

Weaver, Deborah

From: Lazaro Casanueva <LazaroC@Scioninstruments.com>
Sent: Wednesday, March 07, 2018 10:53 AM
To: Valentin-Rodriguez, Celimar
Cc: octavio.cruzaedo; Herrera, Tomas; Lowman, Donald
Subject: [External_Sender] RE: NRC Request for Additional Information, Techcomp USA Inc., DBA Scion Instruments Request dated November 21, 2017
Attachments: NRC Letter 0302018_signed.pdf

Good Morning Celimar:

Please, see attached copy of the original letter dated 03/02/2018 on response of you e mail sent to you via FedEx TRK # 4166 9916 8321.

Do not hesitate to contact me with any questions.

Best Regards,



Lazaro Casanueva
Operations Manager
& RSO

Office: (512) 215-8335 X 8004

V-fax: (512) 368-4488

Cell: (305) 610-2656

E-Mail: Lazaro.Casanueva@techcomp-am.com / www.techcomp-eu.com

!!! We have Moved. !!! Please, update your recods with “Our New Address “:

***4801 Southwest Parkway
Building TWO, Suite 125
Austin, TX 78735.***

Please consider the environment before printing this e-mail

Disclaimer

The information contained in this e-mail is confidential or may otherwise be legally privileged. It is intended for the named recipient only. If you have received it in error, please notify us immediately by reply or by calling the telephone number above and delete this message and all its attachments. Please note that any unauthorized review, copying, disclosing or otherwise making use of the information is strictly prohibited. Thank you.

From: Valentin-Rodriguez, Celimar [mailto:Celimar.Valentin-Rodriguez@nrc.gov]
Sent: Thursday, February 8, 2018 1:23 PM
To: Lazaro Casanueva
Cc: octavio.cruzaedo; Herrera, Tomas; Lowman, Donald
Subject: NRC Request for Additional Information, Techcomp USA Inc., DBA Scion Instruments Request dated November 21, 2017

Good Afternoon Mr. Casanueva,

We have reviewed your amendment request dated November 21, 2017 and found we need more information to complete our review. Please provide the following information.

1. Verify that previous commitments made by Techcomp USA Inc., DBA Scion Instruments in Registration Certificate NR-1385-D-101-E have not changed.
2. Confirm that the new Austin location will follow the procedures outlined in Techcomp USA Inc., DBA Scion Instruments' QA/QC program.

As a reminder, and as requested in Mr. Lowman's email dated February 5, 2018, please provide a copy of your Texas possession license once it has been amended to include the new address.

Please submit the requested information within 30 days of the date of this email. The information should be submitted in an official company letter as an attachment to an e-mail. If we do not receive a response with the complete information within 30 days, we will consider your request as having been abandoned by you. This is without prejudice to the submission of a new request.

Do not hesitate to contact me with any questions.

Thank you,

Celimar Valentin-Rodriguez, Ph.D.

General Engineer

U.S. Nuclear Regulatory Commission

NMSS/MSTR/MSLB

☎ (301) 415-7124

✉ Celimar.Valentin-Rodriguez@nrc.gov

March 2nd, 2018

Celimar Valentin-Rodriguez, Ph.D.
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
US Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 78741

RE: Reply to Letter Dated February 8th, 2018

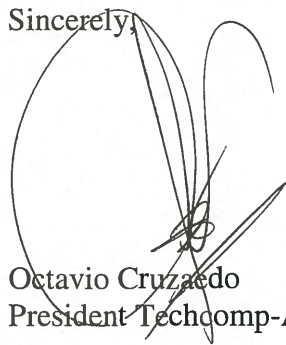
Dear Dr. Valentin-Rodriguez:

Below please find our reply to your letter dated February 8th, 2018.

In reference to the Texas License, the Amendment for the new address is still in process, we will send you a copy as soon as it has been received.

If you have any questions please call me at 1-(512) 215-8335 or email me at octavio.cruzaedo@techcomp-am.com.

Sincerely,

A handwritten signature in black ink, appearing to be 'Octavio Cruzaedo', written over a large, faint circular watermark or background graphic.

Octavio Cruzaedo
President Techcomp-America

Techcomp USA, DBA Scion Instruments Amendment Request dated November 21st, 2017
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Techcomp USA, Inc. Amendment request dated November 21st, 2018, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by Title 10 of the Code of Federal Regulations (10 CFR) 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled, "Applications for Sealed Source and Device Evaluation and Registration."

- 1. Verify that previous commitments made by Techcomp USA Inc., DBA Scion Instruments in Registration Certificate NR-1385-D-101-E have not changed.**

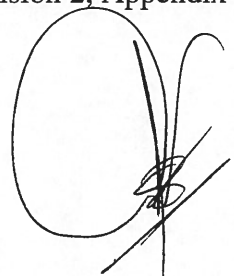
There is no previous commitment changed since the last Amendment and or letter dated on November 23rd, 2016.

- 2. Confirm that the new Austin location will follow the procedures outlined in Techcomp USA Inc., DBA Scion Instruments' QA/QC program.**

We confirm that our new distribution site in the Austin TX, is following the procedures on QA/QC program in accordance to previous QA documents submitted.

Also we confirm our manufacturing site in The Netherlands is an ISO 9001 certified QA program, they will provide a product which will fully comply with the design conformity in accordance with accordance with the commitments made in NR-1385-D-101-E, will leak test all units to 185 Bq (0.005 μ Ci), will test all units for proper operation of all safety features, and will survey all units to verify that radiation levels do not exceed the maximum values in the device registration, which are at background levels.

In addition, Techcomp USA commits to auditing the QA program of the manufacturer on an annual basis in order to comply with the requirements of NUREG 1556, Vol 3, Revision 2, Appendix G. All records of audits will be maintained at the Texas facility as per 10 CFR 110.53(b).

A handwritten signature in black ink, consisting of a large, stylized 'O' followed by a series of loops and a final vertical stroke.