

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 11, 2021

EA-20-084

CampCo, Inc. ATTN: Motti Slodowitz, President 4625 West Jefferson Blvd. Los Angeles, California 90016

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -

\$75,000, NRC INSPECTION REPORT 030-36619/2017-001 AND OI

INVESTIGATION REPORT NO. 4-2017-036 - CAMPCO, INC

Dear Mr. Slodowitz:

This letter refers to the investigation initiated by the U.S. Nuclear Regulatory Commission's (NRC's) Office of Investigations (OI) on June 20, 2017, and the inspection at your facility in Los Angeles, California, on May 11, 2017, with subsequent records review, conducted by NRC staff from May 11, 2017, to September 3, 2020. The purpose of the investigation and inspection was to examine activities conducted under your license and to determine CampCo, Inc. (CampCo) compliance with the alternative dispute resolution (ADR) Confirmatory Order Modifying License, dated June 20, 2016, issued under Enforcement Action EA-14-080. A final telephone exit meeting to discuss the inspection was conducted with Mr. Jason Dykert on November 18, 2020. The inspection report can be found in NRC's Agencywide Documents Access and Management System (ADAMS) at accession No. ML20322A351. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

In the letter transmitting the inspection report (ML20322A351), dated November 18, 2020, we provided you the opportunity to address the apparent violations identified in the report by attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated December 18, 2020, you provided a written response to the apparent violations (ML20363A056).

Based on the information developed during the inspection and the information that you provided in your response dated December 18, 2020, the NRC has determined that nine violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice).

We have grouped the violations into four focus areas: (1) three violations for failure to comply with the license and regulations (repeat violations), (2) three violations for failure to comply with the license and regulations, (3) one violation for failure to provide complete and accurate information to the NRC, and (4) two violations for failure to comply with the Confirmatory Order.

We have a number of concerns about CampCo's apparent lack of compliance with regulatory requirements, the specific conditions of the license, and the Confirmatory Order. The investigation and inspection results indicate a lack of management oversight and are indicative of particularly poor licensee performance. The failure to distribute licensed material in accordance with the applicable requirements (both regulations and in your license), in particular the recurrent lack of compliance, is significant because these requirements ensure that the products are safe for distribution to members of the general public. Further, your failure to submit timely and complete required annual reports to NRC, and to provide complete and accurate information to NRC, is significant because they inhibit the process of regulatory oversight. Finally, CampCo's failure to (1) seek NRC comments prior to providing training to applicable personnel, (2) accurately capture applicable requirements in the draft training material, and (3) develop applicable procedures, as required by the Confirmatory Order, causes significant concern since they imply that you comprehend neither what requirements apply to you, nor how to implement those requirements.

Each of these violations has been assessed in accordance with NRC's Enforcement Policy. The current Enforcement Policy may be found on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Since the three violations in the first focus area are repeat violations from the previous escalated enforcement action (EA-14-080), they are each being issued as a separate SL III violation. The three violations in the second focus area are being issued as one SLIII problem. The violation in the third focus area is being issued as an SLIII violation. The three violations in the fourth focus area are being issued as one SLIII problem.

For Apparent Violation F, you stated that you believed that the current labeling was adequate. However, you also provided an alternate labeling commitment which you proposed to use if the NRC did not find your current labeling practice acceptable. NRC staff determined that the current labeling is not adequate and that your alternate labeling is adequate. On February 2, 2021, you submitted a request to amend your licensee to change the labeling to that described in your December 18, 2020, letter. Your amended license is attached (Enclosure 3).

In accordance with the Enforcement Policy, because your facility has been the subject of escalated enforcement actions within the last two inspections, we considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. We also considered the information you provided since the 2017 inspection to the inspectors and investigators, including your response dated December 18, 2020. We have determined that the corrective actions proposed are acceptable to address all violations. Based on this determination, we are granting corrective action credit for each violation. However, we have determined that it is appropriate to propose a base civil penalty for each violation or problem, with the exception of the SL III violation for failure to provide complete and accurate information to the NRC which is beyond the 5-year statute of limitations. We will review and verify the adequacy of your corrective actions for all violations in a future inspection.

Therefore, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the total amount of \$75,000. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection. The NRC also includes significant enforcement actions on its website at http://www.nrc.gov/reading-rm/doccollections/enforcement/actions.

The NRC recognizes that many licensees have been impacted economically by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, as described in the enclosed Notice, the NRC is extending by 30 days the period of time by which the civil penalty must be paid (i.e., extending the deadline from 30 days to 60 days from the date of this Notice), and the NRC would consider a request for additional time, if appropriate. Please refer to the enclosed Notice for further instructions.

The NRC has concluded that information regarding (1) the reason for the violations, (2) the corrective steps that have been taken and the results achieved, and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-36619/2017-001 in your response dated December 18, 2020, and in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. NRC will confirm the completion of the corrective actions in a future inspection.

In accordance with 10 Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's 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, proprietary, or safeguards information so that it can be made available to the public without redaction.

Any information forwarded to NRC should be clearly labeled on the first page with the case reference number: "EA-20-084," and addressed to Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy mailed to David Alley, Chief, Material Safety and Tribal Liaison Branch, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738. A courtesy copy may also be sent via email to david.alley@nrc.qov.

If you have any questions concerning this matter, please contact Dr. David Alley at David.Alley@nrc.gov or at 301-415-2178.

Sincerely,

George A. Wilson, Director Office of Enforcement

Docket No. 03036619 License No. 04-23910-01E

Enclosure:

(1) Notice of Violation and Proposed Imposition of Civil Penalty

- (2) NUREG/BR-0254 Payment Methods (Licensee only)(3) NRC Letter issuing License Amendment No. 6

cc: State of California Gonzalo Perez, Chief California Dept. of Public Health (CDPH) Radiologic Health Branch P.O. Box 997414, MS 7610 Sacramento, CA 95899-7414

M. Slodowitz - 5 -

SUBJECT: NRC INSPECTION REPORT 030-36619/2017-001 AND OI INVESTIGATION

REPORT NO. 4-2017-036 - CAMPCO, INC DATED: February 11, 2021

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ADAMS Package No.: ML21035A139

NOV ML21035A136

OFFICE	NMSS/MSST	NMSS/MSST/BC	RIV/DNMS	RIV/DNMS/BC	RIV/DNMS	NMSS/MSST
NAME	SXu	DAlley	JDykert	DBradley	LHowell	KWilliams
	Via email	Via email	/RA/	Via email	Via email	Via email
DATE	01/21/21	01/26/21	01/21/21	01/22/21	01/26/21	01/26/21
OFFICE	NMSS/EC	OE	OE	OGC	OE	
NAME	MBurgess	LSreenivas	JPeralta	RCarpenter NLO	GWilson	
DATE	01/27/21	1/27/21	02/03/21	01/28/21	02/11/2021	

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NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

CampCo, Inc. Los Angeles, CA Docket No. 03036619 License No. 04-23910-01E EA-20-084

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted May 11, 2017, at your Los Angeles, California, facility, with continued review through September 3, 2020, nine violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and Title 10 of the *Code of Federal Regulations* (CFR), Section 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

Violation A:

License Condition 10 of Materials License 04-23910-01E, Amendments No. 3 and No. 4, require, in part, that the licensee distribute only timepieces whose model numbers are specifically authorized on the license.

Contrary to the above, from March 1, 2016 through January 23, 2018, the licensee failed to distribute only timepieces whose model numbers were specifically authorized on the license. Specifically, CampCo distributed tritium timepieces whose model numbers were not listed in License Condition 10: HMV-W-ZT1; SWW-77; SWW-MP18; UZI-18B; UZI-26; and UZI-32.

Violation A is a Severity Level III violation (6.3) Civil Penalty - \$15,000 (EA-20-084)

Violation B:

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

10 CFR 32.16 requires, in part, that each person licensed under 10 CFR 32.14 shall maintain records of all transfers of byproduct material and file a report identifying the products transferred which must include identification of each product, the model numbers, and the number of units of each type of product transferred during the reporting period by model number.

Contrary to the above, reports filed by the licensee for calendar years 2010 - 2017 were not complete and accurate in all material respects and failed to include identification of each product, the model numbers, and the number of units of each type of product transferred during the reporting period by model number. Specifically, the licensee's annual reports did not identify that timepieces of model numbers:

SWW-MP18 and UZI-18B in 2014, 2015, and 2016; or that UZI-32 in 2017 had been transferred.

Additionally, the annual reports submitted for calendar years 2006 - 2016 have an incorrect listing of activity per timepiece for each model, and incorrect listing of total tritium transferred annually, specifically for timepieces: UZI-001; SWW-12T; SWW-MP18; SWW-900; SWW-1864T; SWW-GRH-1; or SWW-88; SWW-357; and SWW450.

Violation B is a Severity Level III violation (6.3) Civil Penalty - \$15,000 (EA-20-084)

Violation C:

License Condition 11 of Materials License 04-23910-01E, Amendments No. 3 and No. 4, require, in part, that each lot of timepieces, hands, and dials received, containing tritium for distribution pursuant to 10 CFR 30.15, must be accompanied by a certificate which attests that, the timepieces were manufactured in accordance with recognized industry standards, and that the amount of tritium on the timepieces is not in excess of the amounts authorized in 10 CFR 30.15(a).

Contrary to the above, five shipments of lots in 2014, six shipments of lots in 2015, and three shipments of lots in 2016, all of which contained timepieces containing tritium for distribution, were received by the licensee and were not accompanied by a certificate which attests that the timepieces were manufactured in accordance with recognized industry standards, and that the amount of tritium on the timepieces is not in excess of the amounts authorized in 10 CFR 30.15(a).

Violation C is a Severity Level III violation (6.3) Civil Penalty - \$15,000 (EA-20-084)

Violation D:

License Condition 15 A of Materials License 04-23910-01E, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the license application.

CampCo's license renewal application, dated April 23, 2014, commits to the statements made in the initial license application dated July 9, 2004. In the Checklist section of the initial license application, CampCo committed to implement quality assurance measures that include visually inspecting each watch containing tritium upon receipt under natural light for visual defects and then in a completely dark room to verify that all tritium markings are glowing consistently and that there are no leaks visible. In Appendix B of the application, CampCo committed to keeping a logbook registering the date and time of each receipt of product, and to record the number of watch units received and their activity on the inventory record logbook.

Contrary to the above, from issuance of the initial license on October 12, 2004, up until at least the closure of the OI investigation on April 10, 2020, CampCo failed to conduct its program in accordance with the statements, representations, and procedures contained in the license application. Specifically, upon receipt, each watch has not

been visually inspected in a completely dark room to verify that all tritium markings are glowing consistently, and a logbook has not been kept that registers the date and time of each receipt of product, the number of units, and the activity of these products.

Violation E:

10 CFR 30.15(a)(1)(i) requires, in part, that timepieces may not contain more than 25 millicuries of tritium per timepiece.

10 CFR 32.14(c) requires, in part, that each product will contain no more than the quantity of byproduct material specified for that product in 10 CFR 30.15.

License Condition 10 of Materials License 04-23910-01E, Amendment No. 3 requires, in part, that the Hydrogen-3 activity for an individual timepiece shall not exceed 19 millicuries (mCi).

Contrary to the above, as of January 1, 2017, CampCo distributed timepiece of models: UZI 001; SWW-12T; SWW-MP18; SWW-900; SWW-1864T; and SWW-GRH-1 that possessed a Hydrogen-3 activity exceeding 19 mCi, and timepieces of models: SWW-88; SWW-357; and SWW-4503 that possessed a Hydrogen-3 activity exceeding 25 mCi.

Violation F:

10 CFR 32.15(d)(1) requires, in part, that the licensee label each unit's container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

Contrary to the above, from August 2016 to August 2017, the licensee failed to label each timepiece container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Specifically, the label for each timepiece's container did not identify CampCo as the manufacturer or initial transferor, did not identify the radioisotope within as tritium, and referenced non-applicable manufacturing criteria in 10 CFR 32.22, instead of the applicable quality assurance criteria found in 10 CFR 32.15 for each timepiece.

Violations D, E and F are a Severity Level III problem (6.3) Civil Penalty - \$15,000 (EA-20-084)

Violation H:

Confirmatory Order Modifying License number 04-23910-01E, issued on June 20, 2016, Section V, item 6, requires CampCo to engage a third party independent consultant to provide initial training to key employees on NRC compliance responsibilities for exempt distribution licenses, as well as the specific requirements and obligations associated with CampCo's NRC license, and within 9 months to submit a draft of the training content to the NRC for review and approval, and incorporate any comments.

Contrary to the above, prior to March 20, 2017, within 9 months from issuance of the Order, CampCo failed to submit a draft of the training content to the NRC for review and approval, and incorporate any comments. Specifically, (1) the training material provided

by CampCo letter dated August 30, 2016 was not a draft of the training content submitted for review and approval because CampCo had already provided it to key employees as completed training; (2) the CampCo letter dated February 13, 2017, did not contain training content for review and approval; and (3) the CampCo training content dated May 19, 2017, that accompanied the letter dated May 24, 2017, was not submitted within the 45 days granted by NRC's letter dated January 4, 2017, or by March 20, 2017, nor did it contain the training content required by the Order.

Violation I:

Confirmatory Order Modifying License number 04-23910-01E, issued on June 20, 2016, Section V, item 11, requires CampCo to develop written procedures and/or checklists identifying NRC compliance responsibilities for exempt distribution licenses in accordance with the regulations, as well as the specific requirements and obligations associated with CampCo's NRC license within 9 months from the date of the Order.

Contrary to the above, within 9 months from the date of the Order, March 20, 2017, CampCo failed to develop written procedures and/or checklists identifying NRC compliance responsibilities for exempt distribution licenses in accordance with the regulations, as well as the specific requirements and obligations associated with CampCo's NRC license. Specifically, written procedures and/or checklists were not developed to include, for example, the process to be followed should there be a change in sources or watches to be distributed by CampCo, what actions to take if a lot of timepieces is received without the required certificates, written instructions detailing the models authorized for distribution, and employee responsibilities for the timing and content of annual reports.

Violations H and I are a Severity Level III problem (6.3) Civil Penalty - \$15,000 (EA-20-084)

II. Violations Not Assessed a Civil Penalty

Violation G:

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

Contrary to the above, on August 14, 2014, information provided to the Commission by CampCo was not complete and accurate in all material respects. Specifically, CampCo provided testimony under oath that all distribution of tritium timepieces was halted after July 30, 2013. However, 1,360 tritium containing timepieces were distributed from July 30, 2013 through February 20, 2014.

This is a Severity Level III violation (6.9)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket on the docket in Inspection Report No. 030-36619/2017-001, in your response dated December 18, 2020, and the letter transmitting this Notice of Violation (Notice). However, within 30 days

of the date of the letter transmitting this Notice, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-20-084".

The licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part. Within 30 days of the date of this Notice, the licensee must either confirm to the NRC in writing that it will pay the civil penalty or provide its written answer protesting the civil penalty. However, in the event the licensee elects to pay the civil penalty, in recognition of the economic impact to licensees by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19), the NRC is extending the period of time by which the civil penalty must be paid from 30 days to 60 days from the date of this Notice. Should the licensee fail to pay the civil penalty within 60 days of the date of this Notice, the NRC will issue an Order imposing the civil penalty. Your statement and payment should be clearly marked as an "Payment of Civil Penalty (EA-20-084)".

Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation (EA-20-084)" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the civil penalty. Separately, you may request an additional extension of time to pay the civil penalty as a result of impacts to the licensee from COVID-19. Such an extension request must be in writing and should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 50 days from the date of this Notice (i.e., at least 10 days before the initial 60-day deadline to pay the civil penalty).

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205, should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty. Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Extension of time to pay the civil penalty, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: George Wilson, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy mailed to David Alley, Chief, Material Safety and Tribal Liaison Branch, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738. A courtesy copy may also be sent via email to david.alley@nrc.gov.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 11th day of February 2021.