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Our reference: GQ-15-036

Date: May 20, 2015

Your Reference: NRC Vendor Inspection Report Number 99900404/2015-202

Subject: Reply to Notice of Nonconformance Cited in NRC Inspection Report No. 99900404/2015-202 Dated April 24, 2015

Westinghouse acknowledges receipt of NRC Inspection Report Number 99900404/2015-202 dated April 24, 2015 and the following Notices of Nonconformance: 99900404/2015-202-01, 99900404/2015-202-02 and 99900404/2015-202-03. Westinghouse takes any Notice of Nonconformance received from the NRC seriously, is taking appropriate actions to resolve these issues, and is committed to comply with the provisions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocess Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Westinghouse also values the results from this review of the Westinghouse implementation of quality activities associated with oversight of suppliers, the resolution of technical issues, and our corrective action program.

As requested, details of the corrective actions associated with these nonconformance issues are described in the attachment to this letter.

Very truly yours,

Steve Hamilton, Senior Vice President
Quality, Environment, Health & Safety &
Chief Quality Officer

IE09
NRO

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Nonconformance 99900403/2015-202-01

Criterion I, "Organization," of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 states, in part, that "The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed."

Section 2.3.1, WEC Quality Management System (QMS), Revision 7, dated October 1, 2013, states, in part, that "Senior management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result." It further states that "The Senior Vice Presidents have overall responsibility and are accountable for the effective implementation of the QMS for applicable activities."

Contrary to the above, as of January 30, 2015, WEC failed to ensure that portions of the QA program were effectively executed, and verify that activities affecting safety-related functions have been correctly performed. Specifically, WEC failed to take timely and effective corrective actions to address significant conditions adverse to quality. This included the oversight of suppliers and the proper use of the qualified supplier list. Additionally, WEC failed to verify that its suppliers had measures in place to assure that purchased material, equipment, and services conformed to the procurement documents. These examples occurred dating back to January, 2010, which indicated WEC did not effectively implement portions of their NRC-approved QA program.

Response:

1) The reason for the noncompliance or, if contested, the basis for disputing the noncompliance:

Senior management did not dedicate sufficient time to setting expectations and monitoring results and effectiveness of the implementation of the Westinghouse Quality Program. They did not consistently stress first-time quality achievement as a core value or an integrated part of all employees' jobs. Senior management left the oversight of the implementation of the Westinghouse Quality Program to lower levels in the organization.

2) The corrective steps that have been taken and the results achieved:

While Westinghouse did self-identify many issues and has taken many actions, we also recognize there remains work to be done. We are dealing with past and current issues, and are prepared to address any further legacy issues that emerge as we work to improve our program. The following actions are a combination of actions taken based on our self-identified issues and the nonconformances identified by the NRC. Therefore, many of our actions started before the NRC inspection and subsequent inspection report. We have included the earlier actions because they provide the overall picture of how Westinghouse is addressing these weaknesses.

a. <u>September 2012</u> – *Westinghouse announced the appointment of a new President and CEO (herein after identified as CEO). He immediately began open communications with the employees across the company. He brought in a philosophy of leadership engagement and open communication that drove senior leaders to reestablish their connection to the workforce to raise awareness of organizational performance and provide direction in a timelier manner. This level of transparency provided employees unprecedented access to the senior leaders of the company, allowing the workforce to openly ask questions and understand the direction the company was heading and the reasons for decisions.*

b. *August 2013 - The Project Command Center (PCC) was launched to support delivery of Westinghouse new plant projects. Embracing a Nuclear Safety Culture, the PCC is the new plant entity focused on project integration and delivery certainty, overseeing and supporting new plant projects in overcoming delivery challenges and achieving key program milestones. The PCC is a resource and tool that is engaged by new plant project teams to prioritize work and lead the resolution of critical issues that could hamper the successful delivery of new plants. It is staffed by a team of highly qualified individuals who are capable of making priority decisions and who focus on bringing closure to emergent project issues. PCC members engage with all functions involved in new plant delivery, as well as Westinghouse delivery partners to ensure achievement of new plant project goals with a focus on safety and quality.*

c. *November 2013 – The CEO established a new Quality, Environment, Health, and Safety (QEHS) Senior Vice President (SVP) position, and filled that position with a respected nuclear industry executive with 32 years of nuclear quality assurance background at Brunswick NPP, AREVA, and General Electric-Hitachi. The position reports directly to the CEO. This raised the recognition of the importance of the Quality Program by placing the Chief Quality Officer (CQO) as a peer to the other SVPs in the business, thereby increasing the influence of the Voice of Quality.*

d. *November 2013 – The CEO established the Nuclear Safety Review Board (NSRB), an independent team of ex-NRC and nuclear industry experts who conduct regular reviews of the implementation of the Westinghouse Quality Program. To date, the NSRB has conducted four (4) reviews, and Westinghouse has entered 38 issues in our corrective action program database. Of the 38 recommendations provided by the NSRB, 26 actions are complete and 12 are in process.*

e. *February 2014 – The CQO identified a potential issue within the management ranks of our supplier quality organization, and commissioned an independent team (Conger-Elsea Inc., including former NRC inspectors) to investigate and evaluate the circumstances. This investigation uncovered latent organizational weaknesses and a potentially chilled environment. Westinghouse took swift action to address the identified issues; conducted an organization-wide stand-down to convey leadership expectations; and kept personnel informed of the changes made to correct the problems identified. Additionally, the CQO shared the discovery with the U.S. NRC in a face-to-face meeting. During the meeting, the CQO provided the NRC staff with the facts of the discovery and an explanation of the action plan put in place to address the issues. Subsequent to this initial meeting, the CQO provided updates to the NRC staff to assure them that Westinghouse was appropriately addressing the issues. These issues contributed to less than acceptable supplier oversight performance prior to 2014.*

f. *March 2014 – The CEO and CQO drove implementation of the Strategy Deployment Process across the organization. This process standardizes metrics and goals to ensure alignment with Westinghouse strategy. This action has ensured that all organizations are reviewing the information on a regular basis, and that standard performance metrics (including corrective action timeliness) exist across the company in order to achieve common goals. Additionally, the leadership team developed and implemented a company-wide balanced score card, which is a one-page dashboard discussed at executive staff meetings and visible to employees across the company. This score card provides both current status and a 30-day look ahead of key performance indicators.*

g. *April 2014 – Westinghouse extracted the information specific to the conduct of Issue Review Committees (IRCs) from Level 2 Procedure WEC 16.2, "Westinghouse Corrective Action Program" into a stand-alone procedure. The new procedure, WEC 16.11, "Issue Review Committee," expanded on the contents of WEC 16.2 and provided improved guidance on the process used by IRCs to evaluate and classify issues. This expanded guidance includes a broader selection of examples of circumstances and their categorization, as well as the NQA-1 definitions of "condition adverse to quality" and "significant condition adverse to quality." The changes have helped the IRCs make better decisions on categorization of issues and support more uniform IRC performance across the company.*

h. *April 2014 – The CQO identified that the influx of new personnel during the 2008-2009 timeframe, followed by a reduction in force that allowed the retirement of established workers, had lowered the experience level of the personnel entrusted with execution of the Quality Program. The actions outlined below were taken to increase the level of understanding of nuclear quality requirements across the Quality organization.*

   1) *The CQO contracted JETS Consultants to conduct classroom training with Quality personnel that included the following courses:*

      a) *Nuclear Codes and Standards*

      b) *10CFR21 Reporting of Defects*

      c) *Improving Observation Skills*

      d) *Basic/Lead Auditor Training*

      e) *Supplier Audits and Surveillance*

   This training has provided auditors and surveillance personnel with a better understanding of the industry requirements, which has led to more intrusive oversight of internal and supplier operations.

   2) *Westinghouse brought in lead auditors with utility experience to collaborate with existing supplier audit teams to improve the execution of supplier audits and surveys.*

   3) *The CQO established a cooperative agreement with a nuclear utility licensee to allow Westinghouse Quality personnel to attend the utility's nuclear oversight training. The first Westinghouse attendance occurred in October 2014. Subsequently, the nuclear utility licensee provided all course materials to Westinghouse so that we can begin teaching the methodology in-house.*

i. *April 2014 – The CQO chartered a Quality Improvement Program (QIP) that identified areas for improvement across the QEHS organization through the six (6) projects listed below:*

   1) *Optimize and enhance the QEHS operating model*

   2) *Focus on people development, training, and qualification*

   3) *Improve process and effectiveness for supplier quality*

   4) *Improve Quality programs*

   5) *Reduce cost of poor quality*

   6) *Improve Nuclear Safety Culture (NSC)*

These projects supported the CQO's goal to raise the bar on organizational effectiveness, personnel proficiency, supplier oversight, process improvement, and cost of poor quality (COPQ). The CQO has institutionalized the QIP as an annual program in QEHS, and is sharing this process as a best practice with the rest of the Westinghouse.

j. *June 2014 – The CQO contracted with Conger-Elsea Inc. to conduct training on the Management Oversight & Risk Tree (MORT) analysis tool for application in the Westinghouse root cause analysis (RCA) process. There have been two (2) sessions conducted so far (in June and July 2014), and twenty-six (26) analysts successfully completed the training. Collectively, they agree that adding this tool to the RCA process has aided them in building the bases of their causal analysis findings.*

k. *July 2014 – The CQO established the position of Global Quality Programs Vice President and filled that position with a well-regarded leader who brought 35 years of engineering and quality assurance experience in the nuclear industry to the company. Responsibilities assigned to this role are for all quality programs across Westinghouse, including oversight of quality audits, the corrective action program and other related areas.*

l. *July 2014 – The CQO contracted external consultants with former utility experience to conduct a Nuclear Industry Evaluation Program (NIEP)-style audit of the Westinghouse 10 CFR 50 Appendix B program. The evaluation identified gaps in corrective action program implementation, audits and supplier oversight. Issues identified during the audit were entered into the corrective action program database, and the project plans for QIP projects affected by the findings were adjusted to address the identified gaps.*

m. *August 2014 –The CEO established the new position of Employee Concerns Manager to provide senior management better oversight of the concerns within the company, and ensure global compliance with our Employee Concerns and Safety Conscious Work Environment (EC/SCWE) Policy. This independent employee advocate serves as a single point of contact for any/all employee concerns, and drives uniform implementation and enforcement of the Westinghouse EC/SCWE Policy across the company.*

n. *August 2014 – The CQO arranged for a NUPIC Limited Scope Audit (LSA) focused on the QIP projects. The NUPIC team spent a week reviewing all of the projects, and provided positive feedback on the areas identified for improvement and the progress achieved. The audit did identify three (3) findings, to which Westinghouse responded within the defined timeliness requirements. NUPIC has accepted the responses.*

o. *October 2014 – The CQO restructured the Quality organization to maximize effectiveness. He established Director roles that expanded the oversight of various facets of the Quality Program. Four (4) of the positions are Quality and Performance Improvement Directors for the product lines (PLs) and the Engineering Center of Excellence (ECoE). These Directors report directly to the CQO, and matrix-report to the SVPs of the organizations they support; they sit as SVP staff members for the PLs and the ECoE to provide visibility and accountability on corrective action performance and advise on quality-related issues. This further reinforces the independence of the Quality organization and supports the greater influence of the Voice of Quality. The CQO, Global Quality Programs VP, and the additional directors represent over 160 years of combined nuclear quality assurance experience added to the Westinghouse Quality organization.*

p. *November 2014 – The CQO established a new position of Nuclear Safety Culture (NSC) Manager to develop and implement a Westinghouse program that complies with NEI 09-07, "Fostering a Strong Nuclear Safety Culture." This new position has:*

1) *Improved the corporate monthly safety brief, which pulls together Quality, EHS, and Human Performance discussion points, with a focus on the Institute for Nuclear Power Operations (INPO) Traits of a Healthy Nuclear Safety Culture to drive meaningful discussions.*

2) *Initiated the Nuclear Safety Advocate program that focuses personnel on procedure compliance, identification of risk and mitigating actions, conservative decision-making and identification of concerns to remind all in attendance to always consider the safety impact of discussions and decisions.*

3) *Rolled out the Nuclear Safety Culture Champion program with 70 individuals in place at 28 global locations who are chartered with working with management to:*

- *Identify and aid in the removal of obstacles, barriers and challenges that prevent Nuclear Safety Culture change initiatives from succeeding;*
- *Identify wins, both large and small, and good practices to be communicated to the organization; and*
- *Guide management in understanding Nuclear Safety Culture changes and initiatives, and the impact these changes have on our business.*

q. *November 2014 – The CQO and Global Quality Programs VP began regularly attending internal audit opening and closing meetings. The CQO set the expectation with the other senior leaders across the organization that they attend the exit meetings of the audits of their areas, as well. The internal audit organization tracks senior management participation at the closing meetings, and reports attendance to the CQO. This has raised the awareness of audit results and increased the sense of urgency for addressing findings.*

r. *December 2014 – The CQO brought in INPO to conduct an independent review of the Quality training plan developed by the 2014 QIP project team focused on people development, training and qualification. INPO's review brought to bear the nuclear industry's vast experience and lessons learned from training program development and recommended changes to the initial effort that will ultimately result in an improved training program for the Quality organization.*

s. *February 2015 – The CEO chartered an Employee Engagement Survey. This survey, conducted globally in February with all Westinghouse employees, achieved an 83% participation rate. The survey included questions related to job satisfaction, safety, and Nuclear Safety Culture. The CEO used the survey results to engage senior leadership in the oversight of the organization. He and the SVPs reviewed the results of the survey and shared the results with all management. Managers shared their results with the employees, and the entire management team must develop action plans to address the opportunities identified in the survey. Accountability for addressing the opportunities is through specific individual performance evaluation goals assigned to each leader.*

t. *March 2015 – The CQO revamped the Westinghouse management review process to correct legacy leadership behaviors that treated the annual review of Quality Program implementation as a "ticket punch" activity. The reporting period was changed from a fiscal year to a calendar year to align with the company strategic planning cycle. Prior reviews suffered from a lack of leadership support to drive a sense of urgency for collection and review of performance data. The 2014 management review meeting was a detailed, in-depth review of critical performance data, the results of which were entered into our corrective action program.*

u. *April 2015 – The Human Resources SVP, in conjunction with the CQO, created a new position of Global Technical Training Director. The ultimate goal is to create a systematic approach to training (SAT)-based, accreditation-light technical training program. The position was filled with an individual with 30 years of experience building technical capabilities at organizations in the nuclear industry, and is assigned the following responsibilities:*

- *Working with the product line technical training leaders to develop common standards and processes based on industry best practices*
- *Creating a technical training committee structure and technical training advisory board for oversight*
- *Ensuring that the technical training needs are properly identified and addressed to ensure the highest standards are achieved*
- *Monitoring organizational and operational performance as a verification of technical training effectiveness, making necessary improvements*
- *Driving a consistent approach to training across the organization*
- *Leveraging our central learning operations team to support technical training objectives*

v. *May 2015 – The CEO and CQO formalized a Westinghouse Executive Corrective Action Review Board (CARB). This CARB is responsible for the review and approval of the root cause analyses and corrective action plans for key Level 1 significance issues including, but not limited to, those that are regulator or customer-identified, have cross-organizational implications, or are selected by the Westinghouse executive staff as needing executive-level oversight. The Executive CARB effectively "raises the bar" for ownership and accountability for our most important issues; sets the standard for consistent oversight of RCAs and corrective action effectiveness determinations; and aligns senior management expectations with industry norms.*

3) The corrective steps that will be taken to avoid noncompliance:

a. *Control plans are in place for all of the 2014 QEHS QIP projects, and the QEHS staff regularly monitors implementation to assure achievement of the desired goals. Charters are drafted for the 2015 QIP projects, some of which build on improvements made in 2014, and are awaiting final CQO approval. The targeted improvement projects for 2015 are focused on:*

- *Technical training*
- *Supplier quality*
- *Performance monitoring*
- *Corrective action program improvements*

- *Cost of poor quality reduction*
- *Operating Experience program improvements*
- *Alignment of Quality organization across Westinghouse*
- *Global Quality cost improvement (operating costs)*
- *Level 2 procedures consolidation*
- *Quality Program evaluation against regulatory and standards changes*

b. *Subsequent to the first Westinghouse personnel participating in the nuclear utility licensee nuclear oversight training, the nuclear utility licensee agreed to provide all course materials to Westinghouse so that we can begin teaching the methodology in-house more rapidly than the nuclear utility licensee training schedule would permit.*

c. *The Westinghouse Quality Training Plan Guideline (QAG-2.6) was issued to support the changes underway to better define and standardize the training for Quality personnel. QAG-2.6 was issued as a guideline to allow managers across Quality to begin changing the standardized training requirements, and to permit the project team to address the feedback from INPO. The project team will retire the guideline and issue it as a Quality Level 3 procedure once all the INPO feedback has been addressed.*

d. *As part of a causal analysis improvement plan, and the successful initial application of the MORT analysis tool, efforts are underway to incorporate the MORT tool into RCA qualification and refresher training. Additionally, Westinghouse recognized that our apparent cause analysis (ACA) process needed improvement, so we revamped and expanded the training from a 1-day class to a 3-day class to ensure that resources are fully qualified. The new class is required for all new prospective analysts, and all current analysts are required to requalify by attending the new class in order to maintain their certification.*

e. *To address the authorization of an Executive CARB, Westinghouse Level 2 procedure, WEC 16.3, "Corrective Action Review Board" will be revised to incorporate the requirements and expectations associated with the new CARB.*

4) The date when the corrective action will be completed:

a. *Westinghouse will start delivering the nuclear oversight training internally by August 31, 2015.*

b. *The MORT analysis tool will be incorporated into the Westinghouse RCA training by August 31, 2015.*

c. *The revision to WEC 16.3 to institutionalize the Westinghouse Executive CARB will be completed by August 31, 2015.*

d. *The open items in QAG-2.6 will be closed and the Quality Level 3 procedure will be issued by December 31, 2015.*

e. *Retraining and requalification of current apparent cause analysts will be completed by December 31, 2015.*

f. *The 2015 QIP projects will be completed by March 31, 2016. Each chartered project is assigned a completion date based upon complexity of the work required.*

Nonconformance 99900404/2015-202-02

Criterion XVI, "Corrective Action," of Appendix B, to 10 CFR Part 50 states, in part, that, "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformance are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."

Section 5.5.1 of the WEC QMS, Revision 7, dated October 1, 2013, states that "Conditions adverse to quality of items and services are identified, documented, analyzed, and corrected in accordance with established procedures. For significant conditions adverse to quality, these procedures provide for identification; assignment of responsibility for corrective action; documentation of the cause and corrective action taken, implementation, evaluation, and verification of corrective action to prevent recurrence; and reporting to the appropriate levels of management."

Section 7.5.1 of WEC Procedure 16.2, "Westinghouse Corrective Action Program," Revision 7.0, dated April 3, 2012, states, in part, that "A Corrective Action plan shall be developed for each issue commensurate with its consequences, complexity and Significance level, and in a manner that ensures all conditions adverse to quality are effectively addressed."

WEC Procedure 16.11, "Issue Review Committee," Revision 1.0, dated August 20, 2014, Appendix A, "Guidance For Classifying Conditions Adverse to Quality," includes the following example for significant condition adverse to quality (SCAQ), "A repetitive problem indicating a programmatic failure or a precursor of a major technical deficiency."

Contrary to the above, as of January 30, 2015, WEC failed to establish measures to assure that conditions adverse to quality were promptly corrected, and for significant conditions adverse to quality, corrective actions were taken to preclude repetition.

General Response:

1) The reason for the noncompliance or, if contested, the basis for disputing the noncompliance:

Inadequate oversight and lack of accountability at all organizational levels resulted in less than effective implementation of the corrective action program requirements delineated in the Westinghouse Quality Program, WEC 16.2, "Westinghouse Corrective Action Program," and seven (7) other corrective action program-related procedures.

2) The corrective steps that have been taken and the results achieved:

a. *April 2014 – Metrics were implemented to raise the visibility of the corrective action program (CAP) implementation effectiveness company-wide, including those for issue aging and causal analysis timeliness. These key performance indicators were reviewed monthly at the CEO's staff meeting throughout 2014 and both showed performance improvement over the past six (6) months. In April 2015, metrics for issue closure quality; corrective action to prevent recurrence (CAPR) quality and timeliness; and supplier corrective action request (SCAR) quality and timeliness were added to the monthly reporting. In addition, the 2015 metric goals for issue aging were increased by 10% across the board to align with industry standards and raise expectations for on-time completion of corrective actions.*

b. *April 2014 – A new corrective action program database for tracking problem identification and resolution was implemented ("Corrective Action, Prevention and Learning" database or "CAPAL"). CAPAL requires more information when entering an issue, which in turn, offers more detail and data for trend analyses and corrective action program oversight. Multiple job aids and training modules were created when CAPAL was implemented to help users mitigate the learning curve associated with the use of the new database.*

c. *April 2014 – Commensurate with the implementation of the CAPAL database, all of the Level 2 CAP-related procedures and related training were revised to streamline and clarify program requirements and clearly define CAP roles and responsibilities. The suite of Level 2 CAP-related procedures now includes WEC 16.2, which provides the requirements for overall CAP management, oversight and expectations, and seven (7) others that provide the requirements for implementation of various CAP processes (e.g., root cause analysis, corrective action review board (CARB), common cause analysis, effectiveness review, etc.).*

- *The CARB procedure includes specific responsibilities and requirements for CAP oversight, including review of issues that represent significant conditions adverse to quality, to reduce variability in corrective action quality and implementation.*
- *The NQA-1 definitions of "condition adverse to quality" and "significant condition adverse to quality" were adopted verbatim based on utility benchmarking, and detailed guidance was incorporated into a new procedure that has improved consistency in issue assessment and classification by IRCs.*
- *WEC 16.2 now includes timeliness expectations for issue closure, depending on significance level. The timeliness guidance has provided increased oversight for issues that are languishing and need attention.*
- *The Differing Professional Opinions (DPO) process that Westinghouse implemented in June 2013 (procedure WEC 21.3) was integrated into the CAP procedures to provide an avenue for issue owners and causal analysis personnel who cannot come to alignment regarding the results of investigations to have their positions reviewed by an impartial board for a final determination.*

d. *July 2014 – The CQO established the position of Global Quality Programs Vice President (VP), and filled that position with an industry recognized leader with 35 years of engineering and quality assurance experience. The Global Quality Programs VP is responsible for all Westinghouse quality programs, including oversight of the corrective action program.*

e. *August 2014 – The Global Quality Programs VP appointed a Global Corrective Action Program (GCAP) Manager with extensive nuclear utility and performance improvement experience. The GCAP Manager has direct responsibility for managing the Westinghouse corrective action program and for focusing on continuous improvement of the program through benchmarking of industry best practices.*

f. *August 2014 – A company-wide focus was initiated to reduce the backlog of open CAP issues and improve corrective action implementation timeliness. The number of open issues was reduced by 32% from the inception of the project through the end of April 2015. Issue timeliness companywide improved from 45% meeting expectations to 67% during the same timeframe. This effort continues across the company with increased accountability at lower organizational levels.*

g. *March 2015 – The CEO and his staff began reviewing the top twelve (12) oldest CAPAL issues at monthly staff meetings.*

3) The corrective steps that will be taken to avoid noncompliance:

a. *An ongoing self-assessment of CAP compliance and implementation effectiveness will be implemented. It will be led by the GCAP organization with team members included from all functional areas. The assessment scope will include, at a minimum (and as approved quarterly by the Global Quality Programs VP): issue closure quality; CAPR implementation and closure quality; causal analysis quality; trend analyses; use of long term commitment designations; and internal audit results related to CAP implementation. The self-assessment*

results will be provided to senior leadership on a quarterly basis and actions required to drive continued performance improvement will be defined and implemented.

b. *CAP metrics will be monitored, analyzed and reported monthly in order to achieve the established metric goals in a manner that meets CAP requirements for effective corrective action completion and issue closure.*

c. *The extent of condition evaluation methodology used during causal analyses will be evaluated to define any improvements needed in the definition, methodology, procedure and training.*

4) The date when the corrective action will be completed:

a. *Initial implementation of the CAP self-assessment process, including communication of the first quarterly results, will be completed by July 31, 2015.*

b. *Issue aging and causal analysis timeliness goals will be met by December 31, 2015.*

c. *The review of the methodology used for extent of condition evaluation will be completed by June 15, 2015.*

Specific examples include:

Example 1:

WEC failed to promptly correct or prevent recurrence of a significant condition adverse to quality associated with safety-related purchase orders placed to suppliers not on the Qualified Supplier List (QSL) or without restrictions required by the QSL. Specifically, Corrective Action Process (CAPs) Issue Report 10-014-W012, issued in January 2010, "Purchase Requisition/Purchase Order Processing Violates Numerous WEC-7.5 Requirements," remained open for approximately 56 months, had been ineffective in resolving the significant condition adverse to quality, and was closed to Corrective Action, Prevention, and Learning System (CAPAL) Issue ID 100000472. CAPAL 100000472 documented that CAPs 10-014-W012 had not been effective and that from January 2011 to August 2013 there were over 50 CAPS issue reports, including four high level issues that documented problems with supplier control issues. CAPAL 100000472 was initiated in May 2013 and remains open as of January 30, 2015. The recurrent issue of significant condition adverse to quality associated with safety-related purchase orders placed to suppliers not on the QSL or without restrictions required by the QSL was documented in January 2010 and has not been resolved.

Response:

1) The reason for the noncompliance or, if contested, the basis for disputing the noncompliance identified in this (#1) example:

There was a lack of ownership and management accountability for promptly resolving and preventing recurrence of issues associated with safety-related purchase orders placed with suppliers either not on the Qualified Supplier List (QSL), or without restrictions required by the QSL. The original owner of CAPs issue 10-014-W012 (initiated in January 2010) did not implement the corrective actions resulting from the root cause analysis (RCA) and lack of oversight allowed the issue to stagnate. The responsible CARB ultimately found the corrective action plan to be ineffective and the corrective actions to prevent recurrence (CAPRs) were transferred to CAPs issue 13-151-M013, which was initiated in May 2013. Ownership of issue 13-151-M013 (which was migrated to CAPAL as issue 100000472 in March 2014) was assigned within the finance organization, rather than within the

supply chain organization. Here again, there was a lack of accountability and management oversight for completing effective corrective actions in a timely manner.

2) ***The corrective steps that have been taken and the results achieved identified in this (#1) example:***

The following interim actions were taken to address CAPAL issue 100000472:

- *A stand-down was conducted with all requisitioners and buyers to raise visibility of the issue in March 2014;*
- *All open safety-related purchase orders were reviewed to ensure that they were all placed with suppliers on the QSL at time of issuance in June 2014; and*
- *Ownership of CAPAL issue 100000472 was transferred to Supply Chain Management in March 2015.*

Following reassignment to the new issue owner, a review was performed to define the actions required to effectively resolve the noncompliance and drive the issue to closure in a manner that meets Westinghouse corrective action program requirements.

3) ***The corrective steps that will be taken to avoid noncompliance identified in this (#1) example:***

a. *The interim process implemented for quality and technical reviews of safety-related purchase orders prior to placement with suppliers (and that will remain in effect until a permanent system-based defense is in place) will be reviewed for adequacy.*

b. *System-based defenses will be implemented as follows:*

- *Phase 1 – Requires the safety class to be clearly identified on all new requisitions and purchase orders. This action has already been completed.*
- *Phase 2 – Will prevent purchase orders from being issued when the safety class requires procurement from a QSL supplier and the supplier selected is not on the QSL.*
- *Phase 3 – Will require new quality and technical approvals for any purchase order when any changes are made to the requisition technical and quality requirements, including selection of a new QSL supplier.*

c. *Applicable procedures will be revised to clearly define associated roles and responsibilities. Qualifications for all roles in the procurement process will be established, and training for all roles will be implemented and completion monitored.*

4) ***The date when the corrective action will be completed identified in this (#1) example:***

a. *The review of the adequacy of the interim process implemented for quality and technical reviews of safety-related purchase orders prior to placement with suppliers will be completed by May 29, 2015.*

b. *CARB review and approval of the new due dates will be completed by May 31, 2015.*

c. *Phase 2 will go live by July 31, 2015.*

d. *Phase 3 will go live by October 31, 2015.*

e. *All other corrective actions associated with issue 100000472 will be completed by November 30, 2015.*

f. *The final effectiveness review for issue 100000472 will be completed by April 30, 2016 (i.e., approximately 6 months following CAPR completion).*

Example 2

WEC failed to promptly correct or prevent recurrence of a significant condition adverse to quality associated with the root cause for CAPs 12-045-C037, "Root Cause Analysis for Nonconforming Fuel Assembly Shipped to Indian Point 2." Specifically, the root cause for CAPs 12-045-C037 was identified as management failed to reinforce established standards, which resulted in an incomplete supplier audit checklist, acceptance of finding responses without objective evidence and not issuing a Stop Work Order in compliance with WEC 15.5, "Stop Work," Revision 5.0 dated December 12, 2014. The corrective actions provided for retraining of the Auditors, but did not specifically address the management aspect of enforcing established standards and program requirements. WEC identified in the final effectiveness review for the root cause that the corrective action was ineffective and similar problems continued to occur. WEC closed CAPs 12-045-C037 to CAPAL 100026711 to resolve the issues. The recurrent issue of the significant condition adverse to quality associated with management failing to reinforce established standards for supplier audits was identified in January 2013 in the root cause for CAPs 12-045-C037 and has not been resolved. WEC also failed to initiate CAPAL or document action to address why this root cause corrective action was not effective.

Response:

1) ***The reason for the noncompliance or, if contested, the basis for disputing the noncompliance identified in this (#2) example:***

The effectiveness review for CAPs issue 12-045-C037 concluded, although the CAPRs identified in the RCA corrective action plan were effectively implemented and prevented recurrence of the specific elements addressed, there was no clear linkage from the CAPRs to the root cause. It further concluded that despite this, the organization changes, process improvements (both completed and planned), and specific corrective actions associated with another Level 1 significance issue (100026711) would directly address the root cause identified in 12-045-C037. The effectiveness review also found, with respect to the management aspect of reinforcing established standards and program requirements, that the new CQO had provided clear direction regarding expectations to the organization through employee meetings; individual conversations; and development and implementation of a supplier accountability model. The report also acknowledges that changes had been made in the QEHS leadership positions associated with supplier quality and oversight.

The Westinghouse CARB procedure (WEC 16.3) includes provisions for when an effectiveness review concludes the corrective action plan for a Level 1 issue was ineffective. One of the provisions allows new CAPRs to be added to another open Level 1 issue identified as a repeat event of the ineffective issue, with the issues cross-referenced in the corrective action program database. In this case, the original issue may be closed as "ineffective" with a pointer to the more recent issue. This was done when issue 12-045-C037 was closed to issue 100026711. However, the RCA for issue 100026711 did not include a determination of why the corrective action plan for 12-045-C037 was ineffective, which is required by procedure. This occurred because 1) it had already been determined why the corrective action plan for 12-045-C037 was ineffective, and 2) the RCA for 100026711 was completed prior to the effectiveness review for 12-045-C037. Westinghouse acknowledges that this deviation from procedure requirements, given the situation, should have been more clearly documented.

2) ***The corrective steps that have been taken and the results achieved identified in this (#2) example:***

The CAPRs implemented for issue 100026711 addressed the root cause for issue 12-045-C037. Specifically, the applicable procedure was revised to clarify the requirements for assessing product that has already been shipped based on extent of condition evaluations and requirements for supplier corrective action request (SCAR) closure. Supplier letter templates were also revised to clarify the expectations regarding objective evidence of responses and corrective action completion.

3) The corrective steps that will be taken to avoid noncompliance identified in this (#2) example:

All CAPRs for issue 100026711 were completed as of April 15, 2015 and the issue is awaiting effectiveness review.

4) The date when the corrective action will be completed identified in this (#2) example:

The effectiveness review for issue 100026711 will be completed by October 31, 2015 (approximately 6 months following CAPR completion).

Example 3

WEC failed to promptly correct and prevent recurrence of a SCAQ associated with the internal audit program. Specifically, WEC identified repetitive issues with significant weaknesses in the internal audit program, which indicate a programmatic failure that, in accordance with guidance in WEC 16.11, "Issue Review Committee," Revision 1.0 dated August 20, 2014, should have been classified as a SCAQ, to ensure that there was an adequate and effective corrective action. CAPAL 100016265 was issued on March 19, 2014, and identified concerns with the internal audit program, including planning, scheduling, coordinating, scope definition and depth. WEC did not consider these issues to be a SQAC and closed the CAPAL on August 26, 2014. On October 17, 2014, WEC initiated CAPAL 100052988 which identified significant weaknesses in the conduct of internal audits, missed audits, audit frequency mismatch, inadequate audit scope, inadequate audit objective evidence, and inadequate audit plan. WEC did not consider this CAPAL a SCAQ and corrective actions were still open. In addition, the programmatic failure in the WEC internal audit program resulted in a failure to identify and correct issues, with the consequence of WEC being in non-compliance with regulatory requirements. The 2013 internal audit of Newington, WEC 13-35: Westinghouse Newington, identified a procedural issue with commercial grade dedication, but did not identify any issues with implementation of commercial grade dedication at Newington. The 2013 internal audit of NuCrane, WEC 13-40: Westinghouse Par Nuclear - NuCrane, did not identify any issues related to measuring and test equipment (M&TE). However, the NRC inspections of Newington in October 2014, documented in Inspection Report No. 99901392/2014-201, and Westinghouse Fuel Handling Equipment and Crane Manufacturing (NuCrane Manufacturing) in October 2014, documented in Inspection Report No. 99901452/2014-201, resulted in the issuance of Notices of Nonconformance related to programmatic issues with inadequate commercial grade dedication and not implementing part of the M&TE program, respectively.

Response:

1) The reason for the noncompliance or, if contested, the basis for disputing the noncompliance identified in this (#3) example:

Inadequacies in the internal audit program persisted for some time due to lack of management oversight and ineffective program management. The status quo was accepted and audits were conducted without making necessary improvements. CAPAL issue 100016265 self-identified known weaknesses in the internal audit program and was initiated in March 2014 as a means to track the internal audit improvement actions planned for the2014 QIP. Subsequently, Westinghouse contracted with external consultants to conduct a Nuclear Industry Evaluation Program (NIEP)-style audit of the internal audit program as part of the planned corrective actions. CAPAL issue 100052988 was initiated in October 2014 to document the results of that assessment, and the actions from the first issue (100016265) were deferred to the actions from the assessment.

The initiation date of issue 100016265 preceded the implementation of WEC 16.11, Revision 0. However, guidance for classifying issues did exist in WEC 16.2 in March 2014, and the issue was classified as a condition adverse to quality in accordance with that guidance. It had been entered to track actions already planned to address the identified internal audit program deficiencies. The

guidance for issue classification was significantly improved when WEC 16.11 was implemented in April 2014, and the verbatim NQA-1 definitions of "condition adverse to quality" and "significant condition adverse to quality" were incorporated. In October 2014, issue 100052988 was classified as a Level 3 significance condition adverse to quality in accordance with WEC 16.11. A limited cause analysis was conducted to assess extent of condition, and a corrective action plan that included the recommendations from the contracted assessment was defined.

2) ***The corrective steps that have been taken and the results achieved identified in this (#3) example:***

Management oversight of the internal audit program has improved significantly since March 2014. The CQO appointed a new Global Quality Programs Vice President (VP) with experience in quality audit oversight; codes and standards compliance; and corrective action program management. A new Quality Programs Manager was also appointed to provide direct management oversight of internal audits, and program management expectations were raised to ensure a more appropriate and rigorous level of oversight is sustained.

A defined basis for developing the internal audit schedule was established to ensure that all regulatory requirements are met. The schedule is now approved by the Global Quality Programs VP, and any changes to the schedule are subject to his approval. Senior-level Quality management, including the CQO and the Global Quality Programs VP, regularly attend internal audit opening and closing meetings. In addition, attendance by management of audited organizations is recorded.

Extensive actions have been taken to address the CAPAL issues identified above (100016265 and 100052988), CAPAL issues initiated during the January 2015 inspection, and the 2014 QIP, as follows:

- *Pre-job brief templates were implemented that provide improved guidance to team members regarding expectations for covering assigned audit scopes and details pertaining to audit execution.*
- *Audit Team Leads develop more thorough audit plans that include specific information regarding audit scope, standards, projects, applicable documents, and team members. While much of this was done in the past, previous audit plans often lacked the detail necessary to determine whether all of the required scope was actually covered during an audit.*
- *Improved audit checklists guide auditors of varied experience and skill levels to submit more complete, accurate and consistent details to document their respective parts of an audit. In particular, expectations around sufficient and appropriate objective evidence to support conclusions are more apparent.*
- *Audit team member training was created to reinforce the new standards for audit performance, and completion of the training is required for all team members prior to participating on an audit. Audit Team Leads were also required to attend the JETS Consultants "Basic/Lead Auditor" course.*
- *Audit Team Leads utilize newly-created templates for audit opening and closing meetings to drive a more effective and consistent approach to communicating with audited organizations.*
- *A peer review checklist was implemented to facilitate more thorough reviews of internal audit reports, and management review and approval of final audit reports are conducted with a high level of scrutiny.*
- *Finally, a focused effort was made to consistently produce on-time internal audit reports; to date, all 2015 audit reports have been issued on time and in compliance with program requirements.*

During the course of the January 2015 NRC inspection, three (3) CAPAL issues were self-identified to address audit program weaknesses.

- *Issue 100075362 was entered to develop procedural requirements for follow-up audits. Training was conducted for all Audit Team Leads to raise awareness of the concerns around missed audit scope and the expectations for sufficient audit planning, execution and actions required when audit scope is not covered. A limited cause analysis conducted to identify audits with potential missed scope found no noncompliance to regulatory requirements.*
- *Issue 100075368 identified a gap in both the internal audit and corrective action programs that allowed a Quality Controlled CAPAL issue (e.g., quality-related internal audit finding) to be closed to another issue without Quality Controlled designation. WEC 16.2 was revised to address this gap (Revision 8.0, effective May 12, 2015).*
- *Issue 100075385 was initiated to identify that the internal audit group was not actively tracking open audit findings. An "Audit Finding Scorecard" was developed and will be fully implemented with the release of WEC 18.1, Revision 4.0, "Internal Audits."*

As a result of the NIEP audit, a mentoring program was established in which selected Audit Team Leads conducted audits with a mentor. The mentor was a member of one of the third-party team of consultants who conducted the assessment. The mentor provided real-time coaching to each selected Audit Team Lead during audit execution, and also provided a written report to the Audit Team Lead and QEHS management following the mentoring experience. Lessons learned from these mentoring opportunities provided input to internal audit program improvements and contributed to the ongoing development of Audit Team Lead competencies.

Finally, a change implemented relative to audit execution with the highest potential impact is the "bucketing" of nonconformances identified during audits into audit findings. Past internal audits resulted in large numbers of CAPAL issues at a relatively low significance level. Too often, opportunities for implementing effective corrective actions were lost because the nonconformances were not grouped into meaningful issues that would warrant assignment of a higher significance level and drive extent of condition and causal analyses. This new approach has been successfully implemented on audits conducted since March 2015, and has enabled a better assessment of the status of the Westinghouse Quality Program, with the added benefit of audited organizations taking more ownership of identified nonconformances. This will contribute to the effectiveness of both the internal audit and corrective action programs.

3) The corrective steps that will be taken to avoid noncompliance identified in this (#3) example:

a. *Level 2 procedure WEC 18.1, "Internal Audits," is being revised to include requirements that will drive consistent and sustained execution of the identified improvements. Until the release of WEC 18.1, Revision 4.0, Quality management is providing rigorous oversight to ensure these changes are effectively implemented. Weekly Audit Team Lead meetings are held to review plans for upcoming audits and lessons learned from past audits.*

b. *In addition, improvements and modifications needed to the internal audit management system in support of the program changes are planned.*

4) The date when the corrective action will be completed identified in this (#3) example:

a. *WEC 18.1, Revision 4.0 will be released by July 31, 2015.*

b. *Modifications to the internal audit management system will be completed by September 30, 2015.*

Example 4

WEC failed to promptly initiate an issue report for a SCAQ that adversely impacted the AP1000 design of the containment condensate return portion of the Passive Core Cooling System needed to maintain the reactor in a safe shutdown condition. Specifically, an invalid design assumption was identified in 2010; and WEC did not initiate an issue report until July 9, 2012. Also, once initiated, CAPS Issue Report 12-191-M015 was not treated as a SCAQ. Additionally, WEC failed to perform an adequate extent-of-condition review for other possible incorrect design assumptions because their evaluation only focused on potential process issues rather than sampling other similar design assumptions.

Response:

1) ***The reason for the noncompliance or, if contested, the basis for disputing the noncompliance identified in this (#4) example:***

Westinghouse agrees that the totality of the issues associated with passive residual heat removal (PRHR) system performance and condensate return represent a significant condition adverse to quality and warrant root cause analysis. At the time the initial CAPs issue was identified (12-119-M015), responsible management believed that an RCA was not needed and that the appropriate issue classification criteria were applied. The scope of the issue and work required to address it was believed to be less effort than it actually was, as other issues were identified over time and were assessed individually. The RCA and review of the comprehensive set of issues was initiated soon after Level 1 significance CAPAL issue 100073951 was initiated in January 2015 and classified as a significant condition adverse to quality.

Westinghouse recognizes that this should have occurred sooner, and acknowledges that the original CAPs issue was not created in a timely manner following discovery of the initial problem. Causal factors include inadequate validation of assumptions regarding technical questions from a regulator. Further, the extent of condition review conducted at the time of the original CAPs issue was process-focused; Westinghouse agrees that a performance-based extent of condition evaluation is required and is in progress.

2) ***The corrective steps that have been taken and the results achieved identified in this (#4) example:***

Westinghouse has taken numerous steps to improve the timely resolution of AP1000 technical issues.

As part of the Project Command Center (PCC), a process was implemented for the identification, severity-based prioritization, management and resolution of significant issues. The PCC significant issue process operates in close coordination with the corrective action program. During the daily AP1000 IRC CAPAL issue reviews, critical technical issues are identified and referred to the PCC for further screening, prioritization and inclusion into the significant issues process. The more significant issues are assigned dedicated issue managers who ensure timely and complete resolution of all associated corrective actions. Issue managers follow established guidelines for managing and reporting the progress of resolution of the significant issues. Scheduled, published reports provide increased organizational focus and accountability.

The most recent CAPAL issue (100073951) was generated to determine the root cause for the initiating issue (12-191-M015), and examines the challenges encountered during the issue resolution process including those identified in this example. Three (3) remedial actions, one (1) CAPR, and 14 other corrective actions were approved by the responsible CARB to address the single root cause and eight (8) contributing causes identified for the condensate return issue. Sixteen (16) separate issue reports related to PRHR HX performance were integrated into the scope of the RCA.

Remedial actions to update calculations and assess/modify performance calculation methodology were completed in April 2015, as was the CAPR to issue the design plan that includes direction to create configuration sets that will flow down the inputs and requirements for the plant analysis topic, including safety analyses.

3) The corrective steps that will be taken to avoid noncompliance identified in this (#4) example:

The supporting corrective actions to address CAPAL issue 100073951 include:

a. *Determining if AP1000 licensing plans are adequate for addressing regulatory questions*

b. *Conducting reinforcement training with engineering regarding inputs and assumptions, and when an open item is appropriate*

c. *Improving the project management process for licensing and developmental activities*

d. *Completing the extent of condition evaluation by reviewing targeted documentation for potential undesignated requirements, un-validated assumptions and unidentified open items*

4) The date when the corrective action will be completed identified in this (#4) example:

a. *The extent of condition evaluation (including the targeted documentation reviews) will be completed by August 31, 2015.*

b. *The remaining corrective actions from CAPAL issue 100073951 will be completed by August 31, 2015.*

c. *The final effectiveness review for CAPAL issue 100073951 will be completed by October 30, 2015 (i.e., six (6) months following completion of the CAPR).*

Nonconformance 99900403/2015-202-03

Criterion VII, "Control of Purchased Material, Equipment, and Services" of Appendix B, to 10 CFR Part 50, states, in part, that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for 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. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Section 4.3.2, "Supplier Selection," of WEC QMS, Revision 7, dated October 1, 2013, states, in part, that "The purchasing organization is responsible for placing orders only with suppliers that have been found acceptable in accordance with established procedures." Section 4.3.2 further states that "Suppliers of safety-related items and services are evaluated and selected prior to their designation as a qualified supplier. These methods include one or more of the following: (a) evaluation of the supplier's history (including current CAPs ability) of providing the same or similar item in accordance with specified requirements; (b) review of the supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated; and/or (c) the supplier's technical and quality CAPs ability determined by a source evaluation of their facilities, personnel interviews, and the content and implementation of their quality program. Suppliers of safety-related items and services for nuclear power plants not subject to NRC regulations are evaluated and qualified in accordance with the requirements of the governing regulatory agency or customer contract."

Contrary to the above, as of January 30, 2015, WEC failed to verify that their suppliers had measures in place to assure that purchased material, equipment, and services conform to the procurement documents. Specific examples include:

1. WEC failed to perform an adequate evaluation of L&S Machine Company LLC (L&S) to verify L&S's qualifications to perform dedication and special processes such as welding, nondestructive examination (NDE), and heat treatment and plating, which was required for the procurement of reactor fuel assembly top and bottom nozzles, top nozzle spring clamps and spiders. The Supplier Audit Evaluation Summary (SAES) completed by WEC for L&S indicated that L&S was qualified to perform machining services. Purchase orders issued to L&S from WEC required L&S to perform dedication, welding, NDE, heat treatment and plating which is outside of the approved scope of work identified in the SAES. This discrepancy in qualification resulted in products manufactured by L&S being in an indeterminate status relative to quality standards.
2. WEC failed to perform an adequate evaluation of Peerless Manufacturing Company (PMC), prior to issuing a safety-related purchase order (PO) 4500429292. Also, after changing PMC's supplier status on the QSL to indicate that PMC was a supplier of non-safety related items and services, WEC failed to re-evaluate PMC's QA program, to verify that it was adequate for the existing procurement under PO 4500429292. Further, WEC failed to maintain the supplier in qualified status throughout the duration of the purchase order. As a result, products shipped from PMC are considered to be in an indeterminate status relative to quality standards.

Response:

1) The reason for the noncompliance or, if contested, the basis for disputing the noncompliance:

Westinghouse initiated a Level 2 significance CAPAL issue in February 2015 (issue 100077746). The apparent cause analysis (ACA) determined the following causes of the noncompliance:

- *When the subject supplier audits (2011 through 2013) were conducted, there was a lack of understanding regarding the depth and breadth of objective evidence required to support the supplier's ability to implement its quality program for the required scope of supply. In addition, procurement documents issued to L&S Machine did not clearly convey the appropriate quality and technical requirements due to inconsistent implementation of Westinghouse procedure requirements.*
- *The review of the procurement document associated with Westinghouse QSL listing for Peerless Manufacturing Company (PMC) conducted prior to issuing of the purchase order was ineffective.*

2) The corrective steps that have been taken and the results achieved:

a. *April 2013 – Westinghouse implemented the suspension state as a new supplier quality program status on the Westinghouse QSL. The suspension state is used to mitigate potential risk to Westinghouse and its customers. No new safety-related purchase orders or change notices can be issued to a supplier in the suspension state, and safety-related product is not permitted to be released from the supplier's facility until the suspension is properly resolved. The suspension state is initiated manually if deficiencies are identified through an audit or surveillance activity, and is automatically initiated if a supplier's onsite assessment activities have not been performed within the required frequency (i.e., three (3) years).*

b. *May 2013 – ASME conducted a 4-day NQA-1 Lead Auditor Training course for 21 current and prospective Westinghouse lead auditors. The course provided personnel with a body of knowledge and understanding of auditing methods and techniques to conduct audits of nuclear quality assurance programs. Completion of this training improved the skills of the auditing staff.*

c. *March 2014 – A project was initiated to resolve specific concerns relevant to the flow down of quality requirements in safety-related purchase orders. Level 3 procedure QA-7.2, "Review of Procurement Packages," was revised to clarify the role of the purchase requisition Quality reviewer. Changes were also made to better align the process with the expectations identified in Level 2 procedure WEC 7.5, "Control of Purchased Items and Services." QA-7.2 now provides detailed information regarding the flow down of quality requirements; a detailed evaluation checklist to assure supplier qualifications; and a flowchart that explicitly states the process steps to ensure that the Quality review process is consistently implemented. Mandatory training for all Quality personnel who review procurement documents was conducted by the process improvement team.*

d. *In addition – The following interim actions were taken through CAPAL issue 100000472 by Supply Chain Management:*

   - *A stand-down was conducted with all requisitioners and buyers to raise visibility of the issue in March 2014;*
   - *All open safety-related purchase orders were reviewed to ensure that they were all placed with suppliers on the QSL at time of issuance in June 2014; and*
   - *Ownership of CAPAL issue 100000472 was transferred to Supply Chain Management in March 2015.*

e. *April through September 2014 – Supplier Quality personnel attended the JETS Consultant training, including:*

   - *Nuclear Codes and Standards*
   - *10 CFR 21 Reporting of Defects*
   - *Improving Observation Skills*
   - *Basic/Lead Auditor Training*
   - *Supplier Audits and Surveillance*

f. *July 2014 – SAP procurement stand-down was held with all SAP requisitioners, supply chain, and procurement Quality personnel in response to CAPAL issues 100000472 and 100000032 to raise visibility of the gaps in the procurement process.*

g. *April 2015 – A new VP with extensive nuclear utility experience was selected to lead the supply chain organization.*

h. *May 2015 – Westinghouse developed and implemented training to address CAPAL issue 100041382 regarding ASME Section IX Code training for supplier quality auditors. The training objectives and topics included:*

   - *Examples of ASME Section IX Welding Code Welding Procedure Specification (WPS), Procedure Quality Record (PQR), and welder qualification requirements*
   - *The general differences between welding standards for ASME Code applications and AWS code applications along with general WPS/PQR differences*

- *Guidance on assessing ASME Section IX Code WPS, PQR "essential, non-essential, and supplementary essential variables"*
- *Guidance for interpreting ASME Section IX Code variables and determining supplier WPS & PQR compliance*

i. May 2015 – *A stand-down was conducted with supplier quality auditors to ensure QSL consistency of supplier information.*

j. In addition – *Westinghouse Engineering evaluated whether any products are in an indeterminate status relative to quality standards and determined:*

- *Purchase order 45600449276 was issued to L&S Machine for the machining of enclosure pins, material numbers V6-434-1 and V6-434-2. The raw material for the machining of the enclosure pins was supplied to L&S Machine by Westinghouse. A source surveillance was performed by a Westinghouse Level II Mechanical Inspector for a sample sized lot of V6-434-2. L&S Machine performed the dimensional inspection of the remaining lot. Receipt inspection of all items was performed by Westinghouse Newington to verify certification documentation, material identification, quantity and visual examination. The scope of work issued to L&S Machine for this purchase order was within the scope of the supplier's qualification and there is no risk to product quality.*
- *For purchase order 4500601734, Westinghouse supplied approved material for the lock cups and special guide plates to L&S Machine. Per the Westinghouse reviewed and approved integrated manufacturing quality plan, no nondestructive examination (NDE) was performed by L&S Machine for material supply or any manufacturing steps. Although the Westinghouse purchase order referenced material dedication, welding, NDE, heat treatment and/or plating, L&S Machine was not responsible for any of these services. The manufacturing operations for the items on the purchase order were followed by Westinghouse Engineering with required oversight and are deemed acceptable as supplied.*
- *For purchase order 4500402277, Westinghouse supplied approved material to L&S Machine for use. The services provided, welding and machining, were within the scope of supply approved by Westinghouse. WPS/PQR documentation was reviewed and approved by Westinghouse Engineering prior to start of work. Although the Supplier Quality Assurance Requirements (SQAR -1030) referenced material dedication, NDE, heat treatment and/or plating, L&S Machine was not responsible for any of these services. Activities performed by L&S Machine for this purchase order are deemed acceptable as supplied.*
- *For purchase order 4500429292, Westinghouse Engineering performed independent design verification for the computational fluid dynamics (CFD) analysis performed by Peerless Manufacturing Company (PMC) to provide reasonable assurance that the outputs produced from PMC's analysis were suitable for use as nuclear safety-related design inputs. The independent verification activities were conducted in accordance Westinghouse procedures, and included the review of PMC's CFD analysis reports, design procedure, and software used in the calculations. The execution of these activities verified acceptability and provides reasonable assurance that the products shipped from PMC are not in an indeterminate status relative to quality standards.*

3) The corrective steps that will be taken to avoid noncompliance:

The corrective action plan for issue 100077746 includes the following:

a. *Conduct a limited scope audit of L&S Machine.*

b. *Implement targeted training for supplier auditors to enhance depth of knowledge and improve the documentation of objective evidence collected during the audit process.*

c. *Complete the extent of condition of the Westinghouse QSL and define additional corrective actions based on the results.*

d. *Formalize a process to ensure that changes or updates to supplier qualifications or restrictions on the Westinghouse QSL are communicated to stakeholders.*

e. *Review and revise the current QSL structure/format to promote a clear understanding of the information.*

f. *Develop and implement targeted training of the nuclear regulatory requirements and standards related to procurement document control and control of purchased items materials services for purchasing personnel.*

g. *Revise L&S Machine's Supplier Quality Assurance Requirements (SQAR-1030) to provide clarity to the scope of work being request, eliminate outdated product references, and issue change notice imposing the new revision of SQAR-1030 for the procurement of reactor fuel assembly parts.*

h. *Review the adequacy of the interim process implemented for quality and technical reviews of safety-related purchase orders prior to placement with suppliers (will remain in effect until a permanent system-based defense is in place).*

i. *System-based defenses will be implemented as follows:*

- *Phase 1 – Requires the safety class to be clearly identified on all new requisitions and purchase orders. This action has already been completed.*
- *Phase 2 – Will prevent purchase orders from being issued when the safety class requires procurement from a QSL supplier and the supplier selected is not on the QSL.*
- *Phase 3 – Will require new quality and technical approvals for any purchase order when any changes are made to the requisition technical and quality requirements, including selection of a new QSL supplier.*

j. *In addition to the system-based defenses, applicable procedures will be revised to clearly define associated roles and responsibilities. Qualifications for all roles in the procurement process will be established, and training for all roles will be implemented and completion monitored.*

4) The date when the corrective action will be completed:

a. *The review of the adequacy of the ongoing interim process implemented for quality and technical reviews of safety-related purchase orders prior to placement with suppliers will be completed by May 29, 2015.*

b. *L&S Machine's Supplier Quality Assurance Requirements (SQAR-1030) will be revised by June 30, 2015.*

c. *The limited scope audit for L&S Machine will be completed by June 30, 2015.*

d. *The process to ensure that changes or updates to supplier qualifications or restrictions on the Westinghouse QSL are communicated to stakeholders will be completed by July 31, 2015.*

e. *The extent of condition of the Westinghouse QSL and definition of additional corrective actions based on the results will be completed by August 31, 2015.*

f. *The targeted training on the nuclear regulatory requirements and standards related to procurement document control and control of purchased items materials services for purchasing personnel will be completed by October 31, 2015.*

g. *CARB review and approval of the new due dates will be accomplished for CAPAL issue 100000472 will be completed by May 31, 2015.*

- *Phase 1 has been completed*
- *Phase 2 will go live by July 31, 2015*
- *Phase 3 will go live by October 31, 2015*
- *All other corrective actions associated with issue 100000472 will be completed by November 30, 2015*
- *The final effectiveness review for issue 100000472 will be completed by April 30, 2016*

h. *The training for supplier auditors to enhance depth of knowledge and improve the documentation of objective evidence collected during the audit process will be completed by November 30, 2015.*

i. *The current QSL/ASL structure will be reviewed and revised by November 30, 2015.*