From:	Parillo, John
To:	RulemakingComments Resource
Subject:	Comment on Part 53 Rulemaking Docket ID NRC-2019-0062 ML20289A534
Date:	Friday, August 26, 2022 5:45:46 PM
Attachments:	Comment on the use of 25 rem in Part 53.docx

Rulemaking personnel,

Please consider the attached comment in the rulemaking for advanced reactors.

Respectfully,

JGP

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Comment:

The value of 25 rem total effective dose equivalent (TEDE) in § 53.22, First Tier Safety Criteria, as an acceptance criterion for the evaluation of design basis accidents (DBAs) for advanced reactors is an inappropriate reference value that does not provide adequate protection of the public. Current Nuclear Regulatory Commission (NRC) policy is to assess the 25 rem TEDE criteria utilizing dose coefficients based on biokinetic and dosimetric data described in the NRC-endorsed ICRP 26/30 recommendations for the so-called "standard man model" (e.g., Caucasian male, between 20-30 years of age, and about 150 lbs). The reference value of 25 rem is not supported by any recommendations from the health physics community for members of the public during emergency conditions. In fact 25 rem TEDE is significantly higher than the upper end of the reference levels for emergency exposure situations recommended by the international commission on radiation protection (ICRP)[1]. There is an abundance of readily available evidence that a dose of 25 rem TEDE can cause significant harm to members of the public especially to dose sensitive persons such as expecting mothers and children. In fact, a source term which results in a value of 25 rem TEDE using the standard man model would in fact produce equivalent results significantly higher using dose coefficients which contain biokinetic and dosimetric models for a 'family' of individuals (e.g., a range of ages from infants to adults). This information would be important for members of the public to know and understand when considering the siting of a nuclear power facility in or near their community. There is also an abundance of information suggesting that a maximum level of 10 rem[2] would provide an appropriate upper level reference value for the evaluation of DBAs. A reference value of 10 rem would ensure that compliance with NRC's regulations provides reasonable assurance of adequate protection of the public.

General Design Criterion (GDC) 19 – Control room, specifies that: "…adequate radiation protection shall be provided to ensure that radiation exposures shall not exceed 0.05 Sv (5 rem) total effective dose equivalent (TEDE) as defined in § 50.2 for the duration of the accident." The Commission's regulations provide a value of 5 rem TEDE as an upper bound to provide adequate radiation protection for occupational workers in the control room. How can the same Commission endorse a value of 25 rem TEDE as providing adequate protection for members of the public? This disparity is magnified when the exposure times in the respective regulations are examined. The 5 rem control room value is determined for the duration of the accident (30 days by guidance) while the 25 rem public dose limitation at the exclusion area boundary is for any 2 hour period following the onset of the postulated fission product release. There is no scientific basis for continuing these disparities in new regulations for advanced reactors. There is no reputable organization representing health physics expertise that endorses a value of 25 rem as an appropriate reference value for providing adequate protection of the public.

In your response to this comment please explain how the continued use of 25 rem TEDE for advanced reactors will provide adequate protection for members of the public in light of the following recommendations:

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[1] ICRP 2007 recommendations state the following concerning the factors influencing the choice of source-related dose constraints and reference levels: "At doses higher than 100 mSv [10 rem], there is an increased likelihood of deterministic effects and a significant risk of cancer. For these reasons, the Commission [ICRP] considers that the maximum value for a reference level is 100 mSv incurred either acutely or in a year. Exposures above 100 mSv incurred either acutely or in a year would be justified only under extreme circumstances, either because the exposure is unavoidable or in exceptional situations such as the saving of life or the prevention of a serious disaster. No other individual or societal benefit would compensate for such high exposures."

[2] The NRC public website under the heading, Radiation Exposure and Cancer, includes the following statement, "Although radiation may cause cancer at high doses and high dose rates, public health data do not absolutely establish the occurrence of cancer following exposure to low doses and dose rates — below about 10,000 mrem (100 mSv)."

1. The environmental protection agency (EPA) protective action guideline (PAG) Manual EPA-400/R-17/001 (EPA, 2017) recommends PAGs of 1 to 5 rem TEDE projected over four days for sheltering-in-place or evacuation of the public and 5 rem projected child thyroid dose from exposure to radioactive iodine for supplementary administration of potassium iodide (KI).

    a. Please explain how a 25 rem TEDE dose for 2 hours (12.5 rem/hour) as an accident dose acceptance criterion can be justified when compared to the EPA guideline of a projected dose of 5 rem TEDE over four days (~50 mrem/hour) as an upper level value for recommending sheltering or evacuation of the public.

    b. Noting that DBA dose calculations use adult dose coefficients, and that Child thyroid dose projections would be approximately a factor of two higher using the dose coefficients for children, please explain how a 25 rem TEDE criterion that allows for a child thyroid dose in excess of 1,000 rem provides adequate protection for children.

2. Given that the international committee on radiation protection (ICRP) Publication 103 (ICRP, 2007) recommends a dose range of 2-10 rem for the public during an accident, please explain how the continued use of 25 rem TEDE as a DBA acceptance value for advanced reactors will provide adequate protection for members of the public.

3. Given that the national council on Radiation Protection & Measurements (NCRP) Publication 180 (NCRP, 2018) recommends that the effective dose to emergency workers should not exceed 10 rem, please explain how the continued use of 25 rem TEDE as a DBA acceptance value for advanced reactors will provide adequate protection for members of the public.

4. Given that the international atomic energy agency (IAEA) Publication GSG-8 (IAEA, 2018) recommends 2-10 rem for emergency exposure situations, and that the IAEA integrated regulatory review service (IRRS) mission to the United States of America conducted in October 2010 identified a concern[3] with the NRC's DBA acceptance criteria, please explain why the 25 rem criterion should be continued in a new rule for advanced reactors.

Background information:

The 25 rem TEDE value was derived from the original siting dose criteria in § 100.11, which specified a duel criteria of 25 rem whole body and 300 rem to the thyroid from iodine exposure. The 25 rem whole body dose criterion was based solely on the consideration of the direct dose from unshielded containments which were common for reactors sited in the 1950s and 1960s (see Technical Information Document (TID)-14844[4] Assumption 11[5]). As shown in Figure 1

[3] Quote from October 2010 IRRS mission, "Another issue related to the review and assessment is associated with determination and use of legally established criteria, in particular of the radiological acceptance criterion for design basis accidents, i.e. 250 mSv effective dose (in accordance with 10 CFR 50.67). This value is considerably higher than equivalent numbers currently used in many countries, even taking into account large conservatism embedded in demonstration of compliance with the criterion." IAEA-NS-IRRS-2010/02.

[4] TID-14844, "Calculation of Distance Factors for Power and Test Reactor Sites," USAEC, March 23, 1962. ADAMS Accession No. ML021720780.

[5] TID-14844, Assumption 11: "In determining the whole body direct gamma dose, only the external gamma dose due to the fission products contained in the reactor building was considered significant for the assumed conditions. The whole body direct gamma

from TID-14844, the only reactors for which the 25 rem whole body criterion controlled the siting evaluation were reactors with unshielded containments and power levels below approximately 300 megawatts thermal (MWth). Even for reactors with unshielded containments, the 300 rem thyroid criterion controlled the siting evaluation for reactors with power levels more than approximately 300 MWth. Therefore, for all modern reactors the 25 rem whole body dose criterion had no impact on the siting evaluation. All modern reactors were sited based on the restriction provided by meeting the 300 rem thyroid dose criterion. The rulemaking in 1996[6] did not adequately consider this important fact when technically questionable reasoning was used to convert the duel criteria of 25 rem whole body and 300 rem thyroid to a single 25 rem TEDE criterion with no organ dose limitation. This oversite allowed new reactors and existing reactors adopting § 50.67 Accident source term, to be sited and operated with accident dose criteria substantially less conservative than reactors sited in the earliest days of commercial nuclear power in the United States. In fact there are new reactor certified designs that will allow DBA thyroid dose values to exceed 500 rem[7]. This condition is further aggravated by the fact that DBA dose consequence analyses use adult dose coefficients. If the calculations were performed using child dose coefficients the thyroid dose could exceed 1,000 rem while still meeting the acceptance criterion of 25 rem TEDE. For comparison, the EPA recommendation for administering KI is a projected child thyroid dose of 5 rem. Although the Commission acknowledged that the TEDE criterion represented a relaxation relative to the §100.11 duel criteria, it is not clear that the Commission fully realized the significance of the relaxation.

Given that the §100.11 duel criteria were developed to reflect siting characteristics of the earliest reactors (circa 1960) and that the conversion to a single TEDE criterion represented a significant relaxation relative to the original siting criteria, the continued use of this non-conservative 25 rem TEDE criterion for advanced reactors is unjustifiable and is not an appropriate benchmark to define adequate protection of the public.

The following discussion points dispute the rational used in 61 FR 65157 to justify the 25 rem TEDE criterion:

Point 1: The assertion in 61 FR 65157 that the use of a single TEDE criterion is consistent with Part 20 is not correct.

The Rationale for Individual Criteria in 61 FR 65157 states that, “The proposed use of the total effective dose equivalent, or TEDE, was noted as being consistent with Part 20…” However the Part 20 occupational 5 rem TEDE annual dose limitation includes a limit of 50 rem for any organ. Some have noted that the 100 mrem TEDE value for annual exposure to the public does not include any organ dose considerations. However, the exclusion of an organ dose limitation is justifiable for the public dose annual limit of 100 mrem TEDE since any associated organ dose would be considerably less than that which could result in harm to an organ. This reasoning does not hold up with the significantly higher TEDE dose of 5 rem. That is why Part 20 specifies an organ dose limitation of 50 rem in addition to the 5 rem TEDE annual limitation. Therefore, the statement in 61 FR 65157 that, “The proposed use of the total effective dose

dose due to the cloud passage for the assumed conditions would contribute on the order of 1-10 percent of the total whole body direct gamma dose at the exclusion and low population zone distances.”

[6] 61 FR 65157 Reactor Site Criteria Including Seismic and Earthquake Engineering Criteria for Nuclear Power Plants, December 11, 1996.

[7] The AP1000 does not have active safety systems to reduce the post-accident iodine and particulate activity available for release due to design basis containment leakage. Therefor the source term released to the environment has a relatively high proportion of iodine which can result in a thyroid dose in excess of 500 rem when the TEDE dose approaches the acceptance criterion of 25 rem.

equivalent, or TEDE, was noted as being consistent with Part 20," is misleading and indicative of a cursory understanding of the radiation protection standards codified in Part 20.

The proposed rule (59 FR 52255) states the following concerning the use of a single TEDE criterion without an additional organ dose limitation:

> "Finally, because the thyroid weighting factor is equal to a value of 0.03, there exists a theoretical possibility that an accidental release composed only of iodine could result in a TEDE less than 25 rem, yet result in a thyroid dose of over 800 rem. Although the Commission believes that the likelihood that an actual accident would release only iodine is highly unlikely, comments are also requested as to whether the dose criterion should also include a "capping" limitation, that is, an additional requirement that the dose to any individual organ not be in excess of some fraction of the total."

The final rule (61 FR 65157) included the response to this request for comment as follows:

> "Based on the comments received, there was a general consensus that the use of the TEDE concept was appropriate, and a nearly unanimous opinion that no organ "capping" dose was required, since the TEDE concept provided the appropriate risk weighting for all body organs."

Since the only DBA off-site dose acceptance value challenging the nuclear industry at the time was showing compliance with the thyroid dose limitations in § 100.11, it is not surprising that the industry responded to this request by indicating that no organ "capping" dose should be included in the rule.

Point 2: The assertion in 61 FR 65157 that Part 20 permits a once-in-a-lifetime planned special dose of 25 rem TEDE is not correct.

The rationale in 61 FR 65167 states that, "In addition, in terms of occupational dose, Part 20 also permits a once-in-a-lifetime planned special dose of 25 rem TEDE." This statement is a gross misinterpretation of § 20.1206, Planned special exposures. There is nothing in Part 20 that allows a once-in-a-lifetime planned special exposure of 25 rem TEDE. Rather § 20.1206 allows for a maximum planned special exposure not to exceed 5 rem in any one year providing the total of the planned special exposures accumulated over the individual's lifetime does not exceed 25 rem. This rule specifies the conditions that must be met for a licensee to authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in § 20.1201. The rule is only intended for an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical. Before the planned special exposure occurs, the exposure must be authorized in writing. The individuals involved must be: (1) informed of the purpose of the operation, (2) informed of the estimated doses and associated risks, and (3) instructed in the measures to be taken to keep the dose as low as reasonably achievable. Planned special exposures are not authorized that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed (1) The numerical values of any of the dose limits in § 20.1201 [5 rem] (a) in any year; and (2) Five times the annual dose limits in § 20.1201 [25 rem] (a) during the individual's lifetime. Notwithstanding the incorrect representation of § 20.1206 in both the proposed rule (59 FR 52255) and the final rule (61 FR 65157), citing a rule intended for the control of occupational doses for radiation workers under exceptional situations as an implied justification for the use of 25 rem TEDE as a DBA acceptance value for members of the public is totally inappropriate and

should be a source of embarrassment to anyone charged with ensuring reasonable assurance of adequate protection for members of the public.

Point 3: The assertion in 61 FR 65157 that the 25 rem TEDE is essentially the same level of risk as the current criteria is not correct.

The rationale in 61 FR 65167 states that, “the Commission proposed to use 25 rem TEDE as the dose criterion for plant evaluation purposes since this value is essentially the same level of risk as the current criteria.” The proposed rule, Reactor Site Criteria…. (59 FR 52255) contains a discussion of the derivation of the 25 rem TEDE equivalency. The 25 rem dose to the whole body (WB) was equated to a latent cancer fatality risk of 0.025 based on the risk coefficient from BEIR V doubled for short term exposure ($5.0 \times 10^{-4} \times 2 = 0.001$ per rem); the 300 rem to the thyroid from iodine exposure was equated to a latent cancer fatality of 0.002. The Thyroid risk coefficient appears to be from NUREG/CR-2414 ((6.4 per 1,000,000) x 300) = 0.0019 rounded to 0.002). The individual risks were added for a total cancer risk of 0.027. Then a risk coefficient of 0.001 per rem was used to convert the total cancer risk back to a dose of 27 rem. This value was then rounded to the final 25 rem TEDE value which was incorrectly represented as being consistent with latent cancer fatality.

The analysis in 59 FR 52255 was somewhat circular. The 25 rem WB in § 100.11 was stated to correspond numerically to the 25 rem once-in-a-lifetime dose allowed to radiation workers by National Bureau of Standards (NBS) Handbook 69 dated June 1959. This handbook was based on the methodology of ICRP-2 for occupational exposure. ICRP-2 defines "permissible dose" as that dose, accumulated over a long period of time or resulting from a single exposure, which, in the light of present knowledge, carries a negligible probability of severe somatic or genetic injuries. NBS 69 was based on a non-stochastic somatic dose, not on stochastic latent cancer fatality. There was never any stated basis for the 300 rem thyroid dose however it certainly was not based on any consideration of latent cancer fatality. Converting deterministic dose values to latent cancer fatality risks, adding the risk numbers, and then converting back to dose is not good science.

The 25 rem whole body criterion in § 100.11 was based solely on considerations of the direct dose from unshielded containments and had no impact on the siting of any modern power reactor. If the Commission’s intention was to provide a TEDE value that had essentially the same level of risk as the current criteria, then a TEDE value should have been chosen that would limit the corresponding thyroid dose to approximately 300 rem. Given the Part 20 thyroid weighting factor of 0.03, a TEDE dose of 10 rem would limit the corresponding thyroid dose to approximately 300 rem.

Further, the analysis in 59 FR 52255 and the conclusions in 61 FR 65167 did not consider the significant increase in risk to dose sensitive members of the public from a given radiological exposure. There is readily available dosimetry data and radiogenic risk information that discredits the justifications in 61 FR 65167 when relating the 25 rem TEDE value to an equivalent criterion for members of the public (infants, children, women, and pregnant women). This information can be used to assess the relative increase in cancer mortality and morbidity risk to these dose sensitive members of the public.

This can be done by utilizing dose coefficients which contain the biokinetic and dosimetric models derived for a ‘family’ of individuals (e.g., infancy (100 days); 1, 5, 10, and 15 years; and maturity (usually 20 years, but 25 years in the biokinetic models for some elements) and risk coefficients for broader age-ranges to estimate radiation risk to human tissues from

exposure to radionuclides. The EPA Federal Guidance Reports (FGR) 12 and 13 contain the necessary dose and risk coefficients based on the Oak Ridge National Laboratory (ORNL) age-specific anatomical phantoms and biokinetic models. These coefficients consider gender dependence of intake, metabolism, and dosimetry based on ICRP Publications 56, 67, 69, 71, and 72. These selected biokinetic models describe the biological behavior (i.e., the time-dependent distribution, retention, and excretion) of radionuclides deposited in the human body through inhalation, ingestion, wounds, or injection. Using this information, one can clearly demonstrate the significant increase in risk to dose sensitive members of the public from a TEDE dose of 25 rem that is based on the assumptions in the "standard man model."

Point 4: Justifications in 61 FR 65157 for the use of 25 rem TEDE as a reference value for members of the public fail when compared to the 5 rem DBA acceptance criterion for the control room.

One such justification in 61 FR 65157 states that, "…the Commission's use of this value [25 rem] does not imply that it considers it to be an acceptable limit for an emergency dose to the public under accident conditions, but only that it represents a reference value to be used for evaluating plant features and site characteristics intended to mitigate the radiological consequences of accidents in order to provide assurance of low risk to the public under postulated accidents." The justification goes on to mention the conservative assumptions used in the dose analysis such as the large fission product release, maximum allowable containment leakage, the single failure criterion, adverse site atmospheric dispersion characteristics and assuming an individual located at the exclusion area boundary for a period of two hours without protective measures. If the off-site criterion were the only DBA acceptance criterion in the regulations these arguments may be somewhat defendable. However, the dose analysis to show compliance with the control room criterion of 5 rem TEDE adhere to the same conservative assumptions for the same accident scenario. Regarding the time duration of the assumed exposure, this aspect of the comparative analyses magnifies the discrepancy in the acceptance values. If the integrated doses are converted into a constant dose rate over the respective exposure times, the normalized control room dose rate would be less than 10 mrem per hour, whereas the equivalent dose rate at the exclusion area boundary would be 12.5 rem per hour.

The discussion in 61 FR 65157 states that, **"**Although the Commission recognizes that evaluation of the dose to a hypothetical individual over any two hour period may not be entirely consistent with the actions of an actual individual in an accident, the intent is to assure that the short-term dose to an individual will not be in excess of the acceptable value[8], even where there is some variability in the time that an individual might be located at the exclusion area boundary. In addition, the dose calculation should not be taken too literally with regard to the actions of a real individual, but rather is intended primarily as a means to evaluate the effectiveness of the plant design and site characteristics in mitigating postulated accidents."

Arguments justifying the use of 25 rem in regulation often explain that the accident dose guidelines and criteria are not dose limits to be applied during an actual event, but rather, criteria against which the robustness of the plant design can be evaluated. These arguments often refer to the wording in the accompanying footnotes such as footnote 7 in § 50.34 which states the following:

[8] There are some irregularities in 61 FR 65157 regarding the acceptability of the 25 rem value. The footnote in the regulation clearly states that the Commission does not consider this value as being an being acceptable yet here it is referred to as an acceptable value.

> *"A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, in order to assure that such designs provide assurance of low risk of public exposure to radiation, in the event of such accidents."*

Notwithstanding the fact that the citation from NBS Handbook 69 conflicts with § 20.1201 and refers to a whole body dose when the regulation is for TEDE, the footnote emphasizes that the value should be viewed as a reference value for the evaluation of plant design features and not as an acceptable limit for an emergency dose to the public under accident conditions. Indeed DBA dose calculations should be viewed as a means to evaluate the effectiveness of the plant design. Given that the calculations for off-site locations and for the control room use the same conservative assumptions and are evaluated for the same accident scenario, how is it that the control room design must meet a reference value one fifth the magnitude of the reference value for members of the public and for a time period that is 360 times as long as the 2-hour dose at the EAB? There is an obvious and significant disparity between the emphasis on adequate protection provided by the control room criterion and the lack of adequate protection provided for off-site individuals. Clearly, the Commission's DBA dose criteria and the resulting design of accident mitigation systems emphasize protection of the control room operator over protection of the public. In addition, the DBA dose acceptance values represent the only instance in the Commission's regulations where the acceptance value for members of the public is higher than the acceptance value for occupational workers. It should be noted that § 20.1207 Occupational dose limits for minors, acknowledges the age related radiosensitivity of individuals by limiting the occupational dose for minors to 10 percent of the annual dose limits specified for adult workers in § 20.1201. The fact that the radiosensitivity of members of the public has been disregarded in the NRCs DBA dose acceptance criteria should not be used as an excuse not to consider dose sensitive members of the public in a new rule for advanced reactors.

Conclusion:

The promulgation of a new rule for advanced reactors provides an opportune time to examine the NRCs DBA dose acceptance criteria. An objective examination should conclude that it is not advisable to continue the use of what is unquestionably a non-conservative value of 25 rem TEDE as an acceptance criterion for use in the siting and design of advanced reactors since this value does not provide adequate protection for members of the public.