Jeb Bush
Governor

FLORIDA DEPARTMENT OF HEALTH

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Secretary

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Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2000-03

Licensing Requirements for the Performance of Coronary Brachytherapy Procedures

The Food and Drug Administration (FDA) recently approved the use of radioactive sources in the treatment of cardiovascular disease. This is to provide information to radioactive materials licensees who perform brachytherapy procedures, not involving high dose rate remote afterloading, and who wish to provide intravascular (coronary) brachytherapy procedures. An amendment to your existing license is required. The amendment request should specifically request the authority to use radioactive material for the prevention of restenosis of cardiac vessels. The following information will need to be sent with your request to perform these procedures:

- The name and FDA approval number of the device used in the procedure.
- The type of radioactive material used and sealed source model number or numbers.
- The maximum quantity of radioactive material you wish to possess.
- A facility diagram indicating the location where the material will be used and where the material will be stored. Describe security measures in place to control access to the material.
- Confirmation that the radiation safety committee has approved the medical institution to perform intravascular brachytherapy procedures.
- A description of the instrumentation used to calibrate the radioactive sources and your procedures for calibrating the sources prior to use.
- A description of any personnel monitoring program changes.
- A description of the training program for authorized users and personnel who care for the patients undergoing the procedure.
- A description of your radiation safety and emergency procedures for the prevention of unnecessary exposure to patients and occupational workers. Including use of shielding, safe handling of the sources, and other methods of reducing exposure.

- Procedures for performing coronary brachytherapy.
- A revised member of the public dose study.
- A revised quality management program.
- Procedures for sealed-source leak testing.
- Procedures for disposing of your radioactive waste generated by the new procedures.

Once we have received this information, it will take about 30 days for the department to respond. If you have any questions, please contact our office at (850) 245-4545.