



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

February 9, 2018

Mr. Octavio Cruz-Aedo
Techcomp, USA
dba Scion Instruments
4801 Southwest Parkway
Suite 125
Austin, TX 78735

SUBJECT: NRC INSPECTION REPORT 030-39024/2017-001 AND NOTICE OF VIOLATION

Dear Mr. Cruz-Aedo:

This letter refers to the inspection conducted on November 16, 2017, at your facility in Austin, Texas; and continued in-office review until February 6, 2018. The inspection was an examination of activities conducted under your exempt distribution license as they relate to compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records and interviews with personnel. On March 23, 2015, Techcomp, USA, acquired NRC license 04-35093-01E from Bruker Daltronics, Inc., through a change of ownership. On February 8, 2017, after Techcomp, USA, relocated to Texas, NRC license 04-35093-01E was retired and NRC license 42-35093-01E was issued. The inspection examined your licensed activities that occurred under NRC exempt distribution licenses 04-35093-01E and 42-35093-01. The preliminary inspection findings were discussed with Ms. Sylvie Mutombo of your staff at the conclusion of the on-site inspection on November 16, 2017. Following the on-site inspection, your staff provided additional records that were not available during the on-site inspection. A final telephonic exit briefing was conducted with Mr. Lazaro Casanueva of your staff on February 6, 2018.

Please note that your amendment request to change your exempt distribution location is currently under review by the NRC and you will be contacted by separate correspondence regarding this matter.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the enclosed Notice because they were identified by the NRC during the inspection. The violations involved the failure to: (1) file a report with the NRC on or before January 31, 2017, for distributions of exempt devices that occurred in calendar year 2016; and (2) label or mark each device and its point-of-sale package so that each item has a durable, legible, readily visible marking on the

external surface of the device containing instructions and precautions necessary to assure safe installation, operating, and servicing of the device.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: <http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf>. Information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

Should you have any questions regarding this letter or the enclosed Notice, please contact Dr. Janine F. Katanic, CHP, at 817-200-1151 or the undersigned at 817-200-1455.

Sincerely,

/RA/

Michael C. Hay, Chief
Materials Licensing and Inspection Branch
Division of Nuclear Materials Safety

Docket Nos.: 030-39024 and 030-38672
License Nos.: 42-35093-01E and 04-35093-01E

Enclosure:
Notice of Violation

cc w/Enclosure:
State of Texas Radiation Control Program Director
State of California Radiation Control Program Director

NRC INSPECTION REPORT 030-39024/2017-001 – DATED FEBRUARY 9, 2018

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ADAMS ACCESSION NUMBER: ML18039A440

Cover Letter (w/ Enclosure)	ADAMS	<input checked="" type="checkbox"/> Publicly Available	<input checked="" type="checkbox"/> Non-Sensitive	Keyword:
X SUNSI Review by: JFK	X Yes <input type="checkbox"/> No	<input type="checkbox"/> Non-Publicly Available	<input type="checkbox"/> Sensitive	N/A
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NOTICE OF VIOLATION

Techcomp, USA
dba Scion Instruments
Austin, Texas

Docket No. 030-39024
License No. 42-35093-01E

During an NRC inspection conducted on November 16, 2017, at the Techcomp, USA, facilities in Austin, Texas, with continued in-office review through February 6, 2018, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 32.32(c)(4)(i) requires, in part, that the licensee maintain records of all transfers and file a report with the Director of the Office of Nuclear Materials Safety and Safeguards, covering the preceding calendar year, on or before January 31 of each year.

Contrary to the above, for calendar year 2016, the licensee failed to file a report with the Director of the Office of Nuclear Materials Safety and Safeguards, on or before January 31, 2017. Specifically, during calendar year 2016, the licensee distributed at least 14 exempt devices to end users in the United States and failed to file a report regarding these distributions with the Director of the Office of Nuclear Materials Safety and Safeguards, on or before January 31, 2017.

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.9.d).

- B. 10 CFR 32.32(b)(1)(iv) requires, in part, that the licensee label or mark each device and its point-of-sale package so that each item has a durable, legible, readily visible marking on the external surface of the device containing instructions and precautions necessary to assure safe installation, operating, and servicing of the device.

License Condition 14 of NRC license 42-35093-01E, dated February 8, 2017, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in License Condition 14. License Condition 14, letter dated January 10, 2017, provides a copy of the licensee's label to meet the requirements of 10 CFR 32.32(b)(1)(iv). The label includes the words "THIS PRODUCT MUST BE USED IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS. PLEASE REFER TO THE USER MANUAL FOR PROPER OPERATING INSTRUCTIONS."

Contrary to the above, from February 8, 2017, to November 16, 2017, the licensee failed to label or mark each device and its point-of-sale package so that each item has a durable, legible, readily visible marking on the external surface of the device containing instructions and precautions necessary to assure safe installation, operating, and servicing of the device. Specifically, from February 8, 2017, to November 16, 2017, the licensee distributed 14 exempt devices to end users in the United States and the device and the label on its point-of-sale package did not include the words: "THIS PRODUCT MUST BE USED IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS. PLEASE REFER TO THE USER MANUAL FOR PROPER OPERATING INSTRUCTIONS."

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.3.d).

Pursuant to the provisions of 10 CFR 2.201, Techcomp, USA, dba Scion Instruments, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include, for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 9th February 2018