June 28, 2001

Mr. John M. Buckman
General Manager
IMS Systems, Inc.
10521 Perry Highway
Suite 310
Wexford, PA 15090

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE APPLICATION FOR A CERTIFICATE OF REGISTRATION FOR THE MODEL 5321 THICKNESS GAUGE

Dear Mr. Buckman:

We have reviewed your application, dated February 7, 2001 (sent by Engelhardt & Associates, Inc.), requesting registration of the Tube Wall Thickness Gauge, Model No. 5321 and your additional correspondence dated February 16, 2001, correcting your application. In reviewing the correspondence together with your application, we find that some information needed for us to reach a decision is still lacking. Therefore, we request that you address the issues outlined in the attached Enclosure.

Please refer to NRC's NUREG-1556, Volume 3, for additional information regarding the type of information that would fully address these items. NUREG-1556, Volume 3, can be found on NRC's website (www.nrc.gov).

Please submit the requested information within thirty days of the date of this letter and be certain to address all the areas of concern cited herein. If you have any questions, please contact me at (301) 415-7038 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

***/RA/***

William R. Ward, P.E.
Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated
cc (w/encl.): S. Kimberly, LFARB

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**Additional questions for the IMS Systems, Inc. Model 5321 gauge application**

## 1 Summary Data

1.1 In your application, and subsequent correspondence, you indicate that the name of the German manufacturer is Isotope Measuring Systems. Previous certificates for products produced by this manufacturer show the name as IMS Messsysteme GmbH. Additionally, the form of the address for the manufacturer as listed on the certificate issued to you for the Model 5245-xx series (NR-1120-D-101-S) differs from the form of the address in your summary data. Please confirm the name and address of the manufacturer.

1.2 In your application, and subsequent correspondence, you indicate that the applicable certificate of registration for the source (CDC.711M) you will use is NR-0136-S-232-S. However, this certificate was superceded on March 2, 1999 with the issuance of certificate number IL-0136-S-232-S for the CDC.711M source. Please confirm that this is the current certificate for the source you intend to use. Also, please note that the referenced certificate, NR-0375-D-104-S was inactivated on May 3, 2001 as certificate number NR-0375-D-804-S.

## 2 Use and Construction

2.1 Please note that the source model CDC.PE2, referred to on page 4 of this section, was inactivated on October 23, 1997 with the issuance of certificate number IL-136-S-197-S. Only the CDC.711M source is currently available.

2.2 On page 4, you stated that the ANSI classification of the CDC.711M source was 77C6444. We realize that you intended to state the classification as 77C64444, as you did later on page 12. However, please note that the later certificate for this source (see paragraph 1.2 above) now gives this source an ANSI classification of 77C66646.

2.3 On pages 4 & 5, you stated that the many parts of the source housing are constructed of SM-18 Sintered Tungsten Alloy. You provided the properties of the SM-18 Alloy as well. In drawings 5321-025M1, and 5321-025-01 through -04, these same parts are indicated as being of a material S-18. When we reviewed the Model 5245-xx series gauge (NR-1120-D-101-S), you provided in correspondence dated September 22, 2000, a data sheet for the material properties of the Tungsten Alloys you use. That data sheet did not have a listing for SM-18, but did for S-18. The properties listed for S-18 are not the same as the properties you list for SM-18. Please re-affirm the Tungsten Alloy used in the source housing and provide a manufacturer's data sheet showing the properties of the Alloy.

2.4 On page 3, you stated that the operating temperature within the inner frame is in the range of 0 to 100°C. On page 6, you stated the temperature range for the pneumatic air cylinder is -20 to 80°C. Please explain how the pneumatic air cylinder is affected by operating temperatures between 80 and 100°C.

2.5 On page 7, you stated the air gap can vary between 25 and 35 cm. Your description mentions a 'Roller plate' as part of the mechanism which changes the air gap size. However, from you description and the drawings, it is not clear to us how the distance between the beam outlet from a source housing to the detector inlet on the other side of the gap can change. Please clarify how the air gap can change and what role the 'Roller plate' has in this change.

2.6 Drawing 5321-025-01 shows the centerline of the source opening in the source housing to be 23.7 mm from the centerline axis of the shutter [56.4 mm (distance of shutter centerline from housing side) - 32.7 mm (distance of opening centerline from housing

side) =23.7mm]. Drawing 5321-025-02 shows the centerline of the source in the shutter to be 33.5 mm from the centerline axis of the shutter. Allowing for a 5 mm radius in both the shutter opening and the housing opening, this means the two openings overlap by only 0.2 mm. Is this correct?

2.7 Drawing 5321-025-01 shows a <2mm deep, 120° chamfer cut in the source housing in line with the shutter centerline axis. This appears to indicate a center pivot point for the source shutter to contact the housing and to help support the shutter. However, drawing 5321-025-02 does not show any pivot point existing above the plane surface of the end of the shutter. Does the shutter contact the source housing at the end of the shutter away from the bearings? What is the normal clearance between the shutter and the housing at the end? What is the maximum axial movement of the shutter allowed by the bearings and at what load does this occur? Is this load achieved during normal or abnormal operations?

2.8 Drawing 5321-025-15 shows four 5.2 mm diameter holes on a diameter of 42 mm about the center hole in the plate. These holes are 90° apart starting at 45° from a horizontal orientation in the drawing. The color pictures you provided entitled “Interlocks” and “Proximity Switches” show a completed source housing with these holes apparently starting 0° from the horizontal orientation. Additionally, the lengths and angles of the sides of the plate do not seem to agree with the drawing. Please explain why the housing as fabricated doesn’t agree with the drawings you provided.

## 3 Labeling

3.1 You stated that the source housing label would include the word “Radioactive”. Subpart J of 10 CFR 20 requires “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” or on the source housing (as a container) label. In the picture you provided entitled, “Source Label”, neither “Radioactive”, nor the words of Subpart J appear on the label. Please explain why the label is different from your description and 10 CFR 20.

3.2 In the picture of the source label, it appears that the radioactive symbol is painted on and not engraved, etched, stamped or otherwise equivalently permanently made as you stated it would be. Per 10 CFR 20, etching etc. is an acceptable alternative to painting in high temperature environments as you have stated the gauge would be in. Please explain why the symbol is only painted.

## 4 Radiation Profiles and Prototype Testing

4.1 In your drawings numbered 5321-025, 5321-025 A1, and 5321-025 M1, you list the source housing as type TIAS 211. Type TIAS 211 is also listed as the type used in the ANSI testing section. In the color drawing, 5321-035 A1, you list the source housing as type TIAS 212. In your radiation profile drawings, 5321-02 I1 and 5321-00 I1, you list the housing as type TIAS 210, 211, and 212, depending on the drawing. What is the difference in the 3 types, TIAS 210, 211, and 212? If there are differences, please discuss their effect on shielding, structural strength, ANSI testing and operation of the housings.

4.2 In your description of the radiation profile on page 13, you provided radiation levels which all appear to be exactly equal to one of the levels in the ANSI N538 classification scheme. These do not appear to be direct measurements. Your NOTE at the bottom of the page appears to confirm this. Additionally, you did not provide the identification of the survey

meter and mass per unit area of absorbers used in making the stray radiation measurements as ANSI N538, paragraph 7.3.3 requires. Please provide the actual stray radiation measurements and information required per ANSI N538 (now ANSI N43.8). Also, note that your radiation profile drawings appear to indicate closed shutter stray radiation levels as high as 2.5μSv/hr up to 3500 mm away in some directions while your table lists the same radiation level at only 30 cm away. Please discuss this inconsistency.

## 5 QA/QC Program

5.1 The QA program submitted previously has many specific references to the previous gauge, not the Model 5321 gauge, and other references which are outdated (AEG, IMS Ltd.). Additionally, the organizational chart is not complete up to the company officer presiding over the three major departments. Please provide a complete, current QA program description.

## 6 ANSI Testing

6.1 In the section on ANSI testing, you tested the prototype in the temperature range of 0°C to 85°C (consistent with the ANSI rating of 43 for temperatures). However, you did not explain why the range from 85°C to 100°C was not tested. Please explain why this range was not tested and justify the gauge operating range of 0 to 100°C as stated in the 'Conditions of Use'. Also note that you state that the cooling system is designed to maintain inner frame temperature below 100°C when the ANSI rating is only to 85°C.

## 7 Installation/Maintenance

7.1 In section 1, you list and describe the Fault Conditions for the Model 5321. For the following Fault Conditions, please provide the set point where the condition occurs, and the normal operating range for the parameter.

Frame temperature too high
Cooling water temperature too high
Cooling water flow fault
Cooling water pressure too low

7.2 In drawing 5321-02L1 for air, and 5321-02 H2 for water, you provide some conditions for customer-supplied air or water, but do not state any minimum/maximum requirements anywhere else in your application. Please state your minimum and maximum requirements for temperature, pressure, flowrate, and quality of the customer-provided air and water.

## 8 Engineering Drawings

8.1 Most drawings are in German. Please heed the guidance in Chapter 6 of Volume 3 of NUREG-1556, Consolidated Guidance About Materials Licenses/Applications for Sealed Source and Device Evaluation and Registration, and provide any future drawings in English or with English translation next to the German text.