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IEER Comments on the U.S. Environmental Protection Agency's Environmental Radiation Protection Standards for Nuclear Power Operations— Advance Notice of Proposed Rulemaking (ANPR) (40 CFR Part 190; Docket ID No. EPA-HQ-OAR-2013-0689)[1]

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These are initial comments of the Institute for Energy and Environmental Research (IEER) on EPA-HQ-OAR-2013-0689, the Advance Notice of Proposed Rulemaking (ANPR) for a revision of 40 CFR 190. They are organized according to the questions that the EPA raised in the ANPR. Additional comments are provided after the responses to the various questions. Each section starts with the EPA's description of the issue, followed by the EPA's questions. IEER's responses follow each question.

"A. **Issue 1: Consideration of a Risk Limit to Protect Individuals.** Should the Agency express its limits for the purpose of this regulation in terms of radiation risk or radiation dose?"

EPA question:

a. *Should the Agency express its limit for the purpose of this regulation in terms of radiation risk or radiation dose?*

IEER prefers a dose-based approach based on *organ doses alone*. If a risk based approach is adopted, it should limit lifetime cancer incidence risk to at most 1 in 10,000. While both approaches would limit harm to public health, it is important not to mix them up in the regulation. The regulation must be internally consistent and based either on annual dose or on lifetime risk.

For a dose-based rule, we recommend very specific language that should be adopted to replace the language at 40 CFR 190.10(a) in the present rule. A dose-based rule should have the following features:

1. *Organ dose focus:* The committed equivalent internal dose to any organ due to intake of radionuclides from all pathways in any year combined plus the external dose to that

[1] EPA ANPR 2014

organ in that year should meet the limits specified in the modified 40 CFR 190.10(a), specified below in IEER's recommended text. Note that we *explicitly reject the proposed exclusion of organ dose limits* from the rule. In fact, *we recommend organ dose limits only*. The basis for this is discussed below under Issue 2, Question a. The EPA should update dose conversion factors to those published in the EPA's Federal Guidance Report 13, Compact Disk Supplement.[2] They are the most current factors; FGR 13 specifies dose conversion factors by age.

2. *Drinking water limits*: The concentrations of radionuclides, including from private wells or non-public water sources that are near facilities covered by 40 CFR 190, should not exceed the limits (including organ dose limits) set forth in or implicit in the EPA drinking water rule at 40 CFR 141.66. These concentrations should be complied with at the boundary of the regulated facility and at all points beyond it. While regulation of onsite operations is the purview of the NRC, the EPA should provide the NRC with guidance to the effect that a limitation of onsite groundwater and surface water contamination to drinking water limits would be the best way to ensure protection of offsite water resources and compliance with the new rule as proposed in these comments.
3. *Most exposed member of the public*: The limitation of annual organ dose limits to "any member of the public" should be interpreted to include all people, male and female, of all ages. Therefore the annual dose limits should be applied to the most exposed member of the public. Currently, FGR 13 dose conversion factors are averages of male and female values. The EPA should disaggregate the averages and publish dose conversion factors for males and females of all ages. The revised rule should require that sex-specific and age-specific dose conversion factors automatically become part of the rule when they are published.

The EPA should also begin a process for estimating doses to the embryo/fetus in the first trimester of pregnancy and especially during the first eight weeks of pregnancy for weak-beta-emitters like tritium and carbon-14 that cross the placenta. It is unacceptable that environmental rules still do not take account of the potential harm to the embryo/fetus from the operation of regulated facilities. This needs to be remedied expeditiously.

If a risk-based rule is specified, it should respect all of the following caveats:

- The lifetime cancer incidence risk for the member of the public who is most at risk (generally a female) is not increased from the lifetime risk implicit in the present rule as a result of the revision of the rule.
- The lifetime incidence cancer risk for the member of the public most at risk (generally a female) is at most 1 in 10,000, strictly interpreted.[3]
- Cancer risk is for incidence and not mortality.
- Risks other than cancer are taken into account especially during the first trimester.

[2] FGR 13 CD Suppl. (2002)

[3] At present, the agency as well as states often interpret the CERCLA limit of lifetime cancer risk of 10^{-4} as several times 10^{-4}, for instance 2×10^{-4} or even greater. This is an unacceptable interpretation of CERCLA rules that should not, on any account, be carried over into 40 CFR 190.

We note that if the rule is risk-based, a lifetime risk of at most 1 in 10,000 (assuming a 70-year lifetime) would correspond to an annual external plus committed effective dose of at most 1 millirem per year to any member of the public.

b. *Should the Agency base any risk standard on cancer morbidity or cancer mortality? What would be the advantages or disadvantages of each?*

A risk standard should be based on morbidity, which is the risk created by the operation of the licensed facility. Cancer mortality depends, in addition, on the state of medical technology at any time. Medical technology changes over time. A change in mortality rates of particular types of cancer has nothing to do with the licensee. For instance, if cancer mortality increased due to a drug or procedure being mistakenly licensed, would the licensee be required to tighten their operations? It makes no sense to allow licensees to emit larger amounts of pollutants because medical technology improvements result in declines in mortality. A specification of a risk standard based on mortality offends both common sense and practical enforcement considerations.

c. *How might implementation of a risk limit be carried out? How might a risk standard affect other federal regulations and guidance?*

The EPA would have to specify maximum concentrations for each radionuclide (and the ratio rule for combinations) so as to limit the risk to the specified value for the member of the public (as defined by IEER below) most at risk for that radionuclide. Risk from external exposure, for instance due to immersion in a radioactive cloud or from ground shine, would have to be added to risk from internal exposure.

"B. **Issue 2: Updated Dose Methodology (Dosimetry).** How should the Agency update the radiation dosimetry methodology incorporated in the standard?"

a. *If a dose standard is desired, how should the Agency take account of updated scientific information and methods related to radiation dose—such as the concept of committed effective dose?*

For a dose standard, the EPA should update its methodology by adopting the organ dose conversion factors in FGR 13, focusing on total organ dose (internal equivalent dose committed due to intake in one year plus external dose to the same organ in that year), reducing the maximum annual thyroid dose, eliminating the radon dose exception, and rejecting the use of effective dose. In other words, the EPA should refocus 40 CFR 190.10(a) on organ dose alone. **On no account should committed effective dose be used as a rationale for eliminating organ dose limits from the rule**. The EPA's proposal to go to a committed effective dose limit to the exclusion of organ doses is based on specious arguments that would, moreover, result in an egregious relaxation of permissible emissions, discharges, and contaminant limits.

We note that while the ICRP has updated its methodology for organ dose calculations, it has not done away with them. Indeed, organ dose calculations are the foundation of committed effective dose. This is evident in the very definition of effective dose provided in the ANPR ("Effective dose…is the weighted sum of the equivalent doses to individual organs of the body."[4]) Organ doses must first be calculated before effective dose can be calculated; they remain the most fundamental quantity in estimating internal dose.

The calculation of effective dose from organ doses requires the interposition of "weighting factors" whose crude nature and even arbitrariness is evidenced, among other things, by the fact that they have changed greatly in several ways since ICRP 60 was published in 1991. Table 1 shows the weighting factors in ICRP 60 published in 1991 and in ICRP 103 published in 2007.

Table 1: Organ or Tissue weighting factors in ICRP 60 (1991) and ICRP 103 (2007)

Organ or Tissue	**ICRP 60**	**ICRP 103**
Gonads	0.20	0.08
Bone marrow (red)	0.12	0.12
Colon	0.12	0.12
Lung	0.12	0.12
Stomach	0.12	0.12
Bladder	0.05	0.04
Breast	0.05	0.12
Liver	0.05	0.04
Oesophagus	0.05	0.04
Thyroid	0.05	0.04
Skin	0.01	0.01
Bone surface	0.01	0.01
Brain	N/A	0.01
Salivary glands	N/A	0.01
Remainder (Notes 1 and 2)	0.05	0.12

Source: ICRP 60 (1991) p. 8 and ICRP 103 (2007) p. 65. "N/A" means" not applicable."
Notes: 1. Remainder in ICRP 60: adrenals, brain, upper large intestine, small intestine, kidney, muscle, pancreas, spleen, thymus, and uterus.
2. Remainder in ICRP 103: adrenals, extrathoracic (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (males), small intestine, spleen, thymus, uterus/cervix (females).

Note the large differences in the weighting factors for gonads (down by 60 percent in ICRP 103), breast (up by 140 percent in ICRP 103) and the "remainder" (up by 140 percent in ICRP 103). The list of radiosensitive organs that had individual weighting factors is longer in ICPR 103; the list of organs in the "remainder" also increased in ICRP 103. For instance the lymphatic nodes were not included in weighting factors at all in ICRP 60. *Indeed, seven new organs appeared in ICRP 103 that were not mentioned at all in ICRP 60*: salivary glands, the ET region, gall

[4] EPA ANPR 2014 p. 6510

bladder, heart, lymphatic nodes, oral mucosa, and prostate (males). *One was eliminated*: upper large intestine, which, in ICRP 60 was part of the "remainder" in addition to the colon being listed as a separate organ.

The averaging of male and female gonads (testes and ovaries, respectively) also does not make sense in the context of the rule of protecting the most exposed member of the public. It is also highly prejudicial to women and to future generations. Specifically, primary oocytes are formed in utero; females are typically born with a million or more of them. Sperm, in contrast, are continuously created. Moreover, the contribution of the ovum to a person is far greater than that of the sperm; for one thing, all mitochondria, which are the foundation of the human energy system, come from the ova. In contrast, radiation damage to an embryo arising from damaged sperm would typically occur due to exposure in the weeks just before conception; moreover sperm contribute no mitochondria.

Similarly, averaging the male and female breast makes no sense from the point of view of a rule seeking to protect all members of the public to a standard that is equal to or better than that of the most exposed member of the public. Female breast cancer is 100 times more common than the male breast cancer.[5] The risk factors for breast cancer incidence in BEIR VII show the female breast to be a highly radiosensitive organ of all; the male breast cancer risk was low enough that it was lumped together with the remainder of the cancers not explicitly listed. Female infants have a risk of 0.117 cancers per sievert for breast cancer alone. This risk is about the same as the lifetime average for all cancers (male and female average risk). In contrast, the prostate cancer risk for male infants is more than ten times lower – 0.0093 cancers per sievert. A weighting factor that averages male and female breasts therefore is highly stacked against females, especially female children who are highly vulnerable to breast cancer risk compared to almost all other cancers except non-fatal skin cancers, for which male infants have the greatest radiosensitivity, according to the EPA. [6]

It is clear that sex averaging of weighting factors is unjustified for a dose-based rule that seeks to protect "any member of the public."

Averaging organ weighting factors by age also makes no sense in a regulatory context in which the aim is to limit dose to the most exposed member of the public, who will often be a child. Children's organs are still developing; for some organs that process extends through puberty. Averaging them with adult organ weighting factors is scientifically unacceptable in a dose-based standard.

Including females and males of all ages must be a basic aim of updating the rule, given that we now know that children face much higher risks per unit of dose, get higher doses per unit of radioactivity intake and often get higher doses per unit of environmental contamination than adults even when higher intakes by adults are taken into account. Further, the cancer risk per

[5] American Cancer Society 2014

[6] NAS/NRC 2006 Table 12-D1 (p. 311); units converted to risk per sievert. The EPA estimates female breast cancer incidence risk as 0.126 cancers per Sv (EPA 2011 Table 3-12b (p. 54)). It is the most radiosensitive cancer of all excluding non-fatal skin cancers, for which male infants have the greatest radiosensitivity at 0.172 cancers per Sv (EPA 2011 Table 3-12a and Table 3-12b (p. 54)).

unit of exposure faced by females is now estimated to be much higher overall and much higher for most cancers than that faced by males. This is dramatically different than the risks estimated in the 1990 BEIR V report, when females were estimated to face a cancer mortality risk only about five percent more than males.[7]

The EPA's argument that organ dose should be eliminated because the ICRP 2 approach was based on an obsolete "critical organ" approach is specious. Organ dose is still fundamental to internal dosimetry. There is nothing obsolete about this approach. Moreover, current science continues to show that many radionuclides target specific organs like the thyroid or bone surface. This means that limiting organ doses is the most protective way to limit harm to public health.

The organ dose approach is entirely modern; as noted, organ doses are the basis for effective dose estimates. The method of calculating organ doses has changed. The new method of calculation should be adopted. That is the proper way to update the rule to reflect recent scientific understanding. For internal dose this will mean limiting the committed equivalent organ dose due to intake in one year to any member of the public to a specified limit.

As further evidence of the current validity of organ dose, we note that U.S. government is implementing a large compensation program for current and former nuclear weapons complex workers stricken with cancer likely caused by radiation exposure at work based entirely on organ dose calculations. Internal doses to a specific target organ (relevant for a particular cancer) from a multiple radionuclides are calculated; external organ doses are added to them. Effective doses are not involved in compensation decisions.

The ICRP itself has explained that effective dose, while convenient for regulatory purposes and for estimating risk to the public on some aggregated basis, is not intended for individual protection:

> Effective dose is an *indicator for stochastic risk* but it is *not intended for the assessment of risks of individuals*.[8]

The reason is that there are "uncertainties in the low-dose range, underlying approximations, simplifications, sex and age - averaging)."[9] While the uncertainties and the degree of arbitrariness in weighting factors and the variable grouping of organs under the rubric of "remainder" of the body is not explicitly mentioned in this quote, any reasonable understanding of current dose estimation methods and of cancer induction

[7] The BEIR V report estimates are at NAS-NRC 1990 (1996 printing) Table 4-2 (pp. 172-173). As examples of the risks in the BEIR VII report, the cancer incidence risk faced by a 30 year old female for all cancers is 55 percent more than males; at an age of five years, the female risk is 86 percent greater than males (percentages calculated from NAS-NRC 2006 Table 12D-1 (p. 311)). BEIR V did not provide cancer risks by age. EPA 2011 cancer incidence risks are generally higher than those in NAS-NRC 2006; the female-male risk ratios are still high but a little lower than the BEIR VII ratios (44 percent and 71 percent respectively in EPA 2011 – see Table 3-12a and Table 3-12b (p. 54)).

[8] Menzel 2011 Slide 20, italics added

[9] Menzel 2011 Slide 20

points to organ doses as the most fundamental quantity in radiation dosimetry and the protection of public health if a dose-based standard is used.

ICRP 103 explains that the weighting factors are averages over populations so not apply to particular individuals:

> They represent mean values for humans *averaged over both sexes and all ages* and thus do not relate to the characteristics of particular individuals.[10]

But 40 CFR 190 is fundamentally about the limitation of *individual* dose. By limiting the dose to "any member of the public" to a specified value, the rule ensures that all members of the public are protected to the same or higher levels than the most exposed member of the public (that is, to a level of dose or risk that is lower than the most exposed member of the public). *This goal is substantially compromised when average weighting factors are used. It is utterly compromised when male and female weighting factors for all age groups are averaged as is the case with present weighting factors in both ICRP 60 and ICRP 103.* This is because current understanding of radiation risk shows that females and children face substantially higher risk for most cancers than adult males for the same radiation dose. Children also generally get higher committed equivalent organ doses than adults per unit of radioactivity inhaled or ingested.[11] *These understandings of the higher risk faced by females and children and the higher doses experienced by children represent the most fundamental updating of the science that needs to be reflected in the revised rule. Committed effective dose does not do that job.*

The goal of a dose-based rule is to protect all members of the public by limiting annual dose to the most exposed member of the public. The EPA rule must therefore be essentially and inherently oriented to that individual; this allows all of society to be protected. It is essential to have annual dose limits for the most exposed *individual* member of the public. The term "any member of the public" inherently includes all people, males and females, of all ages. This must be made explicit in the revised rule.

It would be unacceptable and unscientific to drop organ doses; it is all the more egregious that the EPA is proposing to do so on the grounds of modernizing and updating the science. As I have pointed out more than once, both to the EPA and the NRC, we still have organs. Organ doses are still calculated in the most up-to-date science, though somewhat differently than before. The present science still shows that many radionuclides preferentially target certain organs, as a simple fact of human biology. *Organ doses are the most fundamental quantities in modern radiation dose estimation.* It is the weighting factors that are used to calculate effective dose that add a large element of uncertainty and even arbitrariness to the process. As they currently stand, they also obliterate essential differences between males and females and between children and adults.

[10] ICRP 103 (2007) p. 68, italics added
[11] FGR 13 CD Suppl. (2002)

Effective dose may be convenient for regulators and licensees because it enables them to roll everything into a single number. But regulation is not for the convenience of licensees and regulators. It is for the protection of the public.

For a dose-based standard, modernizing and updating the science points in the direction of dropping effective dose and limiting the rule to organ doses, including internal doses from combinations of radionuclides added to the external dose. It is also relevant in this context to note that whole bodies do not get cancer (though, once contracted, it can spread throughout the body). Cancer initially affects a particular organ or system. Even circulatory and lymphatic system cancers have target organs, like the bone marrow and lymph nodes.

In sum, for a dose-based standard, the most reliable current science points in the direction of focusing 40 CFR 190.10(a) on organ dose alone and rejecting committed effective dose.

Finally, it is important to note that dropping organ doses from the rule in favor of effective dose alone would substantially relax the implicit permissible concentrations of all radionuclides that preferentially target certain organs. Examples include all actinides and strontium-90, which target the bone surface, and radioactive isotopes of iodine which target the thyroid. This was pointed out in a study commissioned by the EPA itself as long ago as 1997.[12] It would be completely unacceptable to relax radiation protection under the guise of modernizing and updating the science, especially when recent science, including the risks published by the EPA in 2011,[13] has concluded that the cancer risks of radiation are far greater than those estimated when 40 CFR 190 was first promulgated.

In light of the above, we recommend that 40 CFR 190.10(a) be revised to read:

> 190.10 Standards for normal operations
> "Operations covered by this subpart shall be conducted in such a manner so as to ensure that:
>
> a. The total annual internal and external dose to any organ of any member of the public as the result of exposures to planned discharges of radioactive materials to the general environment from uranium fuel cycle operations and to radiation from these operations does not exceed 25 millirem, with annual internal dose being defined as committed equivalent dose to any organ due to intakes of radionuclides in one year; all pathways are included in the estimation of dose, including the drinking water pathway from all sources of drinking water affected by the said operations; and drinking water concentrations specified in or implicit in 40 CFR 141.66 are not exceeded in surface water or groundwater at any point on or beyond the site boundary due to operations of the facility."

[12] SC&A 1997
[13] EPA 2011

We have reduced the allowable dose to the thyroid from 75 millirem per year in the existing rule to 25 millirem per year. The BEIR VII risk assessment for thyroid cancer shows that 75 millirem per year to the thyroid of female children from infancy to five years of age would by itself produce a thyroid cancer risk of about 2 in 10,000.[14] Exposures after that would further increase the risk. The new assessment of this disease and of sex differences in risk requires a lowering of the allowable thyroid organ dose to 25 millirem per year at most.

Note that the doses from all sources of drinking water must be included. Given the widespread contamination of groundwater created by nuclear power reactors and other licensed facilities, also noted in the ANPR,[15] protection of water that may be used for drinking is an essential addition to the rule. We appreciate that in light of such contamination, the ANPR has deemed it "prudent to re-examine its [the EPA's] initial assumption in 1977 that the water pathway is not a pathway of concern."[16] The best way to ensure that licensee operations remain within the drinking water rule is for the rule to require that maximum contaminant levels at or beyond the site boundary in groundwater or surface water should be those specified in or implicit in 40 CFR 141.66. One way to ensure this level of protection of offsite water resources to the drinking water standard would be for the NRC to require onsite groundwater and surface water to drinking water limits. EPA guidance for the rule should recommend such a course to the NRC.

Currently, explicit calculations are not required for doses from tritium emitted via the stacks that may contaminate private wells, for instance. These would be included under the new 40 CFR 190.10(a) as framed above. The exclusion of private wells and other non-public drinking water sources from the purview of 40 CFR 141.66 was meant to protect small communities and individual families from the burdens of complying with federal regulations. This was a reasonable thing in the context of protecting small water systems and individual well owners from a federal mandate that may have required onerous expenditures in some cases. But the exclusion has also meant that NRC licensees have had a free pass to pollute the drinking water of their neighbors without so much as a by-your-leave or a requirement that the pollution be monitored or that licensees provide private parties and small water systems with the resources to monitor their water supplies should they wish to do so. Moreover, special attention needs to be paid to tritium and carbon-14 emissions from nuclear reactors in order to protect pregnant women.

Even Milton Friedman, an eminent apostle of the free market and limited government, noted that the freedom of individuals should be limited in a variety of ways. Among other things he noted that "one man's freedom to murder his neighbor must be sacrificed to preserve the freedom of the other man to live." He noted this in the context of determining the "appropriate activities of

[14] Calculated from NAS-NRC 2006 Table 12D-1 (p. 311). EPA 2011 estimates thyroid cancer risks to be somewhat lower at 1.4 in 10,000 (calculated from EPA 2011, Table 3-12b). In any case, even with the lower thyroid cancer risks in EPA 2011, the life risks from thyroid cancer alone at 75 millirem per year would exceed 3 in 10,000 were exposure at 75 millirem per year permitted. This clearly points to a lowering of the annual thyroid exposure limit by at least a factor of three, which is the recommendation in these comments.

[15] EPA ANPR 2014, p. 52

[16] EPA ANPR 2014, p. 53

government." In the same general context, he also opined that they should not be free to pollute the water flowing through their property because that action "in effect forc[es] others to exchange good water for bad" involuntarily: that is, an exchange when people are in situations where "it is not feasible for them, acting individually, to avoid the exchange or to enforce appropriate compensation."[17] This precisely describes the situation in which neighbors of NRC licensees find themselves. It is therefore the responsibility of the EPA, even in a minimalist interpretation of the appropriate role of government, to prevent that enforced exchange of good water for bad.

As noted above, the structure of the drinking water rule was originally meant to protect individuals and small water systems from possible large expenditures of a federal mandate. This was reasonable enough; but the same structure has, all too often, allowed corporate polluters to force their neighbors to involuntarily exchange good water for bad. It is time to plug this hole in the drinking water rule. The free pass that the EPA and the NRC have given to licensees to pollute their neighbors' water supplies must be revoked. The above recommended text for 40 CFR 190.10(a) does that.

Note also that we have dropped the current rule's exclusion of radon from the dose limits. Radon is a primary pollutant in certain parts of the uranium fuel cycle (notably mining and milling operations). It targets the lung. There is no reasonable basis for its exclusion. Quite the contrary, its exclusion has allowed severe environmental injustices by exempting widespread radon-emitting contamination in uranium mining and milling operations, to the detriment of large numbers of people, notably Native Americans. Environmental justice was not an explicit regulatory consideration when 40 CFR 190 was promulgated. Eliminating the radon exception is essential for compliance with environmental justice rules and goals. It is also necessary to provide equal protection to those who may live near mining and milling facilities as compared to those who live near other facilities, such as reactors.

Finally, we have changed the phrase "provide reasonable assurance that" in the preamble of 40 CFR 190.10 to "ensure that." The phrase "reasonable assurance" creates a vague and potentially large loophole by providing ample room to escape strict compliance and to allow measurements that are far short of complete and rigorous. The measurement basis for enforcement of 40 CFR 190.10(a) today is mediocre at best and has serious gaps. For instance, no measurements of carbon-14 releases are made. The phrase "ensure that" implies rigorous, verifiable measurements and estimates that would result in a demonstrable compliance with the rule.

b. *In updating the dose standard, should the methodology in ICRP 60 or ICRP 103 be adopted, or should implementation allow some flexibility? What are the relative advantages or disadvantages of not specifying which ICRP method be used for the dose assessment?*

EPA should use ICRP 60 for now, since the dosimetry associated with ICRP 103 is still under development. FGR 13 and the associated dose conversion factors are sound enough for updating

[17] Friedman 1962 Chapter 2, on web at http://books.cat-v.org/economics/capitalism-and-freedom/chapter_02

the rule. The rule should specify that once dose conversion factors are updated, the new factors would automatically be used after a simple Federal Register notice. As noted, it is important for the EPA to publish sex-specific dose conversion factors for all ages and to make provision for automatic inclusion of those dose conversion factors when they are published.

"C. **Issue 3: Radionuclide Release Limits.** The Agency has established individual limits for release of specific radionuclides of concern. Based on a concept known as collective dose, these standards limit the total discharge of these radionuclides to the environment. The Agency is seeking input on: Should the Agency retain the radionuclide release limits in an updated rule and, if so, what should the Agency use as the basis for any release limits?"

a. Should the Agency retain the concept of radionuclide-specific release limits to prevent the environmental build-up of long-lived radionuclides? What should be the basis of these limits?

40 CFR 190.10(b) relates mainly to reprocessing plants. Changes to it can be considered if a reprocessing plant application appears imminent. This is a remote possibility at the present time. Among other things the NRC does not have regulations governing such plants. Changes to 40 CFR 190.10(b) are therefore very premature.

b. Is it justifiable to apply limits on an industry-wide basis and, if so, can this be reasonably implemented? Would facility limits be more practicable?

See answer to Issue 3 a., above.

c. *If release limits are used, are the radionuclides for which limits have been established in the existing standard still appropriate and, if not, which ones should be added or subtracted?*

See answer to Issue 3 a., above.

"D. **Issue 4: Water Resource Protection.** How should a revised rule protect water resources?"

a. If a ground water protection standard is established in the general environment outside the boundaries of nuclear fuel cycle facilities, what should the basis be and how should it be implemented?

The groundwater standard should align with the drinking water rule at 40 CFR 141.66. The assumption should be that offsite groundwater would be used for drinking. Therefore, the drinking water maximum contaminant levels that are explicit or implicit in 40 CFR 141.66 should be applied at the site boundary and all points beyond to both surface and groundwater. See also answer to Issue 2, Question a., above. The EPA should provide guidance to the NRC to similarly limit water contamination onsite to the same maximum values. This would ensure protection of offsite water supplies.

b. Are additional standards aimed at limiting surface water contamination needed?

Additional standards are likely to be needed, especially to protect the embryo/fetus in the early stages of pregnancy from non-cancer effects. The science to do so is still not well developed and the EPA needs to embark on the process of doing so with some urgency. Specifically, far better calculation methods due exposure to alpha-emitters and to weak beta emitters (notably tritium and carbon-14) than are available at present are needed to estimate doses to the embryo/fetus in the first eight weeks after fertilization. These are important for estimating non-cancer effects like early failed pregnancies (also known as "chemical pregnancies") and malformations. Exposure of pregnant women to tritium, carbon-14, to alpha emitters like uranium-238 and uranium-234, and to the decay products of entrained and dissolved gases discharged into surface waters and emitted to the air needs to be estimated. A section of the rule should be reserved for future tightening of the standard to protect the embryo/fetus in the first trimester and especially in the first trimester and, within that, the first eight weeks of pregnancy.

"E. **Issue 5: Spent Nuclear Fuel and High- Level Radioactive Waste Storage.** How, if at all, should a revised rule explicitly address storage of spent nuclear fuel and high-level radioactive waste?"

a. How, if at all, should a revised rule explicitly address on-site storage operations for spent nuclear fuel?

It would be useful to the process of high-level waste and spent fuel management if 40 CFR 190.10(a) revised as above were extended to storage and disposal facilities for high-level waste and spent fuel. In other words, the same dose limits (including limitation of doses via the drinking water pathway) should apply to high-level waste and spent fuel storage and disposal as applies to uranium fuel cycle to operations. There is no moral basis for protecting the present generation, that benefits from nuclear electricity or medical and research applications of nuclear technology, better than future generations who may find better ways for doing the same things and who may have no need of nuclear fission technology and the radioactive waste and radiation risks it produces.

b. Is it necessary to clarify the applicability of 40 CFR part 190 versus 40 CFR part 191 to storage operations? Should the Agency clarify the scope of 40 CFR part 190 to also cover operations at separate facilities (off-site) dedicated to storage of spent nuclear fuel (i.e., should we clarify the definition of the ''nuclear fuel cycle'' to include all management of spent nuclear fuel up until the point of transportation to a permanent disposal site)?

40 CFR 191 should be limited to the Waste Isolation Pilot Plant. It should not be extended to high-level waste or spent fuel disposal or storage. 40 CFR 190 should be applied to high-level waste and spent fuel storage and disposal provided it is revised as recommended in these comments. If not, storage and disposal of high-level waste and spent fuel should be left out of the revision of 40 CFR 190 and considered separately on their own merits.

"F. **Issue 6: New Nuclear Technologies.** What new technologies and practices have developed since 40 CFR part 190 was issued, and how should any revised rule address these advances and changes?"

"The Agency is seeking input on the following aspects regarding this issue:"

a. *Are there specific new technologies or practices with unique characteristics that would dictate the need for separate or different limits and do these differences merit a reconsideration of the technical basis for 40 CFR part 190?*

There is no need to speculate about new nuclear technologies that are qualitatively unlike those that are covered at present.

b. *Should the Agency develop standards that will proactively apply to new nuclear technologies developed in the future, and if so, how far into the future should the Agency look (near-term, mid-term, etc.)?*

See answer to a., just above.

c. *In particular, do small modular reactors pose unique environmental concerns that warrant separate standards within 40 CFR part 190?*

Small modular reactors will fit into 40 CFR 190 as recommended above. No special provision or dispensation is required for them.

"G. **Other Possible Issues for Comment**

If revised, the Radiation Protection Standards for Nuclear Power Operations may also address any number of issues identified during the public comment period. We will consider the comments submitted in response to this ANPR as we consider revision of the existing standards."

IEER believes that three additional issues should be addressed in the revised rule.

1. Definition of "member of the public"

There is no definition of the term "member of the public" in the ANPR. It appears therefore that the EPA intends to continue with the definition in the present 40 CFR 190, which states:

> Member of the public means any individual that can receive a radiation dose in the general environment, whether he may or may not also be exposed to radiation in an occupation associated with a nuclear fuel cycle. However, an individual is not considered a member of the public during any period in which he is engaged in carrying out any operation which is part of a nuclear fuel cycle.[18]

[18] 40 CFR 190.02 (2013)

We appreciate that the ANPR has put the issue of Reference Man on the table for public comment.[19] But the ANPR makes no commitments to actually retire Reference Man or to end the mixing of lifetime risk with annual dose limits in ways that are unscientific and prejudicial to females and to children.

The conclusions of science since the late 1990s (including the EPA's Federal Guidance Report 13 (FGR 13), the BEIR VII report of the National Academies (NAS-NRC 2006)) and EPA's own review in 2011 (EPA 2011) show that children and females are more vulnerable to radiation; therefore, an explicit inclusion of females and children in the definition of the term "member of the public" is needed.

In the case of a dose-based standard, children often get higher doses than an age-averaged or Reference Man-based calculation even when differences in intakes are taken into account. We recognize that there may be certain situations in which the most exposed person may be an adult male due to greater inhalation or ingestion rates. But these cases can all be covered by a suitable definition.

A risk-based rule that protects an average of males and females would necessarily harm females more than the maximum allowable risk. This would be unacceptable.

In light of the above, an updating of the science necessarily involves an explicit inclusion of females and children in the definition of the term "member of the public" is needed whether the EPA chooses a dose-based or risk-based approach to the revision. As noted at the start of these comments, it is essential not to mix up these two approaches in the regulation and to have a rule that is internally coherent and consistent in its approach to protection of the public.

We recommend the following revised definition of the term be included in the "Definitions" section of the rule:

> Member of the public: A male or female of any age affected by the operations of a facility covered by this rule except during a period when he or she is carrying out any operation which is part of a nuclear fuel cycle.

If the rule is based on risk, then risk should be calculated for the individual most at risk from emissions and discharges from the facility. As the ANPR notes, a risk basis for the rule will have to be translated into measurable quantities, such as concentrations of radionuclides in air, water, and food, in any case:

> If a standard were developed in the form of a risk level that was not to be exceeded, then any meaningful discussion on implementation would need to address how the risk would be translated into measurable quantities such as an effluent release rate into the environment, a concentration in environmental

[19] EPA ANPR 2014 p. 37.

> media, an *intake by an individual* or external radiation exposure at specific locations or to *specific persons*.[20]

It would not provide equal protection if the enforcement of the risk limit averaged risks to males and females with the full knowledge that the best available science has concluded that the risk to females is considerably higher than for males. Averaging would mean that males would always have a risk below the specified regulatory limit, but that that limit would be exceeded for females if the male-female average approached or equaled the regulatory risk limit. Averaging risk would institutionalize inherently unequal protection. Specifically it would allow females to face higher lifetime risks than the maximum risk specified in the rule, because that maximum would apply to the average of male and female lifetime risks.

If the regulation is based on annual dose limits, then the limit must apply to most the exposed person, of any age, including infants and children. FGR 13 should be specified as the guidance in the rule since it provides age-specific dose conversion factors. As noted above, the EPA should publish dose conversion factors that are sex-specific (in addition to being age-specific). The rule should specify that they would automatically be applied when they are published.

Age-averaging also violates the Executive Order on Children, E.O. 13045. The relevant paragraph from the Executive Order on Children (E.O. 13045), which requires special attention to children specifically because they are at greater risk, is as follows:

> 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.[21]

We note that the ANPR has sought to dismiss the concerns about explicitly limiting annual doses to children on the ground that the rule is aimed a lifetime "protection":

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[20] EPA ANPR 2014 p. 6515, italics added

[21] E.O. 13045 (1997) Section 1. President George W. Bush extended this Executive Order. Other parts of it were amended by Bush's E.O. 13296 (2003).

> We note that, while the current standard is presented as an annual dose, it is established at a level that provides protection for an individual over a lifetime (i.e., at all ages).[22]

While the above sentence does not explicitly use the term "risk," there is no other sensible or scientifically meaningful interpretation of the term "protection" in this context. The EPA is mixing and matching different approaches to regulation in an unacceptable and unscientific way. What the above paragraph means in practice is that the doses to children are allowed to be much higher because doses later in life would be lower, since dose conversion factors for the same radionuclide intake decline with age. Indeed, in many cases, the children get a considerably higher dose even when the lower intakes of food or water by children are taken into account.

Moreover, it is illogical and contrary to the facts to assume that everyone lives to some average age. Some die young, and some in middle age, and some live to very old age. Suppose that a person gets a relatively high dose as a child and incurs a high risk in the first few years of life and gets cancer early. In such a case, an assumption of a 70 or 80-year lifetime to set a dose limit is patently unfair; it institutionalizes inequality. A dose-based rule must apply to the most exposed individual, male or female, whatever age they may be.

A rule that claims to limit lifetime risk and then specifies an annual dose limit clearly fails to provide equal protection to children, and especially to female children who generally incur a higher risk compared to male children of the same age. It is an unscientific mix and match approach. The EPA should either consistently apply a risk-based approach (at most 1 in 10,000 lifetime risk) or a dose-based approach as specified above. *It is only reasonable to assume a long lifetime in the context of a rule that would limit lifetime risk. Dose limits must be applied for every year of operation of the facility to the most exposed member of the public, according to the definition we recommend above.*

We note that the ANPR says nothing about external dose in regard to the exposure of children. The current EPA reference publication in this regard is FGR 12, which is based on Reference Man. This is unsatisfactory and also not in conformity with E.O. 13045. For instance, children, being shorter, have organs closer to the ground. Their internal organs are also less shielded by fat and muscle than those of adults. Ground shine and immersion in air or water contaminated with gamma emitting radionuclides would generally produce higher doses in children than in adults. It is therefore essential to develop and publish external dose conversion factors for children. This is in addition to the need for publishing internal dose conversion factors for males and females; this would complement the risk factors by age and sex that have already been published in the BEIR VII report.

In sum, it essential to explicitly define member of the public to explicitly include males and females of all ages independently of whether the EPA chooses a dose-based or risk based approach to the rule.

[22] EPA ANPR 2014 p. 6517

2. Measurements

The measurement basis for evaluating compliance of nuclear reactors with this rule is at present mediocre at best and, in some respects, poor. For instance, no measurements are required for carbon-14 emissions (either in water or to the air) or of entrained and dissolved radioactive noble gases that then decay into strontium and cesium isotopes. Tritium measurements in rainwater or in offsite private wells are not required, even though every reactor emits some tritiated water vapor that comes down as rain.

We recognize that enforcement is the purview of the NRC. But ensuring that the rule is written so as to be enforceable is the responsibility of the EPA. The EPA must specifically write in language that requires measurements of all radionuclides discharged to the water, onsite and offsite (since onsite groundwater can be expected to migrate offsite) and emitted to the air. This must include measurements of tritium and carbon-14 emissions to the air and their concentrations in rainwater. It must also include measurements of dissolved and entrained noble gases. These measurements must either be continuous or demonstrated to be representative enough to enable reliable and independently verifiable dose calculations. There must also be a requirement for independent verification of measurements, including a guidance indicating the need for a certain number of independent NRC field measurements.

3. Carbon-14 and tritium

The ANPR notes that tritium and carbon-14 "were not included [in the existing rule] because appropriate control technologies were either not feasible or unavailable"[23] This is an unacceptable reason for omitting these two radionuclides, which are both emitted by nuclear power reactors. Moreover, they cross the placenta and could cause damage other than cancer during the early weeks of pregnancy. The absence of carbon-14 data was noted by a National Academies panel in its report on the feasibility of epidemiological studies of cancer near nuclear power plants.[24] The rule must explicitly require measurements of tritium and carbon-14 emissions via stacks, discharges to surface water, concentrations in offsite wells, including private wells (if the owners give permission), and in rainwater.

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