

August 5, 2008

The Honorable Rick Boucher
Chairman, Subcommittee on Energy and Air Quality
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The U.S. Nuclear Regulatory Commission (NRC) intends to publish a proposed rule in the *Federal Register* that would amend Part 35, "Medical Use of Byproduct Material." The proposed rule would amend the regulations that govern medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy. Brachytherapy is a cancer treatment in which small radioactive seeds are implanted inside or next to the area requiring treatment. The proposed amendments would change the criteria for defining an ME for permanent implant brachytherapy from dose-based to activity-based, add a requirement to report as an ME any administration requiring a written directive (WD) if a WD was not prepared, clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.

The proposed changes are based in part on recommendations from NRC's Advisory Committee on the Medical Use of Isotopes and the NRC's Medical Radiation Safety Team. The proposed rule would facilitate the ability of medical licensees to recognize MEs in permanent implant brachytherapy earlier and therefore be able to take corrective actions sooner than under current regulations.

Sincerely,

/RA/

Rebecca L. Schmidt, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Fred Upton

August 5, 2008

The Honorable Thomas Carper
Chairman, Subcommittee on Clean Air
and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The U.S. Nuclear Regulatory Commission (NRC) intends to publish a proposed rule in the *Federal Register* that would amend Part 35, "Medical Use of Byproduct Material." The proposed rule would amend the regulations that govern medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy. Brachytherapy is a cancer treatment in which small radioactive seeds are implanted inside or next to the area requiring treatment. The proposed amendments would change the criteria for defining an ME for permanent implant brachytherapy from dose-based to activity-based, add a requirement to report as an ME any administration requiring a written directive (WD) if a WD was not prepared, clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.

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Rebecca L. Schmidt, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator George V. Voinovich

August 5, 2008

The Honorable Barbara Boxer
Chairman, Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Madam Chairman:

The U.S. Nuclear Regulatory Commission (NRC) intends to publish a proposed rule in the *Federal Register* that would amend Part 35, "Medical Use of Byproduct Material." The proposed rule would amend the regulations that govern medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy. Brachytherapy is a cancer treatment in which small radioactive seeds are implanted inside or next to the area requiring treatment. The proposed amendments would change the criteria for defining an ME for permanent implant brachytherapy from dose-based to activity-based, add a requirement to report as an ME any administration requiring a written directive (WD) if a WD was not prepared, clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.

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Rebecca L. Schmidt, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator James M. Inhofe

August 5, 2008

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Rebecca L. Schmidt, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Joe Barton

August 5, 2008

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Chairman, Subcommittee on Energy and Air Quality
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

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Rebecca L. Schmidt, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Fred Upton

Identical Letters sent to: The Honorable Thomas Carper with cc to Senator George V. Voinovich, The Honorable Barbara Boxer with cc to Senator James M. Inhofe, and The Honorable John D. Dingell with cc to Representative Joe Barton

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