

Eli Lilly and Company
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October 15, 2008

SUBMITTED VIA www.regulations.gov

Michael Lesar
Chief, Rulemaking, Directives and Editing Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Mail Code 6D59
Washington, DC 20555-0001

7/31/08
73 FR 44780
(73)

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RULES AND DIRECTIVES
BRANCH
USNRC

Attention: Docket ID No. NRC-2008-0419 (73 FR 44780, July 31, 2008)

RE: Comments of Eli Lilly and Company on Security and Continued Use of Cesium-137 Chloride Sources

Eli Lilly and Company, appreciates the opportunity to comment on the issue of security and continued use of cesium-137 chloride sources.

At Eli Lilly and Company, the use of Category 1 and 2 CsCl sources occurs primarily in self-shielded irradiators for the purpose of rodent immunosuppression. Immunosuppression allows for rapid growth of cancer cells upon which the effects of investigational cancer compounds can be tested. Immunosuppression by Cs-137 irradiation is an industry standard practice and is well validated in the scientific literature. Preclinical data resulting from these studies determines which compounds will be further investigated and is thus critical to the discovery of life-saving medications in the area of oncology. The introduction of even seemingly minor disruptions to existing techniques (such as increased irradiation times or mechanisms of absorbed dose as would result from suggested alternatives) would require extensive scientific validation and verification before resulting preclinical data would be meaningful, thus introducing delay to life-saving research efforts.

Recent NRC-mandated security controls for category 1 and 2 CsCl sources requires institutions to have improved physical barriers and electronic surveillance for the facilities housing the irradiators as well as limited employee access, and FBI background checks on all personnel granted access to these sources. We recognize that these increased controls are important improvements in the regulation of these potentially dangerous sources and we feel that when implemented properly, provides for a very high level of security with little risk of unauthorized access.

We would like to suggest that the elimination of existing CsCl sources is unnecessary in light of the new controls described above and would have a significant negative impact on our ability to discover new drugs for the treatment of cancer. We would also like you to consider that the potential for public risk and/or unauthorized access to these dangerous sources during the decommissioning process and transport of the CsCl sources for disposal negates any safety gain imposed by regulation disallowing the use of CsCl irradiators.

In summary, we assert that security of currently licensed self-shielded irradiator devices is sufficient, the risks of disposal outweigh any gains from their elimination and that the negative impact to the process of delivering life-saving oncology drugs is unjustified. Accordingly, we suggest that use of currently licensed devices for their foreseeable lifetime is a prudent path forward, at least until such time that available alternatives have a well documented scientific basis in the literature and established benefit to public safety.

SONSI Review Complete

E-RIDS-ADM-03

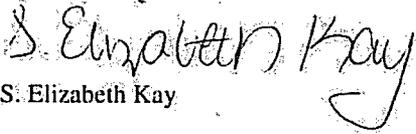
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J. Jankovich Answers That Matter.
(JP2)

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Sincerely,

A handwritten signature in cursive script that reads "S. Elizabeth Kay". The signature is written in dark ink and is positioned above the typed name.

S. Elizabeth Kay