

GMUB 99-01

WARNING

Date: August 12, 1999

Subject: Notice of incidents: GammaMed afterloader units

Units Affected: GammaMed 12i and 12it HDR afterloaders operating in the United States and Canada

We have recently been notified of four incidents involving GammaMed HDR afterloader units in which the source cable became separated from the driving mechanism. In each of these incidents, the source remained in an exposed position, and required intervention to place the source into a shielded position.

We have investigated these incidents, and have concluded that the cause is attributable to a specific lot of cable used by the source manufacturer in the production of these sources. These sources have been installed only in the United States and Canada.

We strongly recommend that your institution suspend use of your GammaMed 12i and 12it HDR afterloader unit until the source is replaced. We are presently working with the source manufacturer to expedite replacement of these sources. A representative of our service department will contact you shortly to schedule a date for replacement of the source in your GammaMed unit.

We, at MDS Nordion, believe that safety of the patient and hospital personnel is of the utmost importance. We will strive to correct this situation as soon as possible.

For further information please contact Dave Marquez, Manager, Installation and Service at 1-800-826-2258 extension 2126.

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