

Katanic, Janine

From: Lazaro Casanueva <LazaroC@Scioninstruments.com>
Sent: Thursday, March 22, 2018 12:17 PM
To: Katanic, Janine
Subject: [External_Sender] RE: response to NRC Notice of Violation
Attachments: NRC - Reply to a Notice of Violation - Dated 02-09-2018.pdf

Follow Up Flag: Follow up
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Dear Janine:

Unfortunately the answer could not be sent before, Mr. Cruz-Aedo was out of the office the last two weeks. Yesterday he instructed to ship it via FedEx Express overnight to a Document Control Desk and one copy to the Arlington Office. Please see copy attached.

Best Regards,



Lazaro Casanueva
Operations Manager

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From: Katanic, Janine [mailto:Janine.Katanic@nrc.gov]
Sent: Wednesday, March 21, 2018 9:21 AM
To: Lazaro Casanueva
Subject: response to NRC Notice of Violation
Importance: High

Lazaro,

The NRC Notice of Violation was issued on February 9, 2018, and Techcomp had 30 days to respond in writing. Has a response been sent to the NRC? If so, when was it sent and please provide a copy to me. If a response has not been sent, it is imperative that you send a written response promptly.

Janine

Janine F. Katanic, PhD, CHP
Senior Health Physicist
US Nuclear Regulatory Commission
Region IV
Division of Nuclear Materials Safety
office: 817-200-1151
email: Janine.Katanic@nrc.gov



March 2nd, 2018

RECEIVED

US Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

MAR 22 2018

DNMS

RE: Reply to a Notice of Violation Dated February 9th, 2018
Docket No. 030-39024
License No. 42-35093-01E
NRC Inspection Report 030-39024/2017-001

To Whom It May Concern:

This letter is in response to the reference NRC Inspection Report No. 030-39024/2017-001, dated November 16, 2017 at our facility located at: 3019 Alvin Devane Blvd., Suite 120, Austin Texas 78741 and closed by a final telephone exit briefing on February 6, 2018.

The referenced letter identified two (2) Severity Level IV violations of NRC requirements. The failure, first on requirement: A-) 10 CRF 32.32 (c)(4)(i), to file a report with NRC for distributions of exempt devices for the calendar year 2016 and second on requirement: B-) 10 CRF 32.32(b)(1)(iv) regarding the labels on device and point of sale package containing instructions and precautions necessary to assure safe installation, operating and servicing of the device.

Each of these Violations are addressed and escalated and as requested per the NRC in the referenced letter. The following is Techcomp response:

1- The Reason for the Violation:

- A- The NRC license was transferred from Bruker to Scion in 2015 and the transition was managed for the Scion Instrument Europe, Research and Development Department located in U.K, out of the Techcomp USA jurisdiction, based in Austin. During the process, the distribution and manufacturing location were located at the office in Fremont, CA. The assigned RSO until the decommissioning process on December 2016 and in charge on decommissioning of the CA location on 2017, failure to file the annual report for the calendar year 2016.

- B- In the process of transferring the manufacturing location to the Scion factory in The Netherlands, the system maintained the same configuration of the labels before we proposed the Amendment to change the distribution locations to Austin and manufacture to the Netherlands. As a consequence, the ECDs transferred to the factory from the office in California and the new ones manufactured in the new location, were erroneously labeled.

2- The corrective steps that have been taken and the results achieved:

- A- At the time the inspection process was open, the R&D management has been informed of a possible violation do to failure to file the Distribution Report for the calendar year 2016.

The production and distribution inventory information for the year 2016 was recovered and an Excel sheet and submitted to the request of the NRC inspector.

All the information was validated in the Epicor system, which controls inventory, shipping and billing to the Scion End Users.

- B- The Manufacturing Management at the Netherlands factory was informed of the possibility that ECDs were erroneously labeled.

A physical proof of the labels and of the configuration in the Build of Materials (BOM) system were requested for the manufacture of the ECD's.

A new labeling configuration on BOM was requested, bearing in mind that the factory will also provide sufficient labels to be sent to the distributors and final customers.

3- The date when full compliance will be achieved:

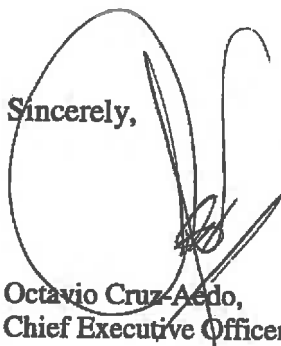
- A- Techcomp achieved full compliance by the date of this letter and we are willing to accept any further action per NRC instructions. Our commitment to report the units distributed or transferred during the calendar year will be set in the fiscal year closing process as a task to be accomplished. As a result the report for calendar year 2017 was submitted on January 18, 2018.

- B- Techcomp achieved full compliance on February 22nd, 2018, when the RSO from the Netherlands factory confirmed the implementation of changes on the BOM (Build of Material) process, to the components of ECD's.

Techcomp is serious about addressing the issues identified in the NRC inspection report and improving our program as a distribution location to our License. We also appreciate the thoroughness and professionalism demonstrated by the NRC inspector during the visit.

If you have any questions please contact Mr. Lazaro Casanueva our RSO at 512-215-8335 Ext 8004 or email him at lazaro.casanueva@techcomp-am.com.

Sincerely,



Octavio Cruz-Aedo,
Chief Executive Officer

CC. Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011