

NRC comments on the uranium white paper

General Comments

1. It is recognized that the available data on renal toxicity of U is sparse, and that estimating the kidney concentration of U is to some extent a circular exercise that uses models to go both ways, i.e. intake to concentration and concentration to intake. In addition, the models and parameters have changed over the years, and values reported in the literature spanned close to half a century may not be directly comparable because of these differences in models. To allow for such uncertainties, generous factors or margins of safety are used that ensure adequate protection of workers and the public without placing an undue burden on industry. The paper does not clearly discuss qualitatively or quantitatively the uncertainties associated with the toxic effects of soluble U to humans of all types and age groups and the application with justification of safety factors used to ensure adequate protection of workers and the public. In general, the paper should explain the limitations of the available data and models and how the shortfall in knowledge may be compensated while still adequately protecting workers and the public.
2. Uranium exposures are discussed at various locations in the report. However, in several instances, it is not clear if the exposure is from uranium in soluble form or not.
3. When identifying regulations, use a space before and after CFR. For example 10 CFR 70.61.

Specific Comments

1. Pg. 9. Prior to (b)(4) include the following quote “High consequence events are those internally or externally initiated events that result in: ...”
2. Pg. 9. Prior to (c)(4) include the following quote “Intermediate consequence events are those internally or externally initiated events that are not high consequence events that result in: ...”
3. Pg. 10, 2nd para. Discussions on additive effects and medical treatment should be removed as these are not considered in 10 CFR Part 70.
4. Pg. 10, 3rd para. The proposed definition of life endangerment is nearly as vague as the definition it is trying to improve on. For example, “more likely than not” is not well defined, but presumably means 50% or greater. However, the term “life endangerment” is more akin to be associated with a much lower number around one percent.
5. Pg. 10, 3rd para. Similar to the previous comment, the attempt at defining “irreversible or other serious health effects” does not capture the meaning. As stated in the proposed definition, a diminished functional capacity may not be permanent or serious. Stronger wording is suggested, such as an effect that would be deemed to permanently diminish the quality of life of the exposed

6. person as a result of diminished ability to conduct normal functions or the need for ongoing and perpetual care or treatment. It should also be considered when defining these effects that a diminished capacity at a young age may not have any immediate consequences, but may manifest itself in diminished survival later in life or at times when the kidneys are challenged by other disease conditions unrelated to uranium exposure. This is not to suggest that we must consider the entire person's likely future, but only that a factor of safety must be allowed for when setting these boundaries because the effect of the U may be synergistic with other existing kidney conditions or with conditions that may develop post exposure. A diminished kidney capacity may have no discernible clinical effects because of reserve functional capacity of kidneys, but it is still a serious consequence because a subsequent kidney illness with no reserve capacity could be very serious.
7. Pg. 11, 1st para. The fourth category is not needed as the presence of urinary biomarkers may be considered to be transient health effects.
8. Pg. 21, 1st para. It would be helpful to provide the age distribution of the 27 cases and to clarify their modes of intakes (eg. inhalation).
9. Pg. 27, Table 4. Convert data in the last column of Table 4 to conventional units of ug/g kidney.

Industry comments on the uranium white paper

Identifier	Comment
General	NRC should take revision control of this document for a period and help make it into something that is better fit for its purpose.
	Overall this document is confusing and must be read several times to understand it. Also, the report provides a great deal of extraneous information whereas informative it is not germane to the subject.
Properties and Uses of Uranium	This section is irrelevant and should be deleted.
P 9	Suggest moving the regulatory requirements after the introduction.
p 4	The discussion of concentration of uranium in the environment on p 4 (first paragraph under the Distribution of Uranium in Man and the Environment) is probably not required for this discussion.
p 5	The discussion of the two male tissue donors does not belong in the first or the second paragraph on this page. Nor does it belong in the first paragraph on p 6 or in the first full paragraph on p 7. Suggest the order be the "Distribution of Uranium in Man" followed by the section "Biokinetics and Biokinetic Models" and then an independent section on the study of the two male bodies if deemed relevant.
p 11	The discussion of the fourth category is not required.
p 11	Suggest deleting the "minor cut to a finger" discussion.
Chemical Toxicity of	Delete the extraneous information provided in this section such as the "Historical" section.

Uranium Suggest	
Chemical Toxicity of Uranium Suggest	It is unclear what information is used to support the author's position. Suggest making it more obvious of why these values were chosen and what data supports the position.
p 23	The information on the attempted suicide is confusing and it is not obvious why this information is provided or if it supports the author's position since death is not a criterion being evaluated.
General Comment	Suggest organizing the data in three sections that correspond to the three criteria and only discuss relevant data in each section.