

# MDEP

# Technical Report

# TR-VICWG-04

Related to: Vendor Inspection Cooperation Working Group

## Technical Report:

## Assessment of Multinational Vendor Inspection of

## Valinox Nuclear

### Participation

Regulators involved in the MDEP working group discussions:	Canada, China, Finland, France, India, Japan, Republic of Korea, Russian Federation, South Africa, Sweden, UAE, UK, and US
Regulators which support the technical report	All
Regulators with no objection	N/A
Regulators which disagree	N/A
Compatible with existing IAEA related documents	Yes

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## 1. Overview

From July 7-11, 2014, the NRC led a team of inspectors representing regulators from France, the United Kingdom, and the United States in performing the first Multinational Design Evaluation Program (MDEP) multinational inspection at Valinox Nuclear in Montbard, France. Valinox Nuclear's primary product line is steam generator tubes for the nuclear industry. The purpose of the inspection was to assess Valinox's compliance with the quality assurance/quality control (QA/QM) criteria described in the Multinational Design Evaluation Program (MDEP) Vendor Inspection Cooperation Working Group (VICWG) Technical Report, TR-VICWG-03, "Common QA/QM Criteria for Multinational Vendor Inspection," Revision 1, dated January 20, 2014 (Reference 1), and MDEP Protocol, VICWG-01, "Witnessed, Joint, and Multinational Vendor Inspection Protocol," Revision 2, dated March 20, 2014 (Reference 2), respectively. The inspection also offered the inspectors an opportunity to pilot the VICWG draft common position document to gain valuable insights into the effectiveness of application of the common QA/QM criteria to vendor inspections performed by a multinational inspection team.

During this inspection, the inspection team evaluated implementation of Valinox's quality assurance (QA) program with respect to the 15 specific criteria described in Reference 1. These criteria include: 1. Quality management system; 2. Grading; 3. Documentation of the quality management system; 4. Control of documents and records; 5. Responsibility and Leadership; 6. Human resources; 7. Process Implementation; 8. Control of planning and implementation changes; 9. Purchasing (including aspects of CSFI); 10. Control of implementation including Control of special processes; 11. Monitoring and measurement of product and service; 12. Assessment; 13. Non-conformances; 14. Corrective and preventive actions; and 15. Safety culture.

By letter dated 26 August 2014 (Reference 3), the NRC issued a vendor inspection report to Valinox Nuclear, which documented four findings (Non-conformances) in the areas of Record Control, Control of Special Processes (Heat Treatment), Corrective Actions, and Auditing. By letter dated 10 October 2014 (Reference 4), Valinox responded to the findings including the corrective actions taken. By letter dated 11 November 2014 (Reference 5), NRC requested

Valinox to provide additional information regarding the corrective actions. By letter dated 12 May 2015 (Reference 6), Valinox provided the additional information requested. By letter dated 4 August 2015 (Reference 7), NRC informed Valinox that it has completed its review and the Notice of Nonconformance and their follow-up request for additional information have been addressed.

## **2. Inspection Team**

4 inspectors from the U.S. Nuclear Regulatory Commission (NRC)  
2 inspectors from the U.K. Office of Nuclear Regulation (ONR)  
2 inspectors from France, Nuclear Safety Authority (ASN)  
The Nuclear Energy Agency (NEA) MDEP Technical Secretariat

## **3. Inspection Scope and Findings**

### **3.1. Quality Management System and Organization (MDEP QA/QM Criteria 1, 2, and 5)**

The inspection team concluded that Valinox applied appropriate organizational controls over activities affecting the quality of steam generator tubing. The inspection team concluded that the implementation of Valinox's quality management system was consistent with the MDEP common QA/QM standard, including Criterion I "Organization," and Criterion II "Quality Assurance Program," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

### **3.2. Control of Documents and Records (MDEP QA/QM Criteria 3 and 4)**

The inspection team identified *one nonconformance of Valinox's failure to implement the requirements of Criterion XVII, "Records," of Appendix B to 10 CFR Part 50. The inspectors cited Nonconformance 99901447/2014-201-01 for failure to provide an adequate storage location for safety-related records related to steam generator tubing.* With the exception of the nonconformance noted above, the inspection team concluded that Valinox was consistent with the regulatory requirements of the inspection criteria.

### **3.3. Training and Qualification of Personnel (MDEP QA/QM Criterion 6)**

The inspection team concluded that the implementation of Valinox's training and qualification program was consistent with the regulatory requirements of the inspection criteria. No findings of significance were identified.

3.4. Process Implementation & Control of Planning & Implementation Changes (MDEP QA/QM Criteria 7 and 8)

The inspection team concluded that the implementation of Valinox's controls over process implementation and planning and implementation changes related to the fabrication of steam generator tubing was consistent with the regulatory requirements of the inspection criteria. No findings of significance were identified.

3.5. Purchasing (MDEP QA/QM Criterion 9)

The inspection team identified *one example of a nonconformance for Valinox's failure to adequately implement the requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. The inspectors cited an example of Nonconformance 99901447/2014-201-02, for failure to identify and record the disposition of out of tolerance surface imperfections on received raw billets on the Receiving Inspection Report.* With the exception of the nonconformance noted above, the inspection team concluded that the implementation of Valinox's receipt inspection program was consistent with the regulatory requirements of the inspection criteria.

3.6. Control of Implementation Including Control of Special Processes (MDEP QA/QM Criterion 10)

The inspection team identified *one nonconformance for Valinox's failure to implement the requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50. The inspectors cited Nonconformance 99901447/2014-201-03 for failure to ensure thermal heat treatment temperature parameters accounted for measurement device uncertainties and remained within the specified technical and order requirements.* With the exception of the nonconformance noted above, the inspection team concluded that the implementation of the Valinox's programs for the control of fabrication and special processes was consistent with the regulatory requirements of the inspection criteria.

3.7. Monitoring and Measurement of Product and Service (MDEP QA/QM Criterion 11)

The inspection team concluded that the implementation of Valinox's program controls over M&TE use for calibration and testing was consistent with the regulatory requirements of the inspection criteria. No findings of significance were identified.

3.8. Assessment (MDEP QA/QM Criterion 12)

The inspection team identified one nonconformance for Valinox's failure to implement the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The inspectors cited Nonconformance 99901447/2014-201-04 for failure to perform an internal audit in a timely manner and failure to adequately complete all audit activities. With the exception of the nonconformance noted above, the inspection team concluded that the implementation of the Valinox's programs associated with internal audits was consistent with the regulatory requirements of the inspection criteria.

3.9. Non-conformances (MDEP QA/QM Criterion 13)

The inspection team concluded that the implementation of Valinox's program for the control of non-conformances was consistent with the regulatory requirements of the inspection criteria. No findings of significance were identified.

3.10. Corrective and Preventive Actions (MDEP QA/QM Criterion 14)

The inspection team identified *one example of a nonconformance for Valinox's failure to adequately implement the requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. The inspectors cited an example of Nonconformance 99901447/2014-201-02 for failure to adequately implement inspection activities associated with corrective actions for an issue regarding independent verification of critical heat treatment parameters.* With the exception of the nonconformance noted above, the inspection team concluded that the implementation of the Valinox's programs associated with internal audits was consistent with the regulatory requirements of the inspection criteria.

3.11. Safety Culture (MDEP QA/QM Criterion 15)

The inspection team generally observed a positive safety culture at Valinox. The inspectors attended various internal Valinox meetings, and noted Valinox staff's openness to raising and addressing issues related to safety and quality. The inspectors noted that

Valinox management made provisions to support individuals and teams in carrying out their tasks safely and successfully, taking into account the interactions between individuals, technology, and organizations.

#### **4. VICWG Assessment of the Multinational Inspection Effort**

##### 4.1. Positives

The experience and multinational perspectives of the team added value by providing a broader regulatory perspective. Issues were developed through discussion with the team resulting in a strong regulatory perspective and basis for significance.

The team was able to focus within the bounds of the Multinational Criteria. Additionally, as the Multinational Criteria are based on the ASME NQA-1, all of the issues identified by the team were easily dispositioned in the US NRC inspection report. This may not always be the case when the leading country regulatory framework differs from the ASME NQA-1. But on the pilot the multinational criteria was a good fit with the issues and with the US NRC requirements.

##### 4.2. Challenges

Challenges exist with scheduling and conducting multinational inspections. This inspection was an example of a vendor that supports the French market, but would not be subject to direct inspection by ASN. In this example it is not likely that ASN would lead an inspection of this vendor. Multinational inspections require a leader with a framework to administer the inspection. However, the French inspectors added value to the team and gained insights that made the inspection worthwhile.

##### 4.3. Going Forward

Participants need to continue to actively participate with the inspection planning phase to assure assignments match with the skills of the inspectors. This is always important to inspection planning, but in the case of a multinational inspection the team leader will likely not be familiar with the expertise of the team members.

Evaluate grouping of inspection areas and inspectors. For the Valinox inspection, it may have been useful to assign one additional resource to the third sub-team. This team had

Criteria 10. Control of implementation including Control of special processes, and 11. Monitoring and measurement of product and service. In the case of the Valinox scope of supply this was a large area to inspect. However, this could shift based on the scope of supply.

Consider inspection leadership by the host country to address cultural issues.

Build flexibility in the common criteria scope to examine areas of international concern.

Consider pre-briefing for all team members prior to participation to clarify MDEP objectives and criteria.

Consider reduction in team size when appropriate, reducing sample size & strategic level engagement.

## References

1. Technical Report, TR-VICWG-03, "Common QA/QM Criteria for Multinational Vendor Inspection," Revision 1, dated January 20, 2014
2. MDEP Protocol, VICWG-01, "Witnessed, Joint, and Multinational Vendor Inspection Protocol," Revision 2, dated March 20, 2014
3. NRC letter dated 26 August 2014, MULTINATIONAL DESIGN EVALUATION PROGRAM INSPECTION OF VALINOX NUCLEAIRE REPORT NO. 99901447/2014-201 AND NOTICE OF NONCONFORMANCE (NRC Agencywide Documents Access and Management System (ADAMS) No: ML14217A535)
4. Valinox letter dated 10 October 2014, Reply to Notices of Non Conformance NRC reference: Docket N' 99901447/2014-201, Valinox Ref. SC112/14 (0) [NRC ADAMS No: ML14295A353]
5. NRC letter dated 11 November 2014, VALINOX NUCLEAIRE RESPONSE TO MULTINATIONAL DESIGN EVALUATION PROGRAM INSPECTION REPORT 99901447/2014-201, AND NOTICE OF NONCONFORMANCE (NRC ADAMS No: ML14314A354)
6. Valinox letter dated 12 may 2015, Reply to Notices of Non Conformance NRC reference: Docket No 99901447/2014-201 Valinox Ref. SC087/15 (0) [NRC ADAMS No: ML15170A103]

7. NRC letter dated 04 August 2015, VALINOX NUCLÉAIRE RESPONSE TO MULTINATIONAL DESIGN EVALUATION PROGRAM INSPECTION REPORT 99901447/2014-201, AND NOTICE OF NONCONFORMANCE (NRC ADAMS No: ML15132A302)