY OF JANUARY 27, 2009, CATEGORY 2 PUBLIC MEETING
REGARDING DEVELOPMENT OF INTERIM STAFF GUIDANCE ON
THE DIGITAL INSTRUMENTATION AND CONTROL SYSTEM
UPGRADE LICENSING PROCESS

On January 27, 2009, the Nuclear Regulatory Commission (NRC) staff conducted a Category 2 public meeting to discuss the development of interim staff guidance (ISG) for the Office of Nuclear Reactor Regulation (NRR) regarding the licensing process for digital instrumentation & control (I&C) upgrades. A notice for this meeting was issued on January 14, 2009, and is available in the Agencywide Documents Access and Management System under Accession No. ML090130250. The attendance sheet is included as Enclosure 1 to this memorandum.

The purpose of this meeting was to foster an open discussion regarding the draft version of the licensing process guidance on digital I&C upgrades, ISG-6.

The meeting was opened by a discussion of the background and objectives of the guidance. A conceptual overview of the ISG was given where the application and review process would have multiple phases where the NRC staff would receive the information available, recognizing that some currently unavailable information would be forthcoming from the licensee. Additionally, this process would allow for interim feedback to reduce regulatory uncertainty. Following this discussion, individual comments on the draft version provided with the public meeting notice were discussed. A copy of the draft ISG, revised based on the comments received, is included as Enclosure 2 to this memorandum.

Two topics were tabled for additional discussion at future meetings. The first was whether there is a need for an exemption if a licensee requests approval based upon a later edition of IEEE-603, "Criteria for Protection Systems for Nuclear Power Generating Stations." Second, although the ISG currently identifies the request for additional information process as a method to communicate preliminary assessments of review areas, alternate methods would be considered.

The presentation slides are included as Enclosure 3 to this memorandum.

Following the discussion draft guidance, meetings in the near future were summarized. A conference call with the industry contacts would be held to ensure all comments were received. The next meeting is tentatively planned for February 24, 2009.

At the conclusion of these discussions, the meeting was opened for public comments. No additional comments were provided.

Enclosures:

1. List of Attendees
2. Revised Draft Guidance
3. Presentation Slides

Sign In Sheet	Discussion of Draft Guidance on Performing Acceptance Reviews
DATE: January 27, 2009	

Name	Organization
G. E. MILLER	NRC/NRR/DORL
MIKE SCHOPPMAN	NEI
SCOTT PATTERSON	Pacific Gas & Electric
GORDON CLETON	NEI
Tom Hayes	Westinghouse
BILL KEMPER	NRC/NRR/DE/EICB
Jerry Wermiel	NRC/NRR/DE
Stewart Bailey	NRC/NRR/DE
Robert Gill	Duke Energy
Bob Hirmanpour	NuStart
Joe Ashcraft	NRC/DE/ICE 2
Patricia Campbell	GE Hitachi
Michael Bailey	Duke Energy / ONS
Lois James	NRC/NRR/DORL
WILLIAM MCCONAGHY	TOSHIBA/KANUK
+ ADDITIONAL PARTICIPANTS VIA PHONE	



DIGITAL INSTRUMENTATION AND CONTROLS

DI&C-ISG-06

**Task Working Group #6:
Licensing Process**

Interim Staff Guidance

(Initial Issue for Use)

Enclosure 2

DIGITAL INSTRUMENTATION AND CONTROLS

DI&C-ISG-06

Task Working Group #6: Licensing Process

Interim Staff Guidance

(Initial Issue for Use)

A. INTRODUCTION

This Interim Staff Guidance (ISG) provides the licensing process to be used in the review of digital I&C (I&C) system modifications in operating plants. This guidance is consistent with current NRC policy on digital I&C systems and is not intended to be a substitute for Nuclear Regulatory Commission (NRC) regulations, but to clarify how a licensee or applicant may efficiently request NRC approval to install a digital I&C system upgrade.

This ISG covers the entire life cycle for the review process including activities prior to submittal of the license amendment request (LAR). Except in those cases in which a licensee or applicant proposes or has previously established an acceptable alternative method for complying with specified portions of NRC regulations, the NRC staff will use the methods described in this ISG to evaluate compliance with NRC requirements.

B. PURPOSE

The purpose of this ISG is to provide guidance for the NRC staff's review of digital I&C systems in accordance with current licensing processes. This ISG also informs licensees of the information and documentation the NRC staff will need for its review of LARs for digital I&C upgrades and when the information should be provided. Review of this document should allow licensees to prepare digital I&C upgrade applications that are complete with respect to the areas that are within the NRC staff's scope of review.

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Use of this ISG is designed to be complementary to the NRC's longstanding topical report review and approval process. Where a licensee references an NRC-approved topical report, the NRC staff will be able to, where appropriate, limit its review to confirming the application of the digital I&C upgrade falls within the envelope of the topical report approval. Additionally, this ISG was developed based upon, and is designed to work in concert with, existing guidance. Where appropriate, this ISG references other guidance documents and provides their context with respect to the digital I&C licensing process for operating reactors.

The NRC staff will review proposed digital I&C upgrades against the design basis of the plant and the guidance in the Standard Review Plan (NUREG-0800), Chapter 7, and other associated guidance including ISGs. Licensees should provide a discussion of the

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licensing basis for the plant, focusing these efforts on areas where the licensing basis differs from current guidance. Additionally, licensees should clearly identify those parts of the licensing basis they are updating as a result of the proposed change.

C. LICENSING PROCESS

C.1 Process Overview

Recognizing that digital I&C upgrades represent a significant licensee resource commitment, a phased approach is appropriate where critical, fundamental, system information is initially vetted through the NRC staff prior to undertaking subsequent steps in the digital I&C system design and licensing process. Therefore, the NRC staff encourages the use of public meetings prior to submittal of the LAR in order to discuss issues regarding the system design development. The intent of this activity is to reduce regulatory uncertainty by resolving major concerns up front. The NRC staff recognizes that some information may not be available upon initial submittal of the LAR, thus it is not expected that information sufficient to address all review topics be submitted until at least 12 months prior to the requested approval date.

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A flow chart of the overall process is included in Figure 1 and the various phases are further discussed in Sections C.2 through C.5.

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Additionally, the NRC staff recognizes that there are different approaches available to licensees regarding use and application of previously-approved digital systems. Therefore, the NRC staff will consider applications to be within one of three tiers of review. The first tier is where a licensee is proposing to reference a previously approved topical report completely within the envelope of its generic approval as described in the topical report. A tier one review would be able to rely heavily upon the previous review efforts, with large parts of the review being confirmatory. The second tier is where a licensee proposes to reference a previously approved topical report with deviations to suit the plant-specific situation. The aspects of a tier two review that are within the envelope of the generic approval would be confirmatory, while the deviations should be expected to require a more significant review effort. Typically, an application citing licensing experience from another plant's previous approval would be considered a tier two review. This, however, is dependent upon the similarities of the application. The third tier is where a licensee proposes to use a completely new system with no generic approval. Licensees should expect that a tier three review will require a very significant review effort within all review areas.

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C.2 Pre-Application (Phase 0)

Prior to submittal of a LAR for a digital I&C upgrade, it is beneficial to have an overall design concept that adequately addresses NRC requirements and policy with regard to key issues, such as defense-in-depth and diversity. To this end, the NRC staff intends to use the public meeting process to engage licensees in a discussion of how their proposed digital I&C upgrade LAR will address defense-in-depth and diversity, significant variances from current guidance, and other unique or complex topics associated with the proposed design. These meetings are intended to be two-way discussions where in addition to the licensee presentation of concept, the NRC staff can provide feedback as to the critical aspects of the proposed design that are likely to affect (both positively and negatively) the NRC staff's evaluation.

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As a minimum, these discussions should include whether the system will have built-in diversity for all applicable events or whether the licensee will rely on diverse manual operator actions or diverse actuation systems. Further, these discussions should include whether the licensee is proposing the use of an approved topical report, any planned deviations from NRC staff positions, and specifics of the software quality assurance plan. If able, licensees should be encouraged to discuss topics from other review areas as well as how any best-estimate evaluations utilize realistic assumptions and models and address uncertainty associated with the results

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Following each meeting the NRC staff will capture the topics discussed via a meeting summary. This summary will include a preliminary NRC staff assessment of the licensee's concept (or those sub-parts of the overall concept discussed) and identify the areas that are significant to this preliminary assessment. Additionally, as appropriate, the NRC staff will include a preliminary assessment of which review tier would be applicable for the proposed upgrade. The licensee will be provided a draft copy of the meeting summary comment prior to its issuance. An example meeting summary is included in Appendix A to this document.

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C.3 Initial Application (Phase 1)

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Once a licensee believes they have a design that adequately addresses NRC acceptance criteria, including defense-in-depth and diversity, variances to existing guidance, and any unique or complex design features, they should prepare and submit a LAR. It is incumbent upon the licensee to identify any deviations in design and concept that may impact the NRC staff's preliminary assessment made during Phase 0. It should be noted that these changes may adversely impact the NRC staff's acceptance of the LAR for review.

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The LAR should include information sufficient to address the following subject areas, which are discussed in further detail in the referenced sections:

- Defense-in-depth & Diversity (Section D.X)
- Hardware Design & Single Failure (Section D.X)
- System Modifications & Configuration Control (Section D.X)
- Data Communication (Section D.X)
- Software Design & Development (Section D.X)
- V&V Plan (Section D.X)
- Cyber Security (Section D.X)
- Technical Specifications (Section D.X)

Initially, the NRC staff will review the application in accordance with the NRR Office Instruction, LIC-109, "Acceptance Review Procedures," to determine if the application is sufficient for NRC staff review. It is recognized that some sets of information may not be available upon initial application and the review process may be more efficiently administered by beginning prior to their availability. Therefore, a digital I&C upgrade application may be found to be sufficient for review provided a clear schedule for submission of omitted information is included. Any proposed changes to the schedule should be agreed upon by the NRC staff prior to a given due-date. Licensees should be aware that the NRC staff will rigorously adhere to the schedule set forth and failure to

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submit information in accordance with the schedule may result in denial of the application pursuant to 10 CFR 2.108.

During Phase 1, the NRC staff will issue a request for additional information (RAI) based on the initial LAR in accordance with LIC-101, "License Amendment Review Procedures" (Note: This document is not publically available). The NRC staff will also communicate those areas of review that, based upon the currently available information, appear to be acceptable. The licensee should respond to the RAIs prior to the submittal of the Phase 2 information. Although the NRC staff may have additional questions based on the responses to the Phase 1 RAI response, the licensee should not delay submission of the Phase 2 information.

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As further discussed in Section C.4, the NRC staff and licensee should be aware that some information needs may be best met by the performance of an audit. Those information needs to be resolved in this manner should be documented and the Project Manager, in consultation with the licensee and technical staff, should schedule the audit. While the documentation needs discussed in Section D.1 through D.X indicate which process will likely be used (i.e., RAI or Audit), individual circumstances will dictate the appropriate vehicle for the NRC staff to obtain needed information.

C.4 Continued Review and Audit (Phase 2)

Following response to the Phase 1 RAIs but at least 12 months prior to the requested approval date, the licensee should submit a supplement containing sufficient information to address any remaining subject areas, including:

- Equipment Qualification (Section D.X)
- Human Factors (Section D.X)
- Commercial Dedication of Computer-Based Systems (Section D.X)
- Test and Calibration (Section D.X)

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During Phase 2, the NRC staff will continue the RAI process until sufficient information has been provided for a decision to be rendered on the acceptability of the proposed digital I&C upgrade. If necessary, either during or after the Phase 2 RAI process, the NRC staff will conduct an audit in accordance with LIC-111, "Regulatory Audits" (Note: This document is not publically available).

Any audits will likely cover information from both Phase 1 and Phase 2, and may result in further requests for information to be docketed. It is the NRC staff's intent to perform the audits as early in the process as is reasonable, but the performance of an effective and efficient audit requires that the LAR and supplements to be sufficiently detailed about the later phases of the system development lifecycle (e.g., V&V and factory acceptance testing). Although the use of an audit is discussed in Phase 2, this does not preclude the performance of an audit during Phase 1 if it is determined to be beneficial.

Phase 2 will conclude with the issuance of a safety evaluation (SE) documenting the approval or denial of the licensee's proposed digital I&C upgrade.

C.5 Implementation and Inspection (Phase 3)

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Following regulatory approval of the digital I&C system, licensees will implement the upgrade by installing the system, effecting associated procedural and technical specification changes, and completing startup testing.

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The startup testing is conducted in accordance with the plan submitted during Phase 2 as addressed in Section D.X, "Test and Calibration." The NRC staff review of startup testing is an inspection function that will be conducted by the appropriate regional staff in accordance with IP-52003, "Digital Instrumentation and Control Modification Inspection."

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D. Review Areas

D.1 Defense-in-Depth & Diversity

D.1.1 Scope of Review

The principle of defense-in-depth may be thought of as requiring a concentric arrangement of protective barriers or means that are sequentially challenged by the failure of a preceding system. In the context of digital instrumentation and control (I&C) defense-in-depth is achieved through four echelons of defense. The first is the control system echelon which functions under normal operations of the plant and either through automatic control or operator intervention maintains the plant in safe regimes of operation. If the control system echelon fails or is otherwise unable to maintain the plant in a safe operating regime, the reactor trip echelon acts to rapidly reduce reactivity and minimize any excursion. In turn, if the reactor trip system (RTS) echelon is unable to return the plant to safe conditions, the engineered safety features actuation system (ESFAS) echelon activates systems designed to maintain or return the reactor to a subcritical and safe configuration. Finally, if these three levels fail, the monitoring and indicator echelon is available to allow operators to make informed decisions regarding response to the transient.

Diversity, in the context of digital I&C, is a principle of using different parameters, technologies, logic or algorithms, and actuation means to provide a similar function. Diversity complements defense-in-depth by increasing the chances that a particular echelon will function appropriately. The diversity of a system can be subdivided into six areas: human diversity, design diversity (hardware), software diversity, functional diversity, signal diversity, and equipment diversity.

Diversity in digital I&C systems is necessitated by their vulnerability to common-cause failures (CCFs) in software. The NRC staff review of a digital I&C system modification will ensure that sufficient diversity is provided to accomplish the required safety function subject to the potential CCF vulnerability.

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D.1.2 Information to be Provided

The licensee should provide sufficient documentation to support the assertion that a proposed digital I&C system is diverse and sufficiently robust against CCF. Additional guidance is available in Interim Staff Guidance DI&C-IGS-02. As further discussed in Section D.1.3, the NRC staff will evaluate the licensee's proposed amendment using Branch Technical Position 7-19, which contains four points to be addressed. To satisfy these four points, the NRC staff would expect a submittal to include:

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- An analysis of the diversity of the system with respect to the six areas discussed in Section D.1.1.
- A best-estimate evaluation of each anticipated operational occurrence (AOO) in the design basis occurring in conjunction with each single postulated common-cause failure.
- A best-estimate evaluation of each postulated accident in the design basis occurring in conjunction with each single postulated common-cause failure.
- An evaluation of all common elements or signal sources shared by two or more system echelons.
- Identification of all interconnections between the RTS and ESFAS provided for system interlocks and justification that functions required by 10 CFR 50.62 are not impaired by the interconnection.
- A list of all manual operator actions credited for diversity.
- Detailed justification for operator actions required in less than 30 minutes.

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Licensee's should be aware that the specific situations and applications of a system may require additional justification or, in some cases, may not apply to each design basis AOO or accident.

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D.1.3 Regulatory Evaluation

As a result of the reviews of advanced light-water reactor (ALWR) design certification applications that used digital protection systems, the NRC position is documented in the SRM on SECY 93-087, "Policy, Technical and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Design," with respect to common-mode failure in digital systems and defense-in-depth. This position was also documented in BTP 7-19, "Guidance for Evaluation of Defense-in-Depth and Diversity in Digital Computer Based Instrumentation and Control Systems." Points 1, 2, and 3 of this position are applicable to digital system modifications for operating plants.

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The NRC staff's review of defense-in-depth and diversity in digital I&C systems is focused on ensuring that the required safety functions can be achieved in the event of a postulated CCF in the digital system. As discussed in BTP 7-19, The NRC staff's review considered the following regulatory requirements:

10 CFR 50.55a(h), "Protection and Safety Systems," requires compliance with Institute of Electrical & Electronics Engineers (IEEE) Standard (Std.) 603-1991, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations," and the correction sheet dated January 30, 1995. For nuclear power plants with construction permits issued before January 1, 1971, the applicant/licensee may elect to comply instead with their plant-specific licensing basis. For nuclear power plants with construction permits issued between January 1, 1971, and May 13, 1999, the applicant/licensee may elect to comply instead with the requirements stated in IEEE Std. 279-1971, "Criteria for Protection Systems for Nuclear Power Generating Stations." IEEE Std. 603-1991, Clause 5.1, requires in part that "safety systems shall perform all safety functions required for a design basis event in the presence of: (1) any single detectable failure within the safety systems concurrent with all identifiable but non-detectable failures." IEEE Std. 279-1971, Clause 4.2, requires in part that "any single failure within the protection system shall not prevent proper protective action at the system level when required."

10 CFR 50.62, "Requirements for Reduction of Risk from Anticipated Transients without Scram [ATWS]," requires in part various diverse methods of responding to ATWS.

Additionally, the NRC staff's review is guided by 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 21, "Protection Systems Reliability and Testability," requires in part that "no single failure results in the loss of the protection system."

GDC 22, "Protection System Independence," requires in part "that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions ... not result in loss of the protection function ... Design techniques, such as functional diversity or diversity in component design and principles of operation, shall be used to the extent practical to prevent loss of the protection function."

GDC 24, "Separation of Protection and Control Systems," requires in part that "[i]nterconnection of the protection and control systems shall be limited so as to assure that safety is not significantly impaired."

GDC 29, "Protection Against Anticipated Operational Occurrences," requires in part defense against anticipated operational transients "to assure an extremely high probability of accomplishing ... safety functions."

It should be noted that the NRC staff intends to provide a preliminary determination on the acceptability of the approach to demonstration of a sufficient level of defense-in-depth and diversity as part of the acceptance review of the amendment request. This will be done to provide the licensee with an appropriate level of assurance that the proposed digital I&C system design development and implementation may proceed as planned.

D.1.4 Technical Evaluation

The two principle factors for defense against common-mode/common-cause failures are quality and diversity. Maintaining high quality increases the reliability of both individual components and complete systems while having diversity affords robustness in the ability to appropriately respond to a situation in light of a component failure.

[Technical evaluation of licensee's application]

D.1.5 Conclusion

The NRC staff has reviewed the licensee's submittal and finds that the proposed implementation of [SYSTEM] is sufficiently diverse and robust against common-mode/common-cause failure that the [control system, RTS, ESFAS, and/or monitoring and indication] adequately address the NRC staff positions stated in BTP 7-19. Addressing the NRC staff positions in BTP 7-19 provides adequate assurance that the proposed change meet the requirements of 10 CFR 50.55a(h) and 10 CFR 50.62. Therefore, the NRC staff finds the proposed digital I&C upgrade to be acceptable with respect to defense-in-depth and diversity.

D.2 Hardware Design & Single Failure

D.3 System Modifications & Configuration Control

MEMORANDUM TO: [NAME], Director
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

[NAME], Director
Division of Engineering
Office of Nuclear Reactor Regulation

FROM: [NAME], Project Manager
Plant Licensing Branch [X-X]
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF [MONTH DAY, YEAR], CATEGORY 1 PUBLIC MEETING TO DISCUSS [LICENSEE] PLANS TO REQUEST NRC APPROVAL OF A DIGITAL I&C UPGRADE OF [SYSTEM] USING [PLATFORM]

On [DATE], the Nuclear Regulatory Commission (NRC) staff conducted a Category 1 public meeting to discuss [LICENSEE]'s plans for upgrading the [PLANT] [SYSTEM] to the [PLATFORM] digital instrumentation and control (I&C) system.

The purpose of this meeting was to discuss the initial design concepts and any site specific issues identified by [LICENSEE]. These discussions focused on the how [LICENSEE] will address the review area of defense-in-depth and diversity.

In these discussions, the licensee identified the following characteristics and design specifications that contribute to the [PLATFORM]'s diversity and robustness against common cause failure (CCF).

- Item 1
- Item 2...

The NRC staff provided feedback to [LICENSEE] that the following aspects of the design seemed conducive to finding the proposed upgrade consistent with the NRC staff's position on defense-in-depth and diversity:

- Item 1
- Item 2...

Additionally, the NRC staff identified that the following aspects of the design would require additional review before finding the proposed upgrade fully consistent with the NRC staff's position on defense-in-depth and diversity:

- Item 1
- Item 2...

Concurrence for this memorandum shall include the Chief, Instrumentation & Controls Branch, the Chief, Plant Licensing Branch X-X, and any other Branch Chiefs whose review authorities may have been discussed.

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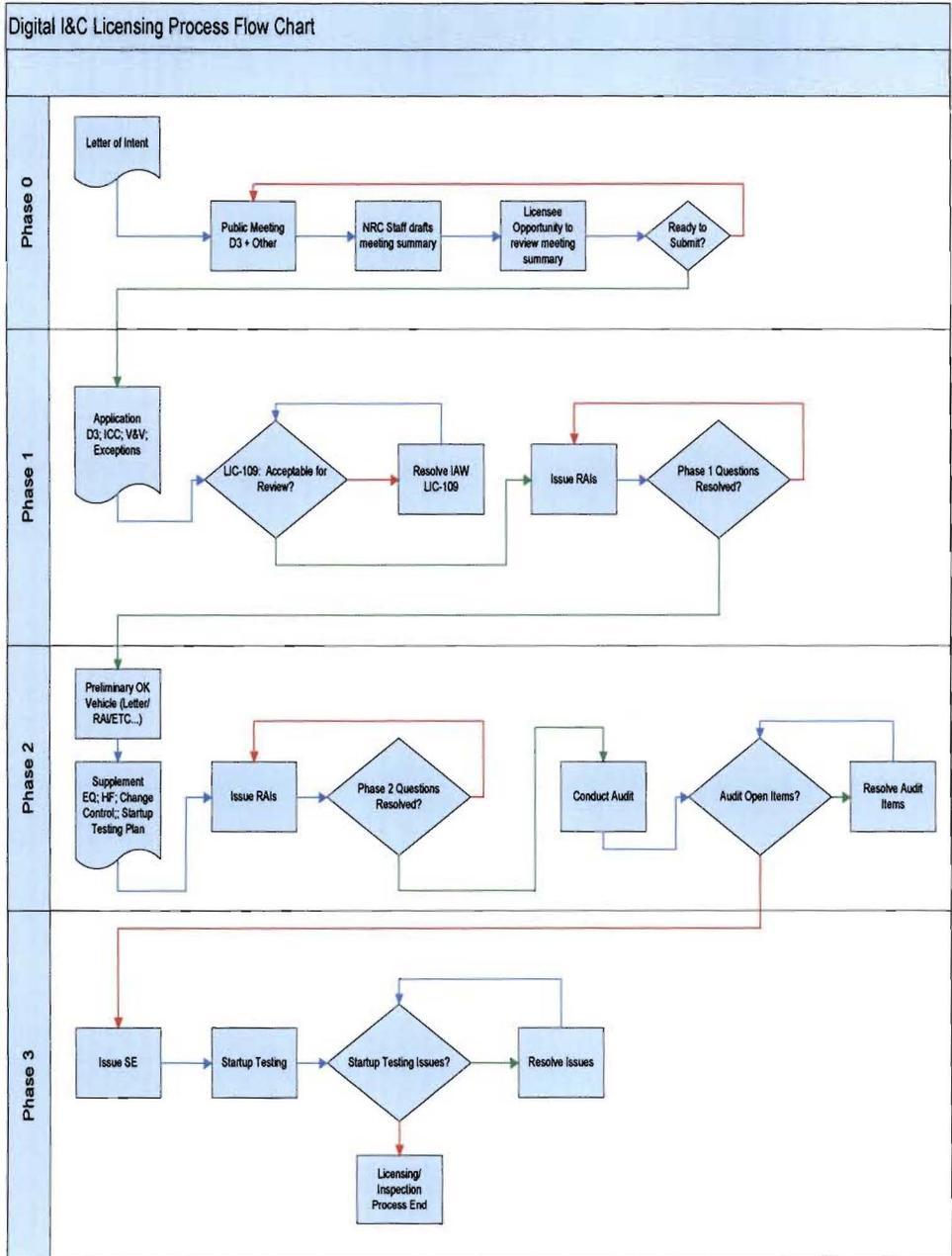


FIGURE 1, "Process Flow Chart"

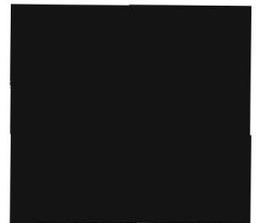


Digital I&C Licensing Process Task Working Group-6

January 27, 2009

Ed Miller, Project Manager
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Enclosure 3





Digital I&C Licensing Process

- Agenda
 - Introduction of Participants and Review of ISG-6 Objectives
 - Licensing Process
 - Review Area: D3
 - Review Area List
 - Schedule
 - Public Comments





Digital I&C Licensing Process

- Introduction of Participants
- Objectives of ISG-6
 - Clearly defined licensing process
 - Expectations for documentation





Digital I&C Licensing Process

- Licensing Process
 - Process Overview
 - Initial Application
 - Continued Review and Audit
 - Implementation and Inspection
 - Review Areas
 - Scope of Review
 - Information to be Provided
 - Regulatory Evaluation
 - Technical Evaluation
 - Conclusion
 - Appendices (Example Formats)





Digital I&C Licensing Process

- Review Area: D3
 - Scope of Review
 - Information to be Provided
 - Regulatory Evaluation
 - Technical Evaluation
 - Conclusion
- Review Area List



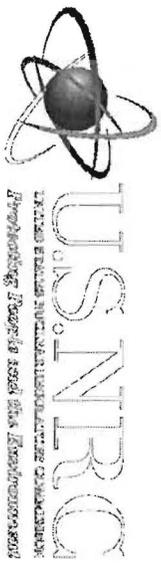


Digital I&C Licensing Process

- Schedule

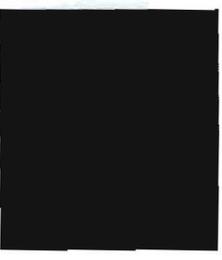
- Conference Call, February 10, 2009 to discuss status.
- Public Meeting, February 24, 2009, to discuss comments on draft process and review areas & Present 2~4 additional draft review areas.
- Conference Call, March 10, 2009 to discuss status.
- Public Meeting, March 24, 2009, to discuss outstanding issues on previous review areas & Present 2~4 additional draft review areas.





Digital I&C Licensing Process

- Public Comments



February 11, 2009

- 2 -

L. James

At the conclusion of these discussions, the meeting was opened for public comments. Following a brief discussion of the comments, the meeting was adjourned.

Enclosures:

1. List of Attendees
2. Revised Draft Guidance
3. Presentation Slides

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