

October 16, 1996

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Subject: **Reply to a Notice of Violation**

Docket Nos. 030-34144 and 99990001
Inspection Nos. 030-34144/96-001 and 99990001/96-007
License No. 20-18489-02

Dear Sir or Madam:

Pursuant to the requirements of replying to the attached Notice of Violation, this letter will address the items cited on the violations.

VIOLATION "A"

(1) reason for violation

Relying on instructions provided by our supplier, NDC Systems, we believed we were in conformance with DOT labeling regulations (see Enclosure 1, second bullet, second sentence). We had a bright orange paper inside the package stating the word "RADIOACTIVE."

(2) corrective steps taken and the results achieved

After the inspection by Mr. Courtemanche, Mr. David S. Powers, our Radiation Safety Officer ("RSO"), contacted NDC Systems to notify them of the inspection findings and to ask for their response. As a result of this inquiry, NDC Systems revised their labeling instructions for shipping (see Enclosure 2). As required, we now have a bright orange paper inside the package stating the word "RADIOACTIVE," along with the required notice (see Enclosure 3).

(3) corrective steps that will be taken to avoid further violations

As stated in item A-1, we believed our labeling conformed to regulations; there was no intentional violation. In the future, changes in DOT regulations will be more closely monitored through our contact with NDC Systems.

(4) date when full compliance will be achieved

Full compliance has already been achieved.

VIOLATION "B"

(1) reason for violation

Our Fehrer test unit was purchased as a complete unit. We relied on Fehrer, the supplier of the unit, to have all of the correct labels in place.

(2) corrective steps taken and the results achieved

After the inspection by Mr. Courtemanche, our RSO contacted NDC Systems to notify them of the inspection findings and to request their assistance. As a result of this inquiry, NDC Systems sent us the required label and we have affixed it to the exterior of the Fehrer test unit (see Enclosure 4).

(3) corrective steps that will be taken to avoid further violations

As stated in item B-1, we relied on Fehrer, as the supplier of the unit, to furnish all of the appropriate labels to conform to regulations; there was no intentional violation. In the future, any newly purchased gauges will be closely examined for proper labeling.

(4) date when full compliance will be achieved

Full compliance has already been achieved.

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U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk

If you have questions or comments regarding this response, please contact me or our RSO, David Powers, at your convenience at 617-828-3350, extension 320 or 356, respectively.

Sincerely,
TAMFELT, INC.

A handwritten signature in black ink, appearing to read 'M. W. Ellen', written over a horizontal line.

Michael W. Ellen
Chief Financial Officer

Enclosure:

Notice of Violation

1. NDC Shipping Instructions (original fax date, 06/12/95)
2. NDC Shipping Instructions (original fax date, 09/09/96)
3. Orange label for inside of shipping container.
4. Copy of exterior label

cc w/enclosure: U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

David S. Powers, Radiation Safety Officer

NOTICE OF VIOLATION

Tamfelt, Incorporated
Canton, MA 02021

Docket Nos. 030-34144
99990001
License No. 20-18489-02
General License

During an NRC inspection conducted on August 28 and 29, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

- A. 10 CFR 71.5 requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, comply with the applicable requirements of the Department of Transportation regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.

Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

49 CFR 173.421-1 requires, in part, that excepted packages prepared for shipment under the provisions of 49 CFR 173.422 must be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement "This package conforms to the conditions and the limitations specified in 49 CFR 173.422 for radioactive material, excepted package - instruments or articles, UN 2910."

Contrary to the above, as of August 29, 1996, the licensee under NRC License No. 20-18489-02 prepared excepted packages containing NDC System Model 104P instruments with 80 millicuries of americium-241 for shipment under the provisions of 49 CFR 173.422 and did not certify the packages as being acceptable for transportation by having a notice forwarded with the package.

This is a Severity Level IV violation (Supplement V).

- B. 10 CFR 31.5(b) requires that the general license in 10 CFR 31.5(a) applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to 10 CFR 32.51 or in accordance with the specifications in a specific license issued by an Agreement State which authorizes the distribution of the devices to persons generally licensed by the Agreement State.

10 CFR 32.51(a)(3) requires, in part, that an application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under 10 CFR 31.5 or equivalent regulations of an Agreement State will be approved if each device bears a durable, legible, clearly visible label or labels approved by the Commission or an Agreement State which contain in a clearly identified and separate statement the instructions and precautions necessary to assure safe installation, operation, and servicing of the device, the requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of material, and date of determination of the quantity, and the information called for in the statement in 10 CFR 31.5(a)(3)(iii).

10 CFR 31.5(c)(1) requires that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in 10 CFR 31.5(a) assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels.

Contrary to the above, as of August 29, 1996, the general licensee possessed a gauge manufactured by Fehrer of Austria which contained an NDC Systems Model No. 102 probe with a nominal 150 millicurie americium-241 sealed source, and the gauge was not appropriately labeled. Specifically, NDC Systems initially distributed the probe to Fehrer who installed the probe into one of Fehrer's gauges. The probe was completely concealed within the gauge and none of the labels on the probe were visible. Also, Fehrer is not licensed by the NRC or an Agreement State to distribute gauges in the United States.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Tamfelt, Incorporated is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary,

or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.



Shipping Instructions For NDC Radioactive Sensor Probes

The NDC probe in your possession is a radioactive device. As such, its shipment is governed by regulations set up by the U.S. Federal Department of Transportation or the Radioisotopes & Transportation Division of the Atomic Energy Control Board of Canada. If you must ship your unit, following these instructions will help prevent problems with shipping companies.

- Be sure that the sensor probe has a shutter and it is closed. (If the shutter is missing, immediately call NDC for instructions.)
- If the activity stamped on the yellow and magenta radiation label on the probe is 80 mCi or less, wrap the probe in bubble pack and place securely in a good quality cardboard container with closure flaps that meet each other. Write the word "RADIOACTIVE" on an internal surface of the box, or on a piece of paper, so that it is obvious upon opening that there is a radioactive device enclosed. No special labeling or paperwork is required. Multiple probes, each containing less than 80 mCi, may be shipped in one box.

If the activity stamped on the yellow and magenta radiation label on the probe is 81 mCi or greater, a "Shipper's Declaration For Dangerous Goods" form must be completed and a Certificate of Approval attached to it. NDC will provide this certificate. These forms must be attached to the outside of the container. Wrap the probe in bubble pack and pack securely in a **Type A** container. (For Canadian customers, the Type A container must meet the requirements set out in the Transport Packaging of Radioactive Materials Regulations. The documentation, placards and labels must comply with Transport Canada, Transport of Dangerous Goods Regulations). The container must have two (2) "White Radioactive I" labels (affixed to opposite sides of the container); two (2) orange "Danger" labels (affixed to opposite sides of the container); and one (1) red "USA DOT 7A" label (affixed to the top of the container). These labels can be obtained from NDC or, possibly, your shipper. Multiple probes may be shipped in one box.

- Enclose a letter stating the reason for the return (repair, disposal, transfer). If it is being transferred, be sure to include the contact name, address and phone number of the person it is coming from and also to whom it is going.
- In order to expedite your request, please include a purchase order number.
- Charges for transferring are freight at actual cost.
- Charges for disposal are \$500 per sensor probe. The disposal fee for sensor probes with serial numbers 1000 and up will be charged at \$100 per probe if the gage electronics are returned with the probe.
- A copy of the current leak test certificate must be enclosed, as required by State and Federal regulations.
- Use pilfer-proof tape (any tape that will show if it has been tampered with) when sealing the box. Make sure all flap seams around the container are well taped.
- Federal Express, Emery or similar shipping companies may be utilized. In Canada, placards are required on vehicles when transporting packages displaying the White-I, Yellow-II or Yellow-III labels.
- Some states require they be notified that radioactive material has been transferred into or out of their area of jurisdiction for 30 days or longer. If you are located in such a state and are disposing of, or transferring a probe to another location, you will receive a letter from us informing you to notify the proper agency that you no longer have the unit. If the unit is transferred, the receiving facility will also receive a notification letter.

If you have any questions, please call the NDC Service Department at (818) 358-1871.



Shipping Instructions For NDC Radioactive Sensors Containing Americium-241 or Curium-244

The NDC sensor in your possession is a radioactive device. As such, its shipment is governed by regulations set up by the U.S. Federal Department of Transportation or the Radioisotopes & Transportation Division of the Atomic Energy Control Board of Canada. If you must ship your unit, following these instructions will help prevent problems with shipping companies.

- An RMA number must accompany any item returned to NDC. In order to obtain an RMA number, please call (818) 939-3855.
- Be sure that the sensor has a shutter and it is closed. (If the shutter is missing, immediately call NDC for instructions.)

U.S. customers should wrap the sensor in bubble pack and place securely in a good quality cardboard container with closure flaps that meet each other. Write the word "RADIOACTIVE" on an internal surface of the box, or on a piece of paper, so that it is obvious upon opening that there is a radioactive device enclosed. The following notice must appear in or on the package. "This package conforms to the conditions and limitations specified in 49 CFR 173.424 for radioactive material, excepted package instruments or articles, UN2910." This notice must include the name of the consignee or consignor. We suggest it be included on the packing list. Multiple sensors may be shipped in one box.

Canadian customers need to complete a "Shipper's Declaration For Dangerous Goods" form. A Certificate of Approval must be attached to it. NDC will provide this certificate. These forms must be attached to the outside of the container. Wrap the sensor in bubble pack and pack securely in a Type A container. The Type A container must meet the requirements set out in the Transport Packaging of Radioactive Materials Regulations. The documentation, placards and labels must comply with Transport Canada, Transport of Dangerous Goods Regulations. The container must have two (2) "White Radioactive I" labels (affixed to opposite sides of the container); two (2) orange "Danger" labels (affixed to opposite sides of the container); and one (1) red "USA DOT 7A" label (affixed to the top of the container). These labels can be obtained from NDC or, possibly, your shipper. Multiple sensors may be shipped in one box.

- Enclose a letter stating the reason for the return (repair, disposal, transfer) and the RMA number. If it is being transferred, be sure to include the contact name, address and phone number of the person it is coming from and also to whom it is going.
- In order to expedite your request, please include a purchase order number.
- Charges for transferring are freight at actual cost.
- Charges for disposal of sensors containing Am-241 are \$500 per sensor. The disposal fee for Am-241 sensors with serial numbers 1000 and above will be charged at \$100 per sensor if the gauge electronics are returned with the sensor. Charges for disposal of sensors containing Cm-244 are \$500 per sensor.
- A copy of the current leak test certificate must be enclosed, as required by State and Federal regulations.
- Seal the box using good quality, strong packing tape. Make sure all flap seams around the container are well taped.
- Federal Express, Emery or similar shipping companies may be utilized. In Canada, placards are required on vehicles when transporting packages displaying the White-I, Yellow-II or Yellow-III labels.
- Some states require they be notified that radioactive material has been transferred into or out of their area of jurisdiction for 30 days or longer. If you are located in such a state and are disposing of, or transferring a sensor to another location, you will receive a letter from us informing you to notify the proper agency that you no longer have the unit. If the unit is transferred, the receiving facility will also receive a notification letter.

If you have any questions, please call the NDC Service Department at (818) 939-3855.



RADIOACTIVE

**This package conforms to the conditions and limitations specified
in 49 CFR 173.424 for radioactive material, excepted
package-instruments or articles, UN2910.**

Consignee/Consignor
Tamfelt, Inc.
28 Draper Lane
Canton, MA 02021
(617) 828-3350

(Enclosure 3)

NDC SYSTEMS - IRWINDALE, CALIFORNIA 91706 - 818-960-3300 - Model 100 Series

The receipt, possession, use and transfer of this device are subject to a general license or equivalent and the regulations of the U.S. NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

Operation of this device shall be immediately suspended until any necessary repairs have been made if there is any indication of possible failure of or damage to the shielding or containment of radioactive material or to the shutter mechanism or indicator.

This device shall be tested for proper operation of the on-off mechanism or indicator at intervals not to exceed six months. Generally licensed users may perform the shutter check using instructions provided by the manufacturer in the Radiation Safety Section of the Users Manual.

The sealed radioactive source contained in this device shall be tested at installation and every three years thereafter for leakage of radioactive material. Generally licensed users may collect the sample using the instructions provided by the manufacturer in the Radiation Safety Section of the Users Manual. NDC or other specifically licensed persons must perform this test.

Maintenance, tests or other service involving the radioactive material, its shielding and containment shall be performed by persons holding a specific radioactive materials license to provide these services.

Initial installation and radiation survey, maintenance, repair, and relocation outside the general licensee's facility of this device and leak testing, installation, replacement, and disposal of sealed sources containing radioactive material used in this device shall be performed only by persons holding a specific radioactive material license to provide these services.

This device shall not be transferred, abandoned or disposed of except by transfer to a person holding a specific radioactive material license to receive this device.

Removal of this label is prohibited.

Made in USA

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