



"Michele Burgess"
<MLB5@nrc.gov>
08/11/2005 07:59 AM

To <Dante.Huntsman@inl.gov>, <Robert.Sant@inl.gov>, <Thomas.Smith@inl.gov>, "Ashley Tull" <amt1@nrc.gov>, "Gregory Morell" <GKM@nrc.gov>
cc "Cynthia Flannery" <CMF@nrc.gov>, "Donna-Beth Howe" <DBH@nrc.gov>

bcc

Subject Re: EN 41880 (NMED 050503) Fractionated Treatment or Separate Treatment?

Donna-Beth says it was individual treatments, not fractionated, and therefore it is a reportable event.

>>> Cynthia Flannery 08/04/2005 3:35:09 PM >>>

There is a lot more information that is needed before a determination can be made as to whether this is a medical event. Donna-Beth has been in touch with Penny from Region I on this issue. Region I is trying to obtain more information from the licensee and will be visiting the facility next week. Donna-Beth may be going along on the trip the licensee.

Please contact Donna-Beth for specific questions on this event.

>>> Michele Burgess 08/02/05 12:42 PM >>>

Could you please read the email from INL below, and could you (or the Team, however you prefer) let me know you are considering this two treatment fractions or two separate treatments?

Thank you,
Michele

>>> Thomas W Smith <Thomas.Smith@inl.gov> 08/02/2005 10:07:50 AM >>>
Michele:

Please review EN 41880. This EN involves a possible medical event. The text uses the phrase "scheduled to be administered two SIR-spheres treatments" and does not mention that these were two fractions of the same treatment. The text continues to use the words "first treatment" and "second treatment" several times. The patient received 46% less dose than prescribed during the first treatment.

If it was 2 treatments, it is reportable per 35.3045(a)(1)(i) - dose differs by 20% or more.

If it was a fractionated treatment, it is not reportable because 35.3045(a)(1)(iii) requires 50% or more. The EN specifically references this requirement in the text.

We coded NMED 050503 as a non-reportable treatment fraction, but the EN reads as if it were two separate treatments.

Tom