PR 31 (74FR38372)



October 16, 2009 (sent via facsimile)

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October 19, 2009 (11:15am)

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Secretary
US Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn. Rulemakings and Adjudications Staff

OFFICE OF SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

Subject: Comments on Proposed Rulemaking Related to 10 CFR Part 31

Dear Secretary,

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them.

Thank you for the opportunity to comment on the proposed regulation titled "Limiting the Quantity of Byproduct Material in a Generally Licensed Device" that was published on August 3, 2009 in the Federal Register. Please consider the following comment:

The basis of the proposed regulation for limiting the quantity of byproduct material in generally licensed devices is to enhance public health and safety through increased security of these devices. We fully support the basis of the proposed rule; however, we do not support Section C of the rule (on pages 38377 & 38378 of the Federal Register) which would "prohibit specific licensees from possessing generally licensed devices under 10 CFR 31.5 at the same site" for the following reasons:

- 1. This prohibition has nothing to do with the basis of the proposed rule which is enhancing public health and safety, and
- 2. The prohibition's rationale is clearly stated at the bottom of paragraph 2 on page 38378 "This proposal would also reduce the number of generally licensed devices that the NRC would need to track".
- 3. The prohibition unfairly mandates additional requirements for specific licensees who own the same sources that could be possessed by a general licensee while, most individuals responsible for specific licensees are much more familiar with the requirements of 10 CFR 31.5 than most general licensees.

Please contact me at 732-594-1434 or vincent williams@merck.com if you have any questions.

Sincerely,

Vincent P. Williams
Radiation Safety Officer

File: NRC Correspondence

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DATE: 10/16/2009

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