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TECHNOLOGIES

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September 14, 2017

Document Control Desk  
U S Nuclear Regulatory Commission  
Washington, DC 20852-2738

Our Reference: NCTR 17-10, Rev. 00

Your Reference: NRC Vendor Inspection Report Number 99901478/2017-201

Subject: Response to Notice of Nonconformance Cited in NRC Inspection Report  
No. 99901478/2017-201 dated August 28, 2017.

Mirion Technologies (IST) Corporation (Mirion IST) acknowledges receipt of NRC Inspection Report Number 99901478/2017-201, dated August 28, 2017 and Notice of Nonconformance 99901478/2017-201-01. Mirion IST takes this Notice of Nonconformance received from the NRC seriously. Mirion IST is taking appropriate actions to resolve these issues; further we are committed to comply with the provisions of Appendix B, to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, and 10 CFR Part 21.

As requested, details of the corrective actions associated with this nonconformance issue are described in the attachment to this letter.

Very truly yours,

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IED9  
NRD



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NCTR 17-10 Rev. 00

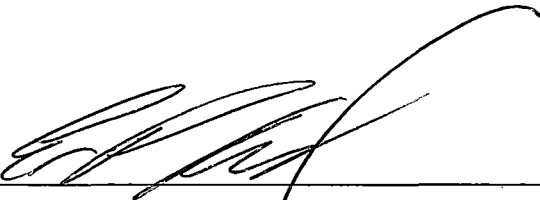
# Response to NRC Nonconformance 99901478/2017-201-01

September 14<sup>th</sup>, 2017

**MIRION TECHNOLOGIES (IST) CORPORATION**

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Rev. No.	Page No.	Description	Prepared By	Reviewed By	Endorsed By
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[1] The reason for the noncompliance or, if contested, the basis for disputing the noncompliance;

Prior to the year 2000, Mirion Technologies (IST) Corporation (“Mirion IST”) possessed a chemical/physical laboratory capable of performing positive material validation. The capabilities included quantitative chemical abilities and the ability to perform mechanical property assessment. These laboratory capabilities were used for the receipt validation process. In 2000, Mirion IST relocated to a new location, and limited in-house laboratory capabilities were established at the new facility. As a result, Mirion IST principally outsourced the receipt validation process to external independent labs evaluated in accordance with the Quality Assurance Program.

In 2010, Mirion IST obtained a Niton Alloy Analyzer for the purpose of performing positive material validation. The Niton Alloy Analyzer was acquired with the intent to increase the internal laboratory capabilities. The Niton Alloy Analyzer was implemented on October 5<sup>th</sup>, 2010.

The Niton Alloy Analyzer correctly identified the alloy of various test coupons. The alloys of these test coupons were analyzed and certified by an independent lab. The test coupons then became the point of use verification references before and after each use. The Niton Alloy Analyzer output was used in conjunction with the vendor submitted certifications to ensure material alloy concurrence. As identified during the NRC Inspection 99901478/2017-201 Mirion IST verified “the material characteristics of purchased metals using a Niton Alloy Analyzer. However, the analyzer failed to verify all chemical and material properties of the metals.”

The reason for noncompliance was determined to be that the Niton Alloy Analyzer was not capable of verifying the specified material properties. It was further determined that Mirion IST did not adequately evaluate the Niton Alloy Analyzer for its capabilities and limitations prior to its implementation. At the time, a process did not exist for the adequate assessment of the purchase/implementation of new analytical equipment.

[2] The corrective steps that have been taken and the results achieved;

- a. On August 24<sup>th</sup>, 2017 Mirion IST placed a stop shipment of safety-related items until the metals and metallic fasteners included in those items have been properly dispositioned.
- b. Mirion IST conducted a preliminary evaluation to determine what programmatic weaknesses allowed this to occur.
- c. Mirion IST suspended usage of the Niton Alloy Analyzer for the receipt acceptance of metals and metallic fasteners on July 31<sup>st</sup>, 2017.
- d. Mirion IST initiated a Corrective Action Request (CAR) in accordance with the Mirion IST Quality Assurance Program.

Mirion IST identified the extent of condition is limited to acceptance of metals and metallic fasteners received on or after October 5<sup>th</sup>, 2010 and until August 15<sup>th</sup>, 2017 as the acceptance of these materials was predicated primarily on the Niton Alloy Analyzer providing positive material validation.

Extent of Condition: Vendor lots of metals and metallic fasteners procured for production of safety-related items from October 5<sup>th</sup>, 2010 through August 15<sup>th</sup>, 2017. The extent of condition was bound to these limiting factors:

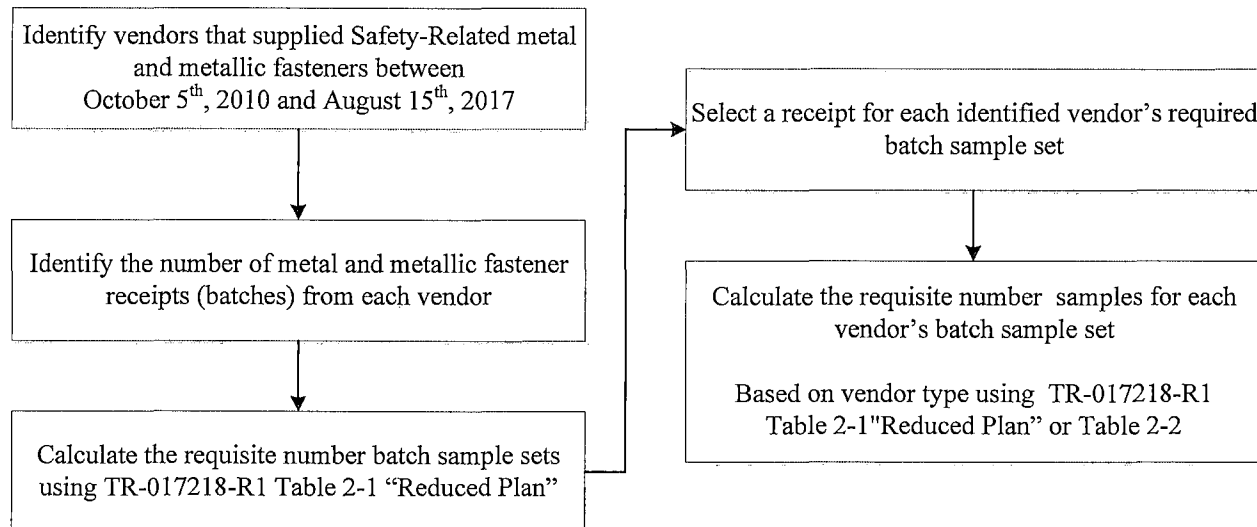
1. The NRC Inspection Report cited the usage of the Niton Alloy Analyzer as being the primary point of concern.
  2. The model of Alloy Analyzer used by Mirion IST, Niton XL3T/900S 50kev, is specifically restricted to metallic substrates.
  3. The first recorded usage of the Mirion IST owned Niton Alloy Analyzer was found to be October 5<sup>th</sup>, 2010.
- e. Prior to the usage of the Niton Alloy Analyzer, the principal method for positive material validation was analysis of the material properties through the usage of a qualified independent laboratory. Mirion IST developed a plan for establishing reasonable assurance that metal and metallic fasteners accepted during the extent of condition period met the imposed procurement requirement.

#### **Overview of Reasonable Assurance Initiative:**

A material validation initiative will be completed by Mirion IST. A statistical sampling approach will be utilized as the primary method to determine the acceptance of the materials. Material batches will be assessed by the independent laboratory analysis and acceptance of the metals and metallic fasteners' requisite material properties. These materials were previously accepted by Mirion IST's program through the usage of the Niton Alloy Analyzer in combination with the vendor-provided material batch certifications. Lot formations and sampling methodologies are based on EPRI's Guideline for Sampling in the Commercial-Grade Item Acceptance Process (hereinafter "TR-017218-R1"). Reasonable assurance that selected characteristics conform to acceptance requirements will be demonstrated through the evaluation of a vendor's material batch quality history record.

**Vendor Lot & Batch Sampling Formation:**

Each vendor was assessed to determine an appropriate lot formation based on TR-017218-R1.



**Independent Analysis and Acceptance:**

The specific test specimens to be assessed will be sent by Mirion IST for analysis for the requisite material properties by a Mirion IST-approved independent test laboratory. Acceptance of the material batch will be predicated on the results from the independent analysis being compared to the requirements for the selected characteristics. Acceptance of the batch lots for each of the identified vendors using the defined sampling methodology will establish reasonable assurance that metal and metallic fasteners accepted during the extent of condition period have met the imposed procurement requirements.

The validation documents for the items in this initiative will be completed and used to evaluate items for acceptability. Existing inventory of conforming items will be “restocked” as the item part number with a delineator. If an item from a given vendor does not conform to its validation document, all items from the vendor that have been used in shipped product will be evaluated using the Mirion IST 10 CFR Part 21 process.

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**Summary of Corrective Steps:**

The Mirion IST vendors who have supplied metals and metallic fasteners since the implementation of the Niton Alloy Analyzer have been identified. An appropriate EPRI based methodology was utilized to determine appropriate sampling of each vendor's receipts and to determine the requisite vendor lots to be validated.

The successful completion of this initiative will provide reasonable assurance that the properties of the previously accepted metals and metallic fasteners met the procurement requirements. Reasonable assurance is based on statistical sampling methodologies and backed by a historical precedence of acceptance and successful use. The prior acceptance of the material batches through the usage of the hardware/mill certifications with a Niton Alloy Analyzer analysis, combined with the material validation initiative being completed, provides reasonable assurance that correct materials were supplied. The aggregation of this information demonstrates the vendors supplying the materials had adequate quality controls in place.

**[3]** The corrective steps that will be taken to avoid further noncompliance;

It was determined that the reason for the noncompliance was primarily attributable to lack of procedural guidance on the evaluation and implementation of new analytical equipment. The following corrective measures will assure future compliance:

- a. A new Standard Operating Procedure (SOP) will be developed to ensure that adequate evaluations are completed prior to the implementation of any new analytical tooling.
- b. The Niton Alloy Analyzer will not be reintroduced as a tool used for acceptance until its capabilities and limitations are evaluated in accordance with the newly created SOP.
- c. Mirion IST Engineering has created a new process that clearly identifies the item's requisite attributes and the methods by which they are to be accepted. This new process introduces specifications referred to hereinafter as the "validation documents".
- d. For items received prior to August 16<sup>th</sup>, 2017 currently held in Incoming Inspection, validation documents will be completed and used to determine acceptability of items, prior to their release from Mirion IST's Incoming Inspection.
- e. Validation documents for items received on or after August 16<sup>th</sup>, 2017 will be completed and used to determine acceptability of items, prior to their release from Mirion IST's Incoming Inspection. Validation documents for new procurement specifications will be created and implemented prior to ordering the items.
- f. Items which do not conform to the validation document requirements will either be rejected by Mirion IST or be dispositioned by the appropriate cognizant organization (Equipment Qualification owner or Design Specification owner).
- g. The validation documents will be integrated into the safety-related product bill of materials and product equipment qualification baseline documents.

The implementation of the validation documents and modified future usage of the Niton Alloy Analyzer requires the following updates to the Quality Assurance Program:

- a. Quality Program Manual (QPM)
  1. Section 3 "Design Control"
  2. Section 6.6 "Technical Documents"
  3. Section 7.6 "Acceptance of Items or Services"
  4. Section 10 "Inspection"
  5. Section 15 "Control of Nonconformances"
- b. Standard Operating Procedures (SOPs)
  1. Create and implement a new SOP to define the newly-created-validation documents.
  2. Create and implement a new SOP to define the evaluation process prior to the implementation of new analytical tooling.
- c. Documentation supporting the acceptance of commercial materials will need to be revised.
  1. Receipt Inspection Instructions - specifically referencing the usage of the Niton Alloy Analyzer.
  2. Niton Alloy Analyzer process specification.

**[4]** The date when the corrective action will be completed. Mirion IST will complete the internal Corrective Actions by December 31<sup>st</sup>, 2017.