Example Procedure

Evaluation and Acceptance of Commercial Grade Items and Services

Prepared by

Commercial Grade Dedication Subgroup
of the
Engineering Practices Working Group
of the
Energy Facilities Contractor's Group

Note that this procedure was prepared for generic application. To make use of this procedure, organization specific information should be added as well as adaptation of site/project/facility specific job roles and responsibilities.

EVALUATION AND ACCEPTANCE OF COMMERCIAL GRADE ITEMS AND SERVICES

1.0 Objective

The objective of this procedure is to establish the process to be used to perform the technical evaluation of and establish the acceptance methods for commercial grade items (CGI) and commercial grade services (CGS), including software, for applications that require performance of a safety function.

2.0 Scope

Items or services intended for nuclear safety applications may be procured from a supplier with a nuclear quality assurance (QA) program or may be dedicated through a technical evaluation and acceptance process. For the purposes of this procedure, procedural steps described for items apply likewise to services. Acceptance activities specified by this procedure are in addition to normal receipt inspection activities.

The technical evaluation is based on information which establishes the suitability of the item or service, such as seismic qualification reports, calculations, etc. Suitability is established as part of the design process before initiating the technical evaluation.

2.1 The Commercial Grade Dedication (CGD) Process

Commercial grade dedication consists of two processes, a technical evaluation and establishment of acceptance activities.

The need to perform a CGI evaluation may be driven by scenarios such as:

- An item is not available from a nuclear supplier
- An item is readily available that can be dedicated to applications that require performance of a safety function
- Equivalent or better level of acceptability can be achieved by dedication vs. nuclear procurement with significant cost avoidance and/or schedule reduction
- Recovery from a classification change for an item previously purchased or being manufactured as commercial material.

Regardless of the origin, the evaluation is completed per this procedure and the output incorporated into other processes as necessary, such as purchase orders and receipt inspection plans.

2.2 Use of the CGD Process

The CGD process for procuring items or services shall include the following:

- Confirmation that the item or service meets the commercial grade definition criteria
- Technical evaluation, including the identification of critical characteristics (CC) to determine that the item performs a safety function.
- Identification of acceptance criteria for the critical characteristics.

When one or more CCs cannot be verified by the dedication methods this procedure shall not be used to accept the CGI or CGS

3.0 Definitions

The following definitions are integral to the performance of this procedure, or have a unique meaning in this procedure.

Acceptance: The use of methods to produce objective evidence which provide reasonable assurance that a CGI will perform its intended safety function. Acceptance encompasses standard receipt inspection activities and verification of critical characteristics and processes.

Critical Characteristics: Identifiable and measurable attributes of an item which once verified, provide reasonable assurance that the item will perform its intended safety function or processes that would adequately control the items critical characteristics.

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 a nuclear QA program.

Commercial Grade Service: A service that is not provided in accordance with the requirements of a nuclear QA program.

Dedication: An acceptance process performed to provide reasonable assurance that commercial grade item or commercial grade service will successfully perform its intended safety function and is deemed equivalent to an item or services provided under the requirements of a nuclear QA program.

Design Bases: That information which identifies the specific functions to be performed by a structure, system or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be: 1) restraints derived from generally accepted “state-of-the-art” practices for achieving functional goals; or 2) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

Graded Approach: The process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement commensurate with: (1) the relative importance to safety, safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of a facility; (4) the programmatic mission of a facility; (5) the particular characteristics of a facility; (6) the relative importance of a radiological and non-radiological hazards (e.g. public protection, co-located worker protection, facility worker protection, or environmental protection); and (7) any other relevant factor.

Item: An all- inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unity, computer software or consumables.

Objective Evidence: Any documented statement of fact, other information, or record, quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Safety Function: The performance characteristics of an item or service necessary and sufficient to achieve the accident mitigation or accident prevention features credited in the design bases, safety analyses, criticality safety analyses or other safety bases documents.

Suitability: The process of confirming that a certain item configuration has been verified to perform the safety functions from the design basis.

4.0 Responsibilities

The roles and responsibilities of the organizations and personnel involved in the CGD process for the items and services are summarized below. Identification of functional responsibilities is the important aspect of this section. It is recognized that individual organizations may use different titles, etc.

4.1 Procurement Engineer

- Coordinates the technical evaluation and establishes the acceptance requirements described in the procedure. This includes investigating design documents and associated information to sufficiently understand the item applications and functions, significance to design, and consequences and likelihood of failure in order to establish commensurate acceptance requirements.
- Obtains input from subject matter experts (SME), such as the Responsible Engineer, Seismic Qualification Engineer or QA, as necessary, and capture that information in the evaluation.
- Coordinates preparation of the CGD plan
- Coordinates selection of CCs for the item/service and method of documentation.
- Conform the CGI/CGS evaluation to the commercial grade survey results
- Interface with other Project groups and suppliers as required, to determine technical requirements, CCs, acceptance requirements for the items/services to be dedicated.

4.2 Procurement Engineering Manager

- Assign PE(s) qualified to perform the technical evaluation and establish acceptance activities.
- Review and approve CGD plans for accuracy and compliance with this procedure
- Coordinate CGD-related activities/issues with other groups, such as Engineering, QA, Licensing and Procurement.

4.3 Subject Matter Experts (SME)

- Provide input as subject matter expert as necessary
- Concur with the CGD plan, as necessary

5.0 Procedure

Notification to Procurement Engineering to perform a commercial grade evaluation may originate from various activities, such as the need to procure an item, to establish acceptability of an item on site, in stock, or in manufacturing, or to resolve a nonconformance. Wherever the term item is used in this procedure, the same guidance may be used for services.

Research of design basis information may not provide detail to the extent necessary to perform the activities addressed in the procedure. In those cases, the PE consults with the Systems Engineer, other Engineering organizations, or Design Basis as necessary to develop this information, and contains their review of the plan as necessary.

In many cases the procurement scenario evolves during the evaluation, thereby changing the approach. There are usually multiple acceptable approaches to dedication of items and services, and the choice is based on which approach is the most prudent. Changes in the dedication approach do not necessarily indicate the previous approach was inadequate.

The PE performs the following activities and documents the information on Appendix B, “Commercial Grade Dedication Plan.”

5.1 Verification of Commercial Grade Definition Criteria

Review the item or service under consideration to verify it is not being supplied in accordance with nuclear quality program criteria, and that acceptance methods are available to establish its acceptability.

5.2 Developing Item Description or Service Scope

Determine an accurate description of the item or service in sufficient detail to clearly identify the scope of the evaluation. For items, this includes defining the configuration by referencing a drawing/revision, model, detailed description of a commodity item, or other source that allows sufficient basis to accurately perform a technical evaluation and establish acceptance methods.

5.3 Application

State the intended application or scope applications for which the item will be used. Bound the application statements so that the extent of design basis information to be evaluation is clearly identified. State information such as facility system, building or component identification. Commodity items may be designated for plant-wide use after appropriate evaluation.

5.4 Function and Design Basis Investigation

Research the design basis information for the intended application of the item. When a specific application is not identified, bound the applications to develop the most conservative requirements.

Consult sources such as:

- System design criteria
- Failure modes and effects analysis
- Documented safety analyis
- Equipment specifications
- Environmental and seismic data sheets and qualification reports
- Piping and instrumentation diagrams, isometric drawings, etc.
- Supplier developed equipment information
- Industry standards

Discuss the item with SMEs when necessary to obtain further information. For example:

- When item functions are not documented to the level of detail necessary, consult the responsible design organization for input.
- When an item is subject to environmental qualification requirements, consult an environmental qualification engineer.
- When detail description requirements are not available, consult the supplier's technical representative.

Integrate input from the SME into the technical evaluation. When the technical input is substantial, reference that individual or group for explanation and/or document their input with reference to the source on the Commercial Grade Dedication Plan.

State the intended function of the item in the parent component/system by explaining the function of the system, then the component contribution to the system, then the item contribution to the component function.

State the safety functions of the item or for services, state the impact of the service on the safety function of the associated items. Include information on the safety significance of the item such as design margin, etc. It is not necessary to consider failure mechanisms that are not credible. The safety significance establishes the basis for the extent to which the CCs are verified.

Often information is available from document sources at the system and component level only. The dedication plan will contain sufficient explanation to provide the basis for conclusions reached and understanding of how the safety functions were determined. Often facts states are qualitative, so the resulting decisions will be sufficiently conservative to allow for some amount of unknown.

State the references used to determine the application and functional information associated with safety functions.

Failure modes and effects analysis (FMEA) in the technical evaluation may be the basis for documenting that the performance or failure of commercial grade items have no adverse impact on the safety function(s) of equipment, or information supporting the grading or rigor to be applied to the acceptance process. A formalized FMEA process is not required; however, credible failure of the safety function(s) shall be considered and documented in the technical evaluation considering functional classification, design margin, and to form the basis for selection of critical characteristics and acceptance methods. Guidance for conduct of a FMEA as applied to performance of a technical evaluation for CGD can be found in Appendix A.

5.5 Acceptance Plan

The PE selects the CC's considering the following:

- Select sufficient characteristics to establish an appropriate level of confidence in the ability of the item to perform its safety function commensurate with its safety significance
- Select characteristics that indicate acceptability and are verifiable, giving preference to those that are cost effective
- Some characteristics, such as pressure retention, provide direct and indirect assurance of acceptability. Pressure retention directly indicates component assembly integrity but also indirectly indicates material properties such as strength.
- For commodity items such as fasteners in broad applications, generally verification of compliance with governing industry standards is appropriate
- The overall level of assurance obtained is the cumulative effect of the characteristics selected, the method of verification, the sample selected, and tolerances selected
- Seismically sensitive or environmentally qualified items may drive selection of specific characteristics

The PE determines how each critical characteristic will be verified, provides the acceptance criteria, and documents the selected critical characteristics on the CGD plan. The PE may provide a rationale for a characteristic which is not included as part of the critical characteristics for acceptance of the CGI/CGS.

Complete the CGD plan by documenting the critical characteristic and value for acceptance. Adapt the format of the CGD plan section as necessary to enter information such that it can be directly applied by groups performing acceptance activities. Attach tables or sketches as necessary for clarification. Explain the basis for selection when necessary to relate the critical characteristics to the safety function.

Develop acceptance methods for the critical characteristics selected. Provide sufficient detail to perform the activity. The PE selects one of the four methods to verify the critical characteristic(s):

1. Method 1 – Special Tests and Inspections
2. Method 2 – Commercial Grade Survey of Supplier
3. Method 3 – Source Verification
4. Method 4 – Acceptable Supplier/Item Performance Record

The acceptance methods shall provide, either individually or in combination, a means to reasonably ensure that:

- The CGI that is received meets the requirements of the item specified and
- The item(s) in the plant affected by the service will perform their safety functions

The selection of a method, or combination of methods, is based on such factors as:

- Selected critical characteristic
- Available supplier information
- Degree of standardization

The CGD plan may contain more than one set of critical characteristics and/or acceptance methods depending on the procurement scenario. State the basis for the sample plan and the extent of lot homogeneity required.

Sampling forms part of the acceptance process when more than one item is procured. The following guidance stems from EPRI TR-017218-R1, *Guideline for Sampling in the Commercial- Grade Item Acceptance Process.* The EPRI guidance is commonly used in the nuclear industry for establishing effective sampling plans for nondestructive/destructive tests and inspections to support the process of dedicating the item from documenting the technical basis for the sampling plan chosen. The sampling plan and documented basis should be provided in the CGD plan.

Effective sampling plans are selected considering qualitative factors, such as supplier product acceptance history, adequacy of the product manufacturer's production controls and quality checks, lot formation, safety function, product performance, test methodology, production to a national standard, and complexity for the item through sound engineering judgment, rather than just pure statistics.

For a given item reasonable assurance is achieved with a combination of selected critical characteristics and sampling plans.

The establishment of the lot to be sampled is an important consideration when selecting the appropriate sampling plan. The confidence level in lot homogeneity is a factor in determining the degree of sampling necessary. For determining the degree of lot homogeneity, it is important to know the following:

- Are items traceable to a heat, production lot, or batch number?
- Are items identifiable to a single purchase order line item?

- Are items shipped from manufacturer or shipped from distributor's stock?
- Are items traceable to a specific product manufacturer?

5.5.1 Method 1 – Special Tests and Inspections

Special tests and /or inspections shall be performed to verify the selected critical characteristic. For each critical characteristic using Method 1, the PE shall establish specific acceptance criteria including values and acceptance ranges where measurements are performed. When applicable, a specific code or standard is used to determine the appropriate acceptance criteria.

The PE shall document the sources or basis for the acceptance criterion in the CGD plan.

For post-installation testing, establish test responsibility and methods appropriate for the type of test to be performed. For example, component functional tests may be performed effectively in a system start-up procedure or performance verification matrix. The PE obtains review and concurrence from the group responsible for carrying out the post- installation test to confirm accuracy and usability of the requirements.

5.5.2 Method 2 – Commercial Grade Survey of Supplier

Controls implemented by the supplier may be credited with providing reasonable assurance that the item(s) perform its intended safety function(s). Commercial grade survey shall not be used as the basis for accepting items from suppliers with undocumented commercial QA programs or with programs that do not effectively implement the supplier's QA program. If method 2 is used, the PE documents the critical processes to be verified during the survey.

Following completion of the survey, the PE reviews the survey report and determines the extent to which the supplier controls were found adequate, including the adequacy of supplier controls for preparation, approval, and issuance of a Certification of Conformance. The PE then makes final determination of which CCs are to be accepted using the survey and documents the basis on the CGD plan.

5.5.3 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 the identified CCs and acceptance criteria. The scope of the source verifications may include activities such as witnessing the fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections, as applicable. It may 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 CCs.

Source verification documentation provides objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance. Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable

location. Source verification is performed in accordance with a checklist or plan and the objective evidence is documented.

Source verification includes and/or addresses the following:

a. Identification of the item(s) or service(s) included within the scope of the source verification
b. Identification of the CCs, including acceptance criteria, being controlled by the supplier
c. Verification that the supplier's processes and controls are effectively implemented for the identified CCs
d. Identification of the activities witnessed during the source verification and the results obtained
e. Identification of mandatory hold points to verify CCs during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed item
f. Documentation of the adequacy and effectiveness of the supplier's processes and controls associated with the CCs and acceptance criteria

5.5.4 Method 4 – Acceptable Supplier / Item Performance Record

Supplier of item performance history may be used to provide confidence in an item's ability to perform its intended function safely.

- The established historical record is based on industry-wide performance data that are directly applicable to the CC(s) and the intended facility applications (i.e. a single source of information is not adequate to demonstrate satisfactory performance).
- The manufacturer/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity.
- Supplier performance history may not be used as the sole basis for acceptance.

5.6 Revision of a CGD Plan

When it is necessary to revise a CGD plan, the PE states the reason for the revisions, such as:

- Add or delete items included in the plan
- Add an alternate dedication method
- Clarify evaluation basis information

The PE evaluates the impact of the change on items installed, in stock and on open purchase orders.

5.7 CGD Plan Approval

The PE obtains the concurrence and/or review of individuals representing disciplines or organizations providing substantial input to the content or revisions of the evaluation including the RE.

The Procurement Engineering Manager reviews the content of the CGD plan for accuracy and compliance with the procedure and verifies input from appropriate subject matter experts and, when acceptable, signs and dates for approval. The CGD plan is then effective.

6.0 Records

Records generated by this procedure shall be submitted to appropriate Plant/Facility/Project Archives.

APPENDIX A

Guidance on Failure Modes and Effects Analysis as It Applies To Commercial Grade Dedication

DEVELOPING THE TECHNICAL BASIS FOR THE EVALUATION

Prior to stating the activity of determining failure modes, it is necessary to understand the design of the item under evaluation. Commercial grade dedication evaluations may be performed in many situations from commodity type items that may be used in any application in the facility, such as pipe, fasteners, cable and chemical testing, to skid mounted assemblies, including motors, valves and structural components where the application in the facility is well defined.

Engineers assigned to perform the technical evaluation typically have available to them the safety functions of the host systems and/or components at a system/component-level. If not, facility personnel who do understand those functions may be contacted to contribute to the technical evaluation. However, understanding the design of the items under evaluation at a lower configuration level is necessary. Techniques for performing this include:

- Contacting the engineering personnel at the company who manufactures the item
- Researching the codes and standards under which an item is provided
- Reviewing the seismic and environmental qualification reports for the items

As with any aspect of commercial grade dedication, the extent of effort invested in this activity is commensurate with the significance of the item being evaluated. The objective of the research is to understand the development of the product, its assembly techniques, procurement of sub- assemblies and commodities in construction of the item, and supplier processes that control production and testing of the item.

The technical basis includes an element of design margin. For any given item in a certain application or scope of applications, there is an inherent level of design margin which, if removed, would not cause the item to not perform its safety function. Design margin information is often elusive, and an engineer performing the evaluation should develop a qualitative margin understanding, which is often difficult to document accurately. However, with confidence in the understanding of the safety function and system component level of failure, qualitative statement is appropriate when there is conservatively low risk for significant consequences of failure.

SYSTEM, COMPONENT AND ITEM FUNCTION AND INTERACTION

For the safety functions of the host system and/or component under evaluation, determine the credible failure modes associated with the host system/component safety functions. Determining what is credible depends on the technical basis determined above. If the safety function requires a high degree of performance under severe conditions, accuracy or with limited design margin, then there are likely more failure modes that may be considered as credible. Consider both failures of functions which must occur to

support the host system/component safety function as well as improperly performed non-safety functions which would cause a safety function to not occur.

Identifying the credible failure modes at a component or subcomponent level typically involves developing an understanding of the design of the component. As part of a commercial grade dedication technical evaluation, this frequently involves close interaction with manufacturer personnel intimately familiar with the design evolution, failure history and maintenance of the item. Performance of the evaluation usually occurs more expeditiously when input from those personnel is available.

For more complex items, failure mode evaluation begins at a high level statement of the functions that are safety related by major portions of the item. For example, for skid mounted equipment consisting of several components, use a schematic layout of those components to identify the safety functions of each as they relate to the skid functions, considering those non- safety functions, such as protective systems, that could malfunction in a manner to prevent the skin from performing. Supplier manuals which provide theory of operation for the equipment are valuable. Capturing the evaluation on block diagrams with annotated functions and interactions is important for follow up failure effects determination and selection of critical characteristics. Identify where embedded software is a factor in the function of the equipment in order to determine the influence of the controls applied to the development of the software and its installation. For more complex items a multi-discipline team is necessary to effectively perform the evaluation. For less complex items, or as complex items are broken down into their components, a successful approach to failure mode determination is to use a component general arrangement drawing with a bill of material of the parts of construction to successively consider each parts contribution. At the level of the evaluation is where it is important to determine the extent to which the evaluation needs to occur to effectively complete the scope of evaluation. Consider the contribution of the item on the host system/component and decide whether pursuing the evaluation to lowers tiers of the configuration, even to each discrete component is necessary. Recognizing that the outcome of the evaluation is input to the selection of critical characteristics, deciding not to pursue the evaluation to lower levels of configuration likewise determines that lower level item critical characteristics will not be selected.

Note that there are situations where there is limited technical information to use for the above evaluation. Two potions are available, with degrees of success which depend on the complexity of the item and the capabilities of the personnel available to perform the evaluation. One option is to engage the manufacturer personnel to develop the information needed, or an outside party with appropriate skills and background. A second option is to perform the reverse engineering in-house. The second option is most likely effective when there is the necessary skill sets available to dissect the item and understand its design, however frequently is resource intensive.

Values for design margin may be stated in design documents such as seismic analyses, etc. If an equipment qualification test has been performed on the item, failure mode information may be available which can be factored into the evaluation. Consider in review of the report whether examination was performed. Incorporate cause analysis information from the report. Failure modes to consider, depending on the type of equipment, are:

- Loss of power
- Degradation of voltage
- Loss of joint integrity
- Excessive corrosion
- Deformation
- Galling
- Signal interruption
- Excessive chatter
- Improper execution code
- Lubricant deterioration
- Failure to respond as expected to a signal

EFFECTS EVALUATION

Given the results of the failure mode evaluation above, an effects evaluation is dependent upon understanding the following information on the scope of the item and its safety function in the intended application(s):

- The service conditions under which the item will perform
- Redundant items able to perform with independent power sources, etc.
- Design features which provide mitigating actions
- Length of time which the equipment must perform
- Coincident postulated events
- Estimated personnel population subject to consequential effects
- Chemical toxicity or radiological consequences anticipated

For the purpose of determining the extent of the consequences of failure, consider whether effects have local, regional or off-site impact, and whether the consequences are expected to be immediate or delayed. At the component and system level, design basis information establishes the length of time equipment is expected to perform its safety function after design basis event. Consider, for each failure mode, whether the failure constitutes only degradation of the item function or whether there is an effect on the safety function.

Whether or not mitigating actions are designed to occur contributes to the assessment of consequences. For example, failures with moderate consequences but substantial mitigating actions (or possibly redundant systems that will perform the actions), affect final judgment on the establishment of critical characteristics and acceptance methods.

Sophisticated FMEA's performed for reasonable scopes of items or systems in commercial applications may have numerical values established that are associated with range of likelihood and consequences of effects. This result in a ranking that facilitates decisions on rigor to be applied for various failure modes. Generally, a numerical ranking system is not valuable when the item is associated with safety functions

since the consequences of failure are more significant than financial loss. However, whether the function is safety class or safety significant is significant in itself to establish relative importance.

APPENDIX B

COMMERCIAL GRADE DEDICATION PLAN
No. _____ Revision _____

Prepared by: _____ Date: _____
Subject Matter Expert: _____ Date: _____
Approved By: _____ Date: _____

SCOPE OF EVALUATION

ITEM	DESCRIPTION

APPLICATIONS

_____
_____
_____
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_____

ITEM DESIGN FUNCTIONS

_____
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ITEM SAFETY FUNCTIONS, SERVICE CONDITIONS AND SAFETY SIGNIFICANCE
_____ _____ _____ _____ _____ _____ _____

BASIS AND REFERENCES
_____ _____ _____ _____ _____ _____ _____ _____

ACCEPTANCE REQUIREMENTS

DIMENSIONS

ATTRIBUTE	VALUE	ACCEPTANCE RANGE	SAMPLE

MATERIAL/PHYSICAL PROPERTIES

ATTRIBUTE	VALUE	ACCEPTANCE RANGE	SAMPLE

ELECTRICAL/MECHANICAL PERFORMANCE CRITERIA

ATTRIBUTE	VALUE	ACCEPTANCE RANGE	SAMPLE

CONFIGURATION

_____
_____
_____
_____
_____
_____

EVALUATION AND ACCEPTANCE OF COMMERCIAL GRADE ITEMS AND SERVICES

OTHER

_____
_____
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_____

BASIS FOR SELECTION

_____
_____
_____
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_____

ACCEPTANCE METHODS

SPECIAL TESTS AND INSPECTIONS

ATTRIBUTE	METHOD

COMMERCIAL GRADE SURVEY OF SUPPLIER

ATTRIBUTES:

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_____
_____

EVALUATION AND ACCEPTANCE OF COMMERCIAL GRADE ITEMS AND SERVICES

SOURCE VERIFICATION

ATTRIBUTES:

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SUPPLIER/ITEM PERFORMANCE RECORD

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SAMPLE PLAN BASIS:

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REVISION EVALUATION

REASON FOR REVISION:

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IMPACT ON ITEMS INSTALLED:_____
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IMPACT ON ITEMS IN STOCK:

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IMPACT ON ITEMS ON ORDER:

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