

January 26, 2023

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of

CAMMENGA AND ASSOCIATES, LLC

(Denial of License Amendment Requests)

Docket No. 030-038679-LA

JOINT MOTION TO APPROVE PROPOSED SETTLEMENT AGREEMENT AND TERMINATE PROCEEDING

Introduction

Pursuant to 10 C.F.R. § 2.338, the U.S. Nuclear Regulatory Commission (NRC) staff (Staff) and Cammenga and Associates, LLC, (Cammenga) (collectively, the Parties) jointly file this motion requesting that the Atomic Safety and Licensing Board (Board) approve the attached proposed settlement agreement (Attachment A) and issue the attached consent order (Attachment B) terminating the proceeding. The proposed settlement agreement fairly and reasonably resolves all of the issues in this proceeding; the Staff now has the information it needs to approve a subset of Cammenga's designs, and Cammenga agrees to withdraw its hearing request for the remaining designs. Additionally, the Parties agree that the public interest does not require the adjudication of the issues for the reasons discussed more fully below.

Background

This proceeding concerns Cammenga's requests to amend its NRC exempt distribution license (License No. 21-26460-03E) and the related registration certificate (Sealed Source and

Device (SS&D) Registration Certificate NR-0210-D-101-E).¹ Cammenga's exempt distribution license and registration certificate currently authorize it to distribute a series of self-luminous products (referred to in the license and certificate as the "VERSA" series) that contain tritium.² In February 2020, Cammenga requested that the Staff amend its exempt distribution license and its registration certificate to allow the distribution of new devices.³ The Staff reviewed Cammenga's application pursuant to the requirements in 10 C.F.R. Parts 30 and 32 and the Commission's Consumer Product Policy Statement, which describes criteria for evaluation of products intended for use by the general public (consumer products).⁴

After conducting an acceptance review and evaluating a response to a request for additional information (RAI),⁵ the Staff notified Cammenga that it had suspended its review because the application did not contain required information but indicated that Cammenga could resubmit the amendment application with additional information.⁶ Cammenga resubmitted its

¹ Cammenga and Associates, LLC, Materials License No. 21-26460-03E (Nov. 18, 2021) (ML21322A246) (Cammenga License); Cammenga and Associates, LLC, Registry of Radioactive Sealed Source and Device, Safety Evaluation of Device (Amended in its Entirety) No. NR-0210-D-101-E (Sept. 23, 2021) (ML21217A090) (non-public) (Cammenga SS&D).

² See Cammenga License, 2-4; Cammenga SS&D, 6-7 (non-public).

³ See Amendment Request to SS&D #NR-0210-D-101-E and E-License 21-26460-03E, Attach. 6 at pdf p. 15 (Feb. 18, 2020) (ML20079D918) (non-public).

⁴ *E.g.*, 10 C.F.R. § 30.19 (2022); *id.* § 32.22 (2022); see Consumer Product Policy Statement, 79 Fed. Reg. 2907 (Jan. 16, 2014).

⁵ Supplemental Information Required for Acceptance of the Request to Amend Cammenga and Associates Exempt Distribution License and Sealed Source and Device Registration for the VERSA Series, 1-2 (Apr. 6, 2020) (ML20085G069) (April 6, 2020, RAIs); see Letter from Cammenga (Apr. 24, 2020) (ML20126G390) (non-public). This April 6 letter refers to an application dated March 9, 2020. April 6, 2020, RAIs at 1. Some attachments within Cammenga's February 18, 2020, application have dates other than February 18, including an NRC Form 313, dated March 9, 2020. To avoid any ambiguity, this Motion and the attachments consistently use February 18, 2020, as the date for Cammenga's application.

⁶ Suspension of Request for Amendment to Exempt Distribution License and Application for New Sealed Source and Device Registration Dated April 24, 2020 for Cammenga and Associates, LLC, 1 (Oct. 27, 2020) (ML20296A362).

application in December 2020.⁷ The Staff sent an additional RAI, and Cammenga responded on April 29, 2021.⁸

By letter dated July 1, 2021, the Staff denied Cammenga's amendment request because "[t]he introduction of tritium into the product, and its subsequent distribution, may result in widespread use of radioactive materials and does not have a clear tangible benefit to the public."⁹

On July 21, 2021, Cammenga submitted its hearing request challenging the denial of its application.¹⁰ On July 29, 2021, the Atomic Safety and Licensing Board (Board) was established to preside over this adjudication.¹¹ On August 16, 2021, the Staff answered Cammenga's hearing request, agreeing that Cammenga's hearing request should be granted but noted that it would contest the merits of Cammenga's claims.¹² On August 25, 2021, the Board granted Cammenga's hearing request but deferred setting a date for a scheduling conference until

⁷ Amendment Request to SS&D #NR-0210-D-101-E and E-License 21-26460-03E (Dec. 30, 2020) (ML21006A199) (non-public).

⁸ See Cammenga and Associates, LLC, Request for Additional Information (Apr. 26, 2021) (ML21111A171); Cammenga Email and Letter (Apr. 29, 2021) (ML21137A111) (non-public).

⁹ Denial of Amendment Request Dated December 30, 2020, for Cammenga and Associates, LLC, License No. 21-26460-03E and Sealed Source and Device Registration Certificate NR-0210-D-101-E, Enclosure at 2 (July 1, 2021) (ML21139A100). Although the Staff characterized the July 1 denial letter as a denial of the application, the accompanying detailed denial statement did not explicitly address two of the designs (CLAM models 2S-6 and 2S-8). *Id.* at 1 & Enclosure at 1-2. The Staff subsequently received additional information from Cammenga necessary to make the requisite regulatory findings and approved CLAM models 2S-6 and 2S-8 outside of this adjudication. See Cammenga and Associates, LLC, Amendment of Exempt Distribution License and Sealed Source and Device Registration Certificate, 1 (Sept. 23, 2021) (ML21217A179).

¹⁰ Hearing Request (dated July 20, 2021) (ML21203A352) (non-public). Cammenga initially emailed its hearing request to the Staff on July 21, 2021. See Cammenga Email and Hearing Request (July 21, 2021) (ML21202A466) (non-public). Cammenga subsequently served the request as a non-public filing on the Electronic Information Exchange on July 22, 2021.

¹¹ Establishment of Atomic Safety and Licensing Board (July 29, 2021) (ML21210A380).

¹² NRC Staff's Answer to Hearing Request of Cammenga and Associates, LLC, 6 (Aug. 16, 2021) (ML21228A230) (non-public).

Cammenga had retained counsel.¹³ The Board granted the Staff's unopposed motion to defer the initial discovery deadlines until after Cammenga had retained counsel.¹⁴

On September 30, 2021, the Board set a scheduling conference for October 12, 2021.¹⁵ On October 8, 2021, the Parties jointly requested that the Board postpone discovery and hold the proceeding in abeyance; the parties also asked the Board to request that a Settlement Judge be appointed to oversee settlement negotiations.¹⁶ On October 12, 2021, the Board granted the Parties' joint motion and referred the request to appoint a Settlement Judge to the Chief Administrative Judge.¹⁷ On October 13, 2021, the Chief Administrative Judge appointed Administrative Judge William J. Froehlich to serve as a Settlement Judge in this proceeding.¹⁸ The Parties held settlement conferences with Judge Froehlich on November 3, 2021; November 29, 2021; February 3, 2022; and November 4, 2022. The Parties also continued to engage in productive settlement negotiations between settlement conferences.

Discussion

The Parties request that the Board terminate this proceeding because the parties have resolved the disputed issues. As a result of the settlement conferences, additional discussions

¹³ See *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Granting Hearing Request; Deferring Scheduling Conference) (Aug. 25, 2021) (ML21237A312).

¹⁴ See Unopposed NRC Staff Motion to Defer Initial Discovery Deadlines Under 10 C.F.R. §§ 2.336 and 2.1203 (Aug. 30, 2021) (ML21242A250); *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Granting Unopposed NRC Staff Motion to Defer Initial Discovery Deadlines) (Sept. 1, 2021) (ML21244A220).

¹⁵ See *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Scheduling Conference) (Sept. 30, 2021) (ML21273A045).

¹⁶ See Joint Motion Requesting to Postpone Discovery, Hold Proceeding in Abeyance, and Request Appointment of a Settlement Judge (Oct. 8, 2021) (ML21281A245).

¹⁷ See *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Granting Joint Motion and Referring to Chief Administrative Judge for Appointment of Settlement Judge) (Oct. 12, 2021) (ML21285A232).

¹⁸ *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Appointment of Settlement Judge) (Oct. 13, 2021) (ML21286A145).

between the Parties, and further submissions by Cammenga, the Parties have developed the proposed settlement agreement, included as Attachment A to this motion. The Parties believe this proposed settlement agreement is a fair, reasonable, and efficient resolution to all the disputed issues in this proceeding.

In particular, Cammenga provided the Staff with sufficient information to make regulatory findings and approve a subset of the designs in Cammenga's various applications. Specifically, under this agreement, the Staff agrees to approve the following designs:

GR-S1.1, GR-S2.1, GR-S3.1, GR-S4.1, SP-S1.1, SP-S2.1, SP-S3.1, SP-S4.1, SP-B1, MJ-S1.1, MJ-S2.1, MJ-S3.1, MJ-S4.1, GR-S1.2, GR-S2.2, GR-S3.2, GR-S4.2, SP-S1.2, SP-S2.2, SP-S3.2, SP-S4.2, MJ-S1.2, MJ-S2.2, MJ-S3.2, MJ-S4.2, GR-S1.3, GR-S2.3, GR-S3.3, GR-S4.3, SP-S1.3, SP-S2.3, SP-S3.3, SP-S4.3, MJ-S1.3, MJ-S2.3, MJ-S3.3, and MJ-S4.3.

Cammenga agrees to withdraw its hearing request for the designs that are not listed above (and the CLAM models 2S-6 and 2S-8 that were approved by the Staff outside of the attached proposed settlement agreement). Additionally, the Parties agree that the public interest does not require the adjudication of the issues because the Staff has made reasonable assurance findings with respect to the devices subject to the settlement agreement, and there are no disputed issues to litigate. The proposed settlement agreement also is consistent with the Commission's policy encouraging the "fair and reasonable settlement and resolution of issues."¹⁹

¹⁹ 10 C.F.R. § 2.338 (2022).

Conclusion

For the reasons stated above, the Parties respectfully request that the Board grant this motion, approve the proposed settlement agreement included as Attachment A, issue the consent order included as Attachment B, and terminate this proceeding.

/Signed (electronically) by/

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Executed in Accord with 10 C.F.R. § 2.304(d)

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Dated in Washington, DC
this 26th day of January 2023

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of

CAMMENGA AND ASSOCIATES, LLC

(Denial of License Amendment Requests)

Docket No. 030-38679-LA

Certificate of Service

Pursuant to 10 C.F.R. § 2.305, I hereby certify that copies of the foregoing "JOINT MOTION TO APPROVE PROPOSED SETTLEMENT AGREEMENT AND TERMINATE PROCEEDING," dated January 26, 2023, have been served upon the Electronic Information Exchange (the NRC's E-Filing System), in the captioned proceeding, this 26th day of January 2023.

/Signed (electronically) by/

Nicolas P. Mertz
Counsel for NRC Staff
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U.S. Nuclear Regulatory Commission
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E-mail: Nicolas.Mertz@nrc.gov

Dated in Washington, DC
this 26th day of January 2023

Attachment A: Proposed Settlement Agreement

**Proposed Settlement Agreement Between
U.S. Nuclear Regulatory Commission
And
Cammenga and Associates, LLC**

This agreement is made by and between the Staff of the U.S. Nuclear Regulatory Commission (NRC Staff or Staff) and Cammenga and Associates, LLC (Cammenga), to wit:

Whereas, Cammenga is the holder of NRC License No. 21-26460-03E and Sealed Source and Device Registration Certificate NR-0210-D-101-E;

Whereas, Cammenga submitted an application requesting amendments to its exempt distribution license and registration certificate to permit the distribution of more than twenty new VERSA series devices;

Whereas, the Staff reviewed Cammenga's application, as supplemented and resubmitted, and issued a July 1, 2021, letter denying Cammenga's amendment requests to allow distribution of certain VERSA models;

Whereas, on July 21, 2021, Cammenga transmitted its hearing request challenging the denial of its application;

Whereas, on July 29, 2021, an Atomic Safety and Licensing Board (Board) was established to preside over the proceeding;

Whereas, on August 16, 2021, the Staff answered Cammenga's hearing request. The Staff agreed that the hearing request should be granted but noted that it would contest the merits of Cammenga's claims;

Whereas, on August 25, 2021, the Board granted Cammenga's hearing request but deferred setting a date for a scheduling conference until Cammenga had retained counsel;

Whereas, on October 12, 2021, the Board granted the Staff and Cammenga's (hereinafter, the Parties) joint motion requesting that the Board postpone discovery, hold the proceeding in abeyance, and that the Board request that the Chief Administrative Judge appoint a Settlement Judge to oversee settlement negotiations;

Whereas, on October 13, 2021, the Chief Administrative Judge appointed Administrative Judge William J. Froehlich to serve as a Settlement Judge in this proceeding;

Whereas, the Parties held settlement conferences with the Settlement Judge on November 3, 2021, November 29, 2021, February 3, 2022, and November 4, 2022. The Parties also continued to engage in productive settlement negotiations between settlement conferences;

Whereas, the Parties agree that the public interest does not require the adjudication of the issues resolved by the settlement agreement because the Staff has made reasonable assurance findings with respect to the devices subject to the settlement agreement, and there are no disputed issues to litigate. The settlement agreement also is consistent with the Commission's policy encouraging the "fair and reasonable settlement and resolution of issues;"¹ and

Whereas, the PARTIES AGREE TO THE FOLLOWING IN SETTLEMENT:

1. Based on application materials and information provided during settlement negotiations, the Staff has determined that Cammenga has resolved the issues raised in the July 1, 2021, denial letter and met the regulatory requirements in 10 C.F.R. § 32.22 and § 32.210 for a subset of the designs in its various applications. The Staff agrees to

¹ 10 C.F.R. § 2.338 (2022).

approve the following designs as described in registration certificate NR-0210-D-101-E, as amended January 19, 2023:

GR-S1.1, GR-S2.1, GR-S3.1, GR-S4.1, SP-S1.1, SP-S2.1, SP-S3.1, SP-S4.1, SP-B1, MJ-S1.1, MJ-S2.1, MJ-S3.1, MJ-S4.1, GR-S1.2, GR-S2.2, GR-S3.2, GR-S4.2, SP-S1.2, SP-S2.2, SP-S3.2, SP-S4.2, MJ-S1.2, MJ-S2.2, MJ-S3.2, MJ-S4.2, GR-S1.3, GR-S2.3, GR-S3.3, GR-S4.3, SP-S1.3, SP-S2.3, SP-S3.3, SP-S4.3, MJ-S1.3, MJ-S2.3, MJ-S3.3, and MJ-S4.3.

The Staff is approving these designs with the nominal dimensions, combined with tolerances of +/- 0.1 millimeter as noted in the drawings included in NR- 0210-D-101E or referenced therein. The Staff will amend Cammenga's exempt distribution license, License No. 21-26460-03E, and Sealed Source and Device Registration Certificate NR-0210-D-101-E, consistent with this approval.

2. The Staff will issue the amended license and registration certificate described in Paragraph (1) to Cammenga within 5 days of the Board approving this settlement agreement.²
3. Cammenga agrees to withdraw its hearing request with respect to designs that are not covered by the description in Paragraph (1) and the CLAM models 2S-6 and 2S-8 that were previously approved by the Staff outside of this settlement agreement. The hearing request withdrawal shall be effective upon the Board's approval of this settlement agreement and termination of this proceeding.
4. All regulatory requirements and conditions that apply to entities holding licenses under 10 C.F.R. § 32.22 and registration certificates under 10 C.F.R. § 32.210 shall apply to

² See 10 C.F.R. § 2.306 (2022) (providing procedures for counting of days).

Cammenga just as they would if the approval in Paragraph (1) had been issued through the traditional licensing process, regardless of whether the relevant requirement or condition uses the example language mentioned in this paragraph or similar but different language. Accordingly, for the purposes of regulatory applicability, Cammenga is deemed to be a “licensee,” a “person licensed under § 32.22,” a “person licensed by the Commission pursuant to regulations” in 10 C.F.R. Part 32, and a “certificate holder.” Similarly, activities authorized by the approval described in Paragraph (1) constitute “activities authorized by the license issued under § 32.22.”

5. Consistent with 10 C.F.R. § 2.338(h), the Parties agree that:
 - a. This proposed settlement agreement admits all jurisdictional facts;
 - b. The Parties expressly waive further procedural steps before the presiding officer, any right to challenge or contest the validity of the order entered into in accordance with this proposed settlement agreement, and all rights to seek judicial review or otherwise contest the validity of the consent order;
 - c. The order implementing this proposed settlement agreement has the same force and effect as an order made after full hearing; and
 - d. The matters identified in this proposed settlement agreement that were required to be adjudicated have been resolved by the proposed settlement agreement and consent order.
6. This settlement agreement shall be effective upon the Board’s approval. Should the Board disapprove this settlement agreement, it shall be null and void.

WHEREOF, the Parties have executed this agreement as of the last date written below.

/Signed (electronically) by/

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Executed in Accord with 10 C.F.R. § 2.304(d)

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Dated in Washington, DC
this 26th day of January 2023

Attachment B: Consent Order

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:

G. Paul Bullwork, III, Chairman
Dr. Gary S. Arnold
Nicholas G. Trikouros

In the Matter of

CAMMENGA AND ASSOCIATES, LLC

(Denial of License Amendment Requests)

Docket No. 030-038679-LA

ASLBP No. 21-972-01-LA-BD01

_____, 2023

ORDER

(Approving Proposed Settlement Agreement and Terminating Proceeding)

1. In February 2020, Cammenga and Associates, LLC, (Cammenga) requested that the Nuclear Regulatory Commission Staff (NRC Staff) amend its exempt distribution license (License No. 21-26460-03E) and its registration certificate (Sealed Source and Device (SS&D) Registration Certificate NR-0210-D-101-E) to allow distribution of new devices.¹
2. The amendment requests relate to Cammenga's VERSA series of devices. By letter dated July 1, 2021, the Staff denied Cammenga's request because "[t]he introduction of tritium into the product, and its subsequent distribution, may result in widespread use of radioactive materials and does not have a clear tangible benefit to the public."²

¹ Cammenga and Associates, LLC, Materials License No. 21-26460-03E (Nov. 18, 2021) (ML21322A246); Cammenga and Associates, LLC, Registry of Radioactive Sealed Source and Device, Safety Evaluation of Device (Amended in its Entirety) No. NR-0210-D-101-E (Sept. 23, 2021) (ML21217A090) (non-public).

² Denial of Amendment Request Dated December 30, 2020, for Cammenga and Associates, LLC, License No. 21-26460-03E and Sealed Source and Device Registration Certificate NR-0210-D-101-E, Enclosure at 2 (July 1, 2021) (ML21139A100). Although the Staff characterized the July 1 denial letter as

3. On July 21, 2021, Cammenga transmitted its hearing request challenging the denial of its application.³
4. On July 29, 2021, this Atomic Safety and Licensing Board (Board) was established to preside over this proceeding.
5. On August 16, 2021, the Staff answered Cammenga's hearing request, agreeing that Cammenga's hearing request should be granted but noting that it would contest the merits of Cammenga's claims.⁴
6. On August 25, 2021, the Board granted Cammenga's hearing request but deferred setting a date for a scheduling conference until Cammenga had retained counsel.⁵
7. The Board granted the Staff's unopposed motion to defer the initial discovery deadlines until after Cammenga had retained counsel.⁶
8. On September 30, 2021, the Board set a scheduling conference for October 12, 2021.⁷

a denial of the application, the accompanying detailed denial statement did not explicitly address two of the designs (CLAM models 2S-6 and 2S-8). *Id.* at 1 & Enclosure at 1-2. The Staff subsequently received additional information from Cammenga necessary to make the requisite regulatory findings and approved CLAM models 2S-6 and 2S-8 outside of this litigation. See *Cammenga and Associates, LLC, Amendment of Exempt Distribution License and Sealed Source and Device Registration Certificate*, 1 (Sept. 23, 2021) (ML21217A179).

³ Hearing Request (dated July 20, 2021) (ML21203A352) (non-public). Cammenga initially emailed its hearing request to the NRC staff on July 21, 2021. See *Cammenga Email and Hearing Request* (July 21, 2021) (ML21202A466) (non-public). Cammenga subsequently served the request as a non-public filing on the Electronic Information Exchange on July 22, 2021.

⁴ NRC Staff's Answer to Hearing Request of Cammenga and Associates, LLC, 6 (Aug. 16, 2021) (ML21228A230) (non-public).

⁵ *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Granting Hearing Request; Deferring Scheduling Conference) (Aug. 25, 2021) (ML21237A312).

⁶ Unopposed NRC Staff Motion to Defer Initial Discovery Deadlines Under 10 C.F.R. §§ 2.336 and 2.1203 (Aug. 30, 2021) (ML21242A250); *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Granting Unopposed NRC Staff Motion to Defer Initial Discovery Deadlines) (Sept. 1, 2021) (ML21244A220).

⁷ *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Scheduling Conference) (Sept. 30, 2021) (ML21273A045).

9. On October 8, 2021, the parties jointly requested that the Board postpone discovery and hold the proceeding in abeyance; the parties also asked the Board to request that a Settlement Judge be appointed to oversee settlement negotiations.⁸
10. On October 12, 2021, the Board granted the parties' joint motion and referred the request to appoint a Settlement Judge to the Chief Administrative Judge.⁹
11. On October 13, 2021, the Chief Administrative Judge appointed Administrative Judge William J. Froehlich to serve as a Settlement Judge in this proceeding.¹⁰
12. The parties held settlement conferences with Judge Froehlich on November 3, 2021; November 29, 2021; February 3, 2022; and November 4, 2022. The parties also continued to engage in productive settlement negotiations between settlement conferences.
13. On January 26, 2023, the Staff and Cammenga jointly submitted to this Board both a proposed settlement agreement that would resolve all of the disputed issues in this proceeding and a motion requesting that the Board approve the proposed settlement agreement and terminate this proceeding.
14. Upon review of the proposed settlement agreement, the Board is satisfied that its terms reflect a fair and reasonable settlement of all the issues in this proceeding and that the public interest does not require the adjudication of these issues. Therefore, the Board grants the parties' joint motion and approves the proposed settlement agreement.
15. The settlement agreement, attached hereto, is hereby incorporated into this Order.

⁸ See Joint Motion Requesting to Postpone Discovery, Hold Proceeding in Abeyance, and Request Appointment of a Settlement Judge (Oct. 8, 2021) (ML21281A245).

⁹ *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Granting Joint Motion and Referring to Chief Administrative Judge for Appointment of Settlement Judge) (Oct. 12, 2021) (ML21285A232).

¹⁰ See *Cammenga and Associates, LLC* (Denial of License Amendment Requests), Order (Appointment of Settlement Judge) (Oct. 13, 2021) (ML21286A145).

16. Because the parties have resolved all issues in dispute, the proceeding is terminated.

It is so ORDERED.