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Security and Continued Use of Cesium-137 Chloride Sources: Granting Extension of Comment Period

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Comment

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(JPJ2)

RE: Comments on Security and Continued use of Cesium-137 Chloride Sources

Dear Mr. Lesar:

These comments are in response to the July 31, 2008 Federal Register Notice (NRC-2008-0419) inviting public comments on the issue of security and continued use of Cs-137 Chloride (Cs-137) sources commonly used in medicine and research. As Certified Health Physicist and Radiation Safety Officer for a large comprehensive cancer research center, I have spent considerable time and effort looking into this issue, talking to our researchers, to peers at other institutions and users who require the use of large Cs-137 sources in self-shielded irradiators.

While security of radioactive materials and especially Materials of Concern is extremely important to us, we urge the NRC to do a full cost-benefit analysis of any plans relating to cesium shelf-shielded irradiators, with a detailed look at the risks vs the benefits of any alternatives. We believe the current security measures in place for the cesium sources are prudent and adequate for the risk they present to the public. Additional controls or measures are not warranted, and the ultimate cost would be much more than is being estimated.

Background
The Fred Hutchinson Cancer Research Center (FHCRC) is a non-profit organization and one of the National Cancer Institute-designated comprehensive cancer research centers. The Center is also a member of the National Comprehensive Cancer Network.
Our mission is ?????????to eliminate cancer as a cause of human suffering and death.?????????
Internationally recognized for its pioneering work in bone marrow transplantation, the Hutchinson Center employs more than 2,500 people and is headed by 2001 Nobel Prize in medicine recipient Lee Hartwell, Ph.D., as president and director. In 2004, another Center faculty member, Dr. Linda Buck won the Nobel Prize in Medicine and Physiology, making her the third Hutch Nobel Laureate, joining Drs. Hartwell and E. Donnall Thomas (1990 Nobel prize in medicine).

My comments on NRC-2008-0419 and the issue of Cesium source replace in general are based on impact to the FHCRC mission. Most of these comments are directed at Q3.1??????????1. (a).

Use
Currently, the FHCRC has 51 Principal Investigator and over 250 users authorized to
use our irradiators. In the last year, our researchers used our irradiators over 1400 times. Are units are used for irradiation studies of cells and animal models, bone marrow and for clinical trials.

The Hutchinson Center needs irradiation facilities that provide

????????? High dose rates
????????? Penetrating radiation
????????? Reliable
????????? Safe and low dose to users
????????? Easy to use
????????? Relatively small size
????????? Economical to use
????????? Reproducible irradiations
????????? Standard use at various facilities

Impacts
Changing the source of radiation could have a range of radiobiological effects. Different radiations and different energies may cause research that has been based
on Cs-137 gamma radiation to be redone, or at least, validated against the Cs-137 based work. This would cause months and possibly years delays in research and affect our grants. Changing the source will also cause delays in clinical trials and amendments of the Food and Drug Administrations (FDA) Investigational New Drug
(IND) applications, which would have to be amended after the new source verifications.
While the delays happen in research and clinical trials the research costs, salaries,
facilities and maintenance will have to be paid for somehow.

Cost
In any of the alternative scenarios presented, there will be at least up-front costs of source replacement, purchasing, installation and disposal of present sources. I believe
this cost will pale in comparison to the amount that will have to be spent on the disruption in research and clinical activities.

Materials of Concern
Since the NRC's Increase Controls order and license amendment for further controls
have gone into effect, the FHCRC has spent thousands of dollars to meet and exceed
the requirements place on them to possess and use materials of concern. This cost
has been borne by the facility, without any compensation from the regulators or

any
other regulatory body. To remove the sources would mean that facilities such as ours
have wasted our money (tax payer money) to increase security.

Source Disposal
The disposal of the hundreds of Cesium or cesium chloride sources is not a simple
task. Most of these greater than class C sources will not be able to be disposed of at
the existing disposal sites. To put them into the federal disposal section could possible
change the EIS for the sites. Without a place to dispose of them or recycle them, the
ideas of alternate sources of radiation should not be considered.

Summary

The FHCRC research requires the use of sample irradiators. Their use is integral with
the FHCRC?????????s mission, and multiple researchers could not complete or start new projects without the Cs-137 irradiators. The risk for malicious use or theft is extremely
low. The present security, increased controls, policies, and procedures in place for the
irradiators are more than adequate to address these risks.

The total cost of the source replacements will include research, grant and clinical trial
delays, along with the actual cost of the new source and disposal of the old source. To
dispose of one source is estimated to be over $20K by one author I contacted. This will
be the smaller amount considering the cost of delays in the clinical trials and research,
which will reach into the millions and billions of dollars. Centers such as ours do not
have the means to shoulder this burden.

A shorter lived radioactive material will need to be replaced more often, and will incur
additional cost and down time for the source exchange, besides the risk of shipping
numerous radioactive sources around the country. Cobalt 60 (Co-60) has higher energy gamma rays, which could have significantly different biologic effects on samples and will produce higher dose rates outside of the irradiators designed for use
of Cs-137.

So far, the technology of using machines for doing routine high dose rate

irradiations
is either cost prohibited or not reliable enough for our researchers to consider. Machines are inherently more complicated than radioactive sources and as such in my
opinion, will have higher operating costs for maintenance and repair, with an increase
in down time. Again, shifting radiation sources, x-ray spectra have significantly different biologic effects on samples, and the use would have to be verified for each experiment, NDI, and clinical trial. In my opinion also, using machine irradiators will
increase operating costs on a long-term basis.

CsCl sources could be replaced with sources using a Cesium matrix material, such as
a ceramic. The cost to replace all of the CsCl sources in the country could be hundreds of millions of dollars, and the time needed to manufacture these sources is
unknown. The availability of facilities with hot cells required to handle the sources and
the technical expertise to create the matrix are also unknowns. It is also very possible
that the new sources would not fit in the current irradiators, needing larger source sizes for the matrix vice powder.

The ultimate cost is going to be in "lives lost", though the delays incurred in clinical
trials and in the life saving research our scientists are doing each day. We urge your
office to consider all costs when looking at this issue.

Thank you.

Very Respectfully,

Bruce Busby, CHP
FHCRC Radiation Safety Officer