January 31, 2022

Katie Tapp
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Dr. Tapp:

The OAS Executive Board (Board) appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) the draft licensing guidance for the "Superficial Manual Brachytherapy CivaDerm™ Device" (RCPD-21-015)

Based on our review of the information, the Board offers the following questions and comments:

1. Under 35.40 on the "10 CFR 35 Placement Evaluation for CivaDerm™ (CivaDerm)", it may be helpful to add in the notes section, that the requirements for the written directive for CivaDerm should include the items in 35.40(b)(7) and 'implant' can be used interchangeably with 'affixed' or 'application' of CivaDerm, just for clarification since CivaDerm is not "implanted".

2. The SSDR states that "CivaDerm[1] sources must only be handled by trained, experienced, and licensed personnel must use standard radio-protective equipment suitable for low dose rate Pd-103 sources." The draft licensing guidance does not detail specific training requirements for AUs regarding how they are trained in source handling and attachment methods.

3. The SSDR states that "The licensing authority will have to obtain details on specific applicators, measuring equipment, and operational procedures from the license applicant in making the licensing determination and licensing approval."

   The SSDR does not include appropriate attachment methods, and the draft licensing guidance states that the CivaDerm be "attached using robust techniques to mitigate risk of detachment as well as minimize patient access to the device" with the attachment method to be determined by the physician which could include techniques using sutures, staples, adhesive glue, temporary casts, and bandages." We as the licensing authorities need to have a better understanding of how this product can and should be attached to a patient. Please include information regarding attachment methods in the licensing guidance.

   Additionally, the SSDR describes that "If a CivaDerm source is re-sized, the user should cut through the bio-absorbable sheet only. The radiation encapsulation on the CivaDerm sources must never be cut. If the radiation encapsulation is accidentally cut, the immediate area and the cutting

[1]Please note that the SSDR states that "Except where CivaDerm products are specifically differentiated in this document, the term CivaSheet will apply to both CivaSheet and CivaDerm products", in this comment letter, for clarity, we have used the term CivaDerm only.

instrument must be surveyed. Breached CivaDerm fragments and contaminated cutting instruments must be properly disposed of as Radioactive Waste." This statement, along with the draft licensing guidance statement that the attachment method may be with staples, or sutures, makes it clear that the licensee will need to develop and submit procedures for this type of activity. The development of these types of procedures should be discussed in the licensing guidance.

4. The licensing guidance describes that "If there is a potential for a source to become dislodged under unique situations, licensees must have preventative measures in place to ensure public dose limits are not exceeded. Preventative measures include providing patients with a shielded container to place the CivaDot(s) if they become dislodged."

   The "Safety Instructions" in the SSDR state that "Loose CivaDerm sources should be handled carefully with tweezers or non-locking forceps", and "CivaDerm sources must never be handled with excessive force, or subject to excessive compression", these are important instructions that would need to be given to the patient if they would be responsible for placing the sources into a shielded container. If the licensee will be sending a patient home with a shielded container to place the source in, they should have to develop specific patient safety instructions. This should be considered as an addition to the licensing guidance.

Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,

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