



DRP INFORMATION NOTICE 02-01

TO: Certain North Carolina Medical Use Licensees
FROM: J. Marion Eaddy III, Health Physicist 
DATE: 14 June 2002
IN RE: **Guidance for Intravascular Brachytherapy (IVB) Devices and Information on $^{111}\text{In}/^{90}\text{Y}$ Zevalin[®]**

➤ **Intravascular Brachytherapy (IVB)**

The U.S. Nuclear Regulatory Commission has put forth licensing guidance for IVB systems. The agency has reviewed the guidance and is making the following notice to you for your consideration. If your current radiation safety policies and procedures do not address the points contained in this notice, you will need to incorporate the guidance in this document as soon as possible. Amendments should be made to your Radioactive Materials License as necessary to ensure that compliance with all of the agency requirements is maintained. Amendment forms are available on our website (www.drp.enr.state.nc.us).

I. **IVB General Guidance (not model specific)**

A. Criteria which must be met:

1. All authorized users (AU) shall have training and experience in accordance with 10 CFR 35.940 "Training for use of brachytherapy sources" (incorporated by reference in 15A NCAC 11 .0117(a)(2))
2. Commit that the AU, interventional cardiologist (IC), and medical physicist (MP) will receive training by the manufacturer for use of the device;
3. Commit that the procedure will be conducted under the supervision of the authorized user and that he will consult with the IC and MP **PRIOR** to initiating treatment. Further, commit that the procedure will be conducted in the **PHYSICAL PRESENCE of the AU and/or MP.**
4. Make the appropriate modifications in the Quality Management Program and submit that program within 30 days of the changes per 15A NCAC 11 .0356;
5. Commit that the written directive shall be made **PRIOR TO TREATMENT** and specify the treatment site(s), radionuclide and dose (per 15A NCAC 11 .0104(145(d)));
6. An independent measurement of source output shall be made prior to the first patient treatment. The output shall be measured with instrumentation that has been fully calibrated within 24 months of the date of measurement. The instrument shall be calibrated by a laboratory accredited by MIST or AAPM;
7. A survey of the **PATIENT and IVB CATHETER** shall be performed **IMMEDIATELY** following source retraction;
8. Appropriate emergency procedures shall be developed, implemented and maintained for agency review. Furthermore, appropriate emergency equipment (e.g. bail-out box) shall be available during the procedure;



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9. Where possible, a “dummy run” should be conducted to ensure proper functioning of all equipment;
10. Provide calculations and/or measurements which demonstrate compliance with 15A NCAC 11 .1611;
11. Discuss the use of personnel dosimetry for Operating Room (OR) personnel other than the AU, IC and MP;
12. Discussion of security of the device(s) in use and in storage;

II. IVB Specific Guidance (in addition to the aforementioned guidance)

A. Cordis System

1. Commit that the sources shall not be used after the “use by” date on the package;
2. Commit to following the manufacturer’s recommendations and schedules for maintenance;

B. Novoste System

1. Commit to following the manufacturer’s recommendations and schedules for maintenance;
2. Commit to the use of introducer sheathes and dual syringe systems, unless such use in medically contraindicated.

C. Guidant System

1. Commit that the source assembly shall not be used after 60 days or 650 cycles, whichever comes first;
2. Commit to following the manufacturer’s recommendations and schedules for maintenance; and,
3. Commit to following the manufacturer’s recommendations for daily QA checks and QA following source exchange.

The agency strongly encourages all licensees to obtain copies of the “Registry of Radioactive Sealed Sources and Devices” Registration Certificate (SSD Sheets) for each source and/or device on the license (not only the IVB devices). This document contains reference materials as well as a section on “Limitations and Other Considerations of Use” which the licensee may find helpful.

A copy of this document has been posted on the agency website (www.drp.enr.state.nc.us). The agency encourages you to check the website often for updates and additional information which will assist you in the safe use of radioactive materials and/or accelerators in North Carolina.



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> Information on $^{111}\text{In}/^{90}\text{Y}$ Zevalin[®]

The agency was notified of the FDA approval for distribution of Zevalin[®] earlier this year. As of the date of the notice, the FDA has not yet added these to the "Groups." Therefore, **prior to any use** of these radiopharmaceuticals, the licensee MUST submit an amendment request to the agency. Radiopharmacy license conditions do not allow for the distribution of a "non-group" item to a hospital without that item being expressly authorized by the recipients license.

The package insert and other information provided by the manufacturer suggests that your amendment request should ask for both the ^{111}In and ^{90}Y forms of the drug. Standard radiation safety protocols should cover the use of the radiopharmaceuticals. Please refer to DRP Information Notice 02-02 for additional information on measurement of alpha- and/or beta-emitting radiopharmaceuticals.