

efficiency bulletin

Dec. 2, 2016

Efficiency Bulletin: 16-28b

Establish Common Finding/Deficiency Definitions Used During Vendor Audits

Implement a uniform approach for identification, follow-up and closure of performance issues found during audits of supplier facilities.

Addressees: Chief nuclear officers, NEI APCs and INPO APCs

Issue: OA-3.2, Establish Common Finding/Deficiency Definitions Used During Vendor Audits

Summary of Efficiency Opportunity

This efficiency bulletin will address a standard graded approach for the industry to meet quality assurance program commitments for identification and follow-up for issues identified during audits of safety-related material and service providers. It will provide additional granularity in the classification of identified issues and direct a threshold for application of more rigorous, time sensitive follow-up activities.

- Desired end-state—NUPIC processes provide specific guidance that allows identification of a broad range of issues but requires formal, resource intensive follow-up activities for only a subset of risk significant issues. Supplier performance issues are consistently and properly classified based upon their significance.
- Value proposition (vision of excellence)—Significantly reduced audit team leader and supplier resources are spent conducting and supporting rigorous follow-up and closure documentation for low risk significant issues.

Color Code: Red
Due: June 2017

DELIVERING THE
NUCLEAR PROMISE



nuclear matters:
my work • my plant • my industry



NUCLEAR ENERGY INSTITUTE

The Nuclear Energy Institute is the nuclear energy industry's policy organization.

This bulletin and additional information about nuclear energy are available at nei.org.

1201 F Street, NW
Washington, DC 20004
NEI.org

- Why is it important?—Currently, issues identified during a NUPIC Audit or Survey are classified as a Finding or Significant Finding. A sample of 10 NUPIC Audits revealed that approximately 70 percent of the issues identified were related to failing to follow established supplier processes, which at many member utilities, would be classified as a deficiency requiring less rigorous or no follow-up activities. Hence, nuclear operator and supplier resources are being expended unnecessarily performing follow-up on lower significance audit issues. In addition, the current practice at times needlessly lengthens the period to “close” audits. The lack of specific NUPIC guidance has allowed for differences in implementation between member utilities resulting in unproductive conflict and delays. Application of a consistent, graded approach will reduce these resources for audit activities and allow them to be used more effectively by the nuclear operating utility.
- Industry benchmark value(s)—Implementing a standardized approach for the definition of a finding and deficiency will result in identification of issues of significance at a common threshold. As a result fewer items requiring follow-up being identified will occur.
- Measure of effectiveness—The total number of audit findings issued will decrease and the need for follow-up will no longer be required for each shortcoming identified during audit performance.

Relevant Standards

- ANSI N18.7-1976 / ANS 3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants, (Revision of N18.7-1972)
- ASME NQA-1-1994 Edition (Revision and Consolidation of ASME NQA-1-1989 and ASME NQA-2-1989 Editions)
- ANSI N45.2 – 1971, Quality Assurance Program Requirements for Nuclear Power Plants
- ANSI/ASME N45.2.12 – 1977, Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants
- ANSI/ASME N45.2.13 – 1976, Quality Assurance Requirements for the Control of Procurement of Items and Services for Nuclear Power Plants
- NUPIC Document No. 3, NUPIC Charter Revision 26, March 1, 2014
- NUPIC Document No. 4, NUPIC Joint Audit Procedure
- INPO 12-013, Performance Objectives and Criteria

Relevant Regulatory Requirements

- Regulatory Guide 1.33, Quality Assurance Program Requirements
- Regulatory Guide 1.144, Auditing of Quality Assurance Programs for Nuclear Power Plants

Guidance

- Currently the NUPIC process does not contain a definition for a Finding. Each utility conducts NUPIC Audits utilizing their utilities procedure in conjunction with NUPIC Joint Audit Procedure (Document Number 4) guidelines. The NUPIC Joint Audit Procedure does contain the following definition:

Significant Adverse Finding: A significant adverse finding, which is deemed severe enough to warrant immediate action, shall be immediately brought to the attention of the team leader.

Immediate notification of significant conditions adverse to quality shall be provided when such conditions have the net result of placing the product's ability to function in its intended application in question. The lack of implementation or breakdown in the supplier's QA Program, caused by, but not limited to, such items as: 1) falsification of documentation; 2) inadequate commercial grade dedication; 3) nullified product qualification; or 4) any potential 10 CFR 21 issue, shall be sufficient basis for notification.

The Audit Team Leader's NUPIC Representative shall provide the above notification via e-mail to, the NUPIC Chairman, the NUPIC Vice-Chairman, all NUPIC Representatives, Management Representatives, and EPRI. The NUPIC Chairman/NUPIC Vice-Chairman shall determine if notification to the NRC is required.

Two New Proposed Definitions:

Finding: Any defect, characteristic, noncompliance or activity that detracts from the quality of products and/or services and is a condition that could have a credible impact to the intended function of the products and/or services provided. It also includes undesirable or abnormal pattern of events, failures, problems and programmatic issues.

Notes:

- Findings are documented on condition reports and follow-up is performed in accordance with the utilities implementing procedures and NUPIC guidelines.
- Immediate notification(s) in accordance with NUPIC guidelines shall be provided when Findings have the net result of placing the product's ability to function properly in its intended application in question such as:
 1. falsification of documentation,
 2. inadequate commercial grade dedication,
 3. nullified product qualification, or
 4. potential 10 CFR 21 issue

Deficiency: A deviation in the implementation of a Quality Assurance Program requirement or a deviation in the implementation of a QA procedure, including inadequate/conflicting procedures.

Notes:

- Deficiencies shall be documented in the vendor's corrective action program and referenced in the applicable Audit Report.
- Deficiency review may be performed during the next scheduled Audit under the Section 13 Checklist titled Corrective Action.

Recommended Industry Actions

- Licensees review and revise utility supplier audit procedures to incorporate or allow standard definitions and follow-up guidelines provided above as appropriate. These changes should not require NRC approval prior to implementation by June 1, 2017.

Key to Color Codes:

Red: NSIAC initiative – full participation required for viability

Blue: Action expected at all sites, but is not needed for broad industry viability

Green: Utility discretion to implement, consistent with its business environment

- NUPIC review and revise procedures and processes as necessary to support implementation of the definitions and follow-up practices identified here by June 1, 2017.
- Communicate the new industry definitions to suppliers on the approved suppliers list.

Other Actions for Consideration (as required)

- None at this time

Change Management Considerations

Industry Activities

- Training requirements for implementation of the revised NUPIC processes and procedures will be determined by the NUPIC Steering Committee. Training will be completed prior to implementation on June 1, 2017.
- NUPIC Steering Committee will determine requirements for communication with vendors as the change is implemented.
- As noted above, a formal protocol will be developed by the NUPIC Steering Committee to efficiently disposition Findings from 2016 and prior years which are open at implementation of the new graded approach.
- Webinars will be conducted to provide background on the initiative, discussion, and an open forum to clarify expectations and ask questions. Webinar information can be found at <https://web.inpo.org/Pages/Nuclear-Promise-Issues.aspx>

Company Actions

- Ensure that implementing documents are changed to support implementation of the auditing process with the new definitions.
- Utility specific change management will be required per individual licensee procedure change process requirements.

Guidelines

- NQML Steering Committee will provide oversight to the NUPIC and industry implementation of this initiative through established Committee representation and reporting of the NUPIC chairperson.

Report Your Site's Results


Please report your company's implementation of this improvement opportunity, including the date of completion. Send this information along with your company point of contact to EfficiencyBulletin@NEI.org.

Industry Contacts

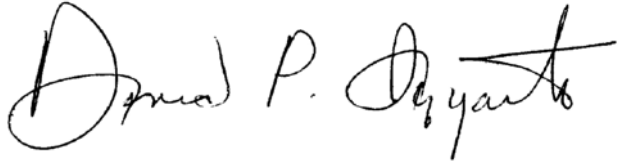
- Industry champion for this issue: Mark Mlachak, 440-666-5124, mdmlachak@firstenergycorp.com
- INPO contact: Gary Waldrep, 770-644-8626, waldrepg@inpo.org
- NEI contact: Chris Earls, 202-739-8078, cee@nei.org
- On the web: www.nei.org/bulletin1628b

Industry Approval:

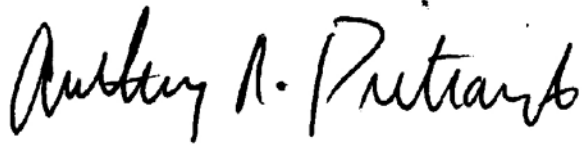
Mano Nazar, CNO Lead

Handwritten signature of Mano Nazar in black ink.

David P. Igyarto, Institute of Nuclear Power Operations

Handwritten signature of David P. Igyarto in black ink.

Anthony R. Pietrangelo, Nuclear Energy Institute

Handwritten signature of Anthony R. Pietrangelo in black ink.