

Sedegliano, 25 October 2010

To the attention of: U.S. Nuclear Regulatory Commission Document Control Desk Washington, DC 20555-0001

Copy to:
Mr. Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Subject:

Reply to a Notice of Nonconformance

Vs. rif.:

US NRC letter dated September 29, 2010

NRC Inspection Report n°99901393/2010-201 and Notice of Nonconformance

Ns. rif.:

DV/25-10-2010-001

## Dear Sir/Madam,

please note here follow the replies to your Inspection Report n°99901393/2010-201 and Notice of Nonconformance received with letter dated September 29, 2010.

#### Reply to Notice of Nonconformance n°99901393/2010-201-01

# Identification of the deficiency

Mangiarotti Nuclear NQAM, Section 14.2.4, "Audit Performance," states, in part, that the lead auditor shall conduct the audit on the basis of the audit plan and checklist.

Contrary to the above, the review of the Mangiarotti Nuclear external supplier audits performed at three Italian forging suppliers identified that the audit report did not include or reference the audit checklist that was to be used during the review of the program implementation. Instead of using the audit checklist required by the NQAM, the lead auditor used a copy of the supplier's quality assurance manual as the checklist and recorded audit annotations and findings directly on the supplier's quality assurance manual in lieu of using the formal audit checklist. As a result, a formal quality record of the supplier audit was not developed in accordance with the written requirements of the Mangiarotti Nuclear NQAM.

This issue is identified as Nonconformance 99901393/2010-201-01.

## Cause of the deficiency

During ASME nuclear survey in October 2009, one of the ASME survey team members suggested that the auditor use the supplier's QA manual in place of a check list when performing and documenting information during external supplier audits.

This suggestion has been implemented without including this possibility into the program or relevant procedure has the used manual was considered a check list.



## Action to correct or prevent recurrence

A corrective action n°RAC064 has been opened on August 30, 2010 consisting in the following activities:

- Revision of procedure PGE.08, managing the auditing activities, to indicate that use of the check list is only allowed (activity already performed);
- Training of the auditors (activity already performed)
- Re-auditing campaign of five (n°5) main suppliers including those whose report was reviewed during NRC audit:
  - > Audit to Forgiatura Morandini performed from September 30 to October 1, 2010
  - Audit to Forgiatura A. Vienna performed from October 11 to 13, 2010 (performed at the presence of a Westinghouse E.C. observer)
  - Audit to Forge Monchieri performed from October 19 to 21, 2010

#### Expected date for the conclusion of the action

Activities related to NRC nonconformance are completed.

The two (n°2) audits still to be performed to complete RAC064 are scheduled before November 30, 2010:

- Audit to Sandvik requested for week 46 (November 15 to 19, 2010): waiting for confirmation.
- > Audit to Voest Alpine to be scheduled before November 30, 2010

## Reply to Notice of Nonconformance n°99901393/2010-201-02

## Identification of the deficiency

Mangiarotti procedure PGE.06, "Calibration Manual," Revision 1, dated January 20, 2010, states, in part, that each thermometer shall be calibrated by comparison with a master gauge thermometer, taking at least two significant readings in the field of use.

Contrary to the above, Mangiarotti's measuring and test equipment calibration practices necessary to ensure that instruments are properly calibrated to maintain accuracy within necessary limits did not meet regulatory requirements. Specifically, Mangiarotti failed to adequately calibrate a contact pyrometer over the entire working range of the instrument or the actual operational temperature range used during the welding fabrication. This issue is identified as Nonconformance 99901393/2010-201-02.

## Cause of the deficiency

The verification instructions given by PGE.06 were considering only two readings in the field of use not identifying the limits required by Criterion XII of 10CFR50 App.B. Due to this the thermometers were verified with two readings into the common range of use (pre-heating and interpass temperatures) without considering the possibility they could be used in a larger range of temperatures.

- Internal analysis identify two main causes for this:
  - · Not complete understanding of the applicable requirements;
  - Limited safety approach on fixing verification/calibration requirements.

#### Action to correct or prevent recurrence

Action to correct and prevent recurrence of above mentioned deficiency has been included in the already opened corrective action n°RAC055 (opened on July 22, 2010) and consists of the following activities:

- Revision of procedure PGE.06, managing the equipment calibration, to indicate the following:
  - > placing of new calibration stickers over old ones is not allowed (activity already performed);
  - > calibration is performed at the usable limits of the equipment and these are indicated into a new calibration label posted in the equipment (activity already performed).
- Re-check of all thermometers in accordance to the new PGE.06 instructions (activity already performed).

Another corrective action n°RAC056 has been opened regarding attention to details in order to emphasize the need for a more attention on doing things and encourage a proactive approach by all the employees.

### Expected date for the conclusion of the action

Activities related to NRC nonconformance, as corrective actions RAC055 and RAC056, are completed.



#### Reply to Notice of Nonconformance n°99901393/2010-201-03

#### Identification of the deficiency

Mangiarotti QAM, Section 4.16, "Corrective Action," states, in part, that Mangiarotti has to promptly identify conditions adverse to quality in order to correct them and determine causes for any significant conditions in order to preclude their recurrence, with appropriate and documented corrective actions.

Mangiarotti procedure PGE.18, "Corrective and Preventive Actions" Revision 0, dated July 9, 2009, states, in part, that conditions adverse to quality should be promptly documented on a corrective action request form.

Contrary to the above, in two instances, Mangiarotti failed to promptly enter conditions adverse to quality into its corrective action program. Specifically: (1) Mangiarotti failed to initiate a corrective action request resulting from a self-identified instance of the use of improper material for temporary welding supports and; (2) Mangiarotti failed to promptly initiate a corrective action request related to the identification of an inadequate quality plan which did not contained all desired surveillance inspection and hold points, developed by one of it's subsuppliers.

This issue is identified as Nonconformance 99901393/2010-201-03.

## Cause of the deficiency

Instance (1) has been caused by an under estimation of the misinterpreting problem.

The non conformance was induced by the use of a "dual grade" information in a WPS and a corrective action was not opened due to the following considerations:

- The use of dual grade material was (even now) uncommon;
- The WPS indicates each type of allowed materials.

Instance (2) has been caused by the fact that big efforts has been immediately put in place to recover the condition before open a formal corrective action process and this was recognized later.

## Action to correct or prevent recurrence

Corrective action n°RAC056 has been opened regarding attention to details in order to emphasize the need for a more attention on doing things and encourage a proactive approach by all the employees.

For instance (1) in particular a training to personnel dedicated to the preparation of welding documents has been made to prevent use of "dual grade" or similar specific terms/definition that could be misinterpreted and induce errors (activity already performed).

For instance (2) in particular a managing plan has been prepared including hiring of a new quality engineer that will be dedicated to the corrective and preventive action program (already hired with starting date expected for November 2, 2010).

### Expected date for the conclusion of the action

Corrective action RAC056 is completed.

Hiring of new quality engineer is already made with starting date expected for November 2, 2010.

Hoping to have been exhaustive on replying to the notified nonconformance we will wait your conclusions and in the mean time we will keep you informed about progress of still open recovery activities.

Best regards angiarotti S.p.A.

(Vanin Davide - Managing Director)