INSTITUTE FOR ENERGY AND
ENVIRONMENTAL RESEARCH

6935 Laurel Avenue, Suite 201
Takoma Park, MD 20912

Phone: (301) 270-5500
FAX: (301) 270-3029
e-mail: ieer@ieer.org
http://www.ieer.org

The Use of Reference Man in Radiation Protection Standards and Guidance with Recommendations for Change

Arjun Makhijani, Ph.D.

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Arjun Makhijani
Takoma Park, Maryland
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The Use of Reference Man in Radiation Protection Standards and Guidance with Recommendations for Change

Summary: Main Findings and Recommendations

1. Main findings

1. The use of Reference Man, a hypothetical 20 to 30 year old Caucasian male, in radiation protection regulations and guidelines, including those designed to protect the general public, is pervasive. This is scientifically inappropriate because the vast majority of people, including women and children, fall outside the definition. In general, it also does not protect those most at risk, who are often women and children.
2. Radiation protection regulations are generally given in terms of limits on radiation dose per year or in terms of maximum allowable concentrations of radionuclides in the environment, which also serve to limit radiation dose. The use of Reference Man in radiation dose calculations underestimates dose to children in a large number of situations, to women in some situations. The underestimation of dose results in an underestimation of cancer risk.
3. Overall, children have a higher risk of cancer for a given radiation dose. This higher risk per unit of radiation dose compounds the problem of underestimation of dose.
4. The regulations and guidelines that rely mainly on Reference Man include the NRC's radiation protection regulations in the workplace and for the general public specified in 10 CFR 20, EPA Federal Guidance Reports 11 and 12, and DOE Order 5400.5 for the protection of the public. The default values in the official computer program used to estimate allowable residual radioactivity use Reference Man. He is also used to assess compliance with the Clean Air Act.
5. The Maximum Contaminant Levels for transuranic radionuclides in drinking water rely on Reference Man.
6. The 2006 report on low-level ionizing radiation of the National Academies, commonly known as the BEIR VII report, concluded that women are at considerably greater risk of dying from cancer from the same radiation dose (higher mortality risk) and also at greater risk of getting cancer per unit of radiation dose, compared to an adult male.
7. Fetal exposure is only taken into account in radiation controlled workplaces in those cases where a woman declares her pregnancy. The standards in effect are obsolete by a factor of five or more.
8. The failure to estimate doses to children and cancer risks to children when they are in excess of doses and risks received by adults would appear to be in violation of President Clinton's 1997 Executive Order on children, which was reaffirmed by President Bush, with some changes, in 2003.

2. Recommendations

1. **End the use of Reference Man**: The use of Reference Man in radiation protection regulations and guidance should be ended both for estimating dose conversion factors and for estimating cancer risk.

2. **Calculate compliance to the part of the population receiving the highest dose**: Compliance with annual maximum exposure limits should be calculated using dose conversion factors for the portion of the population that would receive the highest radiation dose for a given set of environmental conditions.

This change would mean that annual radiation doses for comparison with limits would often be calculated for infants or children, since they often have the highest dose conversion factors for a given set of environmental conditions, though in other cases adults would remain the most exposed. Affected regulations include:

- NRC's annual dose limits and maximum allowable environmental concentrations for the general public specified in10 CFR 20;
- EPA's limit of 25 millirem from nuclear fuel cycle operations (40 CFR 190);
- Safe drinking water regulations (40 CFR 141.66);
- Clean Air Act regulations, decommissioning regulations (40 CFR 61 Subpart H).

3. **Develop and publish dose conversion factors for females**: EPA's guidance report FGR 11 should be retired and replaced with an updated version of FGR 13. This update should publish separate tables showing dose conversion factors and cancer risks for males and females at various ages. At present, dose and risk values at various ages are reported only as averages for males and females.

4. **Develop and publish age and gender specific external dose conversion factors**: The EPA guidance report for external dose calculations, FGR 12, should be revised to include dose conversion factors at various ages for males and females.

5. **Develop and publish fetal dose conversion factors**: These factors should be developed and published for use in compliance calculations for cases of declared pregnancy.

6. **Fill critical gaps in early fetal dose estimation methods and put protective standards into place until then**: ICRP Publication 88 assumption that the dose to the embryo/fetus in the first eight weeks of pregnancy is the same as that to the uterine wall[1] is not valid for alpha emitters and for low-energy beta radiation emitters, such as tritium. Consideration, therefore, needs to be given to tightening the maximum contaminant limits for tritium and alpha-emitters, until a satisfactory scientific framework can be put into place.

[1] ICRP 88 p. 20

7. **Calculate risks for those most at risk**: Lifetime risk calculations should be based on those most at risk. In general, this means that lifetime risks would be calculated for females, unless risks for specific cancers to which men are more vulnerable are being evaluated.

8. **Revise the default parameters in the residual radioactivity computer program RESRAD:** The default dose conversion factors in RESRAD, the official computer program to calculate radiation doses from residual radioactivity, are set to Reference Man. RESRAD program should be modified so that the default calculations always refer to those who would get the highest does and those who are highest risk from a given set of environmental conditions.

9. **Reduce maximum allowable fetal exposure in the workplace**: The maximum allowable fetal exposure in radiation-related workplaces (including Department of Energy facilities and those regulated by the NRC) in cases of declared pregnancy should be reduced from 500 millirem to 100 millirem, which is the level of maximum annual dose for the general population, using dose conversion factors for fetal exposure. Such a reduction is about two decades overdue. This maximum dose limit should be automatically reduced when dose limits to members of the public are reduced.

10. **Publish reference characteristics for populations not adequately covered**: The EPA should examine and publish reference biological characteristics for sections of the U.S. population not adequately covered in ICRP Publication 89, including African Americans and Hispanics.

11. **Reduce maximum allowable exposure to 25 millirem per year from 100 millirem per year**: The EPA is currently considering how the conclusions of BEIR VII should be incorporated in its regulatory framework. We do not agree with the EPA's position that "current standards and guidance are protective" even in light of BEIR VII.[2] For instance, the present radiation protection standard of 100 millirem per year in 10 CFR 20 (issued by the Nuclear Regulatory Commission) is inadequate and obsolete, especially in light of the BEIR VII report's conclusions. According to BEIR VII risk values, females have a lifetime risk of one in a hundred of getting cancer at this level of annual exposure.[3] And this excludes the cancer risks during fetal exposure. This is unacceptably high. We recommend that the NRC should revise 10 CFR 20 to reduce it to 25 millirem per year, which is currently the EPA standard for the maximum dose from a single nuclear fuel cycle facility. The DOE should similarly modify DOE Order 5400.5 to reduce the maximum dose to the public from 100 millirem per year to 25 millirem per year. The EPA should also revise its standard for a single fuel cycle facility to make provision for tightening the dose limit from single facilities in cases where the public is exposed to more than one nuclear fuel cycle source (including any nuclear

[2] Meyers 2008. See Attachment 2.

[3] Based on NAS-NRC 2006, Table 12D-3, which provides the lifetime cancer incidence and mortality values for populations of males and females exposed annually to 1 milligray of low-let radiation, which is generally equivalent to 100 millirem. The corresponding value for males lifetime cancer incidence risk is 1 in 160.

weapons-related facilities). Among other things, a considerable tightening of drinking water standards for transuranic radionuclides is also in order.

12. **Publish a White Paper on risk-based radiation protection:** Current radiation protection standards are based on dose limits (or maximum concentrations derived from dose limits) rather than on risk. Their risk implications are quite varied, with lifetime risk being greater for females and annual risk being generally greater for children, especially female children. Even under the tightened standard proposed here, the lifetime risk to females if the maximum dose were received each year would be about 1 in 400. We recommend that the EPA publish a White Paper on risk-based or risk-informed radiation standards where both doses and risks are calculated on a gender- and age-specific basis and where the lifetime risk to a maximally exposed individual is kept much lower than that implied by the current single fuel cycle facility limit of 25 millirem per year. Specifically, the White Paper should include consideration of EPA guidelines that would keep combined lifetime risks to any and all exposed individuals from nuclear fuel cycle facilities (including DOE facilities and NRC-regulated facilities) to less than 1 in 10,000. Such guidelines could be in the nature of design goals such as those that the Nuclear Regulatory Commission now requires to keep radiation doses "As Low As Reasonably Achievable" (ALARA). A change in the risk framework from consideration of fatal cancers only to consideration of both cancer incidence and degree of malignancy[4] is also necessary and should be an integral part of the White Paper. The implications of using reference biological characteristics and cancer risk data for African-Americans and Hispanics should be examined. Finally, the effect of including non-cancer risks, including during the early periods of pregnancy, from internal and external exposure, should be included in the White Paper.

I. Introduction

This report provides a partial list of examples where "Reference Man" – a young, "Caucasian" male – is currently used in U.S. radiation protection standards or official guidance documents for radiation protection, such as Federal Guidance Reports 11 and 12 of the Environmental Protection Agency (EPA), as well as radiation-related regulations and compliance guidelines, such as those promulgated by the Nuclear Regulatory Commission and the Department of Energy. This report is mainly focused on regulations relating to the protection of the general public, though some aspects of worker protection are also covered. This report is a supplement to the more extensive report on radiation protection published by IEER in 2006.[5]

[4] The use of incidence data for public health protection might be rendered even more useful by parallel consideration of the degree of trauma to the afflicted individual, which is strongly dependent upon the type of malignancy. However, a simple model that is based on the treatability of the cancer and years of life lost is unsuitable, since it omits factors such as lifetime dependence on medication (as is the case in the aftermath of thyroid cancer treatment) and many quality of life factors. It would be useful to consider supplemental regulatory restraints on radionuclides such as plutonium and similar alpha emitters, which produce particularly serious cancers, notably lung and bone cancer, or tritium, which may produce non-cancer effects during pregnancy.

[5] See *Science for the Vulnerable: Setting Radiation and Multiple Exposure Environmental Health Standards to Protect Those Most at Risk*. (Makhijani, Smith, and Thorne 2006)

While it is generally recognized that all individuals are different, Reference Man was an attempt to provide a standard set of biological characteristics that could be used to systematize the calculations that are needed in radiation protection. The International Commission on Radiological Protection's *Report of the Task Group on Reference Man*, defined him as follows:

> Reference man is defined as being between 20-30 years of age, weighing 70 kg [154 pounds], is 170 cm [5 feet 7 inches] in height, and lives in a climate with an average temperature of from 10^{o} to 20^{o}C. He is a Caucasian and is a Western European or North American in habitat and custom.[6]

Evidently, this definition leaves out the vast majority of people, including substantial numbers of workers, from explicit consideration in radiation protection. The continued use of Reference Man is poor practice because it does not take into account the greater radiation doses received by some parts of the population that result from the same environmental conditions and the higher cancer risks per unit of dose that they face.[7] This especially applies to women (including pregnant women) and children. This report also discusses some of the implications of the findings of the report prepared by a 2006 National Academies' panel on the risks of low-level radiation, commonly called the BEIR VII report.[8]

Specifically, the BEIR VII report found that the overall fatal cancer risk experienced by females is 37.5 percent greater than that experienced by males for the same radiation exposure. This finding is in contrast to the estimates in the 1990 BEIR V report, where the overall cancer mortality risk to females was estimated at only five percent greater than that of males. The BEIR VII estimate for differential cancer *incidence* risk is even higher (52 percent higher for women than men).[9]

For children, the fatal cancer risk per unit of dose is higher than for adults. The BEIR VII panel estimated that the risk of developing cancer from exposure is about 3.7 times greater for an infant boy than the risk for a 30 year old adult male receiving the same dose and 4.5 times greater for an infant girl than the risk for an adult female. A female infant has about a seven times greater risk of getting cancer than a 30-year old male for the same radiation exposure.[10] It should be noted that even though Reference Man is taken to be an adult male in his twenties, the definition makes no mention of the possibility that a man may become a father and what that might mean in terms of the impacts on the framework of radiation protection regulations. It should also be noted that, while radiation dose to the gonads is calculated in the Reference Man framework to take account of

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[6] ICRP 23 p. 4

[7] The EPA has now officially stated that it "does not believe in continued use of Reference Man…." See Meyers 2008, which is reproduced in Attachment 2. See discussion below regarding the correspondence between Senator Barack Obama, Congressman Henry Waxman and the EPA. The Obama-Waxman letter to the EPA is reproduced in Attachment 1.

[8] NAS-NRC 2006

[9] NAS-NRC 2006 p. 15 and NAS-NRC 1990 p. 172-173

[10] NAS-NRC 2006 p. 311

possible hereditary effects, non-cancer reproductive effects are not part of the U.S. regulatory framework for radiation protection.

Reference Man is currently the basis of many federal regulations and compliance guidelines, including workplace radiation exposures, cleanup of radioactively contaminated sites, and some radionuclides in drinking water, notably alpha-radiation-emitting transuranic radionuclides. Some key examples of how Reference Man is used by three federal agencies – the Environmental Protection Agency, the Nuclear Regulatory Commission, and the Department of Energy – are provided here.

II. Environmental Protection Agency Radiation Protection Guidance and Regulations

Federal Guidance Reports (FGR)

a. FGR 12

The current guidance for external dose calculations is Federal Guidance Report 12 (FGR 12), published by the EPA in 1993. External radiation refers to situations where the source causing the radiation exposure is outside the body. Examples would include an x-ray machine or radionuclides present in soil that emit gamma radiation. As the quote below from FGR 12 shows, while there has been some effort to include the sex specific organs of women such as the uterus, Reference Man is the basis for the models used to determine radiation dose to the public:

> **Models of the human body**
>
> All organ doses in this report are calculated for an anthropomorphic model of the body derived by Cristy (Cristy and Eckerman, 1987) from ICRP Reference Man data (ICRP, 1975). The model represents an adult of stature 179 cm and mass of 73 kg. For all calculations, except water immersion, the phantom is upright at the air-ground interface. The phantom is a hermaphrodite of design similar to that used in the dosimetric evaluation of ICRP Publication 30 (ICRP, 1979) and is currently being used in the preparation of the various parts of ICRP Publication 56 (ICRP, 1990). ***Gender-specific models*** of adults have also been used in deriving external dose coefficients; e.g., ICRP Publication 51 (ICRP, 1987). However, most calculations of organ dose from the intake of radionuclides are based on the hermaphrodite phantom (ICRP, 1979, 1990).
>
> Organ doses for individuals of specific size and gender may be somewhat different from the values tabulated here. Gender- and age-specific aspects of external dose have been investigated by Drexler et al. (1989) and Petoussi et al. (1991); see also the discussion of organ dose coefficients for monoenergetic environmental photon sources in Section II. **The dose to organs of the body from external radiation increases with decreasing body size.** This effect is more pronounced at low photon energy, and for organs located near the middle of the body, which are shielded by overlying tissues. Petoussi et al. (1991) indicate that **organ doses for an infant may be about 40% higher than those in the adult male for both the ground plane source and submersion exposure at photon energies greater that 100 keV. Below 100 keV the difference may approach a factor of 3 for deeper organs such as the ovaries and colon.** [11]

[11] FGR 12 pp. 184-185 [emphasis added]

Note that FGR 12 calculates "[a]ll organ doses" using a hermaphroditic phantom[12] that is based on the Reference Man model. The weight, location of the organs, density of organs, and other features of this model are, with the exception of the female specific sex organs, those of a male that is slightly heavier than the Reference Man as defined in *Report of the Task Group on Reference Man* by the International Commission on Radiological Protection[13] (73 kilograms versus 70 kilograms) and also somewhat taller (179 cm versus 170 cm). Thus, while FGR 12 does include doses to the ovaries and breasts, the basic geometry of the body and the weight of the model is that of an adult male.

The model does not accurately represent female adult doses to many organs, since women are on average lighter than men. Generally, the lighter a person, the greater the dose from a given amount of external radiation to internal organs, all other things being equal, since there is less shielding of these organs by the rest of the body. Therefore, the same external radiation field would produce a greater dose in the internal organs of females. Moreover, the chemical composition of female bodies is different from that of men. For example, on average females have a greater proportion of their body weight as fat than men. Hence it is critical to have a model that is specific to females of various ages, if external doses to many organs are to be accurately estimated.

The problem is even greater in the case of children. The approach used in FGR 12 would generally underestimate doses experienced by children's organs, for instance, because their bodies are thinner and more radiation gets through the outer layers to reach the various organs. This is acknowledged in FGR 12, as is clear from the quote above. Further the chemical composition of children's bodies is substantially different, including that of radiosensitive organs. For instance, in the model that Cristy and Eckerman (1987) have proposed, the bone composition for infants is substantially different from that of adults.

The reference cited in FGR 12 (Cristy and Eckerman 1987) contains data on infants and children of various ages that could have been used to estimate external exposure doses to people of varying ages. But the EPA did not do so.

The problems of using a Reference Man approach (with a couple of female organs added into the model) are compounded by the facts that

- Children are at higher risk than adults of getting cancer from the same dose of radiation, and
- Females are at higher risk than males of getting cancer from the same dose of radiation.

It is clear that "gender-specific models" and data for children are available, but were not incorporated into FGR 12. Using a hermaphrodite model that is basically a grown man with

[12] A "phantom" is a mannequin constructed to compute radiation doses to various parts of the body under specified radiological conditions. For instance, dose to internal organs due to an external source of radiation can be computed in this way.
[13] ICRP 23 p. 4

female organs added on is not a suitable substitute for scientifically sound models for women and children (of various ages) in their own right.

b. Federal Guidance Reports 11 and 13

The current guidance generally used for *internal* dose calculations is Federal Guidance Report 11 (FGR 11), published by the EPA in 1988. While the later Federal Guidance Report 13 (FGR 13 and Suppl.) published in 1999 and updated in 2002, contains dose and risk factors for children, the dose conversion factors in FGR 11 – the numbers used to convert intakes of amounts of radionuclides to radiation dose (which is proportional to cancer risk) – are still the basis of most radiation protection in the U.S. It is therefore important to note that the dose conversion factors in FGR 11 are based on Reference Man:

> The purpose of the present Report is to set forth derived guides that are consistent with current Federal radiation protection guidance. They are intended to serve as the basis for regulations setting upper bounds on the inhalation and ingestion of, and submersion in, radioactive materials in the workplace. The Report also includes tables of exposure-to-dose conversion factors, for general use in assessing average individual committed doses in any population that is adequately characterized by Reference Man.[14]

The caveat that the dose conversion factors are applicable to "any population that is adequately characterized by Reference Man" has been widely ignored in practice, as will be clear from the discussion below.

The 2002 update to Federal Guidance Report 13 specifies dose conversion factors at various ages, although it continues to average the values for males and females. Hence it is possible to calculate the doses to infants and to children at various ages in order to determine whether the same environmental conditions, such as water or food contamination, produce a higher dose for adults or for children. However, it is not possible to use FGR 13 to determine if boys would receive a higher dose than girls or vice versa.

When FGR 13 is used to estimate the dose from internally deposited radionuclides for a specified set of environmental conditions, the segment of the population that gets the highest dose may or may not be children. For instance, the dose to the thyroid experienced by infants to due breathing air contaminated with iodine-131 will be about 11 times greater than that for an adult male, after taking into account the fact that infants breathe only about one third the amount of air per day on average as an adult male. But the ingestion dose from drinking water contaminated with iodine-129 will be greater for an adult. This is because the higher dose conversion factors for infants are outweighed by the higher water consumption of adults.

However, the *risk* to infants of developing cancer from the ingestion of iodine-129 will still be greater despite the lower radiation dose received, with the difference being greatest

[14] FGR 11 p. 1

between female infants and adult males. This is because radiation doses received in childhood are more likely to lead to cancer than the same dose received as an adult. In the case of the risk of thyroid cancer, for example, the risk to female infants drinking the same contaminated water as adult males is about 26 times greater, even after taking into account the fact that infants drink much less water on average than adults.[15]

c. *Clean Air Standards*

40 CFR 61, Subpart H specifies that the dose to the maximally exposed member of the public due to radionuclides released to the air shall not exceed 10 millirem per year.[16] An air dispersion model, called CAP-88, is generally used to estimate the doses. This model has been updated over the years. The most recent version of the model, which is used for compliance calculations, has been updated, but still recommends the use of adult dose conversion factors, despite the fact that the dose conversion factors for children are available:

> Dose and risk conversion factors include the effective dose equivalent calculated according to the methods in ICRP Publication Number 72. **Although FGR 13 contains age-dependent dose factors, CAP88-PC only uses the adult factors in order to retain consistency with previous versions**. The risk factors used are those for lifetime fatal cancer risk (mortality) per FGR 13.[17]

Hence, the EPA chose to maintain "consistency" rather than update the model to protect children. As for "adults," FGR 13 does not provide dose conversion factors for females but rather uses averages for men and women. Similarly, FGR 13 does not provide risk per unit dose for women, but averages the risk for men and women. The most immediate "previous" version of the internal dose guidance report was FGR 11, which is based on Reference Man and is discussed above.

As noted above, radiation doses to the internal organs of children from external sources will generally be greater for the same environmental conditions, while doses due to intakes (via inhalation or ingestion) may or may not be higher in children that adults. In this latter case, the result depends on the radionuclide, the intake pathway, and the types of activities that lead to the exposure.

III. Nuclear Regulatory Commission Radiation Protection Guidance and Standards

Reference Man is also in the regulations of the Nuclear Regulatory Commission that cover all its licensees, including all nuclear power plants and commercial fuel fabrication plants. NRC licensees are governed by regulations published in the Federal Register at 10 CFR 20.

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[15] Risk calculations as based on NAS-NRC 2006, summarized in Makhijani, Smith, and Thorne 2006 pp. 27 and 38. Intake and inhalation rates are from EPA 1997 p. 5-24 for air and p. 3-26 for water.
[16] See, specifically, 40 CFR 61.92 2007.
[17] CAP88-PC 2007 p. 65. [emphasis added]

Appendix B sets Annual Limits of Intake (ALIs) via the ingestion or inhalation routes and Derived Air Concentrations (DACs) for various radionuclides for workers, and also the maximum allowable concentrations for the general public.[18] The regulations for workers are based entirely on Reference Man, including the intakes that relate to cancer risk (called "stochastic" ALIs):

> The ALIs in this appendix are the annual intakes of a given radionuclide by "Reference Man" which would result in either: (1) a committed effective dose equivalent of 5 rems (stochastic ALI); or (2) a committed dose equivalent of 50 rems to an organ or tissue (non-stochastic ALI). The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep-dose equivalent to the whole body of 5 rems.[19]

Reference Man is still in use even though there are many women in the workforce of licensees regulated by the NRC. The only concession to the reality that there are women in the workforce is for pregnant women. When a woman declares her pregnancy to her employer, then the dose to the fetus must be restricted to 500 millirem for the duration of the pregnancy.[20] (See below for further discussion.)

The use of Reference Man also carries over to the regulations governing exposures of the general public, notably without regard to gender. A reduction in the air concentration limits by a factor of two from those applicable to adults only is made by the NRC in 10 CFR 20 for many radionuclides "to adjust the occupational values (derived for adults) so that they are applicable to other age groups."[21] As with occupational exposure, the regulations for the general public ignore females in the population, despite the fact that they are the majority.

The factor of two adjustment to account for the fact that the general population is exposed from childhood to adulthood does not include gender differences. Moreover, although the factor of two is sufficient adjustment for some radionuclides and routes of exposure, such as the ingestion of cesium-137, it is inadequate for others, especially for the heightened risks of exposure early in life. For instance, for a given level of intake, the thyroid dose due to inhalation of iodine-131 in the first five years of life is over five times greater than the dose received during the entire adult lifetime, defined as ages 18 to 70 years.[22]

For external dose where the person is submerged in an external radiation field, the NRC regulations even drop the factor of two for lifetime exposure:

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[18] The dose conversion factors implicit in the ALIs are close, but not identical, to those in EPA's guidance document FGR 11. The minor differences do not affect the analysis in this report.

[19] 10 CFR 20 2008 Appendix B or NUREG-1736 2001 p. B-1. The entire regulation as well as the associated guidance can be found in NUREG-1736. It is also worth noting that the ICRP has recommended lowering the maximum exposure for workers to two rem per year but this has not been adopted in the United States. See Makhijani, Smith, and Thorne 2006.

[20] NUREG-1736 2001 p. 3-64

[21] NUREG-1736 2001 p. B-3.

[22] Calculated from FGR 13 dose conversion factors in the 2002 CD Supplement, with linear interpolation between the ages of 1 and 5, 6 and 10, 11 and 15, and 15 and 18 years.

> For those radionuclides for which submersion (external dose) is limiting….an additional factor of 2 for age considerations is not warranted…."[23]

As noted above in the discussion of the EPA external dose guidance (FGR 12), this regulatory statement is not scientifically well founded. Due to the smaller weight of their bodies, the internal organs of children are less shielded from sources of external radiation than is the case for Reference Man. Therefore, the dose to internal organs of children submerged in a field of external radiation is larger than that to adults. Air submersion is relevant in many situations, as for instance in the case for air emissions of radionuclides such as radioactive noble gas isotopes of krypton and xenon.

The perverse effect of relying on Reference Man has long been evident. For instance, in the Connecticut Yankee decommissioning proceedings, the utility argued it was only required to consider Reference Man in its decommissioning plan. In summarizing the arguments of Connecticut Yankee, the Commission, referring to its regulations that establish radiation protection standards (10 CFR 20), noted:

> Although the plain language of the regulation does not restrict the terms "critical group," "individual," or "human being" to mean any specific age, race, or gender, CY [Connecticut Yankee Atomic Power Company] argues that the regulation incorporated the Environmental Protection Agency's "Reference Man" concept, which assumes a person is a white male, age 20-30. CY contends that the critical group at Haddam Neck should be composed of resident farmers, as CY described them in its License Termination Plan, and that the "average" member is therefore an average farmer. Doses to children are therefore irrelevant, it argues.[24]

The Commission eventually ruled that the Connecticut Yankee should consider doses to children, but that:

> If the evidence shows, as CY claims it will, that doses to children are lower than doses to adults, CY will prevail without the need for an appeal. But even if the evidence shows that doses to children are higher, CY will still have the opportunity after the [NRC's Atomic Safety and Licensing] Board's final decision to argue before the Commission that our regulations prohibit considering doses to children.[25]

The NRC's decommissioning guidance sets metabolic parameters either for Reference Man or "at the mean of the distribution for an *average human*."[26] The decommissioning guidance also states that

> The metabolic parameters were set at "***Standard*** Man" or at the mean of the distribution for an average ***man***."[27]

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[23] NUREG-1736 2001 p. B-3
[24] NRC 2001 p. 372 (footnotes omitted)
[25] NRC 2001 p. 374
[26] NUREG-1757 v.2 2006 p. H-5. [emphasis added]
[27] NUREG-1757 v.1 2006 Table B-2, footnote a (p. B-3). [emphasis added]

Evidently, the NRC uses the term "average human" and "average man" interchangeably, which is a lamentable confusion, with significant consequences for a majority of the U.S. population.

While the NRC uses Reference Man in its overall regulations specified in 10 CFR 20, it uses a different framework in evaluating the effect of the emissions from power plants. These emissions are supposed to be kept "as low as reasonably achievable" (ALARA). The design criteria for this are specified in federal regulations 10 CFR 50, Appendix I. The 1977 guidance for use by the NRC staff in evaluating nuclear power plant applications includes dose conversion factors for infants, four-year-olds, teenagers, and adults. In its guidance, the NRC specifies the evaluation of internal doses to the public in each of these age groups to ensure that the dose to the most exposed does not exceed ALARA guidelines.[28] In evaluating the design of reactors to meet the ALARA criteria, the NRC's guidance, in effect since the mid-1970s, specifies parameters that enable the calculation of internal radiation doses for exposed individuals of various ages, including infants.[29] However, external radiation doses were not estimated according to age in this guidance.

a. Pregnant women at work

As noted above, the exposure of fetuses is limited to 500 millirem when a woman in a radiological workplace declares her pregnancy. This standard is one tenth of the maximum allowable exposure to workers. The 500 millirem limit was set in the 1970s to provide the fetus with the same protection as was then given to the general public, once a woman declares her pregnancy, which is, in effect, a declaration of her intent to carry the pregnancy to term. However, the maximum allowable exposure for the general public was reduced from 500 millirem to 100 millirem per year in the late 1980s, while the limit for fetal exposure in the workplace has been left unchanged.[30] In view of the discussion above, it is clear that not only does the exposure limit need to be reduced to at least that of the general public, but rather, the fetal limit should be stricter. This is due to the following facts:

- In the latter stages of pregnancy, fetal exposure results in risks that are comparable to those of infants;
- In the early stages of pregnancy, there are risks of non-cancer effects that have not yet been adequately studied or quantified and are not yet considered in radiation protection regulations.[31]

Workplace practices generally try to avoid exposure to pregnant women, once they have declared their pregnancy. However, the current lax standard leaves room for exposure that is five times greater than that allowed for the general public. Furthermore, it does not address the issue of a woman who accumulates a radionuclide burden before she realizes

[28] NRC 1977
[29] NRC 1977
[30] This is discussed at greater length in Makhijani, Smith, and Thorne 2006 pp. 44-45.
[31] See Makhijani, Smith, and Thorne 2006 for further discussion of non-cancer effects in early stages of pregnancy, pp. 42-43.

that she is pregnant. That radionuclide burden will irradiate the fetus and may even be preferentially remobilized and relocated to fetal tissues.

IV. Department of Energy Radiation Protection Guidance and Regulations

Reference Man also makes an appearance in the DOE guidance for Radiation Protection of the Public and the Environment. The DOE does this by incorporating EPA's 1988 guidance FGR 11 into its regulations:

> Radionuclides taken into the body, generally by exposure modes whereby the radionuclide is ingested or inhaled, will continue to irradiate the body as long as they exist and are retained by the body. The dose delivered to a body over the lifetime of the individual from a single [intake of a radionuclide is the committed dose. Tables of] committed dose. conversion factors shall be used, as appropriate, and are presented in EPA-520/1-88-020, Federal Guidance Report No. 11, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," and in DOE/EH-0071, "Internal Dose Conversion Factors for Calculation of Dose to the Public." These conversion factors are based upon the ICRP reference man model, and the committed dose is the dose integrated over an interval of 50 years.[32]

The DOE does allow for exceptions to the use of Reference Man; however, the use of other models requires special permission and must be approved by DOE. The guidance allows parametric variation, such as location of the individual in relation to the radiation source, but does not include variation for gender or age.[33]

For external doses, the DOE guidance specifies using dose conversion factors for submersion from EPA's FGR 12, but also refers to a 1988 DOE document that considers a hermaphrodite model that is an improvement over the Reference Man model:

> In all calculations of photon dose-rate factors, the reference individual is assumed to be an adult hermaphrodite of mass 70 kg and height 174 cm in which the shape, location, and composition of most of the body organs are described by Snyder *et al.* The organs for which the model of Snyder *et al.* was modified for the calculations in this report include ovaries, uterus, breast, and red bone marrow. The dose-rate factors for ovaries and uterus are based on a body mass *(*58 kg) and height (163 cm) that are more appropriate for an adult female, as described by O'Brien and Sanna. Breast was not considered by Snyder *et al.*, and we have assumed that the photon dose-rate factor for breast is the average of the values for skin and lungs at all energies. The description of red bone marrow by Snyder *et al.* assumes that the skeleton is a homogeneous mixture of bone and bone marrow. This model has been modified, as described by Kerr, to take into account that red marrow is located in the trabecular bone cavities of the skeleton,

[32] DOE Order 5400.5 Chg 2 1993 pp. II-12 to II-13. The text in square brackets was supplied by DOE to IEER in an e-mail. (Traceski 2008) The original order was missing these words. See also FGR 11 and DOE 1988.
[33] DOE Order 5400.5 Chg 2 1993 pp. II-13 to II-14

> with the result that bone provides a significant amount of shielding of the red marrow for photon energies below about 0.2 MeV [see also Section 2.2.1 of ref. (l)].[34]

The use of a lower weight, 58 kilograms, and the locations of the ovaries and breasts, are more appropriate than in the EPA's model in FGR 12 discussed above. However, there is still not routine consideration of children in the DOE guidance.

V. Drinking Water Regulations

The EPA's safe drinking water regulations specify the goal for radiation protection, below which no unacceptable adverse effects are to be expected, as well as maximum dose or contaminant limits, depending on the radionuclide. The goal for all radionuclides is zero contamination, since all radiation doses, no matter how small, impose some cancer risk. Smaller doses impose proportionally lower cancer risk, according to the model used in the regulations and the BEIR VII report.

We focus here only on the standards for alpha-emitting radionuclides in water (other than radon and uranium which are regulated separately) for which the Maximum Contaminant Level is set at 15 picocuries per liter, with a sub-limit of 5 picocuries per liter for radium-226. These standards were set in 1976, and the guidance document in effect at the time, NBS Handbook 69, was published by the National Bureau of Standards in 1959, with an addendum in 1963.[35] The model for allowable contamination derived from NBS Handbook 69 uses an earlier version of Reference Man. NBS 69 states:

> The MPC [Maximum Permissible Concentration] values listed for continuous occupational exposure are convenient in obtaining permissible levels for special groups. The appropriate factors to be applied in obtaining permissible levels for these groups are discussed in the ICRP report [ICRP 1 and ICRP 2]. Because **the continuous exposure MPC values listed neglect several important considerations, particularly differences between children and adults**, it should be emphasized that, even when corrected by the above factors, these can only be regarded as interim values for nonoccupational exposure. It is hoped that the term *continuous occupational exposure values* will emphasize the **provisional nature of their use for other purposes.**
>
> Although the data on which the MPC values are based are very incomplete and in some cases uncertain, they embody the latest and best research of hundreds of scientists; and it is believed that these MPC values are the best now available. They should serve as a guide to indicate whether the operational procedures used in practice are adequate to insure that the dose delivered by internally-deposited radioactive material does not exceed the pertinent permissible limit set by NCRP [National Committee on Radiation Protection and Measurements].[36]

[34] DOE 1988 p. 8, which also refers to Kocher 1981 as "ref. (1)."
[35] NBS 69
[36] NBS 69 p. 3. [emphasis in italics in original, emphasis in bold added]

Though Table 1 of NBS Handbook 69 does mention ovaries[37] – see, for example, page 25 – it is clear that the reference to "adults" in NBS Handbook 69 is primarily to Reference Man, then called "standard man":

> **All calculations** are based on a "standard man" and thus do not provide for individual variations….This standard man is designed to represent a typical or average adult who is exposed occupationally.[38]

We have shown in a prior publication that the limit of 15 picocuries per liter for alpha-emitting radionuclides based on NBS 69 is about 100 times too lax when the most recent science is taken into account.[39]

VI. The Decommissioning Compliance Model

Reference Man is also built into the main computer program used by government and industry to assess risks from radioactivity remaining after remediation of radioactively contaminated sites and for projections of radiation doses from low-level waste disposal facilities. This model, called RESRAD, was developed and is maintained by DOE's Argonne National Laboratory.

In the 2007 version of RESRAD, dose conversion factors for children are included, but these new libraries are not required to be used. In fact, its default dose conversion factor library remains that from FGR 11, which is based on Reference Man.[40] This version of RESRAD is an improvement over prior ones, since one can now calculate doses to children using RESRAD which was not possible with previous versions of the program without modification by the user. However, insofar as the decommissioning regulations of the NRC are based on Reference Man – and they generally are, as discussed above -- the nuclear industry is still free to argue that children are not relevant to the regulations and guidance.

VII. Correspondence on Reference Man between Senator Barack Obama, Chairman Henry Waxman, and the EPA

On May 30, 2008, Senator Barack Obama and Congressman Henry Waxman, Chairman of the House Oversight and Government Reform Committee, sent a letter to Administrator Stephen L. Johnson of the EPA, inquiring about the use of Reference Man in EPA guidelines and standards and plans to phase out the use of the Reference Man model. This letter is reproduced in Attachment 1. Robert J. Meyers, Principal Deputy Assistant Administrator of the EPA's Office of Air and Radiation, responded to this letter on July 24, 2008. His response is reproduced in Attachment 2.

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[37] See NBS 69 p. 25, for example.
[38] NBS 69 p. 10 [emphasis added]
[39] Makhijani 2005
[40] The latest version, RESRAD 6.4, is available for download at http://web.ead.anl.gov/resrad/register2.

It its July 24, 2008, letter the EPA made a number of statements about Reference Man. The EPA described the current situation as regards Reference Man as follows:

> EPA regulations, guidance documents, and procedures issued prior to 1990 (prior to ICRP Publication 60) were based on Reference [Standard] Man….For some regulatory applications, numerical values to radionuclide-specific doses – as distinct from risks – are still taken from the adult worker dose conversion factors provided in Federal Guidance Reports 11 and 12. However, for many years, our calculations of risk and our regulatory actions and guidance for environmental exposures have factored in the varying age-sensitivity of the population.[41]

The EPA also made the following statement in the same letter:

> EPA does not believe in continued use of Reference Man, and generally stopped using it in 1990. EPA continues to update and improve its age- and gender-specific models in light of continuing research. EPA's radionuclide-specific cancer risk coefficients are used for calculating the excess cancer risk to the general population from chronic low level exposure to radionuclides in the environment. Our risk coefficients and regulatory actions are "conservative" in that they sum the risks from an entire lifetime exposure, taking into account age-dependent differences in intake, biokinetics, and sensitivity to radiation. Thus, our regulations are fully protective of the entire population, including infants and children.[42]

We applaud EPA's declaration that it "does not believe in continued use of Reference Man." An explicit statement along these lines is long overdue and it is a sign of great progress that it has been made. However, the latter part of the same sentence – that the EPA "generally stopped using it [Reference Man] in 1990" is not fully consistent with the first quote from the EPA letter.

The first quote admits that EPA continues to rely on Federal Guidance Reports 11 and 12, which are based on Reference Man, for "some regulatory applications." As we have shown, these applications are widespread, not only in the EPA but also in the NRC and DOE. In fact, there is no specific guidance that even enables a calculation of external doses to children. Children's external organ doses are estimated as if their bodies were as developed as those of Reference Man, which underestimates doses in many situations. The EPA also has not published guidance for calculating radionuclide-specific internal doses to women of any age for a given intake.

Even though EPA uses updated lifetime risks in its calculations, such calculations are not at issue in its regulations. EPA, NRC, and DOE regulations are NOT based on risk[43] but on radiation dose. If the guidance for calculating doses is based on Reference Man, then doses to women and children will be *systematically underestimated* in many situations, as we have discussed above.

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[41] Meyers 2008
[42] Meyers 2008
[43] In fact, the various radiation dose limits in radiation protection regulations imply risks that are quite inconsistent. See GAO 1994.

Further, even though the EPA has updated its guidance to the more recent Federal Guidance Report 13, which does include age-dependence, it continues to rely on Reference Man in at least one major regulatory application. This is in the regulations pursuant to the Clean Air Act of 1990, as discussed above.

Hence, it is clear that the EPA did not "generally stop" using Reference Man in 1990. Rather, the use of Reference Man continues to be pervasive. And even in the cases where Federal Guidance Report 13 is properly applied to estimating dose that includes age-dependence, the dose conversion factors for males and females continue to be averaged, as are the risk factors. We appreciate that the EPA has committed to review the gender-specific dose and risk situation in light of the publication of the BEIR VII report, as noted in their letter of July 24:

> At issue now is whether separate male and female risk coefficients should be published for the general population, given the approximate two-fold difference in risk per unit dose estimated in BEIR VII. EPA is now examining how best to account for this difference in future guidance and regulations. Any proposed changes in EPA's radiation risk assessment approach will be subjected to interagency review and public comment through the usual rulemaking and guidance development procedures.[44]

Despite this acknowledged "two-fold" difference in risk between males and females, the EPA's letter also claims "that the BEIR VII risk estimates do not differ dramatically from those currently in use by the EPA" and that "current standards and guidance are protective," This is misleading. Current standards are in terms of dose limits, which were largely set in the era of Reference Man. The fatal cancer risk implied by current standards[45] is all over the map, ranging from about 1 in 240 for the overall NRC dose limit of 100 millirem per year to the pathway specific limit of about 1 in 6,000 (rounded) for the 4 millirem per year drinking water limit for most beta and gamma emitting radionuclides that give a whole body dose. However, the fatal cancer risk to females is about 1 in 200 and that to males is considerably lower – about 1 in 300.

The situation is even more problematic when cancer incidence risk is taken into account. The best estimate for cancer incidence risk for women in BEIR VII is more than 60 percent higher than the EPA's estimate in Federal Guidance Report 13[46] which averages the risks for males and females. The lifetime cancer incidence risk for females, using the BEIR VII risk coefficients is about 1 in 100, if the annual dose limit of 100 millirem is maintained. This is very high; a significant tightening of radiation protection standards for the public is in order.

[44] Meyers 2008
[45] Averaged of male and female risks, using a fatal cancer risk coefficients in BEIR VII – see Table 12D-3, page 312.
[46] Meyers 2008, NAS-NRC 2006 p. 291, and FGR 13 p. 182

VIII. Conclusions and Recommendations

Conclusions

While there has been a modest amount of progress in incorporating some recent guidance that concerns women into radiation protection, we have shown in this report that the use of Reference Man in radiation protection regulations remains pervasive. Some guidance does incorporate the ovaries and breasts into the model, but, with the exception of DOE guidance, these organs are generally put into the weight and dimensions of an adult male when estimating exposure from external sources. In NRC guidance for design objectives for routine emissions from a reactor that are intended to keep radiation doses as low as reasonably achievable, internal doses to children have been considered since the mid-1970s. However, external doses are still calculated for parameters relating to adults. The following list on the use of Reference Man in radiation protection should be read with these caveats in mind:

1. NRC radiation protection regulations in the workplace and for the general public specified in 10 CFR 20 generally use Reference Man, with a minor and unsatisfactory adjustment for age in the case of some external exposure calculations.
2. EPA Federal Guidance Report 11, which is generally the basis of radiation protection compliance calculations, uses Reference Man.
3. EPA Federal Guidance Report 13 contains dose conversion factors for children, but in the case of Clean Air Act compliance model, children were specifically excluded from the compliance calculations, to maintain "consistency" with earlier compliance.
4. EPA guidance for external dose (FGR 12) relies on a version of the Reference Man concept.
5. DOE internal orders are generally based on Reference Man, with exceptions as discussed above. Special permission is needed to deviate from the approved compliance estimation methods.
6. The Maximum Contaminant Level for long-lived alpha-emitting radionuclides in national primary drinking water regulations is not only based on Reference Man but also on an obsolete National Bureau of Standards publications dating back to 1959 and 1963.
7. The default dose conversion factors built into the model used for decommissioning compliance calculations, RESRAD, use Reference Man. Even though the most recent version of the model enables dose calculations to children, these are not required for compliance calculations.
8. Fetal exposure is only taken into account in radiation controlled workplaces in those cases where a woman declares her pregnancy. The standards in effect are obsolete by a factor of five or more.

Overall, the use of Reference Man, a 20 to 30 year old "Caucasian" male, is pervasive in radiation protection guidance and compliance, but not uniformly so. Children have often

been ignored, even though the science to determine when they may get higher doses has long been available. Women are either partially included or not included at all.

The above considerations relate to how dose is calculated. It is also worth noting that the biokinetic models used do not necessarily represent gender- or age-specific differences. Often this is because adequate data are not available, but sometimes it arises because those models were developed at a time when the requirement for making such distinctions was not recognized. In addition to the above, current radiation protection standards were mostly set before the publication, in the last decade, of conclusions that women and children are generally at much greater risk of developing cancer than men from the same exposure. Hence, radiation protection standards are outdated in two ways that reinforce a lower level of protection for women and children:

- Radiation dose calculations done for proving compliance with regulations use dose conversion factors for Reference Man, with relatively minor adjustments in some cases. This underestimates radiation doses to children in most cases and to women in some cases for the same environmental conditions.
- Cancer risks from the same radiation dose are generally higher for children and women, though, for some specific cancers, men have a higher risk.

Female children are the most adversely affected in many situations. It is important to note in this context that the definition of Reference Man does not include his potential role as a father and thus no special care is taken to protect his reproductive capacity or to consider the effects on his children from his exposures prior to conception.

The failure to estimate doses to children and cancer risks to children when they are in excess of doses and risks received by adults would appear to be in violation of President Clinton's 1997 Executive Order on children, which was reaffirmed by President Bush, with some changes, in 2003:

> A growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks. These risks arise because: children's neurological, immunological, digestive, and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; children's size and weight may diminish their protection from standard safety features; and children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves. Therefore, to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:
> (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and
> (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks[47]

[47] Executive Order 1997 p. 19885

Recommendations

These recommendations complement those provided in the earlier IEER report on radiation protection, *Science for the Vulnerable*, published in 2006.[48]

1. **End the use of Reference Man**: The use of Reference Man in radiation protection regulations and guidance should be ended both for estimating dose conversion factors and for estimating cancer risk.

Children generally receive higher external doses of radiation to their internal organs from the same environmental conditions; they often also receive higher internal doses even when reduced intakes of food and water in early childhood relative to adults are taken into account. Women also receive higher doses of radiation than men in some cases for the same environmental conditions. Further, both women and children have a higher overall risk of developing cancer per unit of radiation dose. The continued use of Reference Man in radiation protection regulations and dose calculation guidelines has the effect of exposing children and women, and especially female children, to higher cancer risk, and in some cases far higher cancer risk than would be the case if regulatory limits were set using those most at risk as a basis and if guidelines for all exposure situations were both gender- and age-specific.

2. **Calculate compliance to the part of the population receiving the highest dose**: Compliance with annual maximum exposure limits should be calculated using dose conversion factors for the portion of the population that would receive the highest radiation dose for a given set of environmental conditions.

This change would mean that annual radiation doses for comparison with limits would often be calculated for infants or children, since they have the highest dose conversion factors for a given set of environmental conditions, though, in other cases, adults would remain the most exposed. Since compliance with radiation protection regulations is for members of the general public, it is essential that compliance be demonstrated with respect to those who would receive the highest doses from emissions from nuclear facilities and from residual radiation in cases of decommissioning or waste disposal. The use of the Reference Man approach is at often variance with the intent of regulations to protect all members of the general public. Compliance demonstration with respect to radiation protection would be affected in many cases, including:

- NRC's annual dose limits and maximum allowable environmental concentrations for the general public specified in10 CFR 20;
- EPA's limit of 25 millirem from nuclear fuel cycle operations (40 CFR 190);
- Safe drinking water regulations (40 CFR 141.66);
- Clean Air Act regulations, decommissioning regulations (40 CFR 61 Subpart H).

[48] Makhijani, Smith, and Thorne 2006. Some recommendations, such as replacing Reference Man, are repeated here.

Responding to comments from IEER and other members of the public about the undue risk to women and children of basing radiation protection standards on adult males, the Radiation Advisory Committee (RAC) of EPA's Science Advisory Board recommended in its January 2008 report that:

> "the EPA consider the concept described in ICRP Publication 89 as a Reference Family, because it contains reference information on persons at ages from newborns to adults and both genders; it also considers the results of studies of Asian reference populations."[49]

While the term "Reference Family" is not actually found in ICRP 89, the publication does contain data on biological characteristics for different ages and fetal development. So in effect the RAC has recommended that EPA include dose calculations for both sexes and for all ages. This should include implications for female children versus male children, since females are at greater risk, especially when they are young.

ICRP values need to be interpreted according to estimating doses to those who will get the highest dose for given environmental conditions and to those who are most at risk.

3. **Develop and publish dose conversion factors for females**: EPA's guidance report FGR 11 should be retired and replaced with an updated version of FGR 13. This update should publish separate tables showing dose conversion factors and cancer risks for males and females at various ages. At present, dose and risk values at various ages are reported only as averages for males and females.

4. **Develop and publish age and gender specific external dose conversion factors**: The EPA guidance report for external dose calculations, FGR 12, should be revised to include dose conversion factors at various ages for males and females.

5. **Develop and publish fetal dose conversion factors**: These factors should be developed and published for use in compliance calculations for cases of declared pregnancy.

Note that correct models need development for the early fetal development period for tritium and alpha-emitting radionuclides. The present ICRP recommendation that the dose to the uterine wall of the mother may be used is incorrect for these cases.[50] (See next recommendation.)

6. **Fill critical gaps in early fetal dose estimation methods and put protective standards into place until then**: ICRP Publication 88 assumption that the dose to the embryo/fetus in the first eight weeks of pregnancy is the same as that to the uterine wall[51] is not valid for alpha emitters and for low-energy beta radiation emitters, such as tritium. Consideration, therefore, needs to be given to tightening

[49] EPA RAC 2008 p. 26
[50] Makhijani, Smith, and Thorne 2006 pp. 73 and 85
[51] ICRP 88 p. 20

the maximum contaminant limits for tritium and alpha-emitters, until a satisfactory scientific framework can be put into place.

7. **Calculate risks for those most at risk**: Lifetime risk calculations should be based on those most at risk. In general, this means that lifetime risks would be calculated for females, unless risks for specific cancers to which men are more vulnerable are being evaluated.

8. **Revise the default parameters in the residual radioactivity computer program RESRAD:** The default dose conversion factors in RESRAD, the official computer program to calculate radiation doses from residual radioactivity, are set to Reference Man. RESRAD program should be modified so that the default calculations always refer to those who would get the highest dose and those who are highest risk from a given set of environmental conditions.

9. **Reduce maximum allowable fetal exposure in the workplace**: The maximum allowable fetal exposure in radiation-related workplaces (including Department of Energy facilities and those regulated by the NRC) in cases of declared pregnancy should be reduced from 500 millirem to 100 millirem, which is the level of maximum annual dose for the general population, using dose conversion factors for fetal exposure. Such a reduction is about two decades overdue. This maximum dose limit should be automatically reduced when dose limits to members of the public are reduced.

10. **Publish reference characteristics for populations not adequately covered**: The EPA should examine and publish reference biological characteristics for sections of the U.S. population not adequately covered in ICRP Publication 89, including African Americans and Hispanics.

African Americans have higher rates of cancer that Whites. According to the American Cancer Society:

> African Americans are more likely to develop and die from cancer than any other racial or ethnic group. The death rate for cancer among African American males is about 37% higher than among white males; for African American females, it is about 17% higher.[52]

Current radiation protection literature does not shed light on whether there is a difference in radiation-related risk for African American males and/or females at various ages. In view of the generally higher cancer incidence and mortality among African Americans, the topic of their potential vulnerability to radiation in relative terms should receive special attention as radiation protection moves away from the "Caucasian" Reference Man paradigm. This matter should be assessed in the White Paper. A further matter that might be included in the White paper is the diversity of approaches in different agencies of the government. A

[52] ACS 2008 p. 43. Hispanics generally have lower rates than Whites, except for certain infection related cancers.

harmonized approach to radiation protection needs to be developed across the various branches of federal government.

11. **Reduce maximum allowable exposure to 25 millirem per year from 100 millirem per year**: The EPA is currently considering how the conclusions of BEIR VII should be incorporated in its regulatory framework. We do not agree with the EPA's position that "current standards and guidance are protective" even in light of BEIR VII.[53] For instance, the present radiation protection standard of 100 millirem per year in 10 CFR 20 (issued by the Nuclear Regulatory Commission) is inadequate and obsolete, especially in light of the BEIR VII report's conclusions. According to BEIR VII risk values, females have a lifetime risk of one in a hundred of getting cancer at this level of annual exposure.[54] And this excludes the cancer risks during fetal exposure. This is unacceptably high. We recommend that the NRC should revise 10 CFR 20 to reduce it to 25 millirem per year, which is currently the EPA standard for the maximum dose from a single nuclear fuel cycle facility. The DOE should similarly modify DOE Order 5400.5 to reduce the maximum dose to the public from 100 millirem per year to 25 millirem per year. The EPA should also revise its standard for a single fuel cycle facility to make provision for tightening the dose limit from single facilities in cases where the public is exposed to more than one nuclear fuel cycle source (including any nuclear weapons-related facilities). Among other things, a considerable tightening of drinking water standards for transuranic radionuclides is also in order.

12. **Publish a White Paper on risk-based radiation protection:** Current radiation protection standards are based on dose limits (or maximum concentrations derived from dose limits) rather than on risk. Their risk implications are quite varied, with lifetime risk being greater for females and annual risk being generally greater for children, especially female children. Even under the tightened standard proposed here, the lifetime risk to females if the maximum dose were received each year would be about 1 in 400. We recommend that the EPA publish a White Paper on risk-based or risk-informed radiation standards where both doses and risks are calculated on a gender- and age-specific basis and where the lifetime risk to a maximally exposed individual is kept much lower than that implied by the current single fuel cycle facility limit of 25 millirem per year. Specifically, the White Paper should include consideration of EPA guidelines that would keep combined lifetime risks to any and all exposed individuals from nuclear fuel cycle facilities (including DOE facilities and NRC-regulated facilities) to less than 1 in 10,000. Such guidelines could be in the nature of design goals such as those that the Nuclear Regulatory Commission now requires to keep radiation doses "As Low As Reasonably Achievable" (ALARA). A change in the risk framework from consideration of fatal cancers only to consideration of both cancer incidence and

[53] Meyers 2008. See Attachment 2.

[54] Based on NAS-NRC 2006, Table 12D-3, which provides the lifetime cancer incidence and mortality values for populations of males and females exposed annually to 1 milligray of low-let radiation, which is generally equivalent to 100 millirem. The corresponding value for lifetime cancer incidence risk for males is 1 in 160.

degree of malignancy[55] is also necessary and should be an integral part of the White Paper. The implications of using reference biological characteristics and cancer risk data for African-Americans and Hispanics should be examined. Finally, the effect of including non-cancer risks, including during the early periods of pregnancy, from internal and external exposure, should be included in the White Paper.

[55] The use of incidence data for public health protection might be rendered even more useful by parallel consideration of the degree of trauma to the afflicted individual, which is strongly dependent upon the type of malignancy. However, a simple model that is based on the treatability of the cancer and years of life lost is unsuitable, since it omits factors such as lifetime dependence on medication (as is the case in the aftermath of thyroid cancer treatment) and many quality of life factors. It would be useful to consider supplemental regulatory restraints on radionuclides such as plutonium and similar alpha emitters, which produce particularly serious cancers, notably lung and bone cancer, or tritium, which may produce non-cancer effects during pregnancy.

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Attachment 1

Letter from

Senator Barack Obama and Representative Henry A. Waxman

to

Stephen L. Johnson
Administrator, U.S. Environmental Protection Agency

May 30, 2008.

BARACK OBAMA
ILLINOIS

COMMITTEES:
HEALTH, EDUCATION, LABOR AND PENSIONS
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
FOREIGN RELATIONS
VETERANS' AFFAIRS

United States Senate

WASHINGTON, DC 20510

May 30, 2008

The Honorable Stephen L. Johnson
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW, Room 3426 ARN
Washington, DC 20460

Dear Administrator Johnson:

We are writing to inquire about the continued use by the Environmental Protection Agency of the so-called "Reference Man standard," a benchmark for radiation exposure in humans. The Reference Man is used to evaluate the risks of developing cancer from a given level of radiation.

According to the *Report of the Task Group on Reference Man* (1975), issued by the International Commission on Radiological Protection, the "Reference Man standard" refers to the effects of radiation exposure on a male "between 20-30 years of age, weighing 70 kilograms [154 pounds], who is 170 centimeters [5 feet, 7 inches] in height, and lives in a climate with an average temperature of from 10 degrees to 20 degrees Celsius [50 to 68 degrees Fahrenheit]. He is a Caucasian and is a Western European or North American in habitat and custom."

Recently, the National Academies of Sciences issued its updated report on the effects of low-levels of radiation on humans, the Biological Effects of Ionizing Radiation Report (BEIR VII). This report concludes that females have a considerably higher risk of cancer compared to males exposed to the same levels of radiation, and that children have a higher risk of cancer compared to adults exposed to the same levels of radiation.

On January 31, 2008, the Radiation Advisory Committee of the EPA Science Advisory Board reported to you on their review of EPA's response to the National Academies' report. Among other things, the Science Advisory Board recommended that EPA consider the applying the concept of a "Reference Family," described by the International Commission on Radiological Protection, which would be more inclusive than present approaches.

It is our understanding that the "Reference Man standard" continues to form the basis for many EPA regulations and guidance documents governing radiation exposure to humans. These include EPA's Federal Guidance Report No. 11, which addresses occupational exposures to radiation, and Federal Guidance Report No. 12, which addresses exposure to external radiation from contaminated soil. We are interested in receiving information on the EPA standards, guidance, and procedures that explicitly or implicitly use the Reference Man standard.

Specifically, please provide the following information.

1. Identify and briefly describe the existing regulations, guidance documents, and any analytical procedures that were explicitly or implicitly based on the Reference Man standard.

WASHINGTON OFFICE
713 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
OFFICE (202) 224-2854
FAX (202) 228-4260

CHICAGO OFFICE
230 S. DEARBORN
SUITE 3900
CHICAGO, IL 60604
OFFICE (312) 886-3506
FAX (312) 886-3514

SPRINGFIELD OFFICE
607 EAST ADAMS
SUITE 1520
SPRINGFIELD, IL 62701
OFFICE (217) 492-5089
FAX (217) 492-5099

MARION OFFICE
701 NORTH COURT STREET
MARION, IL 62959
OFFICE (618) 997-2402
FAX (618) 997-2850

MOLINE OFFICE
1911 52ND AVENUE
MOLINE, IL 61265
OFFICE (309) 736-1217
FAX (309) 736-1233

2. Identify and briefly describe any ongoing rulemaking actions or work to develop new or updated guidance where EPA is explicitly or implicitly relying on the Reference Man standard.

3. Explain whether EPA believes the continued use of the Reference Man benchmark in existing or ongoing regulations and guidance is scientifically valid in light of the most recent findings of the National Academy of Sciences regarding the higher risks for women and children from radiation exposure.

4. Explain whether EPA agrees with the Science Advisory Board that the "Reference Family" would be a more representative approach. If yes, please explain how and when EPA plans to update its existing guidance and regulations to incorporate this approach. If no, please explain why not.

Please provide this information by June 30, 2008. Thank you for your attention to this request.

Sincerely,

Barack Obama
United States Senator

Henry A. Waxman
Chairman, House Oversight and
Government Reform Committee

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Attachment 2

Letter from Robert J. Meyers
Principal Deputy Assistant Administrator
Office of Air and Radiation, U.S. Environmental Protection Agency

to

Senator Barack Obama

July 24, 2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 24 2008

OFFICE OF
AIR AND RADIATION

The Honorable Barack Obama
United States Senate
Washington, D.C. 20510

Dear Senator Obama:

Thank you for your letter of May 30, 2008, co-signed by Chairman Henry Waxman, in which you were inquiring about the U.S. Environmental Protection Agency's (EPA) use of the Reference Man standard. I appreciate your interest in this issue.

EPA is at the forefront of incorporating age- and gender-specific differences in our risk-based radiation protection guidance and regulations. Many of the older dose-based worker protection regulations and guidance documents written when Reference Man was the state of the science are now under consideration for updating. As described in our responses below, more recent guidance and regulations already incorporate the age-specific risk differences implied in the term, "Reference Family."

Your letter refers to both the National Academy of Sciences (NAS) 2007 report on the Biological Effects of Ionizing Radiation (BEIR VII) and the International Commission on Radiological Protection's (ICRP) Publication 89 that supplements Reference Man with more detailed age- and gender-specific data. EPA was a major sponsor of BEIR VII and also supported the scientific work at Oak Ridge National Laboratory that provides part of the underpinnings of ICRP Publication 89. As your letter notes, we requested that EPA's Science Advisory Board (SAB) review our proposed approach for incorporating BEIR VII recommendations in the upcoming revision of our radionuclide cancer risk coefficients. Taking into consideration the SAB's interim advice, we are submitting a final draft document, detailing our methodology, later this summer.

Radiation protection regulation in the United States is based on extensive scientific data on radiation-induced cancer in humans, including studies of atomic bomb survivors, and of individuals irradiated medically or occupationally. It is an acknowledgement of the mature state of the science of radiation protection that we now are able to consider age, gender, and organ differences when we recommend limits on human exposure to radiation. Among known and suspected human carcinogens, this degree of refinement in cancer risk assessment is exceptional. Nevertheless, EPA agrees that the best available science needs to be considered when developing regulations and guidance. With this information as background, we are providing the following answers to your specific questions.

1. Identify and briefly describe the existing regulations, guidance documents, and any analytical procedures that were explicitly or implicitly based on the Reference Man standard.

EPA regulations, guidance documents, and procedures issued prior to 1990 (prior to ICRP Publication 60) were based on Reference [Standard] Man, i.e. the healthy young adult male occupationally exposed to radiation. For some regulatory applications, numerical values for radionuclide-specific doses – as distinct from risks – are still taken from the adult worker dose conversion factors provided in Federal Guidance Reports 11 and 12. However, for many years, our calculations of risk and our regulatory actions and guidance for environmental exposures have factored in the varying age-sensitivity of the population.

2. Identify and briefly describe any ongoing rulemaking actions or work to develop new or updated guidance where EPA is explicitly or implicitly relying on the Reference Man standard.

There are no ongoing rulemaking actions or work to develop new guidance relying on the Reference Man standard. Pursuant to the recent (February 2008) release of new general recommendations from ICRP in Publication 103, EPA is having discussions with the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC) on how best and at what pace to update existing guidance based on Reference Man. The Interagency Steering Committee on Radiation Standards (ISCORS), co-chaired by EPA and NRC, has selected this topic as the main area for discussion at its fall public meeting.

3. Explain whether EPA believes the continued use of the Reference Man benchmark in existing or ongoing regulations and guidance is scientifically valid in light of the most recent findings of the National Academy of Sciences regarding the higher risks for women and children from radiation exposure.

EPA does not believe in continued use of Reference Man, and generally stopped using it in 1990. EPA continues to update and improve its age- and gender- specific models in light of continuing research. EPA's radionuclide-specific cancer risk coefficients are used for calculating the excess cancer risk to the general population from chronic low level exposure to radionuclides in the environment. Our risk coefficients and regulatory actions are "conservative" in that they sum the risks from an entire lifetime exposure, taking into account age-dependent differences in intake, biokinetics, and sensitivity to radiation. Thus, our regulations are fully protective of the entire population, including infants and children. For assessing risk to a specific age group exposed to a relatively large dose of radiation (e.g., in the case of a nuclear accident) an age-specific assessment is justified and EPA has published the tools for performing such an assessment.

At issue now is whether separate male and female risk coefficients should be published for the general population, given the approximate two-fold difference in risk per unit dose estimated in BEIR VII. EPA is now examining how best to account for this difference in future guidance and regulations. Any proposed changes in EPA's radiation risk assessment approach will be subjected to interagency review and public comment through the usual rulemaking and guidance development procedures.

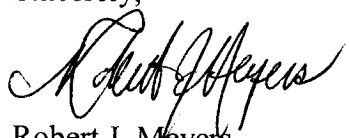
4. Explain whether EPA agrees with the Science Advisory Board that the "Reference Family" would be a more representative approach. If yes, please explain how and when EPA plans to update its existing guidance and regulations to incorporate this approach. If no, please explain why not.

The term "Reference Family" is subject to various interpretations and has not been adopted by ICRP. EPA risk models are already being used for calculating risks to reference individuals, and are organ, gender, and age-specific. Summary risk coefficients are tabulated in Federal Guidance Report 13 for a lifetime exposure to any given radionuclide. Since 1990, EPA has been using this methodology as a basis for developing radiation protection regulations and guidance. These EPA guidance documents use the new ICRP models, particularly ICRP Publication 72, which model dose for six specific age groups. The current EPA dose and risk models calculate dose and risk from birth to age 120 years. These estimates are used in Federal Guidance Report 13 (Cancer Risk Coefficients for Environmental Exposure to Radionuclides; September, 1999), the Radionuclides in Drinking Water Rule (2000), CAP88 version 3.0 (a program for determining compliance with air emission standards under the Clean Air Act), and in the proposed revision to EPA's Protective Action Guides for Nuclear Incidents. Once the proposed changes in EPA's radiation-induced cancer risk models have been reviewed by the SAB and finalized, risks from radionuclide exposures will be recalculated. At that point, EPA will reexamine the need to revise its regulations and guidance for radiation protection.

Finally, we would note that the BEIR VII risk estimates do not differ dramatically from those currently in use by EPA. Therefore, we believe that current standards and guidance are protective.

Again, thank you for your letter. If you have further questions, please contact me or your staff may call Josh Lewis, in EPA's Office of Congressional and Intergovernmental Relations, at 202-564-2095.

Sincerely,



Robert J. Meyers
Principal Deputy Assistant Administrator