FLORIDA DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL
RADIOACTIVE MATERIALS SECTION
4052 BALD CYPRESS WAY, BIN #C21
TALLAHASSEE, FLORIDA 32399-1741

CERTIFICATE – MEDICAL USE OF RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

Subsection 64E-5.206(7), Florida Administrative Code (F.A.C.), establishes a general license authorizing physicians to possess certain small quantities of I-125, I-131, Co-57, Co-60, and Cr-51 for specified diagnostic uses. Possession of radioactive material under 64E-5.206(7), F.A.C., is not authorized until the physician has filed Department of Health (DOH) form, DH 361 and received from the DOH a validated copy of DH 361 with certification number assigned.

INSTRUCTIONS: Submit the original and one copy of this form to the **Department of Health, Bureau of Radiation Control, 4052 Bald Cypress Way, Bin C21, Tallahassee, Florida 32399-1741**. A certification number will be assigned and a validated copy of DH 361 will be returned. Please print or type your name and address (including ZIP Code), within the box below:

NAME:_____

ADDRESS:_____

_____

PHONE: (_____)_____

CERTIFICATION: I HEREBY CERTIFY THAT:

1. I am a duly licensed physician (authorized to dispense drugs) in the practice of medicine. My Florida License number is: _____
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use radioactive material under the general license of 64E-5.206(7), F.A.C., and I am competent in the use of such instruments.
3. I understand that DOH regulations require that any change in the information furnished on this certificate be reported to DOH within 30 days from the date of such change.
4. I have read and understand the provisions of Subsection 64E-5.206(7), F.A.C.; and I understand that I am required to comply with those provisions as to all radioactive material which I receive, possess, use, or transfer under the general license for which this Certificate is filed with DOH.
5. All information in this certificate is true and complete.

Date:_____ By:_____
(Signature of Person Filing Form)

Certification No.: Expires On:

_____

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 64E-5.206(7), F.A.C.

(7) Medical Diagnostic Uses.

(a) A general license shall be issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of (7)(b), (c) and (d), below, the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the Department pursuant to subsection 64E-5.210(7), F.A.C., or by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State pursuant to equivalent regulations authorizing distribution to persons under a general license pursuant to this subsection or its equivalent:

1. Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;
2. Cobalt 57 for the measurement of intestinal absorption of cyanocobalamin;
3. Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;
4. Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;
5. Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;
6. Iodine 131 as sodium iodide for measurement of thyroid uptake; and
7. Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.

(b) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by paragraph (7)(a), above, until he has submitted the original and one copy of the information requested on DH 361 10/12, entitled "Certificate – Medical Use of Radioactive Material under General License" with the Department and received from the Department a validated copy of this form with certification number assigned which is herein incorporated by reference and available at http://www.doh.state.fl.us/environment/radiation/matform.htm.

(c) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by paragraph (7)(a), above, shall comply with the following:

1. The physician shall not possess at any given time, pursuant to the general license in paragraph (7)(a), above, more than

a. Two hundred microcuries (7.4 MBq) of iodine 131,

b. Two hundred microcuries (7.4 MBq) of iodine 125,

c. Five microcuries (185 kBq) of cobalt 57,

d. Five microcuries (185 kBq) of cobalt 58,

e. Five microcuries (185 kBq) of cobalt 60,

f. Two hundred microcuries (7.4 MBq) of chromium 51;

2. The physician shall store the pharmaceutical in the original shipping container until administered, or in a container providing equivalent radiation protection;

3. The physician shall use the pharmaceutical only for the uses authorized by paragraph (7)(a), above;

4. The physician shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The general licensed physician possessing or using radioactive material under the general license of paragraph (7)(a), above, shall report in duplicate to the Department any changes in the information furnished by him on Form 361. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using radioactive material pursuant to the general license of paragraph (7)(a), above, is exempt from the requirements of Parts III and IX with respect to the radioactive material covered by the general license.

(f) Manufacturers of radiopharmaceuticals which are under the general license in this subsection are required to affix a certain identifying label to the container, and in the leaflet or brochure which accompanies the radiopharmaceutical, pursuant to subsection 64E-5.210(7), F.A.C.