

From: [Herrera, Tomas](#)
To: [Joe Rodgers \(RodgersJ@Theragenics.com\)](mailto:RodgersJ@Theragenics.com)
Cc: [Sepulveda, Lymari](#)
Subject: Clarifications for RSL amendment request
Date: Thursday, February 05, 2015 4:53:22 PM

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