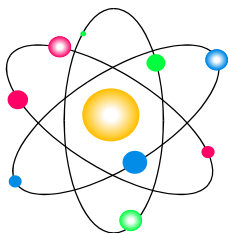
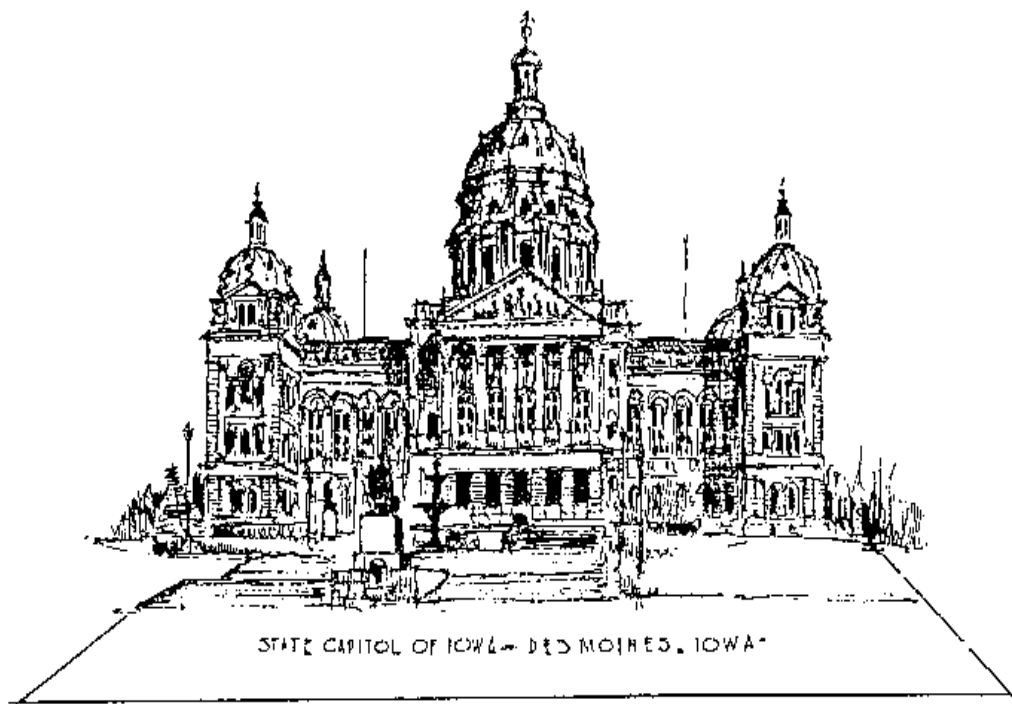

IOWA DEPARTMENT OF PUBLIC HEALTH
REGULATORY GUIDE FOR INTRAVASCULAR
BRACHYTHERAPY (IVB)



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REGULATORY GUIDE FOR INTRAVASCULAR BRACHYTHERAPY (IVB)

The regulations associated with brachytherapy are in 641-41.2(43) through 41.2(48). Vascular brachytherapy (VBT) requires additional commitments from the licensee to ensure the safe use of the sources. Some of the additional requirements are generated by the fact that this application of brachytherapy involves hospital staff that have not routinely been involved with radioactive materials.

Currently there are two authorized protocols that have been granted the Federal Drug Administration Pre-market Approval (PMA) for vascular brachytherapy. The Novoste® protocol uses Strontium-90/Yttrium-90, which emits beta (β^-) radiation, to deliver a dose. The Cordis® protocol employs Iridium-192 sources, which emits gamma (γ) radiation.

Many of the FDA conditions for the use of these products are mirrored by IDPH's requirements. The vendor may ensure that the conditions of the PMA are satisfied. Deviations from the PMA that are identified by IDPH will be reported to the FDA for enforcement. However, as part of the licensing process, the licensee will be asked to commit to the items listed under the appropriate IVB protocol. You should address each item in the application process and must adhere to the commitments in the same manner as with other commitments made to IDPH as part of the licensing action.

IDPH requires the licensee identify the members of the treatment team that will be assigned and required to wear extremity monitoring devices. It is also necessary to submit an annotated drawing of the room or rooms and adjacent areas where the brachytherapy device will be used. Note the following:

1. The scale. Use the same scale for all drawings.
2. The direction of north.
3. The facility layout of the spaces used for IVB (usually the cardiac catheterization lab), the adjoining areas, their usage, and estimated hours of occupancy.
4. The location of the storage area and the use of the adjoining spaces.
5. Any shielding available or planned.

COMMITMENTS FOR THE NOVOSTE® PROTOCOL

1. Commit to using a written directive that shall specify the radioisotope, treatment site, and total dose. For brachytherapy, "*Written Directives*" is defined in 641-38.2 as an order in writing for a specific patient or human research subject, dated and signed by an authorized user, containing the following information:
 - a. Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
2. Commit to establishing a treatment room team that consists of, at a minimum, an interventional cardiologist, an authorized user, and a medical physicist.
3. Commit to requiring that all members of the treatment team be physically present during treatments.
4. Commit to vendor training for all members of the treatment room team.
5. Commit to an independent verification of the source strength.
6. Commit to preparing written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.
7. Commit to the use of an introducer sheath during treatment.
8. Commit to the use of extension tubing with a backup syringe of drive fluid (sterile water) staged for immediate use or commit to the use of a dual syringe system.
9. Commit to inspecting and servicing the device at intervals established by the manufacturer.
10. Commit to having the maintenance and repair of the vascular brachytherapy device performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

The licensee is reminded that regardless of which protocol is used, the Quality Management Program (QMP) should be reviewed and revised as appropriate.

COMMITMENTS FOR THE CORDIS® PROTOCOL

1. Commit to using a written directive that shall specify the radioisotope, treatment site, and total dose. For brachytherapy, "*Written Directives*" is defined in 641-38.2 as an order in writing for a specific patient or human research subject, dated and signed by an authorized user, containing the following information:
 - a. Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
2. Commit to establishing a treatment room team that consists of, at a minimum, an interventional cardiologist, an authorized user, and a medical physicist.
3. Commit to requiring that all members of the treatment team be physically present during treatments.
4. Commit to vendor training for all members of the treatment room team.
5. Commit to an independent verification of the source strength by the licensee.
6. Commit to ensuring that all sources are leak tested at intervals not to exceed six months.
7. Commit to preparing written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.
8. Commit not to use the source train after the "use before date" (expiration date).
9. Commit to providing all members of the treatment team with whole body personal monitoring devices.
10. Commit to evaluating all instances where the source train separation occurs during treatment to determine if they could be misadministrations.
11. Provide the calculations that demonstrate compliance with 641-40.26, "*Dose limits for individual members of the public.*" If there are areas that should have restricted access during the brachytherapy procedure, identify the method(s) that will be used to accomplish that task.
12. Provide the protocol for the use of portable shields.

ADDITIONAL REMARKS

There appears to have been some confusion on whether a physician can perform intravascular brachytherapy outside the confines of the Food and Drug Administration (FDA) Pre-Market Approval. This practice is referred to as working "off label." Because such procedures can be construed as the practice of medicine, deviations from the PMA that are identified by IDPH normally will be reported to the FDA for enforcement.

In telephone conversations with IDPH, FDA representatives have indicated that the primary concern is whether "off label" procedures were performed as a matter of routine or whether they were truly completed on a case-by-case basis based on patient need. The FDA action resulting from reported instances of "off label" use cannot be predicted by IDPH. However, it would be prudent for licensees to establish an internal review process to demonstrate that the "off label" uses were scrutinized to assure medical necessity. Again, nothing in the IDPH authorization relieves a licensee of the need to comply with applicable FDA, other Federal, or State requirements.

Overlapping treatment fields (sometimes referred to as "stepping") is a procedure specifically prohibited by the FDA. The procedures for stepping are not covered by the manufacturer's instructions. Therefore, it would be inappropriate for the licensee to simply follow the manufacturer's instructions if the licensee were to contemplate stepping. If during an inspection, IDPH staff determines that "stepping" has occurred, appropriate enforcement action will be taken.

In some cases, the commitments or the enforcement practices may not be consistent with those of the US Nuclear Regulatory Commission (NRC), or other Agreement States. To further complicate matters, the vendor's representative may be unaware of the licensee's commitments or IDPH rules and, therefore, encourage practices that conflict with IDPH requirements. The licensee is reminded that IDPH has the regulatory authority regarding the use of radioactive material in Iowa. It is important to insure that all commitments, which were made as part of the licensing for intravascular brachytherapy, are adhered to and that the sources are used only as authorized.

Among the commitments necessary to obtain authorization for this type of brachytherapy, your facility has committed to establishing a treatment team that consists of, at a minimum, an interventional cardiologist, an oncologist (the authorized user), and a medical physicist. In addition, you agreed to require that all members of the treatment team be physically present during treatments. Each member of this team has specific training and knowledge that makes their active participation essential for the health and safety of the patient and the treatment team itself.

<u>REVISION</u>	<u>SECTION</u>	<u>DESCRIPTION</u>
06/06/01	All	Editorial Changes only
06/08/01	All	Revised to reflect IDPH Enforcement Policy
06/13/01	All	Revised to reflect NRC licensing guidance. Note: The commitments regarding the presence of three IVB team members and "stepping" have not been altered. IDPH policy is more restrictive in those areas.
07/01/05	All	Changed address for the Bureau of Radiological Health