



To: U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attn: Document Control Desk

c.c.: Chief,  
Construction Mechanical Vendor Branch  
Division of Construction Inspection  
and Operational Programs  
Office of New Reactors

**Subject: Reply to a Notice of Nonconformance**

Your ref.: NRC letter dated December 7, 2012  
NRC Inspection Report No.99901416/2012-201 and Notice of Nonconformance  
Our ref.: GML-20-12-2012-001

Monfalcone, December 20th, 2012.

Dear Sirs,

Mangiarotti S.p.a. acknowledges receipt of NRC Inspection Report No. 99901416/2012-201 and associated Notice of Nonconformance No. 99901416/2012-201-01.

Mangiarotti S.p.a. appreciates the time and effort expended by the NRC in conducting this inspection and takes very seriously the notices of nonconformance provided for our response and action.

**Identification of the deficiency**

Nonconformance 99901416/2012-201-01 is divided into two parts (henceforth mentioned as 1. and 2.). For each of those details are reported as follows:

1. *Mangiarotti placed its international commercial calibration suppliers on its safety-related qualified vendors list based on the accreditation provided through ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," by the American Association for Laboratory Accreditation or another domestic accrediting body. ISO/IEC 17025 accreditation shall not be used as the sole basis for qualifying safety-related calibration services. As stated in Section L.8.h of NRC's "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition – Quality Assurance," dated March 2007, NRC's recognition of the International Laboratory Accreditation Cooperation accreditation process is only limited to U.S. domestic calibration service suppliers, not to international calibration suppliers.*

This part of the Nonconformance is addressed in Mangiarotti CAR 318, already mentioned in NRC Inspection Report No.99901416/2012-201.

2. *Mangiarotti did not document the objective evidence necessary to confirm that the relevant quality criteria of external audits performed. This part of the nonconformance is addressed in Mangiarotti CAR 336, already mentioned in NRC Inspection Report No.99901416/2012-201.*

*IED9  
NRO*



### Reason for the non compliance

1. This part of the Nonconformance has been originated by the interpretation of the NRC REGULATORY GUIDE 1.28 paragraph C.2.b (external audits).

Mangiarotti previously interpreted that calibration laboratories certified in accordance with ISO-17025:2005 by an organization recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) may be used as suppliers of calibration services without survey or audit providing that the accreditation is in accordance to ANSI/ISO/IEC 17025:2005 (General Requirements for the Competence of Testing and Calibration Laboratories).

Thanks to the clarification received by NRC team during the inspection, it was definitely clarified that for non-US based calibration service suppliers it is not possible to use an ILAC accreditation as a substitute for direct auditing of the supplier to ensure adequacy of implementation of the program and additional specific requirements identified in the PO. This condition is valid until NRC will complete the recognition process of ILAC also for non-domestic calibration service provider.

2. This part of the nonconformance has been originated by the lead auditor habit of sometimes, for his convenience, writing down some paragraphs or taking notes on additional sheets of paper included in the final audit report. This means that points were properly checked, but actually they are not linked to the point on the checklist and it may take some time to trace back the link, or in some cases it may be difficult to reconstruct the audit history especially after prolonged periods or unavailability of the Lead Auditor.

### Corrective steps that have been taken and results achieved

1. CARNo.318 was opened to address the issue.

We identified one major and two minor suppliers of calibration services linked to safety related nuclear activities under NRC jurisdiction. We already positively audited the major one and scheduled the audits for the remaining two, to take place before any new orders

2. CARNo.336 was opened to address this issue.

Mangiarotti conducted an indoctrination to all MG Lead Auditors to reinforce that the Audit Check List shall be properly filled-in in all its parts. We have positively reviewed the evidences of subsequent audits to check that this prescription is actually respected.

### Corrective steps to avoid further noncompliances:

1. In the next revisions of Mangiarotti Management Procedure PGE.03 "suppliers selection and assessment", specific prescription will be added addressing that non US based calibration service suppliers shall be qualified by direct audit unless or until the NRC permits otherwise.

2. The Audit Check List will be revised in order to ease the template to address the proper collections of all the evidences.

### Expected date for the conclusion of the action

As stated above, for each of the two points of the nonconformance, actions have already been started and we will complete them by the end of March 2013.

### Conclusion

Mangiarotti S.p.a. believes this response provides sufficient information regarding corrective actions to resolve the nonconformance.

However, I stands ready to provide any additional information or clarifications necessary to satisfy any NRC's further requests of clarification.

Yours truly,

Gian Marco Lupi  
Quality Manager Mangiarotti S.p.a.

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MANGIAROTTI'S REF JOB N°.

**TRASMISSIONE DOCUMENTI  
DOCUMENTS TRANSMITTAL**

DATA  
DATE **20/12/2012**

Doc. N. **0001**

PAG. **1 of 1**

Attn. To: U.S. Nuclear Regulatory Commission

Document Control Desk

Washington DC 20555-0001 - USA

Copy To: Chief, Construction Mechanical Vendor Branch, Division of  
Construction Inspection and Operational Programs Office of  
New Reactors.

**IN ALLEGATO VI INVIAMO I SEGUENTI DOCUMENTI:**

**HEREWITH ATTACHED WE TRANSMIT YOU THE FOLLOWING DOCUMENTS:**

POS.	SCOPO SCOPE				IDENTIFICAZIONE DOCUMENTO DOCUMENT IDENTIFICATION	DOC. REV. DOC. REV.	DESCRIZIONE DESCRIPTION	Q.TÀ DOC. TRASMESSI Q.TY DOC. TRANSMITTED			
	APPROVAZIONE APPROVAL	INFORMAZIONE INFORMATION	FINALE FINAL					ORIGINAL	HARDCOPY	EMAIL (ELECTRONIC FILE)	CD (ELECTRONIC FILE)
1	X				GML-20-12-2012-001	00	Reply to a Notice of Nonconformance	X			
2	X				GML-20-12-2012-001	00	Reply to a Notice of Nonconformance - copy		X		
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**NOTE:**

Please send a scanned copy of this TDO duly signed to:

[zanelli.veronica@mangiarotti.it](mailto:zanelli.veronica@mangiarotti.it) or [lupi.gianmarco@mangiarotti.it](mailto:lupi.gianmarco@mangiarotti.it)

Firma  
Sign. :

**Mangiarotti S.p.A.**  
mangiarotti spa  
Quality Assurance Engineer  
Ing. Veronica Zanelli

20/12/12

Vi preghiamo di restituire una copia della presente controfirmata per ricevuta. - Please return a copy of this TDO duly signed.

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