

From: William Ward
To: Frank Festa
Date: 8/2/01 5:50PM
Subject: Final questions

Frank Festa,

Review of you application is complete. I have 3 final questions as a result.

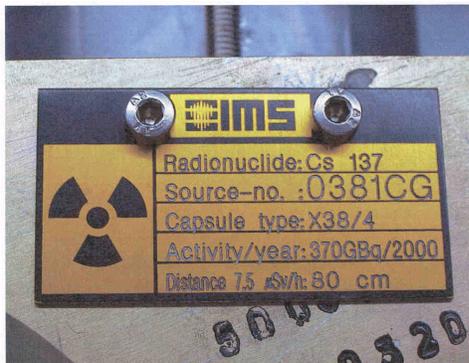
1. No "in-beam" radiation levels were given. Do you have any calculations or estimate to show what this would be?
2. Concerning the activity and date provided on your label, please state if you are entering an actual activity or a nominal activity and date? Is it possible to put month/year instead of just year? I've attached a copy of the label you sent with your application to make for easy reference.
3. Concerning your QA program (8/1 version sent to me is attached). It says it is "Manufacturer's Program Outline". I know that you, the distributor, are owned by IMS-Germany, the manufacturer. Please state to whom this program applies, or if it applies to both of you. Is all manufacturing related QA performed by the manufacturer at their facility?

Also, what is the QA relationship between the manufacturer and distributor? Do you perform audits of the manufacturer? Do they audit you? How often are these audits? Where are QA records kept? Do you keep or have access to all QA records, including any certifications or leak tests, related to the gauges you distribute?

Thank you for your assistance in this.

Bill Ward

William R. Ward, P.E.
NRC/NMSS/IMNS/MSIB
(301) 415-7038
m/s T8-F5



Source Label

Note: the '.jpg' image file shown here and the QA program sent to me by IMS Systems, Inc. on 8/1/01 (ML012130212) were attached to this email.

Mail Envelope Properties

(3B69CB31.C3A : 2 : 50081)

Subject: Final questions

Creation Date: 8/2/01 5:50PM

From: William Ward

Created By: WRW1@nrc.gov

Recipients	Action	Date & Time
IMSSystemsInc.com Frank.Festa (Frank Festa)	Transferred	08/02/01 05:51PM

Post Office	Delivered	Route
		IMSSystemsInc.com

Files	Size	Date & Time		
IMS label.jpg	65321	02/20/01 05:51PM		
QUALITY ASSURANCE AND CONTROL PROGRAM 8-1.doc			198144	08/02/01
05:46PM				
MESSAGE	2466	08/02/01 05:50PM		

Options

Auto Delete: Yes
Expiration Date: 9/1/01
Notify Recipients: Yes
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

To Be Delivered: Immediate
Status Tracking: All Information