



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

**MAR 09 2018**

Glenn P. Sullivan  
Corporate Radiation Safety Officer  
Cardinal Health 414, LLC  
7000 Cardinal Place  
Dublin, OH 43017

Dear Mr. Sullivan:

Enclosed is Amendment No. 06 to your NRC Materials License No. 34-31473-03MD, in accordance with your request dated December 8, 2017, as it relates to modification of your bioassay procedures.

Please note, however, that we did not act on a portion of your request. In your submission, a second letter was included also dated December 8, 2017, and this letter requested the possession and distribution of IRE Galli-Eo<sup>®</sup> Ge-68/Ga-68 generators. Primarily, due to the amount requested, you will need to put financial assurance (FA) in place for this license before being authorized for this activity. Specifically, even though you may be exempted from establishing a Decommissioning Funding Plan (DFP), if you wish to possess up to 20 Ge-68/Ga-68 generators (a total of 1000 millicuries), you must have FA in the amount of \$1,125,000.00 in place.

The NRC guidance related to this issue is dated July 13, 2017, and can be accessed on the NRC website in the Medical Toolkit (<https://www.nrc.gov/materials/miau/med-use-toolkit.html#et>). The guidance also includes a reference to the NRC memo discussing exemption from a DFP, which can be found in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> under Accession No. ML17075A487.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U. S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

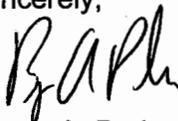
You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary

meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Bryan A. Parker  
Senior Health Physicist  
Materials Licensing Branch

License No. 34-31473-03MD  
Docket No. 030-38748

Enclosure: Amendment No. 06