



Nucletron

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Ray Manley
Radiological Health Program
Maryland Department of the Environment
1800 Washington Boulevard, Suite 750
Baltimore, MD 21230

Our reference:
Cor 103106A

Your reference:

Date:
October 31, 2006

Dear Mr. Manley:

In May, 2006 Nucletron submitted a sealed source and device (SS&D) application for a new afterloader --microSelectron HDR (V3). This afterloader is almost identical to Nucletron's Model 105.999, PDR, and OncoSelect HDR-3 afterloaders currently in distribution. One area of modification, however, concerns the *Treatment Control Station*. In the submission, the Treatment Control Station is referred to as TCS 3.0. TCS 3.0 represents the latest firmware and software revision for the Treatment Control Station. TCS 3.0 is compatible with the Model 105.999, PDR, and OncoSelect HDR-3 afterloaders. Given the changes in TCS 3.0 are significant, Nucletron believed a review for the SS&D registries was in order. At the same time, the added functionality provided in TCS 3.0 is of interest to many afterloader customers and upgrades are imminent. Furthermore, the TCS currently distributed with the Model 105.999, PDR, and OncoSelect HDR-3 will not be manufactured in 2007. Nucletron intended to submit amendments for TCS 3.0 to the existing registries for the Model 105.999, PDR, and OncoSelect HDR-3 afterloaders once the microSelectron HDR V3 SS&D registry was issued. However, issuance of the microSelectron HDR V3 SS&D will not be as timely as anticipated and Nucletron's other registries will now need to be amended for TCS 3.0 sooner than later.

I am writing today to request input from Maryland Department of the Environment on the course to take for the several licensing actions at hand.

Please reply to the undersigned at 443-545-2196 or lisa.dimnick@us.nucletron.com.

Kind Regards,

Lisa Dimmick
Director Regulatory Affairs, RSO

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