



Boston Government Services, LLC

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**Commercial Grade Dedication of Computer  
Programs and Software Services**

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BGS-QA-28

Revision 0

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*8/9/2016*

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Effective Date:

*8/12/2016*

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<b>FUNCTIONAL AREA: Quality Assurance</b>	<b>BGS-QA-28</b>
<b>PROCEDURE TITLE: Commercial Grade Dedication of Computer Programs and Software Services</b>	<b>REV. NO. 0</b>
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### Revision History

<b>Rev. #</b>	<b>Effective Date</b>	<b>By</b>	<b>Type<sup>1</sup></b>	<b>Changes</b>
0	08/12/16	Patricia Loo	N	Initial release. Addresses corrective action, CA-16-10, resulting from EM-PA-16-40 audit finding #3.

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<sup>1</sup> M = major change, mc = minor change, N = new

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## 1. PURPOSE

The purpose of this procedure is to implement the requirements and establish methods in accordance with BGS-QAP-01, *Corporate Quality Assurance Plan*, for the commercial grade dedication (CGD) of computer programs and software services that have not been developed under an American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1 program and are intended to be used to support a nuclear safety function, including the design of a nuclear safety structure, system or component. Computer programs and software services that fall into this category are referred to as Otherwise Acquired Software.

Attachment 1 provides a high-level overview of the CGD process. Implementation of this procedure provides reasonable assurance that the Otherwise Acquired Software is adequate for use in support of nuclear safety applications. The acceptance of Otherwise Acquired Software does not qualify a supplier to NQA-1 requirements.

## 2. SCOPE

This procedure applies to BGS and their dedication of each version of the Otherwise Acquired Software procured, acquired from third party entities, or supplied by customers that have not been developed under an ASME NQA-1 program and are intended to be used to support a nuclear safety function, including the design of a nuclear safety structure, system or component. These computer programs and services include real-time (e.g., operations or process control) as well as nonreal-time (e.g., design and analysis) computer programs and services.

Once the CGD process has been completed for the Otherwise Acquired Software and it is determined to provide reasonable assurance it can support its safety function correctly, subsequent modifications to the computer program under an ASME NQA-1 program does not require CGD.

### 2.1 Exceptions

A CGD is not required in the following cases:

- 1) The commercial grade computer program or service is not intended to be used to support a nuclear safety function.

<b>NOTE</b>
This does not exempt BGS from performing installation testing per BGS-SQ-02, <i>Software Management</i> , and the associated software quality assurance plan.

- 2) The reinstallation of the same software developed by the original company from the same distribution media onto a system with the same exact computer hardware configuration and operating system (including patches).

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### 3. REFERENCES

- 3.1 ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*, (2008 with Addenda through 2009). Referred to as ASME NQA-1 in this procedure.
- 3.2 ASME NQA-1-2012 Subpart 3.2-2.14, *Implementing Guidance for Part II, Requirement 2.14: Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services*
- 3.3 BGS-AD-01, *Document Preparation and Control*
- 3.4 BGS-IM-01, *Application Development and Coding Standards*
- 3.5 BGS-PC-01, *Procurement and Contracts*
- 3.6 BGS-QAP-01, *Corporate Quality Assurance Plan*
- 3.7 BGS-RM-01, *Quality Assurance Records*
- 3.8 BGS-SQ-02, *Software Management*
- 3.9 BGS-QAF-28.1, *Commercial Grade Dedication Plan*
- 3.10 BGS-QAF-28.2, *Commercial Grade Dedication Package*
- 3.11 BGS-TR-01, *Qualification and Training*
- 3.12 BGS-WA-01-PC-01, *Receipt Inspection of Software*
- 3.13 DOE O 414.1D, *Quality Assurance*
- 3.14 DOE Office of Environmental Safety and Quality, September 2011, *Guidance for Commercial Grade Dedication*
- 3.15 EM-QA-001, Rev. 1, *Office of Environmental Management (EM) Quality Assurance Program*

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#### 4. DISCUSSION AND OVERVIEW

##### 4.1 Applicable Requirements and Guidance

4.1.1 This procedure is invoked from BGS-SQ-02, *Software Management*, as part of the BGS acquisition process for each version of the Otherwise Acquired Software. This procedure is designed to meet the CGD requirements of:

- a) ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*, (2008 with Addenda through 2009)
- b) BGS-QAP-01, *Corporate Quality Assurance Plan*
- c) DOE O 414.1D, *Quality Assurance*
- d) EM-QA-001, Rev. 1, *Office of Environmental Management (EM) Quality Assurance Program*

4.1.2 The following guidance was used in the development of this procedure:

- a) ASME NQA-1-2012 Subpart 3.2-2.14, *Implementing Guidance for Part II, Requirement 2.14: Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services*
- b) DOE Office of Environmental Safety and Quality, September 2011, *Guidance for Commercial Grade Dedication*

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**5. DEFINITIONS AND ACRONYMS**

<b>ASME</b>	American Society of Mechanical Engineers
<b>ATLAS</b>	Automated Transportation Logistics and Analysis System
<b>BGS</b>	Boston Government Services, LLC
<b>CCFA</b>	Critical Characteristics for Acceptance
<b>CGD</b>	Commercial Grade Dedication
<b>Commercial Grade Computer Program</b>	A computer program that affects a safety function, which was not designed, developed, or approved in accordance with ASME NQA-1 Parts I and II, Subpart 2.7. Source: ASME NQA-1
<b>Commercial Grade Computer Program Service</b>	A service that was not provided in accordance with the requirements of ASME NQA-1 and that affects the safety function of a computer program or the use of computer programs for design or analysis that supports a safety function. Source: ASME NQA-1
<b>Commercial Grade Survey</b>	A method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier’s commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier’s facility. Source: ASME NQA-1
<b>DCA</b>	Document Control Administrator
<b>Dedication</b>	An acceptance process performed in accordance with the ASME NQA-1 Program 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 under the requirements of ASME NQA-1. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, 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 ASME NQA-1. Source: ASME NQA-1.

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<b>Dedicating Entity</b>	The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third party dedicating entity, or by the facility.
<b>Dedication Team</b>	A team of experts in the computer program or service being dedicated and associated quality requirements. The Dedication Team can be any number, including only the SIPM, or BGS staff, or subject matter experts.
<b>Dependability Critical Characteristic</b>	A critical characteristic that when evaluated helps to develop judgment regarding builtin quality of the computer program. Dependability characteristics include both supplier and user attributes, such as a review of the computer program's lifecycle processes and output documentation at the supplier's facilities, review of the user's configuration management activities, supplier and user testing and verification and validation (V&V) activities, and other activities related to the supplier's software development process.
<b>DOE</b>	U.S. Department of Energy
<b>EM</b>	DOE Office of Environmental Management
<b>FMEA</b>	Failure Modes and Effects Analysis
<b>Identification Critical Characteristic</b>	A critical characteristic (e.g., version, build date, release name, or part or catalog number) that provides a method for linking the computer program with the manufacturer's product description, user's manual, published data, or product specification. This critical characteristic is frequently identified and verified during receipt inspection as defined in the CGD Plan.
<b>Infrastructure as a Service (IaaS)</b>	A cloud-based solution for virtualized computing resources.
<b>NQA</b>	Nuclear Quality Assurance
<b>Otherwise Acquired Software</b>	Software or software service procured, acquired from third party entities, or customer supplied that has not been developed under an ASME NQA-1 program and are intended to support a nuclear safety function.
<b>Performance/Functional Critical Characteristic</b>	A critical characteristic that evaluates the required functionality of the computer program to perform its safety function and the accuracy of its results.



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<b>Physical Critical Characteristic</b>	A critical characteristic associated with the computer program's physical media (e.g., CDs, tapes, downloads, or remote access). This critical characteristic is frequently identified and verified during receipt inspection as defined in the CGD Plan.
<b>Platform as a Service (PaaS)</b>	A cloud-based solution for hosting platform and software tools not installed on development computers.
<b>QA</b>	Quality Assurance
<b>QAP</b>	Quality Assurance Plan
<b>RADCALC</b>	Radiological Packaging Determination and Classification
<b>RADTRAN</b>	Risk Assessment for Transportation of Radiological Material
<b>Reasonable Assurance</b>	The word reasonable connotes a level of confidence that is justifiable but not absolute. In the context of product or service quality, reasonable assurance of performance must be based on facts, actions, or observations (objective evidence). Although these bases are objective and measurable, the inference of adequacy drawn from them – the decision that reasonable assurance has been attained – is inherently subjective, and the judgment of reasonability may vary between different observers. These judgments are commonly referred to as engineering judgment and should be documented. Reasonable assurance of the item's ability to perform its intended safety function results from the combination of the technical evaluation and the acceptance processes.
<b>RMS</b>	Records Management System
<b>Safety Function</b>	The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing. Source: ASME NQA-1
<b>SIPM</b>	Software Implementation Project Manager

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**Software as a Service (SaaS)**

A cloud-based software solution not installed on development computers. Commercial software provided through a service provider that when configured provides a specific BGS function. SaaS includes software licensing and delivery model in which software is licensed on a subscription basis and is centrally hosted. It can be referred to as "on-demand software". SaaS applications are accessed by BGS through a thin client via a web browser. SaaS is a common delivery model for service desk management. Examples: Fresh Desk for ATLAS, RADTRAN, and RADCALC Help Desks.

**Software Service**

Software as a Service (SaaS), Infrastructure as a Service (IaaS), or Platform as a Service (PaaS) solutions procured or acquired from third party entities.

**Source Verification**

A method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics. Source: ASME NQA-1

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## 6. RESPONSIBILITIES

This section contains the description of roles and responsibilities for key personnel associated with this procedure. When necessary, the responsible person may delegate as long as the designee has the appropriate knowledge, required training, and required independence.

### 6.1 Vice President of Operations

- 6.1.1 Approves BGS-QAF-28.1, *Commercial Grade Dedication Plan (CGD Plan)* and BGS-QAF-28.2, *Commercial Grade Dedication Package (CGD Package)* including CGD results.

### 6.2 Quality Assurance Manager

- 6.2.1 Concurs on the CGD Plan and CGD Package.

### 6.3 Independent Reviewer

- 6.3.1 Reviews the CGD Plan and CGD Package.

### 6.4 Software Implementation Project Manager (SIPM)

- 6.4.1 Identifies and ensures completion of required qualifications for personnel performing activities included in this procedure.
- 6.4.2 Ensures the Otherwise Acquired Software is under configuration management prior to dedication.
- 6.4.3 Responsible for the development of the CGD Plan.
- 6.4.4 Responsible for ensuring the execution of the CGD Plan and creation of the CGD Package.
- 6.4.5 Appoints and leads the Dedication Team.

### 6.5 Dedication Team

- 6.5.1 Assists the SIPM in performing the computer program or service failure analysis.
- 6.5.2 Assists the SIPM in identifying critical characteristics, associated acceptance criteria, and verification method determination.
- 6.5.3 Assists the SIPM in executing the CGD Plan.

### 6.6 Document Control Administrator (DCA)

- 6.6.1 Provides a document identifier to the SIPM for the CGD Plan and the CGD Package upon request.
- 6.6.2 Manages the CGD Plan and CGD Package records, including placing the record into the records management system (RMS).

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## 7. PROCEDURE

### 7.1 General

- 7.1.1 The SIPM identifies and documents required qualifications and training necessary for performing activities associated with this procedure per BGS-TR-01, *Qualification and Training*.
- 7.1.2 The SIPM appoints the members of the Dedication Team and other personnel responsible for performing activities associated with this procedure and ensures completion of training per BGS-TR-01, *Qualification and Training*.
- 7.1.3 The SIPM ensures that the Otherwise Acquired Software received in-house, including the computer program, its data, and all associated documentation, have been placed under the BGS's configuration management process in accordance with BGS-IM-01, *Application Development and Coding Standards*, and BGS-SQ-02, *Software Management*.

### 7.2 Develop CGD Plan

The CGD process is initiated through the development of a CGD Plan that governs the activities for the particular dedication process being performed.

- 7.2.1 The SIPM obtains a document identifier from the DCA for the CGD Plan per BGS-AD-01, *Document Preparation and Control*.
- 7.2.2 The SIPM and members of the Dedication Team develop the CGD Plan using BGS-QAF-28.1, *Commercial Grade Dedication Plan* (see Attachment 3), or equivalent. The structure of BGS-QAF-28.1, is suggested, but not required. Any format that addresses the content on that form is acceptable as the equivalent.
- a) Describe the Otherwise Acquired Software to be dedicated including:
- Software name and version or other unique identifier
  - Vendor/Supplier name and contact information
  - Description of the intended use and the capabilities and limitations of that use

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**NOTE**

Non-safety related software does not require a CGD.

- Identification of software as a Commercial Grade Computer Program, Commercial Grade Computer Program Service, or non-safety related software based on intended use.
- Software life cycle and other relevant documentation from the receipt inspection. It is recommended that the receipt inspection checklist from BGS-WA-01-PC-01, *Receipt Inspection of Software*, be included in the CGD Package.

### 7.3 Perform Technical Evaluation

The technical evaluation builds upon the CGD Plan throughout the dedication process and documents the safety functions, credible failures, software and hardware requirements (as applicable), and the level and type of review and testing activities that are appropriate to complete the dedication process. To complete the technical evaluation, the SIPM and members of the Dedication Team:

- 7.3.1 Perform activities to identify the safety function(s) the Otherwise Acquired Software supports and document the safety function(s) in the CGD Plan. This process includes review of the software documentation, interviews with users, and/or the supplier of the Otherwise Acquired Software.
- 7.3.2 Perform the Failure Modes and Effects Analysis (FMEA). Evaluate the potential failure modes of the Otherwise Acquired Software and identify the credible failures. The credible failure modes are documented in the CGD Plan.
- 7.3.3 Specify the necessary hardware and software to test and operate the Otherwise Acquired Software.
- 7.3.4 Consider the following during the technical evaluation:
  - a) Ability of BGS to maintain the Otherwise Acquired Software.
  - b) Adequacy of the supplier testing, including acceptance criteria. The adequacy of the supplier testing determines if additional testing is required to verify a critical characteristic or for BGS to maintain the Otherwise Acquired Software.
  - c) Identification of any mathematical models on which the Otherwise Acquired Software is based.

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- d) Establish the class of problems for intended use.
- e) Specify user interface requirements.

**NOTE**

If the software documentation obtained from the supplier or supplemented by publicly available sources is unavailable and is essential to determining reasonable assurance, dedication may not be possible.

## 7.4 Identify Critical Characteristics

- 7.4.1 Identify the critical characteristics<sup>2</sup> for acceptance based on the intended safety function, complexity, application, and performance of the computer program and its data and document in the CGD Plan.
- a) For computer programs that are not software services, include all critical characteristics.
  - b) For Software Services, include critical characteristics for the cloud-based solution.
    - If IaaS, include critical characteristics for the cloud-based hosting platform solution.
    - If PaaS, include critical characteristics for both the cloud-based hosting platform and software tool solutions.
    - For SaaS, all critical characteristics are based on the supplier's cloud-based solution.

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<sup>2</sup> See ASME NQA-1-2012 Subpart 3.2-2.14 Table 501, Typical Critical Characteristics to Consider for Computer Programs. These critical characteristics should encompass identification, physical, performance/functional, and dependability characteristics of the software, as applicable.

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- 7.4.2 For each critical characteristic, document the acceptance criteria and the appropriate method(s) of acceptance as described in Attachment 2, Methods for Acceptance of Otherwise Acquired Software, that is to be used.
- a) Select acceptance method(s) based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization.
  - b) Employ multiple methods of acceptance when Method 4, Acceptable Supplier Performance Record for the Commercial Grade Computer Program or Service, is selected unless:
    - The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application
    - (or)
    - The manufacturer's/supplier's measures for the control of applicable design process, and material change have been accepted as verified by survey.
  - c) If the documentation is not available to adequately verify the critical characteristic, consider alternate critical characteristics. Should an alternate characteristic not be able to provide reasonable assurance, the dedication may not be possible.

## **7.5 Review and Approve CGD Plan**

- 7.5.1 The SIPM finalizes the CGD Plan and submits for review and approval per BGS-AD-01, *Document Preparation and Control*.
- 7.5.2 The independent reviewer(s) review the CGD Plan for technical accuracy and traceability as the basis for acceptance.
- 7.5.3 The QA Manager reviews the CGD Plan for concurrence that all required elements have been addressed and signs accordingly.
- 7.5.4 The Vice President of Operations reviews the CGD Plan for approval and signs accordingly.
- 7.5.5 The SIPM baselines the CGD Plan by submitting the CGD Plan to the DCA per BGS-RM-01, *Quality Assurance Records*.

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## 7.6 Execute CGD Plan

7.6.1 The SIPM and members of the Dedication Team verify using the identified dedication method(s) (see Attachment 2 for description of dedication methods) that the Otherwise Acquired Software meets the acceptance criteria for each of the identified critical characteristics.

a) For Method 1, Special Tests, Inspection(s), and/or Analyses:

- Generate, if necessary, and execute tests and/or visual inspections of the computer program or software life cycle documentation to ensure the critical characteristic is met. This may be executing a series of software acceptance test procedures, inspection of a software design document, or inspection of the computer program code.
- When utilizing sampling plans, these sampling plans shall be based on standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the Otherwise Acquired Software.

b) For Method 2, Commercial Grade Survey of the Supplier:

- Perform the survey as a method for acceptance only from suppliers with a documented quality program that effectively implements the supplier's own specified processes and controls.
  - 1) Invoke or reference the verified processes and controls including revision level as part of purchase order  
  
(or)
  - 2) Control requirements for the Otherwise Acquired Software and as a critical characteristic require the supplier to provide a Certificate of Conformance as part of procurement documentation attesting to the implementation of the identified processes and controls.
- When accepting Otherwise Acquired Software from a distributor, confirm adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if:



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- 1) The distributor acts only as a broker and does not warehouse or repackage the Otherwise Acquired Software
  - (or)
  - 2) Traceability can be established by other means such as verification of the manufacturer's markings or shipping records.
- If a designated critical characteristic cannot be verified due to controls by the supplier's sub-supplier(s), extend the scope of the survey to include the sub-supplier(s) or select another dedication method(s) to verify the critical characteristic. Prior to choosing another dedication method, obtain approval from the persons originally approving the CGD Plan, revise the CGD Plan, and document approval.
  - Perform the survey at the supplier's facility or reference another organization's survey in accordance with a checklist or plan that includes or addresses the following:
    - 1) Identification of the Otherwise Acquired Software included within the scope of the survey
    - 2) Identification of the critical characteristics to be controlled by the supplier
    - 3) Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics
    - 4) Identification of the survey methods or verification activities performed with the results obtained
    - 5) Documentation of the adequacy of the supplier's processes and controls.
- c) For Method 3, Source Verification:
- Perform a source verification with a checklist or plan at the supplier's facility that includes or addresses the following:
    - 1) Identification of the Otherwise Acquired Software included within the scope of the source verification
    - 2) Identification of the critical characteristics, including the acceptance criteria, being controlled by the supplier

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- 3) Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics
  - 4) Identification of the activities witnessed during the source verification and the results obtained
  - 5) Identification of mandatory hold points to verify critical characteristics during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed commercial grade software or service
  - 6) Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria.
- d) For Method 4, Acceptable Supplier Performance Record for Commercial Grade Computer Program or Service:
- Compile historical performance data related to the Otherwise Acquired Software utilizing one or more of the following:
    - 1) Monitored performance of the Otherwise Acquired Software.
    - 2) Industry product tests.
    - 3) Certifications to national codes and standards.
    - 4) Other industry records or databases.
  - Document the supplier's performance record specific to the Otherwise Acquired Software including the following:
    - 1) Identification of the Otherwise Acquired Software being evaluated.
    - 2) Identification of the previously established critical characteristics specific to the Otherwise Acquired Software.
    - 3) Identification of data examined to evaluate the Otherwise Acquired Software.
    - 4) Identification of basis for determining that performance data substantiates acceptability of the Otherwise Acquired Software.

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- 5) Documentation of the adequacy and acceptance of the supplier's performance record.

**NOTE**

If a critical characteristic cannot be verified by any dedication method, the Otherwise Acquired Computer Program cannot be used for a safety function.

- 7.6.2 If a critical characteristic cannot be verified by the selected dedication method, the SIPM may select another or combination of dedication methods and verify the critical characteristic in accordance with step 6.4.2. Prior to choosing another dedication method, obtain approval from the persons originally approving the CGD Plan, revise the CGD Plan, and document approval.
- 7.6.3 If during the use of Method 2 or 3 deficiencies in the supplier's process or controls associated with a critical characteristic are identified and corrected, the SIPM shall document the deficiency, disposition, and corrective action as part of the performance of the verification.
  - a) Uncorrected deficiencies in processes or controls may result in the selection of another dedication method, if possible, for determining acceptance.
- 7.6.4 The SIPM evaluates the results of the verification to determine if reasonable assurance has been achieved and accepts or rejects the Otherwise Acquired Software for use in a safety function, accordingly.

## **7.7 Create CGD Package**

The CGD Package includes all documentation relevant to the dedication, including the CGD Plan. The CGD Package documents the results of the dedication and provides the overall conclusion if reasonable assurance has been achieved that the Otherwise Acquired Software correctly supports the safety function and a recommendation of acceptance.

- 7.7.1 The SIPM obtains a document identifier from the DCA for the CGD Package per BGS-AD-01, *Document Preparation and Control*.
- 7.7.2 Using form, BGS-QAF-28.2, *Commercial Grade Dedication Package* (see Attachment 4), the SIPM records the results of the verification and evaluation of the results including rationale for determination of acceptability or rejection of the Otherwise Acquired Software for use in a safety function.

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7.7.3 The SIPM compiles the following to include in the CGD Package and lists each reference on the CGD Package Form:

- a) Approved CGD Plan including the technical evaluation, critical characteristics, acceptance criteria, and associated attachments and references.
- b) Test reports and results including review of test coverage and evaluation of test results (applicable for Method 1).
- c) Inspection reports (applicable for Method 1).
- d) Analysis reports (applicable for Method 1).
- e) Commercial Grade survey reports (applicable for Method 2).
- f) Source verification reports (applicable for Method 3).
- g) Historical performance information including, for example: availability and use of user experiences, supplier error notifications (applicable for Method 4)
- h) Otherwise Acquired Software procurement documents<sup>3</sup>.

## **7.8 Review and Approve CGD Package**

7.8.1 The SIPM submits for review and approval per BGS-AD-01, *Document Preparation and Control*.

7.8.2 The independent reviewer(s) review the CGD Package to ensure adequate verification and analysis was completed for each critical characteristic and adequate supporting documentation is included in the CGD Package.

7.8.3 The QA Manager reviews the CGD Package for concurrence that all required elements have been addressed and signs accordingly.

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<sup>3</sup> Procurement documents may need to include (1) a detailed description of the commercial grade computer program or service, title, release version, or other descriptive identifiers; (2) technical specification requirements related to the computer program or service; (3) the media or process used to provide the computer program to the purchaser; (4) identification of the supplier's QA program applicable to the computer program's development and support; (5) identification of the documentation to be provided with the computer program; (6) 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; (7) right of access for performing surveys or surveillances; and (8) need for the supplier to provide error reporting or technical support.

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- 7.8.4 The Vice President of Operations reviews the CGD Package for approval and signs accordingly.
- 7.8.5 The SIPM baselines the CGD Package by submitting the CGD Package to the DCA per BGS-RM-01, *Quality Assurance Records*.
- 7.8.6 If receipt inspection of the Otherwise Acquired Software occurs beyond 90 days after the verification of the critical characteristics associated with a survey, source verification, or historical performance, the SIPM and members of the Dedication Team shall re-evaluate the supplier using Method 1 or Method 2.

## 8. RECORDS GENERATED

The following records are generated and maintained as QA records according to BGS-RM-01, *Quality Assurance Records*.

- Commercial Grade Dedication Plan
- Commercial Grade Dedication Package

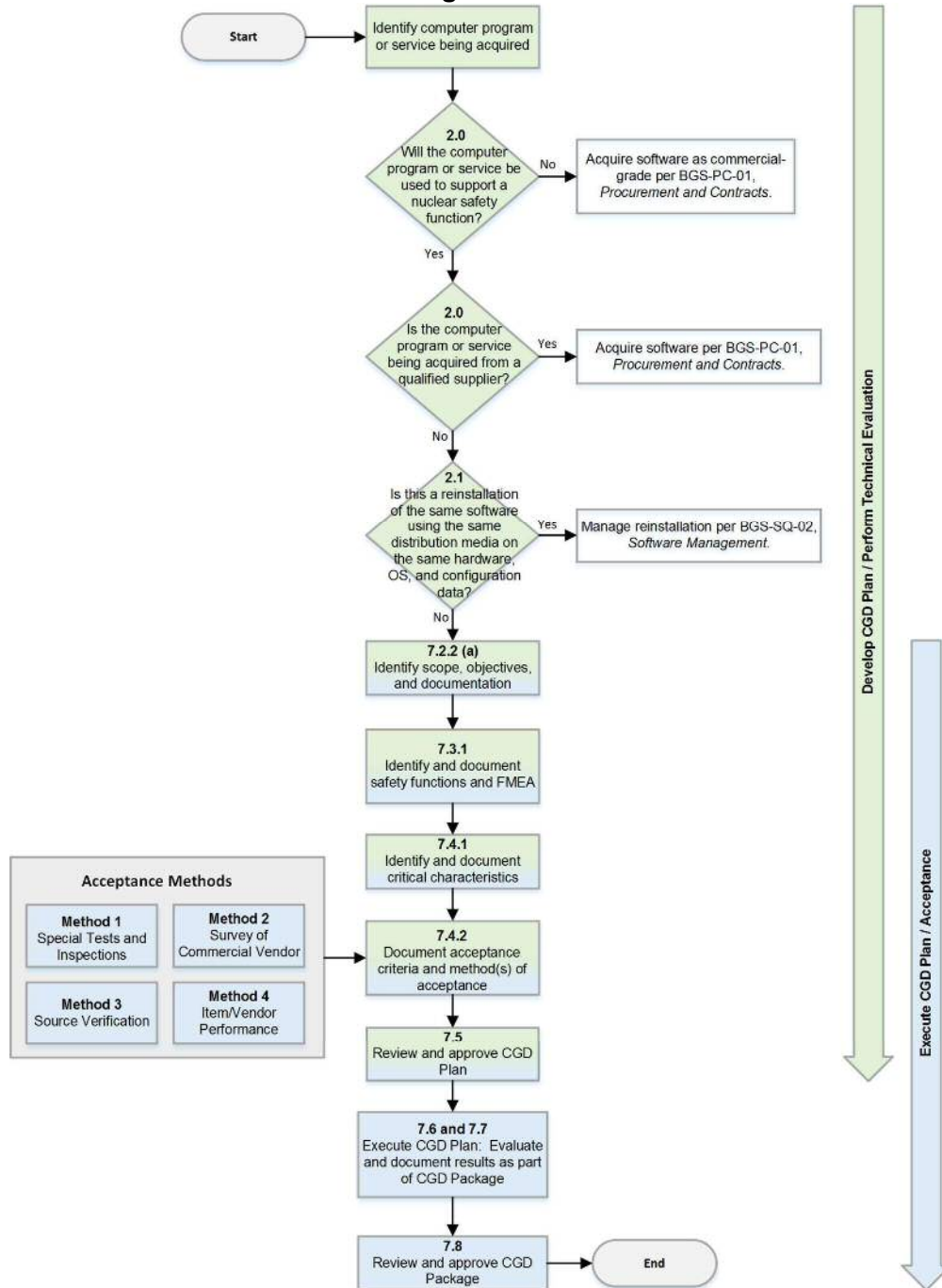
## 9. ATTACHMENTS

- Attachment 1 – Process for the Commercial Grade Dedication of Otherwise Acquired Software
- Attachment 2 – Methods for Acceptance of Otherwise Acquired Software
- Attachment 3 – Commercial Grade Dedication Plan (Sample)
- Attachment 4 – Commercial Grade Dedication Package (Sample)

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## ATTACHMENT 1 – PROCESS FOR THE COMMERCIAL GRADE DEDICATION OF OTHERWISE ACQUIRED SOFTWARE<sup>4</sup>

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<sup>4</sup> Adapted from Revision 1 to EPRI NP-5652 and TR-102260 (EPRI TR-3002002289)

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## **ATTACHMENT 2 – METHODS FOR ACCEPTANCE OF OTHERWISE ACQUIRED SOFTWARE<sup>5</sup>**

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This attachment provides detailed information relevant to the various methods of dedication.

As part of the dedication process, the SIPM will verify that the Otherwise Acquired Software meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods:

Method 1: Special Test(s), Inspection(s), and/or Analyses

Method 2: Commercial Grade Survey of the Supplier

Method 3: Source verification

Method 4: Acceptable Supplier Performance Record for Commercial Grade Computer Program or Service

### **Method 1: Special Test(s), Inspection(s), and/or Analyses**

**Special Tests.** Tests to verify the adequacy of the Otherwise Acquired Software 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 a structure, system, or component (SSC), and documentation of test results. BGS should develop sufficient tests to determine whether the Otherwise Acquired Software produces valid responses when used in the design or analysis of SSCs.

Tests may be performed by third-party entities if they are documented and the tests are controlled in accordance with the requirements of this Standard. 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 Otherwise Acquired Software. The test plan and results conducted by BGS or a third-party entity should be retained as part of the dedication documentation. If tests were performed by the supplier, BGS should verify the adequacy of test coverage consistent with the Otherwise Acquired Software's application requirements.

BGS should confirm that a representative testing set of anticipated program applications was carried out by the supplier and that important design features and major logical paths of the computer program were tested consistent with the technical evaluation and critical characteristics for acceptance. Retesting should be required to repeat some of the supplier's tests, and additional testing should also be required if a supplier's test coverage is found to be inadequate. When tests

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<sup>5</sup> Adapted from ASME NQA-1-2012 Subpart 3.2-2.14, "Implementing Guidance for Part II, Requirement 2.14: Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services

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are used to verify acceptance criteria for the critical characteristics, the Otherwise Acquired Software should be kept under configuration control to preclude inadvertent use or changes prior to satisfactory completion of the dedication activities and to prevent unauthorized release.

If BGS tests Otherwise Acquired Software 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 Otherwise Acquired Software requirements include a clear specification of the range of validity for program responses, an evaluation of test results and documentation that states whether all 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 Otherwise Acquired Software 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 BGS. In such cases, BGS should evaluate the test results or conduct analyses to demonstrate that:

- a) 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).
- b) 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 BGS wishes to take credit for supplier acceptance testing performed at the commercial supplier’s facility.

**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 Otherwise Acquired Software. It is important to the process of implementing Method 1 to understand the difference between standard receipt inspections, computer program installation checkouts, and special tests and inspections performed after receipt. NQA-1 describes the standard receiving inspection in Part I, Requirement 7 as checking the quantity received, damage, general conditions of items, and part number. Otherwise Acquired Software 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 Otherwise Acquired Software’s application requirements or prevent the computer program’s inadvertent use. Inspections for



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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.

**Analyses.** Analyses should include a review of the computer program design related to application requirements. As mentioned above, in cases where design specification documentation 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 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 for software development standards and practices that were in place during the development of the computer program. Existing verification and validation activities carried out by the developer should be considered, evaluated, and credited as long as it is relevant to the computer program’s application. This documentation should be identified and controlled.

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

**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

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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. BGS 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 the test problems for the new computer program or computer program revision.

This method 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 Performance Record for Commercial Grade Computer Program or Service**

Acceptable data for historical performance should evaluate the industry-monitored performance of the Otherwise Acquired Software, 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 listed above.

This acceptance method should have a greater application for the dedication of Otherwise Acquired Software 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 Otherwise Acquired Software should be considered with dedicating the computer program or service. 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.

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**ATTACHMENT 3 – BGS-QAF-28.1, COMMERCIAL GRADE DEDICATION PLAN (SAMPLE)**  
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<b>Document No.:</b> BGS-CGD-	<b>Revision No.:</b>	<b>Date:</b>	<b>CGD Evaluation Title:</b>
<b>Author:</b>			
Complete this form as required by BGS-QA-28, <i>Commercial Grade Dedication of Computer Programs and Software Services</i> , prior to performing the dedication of a commercial grade computer program or computer program service. Note: <i>This form is not for the dedication of a safety SSC with embedded software.</i>			
<b>SECTION A: IDENTIFICATION</b>			
<b>Software Name:</b>		<b>Version Number or Other Identifier:</b>	
<b>Vendor/Supplier Name:</b>		<b>Version Contact Information:</b>	


<b>SECTION B: COMPUTER PROGRAM OR COMPUTER PROGRAM SERVICE INFORMATION</b>	
<b>Computer Program or Computer Program Service Description of Intended Use and Capabilities and Limitations of that Use:</b>	
<b>Commercial Grade Computer Program or Service</b> <i>(Select only one)</i>	<b>Justification</b> <i>(for non-safety related only)</i>
<input type="checkbox"/> Commercial Grade Computer Program <i>(CGD Required)</i>	
<input type="checkbox"/> Commercial Grade Computer Program Service <i>(CGD Required)</i>	
<input type="checkbox"/> Non-Safety Related <i>(no CGD required)</i>	

<b>SECTION C: TECHNICAL EVALUATION</b>	
<b>Identification of Safety Function(s)</b>	
<b>Safety Function(s)</b>	<b>Describe</b>



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<b>SECTION D: CRITICAL CHARACTERISTICS</b>					
<b>Identification and Physical Critical Characteristics</b>					
Identification Attributes	Description of Inspection (e.g., Visual)	Acceptance Criteria	Result	Initial	Date
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
			<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		

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SECTION D: CRITICAL CHARACTERISTICS (CONTINUED)							
Performance/Functional and Dependability Critical Characteristics							
Critical Characteristic	Acceptance Method	Description of Acceptance Activity	Associated Plan	Acceptance Criteria (including tolerances)	Result	Initial	Date
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
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					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		

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<b>SECTION D: CRITICAL CHARACTERISTICS (CONTINUED)</b>							
<b>Performance/Functional and Dependability Critical Characteristics</b>							
Critical Characteristic	Acceptance Method	Description of Acceptance Activity	Associated Plan	Acceptance Criteria (including tolerances)	Result	Initial	Date
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
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					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		



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SECTION D: CRITICAL CHARACTERISTICS (CONTINUED)							
Performance/Functional and Dependability Critical Characteristics							
Critical Characteristic	Acceptance Method	Description of Acceptance Activity	Associated Plan	Acceptance Criteria (including tolerances)	Result	Initial	Date
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
					<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted		
Description of Associated Plan(s) (if "see below" is entered in the Associated Plan column above)							
Description of how verification of selected critical characteristics will provide reasonable assurance Otherwise Acquired Software is capable of supporting the safety function(s)							





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**ATTACHMENT 4 – BGS-QA-28.2, COMMERCIAL GRADE DEDICATION PACKAGE (SAMPLE)**  
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<b>CGD Plan Document No.:</b> BGS-CGD-	<b>CGD Plan Title:</b>		
<b>Author:</b>			
Complete this form as required by BGS-QA-28, Commercial Grade Dedication of Computer Programs and Software Services. Note: This form is not for the dedication of a safety SSC with embedded software.			
<b>RATIONALE FOR CGD EVALUATION RESULT</b>			
<b>CGD EVALUATION RESULT</b>			
<input type="checkbox"/> Accepted <input type="checkbox"/> Not Accepted			
<b>DESCRIPTION OF ANY LIMITATION FOR USE AS SAFETY SOFTWARE</b>			
<b>LIST OF ATTACHMENTS</b>			
<b>CGD PACKAGE REVIEW AND APPROVAL</b>			
<b>Independent Reviewer</b>	<b>Signature:</b>	<b>Date:</b>	
<b>Independent Reviewer (optional)</b>	<b>Signature:</b>	<b>Date:</b>	
<b>Concurrence, Quality Assurance Manager</b>	<b>Signature:</b>	<b>Date:</b>	
<b>Approver, Vice President of Operations</b>	<b>Signature:</b>	<b>Date:</b>	
BGS-QAF-28.2, Rev. 0 (08/16)			