From:	Kennedy, William
To:	RulemakingComments Resource
Cc:	Crawford, Jack; Logan, William
Subject:	on Docket ID NRC-2008-0175
Date:	Wednesday, August 20, 2014 4:25:17 PM
Attachments:	Prostate Implant NRC Proposed Rule My Comments 8-2014.docx

Please see attached.
Thank you,
Bill Kennedy, Ph.D.

Comments on NRC Proposed Rule - Docket ID NRC-2008-0175

for Permanent Radioactive Implants by William Kennedy, Ph.D. 20-Aug-2014

Main Message: With reference to 35.3045 determining Medical Events (ME), **the NRC should simply require Peer Review as part of "high confidence" and not try to regulate the medicine side.** The NRC already requires that we establish an implant procedure that gives "high confidence" that the Written Directive (WD) will be fulfilled by physicians with fully regulated training and experience, so any Medical Event (ME) should just be a rare mistake. This is the intent of ME's, they are the exception in an NRC accepted procedure. So NRC determination of "actual or potential harm to a patient" and review of normal tissue doses are not needed, but should be referred directly to a Medical board or Peer Review. In fact, the NRC should simply require Peer Review of a majority of each AU's cases and stick to the non-medical side of fulfilling the "high confidence" steps and RAM requirements of the WD.

Refer to proposed 35.3045 paragraph (a)(2)(iv), precise control of source location inside the treatment site over several half-lives is impossible (and not necessary), so absorbed dose to intra-target structures is impossible to control and is therefore a medical decision, not a potential location for a Medical Event. Medicine has to operate in a risk-benefit balance when it comes to normal tissues, so the NRC has no role here.

Lots of other problems can be found here. Refer to proposed 35.3045 paragraph (a)(2)(ii), how far is "outside the treatment site"? If 20% of the now uncontrollable sources end up "outside the intended location" by any means, it is an ME. Most of prostate seeds are required to be implanted in and around the periphery of the gland and many, easily 20%, drift around out there, even when linked together. So what is the cutoff distance of drift? In addition, if even one source is apparently "directly implanted … into another (distant from the treatment site) location", it is also an ME. Long distance drift of one seed is common, so who is to say it was not directly implanted there? Again, the ME distance is not defined. These questions will force AU's to simply define a treatment site with huge margins for seed drift. What rule would apply if all seeds are in the treatment site, but badly distributed around the periphery? All normal tissues can be fine, but the treatment site has a bad cold spot. Many implants of the prostate show this tendency naturally 30 days after implant. So who caused it? These kinds of issues should not be an NRC problem. As stated above, the solution is for the NRC to not try and regulate the medical side. **The NRC should simply require Peer Review as part of "high confidence."**