April 28, 2009

MEMORANDUM TO: John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
& Operational Programs
Office of New Reactors

FROM: Antoinette Sakadales, Program Analyst ***/RA/***
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

SUBJECT: NRC RESPONSES TO COMMERCIAL GRADE DEDICATION AND GENERAL QUESTIONS RECEIVED DURING THE VENDOR WORKSHOP ON NEW REACTOR CONSTRUCTION IN DECEMBER, 2008

Enclosed please find the NRC Responses to questions concerning Commercial Grade Dedication and General Topics received during the Workshop on Vendor Oversight for New Reactor Construction, which took place December 10-11, 2008 in Rockville, Maryland.

Responses to Part 21 and Fuel questions will be enclosed in a separate memo.

Enclosures:
1. Commercial Grade Dedication
2. General

CONTACT: Antoinette Sakadales, DCIP/CQVB
301-415-6441

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ADAMS Accession No.: **ML090890707**

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NAME	ASakadales	SCleavenger	DThatcher	JPeralta	JANakoski
DATE	4/28/2009	4/28/2009	4/28/2009	4/28/2009	4/28/2009

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COMMERCIAL GRADE DEDICATION
(including sampling and critical characteristics)

Question 1:

If an item is dedicated as a basic component solely based on a commercial grade survey, how is this different from grading under 10 CFR Part 50 Appendix B?

Answer:

Commercial-grade surveys should be used when the purchaser desires to verify one or more critical characteristics based on the merits of a vendor's commercial quality controls. Grading, or graded approach, is discussed in Criterion II of Appendix B to 10 CFR Part 50 and states that quality assurance shall provide control over activities affecting the quality of structures, systems, and components to an extent consistent with their importance to safety.

NRC inspection procedure 38703, Appendix A, "Graded Quality Assurance," discusses the NRC's position regarding CGI dedication and grading. Since dedication is an activity affecting quality, grading would be applicable to the four acceptance methods contained in EPRI NP-5652, and not uniquely to CGI surveys.

Question 2:

Does the survey team lead need to be a certified nuclear auditor? (2) If not, would NRC expert need to see the qualifications of the survey team members when "inspecting" the adequacy of a survey result?

Answer:

Qualification of team auditors is based on the utility's auditor qualification requirements. Licensees are responsible for designating those activities that require qualification of personnel and the minimum requirements for such personnel. Licensees should select individuals that have the experience or training commensurate with the scope, complexity, or special nature of the activities audited. The NRC would review the qualifications of audit team members when reviewing the adequacy of survey results.

Question 3:

Do you have to complete the CGD process on additional products or runs of dedicated items? (2) Please verify that DG-1070 is not applicable since it has not been approved.

Answer:

This question would appear to request clarification for the use of sampling plans as part of the CGI dedication process. Dedication plans that implement sampling techniques should be prescribed by standard statistical methods that are based on homogeneous product lots. This technical basis includes, in addition to homogeneity, complexity of the item, lot/batch control for items, heat traceability for materials, and adequacy of the vendor's controls as confirmed by a survey. In all cases, the CGI sampling process should be documented to develop the necessary objective evidence of the vendor's ability to consistently provide acceptable items. DG-1070 was never formally issued by the NRC. However, the NRC's guidance to its inspectors for assessing the use of sampling techniques is described in IP 38703 and IP43004.

Question 4:

How should a vendor respond to a request to provide a commercial grade dedicated item for a nonessential-to-function part, having no safety functions (e.g. packing, gaskets or parts that are solely used for maintenance)?

Answer:

The commercial grade dedication process is intended to verify that there is reasonable assurance that a CGI to be used as a basic component will perform its intended safety function. The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is necessary to identify and characterize the design and functional parameters of specific parts or components.

Question 5:

At what point does the licensee or third party dedicating entity QA program directly apply to a CGI? Is it at dedication?

Answer:

The licensee's QA program would be applicable when the licensee identifies a CGI for dedication. The dedicating entity's QA program would be applicable when the dedicating entity identifies a CGI for dedication. The dedication process must be conducted in accordance with

the applicable provisions of 10 CFR Part 50, Appendix B. The dedication process is considered complete when the item is designated for use as a basic component.

Question 6:

EPRI TR-017218-RI is not endorsed by the NRC. NRC DG-1070 is for simple metallic items. It seems the presentations have been based on a document that the NRC neither endorsed nor conditionally endorsed. Is there a present sampling reference/requirement or governing document that the NRC endorses?

Answer:

Currently, the NRC has not officially endorsed a sampling reference such as EPRI TR-017218-R1. However, the NRC has documented its guidance to its inspectors for assessing sampling techniques in IP 38703 and IP43004.

Question 7:

At what point is a "part" dedicated for use? Is it at the verification of the critical characteristic or at the completion of the process?

Answer:

As stated in 10 CFR 21.3, definition for dedication (When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60), the dedication process is considered complete when the item is designated for use as a basic component. As such, the part is only dedicated for use when the dedication process is complete.

Question 8:

For raw material, what is the NRC's position on purchase from commercial distributor relating to acceptance by commercial grade versus use of ASME rules for unqualified source material? Does testing of metal from commercial suppliers have to be defined as "dedicated"?

Answer:

If the raw material is to be used for ASME pressure boundary components, then the ASME rules apply and the process of upgrading of unqualified source material applies. If the raw material is to be used in other safety related applications, then commercial-grade dedication must be performed. Testing of materials would always be part of the dedication process.

Question 9:

How does a small company that supplies safety related material to the nuclear industry and has a CGD program within its industry (NUPIC) approved QA program, but is not an EPRI member, obtain EPRI NP-5652 to ensure its QA program includes the applicable portions of NP-5652 for which the NRC endorses its guidance?

Answer:

EPRI NP-5652 is available for free from the EPRI Website (See the following: http://my.epri.com/portal/server.pt?open=512&mode=2&objID=221.)

Question 10:

What functions normally make up the CG Dedication Survey Team? QA (survey lead)? Engineering?

Answer:

It is the responsibility of the licensee or auditing organization (i.e., NUPIC lead utility) to assemble a survey team that would typically include the appropriate technical specialists for the type of components or services being surveyed.

Question 11:

In a case where the original equipment manufacturer (OEM) has replaced an original item with a replacement item that the OEM says is equivalent - or an "improvement" - could the OEM's literature be used as the sole basis to use the new item as a replacement item? Or, will an equivalency determination be required along with other CGD process activities?

Answer:

The OEM's literature would only be appropriate to use if it provided the engineering design information necessary and sufficient to determine whether the replacement item had the same design, material, manufacturing process, safety, form, fit, function and interchangeability as the OEM. If differences from the original item are identified in the replacement item, an equivalency evaluation is necessary to determine if any changes in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the alternate replacement item's ability to function under all design conditions (including design-basis event conditions) and ultimately the component's ability to perform its required safety function.

Question 12:

In like-for-like component replacements, how is acceptance testing determined without determination of CC? What bases can be used for testing?

Answer:

A technical evaluation confirms that items are like-for-like. If the dedicating entity can demonstrate that the replacement item is identical in the technical evaluation, then the safety function, design requirements and critical characteristics need not be redetermined. However, item acceptance (verifying the completed item's critical characteristics have been met, including testing as necessary) is still required.

Question 13:

Are 10 CFR 50, Appendix B suppliers required to dedicate procured commercial calibration services?

Answer:

Appendix B suppliers are required to provide the appropriate level of oversight, including source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. This oversight is required for safety related and commercial-grade material, equipment, and services.

Question 14:

Can you discuss the use of historical performance as compared to a commercial grade survey?

Answer:

Method 4, "Acceptable Supplier/Item Performance Record," could be used to demonstrate one or more critical characteristics based upon documented acceptable item performance. Examples of such documented performance records include: acceptable quality control of critical characteristics, or acceptable industry-wide performance. The use of industry-wide performance should not be employed alone unless the established documented performance record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application.

Method 2, "Commercial-Grade Survey of Supplier," is used when the dedicating entity desires to verify one or more critical characteristics based on the merits of a vendor's commercial quality controls. This verification is accomplished by reviewing the vendor's program/procedures

controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.

Question 15:

Does testing of metal from a commercial supplier have to be defined as "dedication?"

Answer:

If the metal is to be used in a safety related application and testing of the metal is used to verify a specific critical characteristic, then testing must be part of the dedication process.

Question 16:

As a third tier supplier who does not have access to the design or engineering related to a product, how can I perform an adequate evaluation of critical characteristics? Typically, I am dedicating a product that was specified by the design engineer who is under contract by someone else.

Answer:

Vendors supplying items as a basic component, including dedication activities, are required to establish adequate controls for the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III, “Design Control,” of Appendix B. With this requirement in mind, under the scenario as described in the question, the third tier supplier may have accepted a purchase order to provide a part and service that appears to be outside its scope of supply. While it may have been able to provide the part, it could not effectively provide the service of dedicating the part. In order to complete the dedication process, the third tier supplier either needs to have its own engineering capability to determine the critical characteristics, have formal access to the appropriate engineering or design organizations, or have been provided the critical characteristics by its customer in sufficient detail to develop and implement a dedication plan. When performing dedication, the dedicating entity should identify a set of critical characteristics that are to be based on the item’s safety function to assure the suitability of all parts, materials, and services for their intended safety related applications. Design or engineering involvement is necessary in performing these activities. The level of design control or engineering involvement is dependent on the nature, complexity, and use of the items to be dedicated.

Question 17:

When purchasing a sheet metal fabrication or machining operation, is acceptance by Method 1 (receipt inspection) sufficient or is it required to be supplemented by Method 2 (CGS)?

Answer:

A commercial-grade survey could be used when the dedicating entity desires to verify one or more critical characteristics based on the merits of a vendor's commercial quality controls, in this case machining operations. Additional verification activities may be needed during receipt inspection to confirm adequate controls of the identified critical characteristics. The extent of verification activities has to be consistent with the complexity of the item and the machining operations credited for the control of critical characteristics.

Question 18:

What is the NRC position on purchase from commercial distributor relative to acceptance by commercial grade vs. use of ASME rules for unqualified source material?

Answer:

NCA-3800, Subsection 3855.5(a) provides specific requirements for the use of unqualified source material by Material Organizations to be used in ASME components. The process described in 3855.5(a) is not CGI dedication. Acceptance of commercial-grade material for safety related applications should be based on the identification and verification of the material's critical characteristics.

Question 19:

Are there any commercially available database programs suitable for managing a CGI dedicated program?

Answer:

The NRC is not aware of any such programs.

Question 20:

10 CFR 21.3 Definitions; Dedication - mid paragraph says "this assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests or analysis performed by the purchaser or third party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's

facility, and analysis of historical records for acceptable performance. EPRI NP-5652 prescribes doing any of the former methods or a combination thereof. The question is: are inspections, tests, and analyses the primary method and the other 3 methods supplementary? If so, NP-5652 contradicts 10 CFR 21.3.

Answer:

Any of the EPRI dedication methods can be considered as the primary method, provided that GL 89-02 restrictions have been met. The dedication methods should provide a means to ensure that the CGI meets the acceptance criteria specified for the selected critical characteristics. The selection of acceptance methods should be based on the type of critical characteristics to be verified.

Question 21:

Some in the industry have interpreted the wording in the 10 CFR 21 definition of "dedication" to mean that inspections, tests and analyses performed after item delivery is the "primary" method of dedication, and surveys and source inspections are only "supplemental" methods. NP-5652, as endorsed by the NRC, treats these methods as equivalent. What is the NRC's position?

Answer:

Any of the EPRI dedication methods can be considered as the primary method, provided that GL 89-02 restrictions have been met. The dedication methods should provide a means to ensure that the CGI meets the acceptance criteria specified for the selected critical characteristics. The selection of acceptance methods should be based on the type of critical characteristics to be verified.

Question 22:

EPRI has a series of test plans for commercial grade item dedication. How can the general public get a copy of this?

Answer:

Please contact EPRI for more information.

Question 23:

What is the role of the licensee to accept/decline third party dedicated items?

Answer:

Licensees and dedicating entities are required to provide the appropriate level of oversight, including source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. This oversight is required for safety related and commercial-grade material, equipment, and services. As the ultimate end user of a safety-related part, including those dedicated, the licensee is ultimately responsible for assuring the procured item is of the quality consistent with its safety significance. As such, its role is to assure the item is appropriately dedicated before placing the item into service.

Question 24:

Does the NRC/EPRI have a standardized survey that vendors can pass along to their sub-supplier (commercial grade dedication surveys?). If so, where can vendors obtain a copy?

Answer:

No. The Nuclear Procurement Issues Committee (NUPIC) has established a checklist. The NUPIC Survey Checklist is available on their website: http://www.nupic.com/home_download.asp.

Question 25:

Are new component manufacturers required to dedicate at the piece part level or just rely on the final test? For new plants, i.e., ASME items with commercial safety related parts?

Answer:

The dedication of piece parts is based on the safety function of the piece part and the critical characteristics that are necessary to support the function of the component.

Question 26:

Clarify the last sentence of the definition for commercial grade item. Some in our project feel that it eliminates commercial grade survey, source surveillance or source verification as dedication or verification methods because they involve "in-process" inspections. Also, is there a plan to clarify Part 21 with respect to definitions, substantial safety hazard, etc.?

Answer:

Those critical characteristics that cannot be effectively verified after the component has been manufactured should be identified in order to apply an appropriate verification method during the manufacturing process. In this case, a commercial-grade survey or source surveillance could be used to demonstrate acceptable control of "in-process" manufacturing activities. The NRC continues to evaluate its regulatory framework for possible enhancements, including assessing the needs for changing 10 CFR Part 21 requirements through the rulemaking process. However, at this time, there are no plans to revise the Part 21 definition.

Question 27:

When a commercially dedicated component (basic component) fails in-service, does NRC review the dedication scheme (plan/dedication/acceptance criteria) to determine probable cause of this failure? If so, how?

Answer:

When any basic component fails in service at a licensee facility, it is the responsibility of the licensee to determine the root cause of the failure, extent of condition, and potential reportability under 10CFR21. The NRC oversees the licensee's performance of this type of activity through routine inspections at operating sites and will inspect this activity as part of its oversight of new reactor construction.

Question 28:

When you do a commercial grade survey and you find adequate controls, to what extent do you have to include these controls in procurement documents?

Answer:

The purchase order for these items should invoke the supplier's quality controls found acceptable during the survey by referencing the applicable program/procedure(s) and revision.

Question 29:

What are the specific differences between a survey and an audit?

Answer:

The term survey is used in conjunction with commercial grade dedications. An audit is used in conjunction with 10 CFR Part 50, Appendix B quality assurance programs. A commercial grade survey verifies how a supplier controls the identified critical characteristics through quality

activities. An audit verifies how a vendor's quality assurance program complies with its Appendix B program through its implementing procedures.

Question 30:

With respect to Method 3 (source verification), is there any requirement for witness in addition to being knowledgeable for certification of critical characteristics?

Answer:

Source verifications involve witnessing the supplier performing quality activities on the actual items being procured and adequately verifying the item's critical characteristics. The individual(s) performing the source verification should be skilled in audit practices and knowledgeable in the design and operation of the item(s) and the associated critical characteristics to be verified.

Question 31:

Is there an EPRI or NRC document for CGD Surveys?

Answer:

There are EPRI documents such as NP-5652, and there is an EPRI Training Course (TR102260) that provides guidance on conducting commercial grade dedication surveys. NRC guidance can be found in IPs 38703 and 43004.

Question 32:

If a supplier buys items from various sub-suppliers under an ISO program and does not invoke App B/Part 21, what are those items called?

Answer:

Those items are commercial grade items.

Question 33:

Clarify the relationship between commercial grade surveys and acceptance of items from approved CGS suppliers based on Certificates of Conformance as stated in EPRI NP-5652 and the NRC commercial grade dedication inspection plan. Our project is moving away from this concept, based on experience, and requiring inspection and test documents from the supplier to validate their activities in verification of critical characteristics.

Answer:

When the verification of one or more critical characteristics is based on vendor-certified material test reports or certificates of conformance/compliance, the dedicating entity should verify the validity of these documents through performance of a survey. Acceptance of an item using this method will be completed by performing a receipt inspection that includes the accompanying vendor's certificate of conformance/compliance or certified material test report.

Question 34:

When performing commercial grade dedication of materials, based on a nationally recognized standard (such as ASTM), where the standard identifies the critical characteristics of the materials (chemical & physical), can the standard be the source of engineering input or judgment? (Example: Material suppliers/distributors that do not have the engineering staff).

Answer:

Vendors supplying material as a basic component, including dedication activities, are required to establish adequate controls for the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III, "Design Control," of Appendix B. When performing dedication of materials, the dedicating entity may utilize ASTM standards for the specification of critical characteristics that need to be verified to provide reasonable assurance that the material will perform its intended safety function. Design or engineering involvement is necessary in performing these activities to assure that the selected material is compatible with its intended use (is the ASTM material selected appropriate for the application?). The level of design control or engineering involvement is dependent on the nature, complexity, and use of the items to be dedicated.

Question 35:

For computer software not obtained from App. B suppliers to be used in a safety related application, is it required to be formally dedicated or is routine verification and validation in accordance with NQA-1 subpart 2.7 adequate? This may be software already in house or recently purchased non-safety or even downloaded from the internet.

Answer:

Yes, the software should be dedicated. The dedicating entity may develop a dedication program based on NQA-1 Subpart 2.7, if the necessary critical characteristic(s) of the software can be identified and verified.

Question 36:

Does NLI perform CGD of digital I&C hardware and software?

Answer:

Please contact Nuclear Logistics Inc. for information.

Question 37:

Even though an item may be procured through an Appendix B source (preferred method), is it acceptable to procure the item as a commercial grade item and dedicate the item provided the guidelines are met?

Answer:

Yes.

Question 38:

Are surveys of suppliers required when a dedicating entity is using a sampling plan based on homogeneous lots? The NRC inspection procedure for dedication would suggest that any CGI dedication in which sampling is less < 100% requires some method "2" survey activities.

Answer:

Yes, an initial survey would serve as objective evidence of adequate quality controls by the supplier for establishing lot/batch control.

Question 39:

Your slides indicated that Method 2 (surveys) should be used in conjunction with another method. GL 89-02 put conditions on Method 2, but they were that the supplier's quality controls must be documented and that distributor controls must be included when accepting CGIs from distributors. Method 4 was the only method restricted to not be the sole method of verification. Please clarify/comment.

Answer:

Method 2, “Commercial-Grade Survey of Supplier,” should not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls. The dedication methods should provide a means to ensure that the CGI meets the acceptance criteria specified for the selected critical characteristics. The selection of acceptance methods should be based on the type of critical characteristics to be verified. It is expected that dedicating entities would

perform receipt inspection activities in combination with any of the four EPRI acceptance methods.

Question 40:

If a commercial item is incorporated into a basic component design basis, is dedication required when procuring the item?

Answer:

Dedication of a commercial-grade item is required when the item performs an active/passive safety function, and the failure of the commercial-grade item would prevent the basic component from performing its intended safety function.

Question 41:

If a commercial supplier (with no written program) performs a machining operation for our basic component and we inspect 100% of the machining attributes under our App. B program, document the inspection, and provide as part of final inspection document to customer (utility), is the component considered a commercial grade item?

Answer:

The acceptability of the machining work described above could not be determined with the information provided. For example, the question did not specify that machining work activities were documented in a dedication plan (if these activities were considered part of dedication), did not identify the critical characteristics of the item, did not consider the adequacy of the supplier's undocumented machining controls, and did not identify the qualification of the individuals performing machining operations.

Question 42:

If a supplier or licensee determined that the use of a reduced sample is acceptable, and one of the justifications for this conclusion is an item's acceptance history, what type of documentation/evidence would you expect to see to validate the claim that the item or product has an acceptable history of conformance with specification requirements? Should there be procedural guidance established to address the use of acceptance history at the level of documentation required?

Answer:

The dedicating entity should maintain objective documented evidence of the results of receipt inspection activities and any other special inspections or tests that will support the use of a

reduced sampling plan, consistent with the item's importance to safety. It is expected that this documentation will be included in the dedication plan or appropriate documentation supporting the item's dedication.

Question 43:

If method 4 required verification on suppliers controls by "survey," why isn't this method 2?

Answer:

Method 4, "Acceptable Supplier/Item Performance Record," could be used to demonstrate acceptable quality controls of one or more critical characteristics based upon documented acceptable item performance. The implementation of Method 4 is not solely based on a survey. Method 4 should be used in combination with one or more of the EPRI acceptance methods to document objective evidence necessary to ensure acceptable historical performance of the supplier.

Question 44:

Is a paper "Certified Material Test Report (CMTR)" review acceptable without sampling of actual material to verify CMTR data?

Answer:

No. When the verification of one or more critical characteristics is based on vendor-certified material test reports or certificates of conformance/compliance, the validity of these documents should be verified. The purchaser should verify that the vendor has established adequate traceability controls and that these controls are effectively implemented. Acceptance of an item using this method will be completed by performing a receipt inspection that includes the accompanying vendor's certificate of conformance/compliance or certified material test report. When traceability cannot be established, sampling plans need to be considered on individual, item-specific basis and ensure that they are capable of providing a high level of assurance of the item's suitability for service. There may be situations where each item needs to be tested.

Question 45:

If a commercial item is incorporated into a basic component design basis, is dedication required when providing the item?

Answer:

Dedication of a commercial-grade item is required when the item performs an active/passive safety related function, or when the failure of the commercial-grade item would prevent the basic component from performing its intended safety function.

Question 46:

Is a CGI that is part of a basic component which has been designed, procured, and installed under a licensee QA Program required to be dedicated?

Answer:

If the CGI part performs a safety related function, it must be dedicated.

Question 47:

Is it proper for an OEM Vendor (pumps, motors) to dedicate an item and supply it as safety related to a utility when they do not have knowledge of the safety related functions communicated to them by the utility? Shouldn't in this case the utility actually control the dedication process and the vendor performed testing as part of their verification activities?

Answer:

The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is often necessary to identify and characterize the design and functional parameters of specific parts.

Question 48:

It was indicated that design [engineering] has to be actively engaged in setting dedication CC's. How then can a distributor (materials for example) do a commercial dedication? Is independent of a design authority?

Answer:

It is not typical for distributors to perform dedication activities since they do not perform design and/or manufacturing. However, when distributors are included in the supply chain, the activities of these organizations may need to be surveyed to ensure that material traceability and proper storage conditions are maintained.

Question 49:

Licensee buys basic components from a supplier with an Appendix B & Part 21 Program. Supplier buys items from various sub suppliers under ISO program and does not invoke Appendix B or Part 21. What are those items called? Items purchased are not off the shelf & unique to their product/design and do not meet four parts that define CGI.

Answer:

Since sub-suppliers providing items under ISO Quality Programs are not supplying basic components, these items must be considered commercial-grade items.

Question 50:

May we dedicate ASME certificate holders' raw material with CMTR to the pressure retaining part according to the CGI dedication program without auditing suppliers? [Can a vendor rely on the ASME material certificate holder's CMTR to address the pressure retaining capabilities of the material in the dedication plan without conducting an audit?]

Answer:

No. It is expected that the implementation of the Quality Assurance program of a basic component supplier is audited. NRC Information Notice 86-21 and supplements provide guidance for the recognition of ASME accreditation program for "N" stamp holders.

Question 51:

Should there be a procedural guidance established to address the use of acceptance history and the level of documents revised?

Answer:

Method 4, "Acceptable Supplier/Item Performance History," provides for the use of industry-wide performance data that is applicable to the item's critical characteristics and the intended safety related application. Appendix B requires that activities affecting quality are prescribed by documented procedures appropriate to the circumstances.

Question 52:

We have a division that is Appendix B compliant. This division is in a foreign country and not as able to obtain industry training (US training). They do not have an auditor that has been lead nuclear certified. Can they still do commercial grade dedication and surveys? Would the US Entity need to resource the certified lead auditor? What if they are qualified not certified?

Answer:

Qualification of auditors is based on the vendor's auditor qualification requirements. The vendor is responsible for designating those activities that require qualification of personnel and the minimum requirements for such personnel. Such a vendor should select individuals that have the experience or training commensurate with the scope, complexity, or special nature of the activities audited/surveyed. Provided that the auditor has been qualified to the vendor's auditor qualification requirements and is skilled and knowledgeable about U.S. requirements, the qualified auditor can do the commercial grade dedication surveys.

Question 53:

When performing CGD of materials to a nationally recognized standard such as ASTM, can the standard serve as the engineering involvement?

Answer:

Vendors supplying material as a basic component, including dedication activities, are required to establish adequate controls for the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III, "Design Control," of Appendix B. When performing dedication of materials, the dedicating entity may utilize ASTM standards for the specification of critical characteristics that need to be verified to provide reasonable assurance that the material will perform its intended safety function.

Design or engineering involvement is necessary in performing these activities. The level of design control or engineering involvement is dependent on the nature, complexity, and use of the items to be dedicated.

Question 54:

The 10 CFR Part 21 definition of dedication requires CCs to be verified by purchaser using analysis, test or inspection as supplemented by customer survey. However, NRC Inspection modules and EPRI 5652 indicate customer survey may be the sole basis. Please clarify.

Answer:

GL 89-02 conditionally endorsed the four methods identified in EPRI NP-5652. Specifically, the staff stated that Method 2, "Commercial-Grade Survey of Supplier," should not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls. It is

expected that dedicating entities would perform receipt inspection activities in combination with any of the four EPRI acceptance methods.

Question 55:

Many nuclear suppliers, even with 10 CFR Part 50 App. B Programs, do not have the ability or capability to determine the in-plant safety function of the item being dedicated - Is it acceptable to then "dedicate" items based solely on design information and published product literature (performance specifications)?

Answer:

The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is often necessary to identify and characterize the design and functional parameters of specific parts.

Question 56:

Who determines the critical characteristics of the product being supplied? Vendor or Licensee/Utility?

Answer:

The dedicating entity typically identifies the critical characteristics for the commercial grade item being dedicated for safety related use with input from the licensee, as applicable. The key to determining who identifies the critical characteristics for the supplied item is determining who retains the design authority for the safety functions that the item is required to perform. Ultimately, the licensee is responsible for assuring that the items being used for safety-related applications are of the quality commensurate with their safety significance, including assurance that the critical characteristics of commercial grade items have been met.

Question 57:

The second slide first question was "were the proper CCs verified" (example member). It is my understanding that there is no minimum or maximum number of CC's. Are you saying there is a minimum received number or just verify you've tested to be reasonably assured the component will perform its intended safety function?

Answer:

There is no minimum or maximum number of characteristics to be verified. As stated in GL 91-05, the dedicating entity is responsible for identifying the important design, material, and

performance characteristics for each part, material, and service intended for safety-related applications, establishing acceptance criteria, and providing reasonable assurance of the conformance of items to these criteria.

Question 58:

Is Method 1 - Special Test and Inspection intended to be interpreted as: (1) Special: Tests and Inspections or (2) Special Tests, and Inspections?

Answer:

EPRI NP-5652, Section 3.1, Method 1 - Special Tests and Inspections, Pages 3-1 through 3-4 refers to "Special Tests and Inspections." Special Tests and Inspections are activities conducted after receipt of a commercial grade item to verify one or more critical characteristics as a method to accept the item for safety-related use. Both the tests and inspections referred to in this method are considered special in nature because these activities are specifically designated for the item undergoing dedication and may include activities such as special receipt inspections or post-installation testing.

Question 59:

There are situations where a component is moved within a plant. What should a supplier do if a licensee cannot supply the safety function of this component?

Answer:

Once the supplier has delivered the component, it is the responsibility of the licensee to ensure that the component can perform all of its safety functions in the new application that it is being used.

Question 60:

What is the definition of "use" as a basic component? First placement of a part or the complete assembly after testing?

Answer:

The definition of "dedication" states the following in the last sentence: "The process is considered complete when the item is designated for use as a basic component." In order for a component or service to be ready for "use as a basic component," the item or service must have gone through the dedication process.

Question 61:

You stated that configuration is a critical characteristic. What does this involve? Visual, dimensional, etc.?

Answer:

The staff has not specifically issued guidance that identifies configuration as a critical characteristic for all dedicated items. If a dedicating entity identifies item/component configuration as a critical characteristic, it will have to be verified during dedication.

Question 62:

Should a product not be tested against all critical characteristics to ensure it will still function as intended?

Answer:

The dedicating entity should test the critical characteristics that can be verified through testing. The dedicating entity may use a combination of the other 3 methods to adequately verify all of the identified critical characteristics to provide reasonable assurance that the CGI item can perform its intended safety function.

Question 63:

Can critical characteristics include process controls? For example, can a commercial grade survey verify "material controls" at a supplier site to ensure proper material is used in a component as part of a method to dedication?

Answer:

Yes, EPRI NP-5652, Method 2, provides guidance for the use of commercial grade surveys to verify the implementation of commercial quality controls (including material traceability controls).

Question 64:

Does an OEM need to identify safety functions if they are dedicating a component by enveloping all known functions of the component as critical characteristics in their dedication plan?

Answer:

The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is often necessary to identify and characterize the design and functional parameters of specific parts.

Question 65:

Does the NRC consider the fact that certain materials in an electrical item (dedicated for safety related use) are UL approved as an acceptable basis for determining that material is adequately controlled? An example is a small SEISMIC/EQ electrical component that is dedicated by company Y under their App. B program, supplied to customer as a safety related item, and certified as equivalent to item originally qualified. Technical evaluation states the material of certain piece parts of the component is important relative to the item's safety function in actual service and the App. B supplier performs functional testing of the item, and performs material verification of some piece parts. But not on others. He does not perform material verification on some items on the basis that the material of those items are UL approved. No survey of the UL facility performing the testing has been performed. The supplier further justified the use of UL approval on the basis that there have been no known failures of the component in service. Is this acceptable?

Answer:

No. To accept the UL material certification, the dedicating entity would need to verify the adequacy of the process used to test the material and the validity of the certification issued by UL.

Question 66:

How can a dedication process ensure long term design control over critical characteristics at commercial components? Often these components and the manufacturing processes that produce them are revised without change of part number or external appearance.

Answer:

The dedication process does not assure long term design control of critical characteristics of commercial components. Those critical characteristics identified in the dedication plan, once verified, will ensure the procured item's ability to perform its intended safety function. If the commercial grade item design is revised or modified, it is the dedicating entity's responsibility to perform an equivalency evaluation to determine if any changes in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the item's ability to function under all design conditions (including design-basis event conditions) and ultimately the component's ability to perform its required safety function. If the change to the item affects the ability of the item to fulfill its safety function, then the dedicating entity would

need to determine whether the critical characteristics used for the previous design remain adequate to demonstrate the component is capable of performing safety functions.

Question 67:

How can a structural steel supplier choose the critical characteristics for evaluation when the utility's purchase order does not give guidance regarding the steel's intended use?

Answer:

The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is often necessary to identify and characterize the design and functional parameters of specific parts.

Question 68:

If an App. B type vendor buys materials (A36 plate) from a non-Q sub vendor and then performs all the ASTM required testing (except melt analysis of course) in an effort to make the material safety-related, must the App. B vendor have a commercial grade dedication plan to complete the identified CCs?

Answer:

The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is necessary to identify and characterize the design and functional parameters of specific parts or components.

Question 69:

Is a seismic qualification specific to a part of the system or only the overall system if the system or building is the basic component?

Answer:

If seismic qualification is required for a replacement part or component, then seismic qualification needs to be performed.

Question 70:

Is a CGI vendor required to dedicate a part, or is it the licensee or third party dedicator?

Answer:

The licensee or third party dedicating entity is required to dedicate the CGI for safety-related use. A vendor who supplies only commercial-grade items does not perform dedication.

Question 71:

Often times a purchase order invokes Part 21, but the actual safety function of the basic component is not specified in the design specification. It is therefore difficult to determine exactly which parts of an assembled basic component need to be dedicated. With respect to valves, the supplier does not know if position indication relays, or even operation is safety related. Many times items are dedicated and may not need to be. Is there any requirement for the purchaser to specify the safety related functions when ordering a basic component? This would allow the supplier to reduce dedication costs and make 10 CFR 21 evaluations easier to perform by the supplier.

Answer:

The purchaser needs to include the appropriate level of detail in the purchase order to allow the supplier to address technical and quality requirements of the basic component. Appropriate interface between the utility and the vendor is necessary to identify and characterize the design and functional parameters of specific parts or components.

Question 72:

When performing commercial grade dedication to material that is produced to industry specifications such as ASTM A/B and the dedicating entity does not have design or engineering capabilities, what is an acceptable method for determining critical characteristics?

Answer:

Vendors supplying material as a basic component, including dedication activities, are required to establish adequate controls for the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III, “Design Control,” of Appendix B. When performing dedication of materials, the dedicating entity may utilize ASTM standards for the specification of critical characteristics that need to be verified to provide reasonable assurance that the material will perform its intended safety function. Design or engineering involvement is

necessary in performing these activities. The level of design control or engineering involvement is dependent on the nature, complexity, and use of the items to be dedicated.

Question 73:

Where can you get the FMEA Guidance document?

Answer:

EPRI NP-6406, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)," contains guidance for performing FMEA.

Question 74:

Why are utilities reviewing third party dedication plans and not required to review an OEM/OES CGD plan? Seems like it should be the other way around. The third party dedicators should supply basic components under 10 CFR 21.

Answer:

There are no regulatory requirements for purchasers of basic components to review the suppliers' dedication plan. However, the review of the dedicating entity's dedication program, including dedication plans, would be conducted during audit activities. Utilities can request the review and approval of the dedicating entity's dedication plan as part of the procurement process.

Question 75:

If a licensee does not pass down Part 21, and a vendor's engineering determines that part is safety-related, does the licensee's purchase order have to pass down Part 21?

Answer:

It is the licensee's responsibility to determine the safety classification of parts and components that will be installed in its facilities.

Question 76:

You used the expression "low safety-significance" of a critical characteristic of acceptance to determine sample size. Please explain how you determine that a safety significance is "low" if it has been determined to be a critical characteristic of acceptance?

Answer:

The staff has never provided or accepted guidance for the classification of critical characteristics based on safety significance. When using sampling plans for the verification of critical characteristics, these plans should have an adequate, documented technical basis to support the product's sampling strategy.

Question 77:

Although the frequency has significantly declined over the last decade, there are still instances where a supplier will use a magnet to "verify" material of a metallic item that is subject to the dedication process. Can you provide some insight regarding the validity of this practice? And, what are some situations where this practice would be considered viable?

Answer:

Some vendors use magnet tests to detect ferrous metals such as alpha-iron, cobalt, nickel and gadolinium. Other destructive and non destructive examination techniques may be used to identify material in a certified material test report (CMTR). The dedicating entity should select the appropriate method to verify critical characteristics associated with materials.

GENERAL QUESTIONS

Question 1:

Does the NRC have reciprocity with foreign regulatory agencies?

Answer:

No. The NRC does not have reciprocity agreements with foreign regulators in the area of vendor oversight. Under the umbrella of the Multinational Design Evaluation Program (MDEP), the NRC is participating in the Vendor Inspection Cooperation Working Group (VICWG) with regulators from 10 other countries to determine how best to apply the oversight practices and insights gained as each of the regulators oversees vendors providing parts or services to their domestic nuclear power program and new construction activities. Please see the response to question 5 for additional information.

Question 2:

Quality Assurance Programs for new plants including activities for design certification and COLAs are currently written to the NRC endorsed NQA-1-1994 and 10 CFR 50, App. B. How can the NRC consider endorsing portions of NQA-1 2008 & 2009 for dedication requirements when QAPD's do not commit to that revision?

Answer:

After the NRC endorses the 2008 edition of NQA-1, licensees can choose to revise their QAPDs to commit to this new QA standard.

Question 3:

What is the NRC's position on international supplier documents language (i.e., must be in English)?

Answer:

The NRC does not have language requirements for supplier documentation for U.S. utilities or others purchasing parts for the commercial U.S. nuclear power industry.

It is the responsibility of the purchaser to specify document language requirements. Although there are no NRC requirements for supplier documents to be in English, there is an expectation by the NRC that the licensee be able to audit its suppliers' implementation of the QA program to assure the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 are met. This is more effectively accomplished if the program and related documentation are in English.

Question 4:

Explain the relationship between the NRC and Dept. of Energy regarding commercial grade dedication.

Answer:

10 CFR Part 21 provides requirements for the dedication of commercial-grade items at NRC licensed facilities. Please contact DOE for information related to Commercial Grade Dedication at DOE facilities

Question 5:

Does the international oversight program include comparative evaluation of regulatory requirements, and who are the different countries, and will such assessments be published? Will common structured standards be agreed upon for the international vendor audit programs, so that results and evaluation can be most applicable?

Answer:

The Vendor Inspection Cooperation Working Group (VICWG), as part of MDEP, is in the process of comparing the quality assurance requirements that apply to vendors under each of the different regulatory frameworks for each of the 10 participating countries (i.e., Canada, China, Finland, France, Japan, the Russian Federation, South Korea, South Africa, the United Kingdom, and the United States). The VICWG is also in the process of defining the protocols for sharing information among participating countries, including the scope of information that will be made public. In the short term, the VICWG is coordinating activities to allow members to observe and eventually participate in vendor inspections at the participating countries.

Question 6:

Does NRC actively maintain NUREG-0040? Why are many of the NRC audits done with lots of emphasis in compliance based not performance based audits?

Answer:

NUREG-0040 is no longer being maintained. The NRC now includes inspection reports in the Office of New Reactors' Quality Assurance webpage. NRC vendor inspections are intended to be both compliance and performance based.

Question 7:

What is the official position on audit frequency for suppliers and/or sub-tier suppliers, as the only references to audit frequency is Regulatory Guide 1.144 which has been superseded? Audit frequency is not defined in App. B. What makes a Reg Guide a regulatory requirement?

Answer:

RG 1.28 provides a regulatory position on the frequency of audits necessary to meet Appendix B requirements. When a licensee adopts a Regulatory Guide, it then becomes a regulatory commitment.

Question 8:

"Historical records of calibrations not maintained" - Is three years OK? If not, what is?

Answer:

As noted in RG 1.28, calibration records are considered nonpermanenet manufacturing records. RG 1.28 states "programmatic nonpermanent records should be retained for at least 3 years and product non permanent records should be retained for at least 10 years or the life of the item if less than 10 years." For additional details, see RG 1.28, Table 1.

Question 9:

Defining "independence" is difficult. Clarify if "independence" is internal to the supplier? Example: Customer review & observation is not sufficient. Also, App. B only discusses independence in Criteria III design. What about independence in Criteria XI testing?

Answer:

10 CFR Part 50, Appendix B, Criterion III, states, in part, that "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization."

Question 10:

What are the companies to do while the NRC does its evaluation of EPRI 7218/DG-1070?

Answer:

The NRC staff has not endorsed EPRI-TR-7218. Please refer to Questions 3 and 6 of the Commercial Grade Dedication Q/A for additional information on sampling.

Question 11:

Will the QA and vendor branches be witnessing/verifying ITAAC at vendor facilities? Will the NRC have resident inspectors at major vendors similar to site residents?

Answer:

The NRC staff is developing planning tools for ITAAC related activities at vendor facilities. The NRC staff has not yet determined what inspection resources will be necessary at major vendors.

Question 12:

Are there any plans for the NRC to be more involved with NIAC? During new construction?

Answer:

The NRC has not committed any resources to oversee vendor activities performed by the Nuclear Industry Assessment Committee (NIAC).

Question 13:

Was the NRC involved in the development of NQA-1-1998? When will it be effective? Will it address CGD?

Answer:

The NRC is actively reviewing the 2008 edition of NQA-1 for endorsement via an update to RG 1.28. The NRC staff did not endorse NQA-1-1998.

Question 14:

Is it the intent of the NRC to publish all vendor inspections regardless of region on the NRC QA link? Example: Region 2 inspections are only available via ADAMS. Also, French Regulators advised the NRC of issues with a French company. Can the NRC post this info?

Answer:

The NRC does post vendor inspections on the NRC vendor and QA home page for both NRR and NRO (http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html). The Region 2 inspections are available in ADAMS. The NRC may

publish information notices (INs) related to foreign events if the NRC believes that the issue also applies to NRC-regulated activities.

Question 15:

If the CFRs are law, are Information Notices and NUREGs law as well?

Answer:

No. The NRC website provides information on NRC generic communications, including Information Notices and NUREGS.

Question 16:

Does NIAC have an approved Supplier Audit checklist such as NUPIC, or is each one specific to the member performing the audit?

Answer:

NIAC does have a standardized audit checklist.

Question 17:

We performed nuclear contracts for the DOE to NQA-1-2000 requirements. Is the NRC considering moving to implement the requirements of NQA-1-2000 which are more stringent than the requirements of Appendix B to 10 CFR Part 50?

Answer:

No. The NRC plans to endorse the 2008 edition of NQA-1 via an update to RG 1.28. The provisions in NQA-1 are not requirements.

Question 18:

Does NRC have an expectation that licensees maintain separate lists for approved suppliers of 10 CFR Part 50, Appendix B and approved commercial grade suppliers?

Answer:

No.

Question 19:

Which is the latest NQA Program (year) that is endorsed by the NRC? Any plans on revising the 10 CFR 50, Appendix B standard?

Answer:

RG 1.28 endorses the 1983 edition of NQA-1. There are no rulemaking plans for 10 CFR 50, Appendix B.

Question 20:

Which regulatory guide endorses NQA-1 and which revisions of NQA-1 are endorsed?

Answer:

RG 1.28 endorses the 1983 edition of NQA-1. The NRC staff is currently reviewing the 2008 edition of NQA-1. The NRC plans endorse 2008 edition of NQA-1 via an update to RG 1.28.

Question 21:

Other than NUPIC, who are the third party organizations? Is there a published list?

Answer:

Currently, NUPIC is the only third party audit organization of which the NRC provides direct oversight. NUPIC maintains its own list of approved suppliers for domestic and international utility members. The NRC staff does not have a published list of suppliers.

Question 22:

When we are asked if our Quality Program is a 10 CFR Part 50 or NQA program, what are the criteria to answer this? (We are approved by NUPIC)

Answer:

All licensees and their contractors are required to establish and implement a QA program that meets the requirements of Appendix B to 10 CFR Part 50. As documented in RG 1.28, NQA-1 is one method of meeting the requirements of Appendix B.

Question 23:

John Nakoski stated that "NRC does not certify any vendors." What is done for DCD vendors? The DCD is "certified". Doesn't that imply the vendor was audited and "certified"? What is expected from the licensee for using an NRC approved design?

Answer:

The NRC does certify new reactor designs submitted by applicants for certification through the 10 CFR Part 52 design certification process. These certified designs can then be referenced in new COL applications.

Question 24:

I understand that the NRC has been involved in the development of NQA-1-2008. Is this correct? When will it be effective? Will it address commercial dedication?

Answer:

The NRC has been involved in the revision to the 2008 edition of NQA-1 as part of the NQA-1-2008, agency's standards development process. The staff is also in the process of revising RG 1.28 to endorse the 2008 edition of NQA-1. NQA-1-2008, Subpart 2.14, "QA Requirements for Commercial Grade Items and Services," provides guidance for commercial-grade dedication.

Question 25:

There is misconception in the power industry that non-safety related engineering & vendor work will not be inspected by NRC/licensee and does not fall under NRC regulation. Please clarify.

Answer:

The NRC will continue to provide oversight of vendors providing safety related engineering & services to licensees.

Question 26:

Why is the NRC differentiating its inspection programs between operating and new reactor vendors? It appears the program for new reactor vendors is far more robust. Isn't the current operating fleet at least as important?

Answer:

The NRC vendor inspection program uses common inspection procedures that are reviewed, approved, and implemented by both NRR and NRO. The NRC holds both operating and new reactor vendors to the same standards of quality and regulatory compliance.

Question 27:

The NRC and NUPIC have always stressed the importance of training/education within a vendor's organization. Clearly, with the NRC conducting 12 vendor audits, resulting in 10 out of 12 audits falling w/in 10 CFR 21 non compliance, training and clearly defined requirements are needed. Where do vendors go to get detailed directions/guidance?

Answer:

This NRC web site contains QA and Part 21 regulations, implementing guidance and NRC inspection procedures: http://www.nrc.gov/reactors/new-reactors/oversight/quality-

assurance.html. Valuable lessons may also be learned from reading inspection reports found on the website.

Question 28:

Are these PowerPoint presentations available to the general audience?

Answer:

Yes, The NRC staff handed out flash drives with all the presentation slides during the vendor workshop. The slides are also available on the NRC web site at http://www.nrc.gov/public-involve/conference-symposia/vendor-oversight/index.html.

Question 29:

Specifically related to new reactor construction, is it possible or likely that EPC firms could use the utility ASL for qualification of vendors providing products for new construction?

Answer:

Engineering, Procurement, and Construction (EPC) firms would be expected to maintain an approved supplier lists (ASL) of vendors providing products or services for new construction.

Question 30:

For ASME certification or re-certification, does ASME accept the use of NIAC third-party audits to add a vendor to an approved vendor list if this procedure is described in your NQA-1 program?

Answer:

We are not aware of ASME allowing use of Nuclear Industry Assessment Committee (NIAC) third party audits to approve a vendor on the qualified supplier list. Please contact ASME for additional details.

Question 31:

In reference to the requirement of having detailed design complete prior to construction, what is the NRC's definition of construction? Does this apply to overall design or only those portions necessary for the scheduled activities (i.e., foundation, basement, first floor, etc., open top construction)?

Answer:

Please refer to 10 CFR 50.10(a), “Definitions,” for the definition of construction.

Question 32:

Is there any move to audit NIST by the NRC? Or is this addressed in an Information Notice or NUREG document, etc?

Answer:

The NRC does not plan to audit or inspect the National Institute of Standards and Technology (NIST).

Question 33:

Isn't NVLAP and ILAC acceptance for approving suppliers for use - meaning the supplier must still be audited for implementation?

Answer:

For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs, NVLAP, as recognized through the mutual recognition arrangement (MRA) of the International Laboratory Accreditation Cooperation (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met:

- The alternative method is documented in the QA program description.
- Accreditation is to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- Use of the alternative method is limited to domestic accrediting bodies, as recognized by ILAC signatories.
- The scope of the accreditation covers the contracted services.
- Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements.
- Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
- Purchase documents require identification of the laboratory equipment/standards used.
- The alternative method is limited to the domestic calibration service suppliers.
- The alternative method is applicable to subsuppliers of calibration service suppliers, provided the above conditions are met.

Question 34:

Please address the vendor related quality issues (i.e., concrete supply) at OL3 (Finland), Flamiville (France), Savahah River Mox Facility. What are the issues? How to avoid in the future?

Answer:

The NRC has published generic communication regarding these issues in Information Notice (IN) 2007-04 and IN 2008-17. The NRC continues to monitor both domestic and international operating experience related to the construction of nuclear power plants and fuel fabrication facilities.

Question 35:

What documents and regulations are still relevant and needed? There have been reference to a multiplicity of documents that were written in the last 30-40 years, which ones do we need to know about today?

Answer:

10 CFR Part 50, Appendix B and 10 CFR Part 21 regulations apply to vendors supplying safety related components for US nuclear power plants. Other documents such as Regulatory Guides, NUREGs, and generic communication documents may be found in the NRC website.

Question 36:

What matrix does the NRC have that supports continued utilization of NUPIC or NIAC? Are they delivering the proper assessment/audit/survey?

Answer:

The NRC does not maintain a matrix of NUPIC or NIAC QA audit activities. The NRC posts reports related to NUPIC Joint Utility Audit observations on the NRC QA website.

Question 37:

What, if any, enforcement agreements have been reached with international regulatory agencies? Are these cooperative efforts inclusive of other regulatory law (i.e., PAAA - Price Anderson Amendments Act)?

Answer:

Currently, there are no agreements between the NRC and other foreign regulators for enforcement activities.

Question 38:

Will the NRC address identification of CC's by companies that do not have engineering activities or design responsibilities - REF - DG-1070, although was never finalized issued did provide guidance- there is a must need to work to the same rules!!

Answer:

Vendors supplying basic components, including dedication activities, are required to establish adequate controls for the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III, “Design Control,” of Appendix B. Design or engineering involvement is necessary in performing these activities. The level of design control or engineering involvement is dependent on the nature, complexity, and use of the items to be dedicated. When using sampling plans for the verification of critical characteristics, these plans should have an adequate documented technical basis to support the product’s sampling strategy.