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Our ref: HEM-09-15
Date: February 18, 2009

Subject: ISOCS Validation Information (License No. SNM-00033, Docket No. 070-00036)

Dear Sirs:

During the NRC inspection over the period November 2008 through January 2009, one topic concerned the validation of the In-Situ Objective Counting System (ISOCS) software. Attached to this letter is an explanation of that topic.

If you have any questions concerning this letter or the attached report, please contact Gerald Rood, Hematite Radiation Safety Officer, at 314-810-3382.

Sincerely,

E. Kurt Hackmann
Director, Hematite Decommissioning Project

Attachment: In-Situ Objective Counting System (ISOCS) Software Validation, dated February 13, 2009

cc: J. J. Hayes, NRC/FSME/DWMEP/DURLD
C. Lipa, NRC Region III/DNMS/MCID
B. A. Watson, NRC/FSME/DWMEP/DURLD
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ATTACHMENT

IN-SITU OBJECTIVE COUNTING SYSTEM (ISOCS) SOFTWARE VALIDATION

FEBRUARY 13, 2009

In-Situ Objective Counting System (ISOCS) Software Validation

During the NRC's inspection spanning the period November 2008 through January 2009, one issue was raised by NRC concerning re-loading the ISOCS software onto a replacement laptop computer. The issue involved Validation of the computer code in accordance with the Hematite Decommissioning Project (HDP) QA Procedure, PR-QA-013, "Software Validation." This QA procedure defines Validation as a process at the end of the development process to ensure the computer code works as designed. In common usage, Validation is the process of checking if something satisfies certain criteria. Examples would include checking if a statement is true (validity), if an appliance works as intended, if a computer system is secure, or if computer data are compliant with an open standard. Validation implies one is able to document that a solution or process is correct or is suited for its intended use. In engineering or as part of a quality management system, Validation confirms that the needs of an external customer or user of a product, service, or system are met. HDP performed no computer code development (programming). HDP simply loaded a software code that was previously validated by the vendor (Canberra). Therefore, HDP would not Validate the Canberra software.

The above-mentioned QA procedure further indicates that Verification is outside of the scope of that procedure, and in the event that Verification is required, that will be addressed by other procedure(s). Verification is usually an internal quality process of determining compliance with a regulation, standard, or specification. An easy way of distinguishing the difference between Validation and Verification is that Validation is ensuring "you built the right product" and Verification is ensuring "you built the product right." QA-PR-013 specifies in Section 1.0 "Purpose," last sentence, "If verification of computer software becomes necessary a procedure will be developed to document the requirements of computer verification."

WEC has developed a procedure, HDP-PR-HP-031, ISOCS Operation and Data Verification, for the Verification requirement. This procedure establishes the guidelines for the operation of ISOCS for gamma spectroscopy measurements, including setting up the ISOCS, acquiring data, documenting the results, and verifying the results of operational testing meet defined standards. These measurements were documented as required by the HDP Health Physics Program.

With respect to the ISOCS software which was re-loaded into the replacement laptop computer, after the software was loaded, quality control measurements were made (i.e., the results of measurements of a quality control source were verified to fall within the

range of expected values) to verify proper operation (i.e., the product was built correctly) in accordance with HDP-PR-HP-031, as required by QA-PR-013." These measurements were documented as required by the HDP Health Physics Program.

In summary, WEC purchased the In-Situ Objective Counting System (ISOCS) software with "Validation" from Canberra in accordance with their 10 CFR 50 Appendix B QA program. WEC makes no program changes to the customer supplied software and only inputs information based on configuration/geometry; therefore, Validation under PR-QA-013 was not required; rather, Verification was performed in accordance with QA-PR-HP-031.

It should be noted that the related issue of validation of ISOCS measurements against standards of known activity, also identified during the inspection, is being addressed through the Hematite Corrective Action Process.