

From: Steinfeld Sergio <Sergio_Steinfeld@elgems.com>
To: "Seung Lee (E-mail)" <SJL@nrc.gov>
Date: Tue, Jun 22, 1999 12:02 PM
Subject: response to NRC re ACT for MG

Dear reviewer Mr. Seung Lee :

According to the telephone call that you had with Mr. Beebe , we send you the required information to continue the review and evaluation of the MG ATC System. The answers are written in blue , just after the questions that were send us by Mr. Beebe. Can you send us back your direct fax number in order to send the following documents:

- a) copy of IEC 601-1 , clauses 28 & 22. (3 pages)
- b) Copy of Ball bearing basic rating life equation taken from SKF Catalog (including data sheet of the ball bearing used in the device) (3 pages) .

Thank You

Sergio Steinfeld
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-----Original Message-----

From: Beebe, Jim (MED)
Sent: Thu, June 10, 1999 5:09 PM
To: Steinfeld, Sergio (MED-ELGEMS)
Cc: Hermony, Nathan (MED); Leshem, Daniel (MED); Nir, Elka (MED, Non GE); Beach, Shmuel (MED, Non GE)

Subject: response to NRC : ATC option for MG

Mr. Seung Lee from NRC called me again regarding our application. He had two issues.

* After reading about the ELGEMS QA & QC program, Mr. Lee would like similar information about GE's QA & QC program.

Does GE have a separate QA & QC program for this product? If so, we need to describe it for Mr. Lee.

In order to answer the question above which was asked also in the previous letter dated on May 6, 1999 (paragraph 12), let me clarify the relationship between ELGEMS and GE :

* ELGEMS is the GE division of research, development and production of nuclear medicine medical systems.

* The ELGEMS products are sold and distributed to customers in the U.S. and others countries only by GE sales and marketing department.

* The ELGEMS products include GE's service and operation manuals (see appendices A & B on the previous letter) with all the necessary

instructions for use, inspection, installation and maintenance. These documents fully define the QA & QC program for this product.

* The products are developed and manufactured according to ELGEMS QA & QC program. GE has not a separate QA & QC program for the products.

* The products installation and maintenance is done by GE field engineers according to the service and user manuals. These field engineers are technically trained by ELGEMS.

* The NRC is currently reviewing a license application from Dupont regarding their rod source. The Dupont application quotes an 18-month life. In our ACT application, we quote 5-year life. If Mr. Lee verifies that we and Dupont are talking about the same rod source, then he may have more questions for us.

We've requested the source supplier information and received the following answer :

"The latest registration amendment for our Gd-153 Line Sources (MA-0476-S-117-S; dated April 1, 1999) states the general useful life of the source is 5 years. However, there is a limitation note on ONE model that limits the useful life to 18 months when loaded to the maximum activity of 400 mCi. That is model NES8424, NOT your source. That particular model is a high activity concentration per unit length.

Your model NES8429 would have the general useful life of 5 years."

In our initial submittal on 1 April 1999, in Appendix I, page I-4, Quality System Audits, the first sentence states, "The quality system of ELGEMS is audited periodically both internally and externally."

Mr. Lee had some questions:

o How frequent is "periodically" ? Is it the same for internal audits and external audits?

* ELGEMS' internal audit plan requires that each relevant Chapter of EN 46001 (ISO 9001 +specific requirements for Medical devices) will be annually reviewed.

* By default ELGEMS is annually audited by two external bodies which encompass (each one) all the above EN 46001 requirements . { Thus External audits are done in double frequency in comparison to internal audit.

o Who does the internal audits?

1) ELGEMS QA organization.
2) GEMS QA organization (In terms of Quality Commitment and controls ELGEMS & GEMS is one organization).

o How many internal audits were done by GEMS?

GEMS is yearly audit (see above) ELGEMS. On

Feb 1999 the annual audit has been carried.

o Who does the external audits

- 1) SII - Standard Institution of Israel.
- 2) GMED - GEMS European Notified Body.

In our June 1999 response to the item #3 of Mr. Lee's email to me on 6 May:

o How are the safety factors related to life expectancy of 10 years?

The safety factors are related to the standard IEC 601-1 requirements which specifies the factor according to the expectancy of impairment by wear, corrosion, material fatigue or ageing on the parts during the device life.

o Mr. Lee requested copies of the sections of 601-1 that were used in the design and analysis.

We will fax you the copy of the section used (Section Four , Protection Against Mechanical Hazards Clause 28, Suspended masses and Clause 22, Moving Parts).

o In the last sentence of the third paragraph of our response to item #3, we discuss the ball bearing.

Please explain how the maximum radial and axial loads of 2.5N are related to the life expectancy of 10 years.

Basic rating life of the bearing:
 The bearing used in the device is SKF 618/6.
 The basic rating life equation is (taken from the SKF catalogue that we will fax to you) :

	$L_{10} = (C/P)^p$	L_{10} - Basic rating life,
millions of revolutions		
dynamic load rating, N		C - Basic
Equivalent dynamic load rating, N		P -
Exponent of the life equation		p -

C = 884 N (from the bearing table)
 p = 3 (for ball bearings)
 $P = XFr + YFa$
 Fr = Actual radial bearing load, N
 Fa = Actual axial bearing load, N
 X =

*Actual vs / complete revolutions
 Are there bearings lubricated?*

Radial load factor for the bearing

Y = Axial load

factor for the bearing

$$P = 0.46 \cdot 2.5 + 2 \cdot 2.5 = 6.15$$

$$L_{10} = (884/6.15)^3 = 2.98 \cdot 10^6 \text{ millions of}$$

revolutions

$$L_{10} = 3 \cdot 10^{12} \text{ rev.}$$

The solenoid performs about 1 million of open/close cycles/ 10 years (the solenoid type is an extended life with 10 million cycles) .

The ball bearing, rotates in both directions, clockwise and counterclockwise, during the open and close cycle. Therefore, we can assume that the ball bearing performs 2 million of revolutions/ 10 years < L10.

Not explicitly stated

Regards,
Jim

g GE MEDICAL SYSTEMS

James Beebe
Safety and Regulatory for X-Ray, Nuclear Medicine & PET
Tel: 414-544-3061
Pager: 414-558-7686
Fax: 414-548-5197

CC: "James Beebe (E-mail)" <James.Beebe@med.ge.com>, B...



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DATE: 6/10/99

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY

FAX TRANSMITTAL

	TO	LOCATION
1.	<u>Dr. Jim Beebe</u>	_____
	FAX # <u>(414) 544-3863</u>	VERIFICATION () _____
2.	_____	_____
	FAX # () _____	VERIFICATION () _____
3.	_____	_____
	FAX # () _____	VERIFICATION () _____
4.	_____	_____
	FAX # () _____	VERIFICATION () _____

COMMENTS:

COVER SHEET PLUS 2 PAGES

FROM: Sung Lee

PHONE: (301) 415-5787

FAX: (301) 415-5369

CONVERSATION RECORD
(C:\SJM\gems.con)

TYPE:

Outgoing Telephone (414) 544-3061
Incoming Telephone
Meeting

NAME OF PERSON CONTACTED:

Dr. James Beebe

ORGANIZATION:

GE Medical Systems

TIME:

1:45 PM

DATE:

06/10/99

SUBJECT:

1. In your response No. 3, the IEC-601-1 was mentioned. Provide this document and explain how the safety factors of 8 for elements subjected to fatigue, corrosion, and wear and 4 for all other static elements the statement apply to 10 year life expectancy. Also the maximum radial and axial loads of 2.5N for the ball bearing apply to 10 year expectancy.
2. In quality systems audits in Elgems Quality Procedures, provide the specific frequencies for audit (e.g, quarterly, monthly, annually) and who performs internal audit (GE Medical Systems or Elgems) and external audit? Does GE Medical Systems perform audit for Elgems? If so, provide the annual frequency and actions to be performed. If not, provide the rationale not to audit.
3. Provide GE Medical Systems' QA/QC program.
4. In Service manual page 5-4, it should say "NRC or Agree", not "NRC Agreement," in warning statement.
5. Questions about sealed source will be forwarded later because the State of MA issued new registration certificate (MA-0476-S-117-S) on 4/1/199.

SUMMARY:

ACTION REQUIRED:

Make new Reg. Cer.

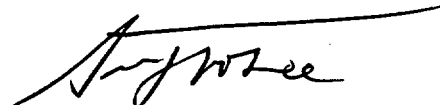
PLACE THIS RECORD IN:

Registration File NR-
QA File
Incident File
General File

PERSON DOCUMENTING THE CONVERSATION:

Seung J. Lee

SIGNATURE:



DATE:

06/10/99

TRANSMISSION REPORT

01.01.2040 00:00

301 415 5369

DATE TIME	DURATION	REMOTE ID	MODE	PAGES	RESULT
01.01 00:00	00'49"	4145443863	83	2	O.K.