

Medical-Surgical Division  
3M Health Care Group

3M Center  
St. Paul, Minnesota 55144-1000  
612/733 1110

Rev 12MB  
11/20/89

Rec'd 10/24/89  
- RMB Bush

October 10, 1989

**3M**

Steven L. Baggett, PhD  
Health Physicist  
U.S. Nuclear Regulatory Commission  
Division of Fuel Cycle & Material Safety  
MS-6-H-3  
Washington, DC 20555

Log	Nov 89
Remitter	
Check No.	892197 / 983311
Amount	120 + 230
Fee Category	9C
Type of Fee	APP
Date Check Rec'd.	11/20/89
Date Completed	12/24/89
By:	Jackson

RE: Sealed source evaluation for new Model No. 6712  
I-125 Seed. Materials License No. 22-00057-59MD

Dear Dr. Baggett:

We are requesting a sealed source evaluation for a new Model 6712 I-125 Seed. I have previously been in communication with Bruce Mallet of Region III on this matter and he suggested that I write to you directly.

Specifically, we are requesting NRC guidance regarding certification requirements for the Model 6712 I-125 Seed. A comparison of the physical characteristics of Model 6712 I-125 Seed with our standard certified Model 6711 I-125 Seed is provided in ATTACHMENT A of this letter. By way of summary, the Model 6712 I-125 Seed uses identical construction and similar components to the Model 6711 I-125 Seed, previously certified by the NRC and described in the document. The notable differences include: 1) smaller outside diameter, 2) smaller diameter of the silver rod inside, and 3) thinner end welds. We have found that weld thickness is directly proportional to titanium can diameter when the titanium cans are welded using our new plasma arc welders.

A comparison of Model 6711 and Model 6712 dosimetry is enclosed as ATTACHMENT B. Dosimetries for both Seeds are similar.

What data do we need to generate and submit to allow NRC to certify the Model 6712 Seed? Are prototype tests required, in view of the similarity between the two Seeds? If prototype tests are required, what protocols are appropriate in view of the small size of the Seed?

Instead of the standard sealed source prototype tests, we propose submitting the compressive shear data for Model 6712 Seeds as shown in ATTACHMENT C. Similar data for the the Model 6711 I-125 Seeds were included in a report to you from J. Bush of 3M dated July 8, 1988 (see ATTACHMENT C.)

9610180086 960216

PDR RC  
SSD

\*

PDR

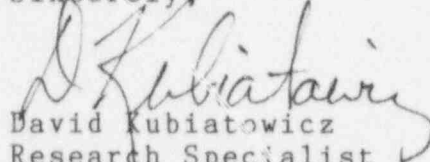
Steven L. Baggett, PhD  
October 10, 1989  
Page 2

We look forward to your timely response. When we understand what the agency requires, we will generate appropriate data to support a license amendment application to allow for distribution of this source to medical licensees.

Enclosed is a \$120 check for the sealed source evaluation.

If you have any questions, please contact me at the number listed below.

Sincerely,



David Kubiatawicz  
Research Specialist  
Assessment & Therapy Products Lab  
3M Medical Device Division  
270-2A-11 3M Center  
St. Paul, MN 55144

612-733-9127

enclosures: Attachments A - C

cc: J.D. Bush            270-4A-05

ATTACHMENT A: Comparison Model 6711 & 6712 I-125 Seeds

	Model 6711	Model 6712
Dimensions	4.5mm long 0.8mm diameter 0.05mm wall	4.5mm long 0.5mm diameter 0.05mm wall
Encapsulation	titanium	titanium
I-125 carrier	silver rod (0.8mm x 3mm)	silver rod (0.5mm x 3mm)
X-ray marker	silver rod	silver rod
end weld thickness	0.4 to 0.6mm	0.2 to 0.3mm
Photon energies	27.4 & 31.4 keV x-rays, 35.5 keV gamma photon, & 22.1 & 25.2 keV fluorescent x-rays from the silver rods.	
Assay Method	CRC 7-R well re-entrant chamber calibrated using a Model 6711 Seed traceable to NIST.	
Dosimetry	Dosimetry of the Model 6712 I-125 Seed is similar to that of the Model 6711 I-125 Seed. Enclosed in ATTACHMENT B is an unpublished report from Huang and Ling (UCSF 1/89) entitled "Dose Distribution of Model 6712 I-125 Sources".	
Seed Strengths	0.1 to 50 mCi	0.1 to 50 mCi

ATTACHMENT B: Dose Distribution of Model 6712 I-125  
Sources by David Huang and Clifton Ling.