

RULES AND DIRECTIVES

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VIVIAN S. LEE, M.D., Ph.D., M.B.A. Vice Dean for Science Senior Vice President and Chief Scientific Officer

REGEIVED

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

7/31/08 431=R 44780

Re: NRC Security and Continued Use of Cesium-137 Chloride Sources Roundtable (Docket No. NRC-2008-0419, 73 FR 44780)

Dear Mr. Lesar.

The New York University School of Medicine (NYUSoM) appreciates this opportunity to provide input on the NRC Security and Continued Use of Cesium-137 Chloride Sources Roundtable Notice and Issue Paper (Docket No. NRC-2008-0419, 73 FR pp. 44780-44783) now open for comment.

NYUSoM has a prominent and vigorous scientific program in biomedical research, funded through grants from the National Institutes of Health, the Howard Hughes Medical Institute, and many other, prominent peer-reviewed funding agencies. In this capacity, the School is dedicated to supporting research in almost every area of human health, from basic studies to better understand human physiology, development, and disease to the development of new therapies and medicines to address and improve the health of Americans. Many of our research programs rely on the availability and use of Cesium-137 chloride radiation sources, and the continued availability of these instruments is crucial for the continuation of these important research projects. Over the past several years, we have made significant improvements to the security of our radiation sources, leading to commendations from regulatory oversight agencies during inspections. These devices are now physically isolated with access limited to authorized personnel, all of whom have undergone background checks and have been fingerprinted, resulting in heightened security that minimizes any risk of misuse. With these security enhancements in place, we are confident that the continued presence and use of these devices on our campus does not pose a significant risk to the public. Rather, their presence provides important benefits to the nation by augmenting a wide variety of important and successful research projects with direct impact on human health.

Research on campus utilizing these devices ranges from studies of immunology, in which irradiation of experimental animals is a crucial and irreplaceable component, to studies of DNA damage and repair, an important aspect in the causation of cancer, to preclinical studies of novel cancer therapies. For these studies, there is either no alternative to Cesium-137 sources or the available alternatives would require major changes to ongoing research protocols that could result in losing years of potential progress in addressing these important diseases.

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NYUSoM opposes the proposed recommendations to phase out irradiation devices containing Cesium-137. The effective protections of these devices that are already in place and that have been developed at considerable expense and after careful consideration and planning minimize any potential harm. We also believe that suggested alternative sources of irradiation are not economically, scientifically, or practically viable. We urge the NRC to consider carefully that the recommendations under review would compromise the basic research that leads to development of clinical treatments for patients, and we ask the NRC to modify the final draft of its recommendations to include the risks to ongoing research inherent in making the proposed changes.

X-ray irradiators have been proposed as an alternative to Cesium-137-containing irradiation devices for current research applications. We considered this alternative here at NYUSOM when we undertook a review of our Cesium-137 sources. However, our review determined that these devices have not proven to been as reliable and are not suitable for many of our research protocols. These devices often malfunction, requiring frequent and costly maintenance as well as backup irradiation devices. Moreover, X-ray irradiators are not an effective alternative for crucial transplantation research involving animal models, one of the major uses of research irradiation on our campus and a cornerstone of our cancer program. Moving our research protocols to a different radiation source would require recalibrating and repeating many of our studies, at enormous cost in both research dollars and research time lost, and would detrimentally impact this important research.

Other suggested alternative sources of irradiation also do not seem to be viable either economically or practically for the research carried out by our scientists and physicians. For example, Cobalt-60 has a shorter half-life than Cesium-137 and requires significantly greater shielding. Therefore, Cobalt-60 sources would need to be replaced more frequently, which can be financially prohibitive and would increase the logistical problems of maintaining security, and the greater required shielding would mean that these larger sized and extremely heavy instruments would not fit in our existing research facilities. NYUSOM is very concerned that the alternatives to Cesium-137 that have been suggested in the recommendations to the NRC are not economically, practically, or scientifically viable. Any change in the availability of Cesium-137-containing device without an acceptable alternative would have serious detrimental effects on vital areas of patient care and fundamental research.

NYUSoM urges the NRC to maintain continued access to Cesium-137 irradiation devices for research purposes under the current security arrangements:

Thank you for your consideration.

Sincerely,

Vivian S. Lee, M.D., Ph.D., M.B.A.

Vice Dean for Science

Chief Scientific Officer and Senior Vice President