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Guide:

Effective Supplier Nuclear QA Practices

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Appendices

1.0 Purpose

The purpose of this Guide is to provide the Hanford Tank Waste Treatment and Immobilization Plant (WTP) project (The Project) supply chain with relevant information and assistance in implementing an effective nuclear quality assurance program that meets WTP requirements. This Guide is intended to be used by primary supply chain functions, to include supplier's general management, contract administration, engineering, procurement, production, and quality assurance. This Guide is intended as an aid and is not considered a change to an existing or a future subcontract or purchase order. It is neither a requirements document nor an exclusive authoritative source. Use of this guidance is at the supplier's option and discretion.

This Guide provides current information and significant Project lessons learned through interaction with the Project supply chain, including frequently asked questions (FAQs) and good practice examples on the subject of nuclear quality assurance. The topics addressed in this Guide are generally ordered in the sequence of occurrence, although no order of precedence is intended.

2.0 Background

The Project is a complex of radioactive waste treatment processing facilities designed and constructed by Bechtel National, Inc. (BNI) for the US Department of Energy (DOE). The facility will process the Hanford Site liquid radioactive waste into a stable glass form. The processed waste will be shipped to other sites for ultimate disposal. Hanford tank waste consists of approximately 190 million curies in 54 million gallons of highly radioactive and mixed hazardous waste stored in underground storage tanks at the Hanford Site. The tank waste includes solids (sludge), liquids (supernatant), and salt cake (dried salts that will dissolve in water, forming supernatant). The facility will remediate, process, and store the radioactive and hazardous tank waste to meet regulatory requirements.

The DOE Office of River Protection (ORP) in Richland, Washington, is responsible for the activities necessary to remediate the Hanford tank waste. Through the WTP Prime Contract, BNI manages and oversees the design, construction, and commissioning of the WTP Site. WTP consists of the following five major facilities:

- High-Level Waste (HLW)
- Low-Activity Waste (LAW)
- Pretreatment Facility (PT Facility)
- Analytical Laboratory (Lab)
- Balance of Facilities (BOF)

The Project Authorization Basis requires that items performing a safety function during plant operations meet ASME NQA-1, Quality Assurance Requirements for Nuclear Facilities. NQA-1 does not provide details on implementation or what may be evaluated to ensure implementation; it provides high-level process requirements from which effective nuclear QA programs are based. The Project establishes technical requirements through general specifications, equipment

specifications, technical supply conditions, Equipment Data Sheets, referenced codes and standards, and specific purchase order or subcontract statements.

3.0 Order Entry

3.1 Supplier Process

3.1.1 Good Practice

The key to effective incorporation of technical requirements is the supplier process for "Order Entry." The following describes an effective review process for suppliers to use for each contract received, including each subsequent revision:

- Assign a designated individual to "own" the contract, or group of contracts, organized by the customer
- Create an established meeting agenda for contract review with mandatory participation from each supplier organization, engineering, and purchasing/production/quality control personnel.
- Hold a roundtable discussion or page turn of the contract to identify work scope and impact of changes for each department, interface points, and actions.
- Use a tool, such as a contract execution checklist, to ensure that these impacts are acted upon and closed.
- Evaluate each contract change for impact on items previously processed, items in process, and future work in the scope of the contract.
- Have the "owner" concur that all actions are closed on the checklist.

Maintain a record that documents the above actions, including the background to explain how the contract requirements are met.

3.1.2 Lessons Learned

Frequently, suppliers closely review contract changes for commercial impact, but not as thoroughly for consideration of impact on changes to the product. NQA-1 requirements for the QA program and organization discuss the need for process controls for inter-organizational activities and external interface controls. An effective order entry process accomplishes two goals. First, the supplier absorbs the content of the contract in the page turn meeting with key department personnel. Second, interfaces between supplier departments are established and responsibilities assigned for applicable activities. The Project contracts contain a broad spectrum of requirements that require careful consideration by technically knowledgeable personnel. Consider the level of process controls applied to order entry, based on the size and complexity of the organization and the contract.

3.1.3 FAQs

1. Q: Supplier: I have contract changes reviewed only by QA for impact on nuclear work. Why isn't this adequate?

A: It is each organization's responsibility to understand contract requirements and how specific changes affect them. As the performer of the work, they are responsible for its conduct and recognize the implications of any given change. Therefore, a review by QA does not suffice for the knowledge other departments have of their processes when they perform a review.

2. Q: Should the same group that reviewed the original contract review contract amendments or revisions?

   A: Not necessarily. For example, if a contract revision is received containing new pricing data, reviews could be limited to personnel on a need-to-know basis. Conversely, contract revisions containing new technical and/or quality requirements are reviewed by the organizations affected by these changes (e.g., engineering, QA).

4.0 Design

4.1 Equipment Suitability for Service

4.1.1 Good Practice

When the Project contract includes design responsibility in the supplier's scope of work, it is expected that the supplier has or develops the technical basis for establishing the functional ability of the item to perform its safety functions. This technical basis may be established by test, analysis, and/or operational experience. Technical justifications made by the supplier need to be documented; many may be contract required submittals. The Project contracts (e.g., Equipment Data Sheets and specifications) state the equipment service conditions (e.g., temperature, seismic, pH), safety functions, and performance expectations. Confirm that this information is available or establish an action to develop the basis during the order entry process. Ensure the technical basis is available by reference to the following:

- Specific qualification test that envelopes the Project functional requirements and service conditions
- Calculation or analysis that envelopes the Project functional requirements and service conditions
- Demonstrated performance history with tangible evidence of satisfactory performance

Include the service conditions in which the safety function is to perform. This is often the problem with using performance history. Ensure the Project safety functions perform either during or after a seismic event. Most performance data is not based on equipment that has seen these conditions. The supplier confirms that the suitability basis information addresses each of the chemical, radiation, temperature, and pressure conditions.

Suitability information is subject to design controls stated in NQA-1, such as preparation by a qualified individual, (i.e., an engineer), then undergoes an independent review, and finally approval. Maintain records of this activity to support the acceptability of the item. The records are subject to revision pending changes to technical requirements.

4.1.2 FAQs

1. Q: Our company provides a standard ANSI model pump. The Project contract invokes design control requirements, and the Equipment Data Sheet states that the system fluid consists of a waste sludge of certain acidity and solid content.

   Should we assume that since the Project specified that pump by model number and material that the Project established that the pump is acceptable for this application?

   A: No. The Project contract includes responsibility for design controls as stated in NQA-1, requirement criteria 3 and has submittal requirements for engineering analyses. These analyses are expected to address the service conditions stated on the Equipment Data Sheet and demonstrate adequacy of the materials of construction with the sludge and the ability to meet the performance conditions stated. This includes evaluation for degradation of seal and liner material in the temperature and radiation exposure expected. Ensure the submittal includes the technical basis for the adequacy, such as tests or analyses performed under the supplier's QA program, or evidence of historical performance under those conditions. When a model number is in the contract, and suitability cannot be established, the supplier is expected to communicate this information to the Project and propose an alternate.

2. Q: Our company provides a standard ANSI model pump. The Project contract does not invoke design controls or statement of service conditions. We assume that since the Project specified the pump by model number and material that the Project established that the pump is acceptable for this application. Is this correct?

   A: Yes, in this case the Project contract does not include design controls, and the Project is responsible for establishing suitability for the application.

4.2 Equipment Qualification Testing

4.2.1 Good Practice

Equipment qualification is a general reference to the engineering activities associated with establishing a basis for the item's ability to perform its safety function after a design basis event. One means of doing this is by testing an item after subjecting it to its actual or simulated operating conditions. It is important for a supplier performing safety-related work on the Project to have knowledge of seismic and environmental test practices, even if the actual testing is subcontracted. This knowledge is necessary so the supplier can identify and evaluate changes to the item, manufacturing nonconformances, or engineering programs.

4.3 Configuration Control

4.3.1 Good Practice

Engineering programs for items subject to equipment qualification include the following steps:

1. Identify candidate items for qualification
2. Capture the configuration of the items as qualified
3. Identify changes to items subsequent to qualification
4. Evaluate each change for impact on the qualification
5. Re-qualification when necessary

Good supplier practices for management of qualified configuration include the following:

1. A documented process includes the following:

    - Document the mechanical and chemical material properties of items in the assembly that contribute to the Q function. This typically takes the form of a bill of material.
    - Document the methods for assembly of the items into a component. This may be welding techniques, torque instructions, fit up criteria, adjustment requirements, shielding, or sealing provisions, etc.
    - Document the mounting requirements of the component to the host skid or system. This is usually part of the information on a general arrangement drawing.
    - Document the controls over purchased items installed in the qualified component for information, the same as those listed in the previous bullets.

Submittal of this information is included in the purchase order to the sub-supplier, along with controls on the information and a requirement for the process to be modified if changes occur to the item.

2. The supplier follows a documented engineering process for evaluating changes to the above information or items qualified. An effective engineering change control process results in documentation of the following:

    - The initial configuration, mounting, assembly, interface, etc.
    - The changed configuration, mounting, assembly, interface, etc.
    - The host safety functions to which the item contributes
    - The impact of the change on the potentially affected safety function, supported by the analytical, operational, or test basis for the impact determination.
    - Evaluation prepared, and reviewer and approver signature by personnel with knowledge of the subject items performance.

4.3.2 Lessons Learned

1. Supplier programs may not effectively capture the information listed above that affects the equipment qualification. For example, component bills of material may list purchased parts by a model or part number, without establishing controls on the configuration of the item to document the item material, dimensions, etc., to ensure equivalency.
2. Fabrication inspection steps, receipt inspection, or sub-supplier qualification requirements do not effectively state the technical information above to facilitate identification of changes subject to evaluation for impact on qualification.
3. Personnel evaluating changes or nonconformances are not sufficiently knowledgeable in evaluation techniques or the threshold for requalification.

4.3.3 FAQs

1. Q: As an alternative to establishing configuration controls that include detection and technical evaluation of changes to qualified configurations, is it acceptable to supply the quality required for identically produced items and perform a qualification test on one of the items to establish acceptability of the lot?

   A: Maybe. That is an acceptable approach if the associated manufacturing and procurement controls are in place to establish that all items in the lot are the same. Supplier ensures these quality program controls are sufficiently rigorous with regard to the technical issues listed above so there is a high degree of confidence in the similarity of the lot.

4.4 Safety Function Evaluation

4.4.1 Good Practice

WTP identifies the safety function and service conditions for safety class, safety significant, or air permit equipment and indicates whether the supplier has design responsibility on an Equipment Data Sheet. The supplier determines which parts of the equipment, and associated services contribute to the safety function during the order entry process. The supplier considers the equipment design, whether it has safety class, safety significant, or air permit significance, and how each item in the assembly contributes to the host component safety function. This evaluation is documented in accordance with the engineering procedure to determine the extent to which NQA-1 QA program criteria apply.

4.4.2 Lessons Learned

A supplier's program that does not distinguish between those items in an assembly that have a Q function and those that do not often warrants a closer investigation. The safety function evaluation activity is a key aspect of a nuclear culture. If not performed well, it may indicate that other program attributes may be weak.

4.4.3 FAQs

1. Q: In lieu of performing a technical evaluation (including safety classification) for each part, may a supplier categorize all items as "safety related" and treat them accordingly via the QA program. Is this effective?

   A: Sometimes, however in the past this methodology has led to significant problems for suppliers when acceptance activities need to be planned for parts of assemblies that do not have a safety function. While the safety function evaluation at the part level causes additional resources to be applied, it is an investment with a high payback in avoidance of future unnecessary work. In addition, the part level evaluation often drives re-consideration, resulting in more effective assembly level activities.

4.5 Use of Software in Design Processes

4.5.1 Good Practice

When a supplier has design and analysis responsibility for a system, structure, or component (SSC) that contributes to the safety function of the WTP, the supplier is expected to implement software management processes. A good practice is to confirm software requirements during the order entry process. Appendix A provides guidance on software use.

4.6 Technical Evaluation of Commercial Grade Items/Services

4.6.1 Good Practice

In general, the supplier ensures personnel who perform the technical evaluation for commercial grade dedication (CGD) have the following skill set mix:

- 50 % Design Engineering – Safety Basis/Licensing and equipment qualification experience
- 30 % Nuclear QA – Lead Auditor experience
- 20 % Commercial – Contract terms and conditions negotiation experience

4.6.2 Lessons Learned

The ability to effectively perform CGD requires technically knowledgeable personnel with sufficient experience in safety classification, equipment qualification design, manufacturing processes, and QA to be able to establish appropriate acceptance methods, including evaluation of commercial suppliers' QA programs. Historically, suppliers who attempt to perform this activity without experienced personnel are not successful.

An effective technical evaluation requires consideration of several issues, such as:

- The host system and/or component safety function
- The contribution of the item safety function to the host system or component
- The safety significance of the functions
- The failure modes of the item and the effects of credible failures. In considering failure modes, it is important to keep in mind that the Project service conditions under which the safety function performs may be different from those under which the supplier's product normally performs. The engineering procedures for performing the technical evaluation include this distinction. See Appendix B for further guidance.
- The design margin for the item considering the Project's service conditions. Design margin information may be quantitative with specific references to calculations or test results or may be qualitative based on history of use, etc.
- An effective approach to selection of critical characteristics is to initially consider those acceptance activities that the supplier routinely performs. Often, these provide some level of assurance that the item is capable of performing its safety function. Adjustments to those acceptance activities may need to be performed for specific tolerances, lot establishment, sample size, etc.

4.6.3 FAQs

1. Q: What are the qualification requirements for personnel performing technical evaluations?

   A: Qualifications are based on the complexity, nature, and end use of the item being evaluated, and they are defined in the supplier's QA program. Experience has shown that suppliers who assign performance of the technical evaluation to personnel unfamiliar with the dedication activity have a low likelihood of performing the activity cost effectively and accurately. If this experience is not available in the organization, consider obtaining subcontracted assistance. As with any other activity that affects the performance of the item's safety function, the suppliers' quality program is expected to address the qualifications required to perform the task.

2. Q: Are suppliers of commodity items (e.g., fasteners, weld filler material, lubricants, etc.) who do not know the end use of the item, required to perform the technical evaluations outlined above?

   A: Not necessarily. The Project contract for these items may or may not include the responsibility to perform the technical evaluation. The supplier is encouraged to clarify this issue at the time of quotation.

5.0 Purchasing

5.1 Preparation and Issuance/Control of Purchase Orders

5.1.1 Good Practice

Procurement requirements are most effectively established by the organization that understands the Project contract requirements and designs the equipment. This responsibility includes establishing acceptance requirements associated with the item's safety functions.

Supplier procurement processes consider two questions before procurement of any item or service.

1. Does the item contribute to the Q function of the component or, if a service, does the service being performed affect the Q function, such as machining, nondestructive examination (NDE), design or welding? If so, the supplier ensures the contract is developed under the supplier's nuclear QA program.
2. Is the item or service being purchased under a contract that invokes a nuclear QA program, such as NQA-1 or ASME Section III? If not, the supplier ensures the item or service is processed under the supplier's CGD program.

It is especially effective for engineering to establish associated quality program requirements related to the safety functions. This practice is consistent with NQA-1 criteria 4 for procurement documents to be reviewed by personnel knowledgeable in the requirements for the items being purchased. Several Electric Power Research Institute (EPRI) guidelines provide valuable guidance on this subject.

5.1.2 Lessons Learned

Too often, development of procurement requirements is assigned to non-technical personnel not familiar with the safety significance, qualification, and quality requirements of the Project contract. This has led to later discovery of latent issues that cause a significant recovery effort. Accurate procurement requirements are critical to maintain qualification, especially with seismically sensitive and environmentally qualified items.

5.2 Use of Purchased Software/Freeware

5.2.1 Good Practice

The supplier's procurement and engineering processes includes evaluation of each procured scope of work. This is done to determine whether software is directly or indirectly included in the deliverable, or if it contributes to the performance of the safety function of the item (see Appendix A).

5.3 Qualification of Nuclear Suppliers

5.3.1 Good Practice

1. Audits of nuclear suppliers are most effectively performed by a team led by a certified lead auditor (as required by NQA-1) and composed of subject matter experts (SME) in design and procurement engineering, equipment qualification, welding, and development and/or based on the complexity of the product and scope of work proposed to the supplier. The lead auditor provides the leadership and organizational skills to perform a comprehensive evaluation, whereby the SMEs provide the subject matter knowledge to be able to judge whether the content of the work performed meets requirements.
2. Audits are not performed using standard checklists; instead, checklists are developed for each contract considering the safety function and critical characteristics of the items/services purchased.
3. Industry audit sharing groups, such as the NIAC, provide audit reports performed by member companies. The quality and content of these audits could provide useful input for qualification of suppliers, and are treated as such:

    - If the scope of the activities evaluated matches or is related to the scope of interest.
    - The objective evidence reviewed is sufficiently dedicated to evaluate the program implementation.
    - Thorough technical evaluation of the supplier's work was performed to allow identification of weakness and effective follow up conclusive action.
    - The program accepting the reports, recognizes the use of this information, and the organization has a method for meeting the qualification and training requirements outlined in NQA-1.

5.3.2 Lessons Learned

Sharing of supplier qualification information can be both a tool for improving supplier performance and cost effectiveness. This is contingent upon the organization using the information to establish suitability for use. Weaknesses have been observed in suppliers who simply obtain an audit report recently performed and endorse it, without review, as a basis for qualification.

A frequently observed weakness is the situation where a supplier subcontracts an activity that the supplier is not capable of performing with available resources. This often presents the case where the supplier may not have the knowledge in-house to evaluate the sub-supplier's activities, which leads to lack of oversight. In this situation, the supplier recognizes the lack of knowledge and either makes alternative arrangements for the knowledge (i.e., on a contract basis) or notifies the Project.

5.3.3 FAQs

1. Q: Can an audit be performed by a one-man team?

   A: Historically, significant problems have occurred in the nuclear power and DOE nuclear facilities because of audit team size (too small) and a lack of SMEs. It is important to recognize that an audit is a sample of the supplier's process implementation, and it establishes a basis for acceptance of work performed over a certain period. Therefore, supplier makes sure appropriate resources are used.

   Generally speaking, a multi-disciplined team performs audits where personnel knowledgeable in the technical requirements of the contract are able to make value judgments on the activities observed.

2. Q: Are commercial grade surveys considered audits under NQA-1?

   A: No. Reference EPRI Technical Report TN 102260.

3. Q: Does NQA-1 require personnel performing or leading commercial grade surveys to be an auditor and/or lead auditor?

   A: No. A CGD is an engineering activity, and it is important that personnel performing surveys understand the safety function and critical characteristics to be able to judge whether implementation is effective for dedication of the item.

4. Q: If the answer to question 3 is "no," what are the qualification requirements for personnel performing or leading commercial grade surveys?

   A: The supplier ensures survey personnel demonstrate proficiency in performance of the task, just as they would for any other activity affecting the safety function of an item. Personnel performing the survey are knowledgeable in the activity being evaluated to have the ability to assess effectiveness.

5.4 Dedication of Commercial Grade Items and Services

5.4.1 Good Practice

Suppliers with an effective CGD program understand and implement the other topics in this Guide, especially:

- Section 3.0 - Design
- Section 4.0 - Purchasing
- Section 6.0 - Organizational nuclear-specific knowledge

5.4.2 Lessons Learned

1. Supplier dedication programs that result in selection of critical characteristics that represent a token indication that the item received is the item ordered are not providing a meaningful level of assurance that the item will perform it's assigned safety function. Examples of token indicators are:

   - Part number
   - Nominal dimensions
   - Positive material identification of material chemistry

2. A dedication process that results in selection of critical characteristics without a technical evaluation of the safety function and safety significance of the item or service is generally inaccurate, resulting in performance of unimportant acceptance activities and likely missing the appropriate characteristics associated with the safety function.

5.4.3 FAQs

1. Q: I have items in stock dedicated for a previous contract. Since they are already dedicated, can I use them on the WTP contract?

   A: Items are dedicated considering certain safety functions, which are based on the design requirements of the intended application. When changing the application, for a different contract, review the initial technical evaluation that dedicated the item to confirm that the design requirements of the new application are bounded.

2. Q: Why is it necessary to focus on acceptance activities to demonstrate ability to perform a safety function when our products are used in many industries with a high degree of reliability?

   A: At a nuclear facility, design basis commitments are made to protect workers and the public in certain design basis events. The service conditions during these events are often different from normal service conditions.

   After a design basis event, supplier ensures the equipment performs without repair or maintenance for a defined period. In normal commercial applications, equipment failures are expected, and they simply cause performance of a maintenance activity to bring the equipment back into service. This is expected periodically and not reported as an unexpected equipment failure

   The consequences of a failure to perform a safety function during or after a design basis event may result in human injury, potentially on a large scale. Typical failures in commercial applications only have financial consequences.

6.0 Document Control

6.1 Control of Documents Subject to Approval by the Project

6.1.1 Good Practice

Project contract requirements include the submittal of design documents for approval.

1. An effective supplier program includes steps for the supplier to review the documents (e.g., special process procedures, dedication documents, etc.) before submittal to the Project to confirm the contract-specific requirements are incorporated.

2. The document control process prevents the use of documents until Project approval is received. The contract with sub-suppliers contains these requirements.

6.2 Review of Documents Submitted from Sub-Suppliers

6.2.1 Good Practice

The Project's contract includes deliverables subject to review and approval by the Project. When sub-suppliers develop these submittals, it is expected that the supplier review the submittal first before submitting to the Project. If the supplier does not have the capability to review the sub-supplier submittals, this exception is identified at the time of quotation. The supplier has a procedure for submittal reviews to ensure technical review and tracking/closure of comments.

6.2.2 Lessons Learned

The Project has observed several situations where suppliers simply pass on sub-supplier deliverables without performing a review. It is important for the supplier to realize that completing contract activities and subsequently certifying that their quality program has ensured compliance with the contract includes subcontracted activities. When the Project reviews a sub-supplier submittal and has comments, the supplier incorporates lessons learned from having missed the deficiency into the next submittal review.

7.0 Organizational Nuclear-Specific Knowledge

7.1 Safety Class, Safety Significant Classifications

7.1.1 Good Practice

A variety of procurement strategies is usually available for any given scope of work. Development of procurement strategy options is an engineering activity that starts with a concise statement of the technical scope of work, then a statement of QA Program requirements that led to that scope of work, and acceptance activities to be performed by the purchaser. Nuclear procurement or CGD options are available for most items.

Prudent business decisions on selecting the best procurement strategy consider the total cost of purchase and acceptance activities.

Suppliers who have the Project (including design responsibilities) contracts for safety-related items are provided information on the safety classification of items and services. Items are designated, generally on Equipment Data Sheets, as safety class, safety significant, or air permit. The intent is for a supplier to use this information to develop technical and quality program activities commensurate with the safety classification. To do this, supplier ensures supplier-engineering personnel are knowledgeable on the background and significance of the classifications. Suppliers who effectively make and appropriately document these judgments are able to focus resources on those areas most critical to the function of the equipment ordered.

Engineering personnel perform the evaluations, which are subject to the controls of NQA-1 criteria 3 for independent review and approval.

7.1.2 FAQs

1. Q: My contract with the Project includes design responsibility and Equipment Data Sheets, but the engineers have had no exposure or training to distinctions in safety classification. Does the Project provide this training?

   A: No. In this situation, you would identify the situation in your corrective action system to evaluate work performed and in process. In future quotations to the Project identify this and any other area(s) where you do not have the capability to meet contract requirements.

7.2 Seismic/Environmental Qualification

7.2.1 Good Practice

Environmental and seismic qualification involves incorporation of certain activities and controls normally expected for work not involving qualification into several QA program processes. Qualification essentially requires accomplishing the following two tasks:

1. Demonstration that a specific item configuration is capable of performing its safety function under service conditions on the Project EQ Data Sheet.
2. Maintenance of that qualified configuration through fabrication.

Key QA program processes to support are as follows:

- Engineering personnel with demonstrated proficiency in qualification
- Drawings or other documents that capture materials of construction, assembly methods, mounting, etc.
- Accurate flow down of qualification information to sub-suppliers
- Effective sub-supplier oversight for configuration control
- Rigorous nonconformance detection and disposition

Supplier ensures personnel are experienced in recognizing and implementing these process requirements.

7.3 Procurement Strategy Development

7.3.1 Good Practice

Suppliers recognize that subcontracting activities to an approved nuclear supplier does not necessarily ensure that the item or service provided meets the Project requirements.

It is important to understand the scope of work assigned to the potential supplier. If suitability is the sub-supplier's responsibility, supplier considers this in the evaluation of the sub-supplier's QA program. Supplier ensures the sub-supplier has knowledge of nuclear safety function and qualification requirements. If a sub-supplier is responsible for performing the technical evaluation for CGD, ensure they have knowledge of the safety function.

Important processes that support these activities are the development of an accurate purchase order and an effective supplier program evaluation.

7.3.2 Lessons Learned

An ineffective practice for subcontracting equipment qualification is for the supplier to send the Project contract to the sub-supplier and rely on the sub-supplier to determine what applies to the qualification of the item. This often leads to inadequate qualification. The supplier ensures an accurate set of technical and quality requirements are developed directly applicable to that scope of work, to avoid technical errors in the qualification expectations and reporting.

8.0 Work Control

8.1 Use of Production Travelers

8.1.1 Good Practice

Production travelers provide a tool to communicate detailed fabrication steps to shop personnel. The most effective travelers include the following information:

1. Identification of the item being produced with reference to a drawing and revision
2. The raw material item and manufacturing steps
3. The acceptance criteria for each dimension or activity on the traveler
4. Reference to controlling documents and procedures for performing each activity
5. Inspection and examination points
6. A mechanism to indicate completion of a step

9.0 Special Process Control

9.1 Special Process Requirements

9.1.1 Good Practice

Special processes are the complex fabrications/examinations that are largely dependent on process controls and/or the skill of the operator. The quality of the end product cannot be easily determined by non-invasive inspections or tests. The following are examples of special processes:

1. Welding (with or without filler material)
2. Heat treatment including but not limited to annealing and hardening of base materials, and post weld heat treatment
3. Brazing
4. Soldering
5. NDE

Special processes require administrative controls (e.g., procedures and checklists) that address the critical elements of the process. Some procedures require qualification before their use. This demonstrates that the process steps provide the capability to accept a task (e.g., welding procedures [NDE], as well as brazing and soldering) to ensure acceptable results.

Personnel who perform special processes such as welding and NDE generally are required to demonstrate capability to perform the process before performance on the Project contract.

The qualifications for welding of structural items and pressure vessels are specified in American Welding Society codes.

NDE personnel qualification and NDE personnel re-qualification are necessary.

The following are common examples of suppler problems that occur with special processes:

1. Failure to recognize that an activity is a special process. For example, some forms of heat treatment (e.g., solution annealing and post weld heat treatment) affect the properties (e.g., ductility, corrosion resistance) of the material and are thus classified as special processes; conversely, preheating base material in preparation for welding does not adversely affect the material properties and is not considered a special process.

2. Failure to recognize which special processes require personnel and procedure qualification.

For example, supplier confirms special processes are performed in accordance with a documented procedure; however, certain processes (e.g., penetrant examination, magnetic particle examination, welding, brazing, hot bending, chemical cleaning, and post weld heat treatment) require that the procedure be qualified to demonstrate the capability of the process.

The Project has discovered less prescriptive practices in the areas of electrical and control assemblies where there is no standard governing qualification for special processes. In these situations, suppliers are expected to consider the contribution of the special process fabrication steps on the component's safety function to determine if special process controls in NQA-1 criteria apply.

10.0 Material Traceability

10.1 Material Identification Identified to Installed Location

10.1.1 Good Practice

The intent of material traceability is to establish a link (e.g., by marking or tagging, etc.) between the supplied item and the records establishing the acceptability of the item. For assemblies, a production traveler-type system may effectively identify the sub assembly identification and the records for those items. It is important to distinguish between commercial/non-acceptance based records and the records used to establish acceptability.

10.2 Lessons Learned

Care is exercised to control material identification to maintain traceability to the acceptance records (i.e., by serial number, purchase order item number and associated test record, etc.). Traceability does not consist of just demonstrating that all material received is acceptable without identification to the records. When acceptance activities involve sampling, and the lot considered for sampling involves reliance on a supplier's traceability system, it is necessary to provide a sound basis for the lot establishment. This often means surveying a sub-supplier's program to determine if traceability has been maintained.

11.0 Inspection And Test Control

11.1 Inspection and Test Planning

11.1.1 Good Practice

Inspections and tests are planned by Engineering to provide reasonable assurance that design requirements are met. Acceptance criteria are established depending on the required host system or component performance requirements. Where routine inspections and tests are used to establish acceptability for a safety function, processes include verification that those normal inspections and tests envelop the item service conditions for the safety function.

11.1.2 Lessons Learned

Personnel not familiar with requirements unique to nuclear safety function are susceptible to assuming that routine inspections and tests automatically provide assurance that nuclear requirements are met. Engineering procedures include steps to confirm applicability as part of the design process.

12.0 Evaluation of Nonconforming Items

12.1 Identification of Nonconforming Conditions

12.1.1 Good Practice

A key component of a QA program is the process for identifying, documenting, and dispositioning nonconforming items thus precluding their shipment or use. Some companies limit the nonconformance process to hardware items (e.g., valves, bolts, coatings, circuit breakers) and rely of other management tools (e.g., corrective action program) to evaluate nonconforming process (e.g., training deficiencies, inadequate design analysis, failure to follow procedures).

An effective quality program addresses the following items relative to nonconformances:

- Identify the individual responsible for identifying nonconformances.
- Identify the method for detecting and segregating the nonconforming item or process, including tagging, labeling, and segregating it from other items to prevent its potential use.
- Identify the individual responsible for dispositioning the nonconformance, which may include the engineer, quality personnel, shop personnel, and/or the customer.
- Identify the individual responsible for implementing the approved disposition, including, rework, reconditioning, re-inspection, and acceptance or rejection.
- Identify the individual responsible for scrapping items, which cannot be repaired or reworked.

12.1.2 Lessons Learned

The following are common problems associated with the nonconformance process:

- Failure to define the term “nonconformance” and its application (e.g., hardware)
- Failure of management and shop personnel to recognize hardware problems as nonconformances
- Failure of shop personnel to document nonconformances
- Failure to segregate nonconforming items
- Inadequate process for dispositioning nonconforming items. Effective disposition consists of evaluation by personnel technically knowledgeable in the safety function

of the item to determine the impact of the nonconforming condition on the safety function.

- Disposition basis, rework and repairs of nonconforming items not adequately documented
- Failure to perform trend analysis to recognize the recurrence of the same problem(s) over time

12.1.3 FAQs

1. Q: Is an engineering evaluation of all nonconformances necessary?

   A: No, the level of approval depends on the nature of the problem. For example, a drawing specifies a 1/2-in. intermittent fillet weld on a piece of structural steel, subsequent inspection identifies that the weld is undersized by approximately 1/16 in. for 50 % of its length. In this case, the inspector documents the problem. Additionally, the foreman may require the additional deposition of weld filler material to restore the weld to its intended design condition, thus increasing the size of the fillet weld. Conversely, if the incorrect filler material was used (e.g., E6010 vs. E7018), a formal engineering evaluation would be required due to the different mechanical properties of the filler material to justify use as is. Alternatively, the foreman could authorize scrapping of the item and replacement.

2. Q: Is a trending program required?

   A: Yes. The supplier's processes include a periodic review of hardware and program deficiencies to determine whether issues identified are isolated occurrences or systemic.

3. Q: Do all nonconformances require a root cause evaluation?

   A: Generally, no. However, all nonconformances are evaluated to determine whether a root cause evaluation is justified.

4. Q: Is the nonconformance program a part of the corrective action program?

   A: Yes. Most companies use the nonconformance program to document and disposition hardware issues. However, serious problems such as violation of design requirements may require in-depth investigations, including extent of condition and cause analysis. Typically, these types of investigations are cross cutting, involve a multitude of individuals, and involve using v the corrective action process.

   In these cases, the QA program needs to provide adequate linkage between the nonconformance and the corrective actions process

13.0 Development of Corrective Actions

13.1 Identifying Cause and Extent of Condition

13.1.1 Good Practice

Conditions that arise due to failures, malfunctions, deficiencies, defective items, and nonconformances require actions to correct the problematic condition. These conditions fail to meet specified requirements in work processes and in contractual requirements. A plan that is graded to the significance of the condition is developed.

Note that a significant condition could have a serious effect on safety of equipment, personnel, or operability of equipment and processes.

To develop a good corrective action plan, the supplier determines the reason the unwanted condition or event occurred and the extent of the condition. The content of the plan and the effort involved in identifying the cause are dependent on the significance of and risk of recurrence of the condition. Identifying the most probable cause that explains why the event occurred and where local control of a fix is identified, may be adequate in most cases. However, a more rigorous, in-depth cause analysis may be required for issues that are more significant.

Cause analysis tools and methods are available through industry references.

Supplier makes certain an investigation of the depth of the conditions is performed during or before the cause. The extent of the condition includes pervasiveness, consequences, and broader ramifications to the programmatic aspects. Some questions to ask include the following:

- How many times did or does this occur?
- How often did or does this occur?
- What does this unwanted condition effect downstream?
- Are there similar conditions in a similar or different process at the facility where this occurs or could occur?

Extent of the condition identifies the degree to which the cause has resulted in other areas, additional weaknesses, and broader implications of an issue. Extent evaluations contribute to more accurate identification of underlying issues.

Once the cause and extent of the condition are identified, develop the actions to correct the issue, problem, or condition. Identify remedial (immediate, quick fix) actions. Additional actions would include actions that prevent recurrence and consist of procedure, process, culture, or management system improvements and changes. In developing corrective actions, supplier ensures they are verifiable, measurable, and sustainable (effective over time).

When developing corrective actions, the SMART criteria approach is helpful. The actions are as follows:

- Specific - The action is clear, concise, and in sufficient detail to allow personnel directly and indirectly involved to understand the activities to be conducted.
- Measurable - Identify activities or mechanisms that could be used to verify completion and determine effectiveness of the completed actions.
- Accountable - Identify specific responsibility for completing the action.
- Reasonable - The actions believably address the cause. The actions are reasonable and achievable within the ability of the organization to develop and implement.
- Timely - The action is scheduled to be performed within a period that corrects the identified issue before it worsens.

Determine the following:

- Specify appropriate corrective action(s) for each cause or determine whether an evaluation is necessary that there is an evaluation that no action is necessary.
- Ensure that the actions are closeable and verifiable.
- Prioritize the corrective actions with consideration of the risk significance and regulatory compliance.
- Establish a schedule for implementing and completing the corrective actions.
- Develop quantitative or qualitative measures of success for determining the effectiveness of the actions to prevent recurrence (effectiveness review criteria).
- Ensure the state following the corrective actions is sustainable.
- Ensure that the actions are necessary and unintended consequences have been considered.

Another part of the corrective action process identifies items, services, and processes that need improvement (10 CFR 830.120). An effective way to identify such improvement opportunities is to perform trending of issues and problems. Trending and monitoring of corrective actions provides (1) detection and prevention of problems, and (2) identifies processes that warrant improvement. In effect, trending and monitoring provide proactive, instead of reactive, improvements.

In addition, visibility by upper management depends on the significance of the condition.

13.1.2 Lessons Learned

When providing corrective action reports (CAR) to the Project, include the following as requested by the Project:

1. Clear statement of the cause of the condition
2. Complete evaluation of the extent of the condition

3. Actions taken to correct the cause of the condition
4. Remedial actions taken to correct the immediate situation
5. Preventative actions taken to preclude the condition from recurring
6. Your internal CAR number(s) initiated

Examples:

1. Observed Condition - If supplier submittals that are rejected more than once and/or more than one supplier submittal has been rejected, the supplier has a process problem or does not understand the requirements.

   Expected Supplier Response - A corrective action is initiated to investigate the misunderstanding.

2. Observed Condition - An item or product is found non-conforming.

   Expected Supplier Response - A nonconformance report (NCR) is initiated and an investigation, cause, and corrective action are performed as defined above.

3. Observed Condition - An incorrect revision of a procedure is found on the floor.

   Expected Supplier Response - An investigation is initiated to determine if it is a one-time incident or if numerous incorrect revisions are in use. If only one is in error and depending on significance, a corrective action may be initiated, especially if the error affects configuration control of an item or process.

4. Observed Condition - Lack of traceability of the NCR number or the CAR number to the actual part number, process, or document.

   Expected Supplier Response - When a process or item is found in nonconformance (i.e., a deficiency), the item or process has documented traceability of issue to the product and vice versa. This issue seems to be lacking in the nuclear culture and stems from a lack of emphasis on detail. This type of issue could lead to legal significance if someone is injured or an expensive equipment/system is damaged. During an extent of condition and cause analysis, fault is identified with a process and the question arises of why a corrective action was not in place and/or effective.

5. Observed Condition - When the Project is in the supplier shop, a nonconformance is identified and the supplier corrects the issue on the spot, however, does not document an NCR or CAR and follow through with extent of condition, cause analysis, and actions to preclude the condition from recurring.

   Expected Supplier Response - Do not just fix the one issue. Initiate the NCR or CAR, and perform the extent of condition and cause to find out if the condition is more pervasive. Then perform appropriate corrective actions to prevent recurrence.

Appendix A: Guidance for Use of Software in Design Processes

BACKGROUND

WTP issues purchase orders to vendors for products, services, or a combination of both. Some suppliers may have outstanding products or fabrication processes but may not have extensive experience performing design and analysis related to nuclear safety functions. This appendix provides guidance for suppliers performing design and analysis using software where the software results are not verified within the design analysis report.

WTP generally includes a number of technical specifications in the procurement documents when awarding a purchase order. It is important that the supplier's bid team consider these specifications since they are the basis for required software management processes performed by the vendor.

A.1 When Does an NQA-1 Software Quality Program Apply

A vendor who uses software to perform design or analysis of a system, structure, or component (SSC) that contributes to a safety function of the WTP facilities, follows one or more of three paths:

Path 1 - Use an alternate method of verifying the design or analysis, such as:

- pressure testing that encompasses the full extent of the Q safety function for confinement
- calculation performed to verify minimum flow where the safety function is related to minimum volumetric flow (generally not achievable when using complex software such as finite element analysis or fluid dynamics

Path 2 - Use one of WTP's approved software items (toolbox software) and manage the software according to the technical specification included in the procurement documents.

Path 3 - Implement an NQA-1 compliant software quality program.

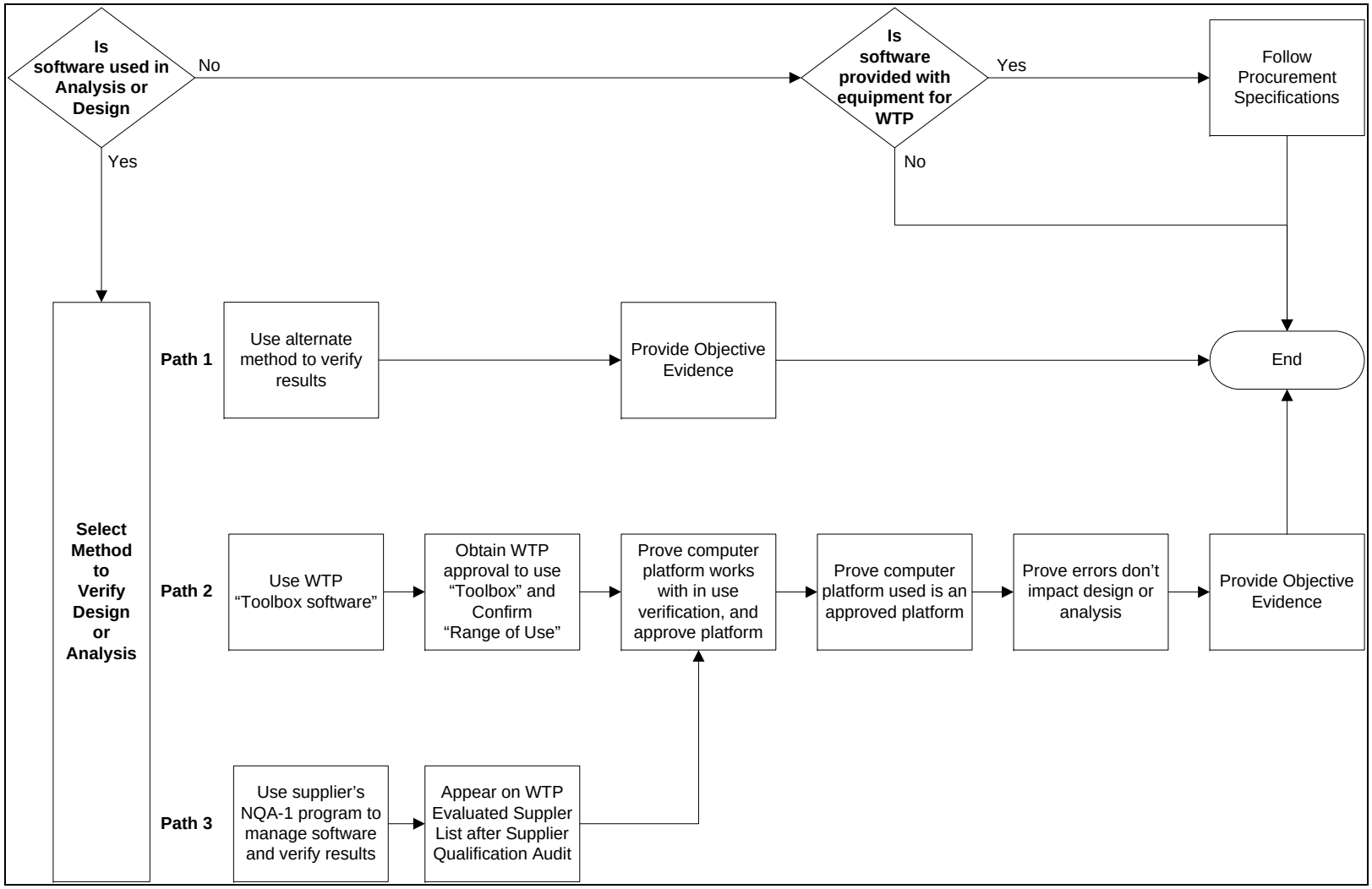
The following sections describe WTP expectations for software management. The discussion includes references to the applicable paths listed above.

A.1.1 Controlling Software

Expectation	Relevant Path(s)
Prove the software works Test plans, test cases, and test results are prepared, reviewed, and approved before approval of the software for use. Documented testing is also required if the software is to be used in a manner, or on a platform, not addressed by previous testing. These tests provide for evaluating the technical adequacy of the software. The software is placed under configuration change control to prevent unintended changes and to ensure that only approved software is used.	Path 3

Expectation	Relevant Path(s)
Obtain WTP Approval to use "Toolbox" software and confirm "Range of Use" The seller requests permission in writing to apply the toolbox approach for the seller's use of the software. The written request identifies the analysis being performed, the name and version of the software, and the intended range(s) of use.	Path 2
Prove the software works when the computer platform changes Tests are developed and documented to permit confirmation of acceptable performance of the software in the operating system when that software is installed on a different computer, or when significant hardware or operating system configuration changes are made. When the computer platform is modified by applying security patches to the operating system or upgrading the processor, testing is performed to demonstrate the software continues to perform its functions correctly for the approved range of use.	Paths 2 and 3
Prove the computer platform used is equivalent to the approved platform A system of configuration management is established and used to prevent unauthorized changes to the computer platform. The configuration management system provides objective evidence that the computer platform has not been changed since the last test results were approved.	Paths 2 and 3
Prove errors don't impact the design or the analysis Requirements are established for the reporting of identified errors between software users, suppliers, and Buyer. Ensure the requirements include procedures for documenting, evaluating, and resolving software errors. Confirm the process includes (1) describing the evaluation process for determining if the error is a software problem or another type of error; (2) defining the responsibilities for disposition of software error notice; and (3) for software errors, identification of identifying how the error relates to the software (software requirement, test plan, or test case), how the error impacts past present and future use of the software, how users are notified of the error and its impact, and how to avoid the error.	Paths 2 and 3
Provide 'objective evidence' of the proof Following the supplier's software procedures result in the generation of objective evidence that the above minimum requirements are satisfied.	Paths 1, 2 and 3

Figure 1 - Software Used in Design Processes



Appendix B: Guidance on Failure Modes and Effects Analysis

BACKGROUND

Failure Mode and Effects Analyses (FMEA) is a tool used in the analysis of design of systems as a means of predicting and developing prudent means of establishing a specified level of confidence in performance. The process described in various standards and guidance documents is written for situations where the personnel performing the evaluation are those who performed the design or have access to the detailed design informed for the items being evaluated. When performing the technical evaluation of an item or service for the purposes of commercial grade dedication (CGD), the techniques described in these documents are adapted to the scope of the technical evaluation.

Throughout this guidance, the focus is on only ultimately establishing a level of confidence in the Q functions commensurate with their significance. Performing an evaluation to establish confidence for commercial reliability is outside the scope of this guidance, but may be performed in a similar manner.

B.1 METHODOLOGY

B.1.1 SCOPE ESTABLISHMENT

The extent of evaluation necessary to determine the failure modes and subsequent effects of the failure of an item is determined by the functional requirements for the item under consideration in the service conditions expected in the design basis conditions. Critical to a successful evaluation is clearly defining the scope of the evaluation. For dedication, the failure modes subject to evaluation are those associated with the Q functions only. Scope establishment is a two-step process:

1. Define the items and services. The CGD package "Description" section states the scope under consideration. Ensure the evaluation includes the items within the scope of evaluation and the associated services. When the scope of the item affected by the service is evaluated as well as the contribution of the service to those functions.

2. Determine the activities performed by those items or, for services, those activities the items affected by the service perform that are Q.

Often, the evaluation is performed after an item is designed. Therefore, the engineer performing the evaluation does not have the benefit of access to the decision making process that led to the production of an item.

B.1.2 DEVELOPING THE TECHNICAL BASIS FOR THE EVALUATION

Before starting the activity of determining failure modes, it is necessary to understand the design of the item under evaluation. CGD evaluations may be performed in many situations from commodity type items that may be used in any application in the facility (e.g., pipe, fasteners, cable, and chemical testing) to skid mounted assemblies (e.g., 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 Q 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 the following:

- 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 CGD, 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 Q function. Design margin information is often elusive, and an engineer performing the evaluation is relentless in their efforts to determine a qualitative margin understanding, which is often difficult to document accurately. However, with confidence in the understanding of the Q function and system component level of failure, the qualitative statement is appropriate when there is conservatively low risk for significant consequences of failure.

B.1.3 SYSTEM, COMPONENT AND ITEM FUNCTION AND INTERACTION

For the Q functions of the host system and/or component under evaluation, determine the credible failure modes associated with the host system/component Q functions.

Determining what is credible depends on the technical basis determined above. If the Q function requires performance to a high degree of severity, accuracy, or with limited design margin, then likely more failure modes may be considered as credible.

Consider both the failure of functions, which occur to support the host system/component Q function, and the improperly performed non-Q functions, which would cause a Q 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 CGD 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 that the functions are Q for 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 Q functions of each as they relate to the skid functions, considering those non-Q functions, such as protective systems, that could malfunction in a manner to prevent the skid 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 to determine the influence of the controls applied to the development of the software and its installation. For items that are more complex, a multi-discipline team is necessary to perform the evaluation effectively.

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 part's contribution. At this level of the evaluation, it is important to determine the scope of evaluation. Consider the contribution of the item on the host system/component to decide whether pursuing the evaluation to lowers tiers of the configuration, (e.g., to each discrete component) is necessary. The outcome of the evaluation is input to the selection of critical characteristics. Deciding not to pursue the evaluation to lower levels of configuration determines that the critical characteristics of the lower level item are not selected.

Note that there are situations where limited technical information is available to use for the critical characteristics evaluation. Two options are available, with degrees of success dependent 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. This second option is most likely effective when the necessary skill sets are available to dissect the item and understand its design. This option is frequently 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 to factor into the evaluation. When reviewing the report, consider whether the service conditions are the same or similar and the extent to which a post mortem examination was performed. Incorporate cause analysis information from the report.

Failure modes to consider, depending on the type of equipment, are as follows:

- 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

B.1.4 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 Q function in the intended application(s).:

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

For the purposes of determining the extent of the consequences of failure, consider whether effects have local, regional, or offsite 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 Q function after a design basis event. Consider for each failure mode, whether the failure constitutes only a degradation of the item function or whether there is an effect on the Q 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 perform the actions) affect final judgment on the establishment of critical characteristics and acceptance methods.

Sophisticated failure mode effects analyses performed for reasonable scopes of items or systems in commercial applications may have established numerical values that are associated with a wide range of effects and consequences. This necessitates a ranking that facilitates decisions on rigor to be applied for various failure modes. Generally, a numerical ranking system that includes dollar risk is not valuable when the item is associated with Q functions since the consequences of failure are more significant than short-term financial loss. Moreover, whether the function is safety class or safety significant, by definition it is imperative to establish relative importance.