June 22, 2014 Comments of Beyond Nuclear on Nuclear Regulatory Commission (NRC) 10 CFR Part 20 [NRC-2009-0279] RIN 3150-AJ29 Radiation Protection Advanced Notice of Proposed Rulemaking on development of a draft regulatory basis. Federal Register Notice/Vol.79 No. 143: 43284-43300 7/25/14

NRC is considering rewriting its radiation exposure regulations. Prenatal and childhood life stages are known to be particularly vulnerable to damage from radiation exposure with prenatal life stages being uniquely vulnerable. However, documents on which NRC might base new radiation exposure regulations have been difficult or impossible for members of the public to obtain. Without provision of these documents, public comment is not as robust as it could be.

Pregnant women, developing embryos and growing children have special vulnerabilities including predilection for certain types of radionuclides, particularly ones that mimic chemicals used to form constituents of growth and aid metabolism. Additionally, little research exists on realistic, chronic, very low dose exposure impacts on pre-implantation, the developing human embryo and developing fetus. Models that only represent radiation damage to organs, the whole body, or even groups of cells may not fully represent the extent of damage to the individual cells that are required for healthy in utero development. *Intrauterine programming*, a recently discovered phenomenon that is just now being researched, offers insight into the vulnerability of the in-utero life stages that can impact the wellness and viability of not only those life stages, but also subsequent adult wellness and viability as well.* Much about this phenomenon is not yet discovered, but this uncertainty should not be used as an excuse to expose humans to undetermined damage from radiation during the most vulnerable stages of life.

Pregnancy begins before conception;[1] therefore women of childbearing years should be treated as potentially pregnant before being aware of a pregnancy. And since a female fetus develops all the eggs she will ever have while she is in utero, protecting pregnancy from radiation is protecting not just the child of the pregnant woman, but her grandchildren as well.

* DNA damage and epigenetic changes in the embryo can manifest permanent structural and functional changes and can lead to other diseases later in child or adult life stages, i.e. diabetes, cardiovascular disease, and premature aging.

The in utero life stage can have disproportionate vulnerabilities to certain radionuclides.[2] Among these are radioactive carbon (C-14) and tritium (radioactive hydrogen isotope). † Each of these can collect in fetal tissue to twice the concentration in maternal tissue. This concentration factor serves as an additional risk to the sensitivity of this life stage. Further, there is indication that the type of radiation given off by these isotopes—a beta particle—could have more impact than is currently assumed. Children and adolescents exposed to radioactive iodine (iodine-131), and who did not receive a protective measure of potassium iodine within a few hours of exposure, were found to have more aggressive forms of cancer.[3]

Radionuclides inside a developing embryo, or the developing placenta surrounding it, could do unique and tremendous damage during this life stage. Induction of cancer is only one disease endpoint. While young children are sensitive to radiation compared to adult life stages—ICRP recognizes that they can be more sensitive—the beginning stages of life (embryonic and fetal) which are unique in structure and development, can at some stages be many times more sensitive than even young children, due to phenomena like intra-uterine programming and organ creation.

Any regulatory changes should protect for these life stages; further, Federal agencies are compelled to make this protection a high priority by Executive Order.

President Clinton's Executive Order 13045 of April 21, 1997 is still in force. The *Protection of Children From Environmental Health Risks and Safety Risks* states "...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."

Aligning NRC's exposure regulations with ICRP 103 would essentially leave out protection of pregnancy life stages. In fact, NRC seems to assume that ICRP 103 goes *beyond* providing adequate protection. However, for embryonic and fetal

† Sr-90 also collects more during periods of growth: Frequently asked questions: Strontium 90. Delaware Health Services. January 2012

development it does no such thing because ICRP fails to specifically account for some unique vulnerability that occurs during this developmental life stage.

NRC states that the goal of this proposed rule-making is "to achieve greater alignment between the NRC's radiation protection regulations and the 2007 recommendations of the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103 (2007)…" and to "establish standards of protection for both members of the public and occupational workers from ionizing radiation resulting from activities conducted under licenses issued by the NRC." NRC notes "The Commission also directed the NRC staff to continue discussions with stakeholders regarding dose limits for … the embryo/fetus."

"Notably, the Commission agreed with both the NRC staff and the NRC's Advisory Committee on Reactor Safeguards (ACRS) that 'the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment.' In this regard, the Commission stated that from 'a safety regulation perspective, ICRP Publication103 (2007) proposes measures that go beyond what is needed to provide for adequate protection.'"

Unfortunately, neither ICRP's large body of multi-decadal radiation exposure recommendations, nor NRC's use of them, offer adequate protection for pregnancy or pre-natal life stages, which can be uniquely sensitive to damage from radiation. NRC's definition of a "general" population does not to include these life stages: "A general population includes individuals of both genders and various age groups that range from newborns to senior citizens."

ICRP assumes "that life-time cancer risk following in-utero exposure will be similar to that following irradiation in early childhood,"[4] and relies on doses to the maternal uterus to assess dose to the embryo (which ICRP defines as up to 8 weeks from conception)[5]. The heart, spinal cord and brain, major blood vessels and the beginning of bones and muscles, are in process of forming from single cells, meaning that assessing damage from radiation during this sensitive development presents unique challenges under circumstances not yet understood. This life stage deserves protection none-the-less.

ICRP does not assess damage to the placenta, a temporary but, immensely important structure that performs organ-like functions during pregnancy. The placenta supplies oxygen and nutrition to the embryo/fetus and removes metabolic products. The placenta provides a limited barrier against some toxins and drugs and is active endocrinologically to support the ongoing pregnancy.[6] "...Radiation affect[s] fetal growth not only by damaging fetal cells but also by impairing placental development and function by the induction of apoptosis and cell cycle arrest in trophoblasts...In human pregnancy, apoptosis is increased in placentas subjected to intrauterine growth retardation or other disorders."[7]

ICRP states that for radionuclides ingested by the mother, "…doses to the embryo, fetus, and newborn child are similar to or less than those to the Reference Female."[8] The *exposure* may be similar, but ultimately, even what is considered a small dose could be much more *damaging* for in-utero development and could increase susceptibility to disease in adulthood because of intrauterine programming. ICRP is partially responsible for a latency time of 40 years to integrate new knowledge of radiation damage into protection policy, and has been unwilling to acknowledge new forms of damage without a historically proven mechanism, even though the science points to a connection between this damage and radiation exposure. NRC adopts ICRP recommendations (which already lag behind the latest science) often a decade after they are released. Therefore, the latest phenomena that indicate heretofore-unrecognized forms of radiation damage -- bystander effect, genomic instability, and now intrauterine programming--may take 4 decades to achieve ICRP recognition and be integrated into exposure regulations.[9] Yet much of the nuclear reactor fleet has already been operating for 40 years. Therefore, NRC's reliance on decades-old-science when new models and studies exist, is arbitrary, capricious and unreasonable.

ICRP makes no attempt to specifically protect *female* fetuses, who create all the eggs that child will ever have during prenatal development. Therefore, radiation exposure during the development of a female fetus could impact *her* children, making this female embryo or fetus the most vulnerable life stage and her damage cross-generational. This means that exposing a female of childbearing age to radiation could impact her grandchildren, depending on the timing of her pregnancy. Many women do not know they are pregnant, but crucial pregnancy development is still occurring. Likewise, doctors can usually not tell the sex of the fetus until 16-20 weeks after conception—and after the fetus is well into

developing its own sex organs. Therefore, every fetus, even though the sex is defined at conception, needs to be protected as a female because its sex cannot be determined until much later in its development.

And because ICRP ignores critical sensitivities during the pregnancy life stage, and also fails to account for the most recent research on realistic risks of radiation exposure during early human life stages, doses ICRP claims are protective of pregnancy life stages pose unrecognized risk. While it is good that NRC recognizes special pre-natal sensitivity, NRC also seems to ignore sensitivities during weeks 0-8 of pregnancy: "The susceptibility of the embryo/fetus to damage by radiation is well established and data suggests that the period from 10 weeks to 17 weeks in the development of a fetus may be especially critical."

Studies of childhood cancer risks indicate‡ that none of the NRC or ICRP current or proposed exposure limits for the in utero life stage are protective enough.

NRC ponders various pregnancy doses in the ANPR, mostly in the context of female worker exposure: "lowering the exposure limits to an embryo/fetus during the gestation period from 5 mSv (500 mrem) to 4.5 mSv (450 mrem); and changing radiation protection terminology and definitions"; "…limiting the dose to the embryo/fetus to 5 mSv (500 mrem) or less during the entire pregnancy is generally considered desirable…" exploring in greater detail "the impacts of a change in the dose limit for the embryo/fetus to 1 mSv (100 mrem)."; "Publication 103 (2007) recommends that the dose limit for the embryo/fetus of a declared pregnant worker be the same as that for a member of the public, which is 1 mSv (100 mrem)."

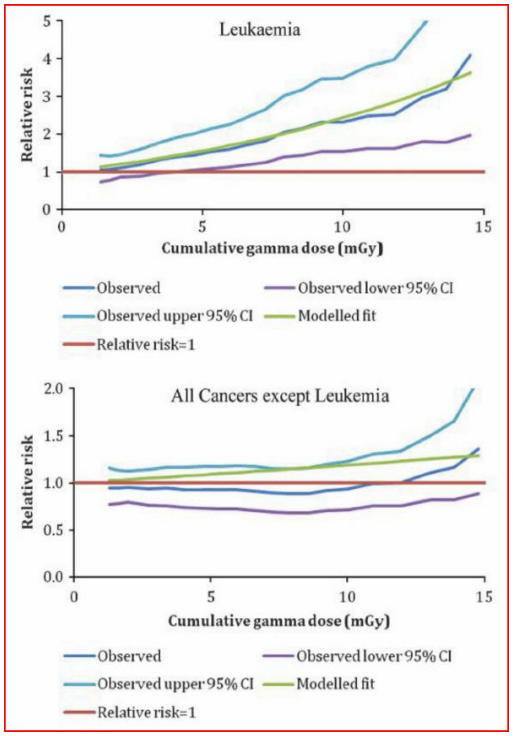
‡ Many radiation studies examine impacts on laboratory animals or special cell lines outside of the body. While such studies can indicate what *kind* of damage could be expected from radiation, a direct comparison between these studies and realistic exposure scenarios from routine or catastrophic releases of radioactivity is tenuous at best for a number of reasons: 1) doses used in the laboratory are often much higher than dose exposures expected from routine releases or from eating food contaminated with small amounts of radiation; 2) laboratory doses are rarely given over a large span of time, which would be needed for assessing whole life or cross-generational damage; and 3) recent research that compared impacts of chronic radiation exposure around Chernobyl with radiation experiments done in controlled environments, indicates that wildlife in nature could be *at least* eight times more sensitive to radiation than animals used in controlled experiments. http://www.ncbi.nlm.nih.gov/pubmed/22336569 For these reasons and others, studies relied upon for assessment of radiation damage must be carefully chosen, especially where vulnerable human life cycles are concerned.

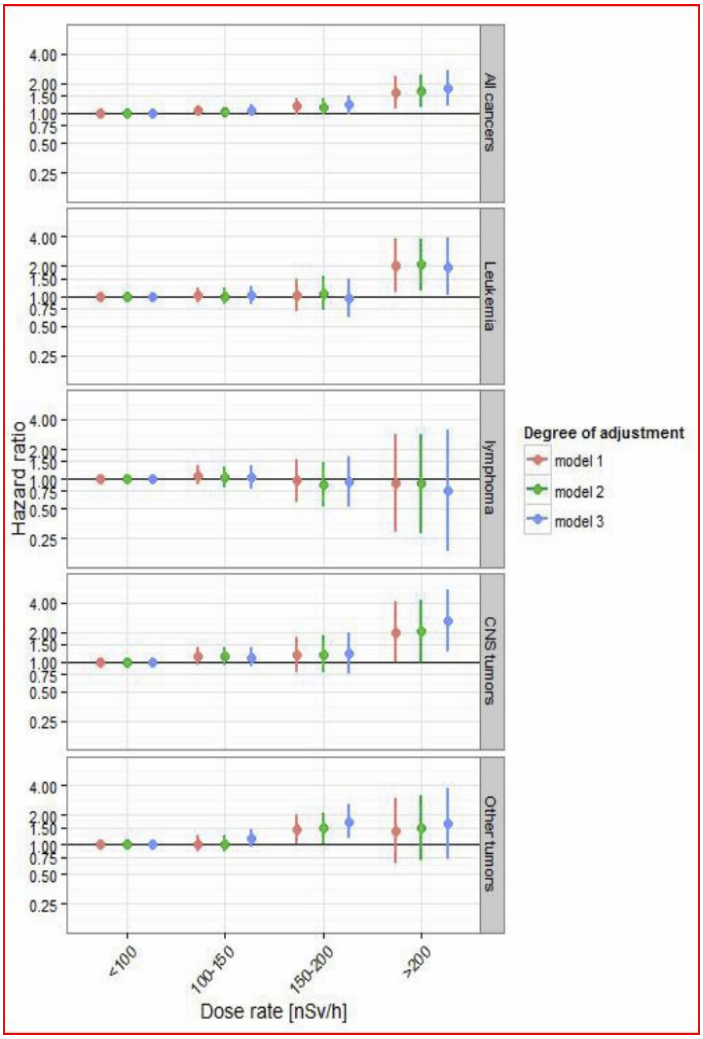
Research summarized in these comments addresses a number of the concerns stated above in that they are *in vivo*, non-laboratory conditions. Many examine real-life, protracted exposure to actual low-doses of radiation.

But in reality, none of these exposure limits is protective enough according to recent studies of childhood cancers (although 100 mrem during a nine month pregnancy would clearly be more protective than 500 mrem). This is because childhood leukemia risks are almost uniformly elevated in studies of young children living near nuclear facilities or in environments of elevated background radiation.

Childhood cancer from natural and man-made background radiation

Studies examining impact of anthropogenic and natural background radiation indicate a statistically significant increase in childhood leukemia from approximately a 4 mSv *cumulative* dose. At about 1 mSv per year, an increased incidence begins to appear for all childhood cancers and continues to increase as the dose increases, reaching 170% increase in incidence at about 2 mSv per year (see Figures from Kendall, et al. and Spycher, et al. below). [10, 11]

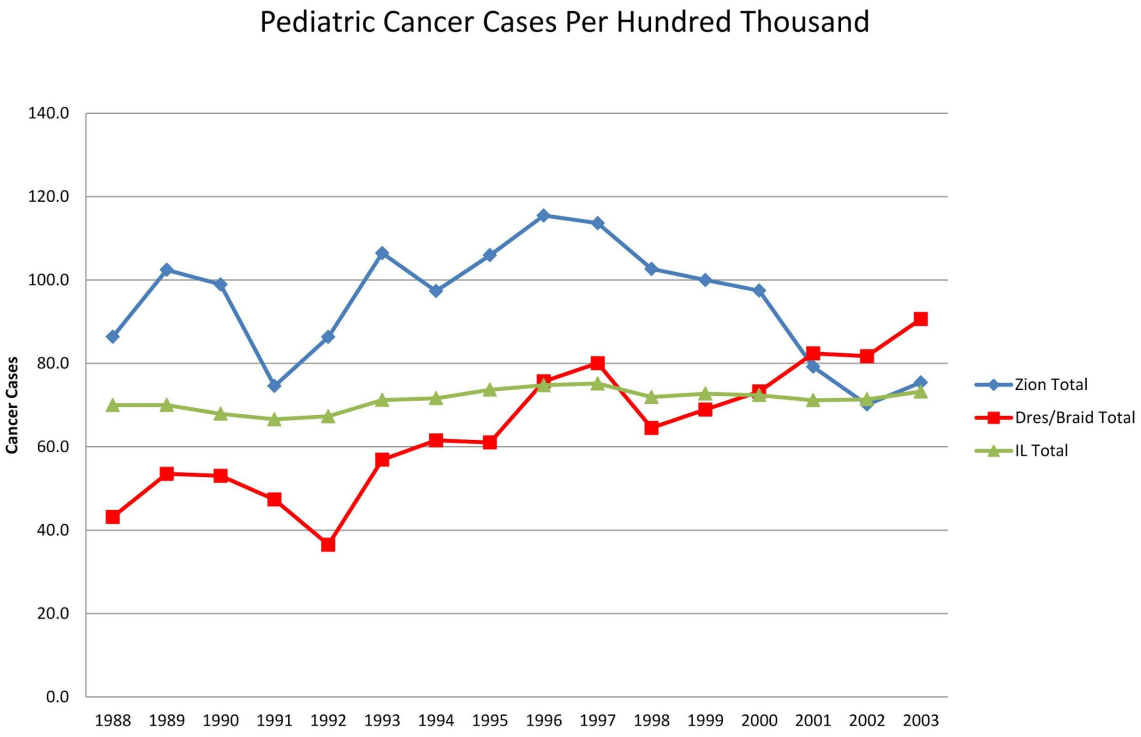




Increased childhood leukemia around nuclear reactors

"Over 60 epidemiological studies world-wide have examined cancer incidences in children near nuclear power plants (NPPs): most of them indicate leukemia increases."[12] This would be an unexpected health impact, because the doses these children received were well below those expected to result in disease by a factor of 10,000.[13]

Dr. Joseph Sauer, a practicing physician, living in Illinois near the Dresden and Braidwood nuclear power stations, obtained Illinois Department of Health statistics segmented on by county and zip code for pediatric cancers in Illinois from 1988 to 2003. In the figure below, Dr. Sauer presented his findings at the National Academy of Sciences, Analysis of Cancer Risks in Populations Near Nuclear Facilities, Phase 1 hearing in Chicago in 2011.[14] Dr. Sauer's slide from his presentation[15] is shown below.



Graph from Dr. Joseph Sauer's presentation at NAS Hearing in 2011[28]

The curve represents total pediatric cancer cases per population total of 100,000 in each year in Illinois; the cases in counties surrounding the Zion station (shut down in 1998); and the cases in counties surrounding the Dresden (started operation 1970 and continues to present) and Braidwood (started operation 1988 and continues to present) stations. This data suggests an approximate excess of 40 cases per population of 100,000 per year around the time Zion was shut down. This health outcome data was analyzed in the context of particular citizen concern regarding unplanned tritium releases from Braidwood and is higher than the EPA least protective cancer risk goal of 1 in 10,000.

Cancer and non-cancer impacts to humans from higher natural background areas and areas contaminated by Chernobyl

A meta-analysis examining impacts of living in areas where the natural background levels of radiation are high, found extensive evidence of increases in "significant negative effects on immunology, mutation and disease frequency", including reduced levels of antioxidants. The effects were small, but consistent and significant. "Note, however, that there is no evidence of radio-tolerance or radioresistance in humans…"[16] Mutation effects, including but not limited to cancer, start at approximately 1 mSv per year of natural background radiation. A recent meta-analysis "suggests a strong impact of radioactive contamination on individual fitness in current and future generations, with potentially significant population-level consequences, even beyond the area contaminated with radioactive material." Plants, humans, and animals were included in this study.[17]

Age and gender averages will NOT protect the pregnancy life stage, even if radiation's status as a privileged pollutant is overturned, and its cancer risk allowance is brought into line with other carcinogenic and mutagenic agents.

"The NRC is considering the use of the age and gender averaged approach to provide a more realistic representation of a member of the public that explicitly considers the presence of infants and children within the population." "Q1–3: How should the calculations of effluent concentration, currently in the 10 CFR part 20 radiation protection regulations, be modified to reflect advances in modeling that are now available? In particular, the NRC is interested

in preliminary views on the age and gender averaged approach."

NRC allows exposure of an additional 100 mrem (1mSv) per year to each member of the public. One in 286 fatal cancers result from 100 mrem per year over a 70-year lifetime, according to the NRC's own calculation (they actually give the number as 3.5 per 1000). Each licensee is allowed to expose a member of the public to 100 mrem per year, so in fact for those living near more than one nuclear facility (as in the Dresden/Braidwood/Zion instance in Illinois), the doses could be much higher to those individuals. Since cancer incidence is about double what fatal cancers are, 1 in 143 cancer incidence would result from a 100 mrem dose per year for a 70-year life. This risk does not adjust for age or gender. Further**,** if you compare the risk of NRC's allowable exposure limit of 100 mrem per year for 70 years to EPA's stated risk goals of 1 in 1 million cancer incidence to 1 in 10,000, it is much higher, essentially allowing radiation a "taking" over other toxins. There is no justification for allowing radioactive emissions to be treated as "privileged" pollutants. Additionally, the NRC risk calculation fails to account for pre-natal exposures. The age and gender-averaged approach will also not *protect* the pre-natal life stage even by NRC's own admission that this approach will "*consider the presence* of infants and children. [only]." (emphasis added) Any change in NRC exposure regulations should *protect* the most vulnerable life stage, which averaging does not do.

Exposing an embryo or fetus to 100 mrem total is certainly safer than exposing it to 500 mrem total. However, it isn't protective enough to meet even a 1 in 1000 cancer risk level when EPA risk goals are 1 in 1 million (and if that is not attainable, 1 in 10,000) risk for cancer incidence.

"The ICRP Publication 60 (1991) made clear that the embryo/fetus should be regarded as a member of the public when considering the protection of female workers who are or may be pregnant." This is a good concept in principle. But as demonstrated above, ICRP's recommendation of 100 mrem per pregnancy—over 9 months and in addition to background radiation already received—is not adequately protective considering evidence of increased cancer incidence at about 1 mSv and a *statistically significant* childhood leukemia risk exists at 4 mSv *cumulative* dose. One hundred mrem per pregnancy is certainly more protective than the current 500 mrem limit during pregnancy set by NRC,

which, according to recently published research, would be enough to increase childhood leukemia risk by a statistically significant amount.

Putting the burden of declaring pregnancy on a radiation worker creates a perverse incentive for a woman NOT to declare her pregnancy for fear of workplace retribution. It further creates a predatory environment whereby radiation entities profit at the expense of the health of a member of the public. Protecting workers in their child-bearing years should be the rule, not the exception.

From the ANPR: "The pregnant worker has the fundamental responsibility for deciding when or whether she will formally declare her condition to her employer. This position is derived from court rulings concerning a woman's rights regarding pregnancy. Having a formal declaration of pregnancy derives from legal, not health protection, considerations (56 FR 23373; May 21, 1991). If an occupational worker chooses not to declare her pregnancy, then the licensee will not be required under the Commission's regulations to limit her dose to the 5 mSv (500 mrem). The undeclared pregnant occupational women are protected under the NRC's regulations for all workers."

Placing the burden of declaration on the pregnant woman sets up a potentially predatory environment that benefits the economics of the licensee while risking the health of a member of the public (the fetus as defined by the ICRP in the context of radiation exposure, should be considered a member of the public). This perverse incentive to not declare a pregnancy is demonstrated in the Perdue University policy regarding pregnancy declaration, which basically warns that once a woman has declared, she could be out of a job:

> The only reason the NRC made this limit is to protect the embryo/fetus from unnecessary radiation levels that may put the baby at risk. You, the worker must make your own decision. There are many factors that must be taken into consideration including individual privacy rights regarding pregnancy/termination of pregnancy, ***equal employment opportunities, and the possible loss of income***. Because of these concerns, the declaration of pregnancy is made entirely on the woman's choosing. (emphasis added)

And, in the FAQ section:

> **"Q: What effect will formally declaring my pregnancy have on my job status?**
> **A:** You and your employer must make this decision. Most of the time, the dose limit is not exceeded under normal working conditions. Sometimes, workers normally work around the 0.5 rem limit during normal working activities. You and your employer must discuss ways that your dose may be limited. In a few circumstances, ***the employer may decide that you can no longer do your job and that there are no more positions that you would be able to work. This is why it is a good idea to discuss pregnancy and declared pregnancy before you decide to have a child. These are some of the considerations that must be dealt with when deciding whether or not to declare your pregnancy."*** (emphasis added)

Warning a woman not to get pregnant without discussing the issue with her employer, and/or that declaring her pregnancy may affect her employment negatively, are punitive ways to deal with the pregnancy life stage. Perhaps other licensees handle their employees in a more equitable and respectful fashion, but NRC's policy on pregnancy clearly allows this draconian interpretation.

A remedy to this perverse incentive would be to provide non-exposure employment to pregnant workers. Lowering the exposure limit for all workers to 100 mrem per year would be more protective than the current worker limit of 5 rem (although 100 mrem is not protective enough for pregnancy, especially if the fetus is female, a status not knowable until the 16th week of pregnancy at the earliest). However, results from a recent study indicate that even the 100 mrem level of exposure is not protective enough for adult workers: "This study provides strong evidence of positive associations between protracted low-dose radiation exposure and leukaemia...The risk coefficient per unit dose was consistent with those derived from analyses of other populations exposed to higher radiation doses and dose rates." The mean yearly dose was 1.1 mGy (100 mrem).[18]

Protection for child-bearing years should be the rule, not the exception. This protection is necessary because a woman may not know she is pregnant during exactly one of the most sensitive developmental times for her pregnancy (pre implantation to 8 weeks) and because sperm have demonstrated damage from radiation exposure.[19] Additionally, women are 50% more likely to get cancer from the same amounts of radiation than men according to the information in the BEIR VII report, raising questions of violations of women's international and constitutional rights to equal protection and health.[20] Therefore, lowering exposure allowance for *all* workers would confer greater protection for females and the reproductive cycle.

The ALARA construct will never be protective enough for prenatal life stages since background radiation already increases risk of contracting childhood cancers.

"The NRC's regulation in 10 CFR 20.1101(b) provides that each licensee 'shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).'"

There is actually no proof that ALARA is protective of in utero health, only that it is achievable for reasonable cost by engineering techniques. In fact, if background radiation is already increasing the risk of childhood leukemia, it is certain that more radiation exposure will increase this risk more. Therefore, ALARA is not, nor has it ever been, about protecting public health by preventing radiation exposure. Rather, ALARA is a way to permit more radiation exposure of already sensitive life stages while keeping the doses low enough to obscure more subtle health impacts. These subtle health impacts can become quite detrimental over time and through further exposure. To this end, NRC should abandon its allowance of nuclides to the sewage systems of this country. These releases are in addition to the 100 mrem releases allowed to members of the public and can be much higher than 100 mrem. Releasing these nuclides to the sewer doesn't mean they just disappear: they can eventually recycle back into soils used to grow food and ground and drinking water, becoming an unrecognized dose. This means that the public dose allowed by NRC can be a good deal higher than 100 mrem per year.

Cancer risk in just the exposed generation isn't the only risk radiation exposure poses. Additionally, non-DNA damage may be caused by radiation, but would be harder to attribute to radiation under current damage assumptions.

Radiation causes DNA damage and epigenetic changes in the embryo. Such damage can manifest permanent structural and functional changes and can lead to diseases other than cancer, i.e. diabetes, cardiovascular disease, and premature aging - the more DNA damage, the less regenerative capacity. This damage is part of intrauterine programming, mentioned above. "Additionally, epigenetic changes that modulate gene expression could provide another explanation for the long-term effects of embryonic stress."[21] Epigenetic effects are generally defined as effects that occur from radiation exposure and which are not attributable to direct genetic damage.[22] These effects occur in *addition* to and/or outside of DNA damage as a consequence of the functional processes of a cell[23] and are so fundamental that they promise to overturn a number of assumed radiation effects and may warrant the creation of new paradigms for health risk from radiation exposure.[24,25,26,27] Effects of prenatal radiation induced DNA damage are largely unexplored in humans, yet what data is available comes from studying the long-term health impacts of nuclear accidents or from the survivors of the atomic bombs dropped over Hiroshima and Nagasaki that were *in utero* at the time of radiation exposure. These studies "focused on the effects of an acute prenatal exposure to DNA damage; a more persistent stress would probably have more lasting effects."[28] The main impact was smaller brain size. Studies of atomic bomb survivors also suggest that seizures, without a known precipitating cause, are related to in-utero radiation exposure.[29]

Because of phenomena like intrauterine programming, models such as the life course health development (LCHD) framework need to be implemented as part of regulatory protection: "This framework organizes research from several fields into a conceptual approach explaining how individual and population health develops and how developmental trajectories are determined by interactions between biological and environmental factors during the lifetime...By focusing on the relationship between experiences and the biology of development, the LCHD framework offers a better understanding of how diseases occur."[30] Such models are completely lacking in radiation exposure recommendations to date.

Organ damage from radiocesium inhaled or ingested

In studies of post-Chernobyl Belarus, cardiac abnormalities develop in children whose bodies contain 10-30 Bq/kg of radioactive cesium. In addition to heart arrhythmias, the radioactive cesium disrupts the energy of cardiac cells in turn decreasing the child's ability to adapt to, and pull through, everyday stresses including physical and mental pressure, infections, allergies and more. Tissue death and irreversible pathologies develop at 50 Bq/kg.[31,32]

Perinatal mortality after internal exposure to radioactive strontium from atomic testing and Chernobyl

Perinatal mortality increased in Germany, Belarus and Ukraine subsequent to the Chernobyl catastrophe, at the time radioactive strontium collected in the bodies of pregnant women. This effect persisted until the end of 1998, when the study ended. Additionally, "…about 80,000 excess early neonatal deaths in West Germany can be attributed to strontium from the fallout of atmospheric nuclear weapons tests."[33] Doses from atomic bomb fallout in Germany were well below 1 mSv/year, indicating that the ICRP assumption that the fetus is protected from certain kinds of damage by a radiation threshold dose of 100 mSv is wrong.[34,35,36]

Pre-implantation birth defects in areas contaminated by radiation from Chernobyl

A recent study demonstrates significantly increased rates of conjoined twins, teratomas, neural tube defects, microcephaly, and microphthalmia in an area of Ukraine polluted by ionizing radiation at levels higher than other places contaminated by Chernobyl. Many of these pregnancies end in termination with no guarantee that the reason for the termination (malformation) is properly listed, thus actual numbers of malformations are underreported. The researchers characterize some of these effects as "blastopathies" which they define as "anomalies that arise prior to embryonal implantation and organogenesis…"[37]

The purpose of the proposed rule is to make 10 CFR 20 more consistent with ICRP 103. Yet, when we, and others, requested electronic copies of ICRP 103 and related

documents referred to in the Federal Register notice and in ICRP 103 through FOIA, our requests were denied. Therefore we, the pubic stakeholders, reserve our right to submit additional comments after the public receives electronic copies of, and has time to review, all documents relied upon by the NRC in the ANPR. The public regards NRC's FOIA denial as a shameful attempt to bar public participation in the review process of a significant rule change that impacts public health.

During the public's attempt to get copies of ICPR 103 and other related documents, stakeholders were forced to purchase a copy, which they could not share with the other stakeholders who requested a copy under FOIA. Nor could they share the purchased copy with medical experts.

Despite limited ICRP 103 access stakeholders have obtained recently, there are many other reports referred to and relied upon by the ANPR. Therefore we, as stakeholders, reserve our right to submit additional comments after the public receives electronic copies of, and has time to review, all referenced documents.

Current NRC exposure standards fail to protect early human life stages. Any change in these standards needs to correct this failure.

Protecting the most vulnerable is key. It should be the focus of any change in exposure regulations. Since background radiation is already associated with an elevated risk of childhood leukemias, and potentially responsible for other disease onset later in life, this makes NRC's job difficult. Clearly NRC's current 100 mrem exposure limit for members of the public is too high for the most vulnerable life stages, as admitted by NRC's own risk calculations and those of EPA whose responsibility it is to protect public health from radiation exposure past the fence line of NRC's licensees. It is clear that if NRC uses the current exposure framework, early human life stages will again disproportionately bear the burden of radiation exposure.

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RulemakingComments Resource

From: Cindy Folkers <cindy@beyondnuclear.org>
Sent: Monday, June 22, 2015 3:46 PM
To: RulemakingComments Resource
Subject: [External_Sender] Docket ID NRC-2009-0279
Attachments: BeyondNuclearcommentsNRC20090279.pdf

Comments attached and pasted below. (accompanying charts and graphs are only in the attached pdf version)

Thank you,

Cindy Folkers, Beyond Nuclear

June 22, 2014 Comments of Beyond Nuclear on Nuclear Regulatory Commission (NRC) 10 CFR Part 20 [NRC-2009-0279] RIN 3150-AJ29 Radiation Protection Advanced Notice of Proposed Rulemaking on development of a draft regulatory basis.

Federal Register Notice/Vol.79 No. 143: 43284-43300 7/25/14

NRC is considering rewriting its radiation exposure regulations. Prenatal and childhood life stages are known to be particularly vulnerable to damage from radiation exposure with prenatal life stages being uniquely vulnerable. However, documents on which NRC might base new radiation exposure regulations have been difficult or impossible for members of the public to obtain. Without provision of these documents, public comment is not as robust as it could be.

Pregnant women, developing embryos and growing children have special vulnerabilities including predilection for certain types of radionuclides, particularly ones that mimic chemicals used to form constituents of growth and aid metabolism. Additionally, little research exists on realistic, chronic, very low dose exposure impacts on pre-implantation, the developing human embryo and developing fetus. Models that only represent radiation damage to organs, the whole body, or even groups of cells may not fully represent the extent of damage to the individual cells that are required for healthy in utero development. *Intrauterine programming*, a recently discovered phenomenon that is just now being researched, offers insight into the vulnerability of the in-utero life stages that can impact the wellness and viability of not only those life stages, but also subsequent adult wellness and viability as well.[*] Much about this phenomenon is not yet discovered, but this uncertainty should not be used as an excuse to expose humans to undetermined damage from radiation during the most vulnerable stages of life.

Pregnancy begins before conception;[1] therefore women of childbearing years should be treated as potentially pregnant before being aware of a pregnancy. And since a female fetus develops all the eggs she will ever have while she is in utero, protecting pregnancy from radiation is protecting not just the child of the pregnant woman, but her grandchildren as well.

The in utero life stage can have disproportionate vulnerabilities to certain radionuclides.[2] Among these are radioactive carbon (C-14) and tritium (radioactive hydrogen isotope). [†] Each of these can collect in fetal tissue to twice the concentration in maternal tissue. This concentration factor serves as an additional risk to the sensitivity of this life stage. Further, there is indication that the type of radiation given off by these isotopes—a beta particle—could have more impact than is currently assumed. Children and adolescents exposed to radioactive iodine (iodine-131), and who did not receive a protective measure of potassium iodine within a few hours of exposure, were found to have more aggressive forms of cancer.[3]

Radionuclides inside a developing embryo, or the developing placenta surrounding it, could do unique and tremendous damage during this life stage. Induction of cancer is only one disease endpoint. While young children are sensitive to radiation compared to adult life stages—ICRP recognizes that they can be more sensitive—the beginning stages of life (embryonic and fetal) which are unique in structure and development, can at some stages be many times more sensitive than even young children, due to phenomena like intra-uterine programming and organ creation.

Any regulatory changes should protect for these life stages; further, Federal agencies are compelled to make this protection a high priority by Executive Order.

President Clinton's Executive Order 13045 of April 21, 1997 is still in force. The *Protection of Children From Environmental Health Risks and Safety Risks* states "...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."

Aligning NRC's exposure regulations with ICRP 103 would essentially leave out protection of pregnancy life stages. In fact, NRC seems to assume that ICRP 103 goes *beyond* providing adequate protection. However, for

embryonic and fetal development it does no such thing because ICRP fails to specifically account for some unique vulnerability that occurs during this developmental life stage.

NRC states that the goal of this proposed rule-making is "to achieve greater alignment between the NRC's radiation protection regulations and the 2007 recommendations of the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103 (2007)…" and to "establish standards of protection for both members of the public and occupational workers from ionizing radiation resulting from activities conducted under licenses issued by the NRC." NRC notes "The Commission also directed the NRC staff to continue discussions with stakeholders regarding dose limits for … the embryo/fetus."

"Notably, the Commission agreed with both the NRC staff and the NRC's Advisory Committee on Reactor Safeguards (ACRS) that 'the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment.' In this regard, the Commission stated that from 'a safety regulation perspective, ICRP Publication103 (2007) proposes measures that go beyond what is needed to provide for adequate protection.'"

Unfortunately, neither ICRP's large body of multi-decadal radiation exposure recommendations, nor NRC's use of them, offer adequate protection for pregnancy or pre-natal life stages, which can be uniquely sensitive to damage from radiation. NRC's definition of a "general" population does not to include these life stages: "A general population includes individuals of both genders and various age groups that range from newborns to senior citizens."

ICRP assumes "that life-time cancer risk following in-utero exposure will be similar to that following irradiation in early childhood,"[4] and relies on doses to the maternal uterus to assess dose to the embryo (which ICRP defines as up to 8 weeks from conception)[5]. The heart, spinal cord and brain, major blood vessels and the beginning of bones and muscles, are in process of forming from single cells, meaning that assessing damage from radiation during this sensitive development presents unique challenges under circumstances not yet understood. This life stage deserves protection none-the-less.

ICRP does not assess damage to the placenta, a temporary but, immensely important structure that performs organ-like functions during pregnancy. The placenta supplies oxygen and nutrition to the embryo/fetus and removes metabolic

products. The placenta provides a limited barrier against some toxins and drugs and is active endocrinologically to support the ongoing pregnancy.[6] "...Radiation affect[s] fetal growth not only by damaging fetal cells but also by impairing placental development and function by the induction of apoptosis and cell cycle arrest in trophoblasts...In human pregnancy, apoptosis is increased in placentas subjected to intrauterine growth retardation or other disorders."[7]

ICRP states that for radionuclides ingested by the mother, "…doses to the embryo, fetus, and newborn child are similar to or less than those to the Reference Female."[8] The *exposure* may be similar, but ultimately, even what is considered a small dose could be much more *damaging* for in-utero development and could increase susceptibility to disease in adulthood because of intrauterine programming. ICRP is partially responsible for a latency time of 40 years to integrate new knowledge of radiation damage into protection policy, and has been unwilling to acknowledge new forms of damage without a historically proven mechanism, even though the science points to a connection between this damage and radiation exposure. NRC adopts ICRP recommendations (which already lag behind the latest science) often a decade after they are released. Therefore, the latest phenomena that indicate heretofore-unrecognized forms of radiation damage -- bystander effect, genomic instability, and now intrauterine programming--may take 4 decades to achieve ICRP recognition and be integrated into exposure regulations.[9] Yet much of the nuclear reactor fleet has already been operating for 40 years. Therefore, NRC's reliance on decades-old- science when new models and studies exist, is arbitrary, capricious and unreasonable.

ICRP makes no attempt to specifically protect *female* fetuses, who create all the eggs that child will ever have during prenatal development. Therefore, radiation exposure during the development of a female fetus could impact *her* children, making this female embryo or fetus the most vulnerable life stage and her damage cross-generational. This means that exposing a female of childbearing age to radiation could impact her grandchildren, depending on the timing of her pregnancy. Many women do not know they are pregnant, but crucial pregnancy development is still occurring. Likewise, doctors can usually not tell the sex of the fetus until 16-20 weeks after conception—and after the fetus is well into developing its own sex organs. Therefore, every fetus, even though the sex is defined at conception, needs to be protected as a female because its sex cannot be determined until much later in its development.

And because ICRP ignores critical sensitivities during the pregnancy life stage, and also fails to account for the most recent research on realistic risks of radiation exposure during early human life stages, doses ICRP claims are protective of pregnancy life stages pose unrecognized risk. While it is good that NRC recognizes special pre-natal sensitivity, NRC also seems to ignore sensitivities during weeks 0-8 of pregnancy: "The susceptibility of the embryo/fetus to damage by radiation is well established and data suggests that the period from 10 weeks to 17 weeks in the development of a fetus may be especially critical."

Studies of childhood cancer risks indicate[‡] that none of the NRC or ICRP current or proposed exposure limits for the in utero life stage are protective enough.

NRC ponders various pregnancy doses in the ANPR, mostly in the context of female worker exposure: "lowering the exposure limits to an embryo/fetus during the gestation period from 5 mSv (500 mrem) to 4.5 mSv (450 mrem); and changing radiation protection terminology and definitions"; "…limiting the dose to the embryo/fetus to 5 mSv (500 mrem) or less during the entire pregnancy is generally considered desirable…" exploring in greater detail "the impacts of a change in the dose limit for the embryo/fetus to 1 mSv (100 mrem)."; "Publication 103 (2007) recommends that the dose limit for the embryo/fetus of a declared pregnant worker be the same as that for a member of the public, which is 1 mSv (100 mrem)."

But in reality, none of these exposure limits is protective enough according to recent studies of childhood cancers (although 100 mrem during a nine month pregnancy would clearly be more protective than 500 mrem). This is because childhood leukemia risks are almost uniformly elevated in studies of young children living near nuclear facilities or in environments of elevated background radiation.

Childhood cancer from natural and man-made background radiation

Studies examining impact of anthropogenic and natural background radiation indicate a statistically significant increase in childhood leukemia from approximately a 4 mSv *cumulative* dose. At about 1 mSv per year, an increased incidence begins to appear for all childhood cancers and continues to increase as the dose increases, reaching 170% increase in incidence at about 2 mSv per year (see Figures from Kendall, et al. and Spycher, et al. below). [10], [11]

Increased childhood leukemia around nuclear reactors

"Over 60 epidemiological studies world-wide have examined cancer incidences in children near nuclear power plants (NPPs): most of them indicate leukemia increases."[12] This would be an unexpected health impact, because the doses these children received were well below those expected to result in disease by a factor of 10,000.[13]

Dr. Joseph Sauer, a practicing physician, living in Illinois near the Dresden and Braidwood nuclear power stations, obtained Illinois Department of Health statistics segmented on by county and zip code for pediatric cancers in Illinois from 1988 to 2003. In the figure below, Dr. Sauer presented his findings at the National Academy of Sciences, Analysis of Cancer Risks in Populations Near Nuclear Facilities, Phase 1 hearing in Chicago in 2011.[14] Dr. Sauer's slide from his presentation[15] is shown below.

Graph from Dr. Joseph Sauer's presentation at NAS Hearing in 2011[28]

The curve represents total pediatric cancer cases per population total of 100,000 in each year in Illinois; the cases in counties surrounding the Zion station (shut down in 1998); and the cases in counties surrounding the Dresden (started operation 1970 and continues to present) and Braidwood (started operation 1988 and continues to present) stations. This data suggests an approximate excess of 40 cases per population of 100,000 per year around the time Zion was shut down. This health outcome data was analyzed in the context of particular citizen concern regarding unplanned tritium releases from Braidwood and is higher than the EPA least protective cancer risk goal of 1 in 10,000.

Cancer and non-cancer impacts to humans from higher natural background areas and areas contaminated by Chernobyl

A meta-analysis examining impacts of living in areas where the natural background levels of radiation are high, found extensive evidence of increases in "significant negative effects on immunology, mutation and disease frequency", including reduced levels of antioxidants. The effects were small, but consistent and significant. "Note, however, that there is no evidence of radio-tolerance or radioresistance in humans…"[16] Mutation effects, including but not limited to cancer, start at approximately 1 mSv per year of natural background radiation. A recent meta-analysis "suggests a strong impact of radioactive contamination on individual fitness in current and future generations, with potentially significant

population-level consequences, even beyond the area contaminated with radioactive material." Plants, humans, and animals were included in this study.[17]

Age and gender averages will NOT protect the pregnancy life stage, even if radiation's status as a privileged pollutant is overturned, and its cancer risk allowance is brought into line with other carcinogenic and mutagenic agents.

"The NRC is considering the use of the age and gender averaged approach to provide a more realistic representation of a member of the public that explicitly considers the presence of infants and children within the population." "Q1–3: How should the calculations of effluent concentration, currently in the 10 CFR part 20 radiation protection regulations, be modified to reflect advances in modeling that are now available? In particular, the NRC is interested in preliminary views on the age and gender averaged approach."

NRC allows exposure of an additional 100 mrem (1mSv) per year to each member of the public. One in 286 fatal cancers result from 100 mrem per year over a 70-year lifetime, according to the NRC's own calculation (they actually give the number as 3.5 per 1000). Each licensee is allowed to expose a member of the public to 100 mrem per year, so in fact for those living near more than one nuclear facility (as in the Dresden/Braidwood/Zion instance in Illinois), the doses could be much higher to those individuals. Since cancer incidence is about double what fatal cancers are, 1 in 143 cancer incidence would result from a 100 mrem dose per year for a 70-year life. This risk does not adjust for age or gender. Further**,** if you compare the risk of NRC's allowable exposure limit of 100 mrem per year for 70 years to EPA's stated risk goals of 1 in 1 million cancer incidence to 1 in 10,000, it is much higher, essentially allowing radiation a "taking" over other toxins. There is no justification for allowing radioactive emissions to be treated as "privileged" pollutants. Additionally, the NRC risk calculation fails to account for pre-natal exposures. The age and gender-averaged approach will also not *protect* the pre-natal life stage even by NRC's own admission that this approach will "*consider the presence* of infants and children. [only]." (emphasis added) Any change in NRC exposure regulations should *protect* the most vulnerable life stage, which averaging does not do.

Exposing an embryo or fetus to 100 mrem total is certainly safer than exposing it to 500 mrem total. However, it isn't protective enough to meet even a 1 in 1000 cancer risk level when EPA risk goals are 1 in 1 million (and if that is not attainable, 1 in 10,000) risk for cancer incidence.

"The ICRP Publication 60 (1991) made clear that the embryo/fetus should be regarded as a member of the public when considering the protection of female workers who are or may be pregnant." This is a good concept in principle. But as demonstrated above, ICRP's recommendation of 100 mrem per pregnancy—over 9 months and in addition to background radiation already received—is not adequately protective considering evidence of increased cancer incidence at about 1 mSv and a *statistically significant* childhood leukemia risk exists at 4 mSv *cumulative* dose. One hundred mrem per pregnancy is certainly more protective than the current 500 mrem limit during pregnancy set by NRC, which, according to recently published research, would be enough to increase childhood leukemia risk by a statistically significant amount.

Putting the burden of declaring pregnancy on a radiation worker creates a perverse incentive for a woman NOT to declare her pregnancy for fear of workplace retribution. It further creates a predatory environment whereby radiation entities profit at the expense of the health of a member of the public. Protecting workers in their child-bearing years should be the rule, not the exception.

From the ANPR: "The pregnant worker has the fundamental responsibility for deciding when or whether she will formally declare her condition to her employer. This position is derived from court rulings concerning a woman's rights regarding pregnancy. Having a formal declaration of pregnancy derives from legal, not health protection, considerations (56 FR 23373; May 21, 1991). If an occupational worker chooses not to declare her pregnancy, then the licensee will not be required under the Commission's regulations to limit her dose to the 5 mSv (500 mrem). The undeclared pregnant occupational women are protected under the NRC's regulations for all workers."

Placing the burden of declaration on the pregnant woman sets up a potentially predatory environment that benefits the economics of the licensee while risking the health of a member of the public (the fetus as defined by the ICRP in the context of radiation exposure, should be considered a member of the public). This perverse incentive to not declare a pregnancy is demonstrated in the Perdue University policy regarding pregnancy declaration, which basically warns that once a woman has declared, she could be out of a job:

> The only reason the NRC made this limit is to protect the embryo/fetus from unnecessary radiation levels that may put the baby at risk. You, the worker must make your own decision. There are many factors that must be taken into consideration including individual privacy rights regarding pregnancy/termination of pregnancy, ***equal employment opportunities, and the possible loss of income***. Because of these concerns, the declaration of pregnancy is made entirely on the woman's choosing. (emphasis added)

And, in the FAQ section:

> **"Q: What effect will formally declaring my pregnancy have on my job status?**
> **A:** You and your employer must make this decision. Most of the time, the dose limit is not exceeded under normal working conditions. Sometimes, workers normally work around the 0.5 rem limit during normal working activities. You and your employer must discuss ways that your dose may be limited. In a few circumstances, ***the employer may decide that you can no longer do your job and that there are no more positions that you would be able to work. This is why it is a good idea to discuss pregnancy and declared pregnancy before you decide to have a child. These are some of the considerations that must be dealt with when deciding whether or not to declare your pregnancy."*** (emphasis added)

Warning a woman not to get pregnant without discussing the issue with her employer, and/or that declaring her pregnancy may affect her employment negatively, are punitive ways to deal with the pregnancy life stage. Perhaps other licensees handle their employees in a more equitable and respectful fashion, but NRC's policy on pregnancy clearly allows this draconian interpretation.

A remedy to this perverse incentive would be to provide non-exposure employment to pregnant workers. Lowering the exposure limit for all workers to 100 mrem per year would be more protective than the current worker limit of 5 rem (although 100 mrem is not protective enough for pregnancy, especially if the fetus is female, a status not knowable until the 16th week of pregnancy at the earliest). However, results from a recent study indicate that even the 100 mrem level of exposure is not protective enough for adult workers: "This study provides strong evidence of positive associations between protracted low-dose radiation exposure and leukaemia...The risk coefficient per unit dose was consistent with those derived from analyses of other populations exposed to higher radiation doses and dose rates." The mean yearly dose was 1.1 mGy (100 mrem).[18]

Protection for child-bearing years should be the rule, not the exception. This protection is necessary because a woman may not know she is pregnant during exactly one of the most sensitive developmental times for her pregnancy (pre implantation to 8 weeks) and because sperm have demonstrated damage from radiation exposure.[19] Additionally,

women are 50% more likely to get cancer from the same amounts of radiation than men according to the information in the BEIR VII report, raising questions of violations of women's international and constitutional rights to equal protection and health.[20] Therefore, lowering exposure allowance for *all* workers would confer greater protection for females and the reproductive cycle.

The ALARA construct will never be protective enough for prenatal life stages since background radiation already increases risk of contracting childhood cancers.

"The NRC's regulation in 10 CFR 20.1101(b) provides that each licensee 'shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).'"

There is actually no proof that ALARA is protective of in utero health, only that it is achievable for reasonable cost by engineering techniques. In fact, if background radiation is already increasing the risk of childhood leukemia, it is certain that more radiation exposure will increase this risk more. Therefore, ALARA is not, nor has it ever been, about protecting public health by preventing radiation exposure. Rather, ALARA is a way to permit more radiation exposure of already sensitive life stages while keeping the doses low enough to obscure more subtle health impacts. These subtle health impacts can become quite detrimental over time and through further exposure. To this end, NRC should abandon its allowance of nuclides to the sewage systems of this country. These releases are in addition to the 100 mrem releases allowed to members of the public and can be much higher than 100 mrem. Releasing these nuclides to the sewer doesn't mean they just disappear: they can eventually recycle back into soils used to grow food and ground and drinking water, becoming an unrecognized dose. This means that the public dose allowed by NRC can be a good deal higher than 100 mrem per year.

Cancer risk in just the exposed generation isn't the only risk radiation exposure poses. Additionally, non-DNA damage may be caused by radiation, but would be harder to attribute to radiation under current damage assumptions.

Radiation causes DNA damage and epigenetic changes in the embryo. Such damage can manifest permanent structural and functional changes and can lead to diseases other than cancer, i.e. diabetes, cardiovascular disease, and premature

aging - the more DNA damage, the less regenerative capacity. This damage is part of intrauterine programming, mentioned above. "Additionally, epigenetic changes that modulate gene expression could provide another explanation for the long-term effects of embryonic stress."[21] Epigenetic effects are generally defined as effects that occur from radiation exposure and which are not attributable to direct genetic damage.[22] These effects occur in *addition* to and/or outside of DNA damage as a consequence of the functional processes of a cell[23] and are so fundamental that they promise to overturn a number of assumed radiation effects and may warrant the creation of new paradigms for health risk from radiation exposure.[24],[25],[26],[27] Effects of prenatal radiation induced DNA damage are largely unexplored in humans, yet what data is available comes from studying the long-term health impacts of nuclear accidents or from the survivors of the atomic bombs dropped over Hiroshima and Nagasaki that were *in utero* at the time of radiation exposure. These studies "focused on the effects of an acute prenatal exposure to DNA damage; a more persistent stress would probably have more lasting effects."[28] The main impact was smaller brain size. Studies of atomic bomb survivors also suggest that seizures, without a known precipitating cause, are related to in-utero radiation exposure.[29]

Because of phenomena like intrauterine programming, models such as the life course health development (LCHD) framework need to be implemented as part of regulatory protection: "This framework organizes research from several fields into a conceptual approach explaining how individual and population health develops and how developmental trajectories are determined by interactions between biological and environmental factors during the lifetime...By focusing on the relationship between experiences and the biology of development, the LCHD framework offers a better understanding of how diseases occur."[30] Such models are completely lacking in radiation exposure recommendations to date.

Organ damage from radiocesium inhaled or ingested

In studies of post-Chernobyl Belarus, cardiac abnormalities develop in children whose bodies contain 10-30 Bq/kg of radioactive cesium. In addition to heart arrhythmias, the radioactive cesium disrupts the energy of cardiac cells in turn decreasing the child's ability to adapt to, and pull through, everyday stresses including physical and mental pressure, infections, allergies and more. Tissue death and irreversible pathologies develop at 50 Bq/kg.[31],[32]

Perinatal mortality after internal exposure to radioactive strontium from atomic testing and Chernobyl

Perinatal mortality increased in Germany, Belarus and Ukraine subsequent to the Chernobyl catastrophe, at the time radioactive strontium collected in the bodies of pregnant women. This effect persisted until the end of 1998, when the study ended. Additionally, "…about 80,000 excess early neonatal deaths in West Germany can be attributed to strontium from the fallout of atmospheric nuclear weapons tests."[33] Doses from atomic bomb fallout in Germany were well below 1 mSv/year, indicating that the ICRP assumption that the fetus is protected from certain kinds of damage by a radiation threshold dose of 100 mSv is wrong.[34],[35],[36]

Pre-implantation birth defects in areas contaminated by radiation from Chernobyl

A recent study demonstrates significantly increased rates of conjoined twins, teratomas, neural tube defects, microcephaly, and microphthalmia in an area of Ukraine polluted by ionizing radiation at levels higher than other places contaminated by Chernobyl. Many of these pregnancies end in termination with no guarantee that the reason for the termination (malformation) is properly listed, thus actual numbers of malformations are underreported. The researchers characterize some of these effects as "blastopathies" which they define as "anomalies that arise prior to embryonal implantation and organogenesis…"[37]

The purpose of the proposed rule is to make 10 CFR 20 more consistent with ICRP 103. Yet, when we, and others, requested electronic copies of ICRP 103 and related documents referred to in the Federal Register notice and in ICRP 103 through FOIA, our requests were denied. Therefore we, the pubic stakeholders, reserve our right to submit additional comments after the public receives electronic copies of, and has time to review, all documents relied upon by the NRC in the ANPR. The public regards NRC's FOIA denial as a shameful attempt to bar public participation in the review process of a significant rule change that impacts public health.

During the public's attempt to get copies of ICPR 103 and other related documents, stakeholders were forced to purchase a copy, which they could not share with the other stakeholders who requested a copy under FOIA. Nor could they share the purchased copy with medical experts.

Despite limited ICRP 103 access stakeholders have obtained recently, there are many other reports referred to and relied upon by the ANPR. Therefore we, as stakeholders, reserve our right to submit additional comments after the public receives electronic copies of, and has time to review, all referenced documents.

Current NRC exposure standards fail to protect early human life stages. Any change in these standards needs to correct this failure.

Protecting the most vulnerable is key. It should be the focus of any change in exposure regulations. Since background radiation is already associated with an elevated risk of childhood leukemias, and potentially responsible for other disease onset later in life, this makes NRC's job difficult. Clearly NRC's current 100 mrem exposure limit for members of the public is too high for the most vulnerable life stages, as admitted by NRC's own risk calculations and those of EPA whose responsibility it is to protect public health from radiation exposure past the fence line of NRC's licensees. It is clear that if NRC uses the current exposure framework, early human life stages will again disproportionately bear the burden of radiation exposure.

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[*] DNA damage and epigenetic changes in the embryo can manifest permanent structural and functional changes and can lead to other diseases later in child or adult life stages, i.e. diabetes, cardiovascular disease, and premature aging.

[†] Sr-90 also collects more during periods of growth: Frequently asked questions: Strontium 90. Delaware Health Services. January 2012

[‡] Many radiation studies examine impacts on laboratory animals or special cell lines outside of the body. While such studies can indicate what *kind* of damage could be expected from radiation, a direct comparison between these studies and realistic exposure scenarios from routine or catastrophic releases of radioactivity is tenuous at best for a number of reasons: 1) doses used in the laboratory are often much higher than dose exposures expected from routine releases or from eating food contaminated with small amounts of radiation; 2) laboratory doses are rarely given over a large span of time, which would be needed for assessing whole life or cross-generational damage; and 3) recent research that compared impacts of chronic radiation exposure around Chernobyl with radiation experiments done in controlled environments, indicates that wildlife in nature could be *at least* eight times more sensitive to radiation than animals used in controlled experiments. http://www.ncbi.nlm.nih.gov/pubmed/22336569 For these reasons and others, studies relied upon for assessment of radiation damage must be carefully chosen, especially where vulnerable human life cycles are concerned.

Research summarized in these comments addresses a number of the concerns stated above in that they are *in vivo*, non-laboratory conditions. Many examine real-life, protracted exposure to actual low-doses of radiation.

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[19]http://www.ncbi.nlm.nih.gov/pubmed/23922858

[20] http://www.nirs.org/radiation/radhealth/radiationwomen.pdf

[21] http://embor.embopress.org/content/embor/11/1/32.full.pdf

[22] Baverstock, K. Some important questions connected with non-targeted effects. Mutation Research 687 (2010) 84–88.

[23]Baverstock, K. Why do we need a new paradigm in radiobiology? Mutation Research 687 (2010) 3–6

[24] *Ibid*.

[25] Mothersill, C. Review: Eco-systems biology—From the gene to the stream Mutation Research 687 (2010) 63–66.

[26] Wright, EG. Manifestations and mechanisms of non-targeted effects of ionizing radiation. Mutation Research 687 (2010) 28–33.

[27] Dubrova, YE. Can non-targeted effects lead to hereditary effects? Non-targeted effects of ionizing radiation (NOTE) presentation on June 14, 2010.

[28] http://embor.embopress.org/content/embor/11/1/32.full.pdf (see figure 2 for a general mechanism explaining how intrauterine damage contributes to aging)

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Radiation-related brain damage and growth retardation among the prenatally exposed atomic bomb survivors.

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