July 20, 2012

U.S. Nuclear Regulatory Commission,
ATTN: Document Control Desk,
Washington, DC 20555-0001

RE: Reply to Notice of Nonconformance 999014113/2012-201-01 & -02 within NRC Vendor Inspection Report 999001413/2012-201

On April 16-20, 2012, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Fauske & Associates, LLC (FAI) facility in Burr Ridge, IL. The purpose of this limited-scope routine inspection was to assess FAI's compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 "Domestic Licensing of Production and Utilization Facilities."

During this inspection, the NRC inspection team found that the implementation of FAI quality assurance program failed to meet certain NRC requirements contractually imposed by our customer and/or NRC licensees. Specifically, the NRC inspection team determined that FAI failed to review the suitability of the application of commercially calibrated measuring and test equipment for use in activities affecting quality as part of a commercial-grade dedication process. Additionally, FAI's nonconformance procedure was inadequate in that it did not provide a clear connection to a formal corrective action process or a formal 10 CFR Part 21 process. The specific findings and references to the pertinent requirements are identified in the 2 nonconformances delineated below. A written response to each nonconformance in accordance with the instructions specified in the NRC inspection report follows.

Nonconformance 99901413/2012-201-01:

Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "Measures shall be also established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components."

Contrary to the above, as of April 20, 2012, FAI failed to review the suitability of the application of commercially calibrated measuring and test equipment (M&TE) for use in activities affecting quality as part of a commercial-grade dedication process. Specifically, FAI did not conduct a

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technical evaluation to identify additional technical requirements for the specific M&TE being calibrated, did not specify the critical characteristics of acceptance associated with the commercial grade dedication of commercial calibration services, which, once satisfied, would provide reasonable assurance that the M&TE calibrated by the laboratory would adequately perform its intended safety function, and did not review the calibration records as part of receipt inspection to verify that the critical characteristics had been met.

Fauske & Associates, LLC Response:

This nonconformance was issued against FAI because FAI failed to review the suitability of the application of commercially calibrated measuring and test equipment (M&TE) for use in activities affecting quality as part of a commercial-grade dedication process. Initially, FAI did not commercially dedicate the calibration process because at the time of the calibration, the calibration services company FAI used to perform the calibration services was on the Westinghouse QSL without a restriction requiring the dedication of the commercial service; therefore FAI did not need to perform a commercial grade dedication. It was not until the audit that it was realized that Westinghouse had improperly interpreted the NRC requirements and placed the calibration services company on the QSL. The supplier does have a valid A2LA Certificate which reflects accreditation to ANSI/ISO/IEC 17025 with the certificate scope covering the calibration activities being supplied.

Since the issuance of the NRC nonconformance and the creation of Westinghouse CAPS Issue Report #12-111-W001 issued to track and assure corrective actions are taken to address this issue, Fauske & Associates has developed a Commercial Grade Dedication Instruction (CDI) per Westinghouse Procedure WEC 7.2, and the equipment in question was returned to the calibration supplier for re-calibration in accordance with the CDI instructions. The calibration results were verified and with the implementation of the CDI, the equipment was subsequently approved for use in the safety-related testing. It was later determined by WEC Licensing Engineering that this issue was not reportable in accordance with 10CFR Part 21 criteria, based on the re-test results that indicated that there were no differences between original calibration results and those that were obtained after issuance of CDI from FAI to J.H. Metrology.

Since Fauske & Associates, LLC operates under the Westinghouse QMS, this nonconformance against FAI has numerous ramifications within Westinghouse as well. Within Westinghouse, an Apparent Cause Analysis (ACA) was performed by Westinghouse QA personnel to identify the cause within Westinghouse as to why this calibration supplier was on the Westinghouse Qualified Suppliers List (QSL) without the restriction for commercial dedication. It was determined that the primary cause of this was incorrect guidance contained within the Westinghouse Level 2 procedure for how calibration suppliers are qualified and their services subsequently used. As a result of the ACA, the Westinghouse Level 2 procedure for Supplier Qualifications (WEC 7.1) will be revised to correct the instructions provided for control and use of suppliers providing commercial calibration services.

The scheduled completion of all commitments within Westinghouse Issue Report #12-111-W001 is November 15, 2012.

Nonconformance 99901413/2012-201-02:

Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50, states, in part, that "Measures shall be established to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, and nonconformances are promptly identified and corrected." Section 1.0 of FAI's Quality Assurance Program Test and Calibration Procedure FAI-TC 1.0, "Nonconformances," Revision 0, dated May 12, 1994, states, in part, that "The purpose of this procedure is to delineate the system for documenting, controlling, and dispositioning nonconformances associated with materials and components to be used in the performance of nuclear safety-related activities." Section 2.0 of FAI-TC 1.0 states, in part, that "It is FAI policy to implement this procedure for any item or material that is being used for a customer contract, which imposes quality assurance requirements, such as Appendix B to 10 CFR Part 50 or ANSI/ASME NQA-1, "Quality Assurance Requirements for Nuclear Facilities."

Contrary to the above, as of April 20, 2012, the NRC inspection team concluded that FAI's processes fail to establish and implement adequate measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, and nonconformances, would be promptly identified and corrected. Specifically, the NRC inspection team concluded that identified conditions adverse to quality entered into the FAI nonconformance process via FAI-TC 1.0 would not be promptly reviewed, corrected or reported. The NRC inspection team also concluded that there was no clear connection for identified conditions adverse to quality entered into the FAI nonconformance process via the same procedure to be entered into WEC's formal processes (Westinghouse Policy/Procedure WEC 16.2, Westinghouse Corrective Action Process, or WEC 21.0, "Reporting of Defects and Noncompliance,") as contractually agreed upon between FAI and Westinghouse.

Fauske & Associates, LLC Response:

Since the issuance of the NRC nonconformance and the creation of Westinghouse CAPS Issue Report #12-111-W002 issued to track and assure corrective actions are taken to address this issue, Fauske & Associates QA personnel have been given direct access to the Westinghouse CAPs system, thereby providing a more direct link for FAI QA to manage and create FAI CAPs rather than rely on Westinghouse QA personnel for CAPs support. In addition, FAI QA personnel are in the process of receiving detailed CAPs training on the CAPs system. Thus FAI QA personnel will have a full understanding of and enable complete usage of the CAPS system.

A commitment within the CAPs Issue Report that FAI QA personnel are pursuing is that Fauske & Associates Test & Calibration Procedure FAI-TC-1.0 will be revised to: 1) address testing nonconformance issues as well as hardware nonconformance issues, 2) provide a direct tie to the Westinghouse CAPs procedure (WEC 16.2), and 3) provide a direct tie to the Westinghouse 10CFR Part 21 procedure (WEC 21.0).

The commitment also has FAI investigating the development of a new Fauske & Associates Instruction & Guidance Procedure (FAI Level 3 procedure) to address nonconformance and error

reporting on the analytical side of our business portfolio. This procedure would also have a direct tie to the Westinghouse CAPs and 10CFR Part 21 procedures.

The scheduled completion of all commitments within Westinghouse CAPS Issue Report #12-111-W002 is October 4, 2012.

If you need any further information please feel free to contact me at (630)887-5242 or you can email me at berger@fauske.com or Robert Reeves at (630)887-5220 or email at reeves@fauske.com

Sincerely,

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Sincerely,

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