January 5, 2012

MEMORANDUM TO: Richard A. Rasmussen, Chief
Electrical Vendor Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Kerri A. Kavanagh, Acting Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

FROM: Andrea Keim, Reactor Systems Engineer***/RA/***
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

SUBJECT: NRC RESPONSES TO QUESTIONS RECEIVED DURING THE WORKSHOP ON VENDOR OVERSIGHT FOR NEW REACTOR CONSTRUCTION HELD IN JUNE 2010

Enclosed please find the NRC responses to questions received during the Workshop on Vendor Oversight for New Reactor Construction, which took place June 17, 2010 in New Orleans, Louisiana. The responses enclosed are for questions directed at the NRC staff.

Enclosure:
As stated

CONTACT: Andrea T. Keim, NRO/DCIP/CQVB
(301) 415-1671

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OFFICE	NRO/DCIP/CQAB	NRO/DCIP/CQAB	NRR/DIRS/IQVB
NAME	AKeim	KKavanagh	CNguyen
DATE	10/24/2011	12/15/2011	01/04/2012
OFFICE	NRO/DCIP/CEVB	OE/	OGC/GCLR/RFC
NAME	RRasmussen	EFries	
DATE	10/28/2011	12/19/2011	08/04/2011

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GENERAL QUESTIONS

Question 1:

Are the [workshop] presentations going to be available to the public?

Answer 1:

Yes, all presentations from the 2010 Workshop on Vendor Oversight for New Reactor Construction are currently available on the NRC public website at http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight/past/2010/index.html, as well as in the Agencywide Document Access and Management System (ADAMS) at accession number ML101610439.

Question 2:

Will the NRC plan to schedule the 3rd NRC Workshop on Vendor Oversight in conjunction with the 2011 June NUPIC meeting in Chicago?

Answer 2:

The NRC plans to conduct this series of workshops on vendor oversight for new reactor construction on a biennial basis. Therefore, the NRC is planning the next Workshop on Vendor Oversight in conjunction with the June 2012 Nuclear Procurement Issues Committee (NUPIC) meeting in Baltimore, Maryland.

Question 3:

How many representatives were present at the 2010 Vendor / Inspector Oversight Workshop?

Answer 3:

The 2010 Workshop on Vendor Oversight for New Reactor Construction was attended by 484 representatives. The 484 workshop attendees represented companies and organizations from 11 countries and broke down as follows: 233 vendors, 3 industry groups, 10 government regulatory agencies, and 45 foreign and domestic utilities, including NRC license applicants (design certification, combined license, and fuel cycle facility).

Question 4:

Has the NRC examined the experience of the aerospace or other industry and developed any applicable lessons learned for the nuclear new build projects in the management of quality of global supply chain?

Answer 4:

The NRC staff has captured important lessons learned from the past construction of nuclear power plants in the United States in NUREG-1055, “Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants,” and summarized the information in Information Notice (IN) 2007-04 in February 2007. In July 2007, the Office of

New Reactors (NRO) staff developed a process to obtain, screen, evaluate and apply construction experience (ConE) information from various domestic and international sources.

In addition, the NRC works with other federal agencies and international groups such as the Multinational Design Evaluation Program (MDEP) to stay abreast of issues and lessons learned related to counterfeit, fraudulent, or suspect items (CFSI), as well as international groups providing overall insights and lessons learned related to new reactor construction. The NRC incorporates this information on an ongoing basis into its planning and inspection infrastructure.

Question 5:

Would it be wise for the NRC to issue a letter to each of the 300 suppliers of safety related material and services top management to strongly encourage their support in providing adequate resources, etc. in making the new nuclear renaissance a top priority?

Answer 5:

Issuance of a letter with this objective could be considered as promoting nuclear power, which is outside the scope of the NRC's statutory functions as a regulatory agency for the civilian use of nuclear materials. However, the NRC is working on communication and outreach tools to ensure that suppliers of safety related material and services, as well as other interested stakeholders, are kept up to date on the continuing development of new nuclear facilities.

Specifically, the NRC Vendor Inspection branches have updated the NRC public website to include key regulations, inspection procedures, and inspection reports, as well as information on commercial grade dedication, presentations from past NRC vendor workshops, and NRC presentations given at related conferences. In addition the NRC plans to continue to host biennial workshops on vendor oversight for new reactor construction, and to continue its participation in related industry conferences and meetings (i.e., NUPIC, ASME, etc.).

NRC PERSPECTIVE ON VENDOR QUALITY ASSURANCE PROGRAMS

Question 6:

NRC recently issued Rev. 4 to R.G. 1.28, endorsing NQA-1-2008. New plant applicants have developed their QA programs using NQA-1-1994. Does the NRC expect that the applicant or vendor revise their Quality Assurance (QA) program to adopt NQA-1-2008?

Answer 6:

No. There is no regulation that requires NRC licensees, applicants for new licenses, or vendors of basic components to adopt any specific version of ASME NQA-1, nor to update their QA programs to adopt a new version of ASME NQA-1 even if a new version has been reviewed and found acceptable to the NRC staff.

NRC licensees, applicants for new licenses, and vendors of basic components are required to meet Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations*, Part 50 (10 CFR Part 50). In addition, licensees and applicants for new licenses are required to conform with the acceptance criteria in the NRC's Standard Review Plan that was in place six months prior to submitting the license

application. As such, ASME NQA-1-1994 and NQA-1-2008 are both acceptable methods of meeting the requirements in Appendix B to 10 CFR Part 50 for design and construction, consistent with the acceptance criteria in the Standard Review Plan.

Question 7:

[Assuming that] base commodities (i.e., pipe, steel) are supplied through a documented NCA-3800 program, [a] licensee approved 10 CFR Part 50, Appendix B program, and to ASME/ASTM consensus standards, [is] a design responsibility required of the vendor in addition to the selection of the consensus standard by the upstream design process that identified and selected the consensus specification?

Answer 7:

No, however design or engineering involvement by the purchaser is necessary to the extent needed to assure that the selected material is compatible with its intended use (i.e., verify that the ASTM material selected is appropriate for the application). The level of design control or engineering involvement is dependent on the nature, complexity, and intended use of the items.

DEFINITIONS

Question 8:

What is the NRC definition of a "finding"? If you have multiple issues with a single procedure, would it be a single finding or would each issue be a separate finding?

Answer 8:

A finding is an issue that is the result of not meeting a requirement or standard where the cause was reasonably foreseeable and correctable, and therefore should have been prevented. The issue would also need to be more than minor. Inspection Manual Chapter (IMC) -0613P, Appendix E provides guidance for determining if an issue is more-than-minor.

The number of findings is based on the number of requirements that are not met and are more than minor, such that multiple issues related to a single procedure would be considered one finding with multiple parts, provided that the issues all involved failure to meet the same criteria or requirement.

Question 9:

As part of the audit process, it was stated that findings would be used to determine program effectiveness. Therefore, a consistent definition of "finding" as well as the grouping of issues is needed.

Answer 9:

See response to Question 8, above.

NRC AND IAEA – VENDOR OVERSIGHT

Question 10:

What is the relationship between the NRC and IAEA?

Answer 10:

The International Atomic Energy Agency (IAEA) is an international organization headquartered in Vienna, Austria. The IAEA was founded in 1957 as the “Atoms for Peace" organization within the United Nations (UN). It now serves as an independent intergovernmental agency controlled by two main policymaking bodies – the 35-member Board of Governors and the General Conference of all Member States. Reports on IAEA activities are submitted to the UN Security Council and UN General Assembly. Three main areas of work underpin the IAEA's mission: Safety and Security, Science and Technology, and Safeguards and Verification. The NRC staff works closely with the IAEA to develop international policies that enhance the safe, secure, and peaceful use of nuclear technology.

Question 11:

How does the NRC view the “integrated program” prescribed in IAEA’s GS-R-3?

Answer 11:

The NRC did not participate in the development of this particular document. In addition, the NRC has not reviewed the document to determine its acceptability.

ITAAC

Question 12:

Should applicant / licensee staff for ITAAC [perform] QA [reviews] to monitor process activities or for validation of each ITAAC and its supporting documentation?

Answer 12:

The ITAAC closure process as defined in 10 CFR 52.99, Inspection During Construction, is not, in and of itself, subject to the requirements of 10 CFR Part 50, Appendix B. However, any activity affecting ITAAC of safety-related structures, systems, and components (SSCs) must be accomplished under the licensee’s Appendix B to 10 CFR 50 quality assurance program. Through its implementation of the ITAAC closure process as defined in NEI 08-01, “Industry Guideline for the ITAAC Closure Process under 10 CFR Part 52, licensees should document ITAAC closure under their QA program because ITAAC have special regulatory significance under 10 CFR Part 52 requirements.

MANUFACTURER LICENSE, LABORATORY ACCREDITATION AND COMMERCIAL GRADE SURVEYS

Question 13:

What is the manufacturer[ing] license referred to in the "Vendor Challenges for New Reactor Construction, Industry Perspective" presentation? Will the license apply to services such as quality assurance?

Answer 13:

A manufacturing license is a license issued by the NRC under 10 CFR Part 52, Subpart F. The license authorizes the manufacturing of nuclear power reactors but not construction, installation, or operation at the sites on which the reactors are to be operated. A manufacturing license applies to a reactor that was manufactured and assembled off-site and then transported to and installed at a site that had a construction permit under 10 CFR Part 50 or a combined license under 10 CFR Part 52. The NRC staff envisions that the manufacturing license provisions will most likely be used for small modular reactors.

The regulations for a manufacturing license granted in accordance with 10 CFR Part 52 are structured to apply to a complete facility, including the nuclear steam supply system and the balance-of-plant components. Every applicant for a manufacturing license is required by the provisions of 10 CFR 52.157 to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor.

Question 14:

[The] NRC Issued a[n] SER to allow licensed utilities to use accredited calibration laboratories. In lieu of performing a [commercial grade] survey, [the SER allowed licensees to] incorporate the SER requirements in[to their] quality program [as outlined in a topical report]. Since issuance of the SER, additional letters were issued by [the] NRC endorsing other accrediting bodies. Are licensed utilities required to receive another SER and a topical [report] revision in order to use the new accrediting bodies?

Answer 14:

License holders are not required to receive another SER provided that they meet the requirements of 10 CFR 50.54(a)(3), which states, in part, that each licensee may make changes to a previously accepted quality assurance program description included in the safety analysis report without prior NRC approval, provided that the change does not reduce the commitments in the program description accepted by the NRC.

Accordingly, the NRC does not consider the use of a quality assurance alternative or exception approved by an NRC safety evaluation a reduction in commitment, provided that the bases of the NRC approval are applicable to the licensee's facility.

Question 15:

Given the emphasis being placed on licensees [being] accountable with regard to rigorous oversight of contractors and subcontractors, can the NRC assure they would welcome the participation of national third party independent certification bodies to assist licensees with their oversight process?

Answer 15:

This question appears to refer to accrediting bodies as independent certification bodies. On September 28, 2005, the NRC approved a request from Arizona Public Service (APS) for use of a nationally recognized accrediting body to provide the accreditation of commercial-grade calibration services, in lieu of performing commercial grade survey or in-process surveillance, provided that all the conditions outlined in the safety evaluation report are met. The NRC did not endorse or approve such accrediting bodies; the agency only recognized that the NRC finds the accreditation programs for commercial grade calibration services acceptable for use within the constraints outlined by the SER associated with the APS QA program document.

Question 16:

What is the time frame for the acceptance of third party accreditation of calibration facilities by signatories of the MRA / ILAC outside of the U.S.A.?

Answer 16:

The NRC is actively reviewing implementation strategies to consider expanding NRC's recognition (beyond domestic accreditation bodies) to international accreditation bodies on the basis that they are all full signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA). The timeframe for final completion of this process depends on many factors, but is proceeding at a steady pace.

Question 17:

When does NRC anticipate the acceptance of other types of accreditation such as mechanical and chemical testing.

Answer 17:

The NRC is actively reviewing implementation strategies to include testing laboratories accredited under the requirements of International Standard Organization (ISO) / International Electrotechnical Commission (IEC) 17025, “General Requirements for the Competence of Testing and Calibration Laboratories,” as part of the agency’s recognition of the ILAC MRA process. The timeframe for final completion of this process depends on many factors, but is proceeding at a steady pace.

Question 18:

Currently [the] NRC reliance on third party calibration accrediting groups such as [the] American Association for Laboratory Accreditation (A2LA) or National Voluntary

Laboratory Accreditation Program (NVLAP) is limited. Is there any effort to expand this [acceptance] to international calibration groups such as [Comité Français d'Accréditation] (COFRAC) in France? Is there any expansion of [this acceptance] process to material testing labs?

Answer 18:

See responses to Question 16 and Question 17, above.

Question 19:

What role does the NRC see for NIAC? Does NIAC meet the NRC expectation of intrusive QA oversight (from the audit standpoint)?
Answer 19:

The NRC views the Nuclear Industry Assessment Committee (NIAC) as an acceptable method for vendors to satisfy the requirements of Criterion VII of Appendix B to 10 CFR Part 50, as it relates to performing external audits of the vendor's suppliers in order to establish their qualification as a supplier of a basic component, provided that the vendor's quality assurance program allows for the acceptance of NIAC (i.e., third party) audits, and the vendor reviews the scope of supply and associated audit criteria for applicability to the services they wish to procure from the supplier.

Question 20:

Are the national metrology organizations of international countries considered equivalent to NIST? Can the calibration services / standards be accepted for safety related (10 CFR Appendix B) applications without audit or third party certification?

Answer 20:

National metrology organizations of other countries are considered equivalent to the National Institute of Standards and Technology (NIST); however, the NRC currently only recognizes the accreditation provided by domestic accrediting bodies that are members of the International Accreditation Laboratory Cooperation (ILAC) Mutual Recognition Agreement. Safety related calibration suppliers must be on the vendor's approved suppliers list and must be audited before use.

Question 21:

If, as opposed to conducting an audit or commercial grade survey to evaluate a calibration facility and adding them to your approved supplier list (ASL), a calibration facility is procured based on their accreditation, is it required that they be listed on your ASL? Similarly, if [a] supplier procured to work under your 10 CFR [Part] 50, [Appendix] B compliant QA program utilizes calibration facilities that are appropriately accredited by A2LA or NVLAP prior to your procurement of this supplier, is it required that you list their calibration suppliers on your approved supplier list?

Answer 21:

The ASL is a tool that allows a licensee (or vendor) to monitor the approval bases and status of its suppliers. As such, the method for selection and approval of a supplier (commercial grade survey or audit) is not relevant to its inclusion on the ASL. Unless the scope of supply of its sub-suppliers is critical to the inclusion of a particular calibration supplier on a licensee (or vendor) ASL, the calibration supplier sub-suppliers are typically not included.

Question 22:

Does the NRC have to issue or modify the Safety Evaluation Report (SER) issued to allow licensed utilities to use accredited calibration laboratories (NVLAP or A2LA) without a commercial grade survey, [in order] to incorporate the new approved laboratories (i.e., LAB, ACLASS, IAS, Perry Johnson)?

Answer 22:

See Answer to Question 14, above.

Question 23:

For new plant construction, will the NRC be performing observations of NIAC audits like it does for NUPIC audits?

Answer 23:

At this time, the NRC staff does not have plans to perform routine observations of NIAC audits as it does for NUPIC audits. However, nothing precludes the NRC staff from performing observations of such audits should the agency find it necessary or beneficial.

Question 24:

If a supplier uses NVLAP / A2LA as the method to utilize commercial calibration labs, do procurement documents require the inclusion of critical characteristics of the calibration service? Reference APS safety evaluations, please clarify.

Answer 24:

Procurement documents for procurement of domestic calibration services provided by commercial calibration laboratories accredited by one of the 6 domestic accrediting bodies (NVLAP, A2LA, IAS, ACLASS, Perry Johnson, or LAB) need to include the following: (1) additional technical and administrative requirements to satisfy the necessary QA program and technical requirements; (2) a requirement for reporting as-found calibration data when calibrated items are found to be out-of-tolerance, and (3) a requirement to identify the laboratory equipment / standards used, as stated on Page 8 of Arizona Public Service Company's safety evaluation report dated September 28, 2005 (ADAMS Accession Number ML052710224).

Question 25:

Will suppliers that have changed their quality program to use NVLAP / A2LA for calibration activities be required to audit / survey the accrediting organization [(i.e., NVLAP, A2LA, etc.)]?

Answer 25:

The Nuclear Energy Institute (NEI) is working with the industry to develop guidance for oversight of ILAC-related accreditation activities.

10 CFR PART 21

Question 26:

Concerning Part 21 evaluation[s] performed by [a] material supplier, in many cases it might not be possible for the vendor to determine the current status of the particular materials / products in question. This would lead a [vendor performed] Part 21 evaluation to conclude as indeterminate, and would therefore need to be discussed with the customer and subsequently turned over to that customer to investigate further. Other than the vendor's corrective action / Part 21 evaluation documentation, what formal mechanism is recommended for this turnover and what further obligation does the discoverer (vendor) have for reporting and/or other notifications?

Answer 26:

If the discoverer (vendor) determines that they cannot perform the Part 21 evaluation within the required 60 day evaluation period, the vendor is required to notify its customers within 5 working days of this determination. The customer would then be responsible for performing the Part 21 evaluation. The 60 day evaluation period for the customer starts when the vendor provides its notification of its inability to perform the evaluation. It then becomes the customer's responsibility to notify the NRC if the defect or failure to comply is reportable. The customer should also inform the vendor if the defect or failure to comply is reportable so that the vendor can identify and inform any other potentially affected customers of the defect or failure to comply.

Question 27:

In many cases foreign suppliers do not impose Part 21 on their foreign sub-suppliers, but do impose Part 21 type requirements for defect notification in [the] procurement documents. The [foreign supplier will have] performed [a] 10 CFR [Part] 50, Appendix B audit to qualify the [foreign sub-]supplier and place them on the approved supplier list. Since Part 21 was not imposed in full [on the foreign sub-supplier] are the materials / services required to be dedicated? Can a supplier be in compliance with [10 CFR Part 50], Appendix B and not Part 21 and still provide basic components?

Answer 27:

If the requirements of Part 21 are not imposed –in full on a foreign supplier or sub-supplier, the material or service provided is not a basic component. In such cases, the purchaser or foreign supplier would be responsible for the dedication of the material or service and assume all 10 CFR Part 21 responsibilities.

Question 28:

Why are dedication requirements in the same CFR section as Notification of Defect, etc.?

Answer 28:

10 CFR Part 21 was initially promulgated in June 1977 to implement Section 223 of the Atomic Energy Act of 1954 and Section 206 of the Energy Reorganization Act (ERA) of 1974. The concept of commercial grade dedication was not part of the initial rulemaking effort. In October 1978, the NRC issued an immediately effective rule defining commercial grade items as a means of exempting suppliers of such items from the reporting requirements of 10 CFR Part 21. This rule amendment also introduced the concept of commercial grade dedication. For these reasons, commercial grade dedication and the reporting requirements associated with Section 206 of the ERA were documented under the same section of Title 10 of the Code of Federal Regulations.

Question 29:

Is there any plan to create a separate document and remove [commercial grade] dedication from 10 CFR [Part] 21?

Answer 29:

Then NRC is reviewing the issue and may address it through rulemaking.

Question 30:

Once a potential Part 21 issue is identified and tied to a specific commodity and/or manufacturer, [w]ould it be prudent to consider the issue across the supply chain in lieu of [only considering] the vendor that brought the issue to the [agency's] attention?

Answer 30:

The NRC evaluates all 10 CFR Part 21 notifications and takes action when warranted. For situations where an issue is specific to a commodity and/or manufacturer, the NRC, through information gathering and evaluation, may choose to focus on the commodity and/or specific manufacturer across the supply chain, rather than solely the vendor who made the initial notification. Depending on the nature of the issue, the NRC may issue generic communications to alert all affected stakeholders.

Question 31:

When did Part 21 go into effect? Are components supplied prior to this affected if a defect is [identified]?

Answer 31:

10 CFR Part 21 is the regulation that implements Section 206 of the Energy Reorganization Act of 1974. Part 21 was first noticed in the *Federal Register* on June 6, 1977. Although applicants or licensees are only required to retain a list of purchased items for 10 years after delivery (15 years for design certification applicants), they are still required to notify the NRC of any defect or failure to comply identified. This also applies to components supplied before 1974.

Question 32:

Is just having information as to the design function of an item enough to establish [the] critical characteristics for dedication?

Answer 32:

A critical element in performing effective commercial grade dedication is to ensure that once the item's critical characteristics have been verified, the dedication will provide reasonable assurance that the item will perform its intended safety function. If the characteristics verified during the design function verification include all of those critical characteristics needed to assure that the item will adequately perform its intended safety function, then that activity could be considered acceptable. If, on the other hand, the critical characteristics associated with the item's safety function are not enveloped by the critical characteristics of the design, additional assurance would be needed to fully address the item's safety function.

NRC / NUPIC INTERACTIONS

Question 33:

For the vendors it is difficult to find knowledgeable professionals (i.e., QA managers, engineers, auditors) to implement 10 CFR [Part] 50, Appendix B and Part 21 programs, [or to] facilitate or develop them. How can NRC / NUPIC support that process?

Answer 33:

The NRC and NUPIC both hold regular outreach activities such as the NRC workshops on vendor oversight for new reactor construction, and the annual NUPIC vendor meetings. The NRC Quality and Vendor Inspection branches currently utilize the NRC public website to give vendors an avenue for obtaining useful information on: past NRC conferences and presentations; inspection reports; inspection procedures; regulations; commercial-grade dedication information; 10 CFR Part 50, Appendix B; and 10 CFR Part 21. The NRC is also working to make improvements to its public web site to further improve communications.

In addition, the Quality and Vendor Inspection branches regularly participate at: NUPIC auditors' conferences; ASME meetings; the Regulatory Information Conference; NEI NQA-1 meetings; the Electric Power Research Institute's (EPRI) Joint Utility Task Group (JUTG) meetings; the

Institute of Electrical and Electronics Engineers' (IEEE) meetings; ILAC meetings; MDEP meetings; and in the Committee of Nuclear Regulatory Activities (CNRA), in order to reach out to nuclear vendors.

Question 34:

Who is the controlling entity and how does a vendor resolve conflicting directions given by NUPIC and the NRC? For example, NUPIC says [that] a vendor of equipment should know if a defect represents a safety issue, while [the] NRC says [that] an equipment supplier cannot necessarily know how the equipment [will be] used. This makes a difference [as] to which reporting rules of 10 CFR [Part] 21 apply.

Answer 34:

The NRC and NUPIC interact frequently to attempt to ensure that a similar approach is taken for the audits / inspections of vendors conducted by both entities. However, in all cases the regulations contained in the applicable 10 CFR sections take precedence and are the determining factor in the outcome of the activities undertaken by both groups.

For the example cited above: According to 10 CFR 21.21(b), if the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to 10 CFR 21.21(a).

SAFETY CULTURE / SAFETY CONSCIOUS WORK ENVIRONMENTS

Question 35:

Safety Culture ethics appear to conflict with what seems to be a trend in the general culture of our society to cut corners, take short cuts, rationalize away ethical behavior for short term gains, etc. How does the nuclear industry effectively offset these trends?

Answer 35:

The NRC defines Nuclear Safety Culture as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." As this definition points out, this is an active, ongoing dedication to safety that an organization, including its leaders and its employees, champions. This culture, by its very nature, conflicts with taking short cuts, emphasizing short-term goals, etc.; however, there is an abundance of information that supports the proposition that a positive safety culture is good for business, e.g., reduction in special inspections, etc. To offset values and behaviors that negatively impact safety, licensees, vendors, suppliers of safety related components, etc. need to educate themselves and their employees about the benefits that a positive safety culture provides to their organizations.

Question 36:

[In regard to a safety conscious work environment] put [the] Policy Statement on the continuum below: Guideline; Recommend → Regulation; Enforce. Why was a policy statement chosen over a regulation that can be enforced?

Answer 36:

The 1996 Safety Conscious Work Environment (SCWE) policy statement, "Freedom of Employees in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation," and subsequent Regulatory Issue Summary 2005-18, "Guidance for Establishing and Maintaining a Safety Conscious Work Environment," outlines NRC's expectations that licensees and other employers create a work environment that is conducive to raising concerns and suggestions for doing so, because such an environment contributes to safe operation of NRC-regulated facilities. The NRC acknowledged, however, that some of the suggestions, programs, or steps that might be taken to improve the quality of the work environment may not be practical for every employer, depending on factors such as the number of employees, complexity of operations, potential hazards, and history of allegations made to the NRC, and that employers have discretion regarding the manner in which a SCWE is maintained at a particular facility.

The NRC staff's view is that a policy statement is currently the best available means to continue the wide-ranging and productive dialogue about both SCWE and safety culture between the NRC staff and external stakeholders. A policy statement permits the Commission to establish focused and defined expectations for a positive SCWE and safety culture, as well as providing a common terminology to facilitate further dialogue.

Question 37:

What is the estimated cost for developing and implementing safety culture programs during construction?

Answer 37:

The cost for developing and maintaining a safety culture program during the construction phase will be based on a variety of factors. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing regulated materials, commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. Input into or influence upon how these factors are approached is beyond the NRC's purview as the regulatory agency; however, the NRC will include appropriate means to monitor safety culture in its oversight programs and internal management processes.

Question 38:

Initially the Commission appeared to want to elevate security [activities] to [the same level as] safety [activities] in the Safety Culture policy statement activities. Based on the post-workshop work comparison, I do not see any elevation of security [activities] as seems appropriate. Why [is this the case]? We just learned of counterfeiting or potential for cyber attack in new fabrication. Are we going forward or backwards?

Answer 38:

As the NRC Safety Culture Policy Statement specifically points out:

"Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort vs. safety. It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy."

Question 39:

How far down in the supply chain does the applicability of [the] SCWE Policy go? [There was a] statement that it applies to NRC regulated activities. Does this apply only to licensees, or does it flow down to contractors and sub-contractors [as well]? Is it the intent [of the SCWE Policy] that it will eventually flow down to [the] sub-contractor level?

Answer 39:

The NRC's Policy Statement on a Safety Conscious Work Environment (SCWE) is a policy statement that precedes the NRC's Safety Culture Policy Statement. SCWE is a subset of an organization's safety culture. In fact, it is one of the traits of a positive safety culture.

The NRC's SCWE policy states that the responsibility for maintaining such an environment rests with each NRC licensee, as well as with contractors, subcontractors and employees in the nuclear industry. This policy statement is applicable to NRC regulated activities of all NRC licensees and their contractors and subcontractors. It specifically states: "This policy statement and the principles set forth in it are intended to apply to licensed activities of all NRC licensees and their contractors, although it is recognized that some of the suggestions, programs, or steps that might be taken to improve the quality of the work environment (e.g., establishment of a method to raise concerns outside the normal management structure such as an employee concerns program) may not be practical for very small licensees that have only a few employees and a very simple management structure."

The Safety Culture Policy Statement specifically points out that it is applicable to "…all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority." The Statement of Policy goes on to state: "The Commission encourages the Agreement States and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy, within their regulated communities."

Question 40:

Does [the] safety culture requirement apply to vendors that only provide commercial [grade] ([i.e.,] non-[10 CFR Part 50, Appendix B], non-[safety related]) items? (Note: this is for [a] construction site.) However, [notwithstanding this fact,] anyone working on [the] site has the right to raise issues without fear of retribution. (This [query] is not [related to] a 10 CFR [Part] 50, Appendix B issue [or activity].)

Answer 40:

In March 2011, the NRC approved the Safety Culture Policy Statement. The Policy Statement provides the NRC's expectation that individuals and organizations performing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. Because safety and security are the primary pillars of the NRC's regulatory mission, considerations of both safety and security issues, commensurate with their significance, is an underlying principle of the Safety Culture Policy Statement. The policy statement applies to all licensees, certificate holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval subject to NRC authority.

Question 41:

How [does the NRC envision] achieving SCWE practices with[in] an organized labor unions workforce?

Answer 41:
Currently, a significant portion of the operating fleet, under a collective bargaining agreement with organized labor, maintains a positive safety conscious work environment. Efforts to establish and maintain a SCWE in the construction phases of new reactor construction, where significant organized labor requirements are anticipated, will require the same level of commitment to public health and safety and cooperation. The NRC expects the highest standards of quality, integrity, and safety are understood to be in the applicant's and its employee's self-interest. Consistent with the policy that the applicant bears the primary responsibility for safely designing, constructing, and operating their facilities, an applicant's work environment must encourage identifying and resolving technical and wrongdoing concerns.

Question 42:

With standardization of [the] SCWE [guidelines] and the transient [nature of the] construction workforce, would it be beneficial to implement a program similar to the Nuclear Passport used in the [European Union]?

Answer 42:

The agency is strongly considering a similar approach and the NRC staff has made this an objective going forward.

Question 43:

Does the SCWE philosophy protect companies as well as individual employees (with Part 21 aside [and considering] non-safety related [activities])?

Example: An engineering company identifies a safety concern that a utility disagrees with. The engineering company continues to question the issue. The utility disagrees again, and proceeds to quickly end the job and the contract with the engineering company. Does the utility's SCWE program address this? If so, how does the engineering company get involved with the utility's SCWE program after being released? If not, how is this [situation appropriately] handled?

Answer 43:

The Commission's policy statement "Freedom of Employees in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation," which was published in the Federal Register on May 14, 1996, describes SCWE as "a work environment where employees are encouraged to raise safety concerns and were concerns are promptly reviewed, given the proper priority based on their potential safety significance, and appropriately resolved with timely feedback to the originator of the concerns and to other employees." As such, the SCWE policy statement and the complementary provisions of 10 CFR 50.7 (Employee Protection) apply to natural persons only and do not extend to business or corporate entities.

The fact that the engineering company no longer has a contractual relationship with the utility company does not negate the engineering company's responsibility to report items that may have safety significance. To this end, there are various avenues available to the engineering company, including the NRC's Allegation Program.

Question 44:

Has the NEI 09-12, "Guidelines for Establishing a Safety Conscious Work Environment for New Nuclear Plant Constructions Sites," document been endorsed by the NRC or reviewed for acceptability?

Answer 44:

The NRC is aware of NEI 09-12; however, the NRC does not review or endorse such documents for acceptability.

COUNTERFEIT, FRAUDULENT, AND SUSPECT ITEMS (CFSI)

Question 45:

Is the NRC considering taking any steps to make the information necessary to support the [CFSI] initiatives promoted by the NRC as important more public? We've seen data sources that are non-public promised at the workshop while being told that "safety is first." If no equivalent public data is available, this appears to be inconsistent.

Answer 45:

First, a brief clarification between public information and free information is warranted. With few exceptions, most of the information retained by the NRC is publicly available, and as such, is subject to the rules and regulations set forth in the Freedom of Information Act (FOIA). Exceptions to the public's access to NRC information include information associated with an ongoing investigation (e.g., criminal investigation, wrongdoing allegation, etc.), among others.

However, when information presented by a "for profit" organization is discussed during any NRC (or other) forum, the rules (and fees) for obtaining that information is mandated by the owner of the intellectual property. Some "for-profit" organizations that have either volunteered assistance to or have been referenced in past Counterfeit, Suspect, and Fraudulent Items (CSFI) presentations include: the Electric Power Research Institute (EPRI), the Institute of Electrical and Electronics Engineers (IEEE), the Society of Automotive Engineers (SAE) Aerospace Division, and the Semiconductor Equipment and Materials International (SEMI) organization.

Individuals wishing to obtain information from one of these organizations should contact them directly for specific purchasing requirements. In the case of the EPRI Technical Report, TR-1019163, "Plant Support Engineering: Counterfeit, Fraudulent, and Substandard Items, Mitigating the Increasing Risk," EPRI initially introduced the free document to only EPRI members, but due to the overwhelming demand for copies, now offers it free to the public.

Question 46:

How would a materials testing laboratory implement a CFSI program / procedure? Will [CFSI initiatives] really apply to the testing services industry?

Answer 46:

The mechanics of implementing a CFSI program for a specific and/or unique product or service is the supplier's responsibility. Each entity, purchaser, or supplier should be fully cognizant of the terms and conditions specified within the individual purchase orders (PO) and their ability or inability to meet those conditions. A supplier should notify the customer immediately when they either do not understand the terms and conditions of the PO, or are unable to comply with them.

If, for example, a customer specifies that the supplier should be performing an assessment for counterfeit, fraudulent, or suspect activity on the item they are attempting to purchase and has not specified what level of assurance is expected, it would be appropriate for the supplier to

contact the customer and request clarification. The supplier also may take exception to that statement in the PO, thereby allowing the customer to re-define the terms of the PO.

In addition, there are "cottage industries" developing around the globe, with an expressed business model of identifying counterfeit, fraudulent, and suspect items. Some of these companies offer a limited scope of items they can adequately assess, while others are less restrictive in the scope of products they evaluate. These services (as applicable) will be available to suppliers for whom conducting a CFSI evaluation may be impractical.

Question 47:

What is the difference between reverse engineering and counterfeit / fraudulent?

Answer 47:

While there is currently no standard definition for either of these terms as they relate to the commercial nuclear power industry, the distinction between the two lies more with the use of the processes rather than in the actual details of the activities themselves. Use of the term counterfeit infers that there is intent to deceive the purchaser into believing he is procuring a legitimate product.

Conversely, reverse engineering is a process that is meant to be used only when the utility has exhausted all other measures, including interface with the original equipment manufacturer (OEM) or the original equipment supplier (OES), and consideration has been given to the use of other methods such as using alternate replacements or modifications. The reverse engineering process is typically employed when the OEM has relinquished or abandoned the Intellectual Property Rights associated with the item being reverse engineered.

Additional information related to reverse engineering can be found in EPRI Technical Document TR-107372, "Guideline for Reverse Engineering at Nuclear Power Plants," and MIL-HDBK-115A, "Department of Defense Handbook – US Army, Reverse Engineering Handbook." However, neither document has been officially reviewed or endorsed by the NRC.

Question 48:

Detection of counterfeit material is dependant to some extent on knowing what to look for. Are there any periodic updates [to information related to CFSI activities] to facilitate recent examples that can be used to supplement training?

Answer 48:

Presently, CSFI information associated with safety related products and/or services (i.e., basic components) is publicly available from the NRC through one or more of the following sources: the 10 CFR Part 21 reporting process, the generic communication process (traditionally issuance of an Information Notice), operating experience updates and information, and construction experience updates and information.

In addition, the NRC is currently evaluating the methods for communication regarding CFSI and plans to implement an improved process to share this information to the extent possible.

Question 49:

To what extent should service-related vendors address CFSI in their quality assurance programs since they don't produce "items"?

Answer 49:

The mechanics of implementing a CFSI program for a specific and/or unique product or service is the supplier's responsibility. Each entity, purchaser, or supplier should be fully cognizant of the terms and conditions specified within the individual purchase orders (PO) and their ability or inability to meet those conditions. A supplier should notify the customer immediately when they either do not understand the terms and conditions of the PO, or are unable to comply with them.

If, for example, a customer specifies that the supplier should be performing an assessment for counterfeit, fraudulent, or suspect activity on the item they are attempting to purchase and has not specified what level of assurance is expected, it would be appropriate for the supplier to contact the customer and request clarification. The supplier also may take exception to that statement in the PO, thereby allowing the customer to re-define the terms of the PO.

In the case of a safety related service provider, the extent to which that supplier's QA program would need to address CSFI is dependent on the safety related service being provided. For example, if the supplier were being contracted to detect CSFI activity, it would be expected that the terms and conditions contained in the purchase order would be more prescriptive in regard to counterfeit or fraudulent items. Conversely, if the supplier is providing intellectual support services such as engineering or licensing, or consulting activities, a licensee may, for example, specify that the supplier have adequate cyber security controls in place, to protect safety related intellectual property while under the responsibility of the supplier.

Question 50:

With the increase in counterfeit parts entering the market, is there any discussion of instituting a more rigorous mandatory testing requirement for vendors?

Answer 50:

The NRC is now, and has been for some time, closely monitoring the threats associated with counterfeit, suspect, and fraudulent activity. The NRC is currently working to assess and evaluate implementation of a formal agencywide strategy and plan to monitor and evaluate CFSIs. The current assessment will help to identify if instituting a more rigorous mandatory testing requirement for vendors or licensees is necessary or prudent.

Question 51:

[Concerning] depth of application, how does engineering determine how important [a] CFSI is beyond safety significant? There could be no end to what could be [considered] critical characteristics for any given item, component, system, [etc.].

Answer 51:

Implementing and maintaining a quality assurance program capable of preventing the intrusion of substandard components or parts into safety related service is an existing regulatory requirement for each NRC licensee. The NRC staff continues to believe that the strongest barrier against the introduction of CFSI into the safety-related supply chains is for licensees to effectively implement rigorous procurement programs. Rigorous procurement programs share the following characteristics: (1) the involvement of engineering staff in the procurement and product acceptance process (2) effective source inspection, receipt inspection, and testing programs, and (3) thorough, engineering-based programs for review, testing, and dedication of commercial-grade products for suitability of use in safety related applications.

Question 52:

Why isn't EPRI consistent with the NRC on the wording for CFSI? Counterfeit Fraudulent and Suspect Items (NRC) vs. Counterfeit Fraudulent and Substandard Items (EPRI).

Answer 52:

There is no fundamental difference in understanding between the NRC and EPRI. However, the acronyms used by EPRI and the NRC do have different origins and purposes. The EPRI acronym was adopted by the working group for the purpose of capturing the scope of concern in developing the associated report. EPRI's interpretation of CSFI utilizes the "S" to stand for "Substandard" and addresses the broader category of supplier performance, including whether the supplier was legitimate or not. EPRI Report 1019163, "Plant Support Engineering: Counterfeit, Fraudulent, and Substandard Items, Mitigating the Increasing Risk," defines the terms counterfeit, fraudulent, substandard, and suspect.

The NRC believes that the current regulations addressing performance issues associated with legitimate suppliers (e.g., receipt inspections, procurement of purchased materials, corrective actions, nonconformances, etc.) is adequate. Therefore, the NRC's use of the term "suspect" affords stakeholders the opportunity to take compensatory actions until the claim is resolved.

This use of the term "suspect" is consistent with terminology adopted by the Department of Energy and the U.S. Department of Defense when unsubstantiated claims are evident. The overall intent of both EPRI and the NRC is to ensure that an item that does not meet the purchaser's requirements is not accepted for use in a nuclear power plant. Both acronyms recognize that an item that does not meet the purchaser's requirements is not acceptable, whether counterfeit or not.

Question 53:

Please clarify [the use of various documents] in this area:

> **NRC: Counterfeit, Fraudulent, and Suspect Items**
> **DOE: Suspect and Counterfeit Items (no fraudulent)**
> **EPRI: Counterfeit, Substandard, and Fraudulent Items (suspect can also mean "unconfirmed" items)**

Answer 53:

Presently there is no single definition addressing counterfeit, suspect, substandard, or fraudulent materials to satisfy all stakeholders. Consequently, a number of industry related standards have emerged to address this issue in terms specific to a particular industry sector.

The use of conventional meanings was chosen by the NRC staff wherever possible. This is evident in the use of the terms counterfeit and fraudulent, which is consistent with the EPRI use of the same terms. The conventional use of the term counterfeit refers to the replication of a tangible object with intent to deceive the buyer into thinking it is something it is not. The conventional use of the term fraudulent is used more often to refer to the falsification of official records, documents, identities, or signatures. The distinction between the terms substandard and suspect is discussed in the response to Question 52, above.

Question 54:

In the acronym CFSI, does the "s" stand for suspect or substandard?

Answer 54:

See responses to Question 52 and Question 53, above.

Question 55:

While we understand the issue of CFSIs, is there any regulatory position, guidance or rule, beyond 10 CFR [Part] 50 and 10 CFR [Part] 21, which are requiring quality program changes at the power plants or suppliers to the industry?

Answer 55:

In addition to Appendix B to 10 CFR Part 50 and 10 CFR Part 21, 10 CFR 50.5, "Deliberate Misconduct," includes regulatory requirements prohibiting any individual from deliberately submitting to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

Appendix B to 10 CFR Part 50 is, however, the fundamental regulation that establishes the requirements for quality at a commercial nuclear facility. Specific regulatory requirements related to activities to deter and/or prevent the infiltration of counterfeit, fraudulent, or suspect items into a commercial nuclear power station exist in two of the criteria presented in 10 CFR Part 50, Appendix B: Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion X, "Inspection." See also response to Question 51, above.

Question 56:

For a testing laboratory, how do we integrate / enforce [CFSI initiatives], especially in light of the fact [that] we are the ones who vendors rely on through testing to tell them something is "real"?

Answer 56:

See response to Question 46, above.

Question 57:

Does a material organization need to have a large sophisticated receipt inspection group to perform detailed inspection on all items received, utilizing sophisticated instruments and gauges?

Answer 57:

Material organizations need to comply with ASME NCA-3800, "Metallic Material Organization's Quality System Program," and should utilize inspection equipment commensurate with their scope of supply. Each supplier and sub-supplier must work with their customers to understand and fulfill all the technical and quality terms and conditions specified in the individual purchase orders, including the customer's desired level of assurance that the part is genuine.

Audits of suppliers and sub-suppliers should assess their ability satisfy the requirements passed on to them. The NRC has learned from benchmarking other industries where counterfeiting and fraud have been prevalent that advances are constantly being made in CFSI detection strategies and techniques.

Question 58:

As [internal control] becomes obsolete, fakes are harder, sometimes impossible, to detect from external markings only. Even if parameters are validated through testing, including E.S.S. testing, counterfeits may still pass. Any comments on the above?

Answer 58:

It remains the licensee's responsibility to assure that procured components and parts will serve their intended safety function. Appropriate measures such as source verification, testing, and destructive testing must be considered to detect any counterfeits.

NRC ENFORCEMENT POLICY

Question 59:

In "NRC Team Inspection Report 99900866/2008-001 and Notice of Nonconformance" related to Energy and Process Corporation, dated May 20, 2008, the NRC stated that the supplier was required to transmit all identified nonconformance reviews (NCRs) to the upper-tier contractor. Does that mean that sub-tier [suppliers] are required to transmit rework / reject NCRs to [the upper-tier] contractors?

Answer 59:

Criterion XV of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation; including, as appropriate, procedures for notification to affected organizations. In the cited example, the transmission of the NCRs up the

procurement chain was governed by provisions in the procurement documents, as well as the quality assurance program and procedures called upon to fulfill the purchase order.

Question 60:

Isn't it true that escalated enforcement for a violation by a vendor is limited to falsification of records, failures to evaluate or report Part 21 defects, or discrimination for raising a safety concern?

Answer 60:

The NRC is not limited to escalated enforcement action related to vendors solely for these issues. The NRC will evaluate each apparent violation on its own merit and take enforcement action as prescribed by the agency's Enforcement Policy.

Question 61:

Has [the] NRC [ever] issued [a] minor violation or NOV for [a] typo?

Answer 61:

Vendor and quality assurance implementation inspection findings are documented in accordance with Inspection Manual Chapter (IMC) 0617. Section 06.01.a of IMC 0617 states that minor violations may be identified at the discretion of the inspection team leader and the appropriate management personnel for non-repetitive noncompliances with little or no safety significance or regulatory impact.

Minor violations are not normally documented in inspection reports (with a few specified exceptions), and do not involve a Notice of Violation. IMC 0617 goes on to state that minor violations may include issues such as typographical or clerical errors in quality documents that do not affect QA program functionality or the validity of QA records.

Therefore, a typographical or clerical error in a quality document that does not affect QA program implementation or the validity of QA records could result in a minor violation, while a typographical or clerical error in a quality document that does affect QA program implementation or the validity of QA records could result in an NOV.

Question 62:

Should a purchase order (PO) be sent back with format or typo changes since this can be considered a violation? Should a company be more insistent that the changes be made?

Answer 62:

Criterion IV, "Procurement Document Control," of 10 CFR Part 50, Appendix B, requires that measures be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services.

If a licensee / applicant or vendor / supplier identifies an error in a PO that affects the regulatory, technical, or quality requirements, or the vendor / supplier's ability to meet those requirements, the licensee / applicant should follow its policies and procedures to correct the deficiency.

In regard to the issue of typos and format changes, see response to Question 61, above.