Kanawha Radiological Physics

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To: **John Pelchet**, USNRC
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From: Warren Bryant
Date: 16 March 2001
Re: edited page one of enclosure 3
Pages: 2, including this page

John

the following page contains an edited item #1 to incorporate details of the written directive. let me know if this is satisfactory.

Thanks

Warren

Intravascular Brachytherapy Operating Procedures

(Manual\IVB.LWP IWB 15Feb01)

Enclosure 3

These procedures are limited to the treatment of in-stent restenosis of coronary arteries utilizing an Ir^{192} protocol from Cordis and/or a Sr^{90}/Y^{90} protocol from Novoste. The following standard operating procedures are applicable to both systems.

a. prior to clinical use, the treatment team will receive and document vendor training
b. the treatment team shall be composed of, at a minimum, an interventional cardiologist, *authorized user and a medical physicist. Physical presence of the treatment team is required during all treatments.
*(training and experience requirements for the authorized user shall be that set forth in 10CFR35.940)
c. written emergency and/or surgical procedures for both stuck and detached sources, including availability of emergency response equipment is already in place in that they will not differ significantly from those developed for the existing angioplasty procedures. the existing procedures will be refined specifically for this procedure if and when the cardiologist(s) and authorized user(s) deem it necessary.
d. independent verification of the source strength by the medical physicist is required before clinical use of the sources. there will be no clinical use of the sources after the vendor's "use by" date.
e. user(s) will adhere to vendor's recommendations for source/device use period and frequency for maintenance and routine replacement/exchange.
f. user(s) will receive, maintain and refer to vendor's instructions for use
g. sources shall be leak tested at intervals not to exceed six months & inventoried quarterly as applicable.
h. source security, storage, transportation, use and personnel monitoring will be in compliance with current NRC regulation. any unique requirements for these systems will be addressed and incorporated into our operating procedures.
i. only an authorized vendor representative will be used for service and maintenance.
j. immediately prior to and just subsequent each clinical use, the treatment unit and the patient will be surveyed to establish pre treatment radiation levels and to ensure that the source has been returned to the fully shielded position after therapy.
k. relevant QA recommendations by the AAPM, NRC and/or product specific requirements/QA by the vendor(s) will be addressed and incorporated into our operating procedures.

1. An authorized user will date and sign a written directive specifying the radioisotope, treatment site, and total dose prior to the administration of any IVB procedure. Instructions for oral directives and revisions to written directives are as follows:

If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision will be acceptable, provided that the oral revision is documented immediately in the patient's record and the revised written directive is dated and signed by the authorized user within 4 hours of the oral revision.

Also, a written revision to an existing written directive may be made for this therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose.

If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 4 hours of the oral directive.