UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 17, 2022

EA-21-157

Cammenga and Associates, LLC
ATTN: Mr. Christopher Karchon, Vice President
2011 Bailey Street
Dearborn, MI 48124

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION OFFICE OF INVESTIGATIONS REPORT NO. 3-2021-008, CAMMENGA AND ASSOCIATES, LLC

Dear Mr. Karchon:

This letter refers to the investigation initiated by the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), on March 15, 2021. The purpose of the investigation was to determine whether Cammenga and Associates, LLC was in compliance with regulatory requirements related to Cammenga and Associates LLC's distribution of products containing radioactive material.

Based on the results of this investigation, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The apparent violations involve initially transferring, for sale or distribution, products containing tritium (H-3), that were not authorized for distribution on an NRC license at the time of distribution.

The failure to conduct activities in accordance with a license is significant because it resulted in the NRC not being able to conduct its regulatory responsibilities to ensure that the products were safe for distribution to members of the general public, and inhibited the process of regulatory oversight. The apparent violations are listed in Enclosure 1.

Additionally, the NRC is concerned that one of the apparent violations may have been willful in nature, based on the available information that is summarized in Enclosure 2. Willful violations are of significant concern to the NRC because the NRC's regulatory programs rely upon the integrity of entities, applicants, and licensees to comply with NRC requirements to ensure the health and safety of workers and the public.

During a March 16, 2022, telephonic exit meeting conducted with you, as Cammenga and Associates, LLC's Vice President, Ms. Maria Arribas-Colon, of the NRC, discussed these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions. As discussed with you, the NRC has not made a final determination regarding the apparent violations or willfulness, or that enforcement action will be taken against Cammenga and Associates, LLC. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. In addition, please be advised that the characterization of the apparent violations may change as a result of further NRC review. Before the NRC makes

its enforcement decision, we are providing you with an opportunity to: (1) respond in writing to the apparent violations described in the enclosures within **thirty (30)** calendar days of the date of this letter or (2) request a Pre-decisional Enforcement Conference (PEC) or (3) request Alternative Dispute Resolution (ADR). If you wish to choose a PEC or ADR, you must contact Ms. Maria Arribas-Colon at (301) 415-6026 within **10** calendar days of the date of this letter to confirm your request for a PEC or ADR. A PEC should be held within **thirty (30)** calendar days and an ADR should be held within **forty-five (45)** calendar days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violation in Investigation Report No. 3-2021-008; EA-21-157." The information should include: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (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. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if it adequately addresses the required information. If an adequate response is not received within the time specified or an extension of time has not been granted, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The PEC is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred and whether willfulness is involved, information to determine the significance of any violation, and information related to any corrective actions taken or planned. For the apparent violation, you should be prepared to address: (1) the reason for the apparent violation, or if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken to avoid further violations. If a PEC is held, it will be closed to public observation because information related to an Office of Investigations report will be discussed and the report will not be made public. However, the NRC may issue a press release to announce the time and date of this closed conference.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral third party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative in long-term corrective actions to prevent recurrence of violations, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained in the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. The ICR would provide both parties with a list of three individuals to choose from who would serve as the independent mediator. Please contact ICR at (877) 733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In presenting any corrective actions, you should be aware that the promptness and comprehensiveness of the actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed NRC Information Notice 96-28, "Suggested Guidance relating to Development and Implementation of Corrective Action," (Enclosure 3) may be helpful.

If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In addition, please be advised that the number and characterization of the apparent violation described in the enclosure may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response, if you choose to provide one, 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, accessible from the NRC's website 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-21-157.

Should you have any questions, please contact Ms. Maria-Arribas Colon of my staff at (301) 415-6026.

Sincerely,


Signed by Williams, Kevin
on 03/17/22

Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Apparent Violations Being Considered for Escalated Enforcement
2. Factual Summary - OI Investigation Report No. 3-2021-008
3. NRC Information Notice 96-28

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION OFFICE OF INVESTIGATIONS REPORT NO. 3-2021-008, CAMMENGA AND ASSOCIATES, LLC
DATED: MARCH 16, 2022

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OFC	MSST/MSTB	MSST/MSTB	MSTR/MSTB	NMSS/MSST
NAME	THerrera TH	SXu SX	MArribas-Colon MA	KWilliams (prior to OE) KW via email
DATE	2/11/2022	2/14/2022	2/15/2022	02/15/22
OFC	NMSS EC	OE ES	OE	OGC (NLO)
NAME	MBurgess MB	CRiveraDiaz CR via email	JPeralta JP via email	RAugustus RA via email
DATE	02/15/22	02/24/22	02/24/22	3/11/22
OFC	NMSS/MSST			
NAME	KWilliams (Final sign)			
DATE	3/15/2022			

OFFICIAL RECORD

APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation 1 (apparent careless disregard):

10 CFR 30.34(c) requires, in part, that each person licensed by the Commission pursuant to the regulations in 10 CFR Parts 30 through 36 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.

NRC License 21-26460-03E authorizes the licensee to distribute certain self-luminous products. License Condition 9a of NRC License 21-26460-03E authorizes the licensee to distribute certain products manufactured in accordance with NRC sealed source and device (SSD) certificate No. NR-0210-D-101-E, to persons exempt from the requirements for a license. License Condition 10 of NRC License 21-26460-03E lists the series of self-luminous products that are authorized for distribution, including the VERSA Series. The materials submitted by the licensee that define the models in the VERSA Series that were authorized for distribution are incorporated by reference in NRC SSD certificate No. NR-0210-D-101-E.

Contrary to the above, the licensee failed to limit its distribution of self-luminous products to the products authorized in its NRC License 21-26460-03E. Specifically, between late 2020 and January 27, 2021, the licensee distributed to an unlicensed entity at least 25 Tritium Pry Bars that were not included in the products authorized in NRC License 21-26460-03E and NRC SSD certificate No. NR-0210-D-101-E.

Apparent Violation 2:

10 CFR 30.34(c) requires, in part, that each person licensed by the Commission pursuant to the regulations in 10 CFR Parts 30 through 36 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.

NRC License 21-26460-03E authorizes the licensee to distribute certain self-luminous products. License Condition 9a of NRC License 21-26460-03E authorizes the licensee to distribute certain products manufactured in accordance with NRC sealed source and device (SSD) certificate No. NR-0210-D-101-E, to persons exempt from the requirements for a license. License Condition 10 of NRC License 21-26460-03E lists the series of self-luminous products that are authorized for distribution, including the glass breaker (GB) Series. The materials submitted by the licensee that define the models in the GB Series that were authorized for distribution are incorporated by reference in NRC SSD certificate No. NR-0210-D-101-E.

Contrary to the above, the licensee failed to limit its distribution of self-luminous products to the products authorized in its NRC License 21-26460-03E. Specifically, between late 2020 and January 27, 2021, the licensee distributed to an unlicensed entity at least 10 Tritium Glow Fobs that were not included in the products authorized in NRC License 21-26460-03E and NRC registration certificate No. NR-0210-D-101-E.

FACTUAL SUMMARY
OFFICE OF INVESTIGATIONS REPORT 3-2021-008

On March 15, 2021, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region III field office initiated an investigation to determine, 1) whether Cammenga and Associates, LLC, willfully distributed products containing tritium without the products being authorized for distribution or registered in the sealed source and device registry by the NRC, and, 2) whether Cammenga, or those associated with Cammenga, willfully failed to conduct its program in accordance with the statements, representations, and procedures contained in its license applications/amendments. The investigation was completed on October 12, 2021, and was documented in the OI Report 3-2021-008.

Cammenga is located in the State of Michigan. Cammenga holds a radioactive materials possession license, exempt distribution license, and three sealed source and device registration (SSD) certificates issued by the NRC. Cammenga is authorized to distribute products containing tritium, such as gun sights, flashlights, firearm safeties, knives, and compasses.

The OI investigation revealed that, starting on or before December 4, 2020, Glow Rhino, an unlicensed entity, was distributing two products containing tritium, called the "Tritium Pry Bar" and "Tritium Glow Fob," on its website (www.glowrhino.com). In a letter to the NRC dated January 27, 2021, Glow Rhino indicated that Cammenga was the initial distributor of these products and that Cammenga had transferred 35 units (10 Glow Fobs and 25 Pry Bars) to Glow Rhino as of that date. Cammenga is authorized under NRC License No. 21-26460-03E to distribute, among other things, VERSA and glass breaker (GB) Series models manufactured in accordance with NRC SSD certificate No. NR-0210-D-101-E.

The Vice President/Director of Strategic Initiatives (VP/DSI) for Cammenga, who was also a co-founder of Glow Rhino, was directly involved in the distribution of these products from Cammenga to Glow Rhino and was aware of the sales of these products by Glow Rhino.

The VP/DSI acted as the preparer, submitter, and primary point-of-contact for Cammenga on the 2018 initial license amendment request to add the VERSA Series (Butterfly and Clam), the 2019 request to add the GB Series, and the 2020 requests (both the February/April initial submittal and the December resubmittal) to add additional models to the VERSA Series. For each of these license amendment requests, the VP/DSI signed NRC Form 313 as certifying officer and indicated that questions concerning the packages should be directed to him. The VP/DSI was the addressee for all NRC staff correspondence regarding the VERSA and GB Series licensing, and was the person who responded to all of the NRC staff's Requests for Additional Information (RAIs).

Pry Bar

During the OI investigation, the VP/DSI stated that the Pry Bar had been approved as part of Cammenga's VERSA Series. Cammenga's SSD certificate No. NR-0210-D-101-E dated February 24, 2020 contains a table listing the four Butterfly and eight Clam models that were initially approved under the VERSA series. The VP/DSI confirmed in correspondence with the NRC during the 2018 VERSA license amendment request review that the four Butterfly and eight Clam models were the only items Cammenga sought approval for at that time.

In February 2020, the VP/DSI submitted a new license amendment request seeking to add new models to the VERSA series. The license amendment request referred to these new models as a "fixed" design. In April 2020, the VP/DSI supplemented this request with clarifying information stating that the proposed new "fixed" models were "always open," unlike the Butterfly and Clam models which had an open/close feature. This design difference is apparent when the drawings

of the Butterfly and Clam models from the 2018 license amendment request are compared with the drawings of the new "fixed" models submitted in February/April 2020. In a September 2020 RAI response, the VP/DSI provided drawings of a number of additional models, including one, the GR-S2.1, that was identical to the Pry Bar design.

In October 2020, the NRC suspended review of Cammenga's amendment request to add new models to the VERSA Series. In December 2020, the VP/DSI resubmitted the request, again including the GR-S2.1 design.

During OI interviews in April and May 2021, the VP/DSI stated that the Pry Bar was the same as the previously approved VERSA Series Clam model 1S-1; however, a comparison of the Pry Bar with the drawings for the VERSA Series Clam model 1S-1 indicates that the devices are different. The VP/DSI also acknowledged to OI that the "exact" Pry Bar design (Model GR-S2.1) was included in the pending, not-yet-approved December 2020 license amendment request, and that Model GR-S2.1 could not be distributed until that request was approved by the NRC.

Based on the results of the investigation, it appears that the VP/DSI acted with careless disregard when he failed to determine whether the Pry Bar was authorized under the NRC license prior to distributing it to Glow Rhino.

Glow Fob

During the OI investigation, the VP/DSI stated that the Glow Fob had been approved as a part of Cammenga's GB Series. In Cammenga's 2019 license amendment request to add the GB Series models, the VP/DSI submitted drawings that depict sources placed in discrete cavities on the outside of an otherwise solid cylindrical device. During the license amendment review, Cammenga provided a photo of the prototype, identified by Cammenga as Model 1C, which the NRC staff included in the SSD certificate as representative of the product. During the OI investigation, the VP/DSI asserted that the GB Series Model 1C is the approved model corresponding to the Glow Fob.

The Glow Fob falls within the range of dimensions in Cammenga's drawings of the approved GB Series models; however, the design of the Glow Fob is significantly different than what is shown in the drawings and in the photo of the prototype. A comparison of the prototype photo with the image of the Glow Fob from Glow Rhino's website shows that the prototype is essentially solid metal over its entire length, while the Glow Fob has a large central "cavity" that is entirely open except for four thin metal strips connecting the two ends of the device. The drawing of Model 1C shows a single source visible from one side of the device but not from the other side. The "Tritium and Protection Detail" drawing applicable to all GB Series models depicts the tritium source cavity as a rectangular prism located on the outer surface of the device. In contrast, the tritium source in the Glow Fob is enclosed in a polycarbonate casing mounted in the center of the device and visible from four sides, with four thin metal strips as protection for the casing.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section 2.3.2 of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified, and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

   Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

   Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

   Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to

provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?