

Weaver, Deborah

From: Struckmeyer, Richard
Sent: Tuesday, September 11, 2018 1:05 PM
To: Mark Brennan
Cc: Herrera, Tomas; Sepulveda, Lymari
Subject: Owlstone amendment application - request for additional information

Mr. Brennan,

We have reviewed your amendment request dated August 1, 2018, and found we need more information to complete our review. Please provide the following information.

1. Please confirm that there have been no changes made to the Lonestar chemical monitor since your last amendment.
2. Please confirm that there are no changes to Owlstone, Inc.'s quality assurance program.
3. Please specify the serial number of the last unit distributed from Owlstone, Inc.'s previous location or provide the date of the last distribution from Owlstone, Inc.'s previous location. In addition, please provide the number of units that were transferred to the new location.
4. Please inform us when you have received you amended possession license.

Please submit the requested information within 30 days of the date of this email. The information should be submitted in an official company letter as an attachment to an e-mail. If we do not receive a response with the complete information within 30 days, we will consider your request as having been abandoned by you. This is without prejudice to the submission of a new request.

Do not hesitate to contact us with any questions.

Regards,

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
301-415-5477