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

October 21, 2002

NRC REGULATORY ISSUE SUMMARY 2002-19
NEW MODALITIES TO BE REGULATED UNDER 10 CFR 35.1000

ADDRESSEES

All medical licensees authorized to use byproduct material for therapeutic administration.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform addressees of how three specific new modalities will be regulated under the revised 10 CFR Part 35, "Medical Use of Byproduct Material." No specific action nor written response is required.

BACKGROUND

There are three new modalities currently authorized by the NRC on some specific licenses. These are Y-90 microspheres (e.g., MDS Nordion Y-90 TheraSphere®); liquid brachytherapy (e.g., Proxima Therapeutics' GliaSite® Radiation Therapy System); and intravascular brachytherapy (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

SUMMARY OF ISSUE

On the effective date of the revised Part 35, October 24, 2002, Y-90 microspheres, liquid brachytherapy, and intravascular brachytherapy will be governed by §35.1000, based on NRC's determination that they do not fit into §35.100 through §35.600. For licensees currently authorized to use these modalities, their existing license conditions applicable to these types of use will remain in effect after October 24, 2002.

Specific licensees that want to be authorized to use one or more of these new modalities on or after the effective date of the final rule should request license amendments in accordance with §35.1000 and §35.12(d).

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This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/

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