



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

July 13, 2017

Suzanne Babcock
Executive Chairman and CEO
CivaTech Oncology Inc.
2810 Meridian Parkway, Suite 144
Durham, NC 27713 USA

Dear Ms. Babcock:

SUBJECT: SEALED SOURCE AND DEVICE EVALUATION WORKSHOP

I would like to thank you and your staff at CivaTech Oncology Inc. for sharing your time, talents, and facility with the U.S. Nuclear Regulatory Commission's (NRC) 2017 Sealed Source and Device Evaluation Workshop. The North Carolina Department of Health and Human Services' Radiation Protection Section hosted this year's workshop in Raleigh, North Carolina from June 19 to June 23, 2017. As you may know, the NRC schedules this workshop periodically to provide training to Agreement State and NRC staff on performing safety evaluations of sealed sources and devices for compliance with the regulatory requirements. In this year's workshop, we had 26 participants from 10 Agreement States and the NRC.

On Wednesday, June 21, 2017, the workshop participants traveled to Durham, where they were greeted with a tour of your facility. This tour was most informative, and the discussions and demonstrations helped the participants appreciate the processes that go into manufacturing and developing the brachytherapy products your firm produces. We would also like to thank Dr. Jainil Shah for answering participant questions during and after your presentation and the tour. The participants were able to get a good perspective on how the regulation of such devices relates to the overall sealed source and device evaluation process. We received positive feedback from participants regarding the visit to your facility. Your organization contributed greatly to the success of this workshop.

Thank you once again.

Sincerely,

/RA/

Hipolito Gonzalez, Chief
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

cc: Jainil Shah, Ph.D.

LETTER TO SUZANNE BABCOCK, SEALED SOURCE AND DEVICE EVALUATION WORKSHOP

Date: July 13, 2017

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