

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

March 9, 1998

**NRC INFORMATION NOTICE 98-10: PROBABLE MISADMINISTRATIONS OCCURRING  
DURING INTRAVASCULAR BRACHYTHERAPY WITH  
THE NOVOSTE BETA-CATH SYSTEM**

Addressees:

All Medical Licensees

Purpose:

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to two reported incidents that have occurred during the conduct of intravascular brachytherapy procedures using the Novoste Beta-Cath system. This system uses Strontium-90 high-dose-rate (HDR) source trains that can range between approximately 1 to 10 Gy/min beta dose output at the surface of the seeds. Licensees should be aware of the potential for similar failures during the course of patient treatments and the possible risk(s) for misadministrations and potential patient harm resulting from the inability to retract these HDR sources at the conclusion of the planned treatment. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

NRC has become aware of two reported failures, while using the Novoste Beta-Cath system for intravascular brachytherapy in multi-center clinical trials. Both of these events are being investigated as probable misadministrations (wrong treatment sites) as the sources failed to return to the device storage safe at the conclusion of the treatments. The Sr-90 source train was observed leaving the treatment site but did not return to the device; in fact, the precise locations of the sources were unknown for some period of time. A brief summary of the two reported failures follows:

1. On January 16, 1998, an NRC licensee reported that on January 15, 1998, a patient receiving treatment with the experimental Novoste Beta-Cath device received a larger than expected dose to unwanted body areas because of difficulty in removing the inserted sources. Twelve Sr-90 sources (total activity of  $1.3 \times 10^9$  Bq (35 mCi)) were inserted in the treatment location via a long catheter. At the conclusion of the treatment the pellets became stuck in the catheter,

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requiring the immediate removal of the catheter containing the sources from the patient. Because of the time needed to remove the catheter (estimated to be 65 seconds) the patient received a larger transit dose than expected, as the normal source transit time is on the order of 3 to 5 seconds; and,

2. On February 9, 1998, the State of Washington notified NRC of a somewhat similar incident reported by one of its licensees as occurring on December 15, 1997. In this misadministration report the licensee reported that at the conclusion of a 3-minute and 32-second treatment (18 Gy dose at 2mm) to the left coronary artery the hydraulic source transport system (syringe) ran out of saline, stalling the source train in transit. It reported that the source train was stalled at an unknown location for 1 minute and 32 seconds delivering an additional unintended 7.8 Gy (maximum) dose to the vessel wall(s).

Although investigation of both of the reported events is ongoing, presently available information attributes the failure of the source transport system in the first event to crimping of the Novoste system catheter by over-tightening of the Touhy-Bourst valve used to tighten around the catheter and prevent the flow of blood out of the insertion point in the patient's femoral artery. This crimp did not completely close the source lumen in the Novoste catheter, allowing the saline flow to continue, but it was sufficient to block the sources from returning to the device. When the saline supply in the delivery syringe was exhausted, an emergency removal of the Beta-Cath treatment catheter from the patient was performed.

In the second reported incident, the syringe saline supply was also exhausted before the sources were returned to the device source storage location. In this event, the syringe was replaced with a fresh supply of saline and the sources were then successfully returned to their storage location using the device's hydraulic source transport system. It is possible that the second reported event may have the same root cause as the first, but this has not yet been determined.

In both events, the respective authorized users report that they do not expect any adverse health consequences for the patients involved.

#### Discussion:

Numerous clinical trials are underway to evaluate the feasibility of using intravascular brachytherapy to prevent restenosis after angioplasty in coronary and peripheral arteries. These trials involve numerous new and innovative sources of byproduct materials and delivery systems that, in most cases, have not undergone formal sealed source and device reviews and listing in NRC's Registry of Sealed Sources and Devices as approved source(s) and device(s) for this intended use.

In the first cited event report from our NRC licensee, the immediate cause of the incident appears to be transient damage to the Beta-Cath system source lumen (catheter), because of over-tightening of the Touhy-Bourst valve (this is a valve-like device located at the proximal end of the guide catheter, 15 to 20 cm beyond the external skin surface, and contains an iris-like

shutter designed to tightly grip the Beta-Cath catheter to prevent leaking of blood around the catheter). It is necessary to loosen this valve each time the Beta-Cath source train is moved to or from the transfer device to the treatment site at the distal end of the catheter. Subsequent simulation of the misadministration incident by the licensee showed that tightening the Touhy-Bourst valve one-half turn beyond "finger-tight" created a condition where the sources could not be retracted back into the device. On visual examination, a small depression was clearly evident on the catheter at the location of the Touhy-Bourst valve. Loosening, or even removing the valve did not allow retraction of the source train. After about 20 minutes, it was possible to retract the sources normally with the device's hydraulic transport system. It is believed that, over this 20-minute period, elastic restoring forces reduced the indentation in the catheter to the point where the sources could be retracted normally.

At this time, less information is available concerning the second event reported by the Washington State licensee. However, discussions with Novoste revealed that a second source transfer failure mechanism exists with this device design.

Specifically, if too much pressure is applied to the saline supply syringe during source transport, the supply of saline can be prematurely exhausted before completing the intended source transport procedure. Thus, it appears that at least two source transport failure modes exist that can be induced by the improper application of force in the operation of the device by the user.

In the extensive investigation of its event, our licensee identified a number of factors that it believes contributed to the reported misadministration. These were: (1) The device design allows for over-tightening of the Touhy-Bourst valve, which can block the source train transport pathway; (2) excessive intervals of time between training and start of clinical procedures and successive clinical procedures; (3) less than optimal didactic and practical training; (4) between extremely limited opportunities for self-practice and rehearsal because of restrictions imposed by Novoste; and, (5) lack of a detailed checklist, describing all precautionary checks and warnings, including manipulation of the Touhy-Bourst valve.

During the course of the NRC investigation of these events, an additional possible design related source transport system failure mode was discovered that should be added to the above listing. Specifically, when attaching the syringe to the transfer device, over-tightening of the syringe Luer to the extension connector may cause the sterile sleeve to be pinched, which, could result in the inability to produce sufficient hydraulic pressure. Inclusion of related operational procedures and warnings, addressing all these failure modes should be included in the check-list cited in the preceding paragraph.

The following corrective actions, proposed by our licensee's medical physicist, may be beneficial in addressing radiation safety concerns related to the use of this device in ongoing clinic trials:

1. Improve radiation oncology training quality, including didactic review of relevant interventional cardiology procedures and technical details, as well as more realistic training exercises in a catheterization lab environment;

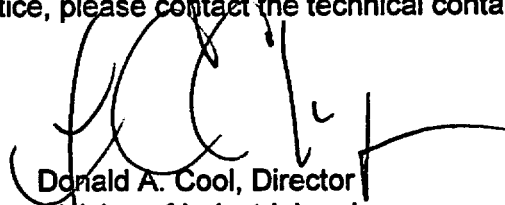
2. Develop an appropriately modified version of American Association of Physicists in Medicine's HDR device quality assurance protocol that gives confidence that all Novoste treatment equipment is functioning properly. At a minimum, this should include: (a) daily testing of all treatment units before treating patients; (b) testing of treatment catheter with the randomly selected radiation afterloading device (RAL) before positioning the catheter in the patient; (c) where ischemia is not a problem, test the inserted catheter with the dummy source RAL for unobstructed passage of the sources before attaching the randomly selected device to the catheter and administering therapy; and, (d) verification of source strength and/or prescription dose rate;
3. Be conscious of the possibilities for damaging the treatment catheter before and during the radioactive source treatment and develop a list of precautions to be made known to all participants;
4. Develop a check list of essential steps, checks, and precautions to be followed in executing these treatments and verbally review this list step by step until procedure frequency and competence are built up;
5. Develop a mechanism for facilitating self-initiated practice and procedure review. This requires vendor cooperation;
6. Redesign the treatment-to-guide catheter interface to eliminate the possibility of catheter damage.

The post-incident investigation and resultant proposed corrective actions appear to be appropriate. Certain of these actions, specifically numbers 1, 3, and 4, can be unilaterally implemented by the licensee. However, the remaining three actions require the approval and support of Novoste Corporation.

All licensees contemplating use of the Novoste Beta-Cath system or any of the other emerging intravascular brachytherapy procedures should ensure that either: (1) the device(s) and/or source(s) have undergone a thorough radiation safety review and approval by the NRC or Agreement State, as required by 10 CFR 35.49(a); or, (2) for broad scope licensees, who are exempted from the requirements of 10 CFR 35.49(a) through a standard license condition, an equivalent radiation safety evaluation by a broad scope licensee's radiation safety committee should be performed in order to fully satisfy the requirements of 10 CFR 33.13(c)(3)(ii). In addition, licensees should ensure that affected personnel understand all operating parameters necessary for the safe operation of the system. If significant unaddressed safety concerns remain, then it would be expected that the licensee would decline to participate in that particular clinical trial.

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Donald A. Cool, Director  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards

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Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

*LIST FILED in Jacket*

**LIST OF RECENTLY ISSUED  
 NMSS INFORMATION NOTICES**

<b>Information Notice No.</b>	<b>Subject</b>	<b>Date of Issuance</b>	<b>Issued to</b>
98-09	Collapse of an Isocam II, Dual-Headed Nuclear Medicine Gamma Camera	3/5/98	All medical licensees
98-08	Information Likely to be Requested if an Emergency is Declared	3/3/98	All parts 30, 40, 70, 72 and 76 licensees and certificate holders required to have a Nuclear Regulatory Commission approved Emergency plan.
98-06	Unauthorized use of License to Obtain Radioactive Materials, and its Implications Under The Expanded Title 18 of the <u>U.S. Code</u>	2/19/98	All NRC Licensees authorized to Possess Licensed Materials
98-04	1997 Enforcement Sanctions for Deliberate Violations of NRC Employee Protection Requirements	2/9/98	All U.S. Nuclear Regulatory Commission licensees.
98-01	Thefts of Portable Gauges	1/15/98	All portable gauge licensees
97-91	Recent Failures of Control Cables Used on Amersham Model 660 Posilock Radiography Systems	12/31/97	All industrial radiography licensees
97-89	Distribution of Sources and Devices Without Authorization	12/29/97	All sealed source and device manufacturers and distributors
97-87	Second Retrofit to Industrial Nuclear Company IR100 Radiography Camera, to Correct Inconsistency in 10 CFR Part 34 Compatibility	12/12/97	All industrial radiography licensees
97-86	Additional Controls for Transport of the Amersham Model No. 660 Series Radiographic Exposure Devices	12/12/97	Registered users of the Model No. 660 series packages, and Nuclear Regulatory Commission industrial radiography licensees

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NRC INFORMATION NOTICES

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Information Notice No.	Subject	Date of Issuance	Issued to
98-07	Offsite Power Reliability Challenges from Industry Deregulation	2/27/98	All holders of operating licenses for nuclear power reactors
98-06	Unauthorized Use of License to Obtain Radioactive Materials, And Its Implications Under The Expanded Title 18 of the <u>U.S. Code</u>	2/19/98	All NRC licensees authorized to possess licensed material
97-45, Supp. 1	Environmental Qualification Deficiency for Cables and Containment Penetration Pigtaills	2/17/98	All holders of operating licenses for nuclear power reactors except those licensees who have permanently ceased operations and have certified that the fuel has been permanently removed from the reactor vessel
98-05	Criminal History Record Information	2/11/98	All holders of operating licenses for power reactors
98-04	1997 Enforcement Sanctions for deliberate Violations of NRC Employee Protection requirements	2/9/98	All U.S. Nuclear Regulatory Commission licensees
98-03	Inadequate Verification of Overcurrent Trip Setpoints in Metal-Clad, Low-Voltage Circuit Breakers	1/21/98	All holders of operating licenses for nuclear power reactors
98-02	Nuclear Power Plant Cold Weather Problems and Protective Measures	1/21/98	All holders of operating licenses for nuclear power reactors
98-01	Thefts of Portable Gauges	1/15/98	All portable gauge licensees

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OL = Operating License  
CP = Construction Permit

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\* Coordinated with FDA, RIII, State of Washington, and manufacturer

\*\* See Previous Concurrence

OFC	IMAB*		IMAB		IMAB*		IMOB			
NAME	RAyres		GHaney		LWCamper		JPiccone			
DATE	2/25/98		2/ /98		2/26/98					

OFC	**TechEd		DD/IMNS*		D/IMNS*			
NAME	EKraus		FCCombs		DACool			
DATE	2/18/98		2/27/98		2/26/98			

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*2/26/98*

OFC	IMAB	<i>E</i>	IMAB	IMAB	IMOB		
NAME	RAyres <i>RLA</i>		<del>Charney</del>	LWCamper <i>LB</i>	<del>JPiccone</del>		
DATE	2/25/98		<del>2/1/98</del>	2/2/98	2/1/98		
OFC	**TechEd		<del>BD/IMNS/ma</del>	D/IMNS			
NAME	EKrause		<del>FCCombs</del>	<del>DACool</del>			
DATE	2/18/98		<del>2/17/98</del>	2/16/98			

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