



Valinox Nucléaire

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

Cc: Richard A. Rasmussen, Chief /RA/Electrical Vendor Inspection Branch
Division of Construction Inspection and Operational Programs
Office of New Reactors

Montbard, October 10, 2014

Subject : Reply to Notices of Non Conformance
Your reference: Docket N° 99901447/2014-201
Valinox Ref. SC112/14 (0)

Cc: Richard A. Rasmussen, Chief /RA/Electrical Vendor Inspection Branch
Division of Construction Inspection and Operational Programs
Office of New Reactors

Dear Sir,

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Valinox Nucléaire (Valinox) facility in Montbard, France, on July 7–11, 2014, and as per the MDEP report, four (4) notices of non conformance have been raised. The purpose of this document is to provide explanations and root causes that led to non conformances. This document provides corrective actions.

First of all, Valinox Nucléaire opened corrective action requests in its Quality Management System to ensure the follow up of the actions. Below is the corresponding table:

Non conformance	10 CFR 50 App. B criterion	NRC reference	VLX reference
A : Archive Rooms	XVII Quality assurance records	9991447/2014-201-01	14/038
B : Inspection records	X Inspections	9991447/2014-201-02	14/039
C : Special Process	IX Special Process	9991447/2014-201-03	14/040
D : Audits	XVIII Audits	9991447/2014-201-04	14/041

Please find below the explanation and proposed corrective actions:

IED 9
NRD

A: Archive Rooms (9991447/2014-201-01)

Explanations

Valinox had modified two rooms in the lower floor of an independent building, where there is no production or permanent activities. These rooms are named A & B and are kept locked anytime; the keys are available in the Quality department. The room named B is dedicated to production records. The room named A is dedicated to the final certification documents (CMTR and order quality records). The rooms are equipped with shelves and archive cardboards. Shelves and archive cardboards are identified.

For fire protection, four extinguishers are in place before the entrance and inside the rooms. There is a manual fire alarm outside the rooms. The security officers are doing security patrol every 4 hours. The room entrance is a checkpoint during this patrol.

For water & flooding prevention, the room A is equipped with lockers. The archive cardboards containing the final certification records are kept above ground, the lockers are not fireproof lockers. When archive documents are taken out for review, it is documented on a logbook.

In Room B, the archive cardboards containing manufacturing records are kept above ground on shelves. In both rooms, the water pipe system has been condemned and drained.

For rodent protection, raticides are installed and replaced every 3 months.

Meanwhile, there is no systematic record of entrance into the room. The lockers are not fireproof.

Corrective action

Valinox has decided & scheduled to set up an archive service with supplier for room B by end of November 2014. The free space will be restored in accordance with NQA1 (2012), Part III, subparts 3.1-17.2

→ **Due Date : June 31st 2015.**

B: Inspection Records (9991447/2014-201-02)

Case 1): Non conformance detected during receiving inspection.

Explanations

The applicable procedure PAM 100 Rev 4 and corresponding annexes 2 refer to PAM 132 (Supplier Claims) in case of findings. Release by derogation shall be handled as per PAM 130 (Non conformance management).

As per PAM 100, the condition of failure to comply are recorded on the receiving inspection report, the receiving inspector shall ask the supplier to open a non conformance report in the supplier quality system. In parallel, a remarks or claim file is opened by Valinox and forwarded to supplier, this file insure traceability to the supplier's NCR.

The material subject covered by nonconformance report shall not be released before evidence of supplier NCR Closing and new conformity assessment of the products as per PAM 100.

In the case of the out of tolerance surface imperfection, Valinox issued a remark file (SO044/14) to the supplier. The supplier opened a NCR file NCR021-14(A). Products have been repaired and conformity has been demonstrated. Valinox decided to release one lot by derogation of the affected products to evaluate the impact of roughness on first operation. This has not been traced in a Valinox non conformance report. The receiving inspection process was still pending and thus the affected lot was not allocated to an order.

Corrective action

The PAM 100 shall describe that the use of material that has not completed the full receiving inspection process shall be accepted by derogation in a non conformance report.

→ **Due date November, 30th. 2014**

Case 2): Missing independent check signature on heat treatment records.

Explanations

The document that records the loading conditions (cleanliness and bundles positions) before treatment must be checked by QC controller. During the week end, there is no QC inspector; the document has not been signed by QC before loading. The loading conditions have been reviewed by the team leader to authorize the heat treatment cycle to start. The team leader is qualified to evaluate the above criteria but not authorized to sign on behalf of QC.

The QC can check the load after treatment. In addition, the QC reviewed and validated the heat treatment cycles curves and final condition of bundles.

In addition, the results of heat treatment are validated on the products by metallurgical destructive tests on a lot basis as per customer's requirements.

Corrective action

The Heat treatment datasheet shall provide Quality check by independent authorized people, QC validation shall be maintained on the document either to evaluate the initial conditions or to validate afterward that independent check have been done by authorized people.

The document shall be updated to reflect this process.

→ Due date November 30th 2014

C: Special process (9991447/2014-201-03)

Explanations

The heat treatment conformity is established according to quality management system and customer's purchase specifications.

As per our quality management system, the thermocouple used to monitor the product temperature and control the furnaces are subject to calibration according to PAM 110. The conformity statement of thermocouple is established as per acceptance criteria defined in ETA106.

In a same way, the conformity statement of heat treatment cycles is established by review of , both time and temperatures records obtained using calibrated devices as per the applicable procedures.

In addition, the results of heat treatment are validated on the products by metallurgical destructive tests on a lot basis as per customer's requirements.

The quality system is regularly reviewed and accepted by clients, certification bodies during survey & audits.

Corrective action

In order to take into account the as-found calibration data for the thermocouples affected to the products's temperature surveillance, we move forward our quality system.

We will update the life sheet, available on shop floor, of each measurement device to indicate the as-found deviation value and an indicator to restrain the use of thermocouple on the hottest or coldest position in the heat treatment lots, depending on the sign of as-found deviation.

This will provide a safety margin to the requirement corresponding to the as-found deviation data.

For that we have to modify the thermocouple calibration procedure, the acceptance criteria procedures, train the furnace operators and shop inspectors to put in place this modification. This should be completed by end of 2014.

→ Due date December 30th 2014

D: Audits (9991447/2014-201-04)

Explanations

The internal audit 106 has been postponed several times and realized in December 2013. The audit report was released later after the audit, in June 2014.

However, several external audits performed by Customers (Babcock & Wilcox Canada, Doosan, Mangiarotti, DFHM, ie. 4 times between 2012 and 2014) or Third parties (ASME - Sept 2013 / AFAQ – March 2014) have reviewed the activities of process 106. It was found conform to the requirements.

There is no due date or grace period specified in our system and procedures.

Corrective action

The procedure will be modified to implement due dates for the audit reports and a grace period to conduct the audits. Failure to comply with these new requirements shall be documented in a nonconformance report.

→ Due date November 1st, 2014

REULLON CHRISTOPHE
QUALITY MANAGER
VALINOX NUCLEAIRE

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