

Regulatory Aspects of Vascular Brachytherapy

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From its inception, the field of vascular brachytherapy (VBT) necessitated an interdisciplinary approach given the disparate areas of expertise involved. This was nowhere more apparent than in the discipline of interventional cardiology in which the use of radioactive sources for therapeutic purposes represented a dramatic paradigm shift. Although experienced in the beneficial application of x-rays and diagnostic radiopharmaceuticals to cardiology, the concepts of dosimetry and efficacy were foreign to cardiologists not trained in the disciplines of radiation oncology and medical physics. Thus, it was not surprising that this emerging therapeutic approach fell under the aegis of the Nuclear Regulatory Commission (NRC) and the Agreement States for it is these which are charged with the oversight of the therapeutic application of radioactive materials.

The fundamental issues, then, are that 1) by-product material or radiation from by-product material is regulated by either state or federal laws; 2) the NRC regulates the administration of by-product material or radiation there-from in 18 states, the District of Columbia, Puerto Rico and federal facilities, e.g., VA hospitals; thirty states (Agreement States) have an agreement with the NRC to regulate the use of by-product material; and 4) the licensing of by-product material for vascular brachytherapy use has required exemptions to those rules with numerous conditions placed upon users.

The NRC position on vascular brachytherapy is quite clear and is published in numerous Federal Register notices and, with other policies and positions, have culminated in a recent revision to the Code of the Federal Regulations (CFR) — specifically Title 10, Part 35 governing the “Medical Use of By-product Material.” Part 35, subparts F and J, addresses training and experience requirements (for administration) while sub-part F identifies, by criteria, approved vascular brachytherapy sources. Until recently, brachytherapy sources and authorized medical uses were listed in the rule. Table 1 provides a summary of these sources and treatments that were allowed by the rules. It is immediately apparent that, with the exception of Sr-90 for the treatment of eye disease, the approved sources were utilized for cancer therapy.

Table 1. NRC-approved sources for brachytherapy

Source	Use
Cesium-137	Topical, interstitial and intracavitary cancer treatment
Cobalt-60	Topical, interstitial and intracavitary cancer treatment
Gold-198	Interstitial cancer treatment
Iridium-192	Interstitial cancer treatment
Strontium-90	Superficial eye disorders
Iodine-125	Interstitial cancer treatment
Palladium-103	Interstitial cancer treatment

Of equal, if not greater, relevance to the practice of vascular brachytherapy are the training and experience requirements for the use of the above-cited brachytherapy

sources for use in the treatment of cancer. As explicitly indicated in Sections 35.490 and 35.940:

- A physician who is certified in radiology, therapeutic radiology or radiation oncology;
- 200 hours of classroom and laboratory training;
- 500 hours of supervised work experience;
- Three years of supervised clinical experience which may include:
 - One year in RRC-approved radiology training program, and
 - An additional 2 years in therapeutic radiology.

Notably, the past and current requirements of subsection 35.491 and 35.941 for use of Sr-90 to treat eye disease are somewhat less restrictive being summarized as:

- A physician who has completed 24 hours of classroom and laboratory training for ophthalmic radiotherapy; and
- Supervised participation in the treatment of 5 individuals

It can be seen that the extension of “traditional” brachytherapy treatment programs to vascular brachytherapy requires an ongoing tripartite approach in which the interventional cardiologist, medical physicist and radiation oncologist must all participate (Table 2).

The impracticality of rigid adherence to this approach in many environments, coupled with the unlikely prospect of interventional cardiologists completing a formal training program in therapeutic radiology, has prompted the NRC to re-consider the above-noted requirements. Considerable discussion within and between professional specialties and the NRC has led to the suggestion that vascular brachytherapy be categorized as an

Table 2. Participants and responsibilities of the VBT team

Participant	Responsibilities
Interventional cardiologist	Proper patient selection Risk/benefit assessment Target assessment Applicator/modality recommendation and administration Manage acute complications Patient follow-up
Radiation oncologist	Target assessment Modality and dose prescription “Administer” treatment Risk/benefit assessment Patient follow-up
Medical physicist	Dose verification Dosimetry and treatment planning Surveys, source management and quality assurance

“emerging technology” (Part 35.1000). This consideration might also result in a modification of the stringent training and experience requirements noted above. Thus, it is of note that the NRC has recently expressed support for a more flexible approach in

which a portion of the responsibilities of the radiation oncologist delineated above may be assumed by either the medical physicist or interventional cardiologist, after discussions with the radiation oncologist. This becomes increasingly important when the constraints on availability of the radiation oncologist preclude universal attendance during these procedures. However, it is also clear that a more rigorous risk-based curriculum (along with a certificate of added qualification) addressing the fundamentals of vascular brachytherapy should be developed for interventional cardiologists. The extension of this treatment approach, heretofore confined to oncology, to the management of a non-malignant albeit hyper-proliferative condition, i.e., coronary restenosis, will require continued non-biased dialogue between all participants—professional and regulatory.

In summary, from a clinical standpoint, vascular brachytherapy is an emerging (and evolving) technology. From a regulatory standpoint, emerging vascular brachytherapy currently falls within the domain of radiation oncology. However, from the pragmatic and logistical standpoints, VBT must be viewed as an inter-disciplinary, cooperative treatment modality with built-in flexibility designed to enhance the efficiency of patient care.