

Enclosure 1 to AAL-021-005 Rev. 0
Response to Request for Additional Information
Dated June 22, 2021

ATOMIC ALCHEMY INC.

NRC RAI NUMBER	ATOMIC ALCHEMY RAI NUMBER	ATOMIC ALCHEMY RESPONSE
NRC RAI #1	AAL-021-005-01	Response enclosed – see page 2 and Enclosure 2
NRC RAI #2a	AAL-021-005-02	Response enclosed - see page 2
NRC RAI #2b	AAL-021-005-03	Response enclosed –see page 3
NRC RAI #2c	AAL-021-005-04	Response enclosed - see page 3
NRC RAI #2d	AAL-021-005-05	Response enclosed - see page 3
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NRC RAI #2g	AAL-021-005-08	Response enclosed - see page 4
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NRC RAI #1**NRC Letter Date: April 26, 2021****ML21091A114****NRC Acceptance Review of Atomic Alchemy QAPD**

1. **Text of NRC Question:** Provide Atomic Alchemy's basis for using ASME NQA-1-2017. This should include a comparison of the guidance in ASME NQA-1-2017 with the 2015 revision of ASME NQA-1 (ASME NQA-1-2015), the justification for using the newer version, and the basis for how conforming with ASME NQA-1-2017 will demonstrate compliance with the applicable regulations.

Atomic Alchemy Response AAL-021-005-01:

Atomic Alchemy's response to this question is provided in Enclosure 2.

NRC RAI #2**NRC Letter Date: April 26, 2021****ML21091A114****NRC Acceptance Review of Atomic Alchemy QAPD**

2. **Text of NRC Question:** Clarification of References and Definitions:
 - a. **Text of NRC Question:** Clarify Atomic Alchemy's definition of safety-related structures, systems and components that will be covered by the QAPD.

Atomic Alchemy Response AAL-021-005-02:

In NQA-1-2017, Part I, Introduction, Section 400, the term "safety function" is already defined.

Atomic Alchemy expands* the term "safety related" beyond the Part 50 regulatory definitions provided in 10 CFR 50.2, 10 CFR 50.55a(h)(3) and 10 CFR 50.49 to also include "Items Relied On For Safety" (IROFS) as defined in 10 CFR 70.65(b)(4), 10 CFR 70.61(b) and 10 CFR 70.61(c). For simplicity, the additional IROFS defined components will be identified as "safety related" in the FSAR and covered by the QAPD.

Atomic Alchemy FSAR Chapter 3, Section 2, subsection "Safety Related Group Classification" and design input procedure AA0-QAP-AAX-001-01, "Safety Related Classification of Structures, Systems, and Components" defines "safety-related" as follows:

- a) Maintain the reactor coolant boundary integrity.
- b) Maintain the capability to shut down the reactor and keep it in a safe-shutdown condition.
- c) Maintain the capability to prevent or mitigate accidents that could lead to onsite or offsite radiation exposure comparable to the guidelines in 10 CFR 50.34(a)(1) and 10 CFR 20, subparts C and D.
- d) *Maintain the assurance that exposure from licensed material or hazardous chemicals produced from licensed material to an onsite individual will not lead to any irreversible or long-lasting health effects, and any such incident does not exceed a mild transient effect to the public and environment.
- e) *Maintain assurance that a criticality accident is not credible.

Systems, structures, and components that are determined to be safety-related in accordance with the Atomic Alchemy determination design input procedure will be covered under the Atomic Alchemy QAPD.

Associated QAPD Revisions:

No revisions to the QAPD have been identified associated with this response.

- b. **Text of NRC Question:** Section 2.1.1., “Definitions,” refers to ASME NQA-1-2017, Part I, Section 400. Clarify if this reference is Part I, Introduction, Section 400.

Atomic Alchemy Response AAL-021-005-03:

Yes, that is correct. It should state: “ASME NQA-1-2017, Part I, Introduction, Section 400”.

Associated QAPD Revisions:

This will be corrected in the next revision of the QAPD.

- c. **Text of NRC Question:** The Atomic Alchemy QAPD’s “Executive Summary” lists a subset of regulations from Appendix A of NUREG-1537, Part 1. Clarify if 10 CFR 34(a)(6) should be 10 CFR 50.34(a)(6); 10 CFR 34(a)(7) should be 10 CFR 50.34(a)(7); and verify if 10 CFR 50.54 should have (j) listed twice.

Atomic Alchemy Response AAL-021-005-04:

Yes, that is correct. It should state: “10 CFR 50.34(a)(6)” and “10 CFR 10.34(a)(7)” respectively.

No, 10 CFR 50.54(j) should not have been listed twice.

Associated QAPD Revisions:

This will be corrected in the next revision of the QAPD.

- d. **Text of NRC Question:** Section 2.1.5 of Atomic Alchemy’s QAPD commits to compliance with NQA-1-2017, Part II, Section 600-604. Clarify if this reference is Part II, Introduction, Section 600-604.

Atomic Alchemy Response AAL-021-005-05:

Yes, that is correct. It should state: “NQA-1-2017, Part II, Introduction, Section 600-604”.

Associated QAPD Revisions:

This will be corrected in the next revision of the QAPD.

- e. **Text of NRC Question:** When referring to NQA-1-2017 in the Atomic Alchemy QAPD, use the term “Requirement” and a number consistent with NQA-1-2017 instead of the term “Basic Requirement” and a number.

Atomic Alchemy Response AAL-021-005-06:

Yes, that was a typographical error.

Associated QAPD Revisions:

This will be corrected in the next revision of the QAPD.

- f. Text of NRC Question: The Atomic Alchemy QAPD Section 3.1 references ASME QME-1-2017 and ASME B&PV Code Section III 2017 quality standards. The last paragraph of the “Policy Statement” states, “...and the latest edition of ASME BPV Code Section III 2017 quality standards.” The term “latest edition” should be removed because the QAPD should reference a specific version of the Code.

Atomic Alchemy Response AAL-021-005-07:

Yes, that is correct.

Associated QAPD Revisions:

The sentence will be revised to read: “...and ASME BPV Code Section III 2017 quality standards.”

- g. Text of NRC Question: The Atomic Alchemy QAPD Section 18.6 states, “Atomic Alchemy may delegate control of Part I, Criterion XVIII services, if necessary, to qualified suppliers through the contracts....” Clarify what is meant by Criterion XVIII services.

Atomic Alchemy Response AAL-021-005-08:

With respect to 10 CFR 50 Appendix B, Criterion XVIII, Atomic Alchemy may choose to delegate control of conducting program audits to outside consulting firms that specialize in such audits. Their qualifications would be reviewed and approved by Atomic Alchemy.

Associated QAPD Revisions:

The sentence will be revised to read more clearly with respect to the vendor services and Criterion XVIII.

NRC RAI #3

NRC Letter Date: April 26, 2021

ML21091A114

NRC Acceptance Review of Atomic Alchemy QAPD

3. **Text of NRC Question:** Provide current or pre-submittal (construction permit) organization chart and proposed construction organization chart or submit them prior to use for review and approval. Explain how the pre-submittal (construction permit) organization chart and proposed construction organization chart are consistent with the guidance and demonstrate compliance with the applicable regulations.

Atomic Alchemy Response AAL-021-005-09:

Atomic Alchemy is presently in the preliminary design phase. Upon selection of a consortium A/E construction partner(s), a construction organization chart will be developed and provided in SAR Chapter 13, Appendix A, “Construction Related Organization”. The proposed construction organization chart will be submitted to the NRC prior to its implementation.

Associated QAPD Revisions:

No revisions to the QAPD have been identified associated with this response at this time.

NRC RAI #4**NRC Letter Date: April 26, 2021****ML21091A114****NRC Acceptance Review of Atomic Alchemy QAPD**

4. **Text of NRC Question:** Provide clarification on the frequency of audits of the applicable elements of Atomic Alchemy's QA program as it relates to regulatory position C.4.

Atomic Alchemy Response AAL-021-005-10:

Atomic Alchemy interprets Regulatory Guide 1.28, position C.4.a to be applicable to facilities prior to placing the facility into operation. This interpretation would be consistent with NQA-1-2017, Part I, Requirement 18, 201.1 which reads: "Nuclear Facilities Prior to Placing the Facility into Operation. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter". NQA-1-2017, Part I, Requirements 201.2 reads: "*Nuclear Facilities After Placing the Facility into Operation. All applicable quality assurance program elements for each functional area shall be audited within a period of 2 years...*".

Atomic Alchemy will clarify this distinction in its QAPD to be more congruent with NQA-1-2017 and regulatory guide 1.28, position C.4.a.

Associated QAPD Revisions:

The sentence will be revised in the next revision to the QAPD as follows: "During the construction phase, internal audits of selected aspects of licensing, design, construction activities are performed with a frequency to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter".

NRC RAI #5**NRC Letter Date: April 26, 2021****ML21091A114****NRC Acceptance Review of Atomic Alchemy QAPD**

5. **Text of NRC Question:** Clarify Atomic Alchemy's regulatory change process to be used prior to receipt of a license and/or construction permit and how it satisfies the requirements of 10 CFR 50.4(b)(7)(ii).

Atomic Alchemy Response AAL-021-005-11:

Atomic Alchemy interprets "changes" to the QAPD as an approved by management revision to the document. Proposed changes to the QAPD that are annotated in a "draft revision" version of the document are not implemented by Atomic Alchemy until the document's latest revision is approved by both Atomic Alchemy management and the NRC. Prior to implementing any of the changes, the document will be submitted to the NRC under 10 CFR 50.4(b)(7)(ii).

Further, Atomic Alchemy interprets the clarifications that are accepted by the NRC in the docketed RAI responses to also be considered acceptable by the NRC for the purpose of inclusion in the QAPD.

Associated QAPD Revisions:

No revisions to the QAPD have been identified associated with this response at this time.

NRC RAI #6**NRC Letter Date: April 26, 2021****ML21091A114****NRC Acceptance Review of Atomic Alchemy QAPD**

6. **Text of NRC Question:** Clarify how these exceptions and alternatives will be controlled and implemented into the QAPD and reported to the NRC in accordance with 10 CFR 50.4(b)(7)(ii) prior to Atomic Alchemy becoming a license holder.

Atomic Alchemy Response AAL-021-005-12:

Atomic Alchemy interprets “changes” to the QAPD as an approved by management revision to the document. Proposed changes to the QAPD that are annotated in a “draft revision” version of the document are not implemented by Atomic Alchemy until the document’s latest revision is approved by both Atomic Alchemy management and the NRC.

It is presumed that items that would comprise the table in QAPD Part VII, “Exceptions and Alternatives to ASME NQA-1, ASME QME-1, and ASME B&PV Section III,” would not be identified until well into the detailed and final design phases of the facility. They would be tracked at that time by the Enterprise Data Management System (EDMS) of the Atomic Alchemy A/E consortium partner. This is also presumed to take place after receipt of a construction license. Under that scenario, Atomic Alchemy would then submit the revised QAPD under 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(4). These exceptions, and alternatives (if any) would not be used in construction until NRC approval is received.

Should some exceptions or alternatives to the ASME NQA-1, ASME QME-1, or ASME codes and standards be identified earlier in the preliminary or early design phases, they will be tracked by either the EDMS of the A/E consortium partner (if already in place), or by the creation of “tracking” corrective actions items in the Atomic Alchemy CAP program. If this occurs prior to receipt of a construction license, and if the need necessitates, Atomic Alchemy will submit a revision of the QAPD which includes these items to the NRC under 10 CFR 50.4(b)(7)(ii). Atomic Alchemy may choose to procure long lead items at risk, but in no event would exceptions or alternatives to the ASME codes and standards be used in construction prior to receiving NRC Approval.

Associated QAPD Revisions:

No revisions to the QAPD have been identified associated with this response at this time.

NRC RAI #7**NRC Letter Date: April 26, 2021****ML21091A114****NRC Acceptance Review of Atomic Alchemy QAPD**

7. **Text of NRC Question:** Please explain how the quality assurance organization will have direct communication with management so that the required authority and organizational freedom is achieved.

Atomic Alchemy Response AAL-021-005-13:

In the organization chart figure submitted in the topical report, there is already a direct line of communication depicted between the General Manager Quality Assurance Program and the Chief Operating Officer. Additionally, in the QAPD, Part I, Section 1.1.1, the description of the General Manager Quality Assurance Program states: "During the operations phase, the GMQAP reports to the COO". As stated in response to NRC RAI #3, Atomic Alchemy will submit the construction lines of communication and organizational chart in PSAR Chapter 13, Appendix A, "Construction Related Organization". The construction organization chart will depict an identical direct line of communication to the COO. The proposed construction organization chart will be submitted to the NRC prior to its implementation.

Associated QAPD Revisions:

No revisions to the QAPD have been identified associated with this response at this time.

NRC RAI #8

NRC Letter Date: April 26, 2021

ML21091A114

NRC Acceptance Review of Atomic Alchemy QAPD

8. **Text of NRC Question:** In Table 2, "Atomic Alchemy QAPD Regulatory Commitments," clarify if or which of these programs will be incorporated into the QAPD or which programs will be created and implemented in accordance with the controls and provisions of the Atomic Alchemy QAPD.

Atomic Alchemy Response AAL-021-005-14:

Atomic Alchemy commitment AA0-RC-0001, "QAPD to be based on ASME NQA-1-2017 'Quality Assurance Requirements for Nuclear Facility Applications', ASME QME-1-2017 'Qualification of Active Mechanical Equipment Used in Nuclear Power Plants', and 'ASME BPVC Section III 2017 quality standards' and commitment AA0-RC-0012, 'Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)' will be incorporated into the QAPD and controlled by 10 CFR 50.4(b)(7)(ii) until Atomic Alchemy receives a construction license, at which point it will be controlled under 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(4).

The remaining commitments AA0-RC-0002 through AA0-RC-0011, and AA0-RC-0013 through AA0-RC-0017 are programs that are created and will be implemented in accordance with the controls and provisions of the QAPD. These commitments will be controlled in accordance with guidance in NEI 99-04 and NRC RIS 00-017.

Atomic Alchemy identifies all programs in FSAR Chapter 13, Appendix A, "Operational Programs". (None of these committed programs falls under the programs required by regulations).

Associated QAPD Revisions:

This distinction will be clarified/corrected in the next revision of the QAPD.