Idaho National Engineering and Environmental Laboratory

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Achieving WIPP Certification for Software

A White Paper

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Achieving WIPP Certification for Software

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Achieving WIPP Certification For Software

EXECUTIVE SUMMARY

The NMT-1 and NMT-3 organizations within the Chemical and Metallurgical Research (CMR) facility at the Los Alamos National Laboratory (LANL) are working to achieve Waste Isolation Pilot Plant (WIPP) certification to enable them to transport their TRU waste to WIPP. The regulatory drivers are DOE Order 5700.6C, 10 CFR Part 830.120, 40 CFR Part 194, and CAO-94-1012, Revision 1. Some flexibility exists for a "graded approach" based upon the risk and intended use of the waste characterization and analytical results; all the quality assuring activities are risk based to mitigate the risks that could occur if the computational results are incorrect or incorrectly used. If the application is strictly used for chemical characterizations and analyses, then a graded approach is reasonable. However, if the software is used for characterization and analysis of radiological waste, then more stringent requirements are invoked by 40 CFR Part 194 and ASME NQA-2a-1990. If the application is hybrid, i.e., used for both chemical and radiological characterizations and analyses, then the more stringent risk mitigating quality assuring activities are required. As a minimum, the software used for waste characterization and analysis within the NMT-1 and NMT-3 organizations must have:

- a documented inventory to identify the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software;
- software classification system that documents the criteria for classification in the inventory and shall address the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, operations activities, and its importance to safety or significance in managing information or augmenting mission-essential decisions;
- an umbrella software quality assurance plan;
- documented configuration identification, documented configuration change control, and documented configuration status accounting;
- documented and independently reviewed requirements that document the intended function of the software;
- documented test cases and independently verified and documented test results that assure that the software performs its intended function within the stated environment and that the software does not perform any unintended functions;
- verification and validation documentation that describe the activities, including the results of reviews and tests, and the criteria for accomplishing the verification of the software throughout the software evolution and the hardware and software configuration pertinent to the software verification and validation;
- user documentation that contains sufficient guidance for any qualified user to install, execute, and properly respond to errors.

The development and existence of other documents, such as a software design description, will depend upon whether the software was procured or developed by NMT-1 and/or NMT-3. If the software was procured then the documented test cases must assume the form of an user acceptance test to verify the functional capability and the acceptability of the supplier supporting documentation. If the software was developed by NMT-1 and/or NMT-3, then the design and testing must be documented per the requirements.

If any of the requisite documents do not exist, then the software quality assurance will have to be retrofitted to be compliant with WIPP requirements.

1.0 BACKGROUND AND PURPOSE

The NMT-1 and NMT-3 organizations within the Chemical and Metallurgical Research (CMR) facility at the Los Alamos National Laboratory (LANL) is working to achieve Waste Isolation Pilot Plant (WIPP) certification to enable them to transport their TRU waste to WIPP. WIPP certification requires compliance with DOE Order 5700.6C[1], 10 CFR Part 830.120[2], 40 CFR Part 194[3], and CAO-94-1012, Revision 1[4], the Quality Assurance Program Document (QAPD) for WIPP. The documents 10 CFR Part 830.120 and DOE Order 5700.6C specify the requirements for quality assurance within the U.S. Department of Energy, while 40 CFR Part 194 and CAO-94-1012 specifically target the quality requirements for WIPP. The regulatory driver for CAO-94-1012 is 40 CFR Part 194[5], which invokes ASME NQA-1-1989, "Quality Assurance Requirements for Nuclear Facility Applications," and ASME NQA-2a-1990 addenda, Part 2.7, "Quality Assurance Requirements for Nuclear Facility Applications," for radiological activities. Figure 1 on the following page diagrams the relationships between these documents.

In particular, the NMT-1 management is requesting support from the Idaho National Engineering and Environmental Laboratory (INEEL) to assist them in making the Laboratory Information Management System (LIMS) software WIPP certifiable. Thus, LIMS must be compliant with the recognized software quality assurance (SQA) requirements stated within the QAPD. Since the Idaho National Engineering and Environmental Laboratory (INEEL) has achieved WIPP certification, INEEL personnel can provide valuable assistance to LANL by sharing lessons learned and recommendations. Thus, this white paper delineates the particular software quality assurance requirements required for WIPP certification.

2.0 SCOPE

This white paper addresses only the software quality assurance requirements necessary for software used by the NMT-1 and NMT-3 organizations to be WIPP certified. WIPP certified software comprises the software systems used for TRU waste characterization and analyses. Please note that all document references to CMR are referring to the NMT-1 and NMT-3 organizations.

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[1] DOE Order 5700.6C - "Quality Assurance Requirements"
[2] 10 CFR Part 830.120 - "Quality Assurance Requirements"
[3] 40 CFR Part 194 - Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations
[4] "Quality Assurance Program Document," CAO-94-1012, Revision 1, April, 1996, U.S. Department of Energy Carslbad Area Office
[5] op. cit. 3

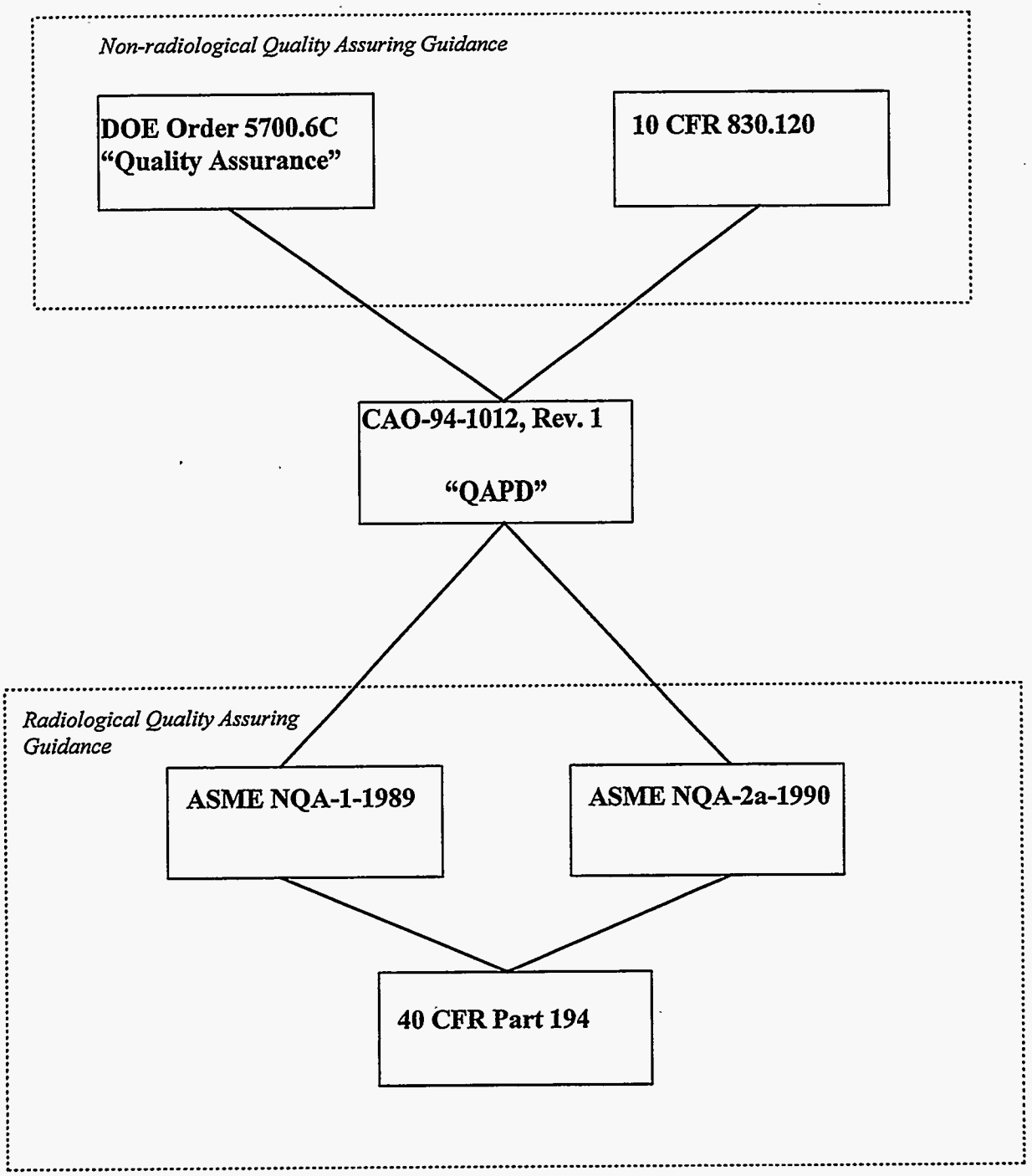

Figure 1 - Document Hierarchy for WIPP Certification Requirements

3.0 WIPP CERTIFICATION REQUIREMENTS

3.1 Applicable Software for the WIPP Certification Requirements

Section 6.2, Paragraph A, of the QAPD states that:

"The requirements in this section apply to computer software that manipulates or produces data that are, in turn, used to process, gather or generate information and whose output is relied upon to make design, analytical, operational, or compliance-related decisions with respect to the performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes. The application of these requirements shall be prescribed in written plan(s), policies, procedures or instructions."

3.2 Software Exempt from the WIPP Certification Requirements

Section 6.2, Paragraph B, of the QAPD exempts software:

"that are considered to be 'systems software,' (e.g., operating systems, administrative and management systems, system utilities, compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheets, database managers, and graphing programs) or other software that do not generate data that are used in the formulation of conclusions." However, specific applications written for use within these types of software, e.g., detailed formulas or macros, that can be verified by hand calculations or other means shall meet the following requirements of the QAPD:

1. A listing of the version of the software used, and
2. Documentation that the specific application provides correct results for the specified range of input parameters."

3.3 General Requirements

WIPP Certification is achievable only by compliance with the QAPD. However, some compliance flexibility exists, which will be addressed in Section 3.3.1. All software, whether exempt or not, must be inventoried and classified based upon its functionality. The QAPD also mandates software quality assurance plan(s) for non-exempt software, user documentation, and verification and validation documentation.

The inventory must identify the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software. The software classification system must include the documented classification criteria, " the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, [and] operations activities, and its importance to safety or significance in managing information or augmenting mission-essential decisions."[6]

[6] Section 6.2.2, op. cit. 4

The software quality assurance plan(s)[7] can either be generic, i.e., programmatic, or targeted for each software project. In either case, the plan must identify[8]: "(A) the software products to which it applies; (B) the types of documentation to be prepared, reviewed, and maintained during the software design, development, implementation, test, and use; (C) the organizations responsible for performing the work and achieving software quality and their tasks and responsibilities; (D) the process for reporting and documenting software discrepancies, evaluating the impact of discrepancies on previous calculations, and determining the appropriate corrective action(s); (E) the standards, conventions, techniques, or methodologies that guide the software development, as well as the methods used to assure implementation of requirements; and (F) the procedure(s) used for establishing and maintaining the integrity of data, embodied mathematical models, and output files."

Paragraph 6.8.6 of the QAPD states that the "User documentation should be sufficient to allow any qualified user (i.e., one having adequate technical background) to 'set up' and run the software and properly respond to errors. User documentation, as a minimum, shall include: (1) the software name and version identifier; (2) statement(s) of functional requirements and system limitations, including hardware; (3) an explanation of the mathematical model(s) and derivation of the numerical methods used in the software design. Physical and mathematical assumptions on which the software is based shall be included along with an explanation of the capabilities and limitations inherent in the software; and (4) user instructions that describe user interaction with the software, user messages initiated as a result of improper input; and how the user can respond, the identification and description of input and output specifications and formats, and input parameters."

Lastly, the QAPD requires software verification and validation documentation to "consist of associated plans and describe the activities, including the results of reviews and tests, and the criteria for accomplishing the verification of the software throughout the software evolution. The documentation shall also specify the hardware and software configuration pertinent to the software verification and validation. Software verification and validation documentation shall be organized in a manner that allows traceability from the software requirements to both the software design and to the validated capabilities of the software."[9]

3.3.1 Graded Approach

If any waste characterizations and analyses are chemical in nature, e.g., headspace gas analysis, or mass spectroscopy, then a graded approach for software quality is *a propos.* This is appropriate since ASME NQA-2a-1990, Part 2.7 is specifically targeted for the quality assuring "requirements for the development, procurement, maintenance, and use of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities." [10] All the quality assuring activities are risk based to mitigate the risks that could occur if the computational results are incorrect or incorrectly used. Thus, the software performing waste characterizations and analyses for chemical wastes can be compliant with "the intent" of ASME NQA-2a-1990 without strictly abiding by the "letter of the law" because there is less risk associated with the use of the chemical analysis results than from the radiological results. Thus, a graded approach should be based upon the:

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[7] IEEE Std. 730—1989, "Standard for Quality Assurance Plans"
[8] Section 6.2.3, op. cit. 4
[9] Section 6.8.4 op. cit. 4
[10] ASME NQA-2a-1990, addenda, Part 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications"

- "level of risk;
- age, status, and condition of a facility or process;
- history of problems at a site or facility;
- adequacy of existing safety documentation; and
- complexity of products or services involved."[11]

This graded approach permits the software quality requirements to be compliant with 10 CFR 830.120[12] and DOE Order 5700.6C[13], thereby permitting greater flexibility for software applications not used for radiological characterizations and analyses. However, these requirements do mandate that:

- "Management should determine that personnel are suitably qualified to accomplish their assigned tasks. Personnel may be qualified by: considering previous experience, education, and training; demonstrating and testing to verify previously acquired skills; or completing a training or qualification program."[14]

- "For records that require electronic processing and control, the hardware and software required to maintain and access the records should be maintained and controlled to ensure that the records remain usable."[15]

- "Computer software used to originate or verify design solutions during the design process should be validated or the status of code validation should be identified and documented prior to use."[16]

- "Inspection/test methods should be established that define the requirements for activities that verify conformance of systems, structures, or components with specified requirements. Results of these activities should be documented and retained as project records. Inspection/test activities should be performed by persons other than those who performed or directly supervised the work being examined."[17]

- "The prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements."[18]

A distillation of the above requirements means that configuration management and verification and validation of any analytical results are required and that all configuration management and verification and validation activities are thoroughly documented and retained to maintain an "audit trail." Thus, all configuration items used to provide waste characterization and/or analytical results including spreadsheet "macros" or spreadsheet formulae must conform to a documented configuration management process and must have documented configuration control. Any application that is used for both chemical and radiological analyses must assume the higher risk mitigation quality assuring methods.

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[11] "Implementation Guide for use with 10 CFR Part 830.120 Quality Assurance," G-830.120-Rev. 0, April 15, 1994
[12] op. cit. 2
[13] op. cit. 1
[14] Paragraph 2.3, op. cit. 11
[15] Paragraph 4.3, op cit. 11
[16] Paragraph 6.3, op cit. 11
[17] Paragraph 8.2, op cit. 11
[18] Paragraph 7.3, op cit. 11

3.3.2 WIPP Certification Requirements for Radiological Software

If the TRU waste characterizations and analyses are radiological, i.e., using non-destructive assay methods, then the more stringent ASME NQA-2a-1990 is invoked by 40 CFR Part 194. The Carlsbad Operations Office documented the software requirements in Section 6, "Software Requirements," of the "Quality Assurance Program Document"[19]. For the development, procurement, maintenance, or use of computer software the provisions of Sections 6.1 and 6.2 are invoked without exception.

Development of a traceability matrix for each subsection of Section 6 of the QAPD will enhance the assurance that all elements of the QAPD Software Requirements have been addressed. (See Appendix A). Creation of a Software Verification and Validation Plan (SVVP)[20] to programmatically address all CMR software used for waste characterizations and analyses also is required by ASME NQA-2a-1990. Lastly, the software quality assurance activities defined within ASME NQA-2a-1990 give special attention to software configuration control, including configuration identification, configuration change control, and configuration status accounting. Other important software quality assuring activities are based upon whether the software configuration items were (1) procured; (2) developed under another QA program; or (3) developed within or under the auspices of the organization for the specific purpose of performing waste characterizations or analyses, i.e., "home-grown." Each of these scenarios are discussed in the following three subsections.

3.3.2.1 Software Procurement. The procuring organization must ensure that all procured items and services meet established technical and QA requirements and that they perform as specified. Prospective suppliers must be evaluated and selected on the basis of documented criteria. The responsible organization verifies that approved suppliers continue to provide acceptable items and services. The preparation and/or revision of procurement specifications will include documenting the following, as a minimum:

- preparer;
- independent technical reviewer(s);
- quality representative reviewer(s), and
- approval signatures.

Section 6.3 of the QAPD also states:

- "Once the software has been installed, but prior to its use, the sponsoring organization shall perform user acceptance to verify the functional capability of the software and the acceptability of the supplier supporting documentation (e.g., the user manual, technical specification, and the results of supplier testing).

- "For procured software, the supplier shall report software errors and failures to the sponsoring organization." The sponsoring organization shall also report software errors to the supplier."

[19] op. cit. 4
[20] IEEE Std. 1012-1986, "Standard for Software Verification and Validation Plans"

Strict adherence to Section 6.3 of the QAPD and documentation of the procured software requirements, verification and validation activities and configuration management activities will support WIPP Certification of any procured software. Use of a tailored IEEE Std. 828-1990[21] and software specific documented and approved test procedures using approved test-case specifications[22] to ensure that the procured software will perform satisfactorily in its operating environment are necessary for WIPP software certification.

3.3.2.2 Software Developed Under Other QA Programs. Section 6.4 of the QAPD mandates that:

> "Software that has not been developed or approved in accordance with this QAPD shall be evaluated using the criteria of this section. The software shall be uniquely identified and controlled prior to the evaluation, accepted by the sponsoring organization, and placed under configuration control prior to use. This evaluation shall serve as the basis to:
>
> A. Determine the adequacy of existing verification and validation activities, and software documentation to support operation and maintenance; and
> B. Identify the activities to be performed and the documentation necessary to accept the software for its intended use and place it under configuration control. The evaluation shall be documented and contain as a minimum:
>
> 1. user application requirements;
> 2. test plans and test cases required to validate the software acceptability; and
> 3. user documentation per Section 6.8.6."[23]

From the above requirements, it can again be seen that configuration management and documented verification and validation activities to determine the software's adequacy to perform its intended functions are critical for WIPP Certification.

3.3.2.3 Software Development & Life Cycle. Software developed by, or at the behest of CMR, must have a defined life-cycle, configuration baselines, documented and reviewed requirements[24], a documented and reviewed design[25], and documented test cases[26]. The QAPD states that:

- "Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces (e.g., hardware limitations). . . . Each requirement shall be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements shall be traceable throughout the software development cycle, and a verification and validation plan shall be prepared at the conclusion of documenting and approving software requirements."[27]

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[21] IEEE Std. 828-1990, "Standard for Software Configuration Management Plans"
[22] IEEE Std. 829-1983, "Standard for Software Test Documentation"
[23] Paragraph 6.4, op. cit. 4
[24] IEEE Std. 830-1984, "Guide for Software Requirements Specification"
[25] IEEE Std. 1016-1987, "Recommended Practice for Software Design Descriptions"
[26] op. cit. 22
[27] Paragraph 6.5.1, op. cit. 4

- "The software design shall be based on the software requirements, and shall be documented and reviewed. The design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation and the verification and validation plans."[28]

- "Test requirements and acceptance criteria shall be specified, documented, and reviewed and shall be based upon applicable design or other pertinent technical bases. Appropriate tests, such as verification test, hardware integration tests, and in-use test, shall be controlled. Software testing, using documented test plans, test cases, and test results, is the primary method of software validation."[29]

- "Testing of software shall be performed to the extent that unintended functions are identified, reviewed, and their impact determined and corrected. If appropriate, determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required."[30]

- "Installation and checkout of the software shall consist of the: (1) execution of tests for installation and integration; (2) documented acceptance of the software for operational use; and (3) the placement of the software under configuration control prior to use."[31]

- "Completion of the installation and checkout activities establishes the software baseline."[32]

Creation of a software requirements specification (SRS), software design description (SDD), and verification test cases based upon the software requirements are necessary and critical for WIPP Certification. Even if the SRS, SDD, and test cases have to be "reverse-engineered," i.e., created using the existing software product as the baseline guide, they are imperative documents to achieve WIPP Certification for CMR waste characterization and analysis software.

The remaining linchpin for WIPP Certification is the establishment and use of configuration management, including a Software Change Control Board.

4.0 SUMMARY

There are eight key ingredients necessary for WIPP Certification for software:

- an inventory of all software;
- a classification for all the inventoried software based upon the software's functionality;
- a tailored software quality assurance plan[33];
- configuration management and control of the software baseline;
- documented requirements for the intended function of the software;

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[28] Paragraph 6.5.2, op. cit. 4
[29] Section 6.5.4, Paragraph A, op. cit. 4
[30] Section 6.5.4, Paragraph B, op. cit. 4
[31] Section 6.5.5, Paragraph A, op cit. 4
[32] Section 6.5.5, Paragraph B, op. cit. 4
[33] IEEE Std. 730-1989, "Standard for Software Quality Assurance Plans"

- documented test cases and independently verified and documented results that assure that the software performs its intended function within the stated environment and that the software does not perform any unintended functions;
- software verification and validation documentation that allows traceability from the software requirements to the validated capabilities of the software; and
- user documentation that permits any qualified user to install, execute and properly respond to errors.

All the quality assuring activities are risk based to mitigate the potential of incorrect results or the incorrect use of the results. If any characterization or analysis software, or set of spreadsheet formulae, i.e., "macros," is used to provide results for chemical and radiological applications, then the application must employ the higher risk mitigating techniques mandated by CAO-94-1012, ASME NQA-1-1989, and ASME NQA-2a-1990. If any quality assuring elements do not currently exist for a software application, i.e., configuration item, then the application must be "retrofitted" with the necessary software quality assuring activities and documents, e.g., requirements, design, and/or verification and validation test cases.

5.0 REFERENCES

ASME NQA-1-1989, "Quality Assuring Activities for Nuclear Facility Applications," The American Society of Mechanical Engineers.

ASME NQA-2a-1990, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," The American Society of Mechanical Engineers.

CAO-94-1012, Revision 1, April 1996, "Quality Assurance Program Document," U.S. Department of Energy Carlsbad Area Office.

IEEE 730-1989, "Standard for Software Quality Assurance Plans," Institute of Electrical and Electronics Engineers.

IEEE 828-1990, "Standard for Software Configuration Management Plans," Institute of Electrical and Electronics Engineers.

IEEE 829-1983, "Standard for Software Test Documentation," Institute of Electrical and Electronics Engineers.

IEEE 830-1993, "Recommended Practice for Software Requirements Specifications," Institute of Electrical and Electronics Engineers.

IEEE 1012-1986, "Standard for Software Verification and Validation Plans," Institute of Electrical and Electronics Engineers.

IEEE 1016.1-1993, "Guide to Software Design Descriptions," Institute of Electrical and Electronics Engineers.

Implementation Guide for use with 10 CFR Part 830.120, Quality Assurance, G-830.120-Rev. 0, U.S. Department of Energy, April 15, 1994.

10 CFR 830.120, April 1994, "Quality Assurance Requirements," *Code of Federal Regulations*, Office of the Federal Register.

40 CFR 194, February 9, 1996, "Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations," *Code of Federal Regulations*, Office of the Federal Register.

APPENDIX A

QAPD TRACEABILITY MATRIX

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
6.1	GENERAL	This section of the QAPD establishes Software Quality Assurance (SQA) requirements for CAO participants that develop, procure, maintain, or use computer software that is important to compliance application and waste characterization.	
6.2A	APPLICABILITY	The requirements in this section apply to computer software that manipulates or produces data that are, in turn, used to process, gather, or generate information and whose output is relied upon to make design, analytical, operational, or compliance-related decisions with respect to the performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes. The application of these requirements shall be prescribed in written plan(s), policies, procedures or instructions.	Software Quality Program Plan (SQPP)
6.2B		Exempt from the requirements of this section of the QAPD are software that are considered to be "systems software," (e.g., operating systems, administrative and management systems, system utilities, compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheets, database managers, and graphing programs) or other software that do not generate data that are used in the formulation of conclusions. However, specific applications supporting 6.2A above, written for use within these types of software (e.g., detailed formulas or macros), that can be verified by hand calculations or other means shall meet the following requirements of this section: 1. A listing of the version of the software	SQPP & Software Configuration Management Plan (SCMP)

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
		used, and 2. Documentation that the specific application provides correct results for the specified range of input parameters.	
6.2.1	Inventory of Software	An inventory of all software shall be maintained to identify the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software.	SQMP
6.2.2	Classification of Software	Software that is not exempt from the provisions of the QAPD shall be classified. The criteria for classification shall be documented in the inventory and shall address the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, operations activities, and its importance to safety or significance in managing information or augmenting mission-essential decisions.	SQMP
6.2.3	Software Quality Assurance	Plan(s) for ensuring software quality shall be prepared for each new software project at the start of the software life cycle. For procured software the software quality plan shall be prepared prior to when the software enters the purchaser's organization. Plan(s) may be prepared individually for each software project, or may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall quality assurance program. The plan shall identify:	SQAP & SCMP
6.2.3A		the software products to which it applies;	SQAP & SCMP
6.2.3B		the types of documentation to be prepared, reviewed, and maintained during the software design, development, implementation, test, and use;	SQAP & SCMP
6.2.3C		the organizations responsible for	SQAP & SCMP

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
		performing the work and achieving software quality and their tasks and responsibilities;	
6.2.3D		the process for reporting and documenting software discrepancies, evaluating the impact of discrepancies on previous calculations, and determining the appropriate correction action(s);	SQAP & SCMP
6.2.3E		the standards, conventions, techniques, or methodologies that guide the software development, as well as the methods used to assure implementation of requirements; and	SQAP & SCMP
6.2.3F		the procedure(s) used for establishing and maintaining the integrity of data, embodied mathematical models, and output files.	SQAP & SCMP
6.3A	SOFTWARE PROCUREMENT	The procurement of software and related services shall be performed in accordance with Section 2.3 of this QAPD. This section of the QAPD identifies responsibilities of the sponsoring organization for procured software upon receipt of the software.	SQAP & procurement procedures
6.3B		Once the software has been installed, but prior to its use, the sponsoring organization shall perform user acceptance to verify the functional capability of the software and the acceptability of the supplier supporting documentation (e.g., the user manual, technical specification, and the results of supplier testing).	SQAP & procurement procedures
6.3C		For procured software, the supplier shall report software errors and failures to the sponsoring organization. The sponsoring organization shall also report software errors to the supplier.	SQAP & procurement procedures
6.4	SOFTWARE DEVELOPED UNDER OTHER	Software that has not been developed or approved in accordance with this QAPD shall be evaluated using the criteria of this	SQAP

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
	QA PROGRAMS	section. The software shall be uniquely identified and controlled prior to the evaluation, accepted by the sponsoring organization, and placed under configuration control prior it use. This evaluation shall serve as the basis to:	
6.4A		Determine the adequacy of existing verification and validation activities, and software documentation to support operation and maintenance; and	SQAP & Software Verification and Validation Plan (SVVP)
6.4B		Identify the activities to be performed and the documentation necessary to accept the software for its intended use and place it under configuration control. The evaluation shall be documented and contain as a minimum: 1. user application requirements; 2. test plans and test cases required to validate the software acceptability; and 3. user documentation per Section 6.8.6.	SQAP & SCMP
6.5A	SOFTWARE DEVELOPMENT & LIFE CYCLE	The activities associated with the evolution of the software shall use an iterative or sequential approach. The approach shall address the analysis of the problem under study, the transformation of the analysis into the design, the implementation of the design into validated computer software, and the development of sufficient documentation to demonstrate that the specified requirements have been successfully implemented in the computer software.	SQAP
6.5B		The iterative or sequential approach to software development consists of phases, with each phase leading to the development of a specific work product representing components of the software baseline. The software phases are: 1. definition of requirements; 2. design; 3. implementation; 4. testing;	SQAP

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
		5. installation and checkout; 6. operations and maintenance; and 7. retirement.	
6.5C		Following the development of the Software Quality Plan, no strict sequence of performing activities is required (i.e., activities may be performed sequentially or recursively) provided that all the specified requirements for each software development phase are met and the intent of the requirements are not subverted.	SQAP
6.5.1	Requirements	Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces (e.g., hardware limitations) as outlined in Section 6.8.2. Each requirement shall be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements shall be traceable throughout the software development cycle, and a verification and validation plan shall be prepared at the conclusion of documenting and approving software requirements.	SQAP
6.5.2	Design	The software design shall be based on the software requirements, and shall be documented and reviewed. The design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation and the verification and validation plans.	SQAP
6.5.3	Implementation	The software design shall be translated into a form (e.g., programming language) suitable for processing by a computer. The executable software shall be analyzed to identify and correct errors.	SQAP

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
6.5.4A	Testing	Test requirements and acceptance criteria shall be specified, documented, and reviewed and shall be based upon applicable design or other pertinent technical bases. Appropriate tests, such as verification tests, hardware integration tests, and in-use tests, shall be controlled. Software testing, using documented test plans, test cases, and test results, is the primary method of software validation.	SQAP & SVVP
6.5.4B		Testing of software shall be performed to the extent that unintended functions are identified, reviewed, and their impact determined and corrected. If appropriate, determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.	SQAP & SVVP
6.5.4.1	Verification Tests	Verification tests are design-driven and shall be used to demonstrate the capability of the software to produce valid results for test problems encompassing the range of intended use as defined by the software documentation. Testing of software used for operational control shall demonstrate the required performance over the entire range of the controlled function or process. Acceptable test problem methods consist of:	SQAP & SVVP
6.5.4.1A		hand calculations;	SQAP & SVVP
6.5.4.1B		calculations using comparable proven problems;	SQAP & SVVP
6.5.4.1C		empirical data and information from confirmed published data and correlations or technical literature;	SQAP & SVVP
6.5.4.1D		comparison with other validated software of similar purpose; and	SQAP & SVVP
6.5.4.1E		manual inspections or qualitative checks, not involving numerical manipulation	SQAP & SVVP

SECTION OF QAPD	TITLE	REQUIREMENT	CMR DOCUMENT TYPES
		such as visual inspection of table reformatting (or plotting).	
6.5.4.2	Validation Tests	Validation tests are requirements-driven and shall be used to validate software by comparing test results of software execution with objective evidence obtained by other acceptable means. The results of this evaluation shall be of sufficient scope and depth to prove the capabilities and limitations delineated in the software documentation.	SQAP & SVVP
6.5.5A	Installation and Checkout	During installation and checkout, the software becomes part of a system consisting of applicable software components, hardware, and data. The process of integrating the software with other applicable components may consist of installing both the hardware and software, initializing or creating databases, and verifying that all components of the system have been included in the installation. Test problems shall be developed and documented to permit confirmation of the acceptable performance of the software in its operating environment. Installation and checkout of software shall consist of the: 1. execution of tests for installation and integration; 2. documented acceptance of the software for operational use; and 3. the placement of the software under configuration control prior to use.	SQAP & SVVP
6.5.5.B through 6.9.C		.....	
6.10	ACCESS CONTROL	To the extent appropriate, controls shall be established to permit authorized and prevent unauthorized access to software that has been accepted in accordance with this section of the QAPD.	SQAP & SCMP