

February 15, 1994

Docket No. 030-09270  
License No. 20-15525-02E  
EA No. 94-002

Ion Track Instruments, Incorporated  
ATTN: William J. McGann, Ph.D.  
Vice President  
340 Fordham Road  
Wilmington, Massachusetts 01887

Dear Dr. McGann:

Subject: Confirmatory Action Letter No. 1-94-002

On February 9, 1994, members of the NRC Region I staff were notified by one of your customers that they had received one of your instruments containing byproduct material. Upon NRC review, it was determined that an apparent violation of NRC requirements had occurred. The instrument, a Model Vixen (97A), was distributed to your customer prior to the completion of a sealed source/device review by the NRC and the approval of a request to amend your distribution license to include this instrument.

Pursuant to a telephone discussion between you and Mohamed Shanbaky of this office on February 15, 1994, it is our understanding that you have taken or will take the following actions with regard to your licensed activities:

1. Immediately cease all distribution of the Model Vixen (97A) instruments until the sealed source/device review is completed and approved by the NRC and your distribution license is amended to include distribution of the instrument.
2. Confirm in writing to NRC Region I under oath or affirmation by February 18, 1994, your statement that only one Model Vixen (97A) instrument was distributed.
3. Immediately recall the one instrument that you have distributed. The instrument would be in your possession by no later than March 1, 1994.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify me immediately if your understanding differs from that set forth above.

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2. Notify me in writing if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change.
3. Notify me in writing when you have completed the actions in this Confirmatory Action Letter.

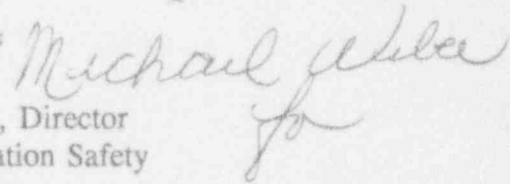
Issuance of this Confirmatory Action Letter does not preclude the issuance of an Order formalizing the above commitments or requiring other actions on the part of the licensee, nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

The response directed by this letter is not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter will be placed in the NRC Public Document Room.

Sincerely,

Original Signed By:

Charles W. Hehl, Director  
Division of Radiation Safety  
and Safeguards



cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Massachusetts

bcc:

- RI Docket Room (w/concurrences)
- H. L. Thompson, DECS
- T. T. Martin, RI
- W. F. Kane, RI
- C. J. Paperiello, NMSS
- J. Lieberman, OE
- M. F. Weber, RI
- S. H. Lewis, OGC
- J. E. Glenn, NMSS
- S. L. Greene, NMSS
- R. R. Bellamy, RI
- K. D. Smith, RI
- D. J. Holody, RI
- M. M. Shanbaky, RI
- S. R. Courtemanche, RI

OFC	DRSS	DRSS	DRSS <i>fx</i>	DRSS	EC	RC	DRA
NME	COURTEM ANCHE <i>spc</i>	SHANBAK Y <i>ms</i>	BELLAMY	HEHL <i>W</i>	HOLODY <i>ms</i>	<del>SMITH</del>	KANE <i>WFL</i>
DTE	2/15/94	2/15/94	2/15/94	2/15/94	2/15/94	2/15/94	2/15/94