

From: [Joe Rodgers](#)
To: [Herrera, Tomas](#)
Cc: [Sepulveda, Lymari](#); [Betsy Cortelloni](#)
Subject: RE: Clarifications for RSL amendment request
Date: Friday, February 06, 2015 7:59:15 AM

Tomas,

For the registry, the maximum activity is a 0.270 mCi-apparent (0.540 mCi-contained).

The radiation profile on page 2 of 6 was measured using a 0.243 mCi-apparent (0.486 mCi-apparent) seed. Radiation levels were measured on 10/8/14 using a Thermo-Electron microRem LE ion chamber, S/N 1509, calibration due date 8/8/15. Measurements were performed in a laboratory setting.

Using that measured profile, the calculated profile for a maximum of 0.270 mCi-apparent is shown in the following table using the measured profile * (0.270/0.243):

Calculated Radiation Levels (mR/hr) for one (1) I-Seed Model AgX100 (0.270 mCi) loaded in a shielded needle.	
Distance	mR/hr
5 cm	0.444
30 cm	0.017
100 cm	0.017

Let me know if you have any questions.

Best regards,
Joe

Joseph J. Rodgers, M.S.
Director of Radiation Physics, Technical Support, & Customer Service
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From: Herrera, Tomas [mailto:Tomas.Herrera@nrc.gov]

Sent: Friday, February 06, 2015 7:51 AM
To: Joe Rodgers
Cc: Sepulveda, Lymari; Betsy Cortelloni
Subject: RE: Clarifications for RSL amendment request

Good Morning Joe,

Thank you for the quick reply.

We will make sure that the correct needle sizes are included in the registry.

For our purposes for the registry we need to have the maximum activity that a seed can contain in the Leison-Loc, whether it is 1.0 mCi or 0.540 mCi, that would be up to Theragenics. The corresponding radiation profile must match the maximum activity contained in the seed in the needle. We can accept calculated or measure radiation profiles, if measured please provide the equipment used and the calibration date.

Please let me know if you have any questions.

Thank you,
Tomas Herrera
SSD Team Leader
NMSS/MSTR/MSLB
U.S. NRC
301-415-7138

From: Joe Rodgers [<mailto:RodgersJ@Theragenics.com>]
Sent: Friday, February 06, 2015 7:29 AM
To: Herrera, Tomas
Cc: Sepulveda, Lymari; Betsy Cortelloni
Subject: RE: Clarifications for RSL amendment request

Tomas,

Thank you for the prompt rely. Here's my response to the questions.

1. The maximum activity of 0.500 mCi-apparent (1.0 mCi-contained) was requested to provide any buffer if a customer requested such a higher seed activity for this application. For the registry, I am comfortable listing the maximum activity as 0.270 mCi-apparent (0.540 mCi-contained). The 0.243 mCi-apparent listed in the radiation profile is a typical seed activity provided for this intended use.
2. The length of the needles are 5 cm, 7 cm, 10 cm and **15** cm. The 12 cm listed on page 2 of 6 of the amendment request is incorrect (typo).

Please let me know if you have any questions.

If needed, I am available for a call today. My only conflicts are 9:00AM-9:30AM and 10:30AM-

11:30AM.

Best regards,
Joe

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From: Herrera, Tomas [<mailto:Tomas.Herrera@nrc.gov>]
Sent: Thursday, February 05, 2015 4:53 PM
To: Joe Rodgers
Cc: Sepulveda, Lymari
Subject: Clarifications for RSL amendment request

Good Afternoon Joe,

As Lymari was drafting the registration certificate, we noticed two items that we need clarification on.

1. On the first page of the amendment request you identified that the maximum activity was I-125, 0.500 mCi-apparent. Yet, for the radiation profiles on page 2 of 6, you identified the activity of 0.243 mCi. Please explain the differences.

Should the 0.500 mCi be listed as contained amount? If not please provide the maximum activity of the contained amount and explain why a quantity of 0.243 mCi was used in the radiation profiles.

2. On page 2 of 6 of the amendment request you stated that the needle would be available in four lengths, the maximum being 12 cm, however in 510(k) issued to IMI, the summary does not list 12 cm, but instead lists 15 cm.

Thank you,
Tomas