



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

December 18, 2024

Eranga K. Haththotuwa, President
Eranga Cardiology, P.C.
64 Stuart Drive,
Dover, DE 19901

SUBJECT: ERANGA CARDIOLOGY, P.C., LICENSE AMENDMENT, MAIL CONTROL NO.
643448

Dear Eranga K. Haththotuwa:

This refers to your license amendment request dated July 23, 2024. Please find enclosed Amendment No. 6 approving the use of Strontium/Rubidium generators and updating your facility diagram at 204 W Liberty Way, Suite 3, Milford, DE. Please note that the medical use of Fluorine-18 is not approved at this time. When you are ready to begin using Fluorine-18, please submit a new amendment request with facility diagrams for the PET quiet rooms and a list of additional hot lab equipment that is specific to 511 keV. The facility diagrams should be to scale and should include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations. The calculations should include the workload assumptions used.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at 610-337-5364 or via electronic mail at Netra.Patel@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the 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(s) 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 NRC Enforcement Policy. The NRC Enforcement Policy is available at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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/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 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

Netra Patel, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-35021-01
Docket No. 03038592
Mail Control No. 643448

Enclosure:
Amendment No. 6

cc: Michael W. Lairmore, M.S., Radiation Safety Officer

ERANGA CARDIOLOGY, P.C., LICENSE AMENDMENT, MAIL CONTROL NO. 643448,
DECEMBER 18, 2024.

SUNSI Review Complete: NPatel

After declaring this document "An Official Agency Record" it **will** be released to the Public.

OFFICE	RI:DRSS			
NAME	Netra Patel/NSP			
DATE	12/17/2024			

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