Jeb Bush
Governor

FLORIDA DEPARTMENT OF HEALTH

John O. Agwunobi, M.D., M.B.A
Secretary

July 2002

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2002-08

Human Use Radiopharmaceutical Therapy
Y-90 Zevalin

The Food and Drug Administration (FDA) recently approved the use of Yttrium 90 (Y-90) monoclonal antibodies under the trade name Zevalin for the treatment of non-Hodgkin's lymphoma. This notice is to provide information to licensees who wish to provide this therapy. If you wish to perform these procedures at your institution you will need to amend your license for the possession of a Y-90 calibration source. Currently dose calibrators are not calibrated for the radiopharmaceutical at the manufacturer. IDEC Pharmaceuticals, the company who developed Zevalin has developed procedures for dose calibrator calibration using a 40 mCi Y-90 source that has the same geometry as the dose. Subsection 64E-5.617 Florida Administrative Code (F.A.C.) only allows for calibration and reference sources up to 15 mCi. Be advised that a copy of the calibration procedures needs to be available for inspection by the bureau.

To obtain the calibration and reference source, your current license will need to be amended. The amendment should specifically request the authority to possess up to 110 mCi of Y-90 as a calibration and reference source.

Other items that may need to be addressed specific to your license include:

- Confirmation that the radiation safety committee has approved the medical institution to perform Zevalin procedures.
- 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 the use of shielding, safe handling of the sources, and other methods of reducing exposure.
- A revised member of the public dose study.
- A revised quality management program.

Please allow approximately 30 days to amend your radioactive material license once all necessary information has been submitted. If you have any questions, please contact our office at (850) 245-4545.

http://www.doh.state.fl.us/environment/radiation/
Phone (850) 245-4545 (SC) 205-4545
Bureau of Radiation Control • Radioactive Materials Section
Bin #C21 • 4052 Bald Cypress Way • Tallahassee, FL 32399-1741
Fax (850) 921-6364 (SC) 291-6364