From: Andrew Zimnoch
To: RulemakingComments Resource
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Comments

when Part 35 was changed in 2002-2004, the term recordable event was eliminated and misadministration was changed to medical event. However, If I remember correctly, the definition didn't change. So the meaning has been that an administration was performed incorrectly vs. what the AU intended. The new aspects of ME for implants are addressing what can go wrong after implantation was performed according to how the AU wanted. This is a different meaning of medical event. Possibly new terms should be used to clarify this. If a doctors think they will "be in trouble" when they performed the administration well and seeds moved afterword, it may inhibit physicians treating patients who could be helped. This must be balanced vs the risk of things going wrong with no "misadministration".

Also, are inspectors capable of evaluating the methods used by the physicist to determine the 5 CC tissue and dosimetry relating to it? If they aren't, how will this regulation be implemented well?

For the definitions of categories under 35.390, the current definitions for 3 and 4 have been confusing. This new version still is. What is the point of specifying the 150 keV limit in number 3? If there ever is an new use for a photon emission that is slightly greater than 150 keV, there is no provision for it under these regs.

Andrew Zimnoch