

**Nuclear Utilities Software
Management Group**



**Guidance Document for
Digital Technology Systems
And Digital Data Management**

Guidance Document for Digital Technology Systems and Digital Data Management

**NEI/NUSMG 00-03
Revision 0**



Scope

- **Develop Guidance for DTS used to manage and operate a nuclear powered generating facility consistent with federal regulations and good business practice**
- **Ensure Guidance is consistent with the DTS or Digital Data's importance to the mission of the generation facility**

Objectives

- Analyze current NRC codes and standards
- Review current industry best practices for DTS, SQA, and Digital Data Management
- Provide a graded approach to DTS and Digital Data Management that ensures regulatory compliance

Objectives

Submit a guidance document, outlining DTS and Digital Data Management programmatic content, to the NRC for consideration as an acceptable method to meet regulatory and license requirements

NEI/NUSMG 00-03 Evolution

- Taskforce of NUSMG utility members, supported by NEI and NUSMG, develop NEI/NUSMG 00-03
- Panel of Independent Reviewers Provide Comments
- Present NEI/NUSMG 00-03 at NUSMG Fall Work Shop
 - Overview and Comments during Breakout Session
 - Individual Comments from Work Shop Attendees
- Present Draft to NRC for comment
- NEI send NEI/NUSMG 00-03 to APOC
- NUSMG SC invite comments from industry groups
- NUSMG Steering Committee Approves
- Submit to NRC requesting Endorsement

NEI/NUSMG 00-03 Contents

- **Definitions**
- **DTS and Digital Data Management Policy**
- **Quality Assurance of DTS and Digital Data**
 - QA Elements
 - DTS Quality Classification
 - Digital Data Quality Classification

Noteworthy Definitions

Digital Technology Systems (DTS)

The elements of software, firmware, computing hardware, operating systems and devices, and the operational computing environment required for the system to meet its intended design functions

Noteworthy Definitions

Digital Data

Information stored in a computer-based format and processed by a software product

Digital Data Management

The controls applied to assure that the quality and integrity of the creation, use, maintenance, and retirement of digital data is commensurate with its importance to nuclear safety

Noteworthy Definitions

Graded Approach

The selective assignment of quality assurance program requirements, used to identify essentials that the DTS must comply with, based on its assigned quality classification as determined by the risk-based evaluation of DTS use.

Policy

- **Senior Management establishes policy for quality assurance of DTS and Digital Data Management to ensure oversight and regulatory compliance**
 - **Defines scope and applicability of controls**
 - **Assigns authority and responsibility**
 - **Interfaces with plant QA program**
 - **Interfaces SQA program**

QA of DTS and Digital Data

- Quality Assurance Elements

- **Responsibility for Quality Assurance and Control**
- **Control of Software Design, Development, Modification and Testing**
- **Control of Digital Data**
- **Training and Qualification**
- **Procurement**
- **Procedures and Instructions**
- **Life Cycle Configuration Management**
- **Reviews or Inspections**
- **Documentation and Records**
- **Error Management**
- **Audits and Assessments**

Quality Assurance of DTS

- DTS Quality Classification

- **High Risk**

- **Direct Active Effect on the ability of a SR SSC to perform its intended safety functions**
- **DTS Classified as SR**
- **Software used for the design of SSC that assures the SSC meets its intended design basis safety function as defined in the nuclear license documents**

Utilities may further distribute classification levels using the graded approach within the levels defined by NEI/NUSMG 00-03.

Quality Assurance of DTS

- DTS Quality Classification

- **Medium Risk**

- **Assesses or validates SSC safety functions and associated risk**
- **Analyzes the performance of SSC to meet its intended safety function**
- **Determines the ability of SSC to meet its safety function**
- **Monitors operation and control functions of plant SSC**

Utilities may further distribute classification levels using the graded approach within the levels defined by NEI/NUSMG 00-03.

Quality Assurance of DTS

- DTS Quality Classification

- **Low Risk**
 - Supports activities that have no direct impact on nuclear operations, design or license commitments but may be used to monitor compliance
- **No Risk**
 - DTS not included in above classifications

Utilities may further distribute classification levels using the graded approach within the levels defined by NEI/NUSMG 00-03.

Quality Assurance of DTS -Digital Data Quality Classification

- **High Risk**
 - **Digital information subject to quality and configuration controls such that it may be used for critical decisions at a nuclear power plant, including plant operation, plant safety determination, and equipment operability decisions.**

Utilities may further distribute classification levels using the graded approach within the levels defined by NEI/NUSMG 00-03.

Quality Assurance of DTS

-Digital Data Quality Classification

- **Low Risk**

- **Digital information that is for reference or information only and that should be verified before use in plant operation, safety, or operability decisions.**

Utilities may further distribute classification levels using the graded approach within the levels defined by NEI/NUSMG 00-03.

SUMMARY

- **Industry Benefits**

- **Simplified compilation of Regulatory, Industry and Utility Best Practice Guidance**
- **Authoritative Guidance, endorsed by the NRC as an acceptable method to meet regulatory requirements**
 - **Concise requirements for control of DTS and Digital Data**
 - **Consistent Definitions and Program Content**
- **Requirements consistent with most existing utility programs**

SUMMARY

- **Benefits to Regulator**

- **Increased consistency of DTS and Digital Data Management Programmatic Content**
- **Application of PRA principles to the control and use of DTS and Digital Data**
- **Industry group develop, maintain, and support guidance document**

F I N A L D R A F T

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**NUCLEAR ENERGY INSTITUTE
NUCLEAR UTILITY SOFTWARE MANAGEMENT GROUP**

**GUIDANCE DOCUMENT FOR DIGITAL TECHNOLOGY SYSTEMS QUALITY ASSURANCE
PROGRAMS FOR NUCLEAR POWER GENERATION FACILITIES**

NEI/NUSMG 00-03

**REVISION 0
Final Draft
January 2, 2000**

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**GUIDANCE DOCUMENT FOR NUCLEAR DIGITAL TECHNOLOGY PROGRAMS AND DATA
MANAGEMENT FOR NUCLEAR POWER GENERATION FACILITIES**

Introduction

The Nuclear Energy Institute (NEI) and the Nuclear Utility Software Management Group (NUSMG) completed a review of industry documents and regulatory guidance for the purpose of consolidating, organizing and simplifying the information in a single nuclear industry guidance document for digital technology systems and data management. This guidance is recommended for use by member nuclear utilities in the development, implementation, maintenance and management of quality assurance programs that govern digital technology systems and data management associated with the safe, compliant operation of nuclear power generation.

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NUSMG STEERING COMMITTEE ACCEPTANCE

This document as approved for issue by the NUSMG Steering Committee on *Approval Date*.

At that time the SC members were :
Nicolleta Durand, Steering Committee Chairperson
Wayne Glidden, Steering Committee Member
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**GUIDANCE DOCUMENT FOR NUCLEAR DIGITAL TECHNOLOGY PROGRAMS AND DATA
MANAGEMENT FOR NUCLEAR POWER GENERATION FACILITIES**

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1.0 Purpose

This document provides guidance for the management of Digital Technology Systems (DTS) in support of the total nuclear quality assurance program. This document establishes minimum quality assurance program requirements for DTS and Digital Data Management.

2.0 Scope

- 2.1 Applies to digital technology systems used for nuclear generation facility operations or to comply with Nuclear Regulatory rules, regulations and license requirements.
- 2.2 Applies to digital data required to support the operation, maintenance, design and other quality-related activities at nuclear generation facilities.
- 2.3 Includes the Software Quality Assurance program (SQA) which is supplemental to existing nuclear utility 10CFR50 Appendix B Quality Assurance Program.
- 2.4 Management of electronic documents and records controlled in accordance with records management processes is excluded from NEI/NUSMG 00-03.

3.0 Definitions

3.1 Digital Data

Information stored in a computer-based format that is processed by a DTS.

3.2 Digital Data Management

The controls applied to ensure that decisions related to the safe operation of the nuclear facility are based on the creation, use, maintenance, and retirement of digital data that has a known pedigree, and assures that quality and integrity is commensurate with its importance to nuclear safety.

3.3 Digital Technology System (DTS)

DTS as used in this guideline is a general term that includes all or part of the elements of software, firmware, computing hardware, operating systems and devices required for the system to meet its intended design functions. A digital system includes the operational computing environment required for computer code to execute.

3.4 Graded Approach

The selective assignment of quality assurance program requirements, used to identify essentials that the DTS must comply with, based on its assigned quality classification as determined by the risk-based evaluation of DTS use.

3.5 Software Quality Assurance (SQA)

The program that establishes quality controls for the development, procurement, operation, use, maintenance, and retirement of software commensurate with its importance to nuclear safety.

3.6 Retirement

The permanent removal of a DTS product or digital data from its operational computing environment.

4.0 Digital Technology Systems and Data Management Policy

Senior Management should establish the policy for quality assurance of the DTS and Digital Data Management. The policy should define the:

- 4.1 Scope and applicability of the DTS quality controls.
- 4.2 Scope and applicability of Digital Data Management controls.
- 4.3 Authority and responsibility for quality assurance governing DTS and Digital Data Management.
- 4.4 DTS and Digital Data Management interfaces with the plant Quality Assurance Program and important operational activities, including those that directly support nuclear operations, maintenance and design.
- 4.5 DTS and Digital Data Management interfaces with the Software Quality Assurance Program to ensure oversight and regulatory compliance.

5.0 Quality Assurance (QA) of DTS and Digital Data

The quality assurance requirements governing DTS and Digital Data should be developed, documented, and implemented to address components of DTS such as software and plant computing systems, as well as control Digital Data. As a minimum, the quality assurance of DTS and Digital Data should define responsibilities, risk based quality level classification, software configuration management, planning, procurement, implementation, and life cycle administration for DTS and Digital Data.

5.1 QA Elements

The quality assurance governance should define quality criteria to be applied to DTS and Digital Data consistent with its importance to safety. Quality assurance criteria should define the requirements and controls for DTS and Digital Data based on the graded approach to quality. The quality assurance criteria should include:

5.1.1 Assign Responsibility for Quality Assurance and Control

- 1. Responsibilities should define accountably for key quality assurance elements necessary to control DTS and Digital Data.
- 2. Responsibilities should establish the authority to carry out DTS and Digital Data Management quality assurance requirements.
- 3. Responsibilities should establish designated ownership and accountability for DTS products and components.
- 4. Responsibilities should establish designated ownership and accountability for Digital Data.
- 5. Ownership should be documented and maintained.

5.1.2 Control of Software Design, Development, Modification and Testing

Procedures should be used to define the process for documenting the planning, design, development, modification and testing of software. The process will

define the design controls and documents such as requirement specification, detailed design, and verification and validation test consistent with the quality classification defined in section 5.2.

5.1.3 Control of Digital Data

Controls are applied to Digital Data consistent with the quality classification defined in section 5.3. Controls may include verification of Digital Data and/or validation of Digital Data.

1. Verification is an activity carried out by the Digital Data owner to demonstrate the accuracy and validity of Digital Data. It establishes the pedigree for the creation, use, maintenance, and retirement of digital data and assures that the quality and integrity is commensurate with its importance to nuclear safety. Techniques include but are not limited to field walk-down, independent verification, and engineering study.
2. Validation is an activity carried out by an Information Technology organization that assures quality controls are applied to changes of the computing environment where digital data is processed. This includes digital data migration, upgrade of DTS that processes digital data, or moving digital data from one database product to another. Techniques used to validate digital data include, but are not limited to statistical sampling.

5.1.4 Training and Qualification

1. Define and document indoctrination and training on the quality assurance requirements that govern DTS and Digital Data Management.
2. Define and document indoctrination and training requirements for safety related DTS products and components.

5.1.5 Procurement

1. DTS procurement documents should specify the quality requirements necessary to assure that the vendor meets the requirements of section 5.1.2 as required by the DTS quality classification.
2. Digital Data procurement documents should specify the quality requirements.
3. Measures should be defined to assure that the DTS meets both quality and procurement specification requirements before the system is placed in operation.

5.1.6 Procedures and Instructions

Procedures governing DTS should be reviewed, approved and controlled.

5.1.7 Life Cycle Configuration Management

Controls should be applied to DTS and Digital Data from the time the specifications are approved until the system is retired according to its quality classification. These controls are to insure that only tested and approved High Risk DTS and High Risk Digital Data are used for nuclear safety activities.

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5.1.8 Reviews or Inspections

1. Controls should be established to assure reviews, testing and inspection of DTS and documentation are completed prior to use according to the DTS classification. This assures that the DTS quality and integrity is commensurate with its importance to nuclear safety.
2. Controls should be established to assure reviews, testing and inspection of Digital Data and documentation are completed prior to use according to the Digital Data classification. This establishes that the Digital Data has a known pedigree, and assures that quality and integrity is commensurate with its importance to nuclear safety.

5.1.9 Documentation and Records

1. Documentation sufficient to prove the quality of the DTS and Digital Data should be maintained in accordance with the records management program.
2. Documentation sufficient to prove the quality of changes to DTS and/or Digital Data should be maintained in accordance with the records management program.

5.1.10 Provisions for Error Management

1. A corrective action program should be used to manage DTS and Digital Data errors and subsequent resolution.
2. Errors should be communicated to users based on DTS and Digital Data quality classification.

5.1.11 Audits and Assessments

Self-assessments and audits of the quality assurance programs governing DTS and Digital Data should be performed and documented.

5.2 DTS Quality Classification

Risk based methods for evaluating digital technology systems important to nuclear safety should be established. A graded approach defines quality classifications determined by the risk-based evaluation of digital technology systems use. Quality assurance elements are applied in a graded manner based upon the quality classification levels. Quality classification levels may be further distributed using the graded approach within those levels suggested below:

5.2.1 High-Risk Digital Technology Systems:

- Direct active effect on the ability of a Safety-Related structure, system or component (SSC) to perform its intended safety functions;
- Digital Technology Systems that are classified as Safety-Related;
- Software used for the design of SSC that assures the SSC meets its intended design basis safety function as defined in the nuclear license documents.

5.2.2 Medium Risk Digital Technology Systems:

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- DTS that assess or validate SSC safety functions and associated risk, or are used to analyze the performance of SSC to meet its intended safety function.
- DTS used to determine the ability of an SSC to meet its safety function or used to monitor operation and control functions of plant SSC.

5.2.3 Low Risk Digital Technology Systems:

DTS used to support activities that have no direct impact on nuclear operations, design or license commitments but may be used to monitor compliance.

5.2.4 No Risk Digital Technology Systems:

DTS not included in the above classifications.

5.3 Digital Data Quality Classification

Risk based methods for evaluating Digital Data important to nuclear safety should be established. A graded approach defines quality classifications determined by the risk-based evaluation of Digital Data use. Quality assurance elements are applied in a graded manner based upon the quality classification levels. Quality classification levels may be further distributed using the graded approach within those levels suggested below:

5.3.1 High Risk Digital Data

Digital information subject to quality and configuration controls such that it may be used for critical decisions at a nuclear power plant, including plant operation, plant safety determination, and equipment operability decisions.

5.3.2 Low Risk Digital Data

Digital information that is for reference or information only and that should be verified before use in plant operation, safety, or operability decisions.

6.0 Reference

- 6.1** 10CFR50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants