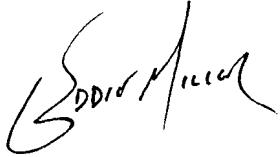# UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 11, 2009

MEMORANDUM TO: Stewart Bailey, DI&C Deputy Director
Division of Engineering
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

SUBJECT: NOTICE OF PUBLIC MEETING OF THE DIGITAL INSTRUMENTATION AND CONTROL (I&C) TASK WORKING GROUP NO. 6 TO ADDRESS DEVELOPMENT OF DIGITAL I&C LICENSING GUIDANCE

DATE & TIME: Tuesday, February 24, 2009
1:00 p.m. - 4:00 p.m.

LOCATION: U.S. Nuclear Regulatory Commission
Executive Boulevard Building, Room 1-B13
6003 Executive Boulevard
Rockville, MD 20852

PURPOSE: The Nuclear Regulatory Commission (NRC) staff is convening this meeting with the Nuclear Energy Institute (NEI) to discuss the development of interim staff guidance on the licensing of digital I&C safety systems for operating nuclear plants. This discussion will focus on draft licensing process and review section for Validation & Verification. Copies of these documents are enclosed with this notice.

CATEGORY 2*: This is a Category 2 public meeting. The public is invited to participate in this meeting by providing comments and asking questions at a designated point during the meeting. There may be limited space at the meeting location, and interested members of the public are encouraged to participate in this meeting via a toll-free teleconference. For details, please email the NRC meeting contact by Thursday, February 19, 2009.

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* Commission's Policy Statement on "Enhancing Public Participation in NRC Meetings," (67 FR 36920), May 28, 2002.

S. Bailey   - 2 -

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in a meeting or need a meeting notice, the transcript, or other information from a meeting in another format (e.g., Braille, large print) please notify the NRC's meeting contact. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Project No. 689

Enclosures:
1. Agenda
2. Draft licensing process and review section

cc w/encl: See next page

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AGENDA

FORTHCOMING PUBLIC MEETING

DIGITAL INSTRUMENTATION AND CONTROL (I&C) TASK WORKING GROUP NO. 6

DEVELOPMENT OF LICENSING PROCESS GUIDANCE

February 24, 2009

1:00 p.m. - 4:00 p.m.

1:00 p.m. - 1:15 p.m.	Introduction and Objectives of Interim Staff Guidance (ISG)
1:15 p.m. - 3:00 p.m.	Draft Licensing Process
3:00 p.m. - 3:30 p.m.	Draft Review Section: Verification & Validation
3:30 p.m. - 4:00 p.m.	Public comments
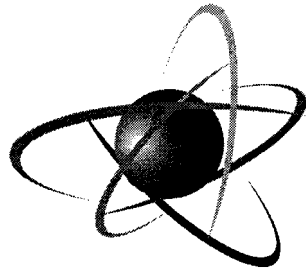
U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

DIGITAL INSTRUMENTATION AND CONTROLS

DI&C-ISG-06

Task Working Group #6:
Licensing Process

Interim Staff Guidance

(Initial Issue for Use)

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 approach for complying with specified portions of NRC regulations, the NRC staff will use the process 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.

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

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. DIGITAL I&C REVIEW 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 through the early resolution of major concerns. 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.

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.

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 list of documents that would typically need to be submitted by the licensee in support of a tier 1 review are contained in Appendix B.1.

The second tier is where a licensee proposes to reference a previously approved topical report with deviations to suit the plant-specific situation. Deviations could include, for example, a revised software development process or new hardware. 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 list of documents that would typically need to be submitted by the licensee in support of a tier 2 review are contained in Appendix B.2.

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. The list of documents that would typically need to be submitted by the licensee in support of a tier 3 review are contained in Appendix B.3. As with any of the lists provided in Appendix B, the plant specific

application may obviate the need for certain listed documents or necessitate the inclusion of other, unlisted, documents.

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. Such unique or complex topics could include, for example, a large scale system application with multiple interconnections and communication paths or major human-machine interface changes. 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.

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.

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.

C.3   Initial Application (Phase 1)

Once a licensee believes it has 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, it 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 staffs acceptance of the LAR for review.

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.1)
- 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.2)
- 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 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 requests for additional information (RAI) based on the initial LAR as necessary to continue the review. These activities will be conducted 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.

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)

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, during 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. The licensing process covered by this ISG ends at the issuance of the associated amendment.

C.5   Implementation and Inspection (Phase 3)

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.

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."

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.

D.1.2 Information to be Provided

Consistent with the list of documents provided in Appendix B, the licensee's submittal should provide sufficient documentation to support to 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:

- 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.

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.

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.

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 to protect 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   Verification & Validation

D.2.1 Scope of Review

Verification and Validation (V&V) is a key aspect of the software design and development process for assuring a quality product. Verification is defined as the process of determining whether or not the products of a given phase of the development cycle fulfill the requirements established during the previous phase. Validation is defined as the test and evaluation of the integrated computer system to ensure compliance with the functional, performance, and interface requirements. Combined, verification and validation is the process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component complies with specified requirements. This determination may include analysis, evaluation, review, inspection, assessment, and testing of the products and processes.

V&V is often managed by use of a Requirements Traceability Matrix. The definition of a Requirements Traceability Matrix is contained in SRP, BTP 7-14, Section A.3, definitions, and says: "An RTM shows every requirement, broken down into sub-requirements as necessary, and what portion of the software requirement, software design description, actual code, and test requirement addresses that system requirement." The RTM should show what portion of the software requirement, software design description, actual code, and test requirement addresses each system requirement.

D.2.2 Information to be Provided

Consistent with the list of documents provided in Appendix B, the licensee's submittal should provide sufficient documentation to support and justify the technical, managerial, and financial independence of the organization performing the V&V. The documentation should provide sufficient justification to allow the conclusion that the plan meets the standard of IEEE 7-4.3.2.

D.2.3 Regulatory Evaluation

The NRC staff's review of the licensee's V&V plan for digital I&C systems is focused on ensuring that the plan adequately assures that appropriate requirements were applied to the system and that the system met these requirements throughout all phases of development. The NRC staff's review considered the requirements of 10 CFR 50.55a(h), which references IEEE 603-1991, and the guidance in IEEE/ANS 7-4.3.2, "American Nuclear Society and IEEE Standard Application Criteria for Programmable Digital Computer Systems in Safety Systems of Nuclear Power Generating Stations."

D.2.4 Technical Evaluation

D.2.5 Conclusion

The NRC staff has reviewed the licensee's submittal and finds that the V&V plan associated with the proposed development and implementation of [SYSTEM] adequately addresses the criteria of IEEE 7-4.3.2. Addressing the criteria provides adequate assurance that the proposed change meet the requirements of 10 CFR 50.55a(h). Therefore, the NRC staff finds the proposed digital I&C upgrade to be acceptable with respect to the associated V&V Plan.

D.3

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.*

Appendix B

Documents to be Submitted in Support of a Digital I&C Upgrade License Amendment Request

Appendix B.1, "Documents for a Tier 1 Review"

<u>Documents Expected Upon Application</u>
1. D3 Analysis
2. System description
   a. Detail to address ISG-4
   b. Detail down to block diagram level
3. Design Analysis Report
4. System Description
5. Hardware & Software Architecture Descriptions
6. Preliminary Reliability Analysis
7. Safety Analysis
8. System Requirements
9. System Test Plan
10. Software Life Cycle Documentation
    a. Software Design Specification
    b. Software Installation Plan
    c. Site Software Maintenance Plan
    d. Software Operations Plan
    e. Software Project Risk Management Program
    f. Application Software Requirements Specification
    g. Software Safety Plan
    h. Software Test Plan
    i. Software Training Plan
11. Requirements Traceability Matrix
12. Equipment Qualification Documentation

<u>Documents Expected Within 12 Months of Requested Approval</u>

1. Final Design Description
2. Final Logic Diagrams
3. Final Reliability Analysis
4. Final System Configuration Documentation
5. Final Test Reports
6. Installation Test Plans and Procedures
7. Summary of Factory Acceptance Testing (FAT)
8. System Test Procedures
9. Software Life Cycle Documentation
10. V&V Reports

<u>Documents to be Available for Audit</u>

1. Completed FAT Procedure & Reports
2. Configuration Management Reports
3. Detailed System and Hardware Drawings
4. Final Circuit Schematics
5. Final Software Integration Report

Documents to be Available for Audit (Continued)

6. Individual Completed Test Procedures & Reports
7. Individual V&V Problem Reports up to FAT
8. Maintenance Manuals
9. Operations Procedures
10. Software Code Listings
11. Training Manuals & Course Material
12. Vendor Build Documentation

Appendix B.2, "Documents for a Tier 2 Review"

Documents Expected Upon Application
1. Commercial Grade Dedication Plan
2. De analysis (Including system modifications and plant specific architecture and use)
3. System description
   a. Detail to address ISG-4
   b. Detail down to block diagram level
4. Design Analysis Report
5. Design Report on Computer Integrity, Test and Calibration, and Fault Detection
6. Theory of Operation Description
7. Equipment Qualification Testing Plans (Including EMI, Temperature, Humidity, and Seismic to the degree to which these are affected by the plant specific application)
8. Software QA Plan and Procedures
9. System Description
10. Hardware & Software Architecture Descriptions
11. Preliminary Failure Mode Effects Analysis (FMEA)
12. Preliminary Reliability Analysis
13. Safety Analysis
14. System Requirements
15. System Test Plan
16. Software Life Cycle Documentation
    a. Site Software CM
    b. Software Design Specification
    c. Software Development Plan
    d. Site Software Maintenance Plan
    e. Software Operations Plan
    f. Application Software Requirements Specification
    g. Software Safety Plan
    h. Software Test Plan
    i. Software Training Plan
17. Requirements Traceability Matrix

Documents Expected Within 12 Months of Requested Approval

1. Commercial Grade Dedication Report
2. Commercial Grade Dedication Procedures
3. Final Design Description
4. Final FMEA
5. Final Logic Diagrams
6. Final Reliability Analysis
7. Final Report on Acceptance of Commercial Grade Dedication
8. Final System Configuration Documentation
9. Final Test Reports

10. Installation Test Plans and Procedures
11. Operations Manuals
12. Summary of Final Environmental Qualification Testing
13. Summary of Factory Acceptance Testing (FAT)
14. Installation Test Plans
15. System Test Procedures
16. Software Life Cycle Documentation
17. Software Life Cycle Documentation
    a. Software management Implementing Procedures
    b. Software Project Risk management Report
    c. Software Test Procedures
    d. Software Tool Analysis Report
18. V&V Reports

Documents to be Available for Audit

1. Completed FAT Procedure & Reports
2. Configuration Management Reports
3. Detailed System and Hardware Drawings
4. Final Circuit Schematics
5. Final Software Integration Report
6. Individual Completed Test Procedures & Reports
7. Individual V&V Problem Reports up to FAT
8. Software Code Listings
9. Vendor Build Documentation

Appendix B.3, "Documents for a Tier 3 Review"

<u>Documents Expected Upon Application</u>
1. Commercial Grade Dedication Plan
2. De analysis (Including system modifications and plant specific architecture and use)
3. System description
   a. Detail to address ISG-4
   b. Detail down to block diagram level
4. Design Analysis Report
5. Design Report on Computer Integrity, Test and Calibration, and Fault Detection
6. Theory of Operation Description
7. Equipment Qualification Testing Plans (Including EMI, Temperature, Humidity, and Seismic to the degree to which these are affected by the plant specific application)
8. Software QA Plan and Procedures
9. System Description
10. Hardware & Software Architecture Descriptions
11. Preliminary Failure Mode Effects Analysis (FMEA)
12. Quality Assurance Plan for Digital Hardware and Software
13. Preliminary Reliability Analysis
14. Safety Analysis
15. System Requirements
16. System Test Plan
17. Software Life Cycle Documentation
    a. Vendor Software CM Plan
    b. Software Design Specification
    c. Software Development Plan
    d. Software Installation Plan
    e. Software Integration Plan
    f. Software Management Plan
    g. Software Management Plan
    h. Software Project Risk Management Plan
    i. Platform Software Requirements Specification
    j. Application Software Requirements Specification
    k. Software Safety Plan
    l. Software Test Plan
    m. Software Tool Verification Program
    n. Software V&V Plan and Procedures
18. Requirements Traceability Matrix

<u>Documents Expected Within 12 Months of Requested Approval</u>

1. Commercial Grade Dedication Report
2. Commercial Grade Dedication Procedures
3. Final Configuration Lists
4. Final Configuration Tables
5. Final Design Description

Documents Expected Within 12 Months of Requested Approval (Continued)

6. Final FMEA
7. Final Logic Diagrams
8. Final Reliability Analysis
9. Final Report on Acceptance of Commercial Grade Dedication
10. Final System Configuration Documentation
11. Final Factory Acceptance test Reports
12. Installation Test Plans and Procedures
13. Qualification Test Procedures
14. Quality Assurance Procedures for Digital Hardware and Software
15. Summary of Final Environmental Qualification Testing
16. Summary of Factory Acceptance Testing (FAT)
17. System Test Procedures
18. Software Life Cycle Documentation
19. Software Life Cycle Documentation
    a. Software management Implementing Procedures
    b. Software Project Risk management Report
    c. Software Test Procedures
    d. Software Tool Analysis Report
20. V&V Reports

Documents to be Available for Audit

1. Completed FAT Procedure & Reports
2. Configuration Management Reports
3. Detailed System and Hardware Drawings
4. Final Circuit Schematics
5. Final Software Integration Report
6. Individual Completed Test Procedures & Reports
7. Individual V&V Problem Reports up to FAT
8. Software Code Listings
9. Vendor Build Documentation

Digital I&C Licensing Process Flow Chart

Phase 0

- Letter of Intent
- Public Meeting D3 + Other
- NRC Staff drafts meeting summary
- Licensee Opportunity to review meeting summary
- Ready to Submit?

Phase 1

- Application D3; ICC; V&V; Exceptions
- LIC-109: Acceptable for Review?
- Resolve IAW LIC-109
- Issue RAIs
- Phase 1 Questions Resolved?

Phase 2

- Preliminary OK Vehicle (Letter/ RAI/ETC...)
- Supplement EQ; HF; Change Control;; Startup Testing Plan
- Issue RAIs
- Phase 2 Questions Resolved?
- Conduct Audit
- Audit Open Items?
- Resolve Audit Items

Phase 3

- Issue SE
- Startup Testing
- Startup Testing Issues?
- Resolve Issues
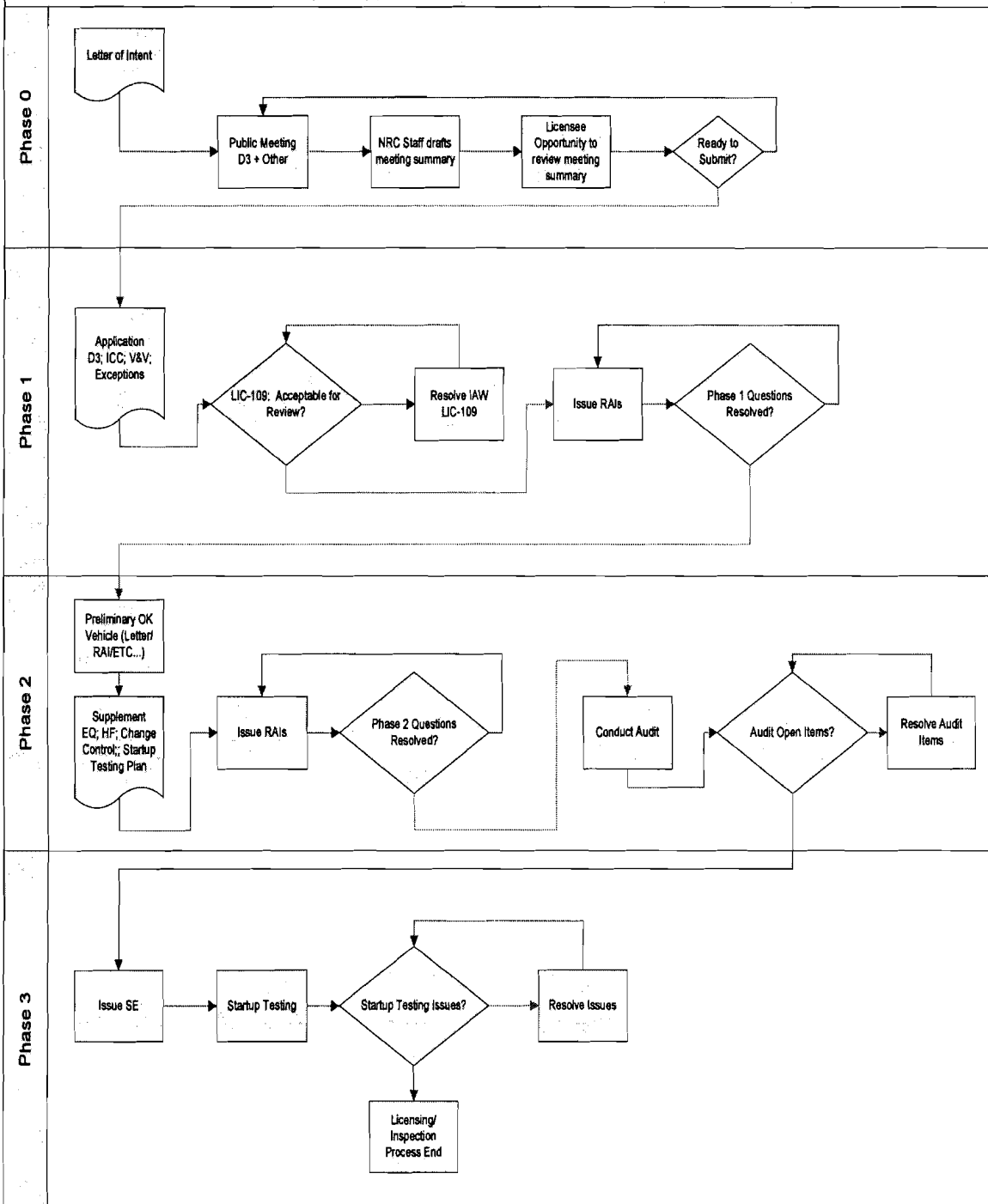- Licensing/ Inspection Process End

FIGURE 1, "Process Flow Chart"

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in a meeting or need a meeting notice, the transcript, or other information from a meeting in another format (e.g., Braille, large print) please notify the NRC's meeting contact. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Project No. 689

Enclosures:
1. Agenda
2. Draft licensing process and review section

cc w/encl: See next page
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RidsNrrDorlLpl2-2 Resource   RidsNrrDorlLpl3-1 Resource
RidsNrrDorlLpl3-2 Resource   RidsNrrDorlLpl4 Resource
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