

# HCI

Heart Care Imaging, Inc.

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|  |                                    |
|--|------------------------------------|
| To: Lizette Roldan   | From: Fairfax Heart Associates, PC |
| Fax No.: 610.337.5269  |                                    |
| Date: 18-Apr-08  | Number of Pages: 7                 |
| <p>Message:</p> <p>Re: License # 45-30978-01</p> <p>03036772</p> |                                    |



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**FAIRFAX HEART ASSOCIATES, P.C.**

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Annandale, Virginia 22003

Telephone: (703) 204-9301

PAUL E. DILORENZO, M.D., F.A.C.C., TESTAMUR NASPE<sub>x</sub>AM

RAYMOND VERGNE, M.D., F.A.C.P., F.A.C.C.

FELIX D. CASTRO, M.D., F.A.C.C.

3 December 2007

Dear Colleague,

I am an Authorized User and Radiation Safety Officer listed on the Radioactive Materials Fairfax Heart Associates, P.C. license number 45-30978-01. This letter is to attest that Felix Castro, M.D., has successfully completed all training requirements set forth by the Nuclear Regulatory Commission section 35.290, paragraph c (1) from February 2005 to present, December 2007. I attest that he has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC guidelines 35.200.

Dr. Felix Castro has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This training and experience included a minimum of the following:

- A. 1) 80 hours of classroom and laboratory training in the following areas:
- a) Radiation physics and instrumentation;
  - b) Radiation protection;
  - c) Mathematics pertaining to the use and measurement of radioactivity;
  - d) Chemistry of byproduct material for medical use;
  - e) Radiation biology
  - f) Generator Elution
- 2) Work experience, under the supervision of authorized user Brigid Castro, MD, which meet the requirements in §§ 35.290, involving:
- a) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
  - b) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - c) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- d) Calculating, measuring, and safely preparing patient or human research subject dosages;
- e) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- f) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- g) Administering dosages of radioactive drugs to patients or human research subjects; and
- h) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs

I certify that Dr. Felix Castro has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC regulations CFR 35.290.

Preceptor Signature : Felix Castro, MD

Date : 12/13/07

NRC FORM 313A (AUD)  
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.100, 35.200, and 35.500)  
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3160-0120  
EXPIRES: 10/31/2008

Name of Proposed Authorized User  
Felix Castro, M.D.

State or Territory Where Licensed  
Virginia

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device \_\_\_\_\_)

**PART I - TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. **Board Certification**
  - a. Provide a copy of the board certification.
  - b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.
- 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
  - a. Authorized user on Materials License \_\_\_\_\_ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
  - b. Supervised Work Experience.  
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

| Description of Experience  | Location of Experience/License or Permit Number of Facility | Clock Hours | Dates of Experience* |
|--|---|-------------|----------------------|
| Fluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs |   |             |                      |

**Total Hours of Experience:**

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

*Felix Castro MD*

*NRC 75-327 A-01*

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

NRC FORM 313A (AUD)  
(2-2007)

U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

 3. Training and Experience for Proposed Authorized User

## a. Classroom and Laboratory Training.

| Description of Training   | Location of Training  | Clock Hours | Dates of Training*           |
|---|---|-------------|------------------------------|
| Radiation physics and instrumentation                                     | Corscan Plus/Authorized User Classroom and Laboratory Training Program, Toledo, OH<br>NRC License # 37-31143-01 | 16 hours    | Completion date:<br>12/05/07 |
| Radiation protection  | Corscan Plus  | 16 hours    | Completion date:<br>12/05/07 |
| Mathematics pertaining to the use and measurement of radioactivity        | Corscan Plus  | 16 hours    | Completion date:<br>12/05/07 |
| Chemistry of byproduct material for medical use (not required for 35.590) | Corscan Plus  | 16 hours    | Completion date:<br>12/05/07 |
| Radiation biology   | Corscan Plus  | 16 hours    | Completion date:<br>12/05/07 |

Total Hours of Training: 80 hours

b. Supervised Work Experience (completion of this table is not required for 35.590).  
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

| Supervised Work Experience   |   | Total Hours of Experience: 650          |                      |
|--|---|---|----------------------|
| Description of Experience Must Include:  | Location of Experience/License or Permit Number of Facility           | Confirm                                 | Dates of Experience* |
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys   | Steven Walter, M.D., Authorized User, Corscan Plus<br>NRC-47-25351-01 | <input checked="" type="checkbox"/> Yes | 11/04 - present      |
|  | Brigid Castro, M.D., Authorized User,<br>NRC-45-30978-01              | <input type="checkbox"/> No             |                      |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | Steven Walter, M.D., Authorized User, Corscan Plus<br>NRC-47-25351-01 | <input checked="" type="checkbox"/> Yes | 11/04 - present      |
|  | Brigid Castro, M.D., Authorized User,<br>NRC-45-30978-01              | <input type="checkbox"/> No             |                      |

NRC FORM 313A (AUD)  
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

**b. Supervised Work Experience. (continued)**

| Description of Experience Must Include:  | Location of Experience/License or Permit Number of Facility   | Confirm  | Dates of Experience* |
|--|---|--|----------------------|
| Calculating, measuring, and safely preparing patient or human research subject dosages   | Steven Walter, M.D., Authorized User, Corscan Plus NRC-47-25351-01<br>Brigid Castro, M.D., Authorized User, NRC-45-30978-01   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | 11/04 - present      |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material  | Steven Walter, M.D., Authorized User, Corscan Plus NRC-47-25351-01<br>Brigid Castro, M.D., Authorized User, NRC-45-30978-01   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | 11/04 - present      |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures  | Steven Walter, M.D., Authorized User, Corscan Plus NRC-47-25351-01<br>Brigid Castro, M.D., Authorized User, NRC-45-30978-01   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | 11/04 - present      |
| Administering dosages of radioactive drugs to patients or human research subjects  | Steven Walter, M.D., Authorized User, Corscan Plus NRC-47-25351-01<br>Brigid Castro, M.D., Authorized User, NRC-45-30978-01   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | 11/04 - present      |
| Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs | Steven Walter, M.D., Authorized User, Corscan Plus NRC-47-25351-01<br>Brigid Castro, M.D., Authorized User, NRC-45-30978-01<br><br>Clinical: >1000 cases Tc-99m Cardiac Imaging | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | 11/04 - present      |

Supervising Individual: Steven Walter, M.D. *Brigid Castro*  
Brigid Castro, M.D.  
License/Permit Number listing supervising individual as an authorized user: NRC-37-31143-01  
NRC-45-30978-01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

- 35.190     35.290     35.390     35.390 + generator experience in 35.290(c)(1)(ii)(G)

**c. For 35.590 only, provide documentation of training on use of the device.**

| Device | Type of Training | Location and Dates |
|--------|------------------|--------------------|
|        |                  |                    |
|        |                  |                    |

**d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.**

NRC FORM 313A (AUD)  
(2-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**PART II - PRECEPTOR ATTESTATION**

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

**First Section**

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that \_\_\_\_\_ has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that Felix Castro, M.D. has satisfactorily completed the 60 hours of training and  
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that \_\_\_\_\_ has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that Felix Castro, M.D. has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**Second Section**

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

|   |                                   |                                 |                 |
|---|-----------------------------------|---------------------------------|-----------------|
| Name of Preceptor<br>Brigid Castro, M.D.  | Signature<br><i>Brigid Castro</i> | Telephone Number<br>703 6984444 | Date<br>1/20/07 |
| License/Permit Number/Facility Name<br>NRC-46-30978-01 Fairfax Heart Associates |                                   |                                 |                 |

This is to acknowledge the receipt of your letter/application dated

4/18/2008, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 45-30978-01  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142323  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.