UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

October 30, 1995

NRC INFORMATION NOTICE 95-50: SAFETY DEFECT IN GAMMAMED 12i BRONCHIAL CATHETER CLAMPING ADAPTERS

Addressees

All High Dose Rate Afterloader (HDR) licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to the manufacturer's recommendation to discontinue use of GammaMed 12i 1.8-millimeter(mm) bronchial catheter adapters. 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

During a bronchial treatment, on November 16, 1994, using a GammaMed 12i HDR, the bronchial catheter pulled out of the catheter clamping adapter. This resulted in the clamping adapter clamping on the source wire, producing an abnormally high amount of friction during subsequent source movement. On detection of this interference to source movement, the device initiated an emergency retract, thus terminating the patient treatment. During this emergency retract, the source became stuck in the clamping adapter, necessitating prompt emergency response, by the Radiation Oncology staff, to evacuate the patient from the high radiation area. The staff's prompt action, limited the excess whole body exposure to the patient to less than 0.4 millisieverts (40 millirem). However, the HDR source and drive mechanisms were damaged and required replacement.

On July 13, 1995, a similar incident occurred while vendor representatives were performing the acceptance testing on a new GammaMed 12i. Again, the source became stuck in the bronchial catheter clamping adapter after the catheter had pulled loose from the adapter. In freeing the stuck source, the vendor's Radiation Safety Officer received an estimated extremity dose of 26 centigray (rads). No patient was involved in this incident.

Discussion

After the first incident in November 1994, Frank Barker Associates, Inc., provided all its GammaMed 12i customers with instructions for proper use of the GammaMed 12i, 1.8-mm bronchial catheter and associated clamping adapter. This notification (Attachment 1) was provided in the form of a BARKER+ TECH-TIP dated November 22, 1994.

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Updated on 11/1/95
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After the second incident in July 1995, Frank Barker Associates, Inc., issued two more notifications, to its customers on the use of the 1.8-mm bronchial catheter clamping adapters, Product Number 931-012. The first of these (Attachment 2) was another BARKER+ TECH-TIP, dated July 18, 1995, which advised customers to avoid the "end test" mode of operation with the white 1.8-mm bronchial catheter, as this mode will stretch the catheter and possibly push the catheter out of the clamping adapter. This TECH-TIP goes on to describe the sticking of the source, in the clamping adapter, should the catheter be pushed out of the adapter.

Frank Barker Associates, Inc. also held discussions with the NRC, regarding radiation safety issues associated with the failure of the GammaMed 12i devices to retract the source into its shielded safe after a bronchial catheter has been pulled out of the clamping adapter. They subsequently sent a letter dated August 18, 1995, (Attachment 3) to all 12i users, advising them to discontinue use of these adapters. The letter further advised the users that new clamping adapters were in production and would be provided to them in October 1995.

NRC is concerned about the possibility of ether patients or licensee staff receiving excessive exposures to radiation if an HDR source fails to retract. Because of this documented defect in the GammaMed 12i bronchial clamping adapters, all affected licensees are encouraged to follow the recommendations of the device vendor, as contained in its letter of August 18, 1995. Any licensee using this adapter to complete a course of treatment started before the vendor's notification should exercise extreme caution.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.

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

Technical Contact: Robert L. Ayres, NMSS
(301) 415-5746

Attachments filed in Jacket

Attachments:
1. BARKER+ TECH-TIP, dated November 22, 1994
2. BARKER+ TECH-TIP, dated July 18, 1995
3. BARKER+ Letter, dated August 18, 1995
4. List of Recently Issued NMSS Information Notices
5. List of Recently Issued NRC Information Notices DOC NAME: 95-50.IN

* See Previous Concurrence

OFC	IMAB		IMAB	E	IMAB	C	SSSS	E	IMOB	C
NAME	*RAyres		*JMPICCONE		*LWCamper		*RBaer		*GPangbun	
DATE	10/16/95		9/19/95		9/19/95		9/20/95		9/20/95	

OFC	TechEd		OGC		DD/IMNS		D/IMNS	
NAME	*EKrause		*STreby		*FCCombs		*DACool	
DATE	9/21/95		10/02/95		10/12/95		10/17/95	

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OFC	IMAB	E	IMAB	E	IMAB	C	SSSS	E	IMOB	C
NAME	RAyres RXA		*JMPICCONE		*LWCamper		*RBaer		*GPangbun	
DATE	10/16/95		9/19/95		9/19/95		9/20/95		9/20/95	

OFC	TechEd		OGC		DD/IMNS		D/IMNS	
NAME	*EKrause		*STreby		*FCCombs		DACool	
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Related Generic Communications:

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NAME	RAyres RA		*JMPICCONE		*LWCamper		*RBaer		*GPangbun	
DATE	10/05/95		9/19/95		9/19/95		9/20/95		9/20/95	

OFC	TechEd		OGC		DD/IMNS		D/IMNS	
NAME	*EKrause		*STreby		FCCombs		DACool	
DATE	9/21/95		10/02/95		10/12/95		/ /	

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The NRC is concerned about the potential for excessive exposures to radiation by either patients, or licensee staff, in the event of the failure of an HDR source to retract, due to this documented defect in the GammaMed 12i bronchial clamping adapters. All affected licensees are encouraged to follow the recommendations of the device vendor, as contained in their letter of August 18, 1995. Extreme caution should be exercised by any licensee using this adapter to complete a course of treatment that was started prior to the vendor's notification.

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NAME	RAyres RZA		JMPICCONE		LWCamper		RBaer		GPangburn	
DATE	9/19/95		9/19/95		9/19/95		9/20/95		9/20/95	

OFC	TechEd		OGC		DD/IMNS		D/IMNS	
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NAME	RAyres	RLA	JMPICCONE		DACamper		RBaer		GPangburn	
DATE	9/19/95		9/19/95		9/19/95		9/20/95		9/20/95	

OFC	TechEd		OGC		DD/IMNS		D/IMNS	
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BARKER+ **TECH·TIP**

DATE: November 22, 1994

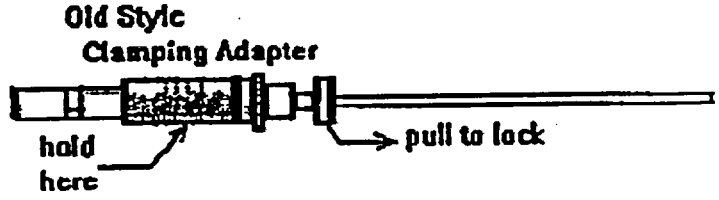
TO: All GAMMAMED 12i Users

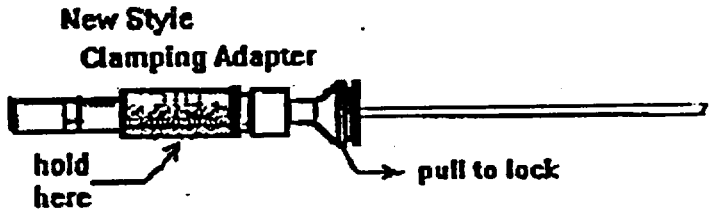
FROM: Garry Nixon - U.S. GAMMAMED Service Manager

RE: GAMMAMED 12i Bronchial Catheters and Clamping Adapters

For the safest operation of your GAMMAMED 12i HDR unit please follow the following procedures when using the white 1.8mm bronchial catheter with its associated clamping adapter.

The proper procedure before inserting the clamping adapter into the treatment head is:
1) depress the end of the clamping adapter,
2) insert the white 1.8mm catheter into the clamping adapter as far as it will go,
3) release the end of the clamping adapter,
4) pull on the end of the clamping adapter while holding it as illustrated below to "lock" it firmly on the catheter,
5) now insert the clamping adapter into the treatment head.





In order to avoid the catheter being pulled from the clamping adapter in the case of the patient moving, insure that slack exists in the catheter between the patient and the HDR treatment head. This will be facilitated by positioning the treatment unit as near as is possible to the patient.

If you have any questions please contact me at our toll-free number 1-800-2-BARKER.

BARKER+ TECH·TIP

DATE: July 18, 1995
TO: All Gammamed 12i Users
FROM: Garry Nixon - U.S. Gammamed Service Manager
RE: Bronchial catheters to be used only in indexer channels 20 - 24

I would like to remind all Gammamed 12i Users that whenever using the white 1.8mm bronchial catheter, that this catheter will stretch if a dummy wire 'end test' is performed. This will most likely cause the console error message "Probe too long in channel 1". There is also the distinct possibility that in the process of the dummy wire pushing against the end of the catheter, it will push the catheter almost completely out of the metal clamping adapter which connects the catheter to the 12i's indexer channel. It is possible that the source could completely push the catheter out of the clamping adapter which would result in the clamping adapter no longer clamping on the catheter but rather clamping on the source wire! During the next movement of the source wire, the abnormally high amount of friction (between the clamping adapter and the source wire) will be detected and an Emergency Retract will be initiated, thus terminating the treatment. If, during this Emergency Retract, the wire becomes stuck in the clamp, it may not be possible to completely retract the source capsule into it's 'safe' position in the depleted uranium shielding. This obviously would necessitate intervention within the treatment room by the Radiation Oncology staff conducting the treatment, to evacuate the patient; and by a BARKER+ Service Engineer to retrieve the source into the shielding or a shipping container.

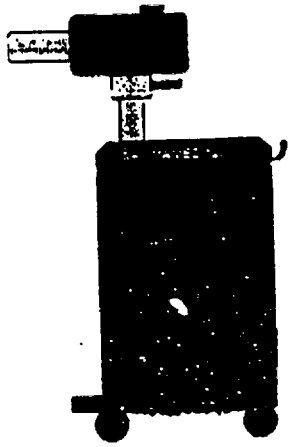
In order to avoid this scenario, it is imperative that this adapter not be used in indexer channels 1-19. These channels are programmed to do an end test with the dummy wire before extending the source wire. Channels 20-24 do not do this end test and were designed this way to be used with this catheter/clamping adapter applicator.

If you have any questions please contact me at our toll-free number 1-800-2-BARKER.

BARKER+

Sales and Marketing Division
33 Jacksonville Road, Bldg.#1
Towaco, NJ 07082

Phone: (800) 222-7537
FAX: (201) 335-1225



Date: August 18, 1995

To:
ATTN:
From:Jeff Stickler
Number of Pages including this one: 1

Dear ,

Frank Barker Associates, Inc. hereby *advises* all 12i Users that are presently using the 12i clamping adapter, product number 931-012, either old style or new style, to discontinue use of these adapters. However, if you are presently treating a patient using these adapters, we would advise that you finish treatments; 1) using the old style adapter if you have one and or; 2) following the Tech Tips which we supplied to be certain that the adapter is in the locked position.

This decision was made after discussion with the NRC and the manufacturer. ITS/GAMMAMED has a new clamping adapter in production which will become available in October 1996. At that time we will replace any of these specific adapters free of charge to the Users.

If you have any questions regarding this matter please contact Jeff Stickler at the above toll-free number and extension 608 at your convenience.

Respectfully,

Jeffrey C. Stickler
Director Customer Support
Extension 608

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
95-44	Ensuring Combatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Conectors	09/26/95	All Radiography Licensees.
95-39	Brachytherapy Incidents Involving Treatment Planning Errors	09/19/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
95-29	Oversight of Design and and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.
95-28	Emplacement of Support Pads for Spent Fuel Dry Storage Installations at Reactor Sites	06/05/95	All holders of OLs or CPs for nuclear power reactors
95-25	Valve Failure during Patient Treatment with Gamma Stereotactic Radiosurgery Unit	05/11/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
94-64, Supp. 1	Reactivity Insertion Transient and Accident Limits for High Burnup Fuel	04/06/95	All holders of OLs or CPs for Nuclear Power Reactors and all fuel fabrication licensees.
95-07	Radiopharmaceutical Vial Breakage during Preparation	01/27/95	All U.S. Nuclear Regulatory Commission medical licensees authorized to use byproduct material for diagnostic procedures.
95-01	DOT Safety Advisory: High Pressure Aluminum Seamless and Aluminum Composite Hoop-Wrapped Cylinders	01/04/95	All U.S. Nuclear Regulatory Commission licensees.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
95-49	Seismic Adequacy of Thermo-Lag Panels	10/27/95	All holders of OLs or CPs for nuclear power reactors.
95-48	Results of Shift Staffing Study	10/10/95	All holders of OLs or CPs for nuclear power reactors.
95-47	Unexpected Opening of a Safety/Relief Valve and Complications Involving Suppression Pool Cooling Strainer Blockage	10/04/95	All holders of OLs or CPs for nuclear power reactors.
95-46	Unplanned, Undetected Release of Radioactivity from the Exhaust Ventilation System of a Boiling Water Reactor	10/06/95	All holders of OLs or CPs for nuclear power reactors.
95-12, Supp. 1	Potentially Nonconforming Fasteners Supplied by A&G Engineering II, Inc.	10/05/95	All holders of OLs or CPs for nuclear power reactors.
95-45	American Power Service Falsification of American Society for Nondestructive Testing (ASNT) Certificates	10/04/95	All holders of OLs or CPs for nuclear power reactors.
95-44	Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-Type Male Connectors	09/26/95	All Radiography Licensees.
95-43	Failure of the Bolt-Locking Device on the Reactor Coolant Pump Turning Vane	09/28/95	All holders of OLs or CPs for nuclear power reactors designed by Westinghouse Electric Corporation (W).
95-42	Commission Decision on the Resolution of Generic Issue 23, "Reactor Coolant Pump Seal Failure"	09/22/95	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit