Response to NRC Request for Additional Information Related to the QAPD Topical Report Submission for Atomic Alchemy’s Non-Power Production and Utilization Facility ASME NQA-1-2019 PART II, Subpart 2.19

ATOMIC ALCHEMY INC.

Dated October 8, 2021
SUBPART 2.19
Quality Assurance Requirements for the Use of Supplier Accreditation for Calibration or Testing Services

(19) 100 GENERAL
This Subpart provides amplified requirements for a Purchaser to accept supplier accreditation for calibration or testing services as an alternative to supplier evaluation and selection requirements. It supplements the requirements of Part I and shall be used in conjunction with applicable requirements of Part I when and to the extent specified by the organization invoking this Subpart.

In this Subpart, the user shall apply the edition of ISO/IEC 17025 to which the applicable supplier’s program was accredited. For the purpose of this Subpart, either the 2005 or the 2017 edition of ISO/IEC 17025 is acceptable.

200 REQUIREMENTS
Purchasers that intend to utilize the requirements of this Subpart shall document this alternative method in their quality assurance program in accordance with the following.

(19) 201 Calibration Services
For a supplier of calibration services, the Purchaser may accept accreditation by accrediting bodies recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), provided the following minimum requirements are met:

(a) A review of the supplier’s accreditation shall be performed by the Purchaser and shall include verification that

(1) the accreditation is to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, from an accredited body recognized by the ILAC MRA
(2) the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties

(b) The Purchaser’s procurement documents shall specify the following as a minimum:

(1) that the calibration service must be provided in accordance with the accredited ISO/IEC 17025 program and scope of accreditation
(2) that the calibration certificate/report shall include identification of the laboratory equipment/standards used

(3) that the calibration certificate/report shall include as-found calibration data when calibrated items are found to be out-of-tolerance
(4) that the calibration service supplier shall not subcontract the service to any other supplier
(5) that the Purchaser must be notified of any condition that adversely impacts the calibration laboratory’s ability to maintain the scope of accreditation
(6) additional technical and quality requirements, as necessary, based on a review of the procured scope of services, including, but not limited to, tolerances, accuracies, ranges, and industry standards

(c) During acceptance of the calibration service, the Purchaser shall be responsible for validating that the supplier’s documentation certifies

(1) that the calibration service was performed in accordance with the supplier’s ISO/IEC 17025 program and scope of accreditation
(2) conformance to the Purchaser’s procurement document’s requirements

202 Testing Services
For a supplier of testing services, the Purchaser may accept accreditation by accrediting bodies recognized by the ILAC MRA, provided the following minimum requirements are met:

(a) A review of the supplier’s accreditation shall be performed by the Purchaser and shall include verification that

(1) the accreditation is to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, from an accredited body recognized by the ILAC MRA
(2) the published scope of accreditation for the testing laboratory covers the needed testing services, including test methodology and tolerances/uncertainty

(b) The Purchaser’s procurement documents shall specify the following as a minimum:

(1) that the testing service must be provided in accordance with the accredited ISO/IEC 17025 program and scope of accreditation
(2) that the testing service supplier shall not subcontract the service to any other supplier