

Best Practice #199

Facility: Hanford Tank Farm/Hanford

Best Practice Title: Regulatory Summary for 10 CFR 830.122 (QA Rule)

Point of Contact:(Barry Thom, 509-376-1814, charles_thom@rl.gov)

Brief Description of Best Practice: The Price Anderson Amendment Act (PAAA) involves several CFRs (e.g., 10 CFR 830, 10 CFR 835, 10 CFR 851, etc.). PAAA Enforcement Coordinators are expected to understand the PAAA regulations and determine whether issues identified within their contract are a PAAA noncompliance. The Regulatory Summary for 10 CFR 830.122 provides a resource for PAAA Enforcement Coordinators to use by providing examples of noncompliances associated with each citation, and by providing a brief summary of what constitutes a nuclear nexus.

Why the best practice was used: Every year there is a new group of PAAA Enforcement Coordinators that often have little to no experience regarding the PAAA CFRs. The subject Regulatory Summary can be used to supplement the inexperience of the new PAAA Enforcement Coordinators and serve as a refresher for the more experienced PAAA Enforcement Coordinators.

What are the benefits of the best practice: New PAAA Enforcement Coordinators will have a better understanding of the associated CFR.

What problems/issues were associated with the best practice: There were no problems associated with the deployment of the best practice.

How the success of the Best Practice was measured: Positive feedback from Enforcement Coordinators.

Description of process experience using the Best Practice: The known operating experience to date is limited to the 2 sites associated with the development of the product since this is the initial deployment of the Best Practice. The best practice supports a better understanding of the subject nuclear safety regulation.

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Introduction:

This document is intended to provide general support information based on the experience of contractors in the Energy Facility Contractor's Group's (EFCOG's) Regulatory & Enforcement Subgroup. It is intended for use by the EFCOG contractors for general support purposes only. It is not intended in any way to constitute binding interpretations of any regulation or DOE requirement.

The information and examples contained in this *EFCOG Support Document for 10 CFR 830.122* do not expand or restrict application of any Quality Assurance (QA) regulation and are not all inclusive. The intent is that these examples are only potential data points that may be used by a contractor when analyzing the applicability of 10 CFR 830.122 regulations and the adequacy of its QA program. EFCOG recognizes that all potential noncompliances are very fact dependent. An event similar to a provided example is not necessarily in and of itself a violation of a QA requirement. This document should not substitute for an individual contractor's interpretation of the 10 CFR 830.122 regulations based on the facts and circumstances of any specific event or set of issues.

Additionally, how each site describes and implements its QA program may impact how the regulations at 10 CFR 830.122 are implemented and interpreted. Further, the concept of a nuclear nexus, as described in 10 CFR 830.1 and 830.120, should be included in all analyses of the applicability of the 830.122 regulations. flag

Some of the examples contained herein clearly indicate that there is a Nuclear Nexus by mentioning a "signal" word/phrase like TSR violation, safety significant system; however, some do not have these "signal" word/phrase. The examples that do not have "signal" word/phrase are included because they are intended to get the user of this document to think about the site specific issue and if there is a connection to Nuclear Safety. Similarly, the following few examples that are intended to cause the user to think a little broader than the obvious nuclear safety noncompliances.

Example 1: A general service standby diesel generator failed because required maintenance was not completed. The required maintenance was not completed because the maintenance date was incorrectly entered in the Preventative Maintenance (PM) management software. The process/procedure used to load maintenance dates into the software had a single point of failure. The same process was used for the maintenance of Safety Significant Systems; however, no failure had occurred to date. In this example, there is a Nuclear Nexus because the only reason a Safety Significant System had not failed due to lack of maintenance was good fortune/luck.

Example 2: General Service components weld records were not being reviewed as required by the welding inspector due to a process error and inadequate training, because this same process error and training deficiency was determined to affect Safety Significant Components there is a Nuclear Nexus.

Example 3: Non-QA records were found to be missing names, signatures and dates. The Non-QA records were being processed using the same process that the QA records were using. At the time of the PAAA noncompliance evaluation there were no examples of QA records that were missing names, signatures and dates; however, since there was a flaw with the process this condition was determined to have a Nuclear Nexus.

The following Office of Enforcement example is summarized from Enforcement Guidance Supplement (EGS) 00-03. EGS 00-03 provides additional examples to further define when there is a Nuclear Nexus. All of these supplements can be found at <https://www.energy.gov/ea/downloads/enforcement-guidance-supplements>.

Example 4: General Service sumps were being installed in an area that was considered to not be a part of the nuclear facility. The sumps were installed to contain any fluid spills to address environmental requirements. The sumps

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were installed in an area that contained switchgear, cabling and power feed for safety features for the nearby nuclear facility. Several problems and noncompliances were involved with this work:

1. The work was performed without a procedure or work instruction.
2. The workers were verbally told approximately where on the concrete floor to cut holes for sump installation
3. No safety review was performed on what was located below the floor
4. The workers were verbally told to connect to a convenient power source.

The Nuclear Nexus is that inadequate work instruction and reviews created the potential for a possible unauthorized interruption of a safety system power supply.

For more detailed explanation of Nuclear Nexus see the next section of this screening tool.

Nuclear Nexus:

The DOE Quality Assurance Regulations at 10 CFR 830, Subpart A, require a nuclear nexus in order for the requirements to be applicable. The regulations provide:

10 CFR 830.1 Scope

This part governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities."

830.120 Scope

This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services, that affect, or may affect, nuclear safety of DOE nuclear facilities.

The DOE Office of Enforcement has stated that the DOE Quality Assurance Rule applies to all DOE activities that have the potential to cause radiological harm. The potential for radiological harm may exist without the presence of nuclear inventory or a particular volume of nuclear inventory. A nuclear nexus exists where a nuclear hazard potentially exists in the present or in the future. So, application of 10 CFR 830.120 can extend beyond radiological and nuclear facilities when the activity affects, or may affect, the safety of DOE radiological and nuclear facilities.

Support for this definition comes from the Nuclear Safety Rules, the Enforcement Coordinator Handbook and two of the Enforcement Guides referenced by the handbook, Enforcement Guidance Supplement 99-01, "Enforcement of 10 CFR 830.120 (Quality Assurance Rule) for Facilities below hazard Category III," dated July 1, 1999, and EGS: 00-03, Enforcement Guidance Supplement 00-03: "Specific Issues on Applicability of 10 CFR 830," dated September 12, 2000.

The following key concepts from the Enforcement Guides are summarized here:

- All work in nuclear facilities may have the potential to affect nuclear related work in the facility and therefore, nuclear safety (ESG 00-03, p.1).
- QA controls are not limited by the language contained in Safety Analysis Reports, Technical Safety Requirements and Technical Specifications (ESG 00-03, p.1).
- Items and services that are not inherently nuclear may affect the safety of DOE radiological and nuclear facilities, so the quality requirements must be applied, in a graded approach, to assure that nuclear safety is not impacted (ESG 99-01).
- Examples of services that are not inherently nuclear that may affect the safety of DOE radiological and nuclear facilities include, but are not limited to, design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, waste management, laboratory sample analyses, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair,

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installation, diagnostic evaluations, planning, surveillance, development of software and other similar activities (ESG 99-01).

- Commercial products as well as small dollar purchases may affect nuclear safety depending on their intended use (66 Fed. Reg. 1812 (10 January 2001)).

So, the management systems set up to implement 10 CFR 830.122, have the potential to affect nuclear safety even if those systems also apply to activities that will not affect nuclear safety. Application of 10 CFR 830.120 should not be limited to radiological and nuclear facilities. The evaluation should center on whether a quality assurance issue or event affects, or may affect, the safety of DOE radiological and nuclear facilities.

Common Deficiencies in Contractor Screening Processes (Noncompliance Identification Process)

When screening issues for noncompliances it is important to adhere to the following information from the DOE Enforcement Coordinator Handbook (page 25).

- *“Failure to consider all appropriate sources for screening (e.g., assessment reports, employee concerns, subcontractor events or deficiencies)*
- *Screening out issues because they were corrected promptly*
- *Screening out issues that are noncompliant with requirements, but are judged to be of low significance*
- *Establishing criteria that are not stipulated in the safety and security regulations, with the effect of limiting the applicability of the regulations;*
 - *for example, treating as noncompliances only matters covered specifically in the safety basis,*
 - *or only violations of work controls for work involving direct handling of nuclear material,*
 - *or only violations of procedures specifically listed in Rule-required program plans.”*

How to Use this Document

- The Row #s are for easy reference only.
- The yellow and green colors are provided to make it clear that the groupings clear (i.e., examples, go with the key words, go with the 830.122 citation).
- The key words are provided to help facilitate a search for a specific subject/noncompliance.
- The blue text is used to emphasize the 830.122 citation
- The examples in the table below should always be used in conjunction with the determination on whether there is a Nuclear Nexus or not. In some of the examples below a nuclear nexus example is provided. In other examples, no specific nuclear nexus is provided. Nuclear Nexus examples have been included based on comments only, the fact that some examples do not have a Nuclear Nexus example merely means that an example has not been provided at this time.
- Note: If a user of this document has an example that the user believes is interesting or would help other PAAA Enforcement Coordinators please submit these examples to the Chair of the EFCOG Regulatory & Enforcement Technical Subgroup.)

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- As a reminder, an actual consequence or event is not required for a noncompliance to occur. For example, even if a weld inspector did not make a mistake, the fact that the welder was not qualified under the contractor training program to do his assigned job is a noncompliance the 10 CFR 830.122(b)(1).

Row #	Noncompliance Examples
1	(a)Criterion 1 – Management/Program
2	<p>Example 1: Interfaces for managing and performing work were not clearly established.</p> <p>Example 2: Nuclear safety relevant work was left undone, because one group or organization brought it to a certain stage of completion, but there was no communication to the next group or organization that the work needed to continue. (Note: This noncompliance most frequently occurs at shift change.);</p> <p>Example 3: Nuclear safety relevant work was completed but the organization completing the work was unaware there was a need to notify another organization of the work completion.</p> <p>Example 4: Interfaces between organizations (e.g., Design, Operations, Maintenance, Procurement, etc.) were not clearly established.</p> <p>Example 5: Changes to the controlled set of as-built nuclear design documents were made by unauthorized personnel.]</p> <p>Example 6: Roles and responsibilities for a worker’s assigned job position were not established, as a result, the worker performed nuclear safety related tasks that he/she was not qualified to perform.</p> <p>Example 7: Organization chart did not exist or did not receive timely (e.g., updated within month of a change) updates.</p> <hr/> <p>Key Words: Organization Chart; Organizational Interfaces; Roles and Responsibilities (R2A2);</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(a)(1): <i>“Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.”</i></p>
3	<p>Example 1: Inadequate resources or no schedule or an inadequate schedule.</p> <p>Example 2: Operators did not have time to recognize temperature was out of specification thus causing a TSR violation (LCOs were not followed).</p> <p>Example 3: A worker was assigned to inspect a safety significant system that the worker was not qualified to inspect. The worker performed the inspection as directed and accepted the system, it was later discovered the worker was not qualified.</p> <hr/> <p>Key Words: Inadequate resources; Inadequate planning</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(a)(2): <i>“Establish management processes, including planning, scheduling and providing resources for the work”</i></p>
4	(b)Criterion 2 – Management/Personnel Training and Qualification.

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Row #	Noncompliance Examples
5	<p>Example 1: Training and qualification had not been developed. The initial training needed by the worker was not offered, or was inadequate or incomplete.</p> <p>Example 2: The contractor did not enforce completion of required initial training.</p> <hr/> <p>Key Words: Training;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(b)(1): "Train and qualify personnel to be capable of performing their assigned work."</p>
6	<p>Example 1: The continuing training needed by the worker was not was not offered, or was inadequate or incomplete.</p> <p>Example 2: A welder performing work at a nuclear facility had not completed the Level II qualification training and all the welds that the welder made are in question.</p> <p>Example 3: The contractor did not enforce completion of required continuing training.</p> <hr/> <p>Key Words: Continuing Training;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(b)(2): "Provide continuous training to personnel to maintain their job proficiency."</p>
7	<p>(c)Criterion 3 – Management/Quality Improvement.</p>
8	<p>Example 1: A corrective action process/program did not exist or was not effective.</p> <p>Example 2: The failure to establish a corrective action program caused the damaged valve in the nuclear waste water plant to go undetected and uncorrected for a long period of time.</p> <p>Example 3: The corrective action process/program was not implemented by management or the workers.</p> <p>Example 4: Management chose not to enter a significant issue related to nuclear operations into the corrective action system; as a result, the issue went undetected until discovered by a DOE Facility Representative.</p> <p>Example 5: A Contractor had organizations that were using an unofficial issues management system to avoid the visibility and rigor provided by the official issues management systems.</p> <p>Example 6: A receipt inspection program had not been implemented to identify non-conforming items related to affected safety/quality class components.</p> <hr/> <p>Key Words: Issue Identification; Corrective Action Program;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(c)(1): "Establish and implement processes to detect and prevent quality problems."</p>
9	<p>Example 1: A problem, once identified was not corrected or not corrected in a timely manner.</p> <p>Example 2: A structure, system or component that did not meet specifications had been installed or discovered in use that did not have an NCR (Nonconforming Item Report) generated.</p>

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	<p>Example 3: A flange that did not meet specifications had not been properly controlled, segregated, or tagged. The nuclear maintenance worker, unaware of the nonconformance, installed the faulty flange in a nuclear facility.</p> <p>Example 4: A break down in the Nonconforming Control System occurred (non-conforming items not segregated, failure to follow receipt inspection protocols, etc.). 1.</p> <p>Example 5: A documented approved process does not exist for adequate dispositioning of non-compliant procured items.</p> <hr/> <p>Key Words: NCR; Untimely Corrective Actions; Nonconformance; Nonconforming</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(c)(2): <i>Identify, control, and correct items, services, and processes that do not meet established requirements.</i></p>
10	<p>Example 1: The same problem continued to occur.</p> <p>Example 2: A problem was identified and corrective action was implemented. However, the corrective action was not effective.</p> <p>Example 3: The Cause Analysis did not adequately determine the causation of the issue.</p> <p>Example 4: Corrective actions did not adequately address the identified causal factors.</p> <hr/> <p>Key Words: Repetitive; Inadequate Corrective Actions; Inadequate Cause; Inadequate Cause Analysis</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(c)(3): <i>"Identify the causes of problems and work to prevent recurrence as a part of correcting the problem."</i></p>
11	<p>Example 1: A contractor did not have or implement a process improvement procedure/process.</p> <p>Example 2: A trending process did not exist, was inadequate, or was not implemented.</p> <hr/> <p>Key Words: Trending; Process Improvements</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(c)(4): <i>"Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement."</i></p>
12	(d)Criterion 4 – Management/Documents and Records.
13	<p>Example 1: Lack of procedures to prescribe a process.</p> <p>Example 2: The procedure did not specify applicable and appropriate requirements from higher documents such as the QA Program or governing standards.</p> <p>Example 3: Procedures contained conflicting requirements or did not effectively specify requirements.</p> <p>Example 4: Procedures did not adequately describe the process or are subject to different interpretations.</p>

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	<p>Example 5: Procedure/drawing/specification could not be followed as written.</p> <p>Example 6: Design documents, calculations, DSA supporting evaluations etc. that are correct, but not under configuration control and/or are not issued as required by prescribed processes.</p> <p>Example 7: Document such as procedures, drawings, specification, calculations, analysis, did not maintain revision control (e.g., Document X was issued as Rev. 1 when it should have been issued as Rev. 2, or Document Y was issued) as required by prescribed processes.</p> <p>Example 8: Documents were issued approved without undergoing specified review process.</p> <hr/> <p>Key Words: Procedure Quality; Unclear Procedures; Requirements Flow-Down; Inadequate drawings; Inadequate Specifications; Inadequate Document Control</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(d)(1): <i>“Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.”</i></p>
14	<p>Example 1: There was no requirement to generate or maintain a record of a quality related activity.</p> <p>Example 2: Records were inadequately completed (contain blanks, are illegible, completed in pencil).</p> <p>Example 3: Records were inadequately reviewed/approved (no evidence of a required review or approval, the person reviewing or approving is not the person with authority to do so).</p> <p>Example 4: Records were inadequately maintained (not adequately stored to protect from loss, deterioration or damage; not stored in a manner to be retrievable).</p> <p>Example 5: Records were missing/lost.</p> <p>Example 6: Records were not submitted.</p> <p>Example 8: Data or information if not recorded at that time is lost forever such as round sheets documenting temperature, pressure, time; valve position etc.</p> <hr/> <p>Key Words: Records; Illegible Records; Missing Records;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(d)(2): <i>“Specify, prepare, review, approve, and maintain records.”</i></p>
15	<p>(e)Criterion 5 – Performance/Work Processes</p>
16	<p>Example 1: Personnel did not follow an approved procedure for a specific activity.</p> <p>Example 2: Approved Work package instructions were not followed.</p> <p>Example 3: Approved work package instructions were not being followed and did not implement the administrative controls that were adopted to meet regulatory or contract standards. This resulted in a TSR violation and noncompliance with LCOs.</p> <p>Example 4: A subcontractor or supplier was not providing the item or device as specified in the contract or procurement document (This is a subcontractor noncompliance.)</p> <hr/> <p>Key Words: Conduct of Operations; Con Ops; Procedural Compliance</p>

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Row #	Noncompliance Examples
	<p>PAAA Noncompliance(s): 10 CFR 830.122(e)(1): <i>“Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.”</i></p>
17	<p>Example 1: Items were not controlled to ensure their proper use because documents that support the pedigree of the item were not traceable to the item. Example 2: Items were not controlled to ensure their proper use because documents that support the pedigree of an item were incorrect or were falsified. Example 3: Items were not identified to ensure their proper use because items of production (batch, lot component part) were not identified. Example 4: An item (chemical joint lock nut washer) to be used in a safety significant system was delivered and installed. After the item was in use it was discovered that the certified material test report (CMTR) provided was not the CMTR for the item. Example 5: Items were not identified to ensure their proper use because items in storage or in use were not tagged, labeled, or marked to indicate their identity. Example 6: Items were not identified to ensure their proper use because rejected or damaged items were not tagged or segregated to preclude their being used. Example 7: Items were not controlled to ensure their proper use because items with limited shelf life were not adequately stored to eliminate the potential for expired items to be used.</p> <hr/> <p>Key Words: Item Pedigree; Item Batch; Item Lot; Item Storage</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(e)(2): <i>“Identify and control items to ensure their proper use.”</i></p>
18	<p>Example 1: Items were not stored in a manner that ensures protection from the environment. Example 2: Items for which special storage conditions are required (e. g. specific temperature range, special packaging, specific type of container) were not provided or maintained. Example 3: Handling, storage, cleaning, packaging, shipping, and preservation of items were not conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions or other pertinent documents or procedures. Example 4: Special handling tools were not used or were used incorrectly. Example 5: Preventative maintenance was not identified, controlled, or performed on schedule.</p> <hr/> <p>Key Words: Item Storage; Item Handling; Item Shipping; Item Special Tools; Item Handling Tools;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(e)(3): <i>“Maintain items to prevent their damage, loss, or deterioration.”</i></p>
19	<p>Example 1: The calibration date had expired on an instrument or tool that was used for process monitoring. Example 2: No records of calibration existed for equipment that required calibration. The equipment was used for data collection.</p>

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	<p>Example 3: The instrument or tool that was used for process monitoring was not labeled in a manner that provides traceability to the calibration records.</p> <p>Example 4: The calibration records for equipment used for data collection were not traceable to a nationally recognized standard.</p> <p>Example 5: M&TE calibration was done incorrectly because a nationally recognized standard was not used to perform the calibration; as a result, temperature measurements (freeze protection) required to be compliant with the TSR were suspect. Since the accuracy of the temperature readings was indeterminate a TSR violation was declared.</p> <p>Example 6: Calibration periods for equipment used for process monitoring were not defined.</p> <p>Example 7: Measuring and Test Equipment (M&TE) used to calibrate equipment used for process monitoring or data collection was not traceable to its application and use.</p> <p>Example 8: M&TE equipment suspected of being out of calibration was continued to be used to calibrate equipment used for process monitoring or data collection.</p> <p>Example 9: M&TE that was used to calibrate equipment used for process monitoring or data collection, was lost, damaged, or found to be out of calibration. The contractor did not evaluate the validity of previous measurements, inspections or test results to determine if the previously inspected or tested items needed to be re-inspected or tested.</p> <hr/> <p>Key Words: Calibration; M&TE; Traceability;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(e)(4): <i>“Calibrate and maintain equipment used for process monitoring or data collection.”</i></p> <p>Note: Do not confuse this item with 830.122(h)(2). This citation (830.122(e)(4) is the same as 830.122(h)(2) shown on Row 32 except it is not for M&TE equipment used as part of an items inspection or acceptance testing.</p>
20	(f)Criterion 6 – Performance/Design
21	<p>Example 1: The design (drawings, specifications, analyses, calculations, etc.) did not include or incorrectly included engineering/scientific principles such as equations, laws of physics, principals, formulas, and algorithms.</p> <p>Example 2: The design (drawings, specifications, analyses, calculations, etc.) did not include or incorrectly included the appropriate codes and standards such as, to be extent applicable, ASME (includes NQA-1), NEC, NFPA, AISC, ACI, and, company specific standards.</p> <p>Example 3: Software design did not include or incorrectly included engineering/scientific principles such as equations, laws of physics, principals, formulas, and algorithms.</p> <p>Example 4: Software design did not did not include or incorrectly included the appropriated standards such as IEEE, and company specific standards.</p> <p>Example 5: Selection of incorrect design standard or code for facility/process design.</p> <hr/> <p>Key Words: Standards, Codes, Engineering, Science, Scientific, Inadequate Design</p> <hr/>

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Row #	Noncompliance Examples
	<p>PAAA Noncompliance(s): 10 CFR 830.122(f)(1): <i>“Design items and processes using sound engineering/scientific principles and appropriate standards.”</i></p> <p>Note: For the purposes of establishing noncompliances codes and standards will be considered synonymous.</p>
22	<p>Example 1: The design (drawings, specifications, analyses, calculations, etc.) did not incorporate applicable requirements necessary to meet the design bases described in the DSA/TSR. Example 2: The design (drawings, specifications, analyses, calculations, etc.) did not incorporate applicable requirements (For example, radiation protection requirements including, as applicable, shielding, containment, HEPA filtration, facility layout, coatings/paint, decontamination, contamination control, ventilation, sump pumps, etc.) Example 3: Applicable requirements and design bases were not identified; and/or their incorporation into design work and design changes was not documented and/or controlled.</p> <hr/> <p>Key Words: Design Bases, Design Requirements,</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(f)(2): <i>“Incorporate applicable requirements and design bases in design work and design changes.”</i></p>
23	<p>Example 1: There was no mechanism that controls design interfaces between internal and external organizations. Example 2: Interface control documents/drawings were not maintained. Example 3: Plant modification designs were not coordinated with affected disciplines</p> <hr/> <p>Key Words: Interface Control; Design Control; External Interfaces; Internal Interfaces</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(f)(3): <i>“Identify and control design interfaces.”</i></p>
24	<p>Example 1: Verification was performed by an individual who participated in the original design. Example 2: Changes to previously verified designs had not been verified. Example 3: A design product (drawings, specifications, analyses, calculations, etc.) was not checked or the checking was inadequate by a second qualified person. (Note: Individual checking of a design product is a subset of the overall larger design verification because in order for the overall verification of a design to be adequate the pieces (e.g., analyses, calculations, drawings, specifications etc.) that make up the overall design must be technically adequate/accurate.)</p> <hr/> <p>Key Words: Design Verification; Checking; Independence;</p> <hr/> <p>PAAA Noncompliance(s):</p>

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	10 CFR 830.122(f)(4): <i>“Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.”</i>
25	<p>Example 1: Design verification had not been performed prior to release for procurement, manufacture or construction.</p> <p>Example 2: Design verification had not been completed prior to relying upon the component, system, structure, or computer program to perform its function.</p> <p>Example 3: Unverified portions of design were implemented.</p> <hr/> <p>Key Words: Design Release; Design Approval; Design Verification; Design Control;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(f)(5): <i>“Verify or validate work before approval and implementation of the design.”</i></p>
26	(g)Criterion 7 – Performance/Procurement
27	<p>Example 1: QA requirements for items were not adequately flowed down in the procurement documents.</p> <p>Example 2: QA requirements for services (e.g., design, construction, inspection, etc.) were not adequately flowed down into contract/Statements of work.</p> <p>Example 3: The performance requirements for the item(s) were not adequately described in the procurement documents.</p> <p>Example 4: Items or services were procured with an inadequate or incomplete commercial grade dedication.</p> <p>Example 5: Procurement documents did not specify Supplier’s reporting of nonconformances.</p> <hr/> <p>Key Words: Procurement Specifications; Requirement flow down; Commercial Grade Dedication</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(g)(1): <i>“Procure items and services that meet established requirements and perform as specified.”</i></p>
28	<p>Example 1: A supplier was selected who was not evaluated by one of the established methods of acceptance (e.g., Certificate of Conformance; Source Verification; Receiving Inspection; Post Installation Testing etc.)</p> <p>Example 2: The supplier evaluation and selection results were not documented.</p> <p>Example 3: The supplier was evaluated with the incorrect or incomplete criteria.</p> <hr/> <p>Key Words: Supplier Evaluation;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(g)(2): <i>“Evaluate and select prospective suppliers on the basis of specified criteria.”</i></p>
29	<p>Example 1: A supplier or services provider (e.g., design, construction, inspection, etc.) received a contract or order and there was inadequate oversight (e.g., source inspection, documentation review, audit, surveillance etc.) to ensure requirements continued to be met.</p>

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Row #	Noncompliance Examples
	<p>Example 2: A Contractor has no sufficient ongoing process to ensure acceptable items or services are provided on a continuing basis.</p> <p>Example 3: A contractor has no Approved/Evaluated Supplier List verification assessment process.</p> <hr/> <p>Key Words: Approved Suppliers; Supplier Oversight; Supplier Inspection; Supplier Audit; Supplier Surveillance</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(g)(3): <i>“Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services”</i></p>
30	(h)Criterion 8 – Performance/Inspection and Acceptance Testing
31	<p>Example 1: Required inspections or tests were not performed.</p> <p>Example 2: Inspection or test records of parts of safety class systems were inadequate or no records of inspection or test exist.</p> <p>Example 3: Testing parameters for the receipt inspection of parts associated were not specified.</p> <p>Example 4: Certain services (e.g., design, construction, inspection, etc.) were appropriately determined to require acceptance reviews, however established acceptance criteria were not used. For example, acceptance of the service did not use any or the appropriate combination of the following methods: (a) technical verification of data produced; (b) surveillance and/or audit of the activity; (c) review of objective evidence for conformance to the procurement document requirements.</p> <p>Example 5: Items were appropriately determined to require acceptance reviews, however established acceptance criteria were not used. For example, acceptance review of the item did not use any or the appropriate combination of the following methods: (a) Certificate of Conformance; (b) Source Verification; (c) Receipt Inspection; (d) Post Installation Testing.</p> <hr/> <p>Key Words: Receipt Inspection; Acceptance; Acceptance Testing; Acceptance of Services</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(h)(1): <i>“Inspect and test specified items, services, and processes using established acceptance and performance criteria.”</i></p>
32	<p>Example 1: See examples for 830.122(e)(4) shown on Row 19, but the M&TE is used for inspection or acceptance testing while out of calibration.</p> <hr/> <p>Key Words: Calibration; M&TE; Traceability;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(h)(2): <i>“Calibrate and maintain equipment used for inspections and test.”</i></p>

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Row #	Noncompliance Examples
	<p>Note: Do not confuse this item with 830.122(e)(4). This citation (830.122(h)(2) is the same as 830.122(e)(4) shown on Row 19 except it is for M&TE equipment used as part of an items inspection or acceptance testing.</p>
33	(i)Criterion 9 – Assessment/Management Assessment
34	<p>Example 1: Management assessments were not performed. Example 2: Findings identified in Management Assessments were not scheduled for corrective action. Example 3: Management Assessments were inadequate (i.e., inaccurate, incomplete, not focused on relevant topics, etc.)</p> <hr/> <p>Key Words: Management Assessment; Inadequate Assessments</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(i): <i>“Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.”</i></p>
35	(j)Criterion 10 – Assessment/Independent Assessment
36	<p>Example 1: Independent assessments to measure the adequacy of the work performance of quality or safety related work processes were not scheduled. Example 2: Independent assessments to measure item and service quality were not conducted because a schedule did not exist, was not maintained to reflect current independent assessment activities, or was not updated on a periodic basis. Example 3: Independent assessments did not adequately (i.e., timely, quality of assessment) evaluate elements (e.g., 10 criteria of NQA-1) of the contractors QA program.</p> <hr/> <p>Key Words: Independent Assessments; Assessment Schedule</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(j)(1): <i>“Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.”</i></p>
37	<p>Example 1: The organizational relationship between the assessor and the assessee was not independent, because both the assessor group and the assessee directly reported to the same line manager, and no clear and effective compensatory measures were taken to address this apparent conflict of interest. Example 2: The group performing independent assessments did not have sufficient authority or appropriate freedom from line management, as evidenced by line management’s improper interference with the conclusions of the independent assessment.</p> <hr/> <p>Key Words: Conflict of Interest; Lack of Independence; Management Interference.</p> <hr/> <p>PAAA Noncompliance(s):</p>

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Row #	Noncompliance Examples
	10 CFR 830.122(j)(2): <i>“Establish sufficient authority, and freedom from line management, for the group performing independent assessments.”</i>
38	<p>Example 1: The qualification requirements for persons leading independent assessments were incorrect, such that the person was not technically qualified and knowledgeable in the areas to be assessed.</p> <p>Example 2: Persons who were not technically qualified and knowledgeable in the areas to be assessed, performed independent assessments.</p> <hr/> <p>Key Words: Assessment Qualifications;</p> <hr/> <p>PAAA Noncompliance(s): 10 CFR 830.122(j)(3): <i>“Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.”</i></p> <p>Note: Consider including 830.122(a)(2), 830.122(b)(1), or 830.122(b)(2).</p>