

Tran, Frank

From: Tran, Frank
Sent: Tuesday, January 17, 2017 11:43 AM
To: 'amy.kerrigan@biostorage.com'
Subject: Request for additional information regarding the renewal application NRC License No. 13-32622-01
Attachments: Model Delegation of Authority to RSO.docx

Dear Ms. Kerrigan:

This refers to the license renewal application for BioStorage Technologies, Inc., NRC License No. 13-32622-01. We have reviewed the application and determined that additional information will be needed to complete the review. On January 17, 2017, we called and discussed the deficiencies with you. You provided the following.

- 1) The licensee requests no changes to the licensed materials and quantities listed on the current license (Amendment No. 5).
- 2) The authorized user will be Mr. Thomas Schumacher and any use of licensed materials will be under his supervision.
- 3) The licensee will provide a copy of the memorandum of delegation of authority for the RSO (a sample is attached for your reference).
- 4) Ms. Tina Agnew, Director of Global Quality Assurance, will also be responsible for the Radiation Safety Program and has authority to stop any unsafe operations involving licensed materials.
- 5) The licensee will provide a copy of the facilities where licensed materials are used or handled, including the receiving/shipping areas and storage areas (scale or dimensions will be indicated on the diagrams).
- 6) The licensee will provide instruction for maintaining security of licensed materials in storage or use.
- 7) The licensee will provide a specific details for radiation survey instrument, including the calibration frequency and method, or provide a standard statement as suggested in NUREG-1556, Volume 18, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix J of NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000.' We reserve the right to upgrade our survey instruments as necessary."
- 8) With regard to the occupational dosimetry, the licensee will provide the standard wording as suggested in NUREG-1556, Volume 18, "We will have a prospective evaluation and determine that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20, or we will monitor individuals in accordance with the criteria in the section entitled 'Occupational Dose' in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000."
- 9) With regard to the monitoring of facilities for contamination, the licensee will detail its survey frequency, administrative contamination levels and actions, etc. or provide the standard wording as suggested in NUREG-1556, Volume 18, "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000."

- 10) It appeared that it was an error with the unit of the radiation contamination levels in the application (cpm v.s. dpm) on Pages 5 and 7. The licensee will correct this error.
- 11) It appeared that Section E.2., "Radiation Safety and Decommissioning Records System", on Page 7 referred to an incorrect regulation (10 CFR 30.g.1-4). It should be 10 CFR 30.35.g.1 through 4. The licensee will correct this error.
- 12) On page 4 of the application, the licensee listed an acronym "ISISS". The licensee will provide a definition for this term.
- 13) On page 2 of the application, the licensee referred the training needed for individuals, who will handle licensed materials outside of their container, in Section II.C; however, Section II.C was not provided. The licensee will provide a copy of Section II.C.

Please provide the above in writing by January 30, 2017 and please indicate Mail Control No. 591666 in the response to facilitate proper mail handling in our office. You could fax the response with a cover letter signed by a senior management to 630-515-1078.

If you have any question or need any clarification regarding the above, please contact me at 630-829-9623 or reply to this email.

Thank you.

Frank Tran

Health Physicist/License Reviewer
NRC Region III/Division of Nuclear Materials Safety
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