DEPARTMENT OF VETERANS AFFAIRS
VA Caribbean Healthcare System
10 Calle Casia
San Juan, Puerto Rico 00921-3201

J-4
MS-16

Date: November 9, 2006

From: Chief Medical Physics Section & Radiation Safety Officer

Subj.: Authorized User Verification

52-31200-01
03037362

To: Lizette Roldán, Ph.D.
Region I Office
Mail Control No. 139614

The present letter is to certify that:

- Bartolo Santiago-Delgado, MD, is an Authorized User of Unsealed Byproduct Materials on the VA Caribbean Healthcare System Permit No. 52-04359-01, Docket No. 030-03514 obtained under Master Material License No. 03-23853-01VA of the Department of Veterans Affairs.

- Bartolo Santiago-Delgao, MD, is an Authorized User for **35.100**, use of unsealed byproduct material for uptake, dilution, and excretion studies for which awritten directive is not required; **35.200**, use of unsealed byproduct material for imaging and localization studies for which a written directive is not required; and **35.300**, use of unsealed byproduct material for which a written directive is required since September, 2004.

Miguel A. Rios-Gerena, MS, DABR
VA Caribbean Healthcare System
Chief Medical Physics Section and Radiation Safety Officer

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NMSS/RGNI MATERIALS-002

and emergencies. If needed, we will revise the procedures using the regulatory requirements in 10 CFR 35.26.

b. Occupational dose: We will complete either a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR 20 or provide dosimetry per the "Criteria" and "Discussion" paragraphs in NUREG-1556, Volume 9, section 8.22, based on the scope of uses of radioactive materials.

c. Area surveys: For medical uses, we have developed and will implement and maintain written procedures for area surveys per 10 CFR 20.1101 that meet the requirements in 10 CFR 20.1501 and 10 CFR 35.70.

d. Safe use of unsealed permitted material: We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

e. Spill procedures: We have developed and will implement and maintain written procedures for safe response to spills of permitted material per 10 CFR 20.1101.

f. Installation, maintenance, adjustment, repair, and inspection of therapy devices containing sealed sources: Response not required.

g. Minimization of contamination: Response not required.

h. For ordering, receiving, and maintaining accountability for radioactive materials. We will complete physical inventories at intervals not to exceed six months to account for all sealed sources and devices, except where regulations require more frequent inventories in which case the inventories will be completed per the applicable regulations.

i. We will complete leak tests at intervals required by regulations or as approved by NRC

11. Waste management. For medical uses, we have developed and will implement and maintain written waste disposal procedures for permitted material per 10 CFR 20.1101 that also meet the requirements of 10 CFR 35.92. **We will meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 for the waste disposal of licensed material.**

Luis M. Gely Latalladi, MD, President

Limited-Scope Permit
Supplement to NRC Form 313, items 5 through 11

5. Radioactive material.

a. Radioactive material for medical uses: We request approval for the radioactive materials, forms, and maximum amounts in the table below for medical uses.

Radioactive Material	Chemical/Physical Form	Maximum Amount
Any byproduct material identified in 10 CFR 35.100	Any unsealed byproduct material identified in 10 CFR 35.100	As needed
Any byproduct material identified in 10 CFR 35.200	Any unsealed byproduct material identified in 10 CFR 35.200	As needed

c. Recordkeeping for decommissioning and financial assurance: Response not required.

6. Purpose(s) for which permitted material will be used.

a. We request approval for the medical uses in the table below.

Categories	Uses
10 CFR 35.100	Medical use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
10 CFR 35.200	Medical use of unsealed byproduct material for imaging and localization studies for which a written directive is not required

7. Individual(s) responsible for radiation safety program and their training and experience. We request approval for the Radiation Safety Officer and authorized users as listed below.

a. Radiation Safety Officer: David Rhoe, RSO of License# 52-25430-03

b. Authorized users for medical use:

Authorized User	Material and Use
Bartolo, Santiago-Delgado, M. D. Authorized under Permit 52-04359-01, from MML 03-23853-01VA Docket No.030-34325	35.100; 35.200;

c. Authorized nuclear pharmacist: Response not required.

d. Authorized medical physicist: Response not required.

8. Training for individuals working in or frequenting restricted research areas (occupationally exposed individuals and ancillary personnel).

We will provide initial, annual, and as-needed training for research and ancillary workers. The topics will be selected from the training guide and 10 CFR Part 19.12 based on the worker's specific uses of, or potential exposure to, radioactive materials. The methods to evaluate training effectiveness may include, but not be limited to, written tests, audits, group discussions, and performance-based interviews. The instructors will either be the Radiation Safety Officer or other staff and/or contractors approved by the Radiation Safety Committee as knowledgeable in the topic being presented. The methods of training may include, but not be limited to, training videos, lectures, handouts, information sheets, computer-based training, and performance-based demonstrations.

9. Facilities and equipment. We request approval for the facilities as shown on the attached facility diagrams. (Refer to attached diagram)

a. Medical facilities:

(1) The unsealed radioactive materials used for procedures will be received in the hot laboratory and stored behind lead shielding, as necessary, to comply with 10 CFR 20 and ensure potential doses are ALARA (as low as reasonably achievable). These radioactive materials will normally be administered in the hot laboratory, an imaging or injection room.

b. Radiation monitoring instruments: Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. Instrumentation used to perform required surveys will be based on NUREG-1556, Volume 9, Appendix K, "Equipment Selection" and based on the scope of uses of radioactive materials. We reserve the right to upgrade instrumentation as necessary as long as the upgraded instruments are adequate to measure the type and level of radiation being used.

c. Dose calibrator and other equipment used to measure dosages of unsealed radioactive material: We will only use unit-dose from radiopharmacy.

d. Dosimetry equipment - calibration and use: Response not required.

e. Other equipment and facilities: Response not required.

10. Radiation protection program.

a. Safe use of radionuclides and emergency procedures for research. We have developed and implemented procedures for safe use of radionuclides, including security of radioactive materials