



Thomas W Smith  
06/03/2004 06:50 AM

To: Dante C Huntsman/DHUN/CC01/INEEL/US, Robert L  
Sant/ZAP/CC01/INEEL/US,  
cc:  
Fax to:  
Subject: NMED#040326, and OGC guidance regarding medical events and  
written directives

OGC is Office of General Council. They state "regarding the need for a written directive in reporting a medical event, under 35.3045 (a) (1) and (3) you need a written directive to have a medical event; (a)(2) does not."

--- Forwarded by Thomas W Smith/SMITTW/CC01/INEEL/US on 06/03/2004 06:50 AM ---



"Michele Burgess"  
<MLB5@nrc.gov>  
06/02/2004 03:06 PM

To: <SMITTW@inel.gov>  
cc: "Angela Williamson" <ARW@nrc.gov>, "Ivelisse Cabrera"  
<IMC1@nrc.gov>, "Linda Psyk-Gersey" <LMP1@nrc.gov>, "Ronald  
Zelac" <REZ@nrc.gov>, "Roberto Torres" <RJT@nrc.gov>, "Stuart  
Treby" <SAT@nrc.gov>, "Susan Chidakel" <SSC@nrc.gov>  
Fax to:  
Subject: NMED#040326, and OGC guidance regarding medical events and  
written directives

Specific question:

that started this email chain was you question to me whether NMED#040326 is a medical event (i.e., Reportable =Y or N in NMED), so we could get NMED coded correctly. The answer to that is that it is Reportable = N. If they do any further review of the inspection report and tell me differently, then I will forward that to you.

General question:

that got answered in the process is that per OGC, regarding the need for a written directive in reporting a medical event, under 35.3045 (a) (1) and (3) you need a written directive to have a medical event; (a) (2) does not.

Let me know if you have any questions.

>>> Susan Chidakel 05/10/2004 1:32:59 PM >>>

If you are talking specifically about Item 97, my advice on that item was that from the information presented it probably wasn't a medical event BUT I stated I couldn't make a determination without seeing the written facts. The Region was going to send an inspection report and we were going to review it.

If you are talking in general terms about the need for a written directive in reporting a medical event, under 35.3045 (a) (1) and (3) need a written directive to have a medical event; (a) (2) does not.

>>> Ronald Zelac 05/10/04 10:33AM >>>

I believe that Angela has, referring to the discussion of Item #97 during the Part 35 teleconference on 2/26/04, which you attended, properly characterized the current Agency position/OGC position with respect to such events. Do you agree? (Please see Roberto's question, below.)

Thanks.

>>> Roberto Torres 05/07/04 12:02PM >>>

Ron:

If the team have not done so, please ask OGC whether they consider such cases as medical event or not and let me know their opinion.

>>> Angela Williamson 05/07/04 11:16AM >>>

Michele: NMED #040326 is an event whereby a patient was administered I-131

although the licensee had not prepared a written directive. The MPWG discussed another event very similar to this one, which is captured in our meeting minutes as Item #097. (In that case, IVB was administered to a patient in the absence of a written directive).

It was determined that a medical event had not occurred in the IVB case because 35.3045 states conditions for the occurrence of a medical event when the licensee performed actions outside the instructions of the written directive. That is also what happened in NMED #040326. Although it could be argued that the lack of a written directive is itself a medical event, it can also be argued that 35.3045 does not specifically state that the lack of a written directive is a medical event. Legally, we would have difficulty citing the licensee against 35.3045, because the lack of a written directive is not one of the medical event criterion listed in 35.3045.

We have already agreed that the lack of a written directive should be one of the criterion for identifying a medical event. I believe that Donna-Beth has, in the user-need memo, listed this issue as one of the items regarding Pt. 35 that we need to fix.

But for now, cases such as those in event 040326 are correctly coded as "N" within NMED, with respect to being a medical event.

>>> Michele Burgess 05/06/2004 3:20:37 PM >>>

Can you let me know if you agree that this is not reportable? We think we read it right. Thanks.