

From: William Ward
To: Traci Kime
Date: 12/07/2001 6:56PM
Subject: SSD case 01-29, MDS Nordion C-168 source

Traci,

On Tuesday, December 4, 2001, I had a phone call with Marc Charette of MDS Nordion. He informed me that Nordion had not yet reviewed the request for additional information sent on November 20 to Nordion regarding the C-168 source. He hoped that he might review it later this week. However, he stated that responding to the C-442 RAI, working on 10 CFR 32.74 labels for the GammaMed 12i/12it device, and preparing a request to make a correction to the GammaMed 212 source certificate were of higher priority at this time. He said it was highly likely he would ask for an extension on the 30 day response time to the C-168 RAI, due 12/20/01

Since he has not provided any more updates this week, and based on the prior information, we have decided to terminate the review on the C-168 source at this time. We will continue the review when they respond to the RAI, probably in January 2002. Please close the case, 01-29, as review terminated, effective 12/4/01, due to Nordion informing us they will not respond to the RAI within 30 days.

Thank you

Bill

CC: John Jankovich; Michele Burgess