President's Symposium: Intravascular Brachytherapy: An Emerging Role for the Medical Physicist"

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The new and escalating interest in investigating the applicability of using ionizing radiation therapy to reduce or eliminate restenosis in coronary and peripheral arteries after angioplasty has led to the continuing development of a varied number of innovative approaches. Most of these involve the use of byproduct material(s) as the source of the ionizing radiation. As such, the use of these materials require licensure by either NRC or an Agreement State. As might be expected, the requirements for the NRC licensure for participation in these varied investigative studies of intravascular brachytherapy are, of necessity, being developed on a case by case basis as each of these evolving intravascular catheter based systems often require unique radiation health and safety considerations. For example, for simple stent systems with microcurie quantities of implanted beta particle emitters, the necessary radiation protection measures required to protect both the health care providers and the patient from unwarranted and potentially dangerous radiation exposures are quite basic and easily implemented. On the other hand, high dose rate afterloading systems, particularly those using sources emitting penetrating gamma radiation, can pose very serious radiation hazards to not only the patient and health care providers, but to members of the public if control of this source is lost for even a short time.

Despite the unique characteristics of each of these device based protocols, using sealed sources containing byproduct materials, there are also several uniform requirements required by the NRC for authorization (licensure) to participate in these investigative studies. These are:

1. The requirements of 10 CFR 35.6, "Provisions for research involving human

subjects," must be met (For intravascular brachytherapy this requirement is met by obtaining the required Food and Drug Administration investigational device exemption (IDE) application approval);

2. Only those physicians meeting the training and experience requirements set forth in 10 CFR 35.940, "Training for use of brachytherapy sources," can be designated as authorized users for these procedures and, in nearly every study, a medical physicist is a required member of the team; and,

3. The radiation sources and/or devices used in the research must have undergone an appropriate sealed source and/or device review(s) and be listed in the Registry of Radioactive Sealed Sources and Devices as approved for use in intravascular radiotherapy (Note: Medical licensees of broad-scope are exempted from this requirement and can participate in human trails using unreviewed and unregistered sealed sources and devices).

The present NRC requirements for medical physicist participation in these studies will be discussed and compared to the forthcoming requirements in the new 10 CFR Part 35 regulations. NRC's present training and experience requirements for medical physicists will also be presented and contrasted with the new 10 CFR Part 35 requirements.

The presentation will conclude with a brief overview of misadministrations and other events that have occurred during these intravascular brachytherapy trials and NRC response to these events.