

June 27, 2014

Document Control Desk U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

Subject:

Potential Part 21 Issue on Irradiations Performed by Steris Isomedix

Services (Steris) in Whippany, New Jersey

Reference:

Steris Isomedix Services Letter dated June 18, 2014 received by

Kinectrics Inc. (Kinectrics) June 24, 2014

Pursuant to the requirements of 10CFR Part 21, this letter notifies the NRC of a Potential Part 21 Condition. Kinectrics received the reference letter from Steris on June 24, 2014 which notified us that the actual dose delivered to our test specimens may have differed up to +/-5.1% from the value initially reported. This service has been provided under contract with Kinectrics to support multiple equipment qualification and related projects for our Customers. Although some projects may have included excess margin in the requirements imposed upon Steris by contract, Kinectrics cannot at this point ascertain whether a defect as defined in 10CFR Part 21 exists.

## KINECTRICS INCORPORATED

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Kinectrics has assembled a team to address this issue and is currently performing the following actions:

- 1. Reporting this potential issue to all of Kinectrics' affected customers.
- 2. Reviewing past and current projects to determine if Steris was utilized for irradiation services.
- 3. For affected projects, Kinectrics is working closely with Steris to verify the variability of the doses applied and determine the actual radiation dose applied to test specimens as accurately as possible.
- 4. For projects in which the unaccounted variability could have resulted in the actual dose being less than that reported to our Customers, Kinectrics will formally notify those affected Customers to the following items:
  - a. Advise them of the potential difference in the reported dose.
  - Work with customers to determine if a defect as defined by 10CFR Part 21 does indeed exist.

Kinectrics will complete the initial evaluation within sixty (60) days of discovery following the requirements stipulated in 10CFR21.21. Should a determination be made that a defect exists which could create a substantial safety hazard, Kinectrics will notify the Commission in accordance with 10CFR21.21(d)(3)(i).

If you have any questions, please feel free to contact Kinectrics' Quality Manager, Justin Hubbard, at (416) 207-6000 ext. 6137 or e-mail at justin.hubbard@kinectrics.com.

Sincerely,

David Harris President & CEO Kinectrics Inc.

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