

Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Date: November 7, 2008

Subject: Reply to Notice of Violations 99901378/2008-201-01 and 99901378/2008-201-02

Greetings,

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted September 9 - 12, 2008, of activities performed at Fairbanks Morse Engine (FME), two Violations of NRC requirements were identified. The first violation (A) has two parts (A1 and A2) and was issued in the NRC Inspection Report No. 99901378/2008-201 as follows:

A. 10 CFR Part 21, Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," paragraph (a) requires in part that "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable."

Contrary to the above, as of September 12, 2008:

1. FME's 10 CFR Part 21 implementing procedure Standard Practice 714.00, "Procedure on Reporting of Defects & Noncompliance to NRC," dated October 2003, was not an appropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, FME did not identify and evaluate potential Part 21 deviations in accordance with Standard Practice 714.00.

2. The Engineering Report, "Cylinder Liner Failure – Delaminated Chrome Plating 38TD8-1/8 OP, Limerick EDG [Emergency Diesel Generator] D24, Cylinder #8," associated with FME's Business Form 5388C, Serial Number 06-02, "Substantial Safety Hazard Evaluation 10CFR21 Standard Practice 714.00," was an inadequate evaluation for determining 10 CFR Part 21 reportability. Specifically, the evaluation failed to address whether the delamination of cylinder #8 would have prevented the EDG from performing its safety function as a basic component, as described in 10 CFR 21.3.

Fairbanks Morse Engine's reply to violation A part 1 is provided as follows:

(A1-1) The reason for the violation was that Standard Practice 714.00 was too general in nature in order to ensure effective identification, simply stating "Employees are responsible to report deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards to the Manager, Quality Assurance." In practice, Quality Engineers have responsibility for identification during the disposition of each Nonconforming Report (NCR) and Corrective Action Request and Report (CAR).

(A1-2) The corrective steps that have been taken and the results achieved are documented in FME quality system CAR 2173. Standard Practices 714.00, 630.20 Nonconforming Material Control, and 700.10 Corrective and Preventive Action dated November 2008 have been updated to include assignment of this responsibility to Quality Engineering. FME Business Form (BF) 4876 used for the CAR was updated to include "Is an evaluation of the nonconformance for reportability per 10CFR21 required? Yes / No." Likewise, the electronic NCR system for quality engineering documentation of Part 21 identification was implemented 8/29/08 via IT request 19242.

(A1-3) The corrective steps that will be taken to avoid further violations are taking the necessary steps to fully implement the procedural changes within the FME quality assurance program. The next open corrective action step is to perform and document training of the revised procedures. This will allow for verification and closure of CAR 2173. Further violations will be prevented by performing internal audits of the updated procedures to ensure ongoing compliance in accordance with FME quality assurance program, Standard Practice 120.10 Internal and External Audits.

(A1-4) The date when full compliance will be achieved is upon verification and closure of CAR 2173 to be completed by 12/8/08.

Fairbanks Morse Engine's reply to violation A part 2 is provided as follows:

(A2-1) The reason for the violation was that Standard Practice 714.00 did not require reviewing the logic of the conclusion when it is determined that a substantial safety hazard does not exist.

(A2-2) The corrective steps that have been taken and the results achieved are documented in FME quality system CAR 2174. Standard Practice 714.00 has been updated to include, "When the finding of the evaluation that a substantial safety hazard or failure to comply does not exist, this shall be a logical conclusion of the evaluation. This conclusion shall be reached independent of the frequency of failures (e.g. an isolated incident can still be reportable)." FME Business Form (BF) 5388 used for the Part 21 evaluation was also updated to include "If NO, is this a logical conclusion of the evaluation? Yes / No." Engineering report R-5.15-4018 revision 1 dated 10/30/08

deleted “This failure is isolated, not felt to be a widespread problem,...” and deleted other references to possibly being an isolated occurrence. Revision 1 of the report reached the same conclusion that a substantial safety hazard does not exist and the new conclusion added to the report states in part, “Based on FME observations of OP engine operational history (with many customers) and based on the limited information (lack of viewing the actual components) available to FME, FME Engineering concludes that in the time leading to the discovery of the delaminated chrome, the D24 EDG would have been able to perform it’s design bases safety function.”

(A2-3) The corrective steps that will be taken to avoid further violations are taking the necessary steps to fully implement the procedural changes within the FME quality assurance program. The next open corrective action step is to perform and document training of the revised procedure. In addition, the FME internal audit checklist not only will be updated to be in accordance with the latest revision of Standard Practice 714.00, but it will also be updated using NRC Inspection Procedure 36100 as a guideline to ensure Part 21 compliance. This will allow for verification and closure of CAR 2174. Further violations will be prevented by performing internal audits of the updated procedures to ensure ongoing compliance in accordance with FME quality assurance program, Standard Practice 120.10 Internal and External Audits.

(A2-4) The date when full compliance will be achieved is upon verification and closure of CAR 2174 to be completed by 12/8/08.

The second violation (B) issued in the NRC Inspection Report No. 99901378/2008-201 was written as follows:

B. 10 CFR Part 21, Section 21.31, “Procurement Documents,” requires that “each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR part 21 apply.”

Contrary to the above, on May 1, 2008:

FME failed to invoke the provisions of 10 CFR Part 21 in Purchase Order 1102554, to Nuclear Logistics Incorporated for safety-related seismic testing services.

Fairbanks Morse Engine’s reply to violation B is provided as follows:

(B1) The reason for the violation was that FME procedures SP645.00 Purchasing Process, SP645.10 Procurement Document Control – Safety Items and SP645.20 Control of Purchased Items and Services – Safety Items, do not clearly specify that Part 21 requirements are placed on procurement documents when purchasing safety related

items or services (e.g. seismic testing). In practice, all safety related items have 10CFR Part 21 applied to the PO by quality engineering during review and application of all quality requirements to the item master within the purchasing system. Once applied to the item master, it prints out the Part 21 requirement on every subsequent PO for that item. This invokes Part 21 applicability of the FME standard PO terms and conditions (see item 25 of the attached terms and conditions). Since quality engineering invokes the Part 21 requirement on the PO for safety items, the buyer issuing the PO for the rarely procured safety service was not aware of the necessity of applying the Part 21 requirement directly onto the purchasing document for safety related services.

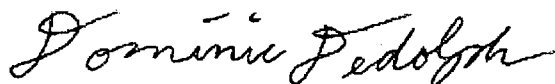
(B2) The corrective steps that have been taken and the results achieved are documented in FME quality system CAR 2175. PO 1102554 revision 1 dated 10/29/08 clearly specifying "10CFR Part 21 required by supplier", was issued to Nuclear Logistics Incorporated. All applicable FME procedures SP645.00, SP645.10, SP645.20, and SP725.00 have been updated to include, "When purchasing safety related items or services, the buyer shall ensure that 10CFR Part 21 is clearly indicated directly on the PO document."

(B3) The corrective steps that will be taken to avoid further violations are taking the necessary steps to fully implement the procedural changes within the FME quality assurance program. The next open corrective action step is to perform and document training of the revised procedure. This will allow for verification and closure of CAR 2175. Further violations will be prevented by performing internal audits of the updated procedures to ensure ongoing compliance in accordance with FME quality assurance program, Standard Practice 120.10 Internal and External Audits.

(B4) The date when full compliance will be achieved is upon verification and closure of CAR 2175 to be completed by 12/8/08.

I sincerely hope this reply meets your expectations. If you have any questions or require any additional objective evidence of corrective action implementation, please feel free to call me at the number indicated in the first page header.

Respectfully submitted,



Dominic D. Dedolph
Manager, Quality Assurance
Fairbanks Morse Engine

C. NRC Director, Division of Engineering

FAIRBANKS MORSE ENGINE - TERMS AND CONDITIONS

1. Acknowledgment and Acceptance - Acceptance is limited to the terms and conditions hereof and Seller's (a) acknowledgment of this order. (b) delivery of materials or equipment, or (c) performance of services hereunder shall in any way modify this order or the terms or conditions hereof. No modifications of the terms and conditions hereof will be affected by reason of any previous or future acknowledgment or acceptance on forms of Seller. Any modification or addition to the terms and conditions herein must be specifically agreed to in writing by Buyer.
2. Delivery - Deliveries are to be made both in quantities and at times specified on the face hereof, or on release schedules furnished against this order. Buyer reserves the right to cancel this order and refuse delivery of material and return same at Seller's risk and expense if Seller defaults in the manner and time of delivery or in the rate of shipment. Goods shipped to Buyer in advance of schedule may be returned to Seller at Seller's expense. Buyer further reserves the right to reject and return at Seller's risk and expense all quantities of materials and equipment delivered in excess of the quantity ordered. All costs incurred by Buyer as a result of Seller's failure to make delivery at the time and place specified herein shall be charged to the Seller. Seller must advise Buyer promptly in writing of delivery at the time and place specified herein shall be charged to the Seller. Seller must advise Buyer promptly in writing of delivery delays. Buyer reserves the right to reschedule delivery dates to a later date without cost to Buyer.
3. Price Warranty - The prices indicated on this order are firm and no change or adjustment will be allowed unless authorized in writing by Buyer. Seller represents that the prices set forth in this order do not exceed current selling price of similar materials having the same or similar quality in like quantity, whether sold to the U.S. Government or to any other purchaser. In the event of such excess price or in the event prices charged hereunder shall exceed prices permitted by any applicable law or regulation. Seller agrees to forthwith refund any such excess price to the Buyer.
4. Samples - Samples required on this order shall be invoiced to the Buyer at no higher cost than the production price indicated thereon. Samples shall be distinctly identified and bear reference to this purchase order. Samples must be approved in writing before production shipments are made.
5. Tools and Materials - Buyer shall retain title to any design, sketches, drawings, blueprints, patterns, dies, molds, tools, plates, cuts, gauges, special items and materials furnished by or paid for by Buyer in connection with this Order. The price indicated on the Order for any of the foregoing shall constitute the entire cost to the Buyer of any such item. All of said items shall be recorded and identified as property of Buyer and retained by Seller on consignment, subject to examination by Buyer. They shall be at Seller's risk and shall be maintained and stored by the Seller and if lost, damaged, or destroyed shall be replaced by the Seller without charge to the Buyer. Such items shall be used exclusively in the production for Buyer of articles ordered hereunder and the use thereof for any other purpose is prohibited unless approved by Buyer in writing. All items covered by the Order are subject to removal by Buyer immediately on demand without charges.
6. Confidential Relationship - Seller agrees to treat as strictly secret and confidential all specification, drawing, blueprints, nomenclature, samples, models and other information supplied by Buyer Unless the written consent of Buyer is first obtained. Seller shall not in any manner advertise or publish or release for publications any statement mentioning Buyer, or the fact that Seller has furnished or contracted to furnish to disclose any information relating to this Order to any person not authorized by Buyer to receive it. Seller shall make no use of the information supplied other than to complete this order and shall return such information to Buyer upon completion of the order.
7. Invoices - Invoices shall (a) be rendered separately for each delivery with bill of lading attached (b) cover not more than one order (c) be rendered with order number noted thereon. If invoice is subject to cash discount the discount period shall date from receipt of material or receipt of proper and correct invoice whichever is later. All invoices shall contain substantially the following assurance:
"Seller hereby certifies that these goods were produced in compliance with all applicable requirements of the Fair Labor Standards Act as amended, and of regulations and orders thereunder, and of all federal, state and local statutes, rules and regulations relating to employment and conditions of employment."
When machinery requires installation to verify satisfactory operation, invoices will not be honored prior to Buyer approval of satisfactory installation and operation.
8. Inspection - All materials are subject to inspection and test at place of manufacture and/or destination under acceptance quality levels established by Buyer in accordance with current Military Standards MIL-105 Sampling Plans. If that portion Buyer inspects is not acceptable, Buyer reserves the right to return the entire shipment and cancel any unfulfilled balances of this order without cost. All rejected material shall be returned at Seller's sole expense including cost of inspection. Any inbound transportation charges applicable thereto will also be charged to Seller. No goods returned as defective shall be replaced without a new order. Payment for material shipped under this contract prior to inspection shall not constitute an acceptance thereof. If material supplied or work performed by Seller at Seller's expense and risk, or to correct the work in Buyer's plant, or by contract or otherwise replace or correct such parts and back charge to Seller the excess cost occasioned to Buyer thereby.
The plans and specifications are intended to compliment each other and anything contained in one shall be deemed to be contained in both. If any discrepancy, difference or conflict exists between the provisions of drawings and specifications, drawing requirements shall govern. Such disagreement shall immediately be brought to the attention of the Buyer who will resolve such conflict.
The Seller is responsible for maintaining an effective and economical system to assure that all supplies furnished under this purchase order are manufactured, inspected and found to conform to all specifications contained herein. Measuring equipment shall be effectively managed to ascertain accuracy to basic recognized acceptance standards. Substantiating objective data shall be maintained by the Seller and shall be available to Buyer upon request.
9. Patent Indemnity - Seller shall indemnify and save harmless and defend the Buyer and its customers from and against any and all suits, actions, claims, demands, damages, costs, expenses and attorney fees incidental to any infringement or any alleged infringement of any U.S. or Foreign patent in the manufacture or sale of the materials or equipment covered by this order, or in any way concerned therewith, or with the use thereof by Buyer or its customers.
10. Shipping Instructions - All materials and equipment must be shipped in accordance with the shipping instructions indicated on the face of this order. In the absence of specific routing instructions, Seller shall ship via least expensive way commensurate with safe and expeditious delivery. Any extra expense in effecting delivery of material and equipment not so shipped will be charged to Seller.
11. Packing - No charges shall be made for crating, packaging or packing materials unless agree to and specified as part of this order. Each shipment must be accompanied by a packing slip showing order number. Packing, crating, and packaging on purchases from outside the United States of America must conform to ISPM 15, International Standard for Phytosanitary Measures Publication Number 15.
12. Part Preservation - No charges shall be made for the preservation of metal items. All material has an expected shelf life of six months or longer for all in-coming material unless otherwise indicated. It is "practical" to prevent contamination and maintain shelf life. Corrosion, the result of oxidation or interaction with air or its environment that causes metals to deteriorate must be prevented. Prevention and/or preservation is the Seller's responsibility. It is the Seller's responsibility to take necessary steps to prevent the parts from deteriorating from the inside out. Seller agrees to accept responsibility for rework on any parts that do not maintain at a minimum a six-month shelf life. All products with a ground surface finish should have some form of preservation treatment and be packaged properly in an effort to extend shelf life. The Buyer must approve any exceptions in writing.
13. Warranty - Seller warrants that the articles and services supplied under this order will conform to the specifications, drawings, samples or other description specified, will be merchantable and of good quality, material and workmanship, will be suitable for the purposes intended and free from defects in workmanship, materials and design. All warranties shall survive inspection, delivery, acceptance or payment by Buyer and Seller shall bear all costs of inspecting rejected articles. Articles which are not as warranted may be returned by Buyer at Seller's expense for full credit, including cost of shipment. Seller agrees that the cost of all labor, shipment, re-working and materials, either in Buyer's plant or in the field, which shall at any time be necessary because of any breach of warranty, shall be charge to Seller. This warranty shall run to Buyer, its successors, assigns, customers and users of the articles sold hereunder by Seller. Seller further agrees to defend and hold harmless Buyer, its customers and distributors from and against any and all claims for personal injury, property damage (including claims for consequential, collateral or special damages) claimed because of negligent manufacture, improper or defective material, workmanship or design. This warranty shall be in addition to any other rights which Buyer may have at law or in equity and shall not be construed to limit Buyer's rights and remedies in any manner. Seller agrees to fill Buyer's orders for spare parts, prime components and/or assemblies, unreasonable quantities, at reasonable prices, commencing from the date of delivery hereunder and

continuing for a period of not less than ten years after the date of last delivery of any unit for which spare parts might be required. This warranty shall also apply for the benefit of Buyer's customer.

14. Cancellation – Buyer reserves the right to cancel this order or any portion hereof if delivery is not made, when and as specified or if Seller defaults in the performance of any of the terms and conditions herein, time being of the essence. Buyer may cancel this order forthwith by written or telegraphic notice if Seller shall become insolvent or make a general assignment or the benefit of creditors, or if a petition under Chapter X or XI of the Bankruptcy Act is filed by or against Seller. Buyer reserves the right to charge Seller for any loss entailed by reasons resulting therefrom Buyer may terminate work upon this order of its convenience in whole or in part at any time by written or telegraphic notice. The Seller shall reserve in all of its orders relating to this contract the right to terminate or cancel. Whether or not such right to terminate or cancel is so reserved by Seller, Buyer's liability for cost arising out of orders terminated for its convenience shall be limited to actual cost incurred by Seller applicable to this order at time of termination and shall not include anticipatory profits or other damages. Unless specifically directed Seller is not authorized to procure raw material or fabricate goods not required to meet specified delivery schedules.
15. Compliance with Federal, State and Local Laws – Seller warrants that in the performance of work under this order it has complied with or will comply with all applicable federal, state, foreign, provincial and local laws and ordinances, and with all lawful orders, rules and regulations thereunder, including but not by way of limitation, the Fair Labor Standards Act of 2938, as amended (29 U.S.C. Sec. 201-209) and insofar as applicable to this order, the Walsh-Healey Public Contracts Act, as amended (41 U.S. C. Sec. 35-45 and, Occupational Safety and Health Act of 1970 as amended, Equal Employment Opportunity the requirement of executive orders 11246, 11375 and 11758, and the requirements of 38 U.S.C. 2012 in the Vietnam Era Veteran Readjustment Assistance Act of 1974, as amended, the requirements of Section 503 of the Rehabilitation Act of 2973, as amended and all lawful rules and regulations thereunder.
16. Plant and Site construction or Installation – In the event Seller performs work on Buyer's premises or on buyer's customer's premises, Seller shall indemnify and save Buyer and Buyer's customers harmless from and against any and all damages for injuries to persons or property by reason of Seller's operations hereunder, except where caused by negligence of Buyer. Seller shall at all times remain an independent contractor, all employees and agents performing such work shall be employees or agents of the Seller. Before commencing such work, Seller shall furnish to Buyer certificates evidencing satisfactory Public Liability and Property Damage insurance for the benefit of Seller and Buyer and Buyer's Customer where applicable, and Workers Compensation as required by applicable law.
17. Waiver – No waiver of any of the provisions contained in this Order shall be valid unless made in writing and executed by both parties. No charges beyond the contract price herein specified will be allowed except with Buyer's written consent. Failure of Buyer to insist upon strict performance shall not constitute a waiver of any of the provisions of this Order or waiver of any other default.
18. Taxes – Unless otherwise indicated, the prices set forth herein shall include all Federal, State and Local Taxes of any kind or nature applicable to the manufacture, use or sale to Buyer of the completed items and the subsidiary items incorporated therein.
19. Assignments and Subcontracts – This Order shall not be assigned or transferred without written consent of Buyer. Seller agrees that it will not subcontract the furnishings of any of the completed or substantially completed articles required by this Order without written approval of Buyer. No assignment of monies due or to become due hereunder shall be binding upon Buyer until its written consent thereto is obtained.
20. Force Majeure – This order is subject to modification or cancellation by Buyer in the event of fire, act of God, public enemy, earthquake, floods, strikes, labor troubles or any other cause beyond Buyer's reasonable control.
21. Changes – Buyer may at any time, by written change order, make changes in the drawings, designs or specifications applicable to the supplies or services covered by this purchase order. If any such change affects the cost of manufacturing such supplies or the cost of furnishing such services an equitable adjustment shall be made promptly in the purchase price or prices by agreement of the parties.
22. Audit – Seller agrees to make available to Buyer or Buyer's representative, without expense to Buyer, such facilities and records as may be necessary to audit, substantiate, and justify Seller's costs, if this

offer on the face hereof specifies time and material, or this order shall have been terminated prior to completion and delivery.

23. Interpretation – This offer shall be considered as executed in, and shall be construed in accordance with, the laws of the State of Wisconsin.
24. Buyer's Customer Contract – In addition to all of the terms and conditions set forth herein, the provisions of the contract between Buyer and Buyer's customer shall be construed in accordance with, the laws of the State of Wisconsin.
25. The Provisions of 10 CFR Part 21 entitled "Reporting of Defects and Non-compliance", when applicable, apply to this Purchase Order. The Regulation requires that Buyer shall give notice to the Nuclear Regulatory Commission when information is obtained that a component supplied to a nuclear facility within the United States contains a defect which could create a substantial safety hazard. If Seller obtains any information reasonably indicating such a defect, related to products supplied for this purchase order, Seller is required to notify Buyer immediately. Attention: Vice President Manufacturing

Revised January 2006