

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 2, 2023

EA-23-010

Donald Smith, Quality Assurance Director Mistras Services 1480 James Parkway Heath. OH 43056

SUBJECT: MISTRAS SERVICES - NOTICE OF VIOLATION

Dear Mr. Smith:

This letter refers to the inspection conducted on March 6 - 10, 2023 at Mistras Services (hereafter referred to as Mistras) facilities in Trainer, PA. The purpose of this limited-scope reactive inspection was to assess Mistras' compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." Inspection results were documented in Inspection Report No. 99902109/2023-01 (Agencywide Document Access and Management System (ADAMS) Accession No. ML23151A458).

The inspection report contained two apparent violations (AV). The first AV (99902109/2023-01-01) was related to Mistras' failure to have adequate procedures to implement its Part 21 program as required by 10 CFR 21.21(a)(1). The second AV (99902109/2023-01-02) was related to Mistras' failure to notify all affected NRC Licensees of a deviation related to its failure to ensure annual calibrations for the Acoustic Emission (AE) systems were performed as required by 10 CFR 21.21(b). The AE systems were used to perform inspections of lift rigs for reactor heads and internals at NRC Licensee facilities.

On July 11, 2023, a Pre-decisional Enforcement Conference (PEC) was conducted with Mistras representatives to discuss the AVs, their significance, and corrective actions. For AV 99902109/2023-01-01, Mistras acknowledged the violation occurred; however, Mistras provided a line of reasoning that the significance of the violation did not warrant escalated enforcement. For AV 99902109/2023-01-02, Mistras stated that no violation occurred because the company had not made a determination "that it does not have the capability to perform the evaluation of the deviation to determine if a defect exists," and thus Mistras was not required to "inform affected licensees of the deviation." A summary of the PEC is available (ADAMS Accession No. ML23209A819). Following the PEC, Mistras provided additional information in response to the NRC's questions during the PEC.

Based on the information presented by Mistras during and after the PEC, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (NOV) (Enclosure 1). Violation 99902109/2023-201-01 cites Mistras for failing to adopt appropriate procedures to evaluate deviations to identify defects as

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soon as practicable as required by 10 CFR 21.21(a)(1). Violation 99902109/2023-201-02 cites Mistras for (1) failing to evaluate a deviation, related to Mistras' failure to secure annual calibrations for the AE systems to determine if a defect exists within 60 days of discovery of this deviation as required by §21.21(a)(1); and (2) failure to submit an interim report to the Commission in accordance with §21.21(d) if the evaluation could not be completed within 60 days from discovery as required by §21.21(a)(2). Violations 99902109/2023-201-01 and 99902109/2023-201-02 are categorized as Severity Level IV violations (see Enclosure 2 for additional information). The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC's review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. Additionally, because the second SL IV violation in the Notice contains a noncompliance that was not included in the AVs, you may contest this violation or its significance.

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), should not include any personal privacy, proprietary, or safeguards information (SGI) so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

Kerri Kavanagh, Chief Quality Assurance Vendor Inspection Branch Division of Reactor Oversight Office of Nuclear Reactor Regulation

Docket No.: 99902109

EPID No.: I-2023-201-0002

Enclosures:

Notice of Violation
 Evaluation of Findings

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SUBJECT: MISTRAS SERVICES NOTICE OF VIOLATION DATE: October 2, 2023

DISTRIBUTION:

Ylaw, NRR Mfitzgerald, NRR PMcKenna, NRR Rfelts, NRR donald.d.smith@mistrasgroup.com

ADAMS Accession No.: ML23263B150

NRR-106

OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IQVB
NAME	Dzhang	Ggalletti	Dpark	MFitzgerald
DATE	9/22/2023	9/25/2023	9/25/2023	9/25/2023
OFFICE	NRR/DRO/IRAB	OE/EB	OGC/LHE/SE	NRR/DRO/IQVB
NAME	Bhughes	DJones	Kgamin	KKavanagh
DATE	9/25/2023	9/26/2023	10/2/2023	9/26/2023

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NOTICE OF VIOLATION

Mistras Services 1480 James Parkway Heath, OH 43056 Docket No. 99902109 Report No. 2023-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Mistras Services (hereafter referred to as Mistras) facility in Trainer, PA from March 6, 2023, through March 10, 2023, two violations of NRC requirements were identified. In accordance with the NRC's Enforcement Policy, the violations are listed below:

A. Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, paragraph (a)(1) requires, in part, that "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations... to identify defects... as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect."

Contrary to the above, as of March 10, 2023, Mistras failed to adopt appropriate procedures to evaluate deviations to identify defects as soon as practicable in order to identify a reportable defect, were it to remain uncorrected, as required by 10 CFR 21.21(a)(1). Specifically, Mistras procedure 100-QC-017.1, "Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21 and 10 CFR 50.55(e)," Revision 5 did not contain accurate criteria for the evaluation of deviations to identify defects. As a result, Mistras failed to perform an adequate evaluation of the deviation related to its failure to ensure annual calibrations for the Acoustic Emission (AE) systems to determine whether a defect exists. The AE system is used during inspections of reactor head and internals lift rigs at multiple NRC licensee facilities.

This issue has been identified as Violation 99902109/2023-201-01.

This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy).

B. Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, paragraph (a)(1) requires, in part, that "each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations to identify defects as soon as practicable, and except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery."

10 CFR 21.21(a)(2) requires, in part, that "each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to ensure that if an evaluation of an identified deviation cannot be completed within 60 days from discovery of the deviation, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5). The interim report should describe the deviation that is being evaluated and should also state when the evaluation will be

completed. This interim report must be submitted in writing within 60 days of discovery of the deviation."

Mistras procedure 100-QC-017.1, "Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21 and 10 CFR 50.55(e)," Revision 5, Section 6.7 states, "If a 10 CFR 21 reportable condition is evaluated by Mistras Services, a written report of the evaluation shall be prepared by the Quality Manager and reviewed by the Quality Assurance Director. The report shall be forwarded to the NRC within 60 days of discovery of the reportable condition. If the evaluation cannot be completed in 60 days, an interim report shall be prepared and submitted to the NRC. The interim report shall describe the reportable condition being evaluated and state when the evaluation will be completed."

Contrary to the above, as of March 10, 2023, Mistras failed to (1) evaluate a deviation to identify whether a defect existed within 60 days of its discovery as required by 10 CFR 21.21(a)(1) or (2) prepare and submit an interim report to the NRC within 60 days from discovery when an evaluation could not be completed within 60 days of discovery of the deviation as required by 10 CFR 21.21(a)(2). Specifically, since the discovery of a deviation on June 15, 2021 (i.e., Mistras' failure to secure annual calibrations for AE systems by the original equipment manufacturer or other approved source), Mistras failed to:

- complete an evaluation of this deviation within 60 days of discovery to determine whether a defect exists, or
- submit an interim report to the NRC in accordance with 10 CFR 21.21(d) within 60 days of discovery of this deviation, if Mistras could not complete its evaluation of this deviation within 60 days from its discovery.

As of the issuance date of this violation, Mistras has not performed either of these actions.

This issue has been identified as Violation 99902109/2023-201-02. This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy).

Under the provisions of 10 CFR Part 2.201, "Notice of Violation," Mistras is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality Assurance and Vendor Inspection Branch, Division of Reactor Oversight, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this notice of violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include (1) the reason for the violation or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence if the correspondence adequately addresses the required response. Where good cause is shown, the NRC will consider extending the response time.

If you contest this enforcement action, provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible it should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the agency can make it available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request that such material be withheld, you <u>must</u> specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements"

Dated this X day of September 2023

EVALUATION OF APPARENT VIOLATIONS AFTER PREDECISIONAL ENFORCEMENT CONFERENCE

On June 9, 2023, the U.S. Nuclear Regulatory Commission (NRC) issued an Inspection Report (ADAMS Accession No. ML2351A458) to Mistras Services (hereafter referred to as Mistras) that contained two apparent violations (AV): AVs 99902109/2023-201-01 and 99902109/2023-201-02.

On July 11, 2023, the NRC conducted a Pre-decisional Enforcement Conference (PEC) with Mistras representatives to discuss the apparent violations, their significance, and corrective actions (ADAMS Accession No. ML23209A819).

I. Restatement of AV 99902109/2023-201-01:

Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, paragraph (a)(1) requires, in part, that "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects as soon as practicable and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect." 10 CFR 21.21(d) requires a director or responsible officer to "notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect" as described in 10 CFR 21.21(d)(1)(i) or (ii).

As of March 10, 2023, Mistras failed to adopt appropriate procedures to evaluate deviations and failures to comply and identify defects as soon as practicable. Specifically, the Mistras implementing procedure for 10 CFR Part 21 did not contain accurate criteria for the evaluation of deviations to determine whether they could lead to a defect as required by 10 CFR 21.21(a)(1). In addition, Mistras procedure 100-QC-017.1, "Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21 and 10 CFR 50.55(e)," Revision 5, did not contain accurate criteria for the reporting of potential defects required by 10 CFR 21.21(d), in violation of 10 CFR 21.21(a). As a result of these issues, Mistras failed to perform an adequate evaluation of the deviation related to its failure to ensure periodic annual calibrations for the Acoustic Emission (AE) systems by the original equipment manufacturer or other approved source, which subsequently resulted in the failure to determine whether the deviation would lead to a defect. The AE system is used during inspections of reactor head and internals lift rigs at multiple NRC licensee facilities.

Summary of Mistras' PEC Response to AV 99902109/2023-201-01:

Mistras stated that AV 99902109/2023-201-01 should at most be a Severity Level (SL) IV violation and does not warrant escalated enforcement. Mistras asserted that the procedural violation identified in AV 99902109/2023-201-01 did not result in safety consequences to impacted Licensees. Mistras stated that examples of Part 21 violations categorized as SL III in the NRC's Enforcement Policy include: (1) inadequate review or failure to review, such that if an appropriate review had been made as required a 10 CFR Part 21 report would have been required, and (2) withholding of information or a failure to make a required interim report by 10 CFR 21.21 occurs with careless disregard. Mistras asserted that the NRC has not alleged a 10 CFR Part 21 report would have been required had the procedural deficiencies in AV 99902109/2023-201-01 not existed. Additionally, Mistras noted that NRC's inspection report did not assert that careless disregard was an element of the AV.

Mistras stated that planned (or partially implemented) corrective actions include: (1) rewriting the Part 21 evaluation procedure, and (2) implementing a new Nuclear Projects Division with oversight responsibilities over all nuclear projects.

NRC Evaluation of Mistras' Response

After considering Mistras' response during the PEC and supplemental information Mistras provided to the NRC following the PEC, the NRC agrees that the apparent violation should be categorized as SL IV. The NRC did not assign a significance of SL III in accordance with Section 6.9.c.5 of the NRC Enforcement Policy, because the NRC staff did not find sufficient evidence that, had Mistras performed an adequate 10 CFR Part 21 evaluation, a 10 CFR Part 21 report to the NRC would have been required, and in addition, the NRC staff did not find sufficient evidence that the withholding of information or failure to make an interim report occurred with careless disregard.

The NRC acknowledges Mistras' contention that the issue described in AV 99902109/2023-201-01 did not result in potential safety consequences to impacted Licensees. The NRC notes that Mistras' letter sent in March – April of 2023 to impacted licensees stated that Mistras has been:

- investigating a nonconformance related to failure to secure regular calibrations by the manufacturer or other approved source for AE systems used for AE testing of reactor head and internals lift rigs and for other various applications,
- evaluating the calibration nonconformance in accordance with 10 CFR Part 21 and Mistras procedure 100-QC-017.1, Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21 and 10 CFR 50.55(e), to determine if this may result in potential (latent) defects in safety-related equipment.

Mistras stated in these letters that it believed with reasonable assurance that the nature of the calibration deficiency would not likely result in any undetected defects in a safety-related component. NRC notes that Mistras' request in these letters for licensees to perform independent assessments indicates Mistras's awareness of potential safety consequences associated with these issues.

Based on the information provided in these letters, the NRC determined that Mistras failed to perform an adequate evaluation of the deviation related to its failure to secure annual calibration of the AE systems to identify if a defect exists. Specifically, Mistras' evaluation of the deviation failed to determine whether the use of non-calibrated AE systems for testing of lift rigs for heavy loads could create a condition or circumstance involving a basic component that could contribute to exceeding a safety limit, as per the definition of a defect in 10 CFR 21.3. The NRC determined that Mistras should evaluate whether this deviation could result in undetected flaws in the lift rig that upon the lifting of heavy loads (e.g., reactor head), could fail and drop the heavy load onto spent fuel, fuel in the core, or equipment that may be required to achieve safe shutdown and continue decay heat removal, and thus resulting in offsite dose that exceeds 10 CFR Part 100 limits or other safety limits in the technical specification of impacted licensees. Therefore, the NRC determined that Mistras failed to perform an adequate evaluation of the deviation related to failure to secure annual calibration of the AE system to identify a defect, in violation of 10 CFR Part 21.21(a)(1).

NRC Conclusion:

The NRC concludes that AV 99902109/2023-201-01 is issued as Violation 99902109/2023-201-01, which cites Mistras for failing to adopt appropriate procedures to evaluate deviations to identify defects as soon as practicable in order to identify a reportable defect, as required by 10 CFR 21.21(a)(1). In accordance with Section 6.9.d of the NRC Enforcement Policy, the significance of Violation 99902109/2023-201-01 is SL IV.

II. Restatement of AV 99902109/2023-201-02:

Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21, paragraph (b) states, in part, that "If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply."

Section 5.3 of Mistras' procedure, 100-QC-017.1, "Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21 and 10 CFR 50.55(e)," Revision 5, states, in part, that "The Quality Assurance Director, in conjunction with Purchasers or Affected Licensees representatives, shall evaluate the...deficiency and determine if it could create a substantial safety hazard..."

As of March 10, 2023, Mistras, a supplier of services associated with basic components, discovered a deviation, and not having the capability to perform evaluations to determine if a defect exists, failed to inform the purchasers, or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the failure to comply. Specifically, on June 15, 2021, Mistras discovered a deviation, related to Mistras' failure to secure regular calibrations of AE systems by the original equipment manufacturer or other approved source, and Mistras failed to notify all affected NRC licensees within five working days. The AE system is used to perform AE inspections of reactor head and internals lift rigs at multiple NRC licensee facilities.

Summary of Mistras' Response to AV 99902109/2023-201-02 during PEC:

Mistras denied AV 99902109/2023-201-02 on the basis that Mistras never made a determination that it was unable to perform the evaluation. Thus, Mistras asserted that the five working day requirement in 10 CFR 21.21(b) for notifying its impacted customers of the deviation related to failure to secure regular calibrations of AE systems in order for the customers to perform their own evaluation of this deviation was not triggered.

NRC Evaluation of Mistras' Response

The NRC carefully reviewed the information provided by Mistras during and following the PEC. The staff determined that there is not sufficient evidence to support the conclusion in AV 99902109/2023-201-02 that Mistras failed to inform the purchasers or affected licensees within five working days of determining that it did not have the capability to perform an evaluation of the deviation related to Mistras' failure to secure regular calibrations of the AE systems. Therefore, the staff determined that a violation of 10 CFR 21.21(b) has not occurred.

However, during the NRC's assessment of Mistras' responses to AV 99902109/2023-201-02, the staff determined that a violation of 10 CFR 21.21(a)(1) and (a)(2) occurred (see Violation 99902109/2023-201-02 of the Notice (Enclosure 1)). Specifically, when Mistras discovered a deviation on June 15, 2021, Mistras failed to:

- complete an evaluation of this deviation within 60 days of discovery of the deviation, or
- submit an interim report to the NRC in accordance with 10 CFR 21.21(d) within 60 days of discovery of the deviation if Mistras could not complete the evaluation of this deviation to determine whether a defect exists within 60 days rom its discovery.

The deviation that was discovered on June 15, 2021, is Mistras' failure to secure annual calibrations of AE systems by the original equipment manufacturer or other approved source.

NRC Conclusion:

The NRC concludes that there is insufficient evidence to support the conclusion in AV 99902109/2023-201-02. However, the NRC concludes a violation against 10 CFR 21.21(a)(1) and (a)(2) occurred. Violation 99902109/2023-201-02 cites Mistras for its failure to (1) evaluate a deviation to identify whether a defect exist within 60 days of its discovery as required by 10 CFR 21.21(a)(1) or (2) prepare and submit an interim report to the NRC within 60 days of discovery when an evaluation could not be performed within 60 days of discovery of the deviation as required by 10 CFR 21.21(a)(2). In accordance with Section 6.9.d of the NRC Enforcement Policy, the significance of Violation 99902109/2023-201-02 is SL IV.