

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

June 23, 2005

NRC INFORMATION NOTICE 2005-17: MANUAL BRACHYTHERAPY SOURCE JAMMING

ADDRESSEES

All medical licensees authorized to possess a Mick applicator.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to alert addressees to recently reported medical events with ruptured seeds that have occurred at different facilities during manual brachytherapy as a result of seed jamming. 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 IN are not new NRC requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

NRC has received ten medical event reports in the last five years, two of them recently, involving the rupture of a jammed brachytherapy seed source while used in a Mick Radio-Nuclear Instruments, Inc. Model Mick Applicator. However, there may be more events with seeds containing accelerator-produced radioactive material that are not required to be reported to the NRC. In one of the ten incidents reported, during the prostate brachytherapy procedure, the cartridge containing seeds jammed in a Mick Applicator. When the licensee attempted to dislodge the seed from the applicator, the seed ruptured. This caused radioactive contamination to spread onto the applicator and surrounding surfaces. The applicator was placed in a plastic bag and stored behind lead shielding in the hot laboratory. This description is representative of all ten incidents.

Licensees' corrective actions included procedure modifications, such as changes in handling of the applicator and cartridge after the occurrence of a cartridge jam, and personnel training.

DISCUSSION

In the ten events over the past five years, the cause of the seed rupture was excessive force applied by the operator to the seed cartridge when trying to dislodge the jammed seed. The force of pulling the cartridge out with the seed jammed is large enough to shear the seed and cause contamination. The manufacturer, Mick Radio-Nuclear Instruments, Inc., is aware that seed jamming may occur and provides instructions in the User Manual to follow when attempting to dislodge the jammed seed. It is not apparent if the licensees involved in these events followed the recommended procedure for dislodging jammed seeds. Attempting to force the seed cartridge out of the applicator is contrary to the manufacturer's instructions. Mick Radio-Nuclear Instruments, Inc. recommends the following techniques to dislodge jammed seeds:

ML051780232

- Partially unscrew the head of the magazine (no more than one turn), thereby relieving the downward pressure on the seeds. Please note that the magazine head and the cartridge are NOT designed or intended to be taken apart. This is only done to relieve the spring pressure on the seeds. Carefully attempt to remove the magazine from the applicator.
- Flush the jammed seed out of the applicator using a light pressure water flush. This must be done over a collection pan situated such that all seeds are collected and accounted for.

If the seeds cannot be removed safely, place the applicator in quarantine. The applicator must be surveyed (for radiation) to determine if the broken seed has contaminated the applicator.

If contaminated, the applicator must remain in quarantine for a minimum of 10 half-lives.

If clean, it is recommended that the applicator be returned to the manufacturer for evaluation and repair/adjustment.

(Source: Mick 200-TPV Applicator Instruction Manual, Pg.15A, Form #:405-06; Rev. E; 4/15/05)

The State of Wisconsin has also identified the recent seed ruptures and has issued an IN on the issue dated June 9, 2005. The Wisconsin IN is attached for your reference.

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

/RA/

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contacts: Nima Ashkeboussi, NMSS
(301) 415-7637
E-mail: naa@nrc.gov

John P. Jankovich, NMSS
301-415-7904
E-mail: jj2@nrc.gov

Attachments: 1. State of Wisconsin Information Notice
2. List of Recently Issued NMSS Generic Communications

Note: NRC generic communications may be found on the NRC public Website, <http://www.nrc.gov>, under Electronic Reading Room/Document Collections.

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ML051780232 *See previous concurrence

OFC	NMSS	NMSS	NMSS	NMSS	NMSS
NAME	NAshkeboussi*	EKraus*	THarris	RCorreia	CMiller
DATE	6/14/05	6/14/05	6/17/05	6/21/05	6/23/05

Jim Doyle

Governor

Helene Nelson

Secretary

**DIVISION OF PUBLIC
HEALTH**

1 WEST WILSON STREET
P O BOX 2659
MADISON WI 53701-
2659

608-267-4797
FAX: 608-267-
3695
dhfs.wisconsin.gov

State of Wisconsin

Department of Health and Family Services

INFORMATION NOTICE

TO: Department of Health and Family Services
Radioactive Material Medical Use Licensees

FROM: Department of Health and Family Services
Radioactive Materials Program

DATE: June 9, 2005

SUBJECT: Information Notice concerning MICK[®] Applicators

PURPOSE:

The Wisconsin Department of Health and Family Services is issuing this information notice to inform medical use licensees of recent incidents involving jamming of the MICK[®] Applicator. It is expected that recipients will review this information for applicability to their licensed activities and consider actions, as appropriate, to avoid similar problems. Suggestions contained in this Information Notice are not new DHFS requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

During the period of April 1, 2005 to June 1, 2005, the Department of Health and Family Services became aware of two incidents in which a MICK[®] Applicator jammed resulting in a Pd-103 seed being ruptured.

In the first incident, the Radiation Oncologist after changing cartridges encountered resistance when implanting the first seed. The Radiation Oncologist was then unable to insert the stylete (i.e., plunger) more than a few millimeters when trying to implant the second seed. Upon trying to remove the cartridge to investigate the problem, a Pd-103 brachytherapy prostate seed broke.

In the second incident, the Radiation Oncologist after changing cartridges encountered a similar problem. The implantation needle became detached from the MICK[®] Applicator during the

process of trying to install a new cartridge. After reattaching the implantation needle, the Radiation Oncologist attempted to implant the first seed. However, the stylete would not insert more than a few millimeters. The Radiation Oncologist then attempted to remove the cartridge to investigate why the applicator had jammed. In the process of removing the cartridge, a Pd-103 brachytherapy prostate seed broke, resulting in the spread of contamination.

In discussions with other licensees, the Nuclear Regulatory Commission and other Agreement States, it was discovered that there have been other reported cases involving the MICK[®] Applicator becoming jammed. In some cases, the licensees were able to get the applicators working again and in other cases the prostate seeds have broken.

DISCUSSION

Failure to perform preventative maintenance on the MICK[®] Applicator may be the cause for jamming incidents. Licensees are reminded that they should perform the manufacturer's recommended preventative maintenance on the MICK[®] Applicator.

Licensees are also reminded not to screw cartridges into or out of the MICK[®] Applicator. Both the reusable and disposable cartridges are designed to seat in the MICK[®] Applicator by simply pushing them into the magazine receptor with a noticeable click.

Licensees should also be aware that the 'Disposable MICK[®] Cartridge' maximum seed capacity is 15 seeds. The maximum seed capacity for the 'Reusable MICK[®] Cartridge' is 10 seeds. If loading more than the maximum seed capacity, the applicator could jam. In addition, the 'Shielded / Disposable MICK[®] Magazines' are designed for one time use **ONLY**.

The MICK[®] web site at <http://www.micknuclear.com> contains information on dislodging jammed seeds. An excerpt from the web site is included for your information.

This Information Notice requires no specific action or written response. If you have any question about the information in this notice, please contact Cheryl K. Rogers at (608) 266-8135 or email at rogerck@dhfs.state.wi.us or Jason Hunt at (608) 266-9443 or email at huntjh@dhfs.state.wi.us.

Implant Sequence - (Continued)

Recommended

Useful Tips During the Implant Process:

When Loading the Magazine into the Applicator, ensure the Magazine sets into the Applicator properly, loading with a noticeable “Click”.

Ensure the needle is properly connected to the Applicator. The needle should “CLICK” into the Needle Receptor and should not disconnect unless the Needle Release Button is depressed.

During implantation, ensure the seed is completely advanced through the needle. Do not advance the seed partially out of the cartridge and retract the Push-Wire Rod. This may cause the seeds to drop unevenly and seeds may become jammed in the cartridge.

When loading Mick Magazines, visually check that the seeds are loaded straight and even in the cartridge. If the seeds are placed askew in the cartridge, it may cause jamming during the implant procedure.

After an implant procedure, it is strongly recommended a physical seed inventory be performed to account for all seeds.

Dislodging Jammed Seeds:

If and when a seed is jammed between the Applicator Needle Chuck and the Seed Cartridge, DO NOT force the seed Magazine out of the Magazine receptor area of the Applicator. Undue pressure on the seeds may cause the seeds to break or fracture.

The following techniques can be attempted:

Partially unscrew the head of the magazine (**no more than one turn**), thereby relieving the downward pressure on the seeds. Please note that the Magazine Head and the cartridge are **NOT** designed or intended to be taken apart. This is only done to relieve the spring pressure on the seeds. Carefully attempt to remove the Magazine from the Applicator.

Flush the jammed seed out of the Applicator using a light pressure water flush. This must be done over a collection pan situated such that all seeds are collected and accounted for. If the seeds cannot be removed safely, place the Applicator in quarantine. The Applicator must be surveyed (for radiation) to determine if the broken seed has contaminated the Applicator.

If contaminated, the Applicator must remain in quarantine for a minimum of 10 half-lives.

If clean, it is recommended that the Applicator be returned to the manufacturer for evaluation and repair/adjustment.

Returning an Applicator for Service or Repair:

1. Call MRNI, Inc., Customer Service Tel. 914-667-3999 to obtain a “Return Authorization” number.
2. Mick Applicators (Instrument only) must be sterilized before sending to MRNI, Inc.
3. MRNI, Inc. will fax you form #414-10 to be completed by you (without the proof of a decontamination form, your Mick Applicator will be returned unserviced).

Upon MRNI’s Receipt of Mick Applicator:

The Mick Applicator will be analyzed to determine the extent of the repair. We will then call the Contact Person to get authorization for repair and cost before we commence with any work. The Mick Applicator will be returned prior to your next case date.

Recently Issued NMSS Generic Communications

Date	GC No.	Subject	Addressees
06/10/05	RIS-05-10	Performance-Based Approach for Associated Equipment in 10 CFR 34.20	All industrial radiography licensees and manufacturers and distributors of industrial radiography equipment.
04/18/05	RIS-05-06	Reporting Requirements for Gauges Damaged at Temporary Job Sites	All material licensees possessing portable gauges, regulated under 10 CFR Part 30.
04/14/05	RIS-05-04	Guidance on the Protection of Unattended Openings that Intersect a Security Boundary or Area	All holders of operating licenses or construction permits for nuclear power reactors, research and test reactors, decommissioning reactors with fuel on site, Category 1 fuel cycle facilities, critical mass facilities, uranium conversion facility, independent spent fuel storage installations, gaseous diffusion plants, and certain other material licensees.
05/17/05	IN-05-013	Potential Non-conservative Error in Modeling Geometric Regions in the Keno-v.a Criticality Code	All licensees using the Keno-V.a criticality code module in Standardized Computer Analyses for Licensing Evaluation (SCALE) software developed by Oak Ridge National Laboratory (ORNL)
05/17/05	IN-05-012	Excessively Large Criticality Safety Limits Fail to Provide Double Contingency at Fuel Cycle Facility	All licensees authorized to possess a critical mass of special nuclear material.
04/07/05	IN-05-010	Changes to 10 CFR Part 71 Packages	All 10 CFR Part 71 licensees and certificate holders.

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