Enclosure 2 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 following pages
NRC RAI #2a	AAL-021-005-02	Response enclosed – see Enclosure 1
NRC RAI #2b	AAL-021-005-03	Response enclosed – see Enclosure 1
NRC RAI #2c	AAL-021-005-04	Response enclosed – see Enclosure 1
NRC RAI #2d	AAL-021-005-05	Response enclosed – see Enclosure 1
NRC RAI #2e	AAL-021-005-06	Response enclosed – see Enclosure 1
NRC RAI #2f	AAL-021-005-07	Response enclosed – see Enclosure 1
NRC RAI #2g	AAL-021-005-08	Response enclosed – see Enclosure 1
NRC RAI #3	AAL-021-005-09	Response enclosed – see Enclosure 1
NRC RAI #4	AAL-021-005-10	Response enclosed – see Enclosure 1
NRC RAI #5	AAL-021-005-11	Response enclosed – see Enclosure 1
NRC RAI #6	AAL-021-005-12	Response enclosed – see Enclosure 1
NRC RAI #7	AAL-021-005-13	Response enclosed – see Enclosure 1
NRC RAI #8	AAL-021-005-14	Response enclosed – see Enclosure 1

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.

The response to this question has been further divided into 3 elements:

- NRC RAI 1: Comparison of the Guidance Between ASME NQA-1-2017 and ASME NQA-1-2015

  Atomic Alchemy Response AAL-021-005-01: Atomic Alchemy has prepared a table matrix (below) identifying the changes in ASME NQA-1-2017 versus ASME NQA-1-2015. There are 45 changes in total identified in the 2017 edition. However, while all the differences have been compared and reviewed, it is Atomic Alchemy's opinion that only the identified differences in Part I and Part II are relevant in responding to the NRC's RAI #1.

- NRC RAI 1: Justification for Using a Version of the NQA-1 Not Previously Endorsed in Regulatory Guide 1.28

  Atomic Alchemy Response AAL-021-005-01: Atomic Alchemy's NPUF design will incorporate digital software, digital I&C controls, commercial grade dedication components, and the transportation and storage of radioactive materials. The Requirements of NQA-1-2017 exceed the Basic Requirements of NQA-1-2015 in these areas. Software engineering, design, development, acquisition, testing, and control requirements identified in NQA-1-2017 are superior in establishing the necessary quality standards for safety related systems and components.

- NRC RAI 1: Basis for Compliance with Applicable Title 10 Regulations

  Atomic Alchemy Response AAL-021-005-01: It is Atomic Alchemy's opinion that its use of any version of ASME NQA-1 will be sufficient in demonstrating to the NRC its compliance with both the acceptance criterion of NUREG-1537 Part 2, SRP Section 12.9, and its compliance with NPUF applicable Title 10 regulations.

  For non-power NPUF designs, the NRC has already established in Division 2, Regulatory Guide 2.5 that the requirements of ANSI/ANS-15.8-1995 are adequate in demonstrating compliance with NUREG-1537, Part 2, SRP Section 12.9, and the NPUF applicable Title 10 regulations. Atomic Alchemy utilizes Regulatory Guide 1.70 and NUREG-0800 as a means of establishing and formatting the basic content of its SAR. ASME NQA-1-2017 follows the NRC guidance for compliance with the specified Title 10 regulations contained within NUREG-0800, Section 17.5 Acceptance Criterion.

  The elements of the quality assurance standards of ASME NQA-1-2017 far exceed the quality standards established in ANSI/ANS-15.8-1995. The acceptance criterion for quality standards of NUREG-0800 Section 17.5 are more prescriptive and exceeds the acceptance criteria provided in NUREG-1537, Part 2, Section 12.9. Therefore, the use of any version of ASME NQA-1 as the basis of a NPUF Quality Assurance Program meets the NRC's expectations for demonstrating compliance with 10 CFR 50.4, 10 CFR 50.34(a)(7) and other NPUF applicable Title 10 regulations.

NQA-1-2017, Part IV, Subpart 4.1.3 Table 300, provides more in-depth guidance to the quality standards for meeting the requirements of 10 CFR Part 71 and 10 CFR 72 regulations.

NQA-1-2017, Part IV, Subpart 4.1.5, Tables 201-1 through 201-21 provide in-depth comparative analysis between NQA-1 and ANSI/ANS-15.8-1995. With very few exceptions[1], NQA-1 is more prescriptive in specifying and defining acceptance criteria for establishing quality standards for safety related components.

Associated QAPD Revisions:

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

[1] See Table 2, in this AAL-021-005-000, Enclosure 2.

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Change Number	**NQA-1-2017 page number(s)[2]**	**Location in NQA-1-2017**	**Change Type Revised/Added/ Deleted**	**NQA-1 2015 Version**	**NQA-1 2017 Version**	**Description of the Change**	**Impact on Quality**
1	vi, vii	Correspondence With the NQA Committee	**DELETED:** "PREPARATION OF TECHNICAL INQUIRIES TO THE NUCLEAR QUALITY ASSURANCE COMMITTEE" **ADDED:** "CORRESPONDENCE WITH THE NQA COMMITTEE"	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Administrative change Revised how to prepare correspondence to and communicate with the ASME Quality Assurance Committee. Expanded the role of the ASME committee communications to include proposed revisions.	No impact on quality
2	18	Part I, Requirement 7, 200	**REVISED:** Subparagraphs (b) and (c)	"(b) Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated. (c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's quality assurance program."	"(b) Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated and may include current third-party certificates that recognize the Supplier's quality assurance program (QAP) or other technical certifications. (c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's QAP."	Significant change Expands the scope of the means of compliance to include third-party certificates.	Provides additional flexibility, no impact on quality.

[2] Unless otherwise noted

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3	34-36	Part II, Contents	**DELETED:** Subpart 2.4, Subpart 2.16, **ADDED:** Subpart 2.17 Subpart 2.19	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Administrative change to the contents section. (The impact of the specific added and deleted sections will be addressed elsewhere in this table.)	No impact on quality.
4	63 in NQA-1-2015	Part II, Subpart 2.4 in NQA-1-2015	**DELETED:** Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities".	Deleted	N/A	Administrative change The "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities" was deleted from this section in its entirety in NQA-1-2015.	No impact to quality. There is no corresponding requirement to this in ANSI/ANS 15.8. NQA-1-2012, Part II, Subpart 2.4 consisted of ANSI/IEEE Std. 336-1985, IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities. IEEE-336-1985 is superseded by IEEE-336-2020. Since this section was deleted earlier in NQA-1-2015, and that version was endorsed by the NRC in Regulatory Guide 1.28, there is no

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							change to the quality by using NQA-1-2017.
5	89, 90	Part II, Subpart 2.14, 603	**REVISED:** Subparagraph (h) **ADDED:** Subparagraph (j)	"(h) Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys. The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s)."	"(h) Organizations performing surveys shall establish processes for performing those surveys. Collectively, personnel assigned to conduct commercial grade surveys shall have the necessary capabilities in auditing functions and shall have appropriate technical knowledge to evaluate the supplier's controls associated with the critical characteristics to be verified. (j) For a supplier of calibration or testing services, the Purchaser may utilize the requirements of Part II, Subpart 2.19 as an alternative to the commercial grade survey requirements of (a)."	Significant change Expands the scope of the means of compliance to offer alternative methods.	Provides additional flexibility; no impact on quality.
6	102 in NQA-1-2015	Part II, Subpart 2.16 in NQA-1-2015	**DELETED:** Part II, Subpart 2.16, "Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities"	Deleted	N/A	Administrative change The entire section "Control of Measuring and Test Equipment" was re-written and moved to NQA-1-2017, Part I, Requirement 12.	No impact on quality NQA-1-2012, Part II, Subpart 2.16 was cancelled due to the cancellation of ANSI/IEEE Std. 498, IEEE Standard Requirements for

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							Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities. Since this section was deleted earlier in NQA-1-2015, and that version was endorsed by the NRC in Regulatory Guide 1.28, there is no change to the quality by using NQA-1-2017.
7	101,102	Part II, Subpart 2.17	ADDED: Part II, Subpart 2.17, "Quality Assurance Requirements for Electronic Quality Assurance Records Systems"	N/A	Subpart 2.17 "Quality Assurance Requirements for Electronic Quality Assurance Records Systems" added in its entirety.	Significant change Entire Subpart 2.17 specific for electronic quality assurance records systems is added.	Provides an improvement to quality assurance of electronic record systems.
8	103,104	Part II, Subpart 2.18, 200	REVISED: Wording in subsection 200	"Design or modification information shall be available to the operating organization so that it can review the adequacy of provisions for the maintenance program in accordance with the requirements of Subpart 2.18."	"Design or modification information shall be available to the operating organization so that it can review the adequacy of provisions for the maintenance program in accordance with the requirements of this Subpart.[1]" Footnote 1 reads: "10 CFR 50.65, Requirements for Monitoring the Effectiveness of	Administrative change to the wording	No impact on quality.

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					Maintenance at Nuclear Power Plants, provides regulatory requirements for U.S.-licensed nuclear power plants."		
9	105	Part II, Subpart 2.18, 402	**REVISED:** Subparagraph (b)	(b) documenting and reporting of failures, in accordance with pre-established criteria, to (1) designated levels of management responsible for failure analyses, authorization of corrective action, and performance of corrective action (2) Supplier and/ or regulatory authority, as required	(b) documenting and reporting of failures, in accordance with pre-established criteria, to (1) designated levels of management responsible for failure analyses, authorization of corrective action, and performance of corrective action (2) Supplier and/or regulatory authority, as required	Administrative change to the wording	No impact on quality
10	106, 107	Part II, Subpart 2.19	**ADDED:** Part II, Subpart 2.19, "Quality Assurance Requirements for the Use of Supplier Accreditation for Calibration or Testing Services"	N/A	Subpart 2.19 "Quality Assurance Requirements for the Use of Supplier Accreditation for Calibration or Testing Services" added in its entirety.	Significant change Additional quality criteria for requirements for the use of supplier accreditation for calibration of testing services. Expands the scope within the standard by which a licensee can outsource quality assurance tasks to a vendor.	Provides additional flexibility; no impact on quality.
NQA-1 PART III AND PART IV ARE NOT REQUIREMENTS TO THE NQA-1 STANDARD. EVALUATION OF THESE CHANGES ARE PROVIDED FOR INFORMATION ONLY							

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11	118, 119	Part III Contents	**REVISED:** Contents table for PART III: "Guidance for Implementing Parts I and II Requirements."	TABLE OMITTED FOR BREVITY	TABLE OMITTED FOR BREVITY	Administrative change to revise the contents section of Part III. (The impact of the specific revised sections will be addressed elsewhere in this table.)	No impact on quality.
12	127, 128	Part III, Subpart 3.1-2.2, Figure 300	**REVISED:** Figure 300	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Sample form for Record of Lead Auditor Qualification—2nd page added for annual assessment of proficiency	Provides an improvement in quality in documenting auditor qualifications.
13	142	Part III, Subpart 3.1-4.1, 701	**REVISED:** Examples (c) through (e)	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Administrative change to the wording	No impact on quality.
14	145, 146	Part III, Subpart 3.1-7.1, 302	**REVISED:** Subsection 302	Objectively evaluate the Supplier's current quality records supported by documented qualitative and quantitative information. This may include review and evaluation of the Supplier's quality assurance program, manual, and procedures, as appropriate.	Objectively evaluate the Supplier's current quality records supported by documented qualitative and quantitative information. This may include review and evaluation of the Supplier's quality assurance program (QAP), manual, and procedures, as appropriate. When reviewing quality records, third party QAP certificates should be included in the review. The degree of reliance placed upon such certificates to satisfy the quality records evaluation should be based on a review of the third-	Revised subsection 302 to be more prescriptive and expands the examples of acceptable third-party certifications.	Provides clarification and improves quality.

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					party process and limited to the scope of activity identified on the certificate. Examples of third-party certificates include, but are not limited to, QAPs developed using the following standards and codes: ASME NQA-1, ASME Boiler and Pressure Vessel Code Section III, ISO 17025, and ISO 9001. Part IV of NQA-1 provides comparisons of some other standards with NQA-1 to facilitate the evaluation of certificates. Certificates issued to standards other than NQA-1 should be evaluated to understand the differences in requirements and define actions necessary to address those differences affecting the purchase. A third-party certificate issued specifying that the supplier's QAP is based on NQA-1 should be the most useful as evidence that it conforms to NQA-1.		
15	149-151	Part III, Subpart 3.1-15.1	**ADDED:** Subpart 3.1-15.1	N/A	FULL TEXT OMITTED FOR BREVITY	Subpart 3.1-15.1 "Implementing Guidance for Part I, Requirement 15: Control of Nonconforming Items" added in its entirety.	Provides an improvement in quality to processing non-conforming items with additional clarification.

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16	150	Part III, Subpart 3.1-15.1	**ADDED:** Figure 100	N/A	FIGURE OMITTED FOR BREVITY	A non-conforming item process chart was added.	Provides an improvement in quality to processing non-conforming items with additional clarification.
17	153	Part III, Subpart 3.1-16.1	**REVISED:** Figure 300	FIGURE OMITTED FOR BREVITY	FIGURE OMITTED FOR BREVITY	A corrective action process chart was added.	Provides an improvement in quality to processing corrective actions with additional clarification.
18	155-158	Part III, Subpart 3.1-17.1	**REVISED:** Subsections 100 through 109. **ADDED:** Subsection 110.	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Miscellaneous additional prescriptive requirements added to subsections 100 through 109. Subsection 110 (Record Destruction) added in its entirety.	Provides an improvement in quality to records with additional clarifications. Adding additional guidance for the destruction of records gives full “cradle to grave” quality control scope.
19	159-163	Part III, Subpart 3.1-17.2	**REVISED:** Subsections 100 through 700 revised in their entirety **ADDED:** Subsections 800 and 900.	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Subpart 3.1-17.2 “Implementing Guidance for Part I, Requirement 17: Quality Assurance Records, Electronic Records” revised in its entirety. Miscellaneous additional prescriptive requirements added to subsections 100 through 700, added	Provides an improvement in quality to records with additional clarifications for electronic record maintenance of records system and system integrity and record recovery.

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						subsections 800 and 900. Requirements for electronic signatures, electronic record systems, media conversion, environmental considerations, portable media storage, disposal and recovery of electronic records are among the added and revised changes.	
20	165, 166	Part III, Subpart 3.1-18.1, 302.5	**REVISED:** Subsection 302.5	The audit plan should identify how the audit will be performed and those key processes and product characteristics that have the greatest influence on item performance. For example, the audit may focus on product manufacturing processes, such as a critical assembly technique. Conversely, if a specific process is routinely inspected and has a stable performance history, the process may not need to be evaluated during the audit.	The audit plan should identify how the audit will be performed and those key processes and product characteristics that have the greatest influence on item performance. For example, the audit may focus on product manufacturing processes, such as a critical assembly technique. Conversely, if a specific process is routinely inspected and has a stable performance history, the process may not need to be evaluated during the audit. When an audited organization holds a current NQA-1QAP certificate (e.g., ASME) that is recognized by the auditor's organization, the Lead Auditor may consider tailoring the audit plan adjusting the scope, team,	Additional prescriptive requirements added to subsection 302.5 to permit adjusting the scope, team, or duration to better tailor the audit.	Provides an improvement in quality of audits being performed by allowing more flexibility to tailor the audit.

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					and/or duration. The tailored audit plan may then allow efforts to focus more on effective implementation of the functions and activities having the greatest impact on the quality of items or services.		
21	177, 178	Part III, Subpart 3.2-2.7.2, 200	**REVISED:** Subpart 200	This Subpart organizes the requirements for software of the Standard into 11 software and NQA-1 related processes that are pictorially illustrated in a series of flowcharts. These 11 processes apply to software and include processes uniquely applicable to computer programs. The processes are: (a) software ·engineering concepts (b) software design requirements (c) software configuration management (d) support software and tools (e) problem reporting and corrective action (f) computer program design (g) computer program implementation (h) computer program testing (i) computer program operation, maintenance, and retirement	This Subpart organizes the requirements for software of the Standard into 12 software and NQA-1 related processes that are pictorially illustrated in a series of flowcharts. These 12 processes apply to software and include processes uniquely applicable to computer programs. The processes are: (a) software engineering (b) software design requirements (c) software configuration management (d) support software and tools (e) problem reporting and corrective action (f) software design (g) software reviews (h) software design implementation (i) computer program testing	Additional prescriptive requirements added, some NQA-1 processes modified. The scope of NQA-1 related processes is expanded to 12 from 11.	Provides an improvement to the quality of selecting, acquiring, testing, and maintaining software.

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				(j) software acquisition, including commercial grade dedication (k) computer program use in design analysis The flowcharts introduce no new requirements for software. The majority of the requirements presented in the flowcharts are in the exact language of the Standard. In those instances where the language of a requirement is modified, clarified, or interpreted, it is specifically noted. Each process or flowchart presents the initial requirement, illustrates how that requirement flows through the Standard, and finally, identifies any related requirements.	(j) software operation, maintenance, and retirement (k) software acquisition (l) computer program use in design analysis The flowcharts introduce no new requirements for software. The majority of the requirements presented in the flowcharts are in the exact language of the Standard. In those instances where the language of a requirement is modified, clarified, or interpreted, it is specifically noted. Each process or flowchart presents the initial requirement, illustrates how that requirement flows through the Standard, and finally, identifies any related requirement		
22	177. 178	Part III, Subpart 3.2-2.7.2, 201	**REVISED:** Subpart 201	Figures 201-1 through 201-3 provide a pictorial illustration of the Standard's computer program requirements for 3 of the 11 processes described above, their flow through the Standard, related requirements, and any interdependencies between these requirements. The three selected processes for	Figures 201-1 through 201-12 provide a pictorial illustration of the Standard's computer program requirements in Parts I and II for the processes described above, their flow through the Standard, related requirements, and any interdependencies	Additional prescriptive requirements added, section modified to address additional flowcharts to cover all 12 of the NQA-1 processes as well as address any interdependencies.	Provides an improvement to the quality of selecting, acquiring, testing, and maintaining software.

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				this edition of the Standard are software design requirements, computer program testing, and software configuration management. Flow charts for the remaining processes will be published in subsequent editions of the Standard. These flowcharts are provided for guidance and illustration only and do not necessarily present all considerations that have to be made to ensure compliance with the Standard.	between these requirements. These flowcharts are provided for guidance and illustration only and do not necessarily present all considerations that have to be made to ensure compliance with the Standard.		
23	179-183	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-1	**DELETED:** Figure 201-1 flowchart "Software Design requirements" **ADDED:** Figure 201-1 flowchart "Software Engineering"	FIGURE OMITTED FOR BREVITY	FIGURE OMITTED FOR BREVITY	The flow chart Figure 201-1 in NQA-1-2015 is deleted in its entirety. A new flow chart is added in NQA-1-2017 as Figure 201-1, "Software Engineering". Computer program requirements are revised to expand the software engineering framework and to add elements in 12 flowcharts. Software engineering quality requirements are added. Life cycle activities, configuration management, problem reporting, design inputs,	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.

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						design verification, computer program testing, development of baseline documents are among the extensive changes included in this new flowchart.	
24	184	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-2	**DELETED:** Figure 201-2 flowchart "Computer Program Testing" **ADDED:** Figure 201-2 flowchart "Software Design Requirements"	FIGURE OMITTED FOR BREVITY	FIGURE OMITTED FOR BREVITY	The flow chart in NQA-1-2015 is deleted in its entirety. A new flow chart is added in NQA-1-2017. Computer program requirements are revised to expand the software engineering framework and to add elements in 12 flowcharts. The software design requirements of NQA-1-2015 flow chart Figure 201-1 are now presented as flow chart Figure 201-2 in NQA-1-2017.	No impact on quality.
25	185	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-3	**REVISED:** Figure 201-3 flowchart "Software Configuration Management"	FIGURE OMITTED FOR BREVITY	FIGURE OMITTED FOR BREVITY	Minor layout and formatting corrections made to the flow chart figure.	No impact on quality.
26	186	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-4	**ADDED:** Figure 201-4 flowchart: Support Software and Tools"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring,

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							testing, and maintaining software.
27	187	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-5	**ADDED:** Figure 201-5 flowchart "Problem Reporting and Corrective Action"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
28	188	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-6	**ADDED:** Figure 201-6 flowchart "Software Design"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
29	189	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-7	**ADDED:** Figure 201-7 flowchart "Software Reviews"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
30	190	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-8	**ADDED:** Figure 201-8 flowchart "Software Design Implementation"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
31	191-193	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-9	**ADDED:** Figure 201-9 flowchart "Computer Program Testing"	N/A	FIGURE OMITTED FOR BREVITY	The software design requirements of NQA-1-2015 flow chart Figure 201-2 are now presented as flow chart Figure 201-9 in NQA-1-2017. The testing criterion is expanded in its scope to include added quality	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.

TABLE 1 - COMPARATIVE ANALYSIS OF CHANGES TO ASME NQA-1-2017 QA STANDARDS FROM ASME NQA-1-2015 QA STANDARDS							
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						requirements for in-use testing, site testing, factory acceptance testing, simulation models etc.	
32	194	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-10	**ADDED:** Figure 201-10 flowchart "Software Operation, Maintenance, and Retirement"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
33	195, 196	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-11	**ADDED:** Figure 201-11 flowchart "Software Acquisition"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
34	197	Part III, Subpart 3.2-2.7.2, 201, Fig. 201-12	**ADDED:** Figure 201-12 flowchart "Computer Program Use in Design Analysis"	N/A	FIGURE OMITTED FOR BREVITY	The 12 software and NQA-1 related processes are pictorially illustrated in a series of flowcharts.	Provides an improvement to the guidance for quality in selecting, acquiring, testing, and maintaining software.
35	219-222	Part IV Contents	**REVISED:** Table of Contents for Part IV	TABLE OMITTED FOR BREVITY	TABLE OMITTED FOR BREVITY	The Part IV table of contents was reformatted, some sections were renumbered for consistency along with other incidental administrative type changes.	No impact on quality.
36	224-238	Part IV, Subpart 4.1.1	**REVISED:** Subpart 4.1.1 Title, and section	"Guidance to Modification of an ISO 9001 :2008, Quality Management Systems	Guidance to Modification of an ISO 9001:2015 Quality Management	Part IV, Subpart 4.1.1 is revised in its entirety. Guidance to modify a	Provides an improvement to quality, the guidance

TABLE 1 - COMPARATIVE ANALYSIS OF CHANGES TO ASME NQA-1-2017 QA STANDARDS FROM ASME NQA-1-2015 QA STANDARDS							
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				Standard for Compliance With NQA-1-2008, Part I with the NQA-la-2009 Addenda". FULL TEXT OMITTED FOR BREVITY	System for Compliance With NQA-1–2015, Part I. FULL TEXT OMITTED FOR BREVITY	quality program from an ISO-9000 standard to NQA-1 standards is revised to conform to the later revisions.	has been revised to meet the more current standards.
37	244-250	Part IV, Subpart 4.1.3	**REVISED:** Subpart 4.1.3 Title and section.	Guidance on the Use of NQA-1-2000 for Compliance With 10 CFR 71 and/or 10 CFR 72 Requirements. FULL TEXT OMITTED FOR BREVITY	Guidance on the Use of NQA-1–2015 for Compliance With 10 CFR 71 and/or 10 CFR 72 Requirements. FULL TEXT OMITTED FOR BREVITY	Part IV, Subpart 4.1.3 is revised in its entirety. Guidance for using NQA-1 standards for conformance to the regulatory requirements of Title 10, Parts 71 and 72 is revised to address the later revision of NQA-1 standards.	Provides an improvement to quality, the guidance has been revised to address the more current standards.
38	289	Part IV, Subpart 4.2.1 Table 600-1	**REVISED:** Part IV, Subpart 4.2.1 Row 15	15. Control of Nonconforming Items: Note (2) Note (2) Note (2) Note (1)	15. Control of Nonconforming Items: Note (2) Note (3) Note (2) Note (1)	Part IV, Subpart 4.2.1, Table 600-1, row 15, reference revised.	Improvement to quality since control of non-conforming items for R&D is now applicable.
39	289	Part IV, Subpart 4.2.1 Table 600-2	**REVISED:** Part IV, Subpart 4.2.1 Rows: "Applied" and "Development and Support"	FULL TEXT OMITTED FOR BREVITY	FULL TEXT OMITTED FOR BREVITY	Part IV, Subpart 4.2.1, Column "Deliverable" for rows "Applied" and "Development and Support" were revised. This is considered an administrative /editorial type change to correctly refer to other renumbered sections in the standard.	No impact on quality.
40	290	Part IV, Subpart 4.2.1, 603.1	**REVISED**: Part IV, Subpart 4.2.1, 603.1	603.1 The NQA-1 design criterion applies to engineering design definition,	603.1 The NQA-1 design criterion applies to engineering design	Part IV, Subpart 4.2.1, 603.1 is revised to provide	No impact on quality.

TABLE 1 - COMPARATIVE ANALYSIS OF CHANGES TO ASME NQA-1-2017 QA STANDARDS FROM ASME NQA-1-2015 QA STANDARDS							
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				verification, and change control in all phases of R&D using a graded approach. Software Design Control (section 800) as an element of Requirement 3 provides for special considerations for software design in order to provide a traceable product that can be reviewed (e.g., peer review). Design control does not apply to design of experiments or experimental plans for basic and applied research; design of experiments and experimental plans should be addressed under Requirement 2.	definition, verification, and change control in all phases of R&D using a graded approach. Software Design Control (section 800), as an element of Requirement 3, directs software activities to Subpart 2.7, providing for special considerations for software design in order to provide a traceable product that can be reviewed (e.g., peer review). Design control does not apply to design of experiments or experimental plans for basic and applied research; design of experiments and experimental plans should be addressed under Requirement 2.	additional reference to Subpart 2.7. This is considered an administrative/ editorial type change to provide further clarification.	
41	290	Part IV, Subpart 4.2.1, 603.4	**REVISED:** Part IV, Subpart 4.2.1, 603.4	603.4 Development and Support. For development and support activities, the level of design control should be applied to support the input needs of the design process. (For software design control, Subpart 2. 7 should also be considered.) In some cases, considerable importance is placed on R&D results to demonstrate the acceptability of innovative design.	603.4 Development and Support. For development and support activities, the level of design control should be applied to support the input needs of the design process. (See Table 600-1 for recommended Standard sections.) In some cases, considerable importance is placed on R&D results to demonstrate the acceptability of innovative design.	Table 600-1 added as reference to NQA-1-2017.	No impact on quality.

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42	292	Part IV, Subpart 4.2.1, 611.2.1	**REVISED:** Part IV, Subpart 4.2.1, 611.2.1	611.2.1 Computer Program. The nature of software efforts, whether as a part (or tool) of the effort being undertaken or the effort itself, benefits from the documentation of testing efforts. As such, it is important to provide documentation of the testing activities in order to provide a traceable process to aid in peer review.	611.2.1 Computer Program. The nature of software efforts, whether as a part (or tool) of the effort being undertaken or the effort itself, benefits from the documentation of testing efforts. (See Table 600-2 for recommended Standard sections.) As such, it is important to provide documentation of the testing activities in order to provide a traceable process to aid in peer review.	Table 600-2 added as reference to NQA-1-2017.	No impact on quality.
43	292	Part IV, Subpart 4.2.1, 611.4	**REVISED:** Part IV, Subpart 4.2.1, 611.4	611.4 Development and Support. Characteristics to be tested and test methods should be specified. The test results should be documented and their conformance to acceptance criteria evaluated. Tests required should be planned, executed, documented, and evaluated. Testing as part of computer program testing should consider Subpart 2.7.	611.4 Development and Support. Characteristics to be tested and test methods should be specified. The test results should be documented and their conformance to acceptance criteria evaluated. Tests required should be planned, executed, documented, and evaluated. (See Table 600-2 for recommended Standard sections.)	Table 600-2 added as reference to NQA-1-2017.	No impact on quality.
44	292	Part IV, Subpart 4.2.1, 615	**REVISED:** Part IV, Subpart 4.2.1, 615	615 NQA-1, Requirement 15: Control of Nonconforming Items FULL TEXT OMITTED FOR BREVITY	615 NQA-1, Requirement 15: Control of Nonconforming Items FULL TEXT OMITTED FOR BREVITY	Part IV, Subpart 4.2.1, 615 is revised to expand the guidance for addressing non-conforming items.	No impact on quality.

TABLE 1 - COMPARATIVE ANALYSIS OF CHANGES TO ASME NQA-1-2017 QA STANDARDS FROM ASME NQA-1-2015 QA STANDARDS							
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						This is considered an administrative/ editorial type change to provide further clarification.	
45	295	Part IV, Subpart 4.2.2	**DELETED:** Part IV, Subpart 4.2.2	SUBPART 4.2.2 Guidance for Managing Electronic Information FULL TEXT OMITTED FOR BREVITY	N/A	Part IV, Subpart 4.2.2 deleted in its entirety. The information and requirements for quality maintenance of electronic information is addressed in Part II, SUBPART 2.17 "Quality Assurance Requirements for Electronic Quality Assurance Records System"	No impact on quality.

TABLE 2 - COMPARATIVE ANALYSIS OF CORRESPONDING ANSI/ANS-15.8 TO ASME NQA-1-2017 SECTIONS[3]			
ANSI/ANS-15.8	**Description**	**ASME NQA-1-2017**	**Atomic Alchemy Method of Compliance**
2.19	Experimental Equipment	No corresponding requirement	In Atomic Alchemy FSAR Chapter 10, quality assurance standards for safety related experimental equipment will be described. Additionally, QAPD, Part I, Section 2, subsection 2.1.9, the Atomic Alchemy Plant Nuclear Safety Review Committee (PNSRC) reviews proposed tests and experiments not defined in the FSAR, Chapter 10.
3.5	Operating Conditions	No corresponding requirement	NQA-1, Part I, Requirement 14, indirectly addresses this since status indicators shall be provided for indicating the operating status of systems and components of the nuclear facility. NQA-1, Part III, Subpart 3.1-17.1, 206 indirectly addresses this, since the control of plant conditions, status records, logs etc. must be maintained. Atomic Alchemy Administrative controls (delineating pre-requisite steps, tag outs, etc.) in ops procedures will further address the verification of the operability of SSCs prior to their being placed in service.
3.6	Operational Authority	No corresponding requirement	NQA-1, Part III, Subpart 3.1-17.1, 206 indirectly addresses this also, since the control of plant operations are by operational procedures, and shift logs, operational logs, status records, etc. must be maintained accordingly. Atomic Alchemy Administrative controls in ops procedures will further address the operators' responsibilities, lines of authority, and delegation of tasks.
3.7	Control Area	No corresponding requirement	The control area is defined by regulations, 10 CFR 73.2 defines the vital area. Access control to the control room (and other vital areas) would be addressed by administrative controls in procedures, the Atomic Alchemy Access Authorization Program will include provisions for limiting access to the control room and other vital areas to specific individuals with appropriate clearances. Abnormal Operations Manuals and Procedures, FLEX Support Guidelines and Severe Accident Management Guidelines and procedures will provide instructions to operators in case there is a need to evacuate the control room.

[3] Excerpted from ASME NQA-1-2017, Part IV, Subpart 4.1.5, Table 200-20 Corresponding NQA Sections (Parts I and II) to ANSI/ANS-15.8

TABLE 2 - COMPARATIVE ANALYSIS OF CORRESPONDING ANSI/ANS-15.8 TO ASME NQA-1-2017 SECTIONS[3]			
ANSI/ANS-15.8	**Description**	**ASME NQA-1-2017**	**Atomic Alchemy Method of Compliance**
3.8	Ancillary Duties	No corresponding requirement	As part of startup and testing, a control room design review will be performed following the guidance of NUREG-0700 to ensure the HFE aspects of the control room design and the tasks to be performed by operators. Atomic Alchemy establishes administrative control room procedures that defines the duties, and lines of authority of control room operators that meet the intent[4] of Regulatory Guide 1.114.
3.9	Emergency Communications	No corresponding requirement	Atomic Alchemy FSAR Chapter 13, Table 13.2-02 will delineate the interfaces including the lines of reporting responsibilities (e.g., from the plant manager to the immediate supervisors), lines of authority, and communication channels. FSAR Chapter 13, Appendix B will describe the Atomic Alchemy Emergency Plan. The emergency planning information will be submitted to the Nuclear Regulatory Commission as a separate licensing document and will be incorporated by reference in the FSAR. Abnormal Operations Manuals and Procedures, FLEX Support Guidelines, Severe Accident Management Guidelines and procedures provide instructions to operators for communicating site conditions and emergencies.
3.14	Operator Aid Postings	No corresponding requirement	Any postings that might be created as an aid to operators will be identified as part of the control room design review. If such postings are deemed necessary, they will be administratively controlled by procedures.
4	Applicability to Existing Facilities	As applicable	Not applicable to the Atomic Alchemy NPUF.
5	Decommissioning	As applicable	NQA-1, Part IV, Subpart 4.26 addresses quality assurance for decommissioning of a nuclear facility.

[4] An exception to 10 CFR 50.54(m)(2)(i) will be submitted to the NRC at a later date, as Atomic Alchemy believes that strict adherence to the regulation and regulatory guide 1.114 is not necessary for an NPUF.