

November 11, 2014

Christophe Reullon, Quality Manager
Valinox Nucléaire
5, avenue du Maréchal Leclerc
21500 Montbard, France

SUBJECT: VALINOX NUCLEAIRE RESPONSE TO MULTINATIONAL DESIGN EVALUATION PROGRAM INSPECTION REPORT 99901447/2014-201, AND NOTICE OF NONCONFORMANCE

Dear Mr. Reullon:

Thank you for your October 10, 2014, letter in response to the Notice of Nonconformance (NON) that was discussed in the subject Multinational Design Evaluation Program inspection report (IR).

We have reviewed your letter and supplemental information provided to us and we find that it is generally responsive to the findings described in the NON documented in IR 99901447/2014-201. However, certain aspects of your response need to be addressed in further detail.

The response to NON 99901447/2014-201-01 did not address all issues associated with the control of records as cited in the NON. Specifically, we understand your response to be as follows:

The corrective action regarding archiving appears to indicate that the records currently in Room B will be stored offsite at a dedicated archive supplier and that Room A will be renovated to make it compliant with the requirements of NQA-1, and the remainder of records will be stored in Room A.

In addition, as part of the corrective action, we would expect Valinox to complete a suitable audit of the archival suppliers programs and facility to ensure compliance with the relevant NQA-1 record storage requirements. Can you confirm that our understanding of the proposed actions, including adequate completion of an audit of the archival service supplier will be completed, prior to implementing such actions?

The response to NON 99901447/2014-201-03 did not address all issues associated with the control of special processes as cited in the NON. Specifically, we understand your response to be as follows:

Revisions to the quality system shall be made to update the life sheet, available on the shop floor, of each measurement device to indicate the as found deviation value and an indicator to restrain the use of thermocouple to either the hottest or coldest position in

the heat treatment lots, depending on the sign of as-found deviation. To achieve this, modifications to the thermocouple calibration procedure, the acceptance criteria procedures shall be made, and training of the furnace operators and shop inspectors on this change in process will be conducted.

In addition, as part of this corrective action as discussed during the inspection, we would expect Valinox to complete an extent of condition review of all previous thermal treatment activities to ensure that no previous heat treatments of tube lots were performed at temperatures outside of the technical requirements. Can you confirm that our understanding of the proposed actions, including an extent of condition review of prior heat treatment activities, will be completed as part of the corrective actions? Please include a timeline for the extent of condition review. Can you also provide the staff with a copy of the revised procedures when they are implemented?

The response to NON 99901447/2014-201-04 did not address all issues associated with Audits as cited in the NON. Specifically, we understand your response to be as follows:

The procedure to conduct audits will be modified to implement due dates for the audit reports and a grace period to conduct the audits.

While this response appears appropriate for future audits, it does not address the concern that audit of Process number 106 was not comprehensive as it only covered a portion of the checklist items required. As part of the corrective action, the staff would like to understand what Valinox has done to ensure that Process number 106 has been comprehensively audited. In addition, as discussed during the inspection, the staff expected Valinox, as part of the corrective action to this issue, to review the extent of condition for other Process areas that had been audited to ensure that those audits were timely and comprehensive in nature. Can you confirm that our understanding of the proposed actions, including an extent of condition review of prior process audits, to ensure timeliness and comprehensive evaluation will be completed, as part of the corrective actions?

The staff may review the implementation of your corrective action during a future NRC staff inspection to determine that full compliance has been achieved and will be maintained.

Please contact Greg Galletti via electronic mail at greg.galletti@nrc.gov, if you have any questions or need assistance regarding this matter.

Sincerely,

/RA/ (GGalletti for)

Richard A. Rasmussen, Chief
Electrical Vendor Branch
Division of Construction Inspection
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Office of New Reactors

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The response to NON 99901447/2014-201-04 did not address all issues associated with Audits as cited in the NON. Specifically, we understand your response to be as follows:

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The staff may review the implementation of your corrective action during a future NRC staff inspection to determine that full compliance has been achieved and will be maintained.

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Docket No.: 99901447

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