

**From:** Seung Lee  
**To:** "David.Duersteler@amermsx.med.ge.com"@GATED.nrcsmt...  
**Date:** Wed, Jul 12, 2000 4:04 PM  
**Subject:** Re: RE: Responses to RAI dated June 5, 2000 for CoDe

Dear Mr. Duersteler:

This is in response to your e-mail requesting 30 day extension for your responses to RAI dated June 5, 2000, for the Attention Correction Option (CoDe AC). As of today, we can not allow 30 day extension. Therefore, we are voiding your application for registration of the Model CoDe AC. This action is without prejudice to the resubmission of a complete application.

We will reopen your application as soon as we receive the responses. Please submit only the responses to each of my questions. We will keep your original application so you don't have to submit an amended application. If you have any questions, please call me at 301-415-5787 or send me an e-mail.

Thank you very much.

Seung

>>> "Duersteler, Dave (MED)" <David.Duersteler@amermsx.med.ge.com> 3:27:35 PM  
Wednesday, July 12, 2000 >>>  
Mr. Lee,

My name is Dave Duersteler. I work in GE Medical Systems Safety & Regulatory Engineering group, as does Jim Beebe. Recently, our responsibilities were reassigned, and I am now responsible for regulatory activities for our Nuclear Medicine products.

Unfortunately, as the transition in responsibility from Jim to me was occurring over the past 2 months, I was not aware of your June 5, 2000 RAI. I now have a copy of the June 5 document, however, we will not be able to fully respond by the end of this week.

Can you tell me if it is possible to obtain a 30 day extension for our response, and if so, what steps I should take to request the extension?

Also, can you tell me the form in which you prefer the response? In other words, should we respond directly to each of your questions, or should our response be in the form of an amended applicatoin that includes the information requested in your RAI?

Thank you for your help and for reminding us of this RAI.

Regards,  
Dave Duersteler  
Safety & Regulatory Engineering  
phone: 262-785-5314  
fax: 262-785-5874

pager: 414-407-6378  
e-mail: [david.duersteler@med.ge.com](mailto:david.duersteler@med.ge.com)

> -----Original Message-----  
> From: Seung Lee [<mailto:SJL@nrc.gov>]  
> Sent: Monday, July 10, 2000 10:16 AM  
> To: [james.beebe@med.ge.com](mailto:james.beebe@med.ge.com)  
> Cc: [jpj2@nrc.gov](mailto:jpj2@nrc.gov)  
> Subject: Responses to RAI dated June 5, 2000  
>  
>  
> Good morning, Dr. Beebe!  
>  
> I did not get the responses to RAI dated June 5, 2000, for  
> the Attention Correction Option (CoDe AC) yet. If I did not  
> get them by the end of this week, I assume that you have  
> abandoned the application as stated in the RAI so our review  
> will be discontinued. If you have any questions, please let me know.  
>  
> Thank you very much.  
>  
> Seung

**CC:** John Jankovich

**Mail Envelope Properties**  
(396CCF4C.506 : 6 : 20584)

**Subject:** Re: RE: Responses to RAI dated June 5, 2000 for CoDe  
**Creation Date:** Wed, Jul 12, 2000 4:04 PM  
**From:** Seung Lee

**Created By:** TWFN\_DO.TWF4\_PO:SJL

Recipients	Action	Date & Time
Post Office GATED.nrcsmtp "David.Duersteler@amermsx.med.ge.com" ("D	Transferred	07/12 4:04 PM
Post Office TWFN_DO.twf4_po JPJ2 CC (John Jankovich)	Delivered	07/12 4:04 PM
<b>Domain.Post Office</b> GATED.nrcsmtp TWFN_DO.twf4_po	<b>Delivered</b>  07/12 4:04 PM	<b>Route</b> GATED.nrcsmtp TWFN_DO.twf4_po

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MESSAGE

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Wednesday, July 12, 2000 4:04 PM

**Options**

<b>Auto Delete:</b>	No
<b>Expiration Date:</b>	None
<b>Notify Recipients:</b>	Yes
<b>Priority:</b>	Standard
<b>Reply Requested:</b>	No
<b>Return Notification:</b>	None

<b>Concealed Subject:</b>	No
<b>Security:</b>	Standard

<b>To Be Delivered:</b>	Immediate
<b>Status Tracking:</b>	Delivered & Opened