Software Quality Assurance Documentation and Records

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NUCLEAR INFORMATION AND RECORDS MANAGEMENT ASSOCIATION
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FOREWORD

[This foreword is not a part of the Nuclear Information and Records Management Association Guideline for Software Quality Assurance Documentation and Records, TG16-2017.]

This guideline document was originally developed under the auspices of the Nuclear Information and Records Management Association (NIRMA) Information Management Business Unit and is now under the control of the Regulations and Information Management Business Unit (RIMBU). This guideline document is intended for use by the membership of NIRMA to assist the Information and Records Manager to adequately address the Software Quality Assurance (SQA) documentation and records requirements associated with the design, development/acquisition, deployment, and management of systems. This guideline covers software used for both QA and non-QA electronic information, and provides recommendations for determining retention periods of the source documents.

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1.0 SCOPE

1.1 Purpose

The primary objective of this technical guideline is to address documentation and records requirements related to Software Quality Assurance (SQA), including source documents that furnish documentary evidence of a software application's quality and configuration control from inception to the end of its life cycle.

It is recommended the specific needs related to the support of this Technical Guideline be included in the SQA Program with guidance provided by American Society of Mechanical Engineers (ASME) document ASME NQA-1-2015, Part III, Section 3.1-17.2, Implementing Guidance for Part I, Requirement 17: Quality Assurance Records, Electronic Records, as applicable.

Consideration should also be made in referencing guidance provided by Nuclear Information Technology Strategic Leadership (NITSL) documents NITSL-SQA-2005-01, Policy for Software Quality Assurance in the Nuclear Power Industry and NITSL-SQA-2005-02, Guidance Document to Implement Policy for Software Quality Assurance in the Nuclear Power Industry.

This document provides guidance for identifying records to be created and retained for each phase of the software life cycle. Software applications that create and/or manage both QA and non-QA records as defined by American National Standards Institute (ANSI) N45.2.9 and American Society of Mechanical Engineers (ASME) NQA-1 are included.

Key supporting objectives include:

- Identifying critical areas of responsibility for the Information and Records Manager (IRM) within each phase of the software life cycle (SLC)
- Establishing a core set of requirements for documentation and records applicable to SQA Programs
- Identifying application-related documentation that provides evidence that appropriate quality measures have been applied to SLC activities

This technical guideline addresses all levels of software. It is further intended to address aspects of an organization's SQA Program, as the view taken is a total program approach.

1.2 Scope

This technical guideline is focused on computer systems and software applications used to execute and/or support daily or routine facility and business functions designated as either quality-related (Q) or non-quality-related (non-Q). By extension:

- The applications themselves typically are considered Q or non-Q, and

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- The electronic records generated and managed within these systems are considered Q or non-Q.

This document also focuses on the business functions of records management that must be considered when generating and storing information/data transactions that are classified as records. This includes assurance that controls required for the administration and management of the electronic records are identified for the application. In addition, guidance for the IRM's management of the documented evidence of the adequacy of the system/application to meet its functional requirements is addressed.

Although this guidance document refers to elements of an SQA Program considered essential for a nuclear operating facility, it is not intended to provide specific direction or guidance on how an organization's SQA Program is developed or managed.

Applicable guidance materials are included in Section 8, References.

2.0 DEFINITIONS

Terminology in this document is consistent with ISO/IEC/IEEE 24765-2017, Systems and Software Engineering - vocabulary, with the following exceptions.

2.1 Development

The set of activities associated with the scoping, definition, design, code generation, testing and compilation of source code to produce executable code.

2.2 Software

Includes computer programs, procedures, operating systems, applications, firmware, rules, documentation and data.

2.3 Software Life Cycle (SLC)

The phases of a given software application or system from initial concept through development, operation, maintenance and retirement. Phases may be sequential or iterative.

2.4 Software Development Lifecycle (SDLC)

Those phases of the SLC that focus on the initial conception, requirements, design, build, test, and release to production (operations). SDLC methodologies include waterfall, validation and verification, and agile.

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2.5 Configuration Management

The discipline applied to the identification, management, and change control of software configuration items, including source code, integrated modules, and executable code, as well as the documentation that identifies and describes the application or system.

2.6 Software Quality Assurance Plan (SQAP)

A documented systematic approach to all actions necessary to provide adequate confidence that the subject application or system conforms to identified requirements and can be maintained throughout its SLC.

2.7 Quality Audit Reports

Documentation of audit activities and results from function audits, physical audits, or in-process audits mandated by the SQAP.

2.8 Software Configuration Management Plan (SCMP)

A documented plan consisting of procedural controls and documentation requirements to be applied to:

- The establishment of applicable software change management items
- Changes made to the application code or any interfacing software
- Status accounting of changes

The SCMP and configuration management activities are initiated during the development cycle and transitioned to an appropriate functional organization after application/system acceptance.

3.0 RESPONSIBILITIES

This section identifies typical roles and responsibilities associated with SQA and Software Configuration Management (SCM) Programs.

For each role, various types of documentation are identified as pertinent to the overall SLC. The IRM should be well-informed regarding the purpose, content, and nature of the evidentiary information each type represents. Through this knowledge foundation, a records retention schedule can be developed for each element of the overall SQA Program.

3.1 SQA Manager

The SQA Manager is responsible for development, maintenance, and documentation requirements of the SQA Program. Types of documentation generated and/or managed within this role include:

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