



03 Jan 2024

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Division of Radiological Safety and Security  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road, Suite 102  
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**SUBJECT: Request for Amendment, NRC License #52-25361-01MD.**

Ms. Nguyen,

Pharmalogic Puerto Rico kindly requests authorization to redistribute Ge-68/Ga-68 generators to other licensed PharmaLogic Holdings Corp. radiopharmacies.

1. Pharmalogic Puerto Rico confirms that:
  - a. Only generators used in accordance with the manufacturer's instructions will be redistributed.
  - b. The generator will not be distributed beyond the expiration date shown on the generator label.
2. Procedures and instructions for safely repackaging the generators.
  - a. The generators will be packaged, prepared, and transported to meet the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, and NRC regulations in 10 CFR part 71.
  - b. The generators will be packaged, prepared, and transported using the manufacturer's original packaging, minimizing the migration of radioactive fluids from the generator during transport.
  - c. The manufacturer's packaging and labeling will not be altered.
  - d. The redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

The return agreement between PharmaLogic Holdings Corp. and Eckert & Ziegler (E&Z) covers all PharmaLogic Holdings Corp. locations and intends to return the generators to E&Z at expiration.

Please feel free to reach out if any of your items need to be addressed in more detail or if you require any additional information.

Regards,

  
Rolando Garcia

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