



Therametric Technologies, Inc.

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January 15, 2019

Materials Licensing Branch
U.S. Nuclear Regulatory Commission – Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: NRC License Number 13-32788-01 Amendment Request

Dear Sir/Madam:

Therametric Technologies, Inc. recently changed vendors for the activation of extracted human teeth for the purpose of determining the abrasive properties of various dentifrices as the approved, authorized use in our current NRC license. While the previous vendor only provided information on the ^{32}P content in the activated teeth, the new vendor initially reported a number of short-lived, gamma-emitting impurities in the teeth that were well below exempt quantities as defined in 10 CFR 30.71, Schedule B; however, they did not initially report the amount of ^{32}P which is the primary radionuclide in the activated teeth. The reason for their not reporting the ^{32}P amount related to the fact that they had no way of directly assaying the teeth as it is a pure beta-emitting radionuclide. We then requested the vendor provide us a calculated value for ^{32}P in each shipment of teeth to verify that we were complying with our license possession limit.

In a recent correspondence from the vendor, they indeed provided a calculated amount of ^{32}P for the next batch of teeth to be irradiated; however, they also calculated an amount for two other pure beta-emitters, ^{45}Ca and ^{47}Ca . Of those two, the calculated amount for ^{45}Ca is 59 microcuries (μCi) which is above the exempt quantity limit of 10 μCi . Thus, we need to amend our NRC license to include ^{45}Ca in any form with a conservative possession limit of 1,000 μCi .

Due to the longer-lived nature of ^{45}Ca ($T_{1/2} = 162.67$ days), it will be necessary to ship the teeth to a licensed radioactive waste broker for ultimate disposal. The licensee will assure that any radioactive waste broker utilized for this purpose is properly licensed by the NRC or Agreement State and will maintain records of all disposals made in this manner.

We also noted that the new vendor calculates the activity in a given batch of irradiated teeth to contain approximately 3.5 millicuries of ^{32}P . That amount is slightly higher than what was

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provided by the previous vendor (usually about 2 millicuries per batch); therefore, to provide an adequate buffer, we would like to increase our ^{32}P possession limit to 10 millicuries.

It should be noted that the current vendor will not activate and send back the current batch of teeth we have sent them until our NRC license is amended to include the non-exempt quantity of ^{45}Ca . **This essentially halts our ability to continue providing services to our clients until this amendment is approved. The abrasivity test performed using these activated teeth is an FDA/ADA/ISO required safety assessment for dentifrice formulations to be marketed in the United States. Therametric Technologies, Inc. is currently one of only two known facilities worldwide capable of performing this specific assessment for the oral healthcare industry, so your prompt attention to this matter would be greatly appreciated.**

Should you have any questions or require further information please contact me at 317-565-8070 or via email at tganovsky@therametric.com Cc: hmcclure@therametric.com.

Sincerely,

Tara J. Ganovsky
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Cc: Heath C. McClure
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