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1.0 PURPOSE AND SCOPE

(7.1.1, 7.1.2)

This procedure establishes the process, methods and instruction for dedication of commercial grade computer programs (software) that affect performance of a Structure System and Component (SSC) safety function or provide controls necessary for adequate protection from nuclear facility or radiological hazards. This procedure is part of a larger process to implement Software Work Activities (SWA) as required by the Quality Assurance Program Description (QAPD) TFC-PLN-02 and as directed by the appropriate SWA procedure identified in TFC-BSM-IRM_HS-C-01.

Dedication of commercial grade computer programs for use in safety applications is performed under limited circumstances. To be dedicated, the computer program proposed is required to be classified and graded for its intended use as Safety Software (grades A, B, or C) and support an identified safety or hazard control function. Software classification and grade are based on SWA documentation provided within the applicable Software Management Plan (SMP) registered on Hanford Information Systems Inventory (HISI) for the specific application. The same computer program may have more than one SMP and more than one HISI registration where multiple uses apply (i.e., one use as Grade B Safety Software and another use as Grade D quality affecting, non-safety software, as determined by TFC-PLN-112).

1.1 Definition Applications

Definitions are important to the understanding of this procedure and are included in Section 5.0. Some definitions are capitalized on first use as an aid to the reader.

One of the concepts of a commercial grade dedication is a determination of whether the item meets the applicable definition of a Commercial Grade Item. Computer programs that may affect safety significant SSC performance or provide protective control(s) from nuclear facility or radiological hazards are evaluated to determine if the Commercial Grade Item (CGI) definition applies prior to use of the dedication process.

1.2 Utilization

This procedure applies only to software meeting both the CGI and “Otherwise Acquired” definitions. Otherwise Acquired software, in contrast to “Acquired” software developed under a program consistent with the QAPD, is obtained as a CGI, without benefit of having been developed under an NQA-1 qualified program (Figure 1). Otherwise Acquired software includes freeware, shareware, and packaged commercial software.

CGI Dedication of software that is installed or embedded in physical plant safety systems, and CGI Dedication of software related services are not a part of this procedure scope, and may be dedicated using procedure TFC-ENG-DESIGN-C-15 (Figure 1).

To utilize a commercial grade computer program as Safety Software, controls are required to provide reasonable assurance that the computer program will support an SSC’s intended Safety Function, or will perform a hazard control function necessary to provide adequate protection from nuclear facility or radiological hazards. Application of this approach to computer programs that control the management or administrative support of safety-related activities (e.g., radiation dose rate or plume migration modeling) may be considered for dedication. These controls include the following:

- Determination that the computer program may affect an SSC safety function as a Basic Component defined by NQA-1 and the QAPD, or
- Determination that the computer program performs design or analysis affecting an SSC safety function or provides protective control(s) from nuclear facility or radiological hazards, as defined by DOE O 414.1D for Safety and Hazard Analysis and Design (SHAD) and Safety Management and Administrative Control (SMAC) software
- Confirmation that the computer program meets the applicable CGI definition
- Identification and documentation of the software Critical Characteristics, including acceptance criteria
- Selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.

Computer programs that successfully complete the dedication process are subsequently subject to the controls of the applicable WRPS Software Management Programs and Procedures (Figure 1), primarily implemented through the software specific HISI registration and SMP controls.

This procedure provides dedication activities and documentation necessary to accept the software in specific Safety Software applications. The resulting documentation and associated software establish a baseline as qualified Safety Software, similar to that of a Basic Component. The dedication process for hardware and embedded software is established through the QAPD in accordance with NQA-1a-2009, Part II, Subpart 2.14, as implemented by TFC-ENG-DESIGN-C-15. Otherwise Acquired software meets the intent of Subpart 2.14 through this procedure in part by meeting the criteria within NQA-1-2008, Part II, Subpart 2.7, Section 302 (a), (b), and (c), which state:

- a) Identification of the capabilities and limitations for intended use as critical characteristics.*

The “identification of the capabilities and limitations for intended use” are addressed during the selection of a set of performance requirements. The SWAs include development of a Failure Modes and Effects Analyses (FMEA) or equivalent analyses within the SMP to identify software capabilities and limitations for a bounded use, identify its safety function(s), failure modes and controls, and are used to establish software application specific functional requirements with acceptance criteria. The FMEA within the SMP along with related SMP software lifecycle plans, contain information applicable to establishing critical characteristics (CCs) through a technical evaluation process for dedication, which include CCs for required functionality capabilities. These and a generic set of software CCs located at the IRM webpage (see sample table in Attachment A) are reviewed and selected for entry onto the Commercial Grade Dedication (CGD) form A-6002-544 located on the Hanford Site Forms webpage.

- b) Utilization of test plans and cases as the method of acceptance to demonstrate the capabilities within the limitations.*

Test plans and cases required to demonstrate those capabilities within the limitations specified by the SMP are exercised through special software test cases and surveys. A Requirements Traceability Matrix (RTM) within the SMP relates selected test cases to key functional requirements considered in the FMEA. The SMP also contains an Acceptance Test Plan (ATP) to

identify range and domain limits and to verify functionality capabilities. ATP test cases are selected from those RTM functional requirements to verify and document capabilities by comparison of test case results with alternate calculations or other means consistent with Method 1 of the CGD process. The technical evaluation considers the ATP report results along with the verification results of CCs from the CGD form to reach conclusion(s) and provide a recommendation.

c) Instructions for use (e.g., a User's Manual) within the limits of the dedicated capabilities.

Selection of the physical or performance critical characteristics include appropriate references to User's Manual, On-line help, or other methods to assist the User in the proper operation of the software within the limits of the dedication. The SMP identifies specific Limitations of Use items, some of which may originate from User's Manual discussion, examples and provided test cases, along with critical error reports and problem tracking/reporting descriptions, and is incorporated into SMP instruction to Users to safely perform software applications.

The adequacy and extent of the controls in place addressing (a), (b), and (c) above are verified, evaluated, and documented during the CGD review. The software is dedicated when the CGD package is completed, including Technical Evaluation and FMEA documentation, and approved in accordance with this procedure. A software HISI entry is made to indicate the software CGD dedication status and provide a link to the completed CGD package for records management purposes.

When the results derived from the use of the computer program are independently verified for every use, the computer program is not required to be dedicated. Independent verification may include use of alternate competitor software to verify the correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program, its associated computer hardware and system software, or other calculation method used also is reviewed. This process is controlled in accordance with TFC-ENG-DESIGN-C-10. Verification for every use is not a surrogate for commercial grade dedication of the computer program.

2.0 IMPLEMENTATION

This procedure is effective on the date shown in the header.

3.0 RESPONSIBILITIES

3.1 Engineering Manager

- Identify the resources needed to perform the dedication plan activities.
- Provide sufficient resources for the dedication plan activities.
- Designate the Discipline Engineer.
- Approve dedication plan documentation.

3.2 Software Owner

- Participate on CGD eligibility determination activities (FMEA review).
- Ensure the dedication plan tasks and documentation is complete and properly authorized.
- Manage the dedicated software through its lifecycle in conjunction with the applicable configuration change control procedure.
- Act as the representative for the dedicating entity.

3.3 Designated Discipline Engineer (aka “Project Lead” within the SMP)

- Lead the dedication eligibility determination and FMEA review.
- Perform the technical evaluation.
- Identify critical characteristics and acceptance criteria.
- Identify the method(s) for dedicating the software.
- Assist the Procurement Engineer and STSA during dedication plan development.
- Maintain communication with the vendor regarding software changes, updates, end-of-life notices, etc.
- Enforce warranty issues made with the vendor during plan implementation.
- Review dedication plan documentation for technical accuracy and completeness.
- Perform installation, validation, and verification activities prior to dedication.

3.4 Procurement Engineer

- Plan the dedication package activities.
- Perform applicable commercial grade surveys per TFC-ESHQ_Q-ADM-C-13.
- Approve the method(s) for dedicating the software.
- Work with the Discipline Engineer to qualify critical characteristics for acceptance.
- Prepare the dedication plan/ package.
- Ensure the dedication activities are performed as planned.
- Identify dedication package problems and weaknesses on the PER system.

3.5 Quality Assurance Engineer

- Review software CGD documents.
- Perform commercial grade surveys in support of the dedication.
- Support acceptance methods as defined.
- Ensure that the dedication plan and implementation adheres to the QAPD and implementing procedures.

3.6 Software Technical Support Analyst (STSA)

- Assist development of the dedication plan and package.
- Act as Subject Matter Expert for initiation and completion of HISI registration for the software undergoing dedication.
- Support representation of the software undergoing dedication at the Software Review Board (SRB).

4.0 PROCEDURE

4.1 Software Work Activities CGD Planning

NOTE: If an FMEA has not been performed (typically contained within the SMP), FMEA performance is required prior to continuing with Section 4.1, step 1.

Designated
Discipline Engineer

1. Assemble an FMEA Review team. Team membership shall include as a minimum the Discipline Engineer as team lead, a SME on use of the software, a Procurement Engineer, and a Nuclear Safety

Representative.

2. Perform a FMEA team review to determine if the proposed software will be used as Safety Software and is appropriate for dedication under this procedure as a Commercial Grade Item.
3. Provide a FMEA report, table and conclusions. If the determination indicates software CGD is not appropriate, exit this procedure and consult with Software Owner or STSA on an alternative to software dedication.

NOTE: CGD packages may be developed for a specific software application, or a range of applications. Dedication requirements are included in the applicable procurement and technical documents as needed to support the dedication.

Procurement
Engineer

4. Initiate a CGD package (CGD form A-6002-544) based on the FMEA Review conclusion to proceed with software CGD.

5. Attach the FMEA report including a table and conclusions.

Designated
Discipline Engineer

6. Initiate a technical evaluation based on a FMEA conclusion to proceed with software CGD.

4.2 Technical Evaluation

Designated
Discipline Engineer

1. Perform the technical evaluation as a report, in accordance with TFC-ENG-DESIGN-C-25.

NOTE: Verify the software is currently in a configuration management process (HISI registration) before evaluating software adequacy for use, to ensure traceability of the software evaluation and testing activities.

2. Address the following considerations, as applicable, during the technical evaluation development:
 - Identify if the computer program can impact a safety-related SSC or impacts a hazard control function necessary to provide adequate protection from nuclear facility or radiological hazards
 - Conformance with the definition for commercial grade item
 - The mathematical model(s)
 - The identification of the capabilities and limitations for intended use
 - Establish the class of problems for which the program is intended to be used
 - Confirm whether the computer program's solution methods are

appropriate based on state-of-the-art knowledge

- Determine whether testing for intended use is complete or if additional testing is needed to ensure adequate validation
- The acceptance criteria to be used in evaluating the range and validity of program responses
- Basis for selection of test cases to be used
- The computer hardware and operating system in which the program will be utilized
- User interface requirements expected to take place in the use of the computer program.

NOTE 1: The following documentation may not be available from the supplier. In those instances, review software User's Manual and other sources for requirements and design information.

NOTE 2: If the supplier documentation cannot be adequately supplemented and the unavailable information is essential to determining reasonable assurance, exit this procedure and consult with Software Owner or STSA on an alternative to software dedication.

3. Review available supplier documentation. Supplier documentation supporting the technical evaluation include:
 - Statement of problem
 - Requirements specification
 - Design specification
 - Source code
 - Test plan and test results
 - Configuration control.

NOTE: The completed technical evaluation is submitted for attachment to the dedication package. SmartPlant Foundation (SPF) automatically generates and attaches a particular Release Form (editable in Microsoft Word) to each document being prepared. TFC-ENG-DESIGN-C-25, Table 1, specifies the particular release method for each document type that is issued in SPF.

4. Issue the technical evaluation report in accordance with TFC-ENG-DESIGN-C-25.

4.3 Determine Software Critical Characteristics for Acceptance

NOTE: The following CGD form is prepared in accordance with specific software instructions for TFC-ENG-DESIGN-C-65 software use. The form and instructions are located on the Hanford Site Forms webpage.

Procurement

1. Perform a CGI dedication within the dedication package using the

Engineer

standard form initiated by Step 4.1.4. (CGD form A-6002-544).

2. Organize critical characteristics associated with the software into the following categories:
 - Identification
 - Physical
 - Performance/Functional
 - Dependability.
3. Identify the software version, build date, release name, or part or catalog number to be a critical characteristic if it provides a method for linking the software with the manufacturer's product description, user's manual, published data, product specification, or procurement documentation.
4. Identify performance/functional characteristics as including the required functionality of the software to perform its safety function and the accuracy of its results.
5. Identify applicable dependability characteristics as those critical characteristics inherent to the built-in quality processes of the computer program.
6. Evaluate critical characteristics selection from all categories (Identification, Physical, Performance/Functional, and Dependability).
7. Apply inclusion from each category when applicable.

NOTE: An updated table of generic Critical Characteristics is maintained at the IRM and the Procurement Engineering webpages.

8. Evaluate, in addition to the technical evaluation input, the table of generic critical characteristics (example shown in Table 1, Table of Tables) when considering critical characteristics for design/acceptance.

NOTE: The FMEA table, the technical evaluation, the SMP, and the Manufacturer's test documentation typically provide important information necessary to define the critical characteristics for design, consistent with the computer program's application requirements.

9. Evaluate specific critical characteristics to be considered, including those identified through a review of the manufacturer's published software documentation or other technical information documents.
10. Finalize selection of critical characteristics, and document in the List of Critical Characteristics in Section 2 of the CGD form (A-6002-544) in accordance with software specific form instructions located with the form.

11. Finalize and document those critical characteristics selected for acceptance in Section 3 of the CGD form (A-6002-544) in accordance with software specific form instructions located with the form.

4.4 Determine Acceptance Criteria and Methods

NOTE: Additional guidance for determining methods and acceptance criteria is provided in Attachments A and B.

Procurement
Engineer

1. Determine and document the acceptance criteria, tolerances and supporting documentation, where applicable, for each of the critical characteristics for acceptance listed in Section 3 of the CGD form (A-6002-544).
 - a. Determine and document the method(s) of acceptance that will be used to verify the critical characteristics for acceptance.
 - b. Determine and document the applicable testing procedure(s) to be used if testing is selected as a verification method.
 - c. Reference or attach the existing or newly prepared test procedure.

4.5 Obtain Initial Reviews and Approval to Proceed with Verification

Signatures of responsible positions below denote that the signer has reviewed all relative and pertinent information for their areas of responsibility, including assurance that the information provided is both complete and accurate. See the software specific instructions located with CGD form (A-6002-544) for detail regarding signature blanks.

Software Owner or
Designee

1. Complete and review the dedication package for completeness and technical adequacy.
2. Sign appropriate blank on cover page of CGD form (A-6002-544).

Quality Assurance
Engineer

3. Review and approve the dedication form for adequate quality assurance (QA) requirements, and sign appropriate blank on cover page of the CGD form (A-6002-544).

Procurement
Engineering Lead or
Designee

4. Review and approve the dedication form for Commercial Grade Dedication Program compliance and sign appropriate blank on cover page of the CGD form (A-6002-544).

Responsible Manager

5. Review and approve the dedication form for technical adequacy, and sign Section 5 of the CGD form (A-6002-544).

Software Owner or
Designee

6. Submit initial reviewed and approved dedication package to Records & Document Control for processing in accordance with TFC-ENG-DESIGN-C-25.

4.6 Verify Critical Characteristics

Software Owner or Designee	<ol style="list-style-type: none">1. Distribute the dedication package to the responsible implementing organization(s) and or positions for verification of critical characteristics and processing as identified in step 2.<ul style="list-style-type: none">• Dedication package consists of the CGD form plus supporting documentation. Supporting documentation shall include the section 3 CGD form signatures verifying that the software accepted: (1) is free from shipping damage, (2) has satisfied the specified criteria for the identified critical characteristics for acceptance, and (3) the specified documentation was received and is acceptable.• Implementing organizations and/or positions shall include QA engineer, procurement engineering lead, and designated discipline engineer's manager, or their designees.
Procurement Engineer	<ol style="list-style-type: none">2. Perform the following implementation activities in accordance with this procedure and acceptance verification instructions provided in Section 3 of the CGD form:<ol style="list-style-type: none">a. Complete the commercial grade dedication activities and documentation form in accordance with the instructions and any test procedures provided.b. If one or more critical characteristics for acceptance cannot be verified by dedication methods, do not use this procedure to procure or accept the commercial software; instead use TFC-ESHQ-Q_C-C-01 to process CGI software as a problem request.
Software Owner or Designee	<ol style="list-style-type: none">3. Identify software within HISI that has been satisfactorily dedicated to ensure traceability back to the dedication package.

4.7 Obtain Final Reviews and Approval

Software Owner or Designee	<ol style="list-style-type: none">1. Review and approve completed dedication package for completeness and technical adequacy, and sign the cover sheet of CGD form (A-6002-544), ensuring the package contains the following:<ul style="list-style-type: none">• Documentation of the commercial grade software dedication process is traceable to its associated safety function(s) or safety hazard control function(s), including the dedication plans or procedures with essential elements of the dedication process.• Related procurement documents.• A technical evaluation of the associated safety function(s).
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- Critical characteristics for acceptance identification referencing an FMEA.
- Test reports and results.
- Applicable commercial grade survey reports, acceptance test/inspection reports, analysis reports, source verification reports and historical performance information.
- Commercial grade dedication forms containing sufficient data to accept the software.

- | | | |
|--|----|--|
| Quality Assurance Engineer | 2. | Review and approve the dedication package and CGD form for adequate QA requirements completion, and sign the cover sheet of CGD form (A-6002-544). |
| Procurement Engineering Lead or Designee | 3. | Review and approve the dedication form for Commercial Dedication Program compliance and sign the cover sheet of the CGD form (A-6002-544). |
| Responsible Manager | 4. | Review and approve the CGD package for technical adequacy, and sign the cover sheet of the CGD form (A-6002-544). |
| Software Owner or Designee | 5. | Submit completed and approved dedication package to Records & Document Control for processing in accordance with TFC-ENG-DESIGN-C-25. |

4.8 Cancelling CGD Packages

There may be instances where an initially approved CGD package is no longer required or has become obsolete. In these cases, the CGD package shall be cancelled.

- | | | |
|----------------------------|----|--|
| Software Owner or Designee | 1. | Process the CGD package cancellations as a revision to the CGD package, noting the reason for the cancellation in the Reason for Revision heading block. |
| | 2. | Identify all CGD package cancellation revisions by a numerical designator (e.g., Rev. 1, 2, 3, etc.). |

4.9 Commercial Grade Dedication Package Changes

NOTE: All revisions shall be numerical (e.g., Rev. 1, 2, 3, etc.).

- | | | |
|----------------------------|----|--|
| Software Owner or Designee | 1. | Process technical and/or safety related changes to initially approved and completed dedication packages in the same manner as the original dedication package in accordance with Sections 4.1 through 4.8 of this procedure. |
| | | <ul style="list-style-type: none"> • A revision may be required to bring the CGD form into full compliance with this procedure (e.g., TBD info for advance procurements, changes in the critical characteristics of |

acceptance, alternate means of verification identified, additional/revised vendor data, etc.).

- Changes to existing non-technical and/or safety related data shall be lined out, initialed and dated, and revised data added.
 - The applicable Section 4.5, Required Initial Approvals actions and Section 4.7, Final Approvals actions shall be documented in the “Additional Information” section of the CGD form (A-6002-544) along with a description of the revision changes and their basis.
2. Process technical and/or safety related changes as a revision to the CGD form (A-6002-544), noting the reason for the change in the Reason for Revision block.

5.0 DEFINITIONS

The following definitions are provided to ensure a uniform understanding of unique terms as they are used herein. Definitions below originate from the QAPD, or have their origin identified. Those stating “For purposes of this procedure” originate here for this procedure.

Acquired Software. For purposes of this procedure, Safety Software acquired in accordance with Part II Subpart 2.7 paragraph 301 of the NQA-1 Standard, for use within its intended safety application.

Basic Component. A structure, system, component, or part thereof that affects its safety function that was designed and manufactured in accordance with the requirements of the NQA-1 Standard, or commercial grade items which have successfully completed the dedication process.

Commercial Grade Item. A structure, system, or component, or part thereof, that affects its safety function that was not designed and manufactured in accordance with the requirements of the NQA-1 Standard.

Commercial Grade Service. A service that was not provided in accordance with the requirements of the NQA-1 Standard that affects the safety function of a basic component. Note: Commercial grade dedication of software services is addressed under TFC-ENG-DESIGN-C-15.

Critical Characteristics. Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

Dedication. An acceptance process performed in accordance with the NQA-1 Standard requirements to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of the NQA-1 Standard. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold-points at the manufacturer’s

facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of this document.

Embedded Software. Items (e.g., components) containing software that are procured, delivered, and installed as an integral part of that item, with software code that cannot be modified by the end user and is tested as part of the hardware (typically referred to as embedded software or firmware), are excluded from the scope of this procedure.

Otherwise Acquired Software. For purposes of this procedure, freeware, shareware or commercial off-the-shelf (COTS) software not procured from a qualified vendor in accordance with the QAPD. Normally contains proprietary or inaccessible code, but may be eligible to be dedicated for use as Safety Software (see Part II Subpart 2.7 paragraph 302 of the NQA-1 Standard).

Safety and Hazard Analysis and Design (SHAD) Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function, as defined by DOE O 414.1D and the QAPD.

Safety Function. The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear material processing. A function that is necessary to prevent or mitigate a release of radioactive material in an accident scenario.

Safety Management and Administrative Controls (SMAC) Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment, as defined by DOE O 414.1D and the QAPD.

Safety Software. Safety System (SS) software, safety and hazard analysis and design (SHAD) software, and safety management and administrative controls (SMAC) software, as defined by DOE O 414.1D and the QAPD.

Safety System (SS) Software. Software for a nuclear facility that performs a safety function as part of a SSC and is cited in either a DOE approved Documented Safety Analysis (DSA) or an approved Hazard Analysis, as defined by DOE O 414.1D and the QAPD.

6.0 RECORDS

The following records are generated during the performance of the procedure:

- Commercial Grade Dedication Package including the CGD Form (A-6002-544) and all applicable attachments.

The record custodian identified in the Company Level Records Inventory and Disposition Schedule (RIDS) is responsible for record retention in accordance with [TFC-BSM-IRM_DC-C-02](#).

7.0 SOURCES

7.1 Requirements

1. ASME NQA-1 2008 and 2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications."
2. TFC-PLN-02, "Quality Assurance Program Description."

7.2 References

1. ANSI/ANS 10.4, "Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry," American Nuclear Society (ANS), 555 North Kensington Avenue, LaGrange Park, IL 60526 (www.ans.org).
2. ANSI/IEEE Std. 7-4.3.2-2010, "IEEE Standard Criteria for Digital Computers and Safety Systems of Nuclear Power Generating Stations."
3. ANSI/IEEE Std. 730-2002, "IEEE Standard for Software Quality Assurance Plans."
4. ANSI/IEEE Std. 1012-2004, "IEEE Standard for Software Verification and Validation," Institute of Electrical and Electronics Engineers, Inc. (IEEE), 445 Hoes Lane, Piscataway, NJ, 08854 (www.ieee.org).
5. EPRI Technical Report 106439, "Guidance on Evaluations and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications."
6. EPRI Technical Report 107330, "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants."
7. EPRI Technical Report 1025243, "Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications," Electric Power Research Institute (EPRI), 3420 Hillview Avenue, Palo Alto, CA 94304 (www.epri.com).
8. ISO 9001: 2008, Quality Management Systems – Requirements Publisher: International Organization for Standardization (ISO), Central Secretariat, 1, ch. De la Voie-Creuse, Case postale 56, CH-1211 Geneve 20, Switzerland/Suisse (www.iso.org).
9. SEI CMMI, CMMI-DEV Version 1.3, November 2010, "CMMI for Development," Carnegie Mellon University Software Engineering Institute, 4500 Fifth Avenue, Pittsburgh, PA 15213-2612 (www.sei.cmu.edu).
10. TFC-BSM-IRM_DC-C-02, "Records Management."
11. TFC-BSM-IRM_HS-C-01, "Software Development, Implementation, and Management."
12. TFC-BSM-IRM_HS-C-03, "Software Management."
13. TFC-ENG-DESIGN-C-15, "Commercial Grade Dedication."

14. TFC-ENG-DESIGN-C-25, "Technical Document Control."
15. TFC-ENG-DESIGN-C-32, "Spreadsheet Development and Verification."
16. TFC-ENG-DESIGN-P-12, "Plant Installed Software."
17. TFC-ESHQ-Q_C-C-01, "Problem Evaluation Request."
18. TFC-PLN-112, "Graded Approach to Quality."

Figure 1. Software Commercial Grade Dedication Requirements Flowchart.

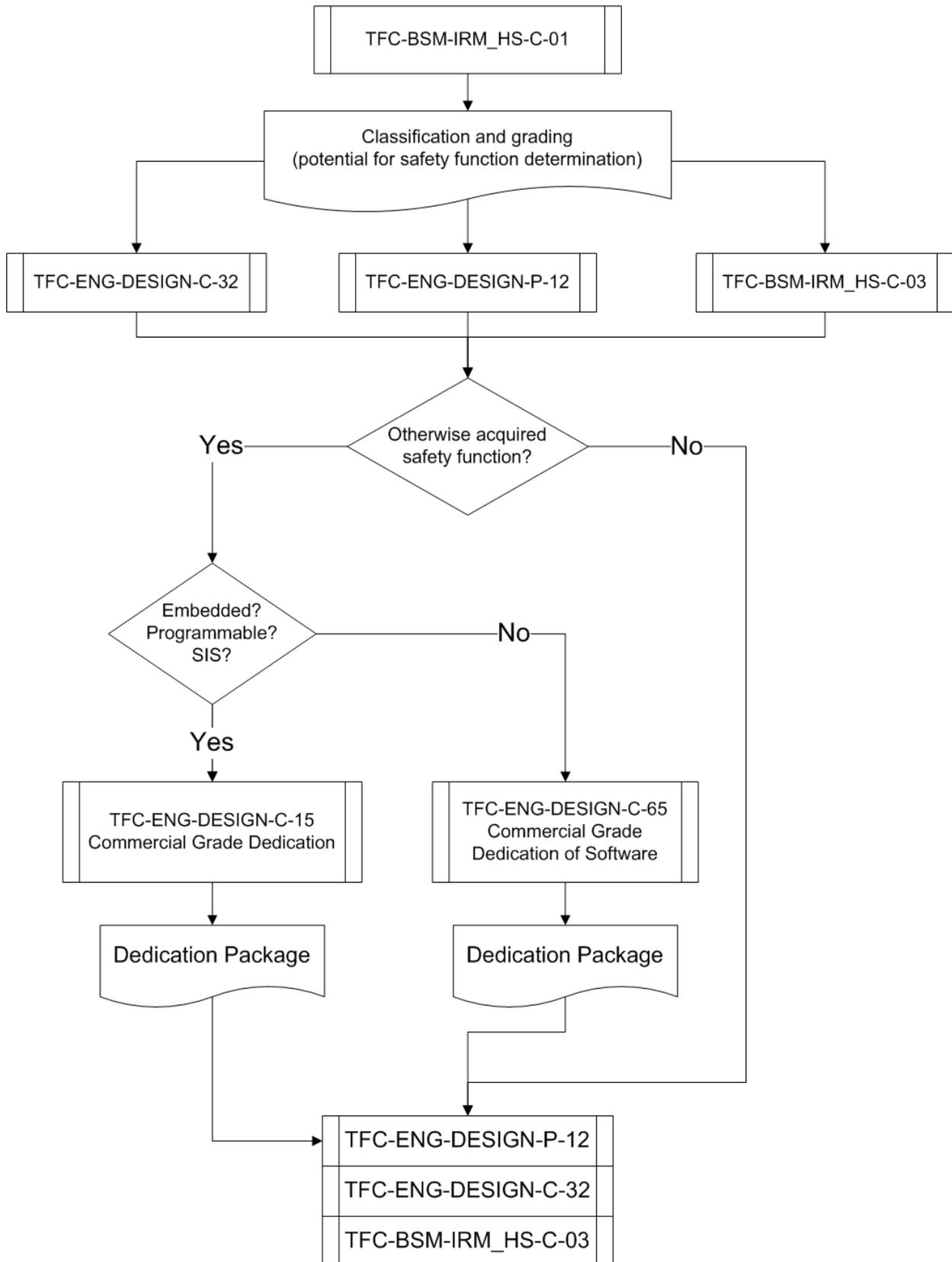


Table 1. Typical Critical Characteristics to Consider for Computer Programs

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
Identification Critical Characteristics	I-1	Host computer operating environment identifiers	The manufacturer, model number, operating system version, service packs, or patch identifiers of the host computer where the computer program is intended to be executed.	The host computer environment identifiers must match the purchase specification.	Verified through one or more of the following: a) Inspection of receipt inspection documentation (Method 1) b) Inspection of operating system identifiers (Method 1)
	I-2	Computer program name and version identifier	The full name of the computer program and version identifier, including all patches. It should be the same identifier as used for the procurement/acquisition process.	Computer program name and version identifier must match the product identifier from the supplier catalog or procurement documents. The version identifier can be the build date of the executable. The computer program version identifier includes the computer program name, major functional version, minor functional version, and correct revision.	Verified through one or more of the following: a) Inspection of receipt inspection documentation (Method 1) b) Inspection of operating system identifiers (Method 1)
	I-3	Support tool name(s) and identifier(s)	The complete name, including version identifier of all support tools that are used during the commercial grade dedication process to assist in performing special tests or other support tools used in the operating environment. These tools, such as database management systems, could impact the correct operation of the safety functions performed by the computer program during special tests or operations.	The support tool name and identifier must match the product identifier from the supplier catalog or specification.	Verified through one or more of the following: a) Inspection of the receipt inspection documentation (Method 1) b) Inspection of operating system identifiers (Method 1)

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
Physical Critical Characteristic	P-1	Life cycle documentation	The documentation that is produced during all phases of the software life cycle. Documentation is evidence of the activities being performed. Documentation from multiple life cycle phases may combined into one or more physical documents.	Life cycle documentation includes separate or combined documents that include software requirements specification, requirements traceability matrix, design documentation, architecture views, design description document, interface documentation, test plans, test reports, and user documentation.	Verified through the inspection of life cycle documents (Method 1)
	P-2	Media	The physical object or distribution media received from the supplier that contains the computer program. This critical characteristic is applicable to all computer programs. Receipt media criteria are expressed as the method in which the computer program is distributed to the dedicating entity (e.g., CD, embedded, or downloadable).	Agreement with published catalogs or as specified in procurement documents.	Verified through the inspection of the received computer program (Method 1).
Performance/Functional Critical Characteristic	F-1	Accuracy/Precision/Tolerance Outputs	For accuracy, the degree to which there is a close correlation with the expected or desired outcome. For precision, the degree of repeatability or degree of measure. For tolerance, the allowable possible error in measurement.	As described in computer program requirements or supplier specification documentation. Criteria may be: accuracy +/- 1%; precision +/- 0.0001; tolerance +/- 0.00001.	Verified through a combination of one or more of the following: a) Observation and review of design (Method 3) b) Inspection and testing (Method 1) c) Review of the installed base to determine performance history (Method 4)
	F-2	Environmental compatibility: portability	The measure of the effort required to migrate the computer program to a different hardware platform, component, or environment. This critical characteristic may only be	As described in computer program requirements or supplier specification documentation. Portability criteria can be expressed as a unit of time (e.g., 16-hours or 15-days).	Verified through performing migration to one or more environments equivalent to the dedicating entities (Method 1).

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
	F-3	Functionality: completeness and correctness	<p>important for computer programs that are expected to be executed in a different environment.</p> <p>The degree to which the computer program requirements, design, and implementation have satisfied the allocated safety requirements. Formal techniques may be used to mathematically prove that the computer program satisfies its specified requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.</p>	<p>Completeness and correctness are based upon how many of the computer program's requirements have been verified to be successfully implemented (e.g., 100% of allocated safety requirements are correctly implemented).</p>	<p>Verified through performing a review of the functional requirements traceability to test cases and verification that the test results indicate correct functionality. If requirements traceability is unavailable, the dedicating entity can develop the traceability matrix from the computer program's requirements or procurement specifications and test cases performed (Method 2).</p>
	F-4	Functionality: consistency with appropriate engineering, scientific research, and professional technical approaches	<p>The degree to which the computer program's sample of complete data sets of results correlate with experimental data, expected data results, or professional analyses and to which any erroneous data sets do not correlate with the experimental data or professional analyses. This critical characteristic most likely is important to computer programs used to perform analysis of accident and structural integrity analyses for determining the proper design of safety components.</p>	<p>Consistency with research and professional technical approaches is based upon peer-reviewed published technical papers or industry-accepted computer programs performing a similar function. The output of the compute program can be viewed as how closely the computer program's output matches the technical report or baseline computer program output (e.g., computer program output correlates with experimental data to +/- 3 sigma).</p>	<p>Verified through a combination of one or more of the following:</p> <ol style="list-style-type: none"> A comparison of peer-reviewed technical publication detail results against the computer program's output for a similar problem being solved (Method 1) A comparison of the baseline computer output against the computer program's output that is being dedicated. The baseline computer program must solve the same or closely similar physical problem as the dedicating computer program (Method 1) A review of the computer program's current user base and

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
					its applicability to the intended use by the dedicating entity (Method 4)
	F-5	Functionality: specific safety functions and algorithms	The critical functions or calculations that are performed. This includes time-dependent functions and functionality to only allow authorized users access to perform the safety functions.	As described in the computer program requirements or procurement specification documentation. Functionality criterion may be similar to given source input data (e.g., calculate dose exposure at 10 m and 0 receptor height).	Verified through a combination of one or more of the following: a) Observation and review of design and/or implementation (Method 3) b) Inspection and testing (Method 1) c) Review of the installed base to determine performance history (Method 4)
	F-6	Interfaces: critical input parameters and valid ranges	The set of input parameters that are used in the critical functions of the computer program and the range of their input values. This critical characteristic is important to ensure that the computer program will function properly for all possible operational inputs.	As described in computer program requirements or procurement specification documentation. For example, this criteria may be deposition receptor height (e.g., 0 ft. to 1 ft.), time (dd/mm/yyyy hh:mm:ss), and length (1.00 to 5.00 m).	Verified through a combination of one or more of the following: a) Observation and review of design and/or implementation (Method 3) b) Inspection and testing (Method 1) c) Inspection of the user's manual (Method 1) d) Review of the installed base to determine performance history (Method 4)
	F-7	Interfaces: output parameters	The characteristics of the critical output parameters include file formats and mathematical notations. This critical characteristic is important to ensure that the computer program output is in the expected format or units of measure.	As described in computer program requirements or procurement specification documentation. This criterion can consist of the output file name (e.g., 28 characters, case-insensitive with a file extension of PDF) or output format specification (e.g., comma-delimited) and units of measure.	Verified through a combination of one or more of the following: a) Observation and review of design (Method 3) b) Inspection and testing (Method 1) c) Inspection of user's manual (Method 1) d) Review of the installed base to

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
Dependability Critical Characteristics	D-1	Built-in quality: adherence to coding practices	The degree to which the computer program complies with the approved coding standards, use of code libraries, or automated configuration management tool. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Coding practice criteria can be a percentage (e.g., 90%) of the supplier coding standards met, and, where appropriate, 100% of possible code library modules are reused instead of recoding.	determine performance history (Method 4) Verified through the review of code inspection reports or other supplier evidence that included reviews of coding practice for the subject code modules. The dedicating entity during a survey may also review the code module's compliance with the supplier's documented coding practices (Method 2).
	D-2	Built-in quality: code structure (complexity, correctness)	The measure to which the computer program is legible, complexity is minimized, and code length is minimized. This critical characteristic can be used to provide an indicator as to the difficulty to verify through reviews and testing that the code will perform as expected.	Code structure criteria can be quantitative, through the use of static analysis tools, or qualitative, through reviews of the documented design or inspection of the code. Code structure criteria may take the form of a number of internal subroutine interfaces, a number of do-loops, numbers of exits from a module, straightforward flow of logic in code module, and code module depth and breadth.	Verified through review of supplier-documented evidence from the use of a static analysis tool or the dedicating entity performing an inspection and manual analysis of the documented design or computer program code (Method 2).
	D-3	Built-in quality: conformance to national codes, standards, and industry-accepted certifications	The computer program's compliance with applicable national codes and standards or industry-accepted certifications.	Conformance criteria can be a measure of how well the program meets industry-accepted practices that provide a qualitative pedigree of the computer program. The criteria can be the degree in which a national code, standard, or third-party certification or recertification programs are achieved (e.g., 90% of achievement of compliance to CMMI SEI maturity level 4 or achieved ISO	Verified through one of more of the following: a) Inspection of supplier-performed assessments of the computer program against the national code or standard (Method 1) b) Review of computer program documentation and artifacts against the national code or standard (Method 2)

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
				9001).	c) Inspection of the proof of third-party certification (Method 1). Verified through one of more of the following:
	D-4	Built-in quality: existence of QA Program	A QA program that included documented procedures or process controls. QA program generally complies with a recognized standard (e.g., ISO 9001, IEEE 730, and IEEE 1012). This critical characteristic can be used to determine whether the foundation of a QA program exists.	QA program criteria are based upon the supplier's procedural compliance with a recognized standard that addresses development and quality assurance for computer programs. This criterion can be expressed in terms of the number of significant findings from a compliance audit against the chosen recognized standard or achievement of certification for the chosen recognized standard.	a) Inspection of evidence of any third-party certification (Method 1) b) Review of internal or external audit reports (Method 2) c) Performance of a survey against the chosen recognized standard (Method 2)
	D-5	Built-in quality: internal reviews and verifications	The degree to which static analysis methods (e.g., peer reviews) are performed during the computer program's development to identify errors and noncompliance with supplier procedures and standards.	Criteria for internal reviews and verifications effectiveness are based upon the ratio of errors identified during the review/verification and the number of errors that are discovered in the next life cycle phase (e.g., ratio of the number of requirements errors identified during requirements review and the number of errors detected during the design phase).	Verified through the inspection and analysis of results from reviews or verification activities performed in two or more adjacent life cycle phases (Method 2 and/or Method 3).
	D-6	Built-in quality: testability and thoroughness of testing	A measure of the completeness of the computer program verification, validation, and installation testing to ensure that the computer program is correct and complete. This critical characteristic may be appropriate to use for ensuring that tests were adequate to provide the reasonable assurance that the safety functions can be performed	Testability criteria are based on the ease or difficulty in conducting verification and validation activities, as well as the breadth and depth of the testing performed. Testability criteria may include the number of hours needed to perform peer reviews, pretest a module, and develop test cases. The thoroughness of computer program testing criteria can be	Verified through one or more of the following: a) Inspection of documented review reports and test records that include the time spent to prepare, conduct, and perform post-review or test activities (Method 1) b) Review of the objective evidence of the errors identified

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
			satisfactorily.	measures that identify the quantity of errors discovered during the various testing activities (e.g., trend analysis of errors per module, comparison of pre and post-release errors) and traceability of tests performed to the safety requirements for the computer program (e.g., 95% of the requirements were tested).	during the testing processes or traceability of safety requirements to tests completed. If objective evidence is not available, the dedicating entity may be able to create the traceability of the safety requirements to tests performed from the computer program's documented requirements and test reports (Method 2).
	D-7	Built-in quality: training, knowledge, and proficiency of personnel performing the work	Staff training, knowledge, and proficiency associated with the design, development, testing, oversight of the computer program, experience in similar projects, and familiarity with specific tools, languages used in design, and implementation. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Staff training, knowledge, and proficiency criteria may include how well the specific staff member satisfies the supplier's qualification requirements for the position held. The criterion can be the percentage of qualification requirements met.	Verified through the review of objective evidence of attendance at courses, staff resumes, and on-the-job training against the supplier qualification requirements to determine how well the staff member satisfies the requirements (Method 2).
	D-8	Problem reporting: notification to customers	Notification by the supplier to customers of potential computer program errors or weaknesses.	This criterion may be the presence and use of a problem reporting system, use of problem reporting metrics, and number of notifications to the users over time.	Verification is performed by reviewing communications of errors with users, any website or other form of communication with the supplier, and a communications log (Method 2)
	D-9	Supportability / Maintainability	The ability for the supplier to continue supporting the computer program over the life of its use or the computer program design that	Supportability/Maintainability criteria can consist of the stability of the supplier based upon business longevity (e.g., 20-years in business),	Verified through one or more of the following: a) Review of the supplier history for the specific computer

Table 1. Typical Critical Characteristics to Consider for Computer Programs (cont.)

<u>Type of Characteristic</u>	<u>No</u>	<u>Critical Characteristic</u>	<u>Description</u>	<u>Acceptance Criteria</u>	<u>Method of Verification</u>
			provides for ease in performing modifications to the computer program. This critical characteristic may be more appropriate for computer programs whose failure could result in few or no alternatives or those alternatives that are not financially feasible.	size of customer base (e.g., 1,000 customers worldwide), planned future product releases (e.g., supplier R&D has updates schedule for the next 3-years), supplier history of discontinuing products (e.g., cancelled three product lines over the past two-years), or the time required to change the computer program (mean time to change or fix).	program, as well as the history in supporting similar computer programs or products (Method 4) b) Review of supplier metrics associated with the length of time to evaluate the change/error correction, make the code change/correction, test the change/correction, update all the computer program documentation, and release the change (Method 2).

ATTACHMENT A –ACCEPTANCE METHODS AND CUSTOMER/SUPPLIER ACTIVITIES

Acceptance Method	Specific WRPS Activities	Specific Supplier Activities
<p><i>Method 1 Special Tests and Inspections</i></p>	<ul style="list-style-type: none"> • Determine sample size. • Determine post-installation testing requirements. • Determine special receipt tests and inspections. • Accept item via special receipt inspections. • Accept item via post-installation testing. <p>Note: Method 1 does NOT require utilization of an additional method.</p>	<ul style="list-style-type: none"> • Furnish technical design information to enable verification of critical characteristics.
<p><i>Method 2 Commercial Grade Survey of Supplier</i></p>	<ul style="list-style-type: none"> • Conduct survey of quality program controls • Require the supplier to invoke the controls necessary to verify critical characteristics. <ul style="list-style-type: none"> • Accept item based on supplier Certificate of Conformance (see ASME, NQA-1, Requirement 7, Section 503 and Section 704.1.(b) verified by commercial grade survey. <p>Note: Method 2 is generally employed for commodity type item and is used in conjunction with a supporting method. (Can be used as primary basis for dedication in addition to normal receipt inspection.)</p>	<ul style="list-style-type: none"> • Implement controls necessary to verify critical characteristics. • Provide customer with a Certification of Conformance (as requested).
<p><i>Method 3 Source Verification</i></p>	<ul style="list-style-type: none"> • Conduct source verification. • Accept item based on documented source verification results. <p>Note: Method 3 is used in conjunction with receiving inspection to verify the documentation of the source inspection/test.</p>	<ul style="list-style-type: none"> • Implement item specific design, fabrication, assembly, manufacturing, testing, or inspections controls substantiated by the source verification for a particular commercial grade item. <p><input type="checkbox"/> Allow customer access to facilities to conduct source verification.</p>
<p><i>Method 4 Acceptable Supplier Item Performance Record</i></p>	<ul style="list-style-type: none"> • Establish documented performance record. • Monitor performance of item. • Confirm applicability of independent product test results, INPO NPRDS, commercial program audits/surveys conducted by industry groups, utilization of national codes and standards, supplier responses to commercial grade program controls, results of periodic maintenance surveillance, results of successfully employing other acceptance methods. • Accept item by issuing certification that is based on supplier/item performance record. <p>Note: Method 4 is only used in conjunction with one or more of the other methods.</p>	<ul style="list-style-type: none"> • Respond to commercial grade program controls questionnaire. • Ensure item complies with national codes and standards, if applicable.

ATTACHMENT B - GUIDANCE FOR THE SELECTION OF ACCEPTANCE METHODS AND THEIR CONTENT

To provide reasonable assurance that a commercial grade computer program will perform its intended safety function or will perform its hazard control function necessary to provide adequate protection from nuclear facility or radiological hazards, the dedicating entity should verify that the commercial grade computer program meets the acceptance criteria for the identified critical characteristics by using one or more of the following CGD methods:

- Method 1: Inspections, Tests, or Analyses performed after delivery
- Method 2: Commercial Grade Survey of the supplier
- Method 3: Source Verification of the item
- Method 4: Acceptable supplier/item performance record.

Once critical characteristics are verified, there is reasonable assurance that the computer program produces valid responses when used in the design or analyses of SSCs or that it will satisfactorily perform the hazard control function necessary to provide adequate protection from nuclear facility or radiological hazards. At this point, the computer program can be accepted as a dedicated safety software and will be subject to the controls the WRPS software management program.

Those planning/performing commercial grade dedications of software should be aware that the method of verification chosen may impact the procurement document content needed for successful verification of the critical characteristics for acceptance.

Method 1: Special Tests

Tests to verify the adequacy of the commercial grade computer program should be documented in a test plan. Test plan activities that should be considered include the tests to be performed, the test method(s) to be utilized, verification of the identified critical characteristics for acceptance consistent with the acceptance criteria determined in the technical evaluation, demonstration that the mathematical equations are adequate to calculate critical parameters in an SSC, and documentation of test results. Tests to determine whether the computer program produces valid responses shall be included in a test plan when used in the design or analysis of SSCs or that it performs the hazard control function necessary to provide adequate protection from nuclear facility or radiological hazards.

Test may be performed by third-party entities if they are documented and the tests are controlled in accordance with TFC-ENG-DESIGN-C-15. The use of test problems based on codes and standards or established technical references should provide an acceptable approach for some types of design and analysis computer programs or computer programs that provide a hazard control function necessary to provide adequate protection from nuclear facility or radiological hazards. The test plan and results conducted by the dedicating entity or a third-party entity should be retained as part of the dedication documentation. If tests were performed by the supplier, the dedicating entity should verify the adequacy of test coverage consistent with the computer program's application requirements.

ATTACHMENT B - GUIDANCE FOR THE SELECTION OF ACCEPTANCE METHODS AND THEIR CONTENT (cont.)

The dedicating entity should confirm that a representative testing set of anticipated program applications was carried out by the supplier and that important design features and major logic paths of the computer program were tested consistent with the technical evaluation and critical characteristics for acceptance. This also applies to computer programs that perform a hazard control function necessary to provide

adequate protection from nuclear facility or radiological hazards. Retesting should be required to repeat some of the supplier's test, and additional testing should also be required if a supplier's test coverage is found to be inadequate. When tests are used to verify acceptance criteria for critical characteristics, the commercial grade computer program should be kept under configuration control to preclude inadvertent use of changes prior to satisfactory completion of the dedication activities and to prevent unauthorized release.

If the dedicating entity is testing a computer program in-house, test cases should be developed to determine the accuracy of the computer program's predictions based on the identified critical characteristics. In situations where computer program requirements include a clear specification of the range of validity for program responses, an evaluation of test results and documentation that states whether all test results fall within the valid range should be acceptable. The range of validity could be determined based on physical observations, such as experimental benchmarks, by analytic means, or by other validated programs. In some instances, the range of validity is known only in very general terms.

The computer program being reviewed is often the only computer program capable of analyzing the problems of interest and providing the needed responses. Physical observations may be available only for simplified, unrepresentative, or distorted problem conditions, and analytic results may be obtainable only for trivialized cases. In such situations, validation becomes a more subjective process dependent on the professional judgment of a professional engineer or other qualified staff of the dedicating entity. In such cases, the dedicating entity should evaluate the test results or conduct analyses to demonstrate that:

- Realistic test cases or test cases representative of the anticipated program used produce physically acceptable results (e.g., no negative temperatures or infinite pressure limits)
- Simplified test cases produce understandable results when compared with physical observations or analytic predictions.

Supplier acceptance tests and purchaser acceptance tests are activities that may be used during dedication. Method 2 should be used along with Method 1 if the dedicating entity wishes to take credit for supplier acceptance testing performed at the commercial supplier's facility.

Method 1: Inspections

Inspections should include verification of objective evidence, including product identification and computer program revision date.

Receipt inspections should be included in the dedication plan and performed to accept the computer program. It is important to the process of implementing Method 1 to understand the differences between standard receipt inspections, computer program installation checkouts, and special tests and inspections performed after receipt.

ATTACHMENT B - GUIDANCE FOR THE SELECTION OF ACCEPTANCE METHODS AND THEIR CONTENT (cont.)

NQA-1 describes the standard receiving inspection in Part I, Requirement 7, Control of Purchased Items and Services, as checking the quantity received, damage, general conditions of items, and part number. Computer program receipt inspections are as simple as checking that the computer program media have not been damaged and that the version identifiers are correct.

Installation and checkout activities may or may not be part of dedication if it can be proven that these will not affect the computer program's inadvertent use.

Inspections for dedication go beyond the standard receiving inspection activities and installation checkouts to verify that the critical characteristics for acceptance are met. While the computer program version identifiers are attributes of a receipt inspection, they should also be part of the dedication process for the item. Even though receipt inspection and simple computer program installation checkouts are important to the dedication process, they are not adequate on their own for dedication.

Method 1: Analyses

Analyses should include a review of the computer program design related to application requirements. In cases where a design specification is not available, the available computer program documentation, such as a user's manual, should be reviewed to identify design specifications and application limits.

The review of the applicable computer program lifecycle processes should demonstrate that all computer program requirements associated with the safety function were implemented adequately, ensure traceability to the computer program safety requirements, and clearly describe required functions, inputs, outputs, and options that are not used to potential users or block from use, as necessary.

Method 2: Commercial Grade Survey of the Supplier

Commercial grade surveys should be performed in accordance with the survey criteria of NQA-1 Part II, Subpart 2.14, which requires the supplier to have a documented and effective quality assurance program that controls the supplier's specific processes.

The survey documentation should provide objective evidence that the lifecycle processes and controls implemented by the computer program's supplier for specified critical characteristics have been observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls should be corrected if the survey is used for acceptance of the identified critical characteristics.

The survey process should take advantage of available program documentation (such as development process artifacts), as well as user experience. Evidence should exist of software development standards and practices that were in place during the development of the computer program. Existing V&V activities carried out by the developer should be considered, evaluated, and credited as long as they are relevant to the computer program's application. This documentation should be identified and controlled.

Method 2 may be used when the dedicating entity relies on the commercial supplier for analyses, testing, and other activities that are related to the dedication process. Given that the dedicating entity is responsible for verifying critical characteristics, delegation of such activity should come with a thorough assessment of the commercial grade supplier's process to effectively control critical characteristics.

ATTACHMENT B - GUIDANCE FOR THE SELECTION OF ACCEPTANCE METHODS AND THEIR CONTENT (cont.)

Method 3: Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with one or more identified critical characteristics and acceptance criteria. This method could be used to witness certain tests or computer program development processes that can only be performed at the supplier's location due to specialized equipment, trained personnel, etc.

Source verification is only applicable to the actual activity related to the critical characteristic and acceptance criteria observed during the surveillance. The dedicating entity may establish a frequency in which to witness these activities to ensure that process controls applicable to the critical characteristics are effectively implemented for subsequent computer program revisions. An example of a surveillance would be to send representative(s) to evaluate the execution of test problems for the new computer program or computer program revision.

Source verification may have limited application and is not applicable to computer programs that have already been developed since the computer development activities have been completed, for which access to the computer program lifecycle documentation may be restricted due to the proprietary nature of the documentation, or when there is an inability to interact with suppliers.

Method 4: Acceptable Supplier Item Performance Record

Acceptable data for historic performance should evaluate the industry-monitored performance of the commercial grade computer program, industry product tests, certification to national codes and standards (nonnuclear-specific), and other industry records or databases. When a computer program has been demonstrated to be reliable based on its historical performance, it should be credited during dedication. Historical performance should be supported by the use of one of the other verification methods.

This acceptance method should have a greater application for the dedication of computer programs used in design or analysis. Computer programs that are commercially available and that have industrywide application may be used successfully hundreds or even hundreds of thousands of times daily. The results of these uses and engineering judgment associated with the acceptance of the computer program should be considered with dedicating the computer program. Errors reported by the users to the supplier and failures associated with structures, systems, and components may be evaluated as part of the failure analysis investigation.

This method is most effective when the supplier provides error reports to the purchaser for applicability and significance evaluation and when the users contact the supplier when computer program errors are suspected. A technical support agreement in the procurement documents provides assurance that there is adequate communication between the supplier and users.

Computer Program Procurement Documents

Depending on the critical characteristics selected and the dedication method, the procurement documents for the computer program may need to include the following:

- A detailed description of the computer program name, title, release, version, or other descriptive identifiers

ATTACHMENT B - GUIDANCE FOR THE SELECTION OF ACCEPTANCE METHODS AND THEIR CONTENT (cont.)

- Technical specification requirements related to the computer program application
- The media or process used to provide the computer program to the purchaser
- Identification of the supplier's QA program applicable to the computer program's development and support
- Identification of the documentation to be provided with the computer program
- Special shipping, storage, and handling requirements for media and any precautionary controls related to consideration of temperature, humidity, electromagnetic interference, etc., to be identified by the supplier
- Right of access for performing surveys or surveillances
- Need for the supplier to provide error reporting or technical support

Documentation of the commercial grade computer program dedication process should be traceable to the computer program and should contain the following types of documents, depending on the applicable dedication method:

- Dedication plans or procedures, including the essential elements of the dedication process:
 - Scope and objectives for the dedication process
 - Requirements document for computer program dedication
 - Plans for a configuration management process for computer program dedication, including planned regression test requirements and expected results
 - Computer program V&V methodology.
- Commercial grade item procurement documents.
- Technical evaluations
 - Computer program requirements, summary, and review
 - Documentation referenced during the technical evaluation
- Critical characteristic identification and acceptance criteria
- Test plan(s), test specifications, test reports(s) or results, inspection reports, and analysis reports
 - Review of test coverage
 - Evaluation of test results – validation
 - Commercial grade survey reports

**ATTACHMENT B - GUIDANCE FOR THE SELECTION OF ACCEPTANCE METHODS AND
THEIR CONTENT (cont.)**

- Source verification reports
- Historical performance information (e.g., availability and use of user experience)
- Dedication report containing sufficient data to accept the item.

Limitations of the scope of the dedication of a computer program that are based on the critical characteristics should be communicated to the computer program users to ensure usage is within the dedication limits. The configuration control of the computer program can usually be used to control the version of the computer program. When limits on the computer program usage exist that are not blocked by the computer program's process controls, a user's manual with the specified limits should be available to users.