

August 17, 2000

Mr. Frank Festa
Project Coordinator
IMS Systems Inc.
Suite 310, 3rd Floor
10521 Perry Highway
Wexford, PA 15090

Dear Mr. Festa:

This letter is in response to your application, dated June 22, 2000, requesting registration of the Model Nos. 5245, 5221, and 5321 devices manufactured by IMS GmbH, located in Heiligenhaus, Germany. We are in the process of reviewing your request. In order to continue our review, we need additional information. Please address the following issues:

1. In your application you indicated that you will abide by all terms and conditions set forth in the previous registrations of these devices. It is our understanding that the current registrant for the devices, Isotope Measuring System, Inc., located in Cranberry Twp., PA, has not authorized your company to assume any of its activities. Therefore, your application must be fully documented, independent of previous submittals of other applications. Please submit a full set of all documents to support your application.
2. In your request you also indicated that you wanted to change the labels, service manuals, and emergency procedures for the devices which are currently in use. Please note that the current registrations for the devices with Isotope Measuring System, Inc., located in Cranberry Twp, PA, is still in effect. Therefore, we ask you the address the issue of the existing labeling, manuals and procedures in view of labeling, manuals and procedures to be issued by IMS Systems, Inc. For example, do you plan to obtain written authorization from both Isotope Measuring System, Inc., and the customer prior to changing any labels or documents?

Mr. Frank Festa

- 2 -

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

If you have any questions, please contact me at (301) 415-7904 or Dr. Seung Lee at (301) 415-5787.

Sincerely,

John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: J. McGrath/NRC Region I

Mr. Frank Festa

- 2 -

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

If you have any questions, please contact me at (301) 415-7904 or Dr. Seung Lee at (301) 415-5787.

Sincerely,

/RA/

John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: J. McGrath/NRC Region I

Distribution:

IMNS r/f SSD-00-30 MNSS-02 Public
DOCUMENT NAME: C:\IMS.wpd

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	MSIB		MSIB					
NAME	JJankovich/jj		SLee					
DATE	08/17/00		08/17/00					

OFFICIAL RECORD COPY