

**From:** [Gaskins, Farrah](#)  
**To:** [Michael Levy](#)  
**Subject:** Request for additional information for LN 45-25221-01MD  
**Date:** Tuesday, November 05, 2019 4:07:00 PM

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**PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION.**

Licensee: SOFIE Co. d/b/a SOFIE  
License No.: 45-25221-01MD  
Docket No.: 030-32974  
Control No.: 616256

Dear Mr. Levy:

This is in reference to your application dated October 3, 2019, requesting to amend Nuclear Regulatory Commission License No. 45-25221-01MD. In order to continue our review, please provide the following additional information:

1. You requested to change your Radiation Safety Officer (RSO) to Timothy Pellegrin, R.Ph. Please provide a telephone number, fax number, and email address for Mr. Pellegrin. Also, please provide a mailing address if different from the corporate address.
2. The submitted Delegation of Authority (DOA) letter states Mr. Pellegrin has been appointed RSO and is responsible for managing the safe and secure use of radioactive materials produced by an accelerator. In our telephone conversation on November 4, 2019, you indicated that you currently only use and store Fluorine-18 at your locations of use. Your license is authorized for a variety of byproduct materials, although you may not currently use, possess, or store all of the materials at any one time. Please confirm your understanding that, as RSO for the license, Mr. Pellegrin will be responsible for all materials authorized on this license.
3. The DOA further states that Mr. Pellegrin is delegated to act as site RSO. In our telephone conversation on November 4, 2019, you stated that the Kansas City location has a site RSO. The NRC does not recognize alternate or assistant RSOs for radiopharmacy licenses. Please confirm your understanding that Mr. Pellegrin, as RSO, will be responsible for overseeing the radiation safety program at both locations of use. The RSO may delegate certain tasks to other qualified individuals, but the RSO must confirm that those delegated tasks were performed as required and in compliance with NRC regulations and your NRC license.
4. Please confirm if you will remain as the licensee management contact.

We will continue our review upon receipt of the requested information. If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your application. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 616256. If you have any questions regarding this deficiency letter,

please call me at (610) 337-5143.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select Nuclear Materials; Med, Ind, & Academic Uses; then Licensee Toolkits, see our toolkit index page. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

*Farrah C. Gaskins*

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