



November 20, 2019

US Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
Attn: Medical and Licensing Assistance Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

Subject: Request for additional information on mail control numbers 614059 and 614055

Dear Sir or Madam,

Item 6 under the section "Radiation protection program changes [10 CFR 35.26]" should read as follows:

"The record will include a copy of the current guidance for use of the Ge-68/Ga-68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management representative who reviewed and approved the change."

This should apply to both mail control numbers listed above. If you have any questions, please do not hesitate to reach out.

Thank you,

Reid Gadziala

Pharmalogic Holdings Corp.
Director of Operations
703.851.3025

Song, Taehoon

From: Reid Gadziala <rgadziala@pharmalogic.info>
Sent: Wednesday, November 20, 2019 2:20 PM
To: Parker, Bryan
Subject: [External_Sender] Request for additional info
Attachments: new doc 2019-11-20 15.18.38-20191120151848.pdf

Bryan,

Please see the attached correction we discussed.

Thank you,

Reid