DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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RE: Public Comments on the Continued Use of Cesium-137 Sources

Dear Mr. Lesar,

In response to the Request for Comments by the Nuclear Regulatory Commission on the issue referenced above, the National Institutes of Health (NIH) wishes to submit the following comments on behalf of the approximately 700 individuals who use Cs-137 self-shielded irradiators at the NIH:

1. Irradiation of cells, blood, animals, pathogens or other materials is an essential component of many research projects performed at NIH and at grantee institutions. This is particularly true for immunologists and basic science researchers. The cesium irradiators have proven to be the "gold standard" in providing effective, reliable, dependable and very experimentally reproducible means of irradiation. With the addition of increased controls already in place to enhance the security of these irradiators at NIH, the perceived need to eliminate future licensing of cesium sources is questioned.

2. The objectives of basic science research, as well as patient care support, would be significantly hampered by a change to a less efficient method of irradiation. Numerous adjustments would need to be made to experimental designs, years' worth of research may need to be repeated, and not all research currently being conducted would be able to be accommodated by alternative technology. Those which could in theory achieve a similar radiation dose as that provided by cesium would be forced to sacrifice efficiency and convenience, and would be forced to accept additional variations in effective dose. Because the NIH supports such a large number of researchers in need of reliable and reproducible radiation doses for research protocols, the cesium irradiators have long been an indispensible part of experimental designs. It would be detrimental to phase them out, and it would be impossible to phase them out for research applications with no alternative technology.

3. Alternative technology is primarily considered to be x-ray sources of radiation. X-ray devices are known to be very expensive pieces of equipment with high routine maintenance and operation costs. Furthermore, of all the factors which suffer by comparison to cesium irradiators, irradiation time is one of the most significant arguments against adoption of x-ray sources. While many cesium irradiation exposures require 2-8 minutes of exposure time, tumor cell irradiations can require more than 30 minutes and some pathogen irradiations can require over an hour. The time required for exposures using an x-ray device would

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increase by a factor of 4- to 8-fold, depending upon design, and that exposure would likely not be as uniform. Many irradiated products are cells cultured in vitro, and the length of time they remain out of culture is critical to their survival and function. Additional time will also be spent re-suspending cells throughout a longer irradiation time, which further adds to the time commitment. With irradiator queues already several researchers deep at times, prolonging each irradiation procedure will only serve to exacerbate the efficiency of this operation.

4. Proper and ethical animal irradiation is of paramount importance; when considering the adoption of alternative (x-ray) technology to this process, the researcher must consider the fact that x-rays have a very short field range in tissue. Thus, dose gradient in animal models is a concern. Researchers must counter that dose variability by accounting for improved statistical control; this may result in an increase in the number of animals used. Any increased use of animals would be counter to the U.S. Government principles that include guidance to minimize the number of animals used in research protocols. Furthermore, there is a real concern that x-ray irradiation in animals will require restraints in order to achieve proper dose gradients and that this will increase the level of stress in those animals.

5. Transitioning to non-cesium irradiators will cause a potential major negative budgetary impact on the NIH and its grantees. The replacement expense is a cost that will need to be borne by the Institutes at a time when budgets are flat; already there have been major cuts to the NIH supplies, services and equipment operating budgets. NIH cannot afford to replace the cesium irradiators on a more than an end-of-useful-life basis, which is a significantly long time given the 30-year half-life of Cs-137. There is currently no disposal outlet for cesium irradiators, and this causes a more significant safety and security threat by placing these sources in storage as opposed to an active use mode. Faced with long-term storage of these irradiators, the NIH will not be able to reduce from the same level of enhanced access control already in place.

The NIH intends to follow the cesium phase-out initiative very closely, and I appreciate the opportunity to provide these comments to you. Basic research needs are currently being met using cesium irradiators and it would be a grave disservice to eliminate such a valuable tool to the NIH research mission.

Sincerely yours,

Michael M. Gottesman, M.D.

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

cc: Mr. Robert Zoon, Radiation Safety Officer, NIH
Dr. Ira Levin, Chair, Radiation Safety Committee, NIH