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General Comment

Attached is one of multiple comments submitted by Nuclear Information and Resource Service arguing against the changes that weaken public protection from man made ionizing radiation. The Regulatory Analysis fails to make the case that the changes will be "safe."

Attachments

NIRS Comments 10 CFR 61 radiation Docket ID NRC–2011– 0012 December 18, 2017

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NIRS Radiation Comments on 10 CFR 61 Draft Regulatory Analysis for Final Rule
Low-Level Radioactive Waste Disposal
Docket 2011-0012 82 FR199 10/17/17

Radiation and the Human Lifecycle

*Nuclear Information and Resource Service (NIRS) hereby submits the following comments on **some** of the ways in which the regulations, policies, practice and other activity of the US Nuclear Regulatory Commission (NRC) do not protect public health. NRC is mandated by law to provide regulations that protect the public from harm due to exposure to ionizing radiation, caused by federally licensed nuclear activities. The NRC completely ignores the costs to the public and environment from it NIRS here declares that NRC has failed that mandate. NRC is in default on its obligations under law. Action must be taken to correct the situation. We offer here:*

Part 1: stipulations on radiation and NRC's activities.

*Part 2: information and citations that serve as evidence for **some** aspects of NRC's failure to provide protection to the public.*

Part 3: outlines next steps and makes recommendations for improvement.

In the interim, NIRS objects to any NRC action including rulemaking, guidance or licensing that will result in further exposure of the public to ionizing radiation. After fifty years of failure to fulfill its mandate under law, NRC should get out in front and initiate redress for its failures.

This document originates in December, 2017; and may be updated from time to time.

Part 1

[Commenters do not necessarily endorse or seek to promote all of the information cited here; cites are made for purposes of further discussion in Part 2]

The following statements are non-controversial:

A. Any exposure of living tissue to ionizing radiation ('radiation' is hereafter used interchangeably) carries the possibility of harm (US Environmental Protection Agency states this in the Safe Drinking Water Standard). NRC states that its radiation regulations are based on a no-threshold model, therefore only zero exposure is zero risk.

B. Since living on Earth exposes the public to naturally-occurring radiation, every additional exposure from licensed activities carries an additional possibility of harm. The greater the level of exposure, the greater the level of harm.

C. Exposures to the general public from federally licensed activities include (but are not limited to) uranium mining and processing, and the wastes and releases from these activities; transport of nuclear materials and wastes, including accidents; nuclear fuel from fabrication to use and wastes generated and releases to our environment from the many steps in production and use of nuclear fuel and management of radioactive wastes. Exposures due to these federally licensed activities are not restricted to adult males.

D. Exposures to the general public may be from non-particle gamma sources (external only) or from internalized radionuclides, once released to our environment. Radioactivity when released may travel in air; surface, ground and atmospheric water; in soil, building materials and other solid forms; contamination may spread by insects, rodents and other animal vectors; re-use may result in radioactive household objects; radionuclides may enter the food chain by many of these vectors and it is likely some exposures occur from additional vectors. End-point exposures to individuals are not routinely assessed, tracked or recorded. None of these exposures are limited to adult males.

E. Internalized radionuclides may emit photons, gamma rays, release beta, alpha or neutron particles, or cause other particles (electrons for one) to be ejected by body-resident atoms. End-point exposures to individuals from internal emitters are not routinely assessed, tracked or recorded, and, indeed many such exposures could not be detected by current technology. None of these exposures are limited to adult males.

F. Most historical evaluations of the impact of radiation on the human body are from external sources (medical X-rays and the A-bomb attack by the USA on Japan in 1945).

G. Cancer is not the only harm that may result from exposure of the human body to ionizing radiation, but for purposes of establishing "protection" cancer is the only outcome that the federal agencies admit, track, or seek to limit. Exceptions are made for atomic workers who report their pregnancy, with a modest reduction in exposure limits. No exceptions are made for non-pregnant women's ovaries, or any male's spermatagonia.

H. NRC, in general, relies upon the use of "Reference Man" when it comes to radiological assessments, including exposure limits and permitted release rates impacting the public. [The Institute for Energy and Environmental Research posted the official definition of the Reference Man from the International Committee for Radiological Protection here: http://ieer.org/wp/wp-content/uploads/2009/01/definition-of-reference-man.pdf]

I. Historically, both "relative biological effectiveness" factors and "dose rate effectiveness factors" are derived coefficients, resting on models that use the Reference Man.

J. Dr David Richardson, et al, published findings [see: BMJ 2015;351:h5359] based on the INWORKs data-set, composed of tens of thousands of US, Canadian, and European atomic workers. The radiation doses resulting from occupational activity to those in the INWORKS group have been measured and tracked for 30+ years. The paper reports that the many small, low, protracted-over-time exposures to radiation among atomic workers can add up to the level of exposure similar to the A-Bomb survivors from Hiroshima and Nagasaki, and when compared, the two groups share the same risk-profile for cancer. Many small doses result in a rate of cancer that mirrors the cancer documented in the Life Span Study of the Japanese A-Bomb survivors where the dose studied is the single prompt pulse of radiation associated with the detonation of the bombs. [See NAS, 2006, BEIR VII Phase 2] This finding supports the linear / no-threshold assumptions utilized, at least to some degree, by the NRC today.

K. Since Richardson, et al use the INWORKS data-set where so far, 97% of the absorbed dose is to adult male atomic workers, Richardson's findings are applicable to NRC analysis, which also rests on adult males. Neither is necessarily representative of the impact of radiation across the human lifecycle.

L. NRC, in general, relies on models which are first based on external exposure, not internalized radioactivity, for establishing its broad regulatory limits and annual permitted radioactive release to our environment.

M. In 1990 NRC published [Expanded Below Regulatory Concern Policy Statement] its risk-assessment for lifetime exposure of Reference Men to various levels of external exposure to ionizing radiation. A table was presented; at 100 millirem per year, over a 70 year lifetime NRC states there will be 3.5 cancer deaths per 1000 [Reference Men] exposed. Reference Man is used in this calculation, though not stated.

N. When "3.5 in 1000" is simplified as a ratio, the result is 1 fatal cancer in every 286 [Reference Men] exposed. [Use of these risk numbers in the following text in no way constitutes NIRS endorsement of these risk-of-cancer values. They are NRC's published values, and we are citing them.]

O. At the dawn of nuclear licensing, in the same timeframe as the establishment of the Atomic Energy Commission, there was a social debate about what constitutes "acceptable harm" to the general public when it is our government that is allowing that harm when it permits (licenses) dangerous activities. The concept of "one death in a million" was discussed, and perhaps even promoted by the federal regulators of the time. This level of sacrifice (never formally approved by the public) was subsequently adopted in broad-brush as the regulatory goal for many hazardous activities.

P. The NRC evaluation of harm cited above (M) from a 100 mr a year lifetime exposure seems (simplistically) to be the same as one of NRC's regulatory limits for exposure to the public, 100 millirems per year results in deaths greatly exceeding the popularized

"one in a million." Indeed, 3.5 deaths in 1000 [Reference Men] is 3,500 cancer deaths in a million Reference Men so exposed. The US Environmental Protection Agency (EPA) has nonetheless taken one cancer in a million people exposed as the overall goal of its regulations for hazardous materials.

Q. The NRC's limits are an annual coefficient of exposure since NRC's radiation standards also include amounts and concentrations of radioactivity that are allowed on an annual basis for unrestricted release to our air, water, sludge and also applying to waste processing and disposal under separate, additional licenses. This regulatory structure results in accretion of both radionuclides in the environment, and cumulative dose in the population, (individuals as well). Since the stated annual exposure limits for the general public are associated only with that year's release limits, this complicates the interpretation (P) that the actual dose limits are comparable to 100 millirem example from the NRC risk assessment (M). We will discuss this point below.

R. Therefore the federal government privileges radiation and radioactivity resulting from licensed nuclear activities, allowing death among Reference Men thousands of times higher than the popularized, so-called "acceptable" death rate from federally authorized industrial activities of "one in a million." [Again: NRC's numbers must be associated with Reference Man]

S. Currently there is no widely available technology or other means to measure and document instant radiation exposure outside occupational areas (i.e. members of the general public). Therefore, any evaluation NRC of radiation exposure of the general public; either as a population, or to the individual, instant or cumulative, due to licensed activities is strictly the result of modeling using assumptions based on Reference Man.

T. There can be no evidence-based record of cumulative exposure since there is no record of instant exposure to individuals or to populations considered to be the general public.

U. The concept of "general public" is rarely defined. In practice, the un-defined use of this concept of a generality in practice, allows NRC to fold communities and individuals at greatest likelihood of exposure from licensed activities, (including adult males, but not limited to them) who live downwind, down-water or are otherwise exposed more regularly than others, into a larger pool of less-impacted people living in the area, but who are less impacted thanks to prevailing winds and or direction of water flow, or other systematic factors governing the distribution of radioactivity permitted to be released, or accidentally released. The few regulations [for example EPA regulations for national permanent radioactive waste repositories] that use a maximally exposed individual (or group) are the exception, not included in the NRC's operating license rule.

V. NRC has made different regulations that reduce occupational exposure somewhat during a "reported pregnancy." Otherwise it is assumed by NRC that all of the phases of the human lifecycle are adequately protected by using information based on Reference Man.

W. In August, 1945 when the US dropped atomic bombs on the cities of Hiroshima and Nagasaki, the cities had not been evacuated, and were full of people. The civilians who died that day, and also those who survived, were of all ages and both genders. Collectively the survivors, the Hibakusha as they call themselves, are the largest group of radiation-exposed individuals that has been tracked over a long period of time. The Life Span Study and other data from the A-bomb survivors is widely used by radiation regulators.

X. The data in the Lifespan Study assumes that the outcome of "excess cancer" in the study population is due to the large gamma and neutron pulse (external, prompt) radiation associated with the detonation of the weapons.

Y. The National Academy of Science (NAS) published 60 years of cancer incidence data in 2006 in its Biological Effects of Ionizing Radiation, VII, Phase 2 (BEIR VII).

Z. BEIR VII is one of the most accessible sources for data from the A-Bomb survivor's lifespan study. Various tables of numbers are presented in appendices, some organized by age-cohorts organized by the age the individuals were in 1945 when exposed to the radiation of the bomb. Much of the data is segregated by gender as well as age.

Part 2

The next set of statements are not yet adopted by federal regulators, but unless NRC and other federal entities that license or permit radiation exposure to the public heed these points, the current generation and those to follow are in harm's way.

Further: the utter ignorance about the human lifecycle that has been allowed among federal regulatory staff and those they advise has resulted in 50 years of harm that must be recognized and redressed. See Part 3.

We treat only post-birth exposures and consequences in these comments. Pre-birth, including pre-reproduction: the ova and spermatagonia, formed when in utero, while still inside the grandmother's body, and carried from birth can be harmed by radiation exposure. Then in reproduction: the fertilized egg, embryo, and fetus where there is a body of information about radiation harm, are nonetheless not part of the BEIR VII data-set that these comments are based on. Certainly pre-birth matters. The following evidence will certainly show, the Reference Man is not acceptable as a model for the pre-birth phases of the human lifecycle, but that will wait for future comment. Here we focus on age and gender, post-birth.

The use of the very first nuclear weapons by the US Military on Japan's Hiroshima and Nagasaki; cities full of people, is in our view an atrocity of war, and each attack falls under the

definition of a war crime. The use of the data from the survivors of these nuclear attacks must be acknowledged in this context. The survivors, the Hibakusha, are the largest data-set of exposed individuals that includes both genders and all ages, and the Lifespan study is the longest track. Our use of the data does not condone its origin, and NIRS formally apologizes to the People of Japan, and the Hibakusha that this history ever happened. At the same time, the findings reported here are only possible because of the suffering of the Hibakusha, and they are a very important message to all human beings.

1. Reference Man does not accurately represent the general public. [Following points refer to the illustration page at the end of this document]

2. BEIR VII data on cancer incidence (Y) in each of the age-of-exposure cohorts (birth to 5, 5-10 years, 10-15 years…and on to 80) when shown in graphic form (See Graph 1 on the Illustration page) clearly shows that the male age-cohorts that correspond to the official definition of the Reference Man (see H) suffered a much lower rate of cancer across their remaining lives than did those who were exposed as children.

3. Comparing the male age cohort between birth and five years of age in 1945 when exposed to the radiation from the A-bomb, the incidence of cancer over the next 60 years is five times higher (per capita) than that of the males in the 25—30 age (at exposure). Therefore Reference Man does not accurately represent males in the general population. Some, possibly most males in the general population have been (and in the future) will be boys when exposed to radiation from licensed activities. A factor of 5 is a big difference; not trivial.

4. Graph 1 on the illustration page shows the age-cohorts in the Life Span Study (age the survivors were in August, 1945 when exposed to the prompt radiation of the US atomic bombs) across the bottom axis. The vertical axis shows 60 years of tracking the age cohorts separated by gender (pink line is female, blue line is male) and reports the incidence of cancer among about 100,000 people during those 6 decades. The numbers are published in BEIR VII, but the NAS did not draw the graph. Dr Arjun Makhijani (IEER) constructed the plot in 2006, and NIRS published the same image, independently in 2011.

5. It must be understood: Graph 1 does not show the age of cancer onset. It should not be assumed that all childhood exposures resulted in childhood cancers. Indeed, most cancer reported were after a typical latency period.

6. Reference Man does not, at any point on Graph 1, accurately represent the harm suffered by females from exposure to radiation. This includes 25-30 years old age-of- exposure-cohort corresponding to the definition of Reference Man. Over the 60 years reported, in this cohort, for every two men who died of cancer, three women died. (See recommendations below).

7. Reference Man is the least applicable to the harm to little girls from exposure to radiation. Females who were between birth and five years at the time of the A-bombs, over the next 60 years suffered ten times more cancer (per capita) than did the males who were 25-30 when

exposed. (Graph 2 on Illustration Page). Ten times is an order of magnitude; it is extremely significant; it renders NRC's assumptions about radiation harm obsolete.

8. Reference Man does not represent any female in the population since many were, are and will be exposed to radioactivity and radiation from licensed activities as young girls. The cancers (and other harm) resulting from these exposures are systematically ignored by NRC.

9. Perhaps most startling is the fact that the difference between males and females in rate of harm is not only across the entire lifespan (See Graph 1) but that it is greatest among young children. For every boy (birth-5years) exposed in 1945 who suffered cancer at some point in his life, two girls got cancer at some point in their lives. (Graph 1 and Figure 2, Illustration page).

10. A doubling of harm from the same exposure level is dramatic. In most biological research a doubling is considered the basis for further analysis. Why is there a difference between group A (little boys) and B (little girls) exposed to the same radiation and studied over the same period of time? Why is biological sex (gender) a factor?

11. A gender difference in early childhood is also dramatic. Not likely to be an occupational difference, or adult habits (smoking), and these age groups are generally closest in typical body mass and overall size.

12. A 100% difference in outcomes (between boys and girls) from exposure means that NRC and other federal agencies are dramatically under reporting cancer (and other) harm from radiation based on gender only.

13. Comparing the consequences of exposing little girls to exposing adult men (like Reference Man) results in the BLOCKBUSTER finding (already stated in 7 above) that there is a full order of magnitude difference between the most-impacted part of the general public and the model used by NRC. A full order of magnitude.

14. NRC is and has been systematically ignoring, or possibly hiding ten times more cancer than it currently attributes to ionizing radiation. The factor of ten is due to a combination of both age-of-exposure and biological sex (gender) of the individual exposed.

15. To date, NRC does not acknowledge gender as a factor in radiation harm, and yet the data available to IEER and to NIRS since 2006 has been available to NRC.

16. Living organisms have a lifecycle. It is not possible for the organism (of any kind, including our species) to skip over a step in its lifecycle. Little girls are an inextricable part of the human lifecycle. It is not possible to protect our species if little girls are not protected.

17. Regulations rooted in Reference Man do not adequately protect those who are exposed when little boys (by a factor of 5), but regulations based on Reference Man are twice as bad at

protecting those exposed when little girls, where harm over the lifetime will be 10 times greater than that of the adult males who underpin Reference Man. These are not all girls getting cancer—they are the percentage of women in "the general public" who were exposed when very young, who may not suffer the cancer until adulthood. The reader, the reader's boss, and anyone else you care to name would not be here without the participation of a little boy and a little girl who grew up and reproduced.

18. Reference Man cannot reproduce by himself.

19. An under-reporting of harm by a factor of five for males (when childhood exposure is included) and by a factor ten for females when we include exposure during girlhood, suggests that we should retire Reference Man now… after 50+ years of inaccurate modeling that has never represented human beings, let alone "the public" which, presumably is composed of human beings.

20. Radiation standards, because of the reality of the human lifecycle, in order to be effective, must protect the part of the lifecycle most subject to harm from radiation.

21. Since NRC brazenly allows 3,500 Reference men to die per 1,000,000 (that is 1 in 286) Reference Men exposed to only 100 mr per year over a lifetime, it is incumbent upon the NRC to now evaluate and disclose how many deaths per 1,000,000 in a "general population" since such a group most certainly includes exposed boys and exposed girls who are at greater risk. In NRC's August 2016 "Draft Regulatory Analysis for Final Rule: Low Level Radioactive Waste Disposal, 10 CFR 61," NRC repeatedly states that 500 mr per year is *"safe"* which, using NRC's own risk numbers, could result in 1 in 57 exposed Reference men dying from cancer and even more females and boys. No definition is provided for this "safe" level.

22. As stated in the preamble, we are not treating that the pre-birth portion of the lifecycle, though surely these comments point to the need to do so. From birth to death, Graph 1 and BEIR VII show clearly, protection must be sufficient to protect little girls.

23. Little girls are exposed from early childhood to radiation at higher levels than prior to the atomic era: more efficiently built homes trap more radon gas; high-altitude aviation is an event that is much more common for young children today; dental and medical evaluations include even relatively large exposures; historic accumulation from licensed and permitted activities in our environment including water and food are widespread; persistent radioactivity from global nuclear weapons test fall-out; direct exposure to annual releases by NRC licensees (see Q).

24. The data from BEIR VII reporting the outcome of 60 years of cancer are the life-time risk from a single prompt external radiation event (so says BEIR VII). As such, they are not a direct comparison to the NRC's risk table (M), which assumes a static age and gender,

Reference Man is getting 70 x 100 mr (7 rems). It is time for NRC to revise its regulations to reflect the public it is protecting.

25. In order to protect little girls to the same risk level provided currently for adult males, the legal limits would have to be reduced 10 times. (Girls are 10 times more likely to get fatal cancer than men at the same dose/dose rate.) The amount of "legal" radiation must be lowered to protect little girls to put them at the same risk as adult males.

26. We do not think that 1 in 286 dying of cancer is good enough. That is the risk to adult males at100 mr/yr. We will not endorse 1 in a million being "acceptable," but 1 in a million is a much better target. The current 10 CFR 61 regulations are at 25 mr/yr to the public from 10 CFR 61 facilities but the "updates" in the proposed final rule and regulatory analysis would increase the legal dose to 500 mr/yr in the "intruder" scenario which would apply to almost anyone in the compliance period-potentially thousands of years.

27. Protection of the public is mandated by law. The public IS a little girl since she is inextricable from the adult phase, either gender. NRC has a long way to go to offer real protection.

28. IF standards protect the exposure to little girls, who will become women, then everyone else will simply be better protected.

29. Professional staff at another federal agency professed their ignorance about the human lifecycle in 2014. At a public meeting it was flatly stated that little girls are a sub-population. NIRS responded "Little girls in Chicago, or little girls in Moscow would be sub-populations—but little girls are an inextricable link in the human lifecycle."

30. Because age-of-exposure and gender dramatically determine the outcome of radiation exposure across 100,000 people of all ages and both genders this calls to question the whole concept of radiation "dose" which has also been based on Reference Man. Units of dose (Rem or Sievert) require extrapolation from Rads and Grays using models that are based on Reference Man. The notion of "biological effectiveness" must now be understood to also be age and gender dependent. Exposure of adult males to radiation causes harm. It is not possible to extrapolate degree of harm from an adult male to any other part of the Lifecycle. Gender and age are factors in radiation harm and can no longer be ignored.

31. What will NRC do to help uncover more information? Will the agency attempt to whitewash, sanitize and continue to apply male-centric decisions? That will not be acceptable. Simply averaging with adult females ignores the real risks to the lifecycle and specifically to the babies and children that are our future.

Part 3

NRC is in default on its obligations under law. NRC has failed to protect the public, many of its workers and our future generations. NRC has not responded to well established bodies bringing data that when properly described, shows that NRC's regulations have systematically under reported cancer (and harm overall) from radiation. A failure to protect the entire human lifecycle and gene pool places our future in jeopardy.

NRC, if it persists, will be guilty of discrimination on the basis of both age and gender.

Action must be taken. In the interim, NRC must not promulgate any rule or license that will continue to increase radiation exposure or release of radioactivity to the environment. In addition, after fifty years of failure to fulfill its mandate under law, NRC should get out in front and issue immediate STOP ACTION orders:

- *Institute a precautionary measure by NRC staff issuing an order for every license, forcing the cessation of all emissions OF ANY KIND until new, protective release limits are established and implemented. The goal should be to reduce, not increase radioactive releases and exposures;*

- *Issue an immediate order to all previously used sites to prohibit occupation / use until new site-release standards are in place;*

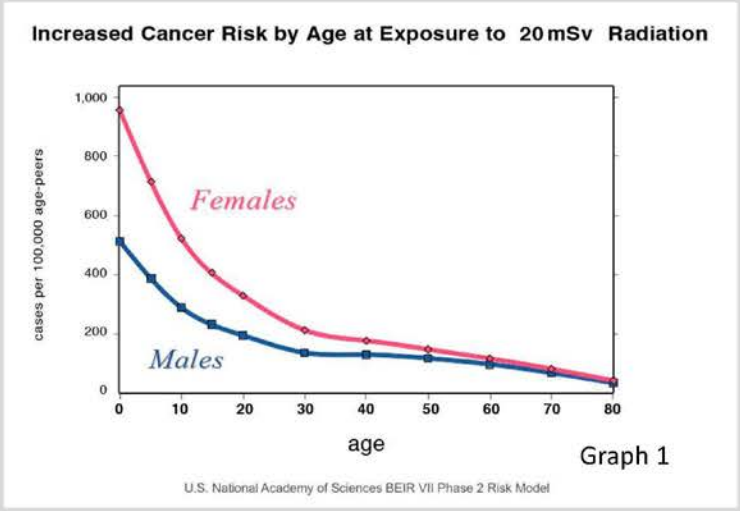
- *Issue an immediate disclosure to all employers of atomic / radiation workers to notify women that they have a significantly greater chance of suffering harm from radiation exposure in their jobs than do their male coworkers, who are also harmed. (Figure 2 reports the 50% greater incidence of cancer in adult women exposed compared to adult males)*

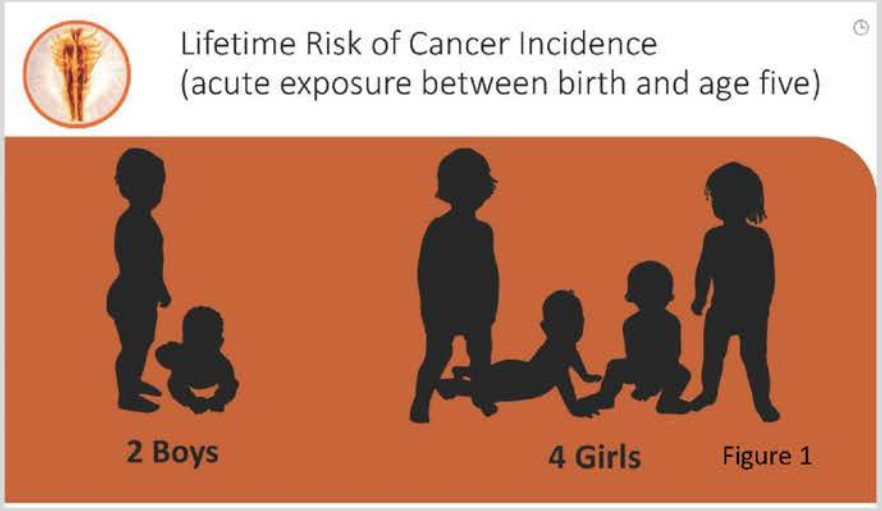
- *Begin work now on how to regulate so that in the general public in all phases of the human lifecycle are protected; and in occupational settings female workers are adequately protected; this is an urgent matter—but should not be rushed.*

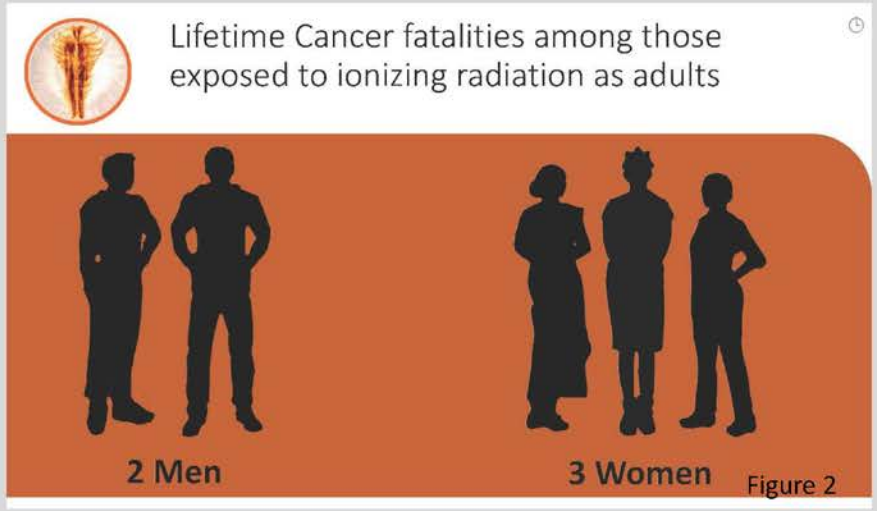
- *Initiate redress for its previous failures; it will be a long process—so get started. A truth and reconciliation approach is recommended;*

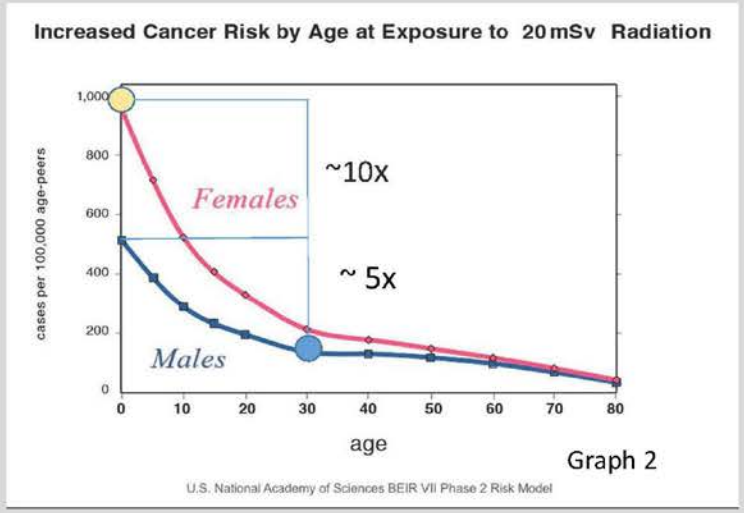
- *There is much we do not know; NRC is not trusted. NRC should build its good-faith by requisitioning funding for biological, medical and epidemiological research which it then awards to foundations that fund open, competitive, peer-reviewed research proposals.*

These are just a few recommendations. There will be the issues of liability. The first best action NRC and its licensees can take with respect to harm done already is to be proactive and embrace these recommendations whole heartedly.









Source of data is BEIR VII, but the report does not present the Lifespan Study data in graphic form, disaggregated by gender.