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<u>FOR</u>: The Commissioners

<u>FROM</u>: Luis A. Reyes
Executive Director for Operations

<u>SUBJECT</u>: STATE-OF-THE-ART REACTOR CONSEQUENCE ANALYSES—REPORTING LATENT CANCER FATALITIES

<u>PURPOSE</u>:

The purpose of this paper is to provide the Commission with <u>a review of</u> the <u>technical and communication issues associated with the selection of an</u> ~~staff's~~ approach <u>to</u> ~~regarding the~~ reporting ~~of~~ estimated latent cancer fatalities (LCF) in state-of-the-art reactor consequence analyses (SOARCA) reports and to seek the Commission's <u>guidance on the</u> ~~approval to implement this approach~~<u>alternatives being considered by the staff</u>.

CONTACT: Randolph L. Sullivan, NSIR
301-415-1123

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BACKGROUND:

In Staff Requirements Memorandum–SECY-05-0233, "Plan for Developing State-of-the Art Reactor Consequence Analyses," (4/14/06) the Commission approved the staff's plan to develop the SOARCA. The plan states that the staff would use a range of dose thresholds (i.e., dose truncation values) including a linear nothreshold model (LNT) for reporting latent cancer fatalities~~consequences~~. ~~The staff believes~~Some of the NRC staff are concerned that the state of scientific information, calculation limitations, and risk communication issues posed by the presentation of consequence estimates to the public will make it difficult to communicate the significant improvements in our understanding of the phenomena, progression, and consequences attributable to a severe accident at a civilian nuclear power plant. ~~that SOARCA consequence results should include estimates of early fatalities and LCF to facilitate comparison with past analyses and that those estimates should serve to focus attention on optimum mitigative action preparedness. However, the staff is concerned that consequence estimates based on LNT place undue emphasis on the non-definitive health effects of low doses and consequently will present an inappropriate characterization of public risk from severe accidents.~~

Comment [evh1]: The staff decision to use a new metrics (5 rem truncation) willno facilitate comparison with past analysis. Rather, any comparison will be impossible because not all exposures will be considered.

~~In past analyses t~~The staff uses the MELCOR Accident Consequence Code System (MACCS) as part of SOARCA to ~~has~~ calculate offsite~~d~~ consequences at great distances (1000 miles). MACCS ~~and~~ uses~~d~~ the LNT dose-response model to estimate LCF consequences. Although the use of the LNT dose response model has been criticized as being too conservative and potentially overestimates the health consequences attributable to radiation exposure, several features and new data inputs have been implemented into SOARCA which drastically improves the realism and decreases the uncertainty in estimating latent cancer fatalities. For example, MACCS uses inputs from Federal Guidance Reports 11, 12, and 13 which apply state-of-the-art methods and models that take into account age and gender dependence of intake, metabolism, dosimetry, radiogenic risk, and competing causes of death in estimating the risks to health from internal or external exposure to radionuclides. Irrespective of these improvements, there remains a debate among the NRC staff and within the external scientific community regarding the actual relationship of consequences to dose at low dose levels (< 5 rem). This debate will continue because the scientific information needed to describe the health consequences attributable to these low radiation exposures is not available. In the absence of additional information, the International Commission on Radiological Protection (ICRP) the U.S. National Academy of Sciences, and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) have each indicated that the current scientific evidence is consistent with the hypothesis that there is a linear, nothreshold dose response relationship between exposure to ionizing radiation and the development of cancer in humans. This dose response relationship is incorporated into MACCS. Conversely, the French National Academy of Medicine advocates that there exists a dose threshold which must be exceeded before additional radiation exposure results in any incremental increase in adverse health consequences. Unfortunately, the French National Academy of Medicine is unable to articulate what exact value should be ascribed to this dose threshold.

Ultimately, external and internal exposure to members of the public are converted to collective dose and latent cancer fatalities. There is concern that the summation of hundreds to thousands of very small, almost trivial exposures (e.g., 10's μSv) ~~This technique~~ may inappropriately attribute LCF to individuals residing within 1,000 miles of the accident site. ~~gives equal importance to very low doses received by a large number of individuals and higher doses received by a few individuals. This approach indiscriminately adds highly uncertain and~~

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~~speculative health effect estimates to those from well established and accepted models based on higher doses.~~ While the possibility of ~~health effects~~latent cancer fatalities from very low doses can not be ruled out, it is considered an inappropriate use of these exposures~~they should not be treated in a manner that obscures health effects that are more predictable and that could inform the prioritization of protective measures.~~

Nevertheless, there remain the issues of assessing public exposure, estimating offsite consequences, and communicating these assessments to the public. Several organizations, such as the ICRP, have ~~Further, the staff believes that the use of LNT for severe accident consequence estimates is a misapplication of the concept of collective dose. The International Commission on Radiological Protection (ICRP)~~ addressed this issue. I~~in~~ its most recent 2007 ~~draft r~~recommendations (ICRP Report 103, in press~~currently in process for publication~~), the ICRP states:

> (161) Collective effective dose is an instrument for optimization, for comparing radiological technologies and protection procedures. Collective effective dose is not intended as a tool for epidemiological studies, and it is inappropriate to use it in risk projections. This is because of the assumptions that have to be made, e.g. when applying the LNT model, due to which the biological and statistical uncertainties involved are too great. Specifically, the computation of cancer deaths based on collective effective dose involving trivial exposures to large populations is not reasonable and should be avoided, such computations based on collective effective dose were never intended, are biologically and statistically very uncertain, presuppose a number of caveats that tend not to be repeated when estimates are quoted out of context, and are an incorrect use of this protection quantity.

In the absence of clear scientific evidence concerning health effects attributable to low dose radiation exposure, the staff sought other possible benchmarks up which to estimate latent health effects and exclude those effects that involve trivial exposures. In ICRP Report 104, Scope of Radiological Protection Control Measures (in press), the ICRP concludes that the radiation dose which is of no significance to individuals should be in the range of 20-100 μSv (2-10 mrem) per year. Similarly, the International Atomic Energy Agency (IAEA) has stated that an individual dose is likely to be regarded as trivial if it is of the order of some tens of microsieverts per year.

Alternately, t~~In addition~~ the U. S. Health Physics Society (HPS), in 1996, ~~has~~ developed a position paper, "Radiation Risk in Perspective," (revised August 2004~~8/04~~). This paper ~~, that~~ concludes that quantitative estimates of risk should be limited to individuals receiving a dose of 5 rem in one year or a lifetime dose of 10 rem, in addition to natural background, but that a range of possible outcomes should be discussed to include the possibility that the outcome might be zero. ~~The basis of the HPS position is consistent with the ICRP statement above.~~

From an epidemiological standpoint, i

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~~I~~In most, if not all cases, the LCF attributable to accidental releases from a severe accident would not be detectable above the normal rate of cancer fatalities in the exposed population (i.e., the excess cancer fatalities predicted are too few to allow the detection of a statistically significant difference in the cancer fatalities expected from other causes among the same population). However, in the past, consequence estimates from NRC studies based on collective dose were described in absolute terms (e.g., 2,700 LCF) without placing the consequence into a proper context or describing a range of possible consequences. This was not possible because a distinct, easily identifiable population at risk from radioactive material released from an accident site could not be ascertained with MACCS. ~~used without proper context to misrepresent risk to the public from severe accidents. The staff believes that even if the appropriate qualifiers and context are provided such consequence estimates would not foster effective risk communication because they are based on speculative low dose health effects and would divert focus from optimum mitigative action preparedness.~~ Briefly, the offsite consequence analysis is the summation of 1,-000 different computer runs each using a different set of meteorological situations that reflect seasonal variations of weather for a specific power plant. Consequently, there is no definitive, easily identified population that is exposed to the radioactive material released during an accident and no way to describe the background rate of cancer mortality or a range of health risks.

For the purpose of radiation protection regulation, the NRC uses a LNT model to estimate radiation-induced cancer and hereditary effects~~treats radiation-induced health effects stochastically~~. Accordingly, ~~In this treatment,~~ the likelihood of occurrence increases with each incremental increase in radiation exposure ~~with no threshold~~. The staff continues to support~~s~~ this ~~conservative~~ approach, as recommended by the ICRP, UNSCEAR, and National Academies, -for regulatory purposes. ~~and this paper does not attempt to identify a threshold for cancer induction or to propose changes to NRC regulatory philosophy (e.g., 10 CFR 50.36.a).~~ However, some members of the staff believe that ~~Instead,~~ the establishment of a dose threshold for reporting ~~consequence estimates~~LCFs is more appropriate because they believe that the use of a LNT dose response model yields ~~will focus public policy on more likely outcomes, rather than on~~ speculative LCF~~estimate associated with assigning risk from collective dose~~. These staff members believe~~s~~ that exclusion of small radiation exposures to members of the public (e.g., < 5 rem) ~~this~~ is appropriate because SOARCA is not a regulatory analysis, but rather an effort to model offsite health consequences more realistically ~~using risk communication techniques to facilitate a common understanding among stakeholders~~. Therefore, ~~the~~ some staff ~~believe~~believes~~s~~ that the use of collective dose and LNT for predicting LCF is neither appropriate nor required.

Another concern among some NRC staff is that the assessment of consequence analysis up to 1,000 miles from the accident site is detracting from the actual purpose of the SOARCA analysis. In general, the low dose contributions at great distances are similar for most of the accident scenarios, and thus are not sensitive to changes in accident mitigation strategies and emergency preparedness. Since one purpose of SOARCA is to inform consideration of optimum mitigative action preparedness, the debate on low dose consequence modeling may in fact distract from the consideration of useful information. Hence, truncation of either low dose or distance may be appropriate given the ultimate use of the analysis.

DISCUSSION:

In SECY-05-0233, the staff stated that the latent health effects analyses will cover a range of dose models with thresholds (truncation values of dose distribution) from 0 to 5 rem. However, some ~~the~~ staff became concerned that reporting a range of values has implications that do not

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necessarily contribute to effective ~~would not support~~ risk communication efforts, as it would provide many ~~answers~~ estimates of offsite health consequences for each scenario analyzed ~~and obscure focus on the optimum mitigative action preparedness~~. Thus, the staff has considered whether a single predictive approach would provide a better communication vehicle for the SOARCA results. The staff acknowledges that there is debate both amongst the staff and external to the NRC regarding what a "best estimate" would be for a particular dose distribution.

As discussed above, the LNT model provides a viewpoint that is consistent with the regulatory approach of the agency. This model has been previously used by the agency and is inherent within MACCS. That is to say, the MACCS use a LNT dose response model to calculate LCF. If there is a desire to compare future analysis with past results, continued use of the LNT model is necessary.

Some staff are concerned that the health consequence output yield large numbers of LCF as a result of summing very small exposures to large numbers of individuals. Furthermore, some staff are concerned about the possible difficulties of presenting large LCF estimates and the inability to present these consequences in context with the existing rates of cancer mortality among the exposed resident population. To address this concern, it has been proposed that exposures to the public could be truncated based on distance, some value less than 1,000 miles, or MACCS could estimate LCF using the LNT dose model and then exclude all LCFs attributable to exposure less than some predetermined dose (e.g., 5 rem).

Truncation based on distance could be viewed as aligning the analysis to existing regulatory requirements, such as emergency planning zones as described in Appendix E of 10 CFR Part 50. Truncation on dose or distance provides a significant advantage in that it allows the results of different mitigation strategies to be clearly demonstrated. The difficulties in communicating the estimate of offsite consequences is not intended to be a complete estimate of all possible consequences, but rather to assist in an understanding of the differences in sequences for various strategies. Unfortunately, many stakeholders will view dose or distance truncation as an opportunity to accuse the government of not providing complete information, and not being truthful about all the offsite health consequences.

The staff ~~identified~~ considered several options for presenting estimated LCF results and analyzed ~~three~~ four in some depth. Again, in all instances, LCF is estimated using a LNT model.~~:~~

(1) Use a range of dose thresholds (truncation values of the dose distribution), from 0 to 5 rem to assess LCF. This option was proposed to the Commission in SECY-05-0233. Under this option, several doses are selected (e.g., 0 rem, 0.1 rem, 3 rem, or 5 rem), below which all individual doses are excluded from further consideration. LCFs are only calculated for those individuals who received exposures that exceed the selected truncation dose.

This option offers the following advantages:

- It would not affect cost or schedule.
- ~~It is consistent with SECY 05 0233.~~
- It would include ~~multiple~~ the LNT risk models and multiple truncation ~~end~~ points.
- It is consistent with the draft 2007 ICRP recommendations in that ~~no single dose threshold is proposed~~ estimates are presented that do not rely on use of collective dose at low dose levels.
- The range of answers might be perceived as providing the most complete picture

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of information, as well as answers that could assist in understanding of the differences in consequences based on mitigation strategies.

- A zero threshold will allow comparison with previous offsite consequence analyses.
- ~~The range of answers would reflect uncertainty regarding dose effects.~~

The disadvantages of this option include the following:

- It includes estimates which aggregates~~s~~ collective dose calculated using ~~by including~~ trivial exposures to large population groups~~ thus obscuring focus on optimum mitigative action preparedness accident~~.
- The use of different thresholds for assessing LCF for the same scenario could be difficult for stakeholders to understand~~ and accept~~.
- It c~~w~~ould be poor for risk communication purposes because it would not necessarily facilitate common understanding by stakeholders and would invite selective misinterpretation in both the underestimation and possible overestimation of offsite health consequences.
- The results of a single analysis could be interpreted in various ways according to stakeholder view.
- ~~It would not facilitate the presentation of the staff's estimate of consequences.~~
- ~~It would not focus attention on optimum mitigative action preparedness~~

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(2) Use an LNT model to assess LCF.~~—~~

This option offers the following advantages:

- It would reduce cost and support the existing schedule.
- It would promote a common understanding among the stakeholders by providing a single consequence for each scenario analyzed.
- It is consistent with the models used in previous consequence analyses.
- It is consistent with the recommendations of the National Council on Radiation Protection and Measurement (NCRP) in Report 121, "Principles and Application of Collective Dose in Radiation Protection".
- It is consistent with analysis recommended by the U.S. National Academies of Science and employed by the World Health Organization.
- It is consistent with the Commission's policy for developing regulations to protect public health and safety.

The following are the disadvantages of this option:

- ~~It would require the staff to estimate potential LCF in individuals who have received doses below public and occupational worker limits.~~

- It ~~would~~ uses and estimate which ~~inappropriately~~ aggregates collective dose ~~by~~

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~~including~~calculated using trivial exposures to a large population which would be contrary to the statements of the ICRP and HPS that such calculations are inappropriate.

- The ICRP ~~and HPS~~ does not support the use of all collective dose ~~its use~~ for estimating LCF because it inappropriately incorporates all radiation exposure; ~~rather~~thus, it is considered a misapplication of the use of collective dose.
- ~~It would not represent the staff's realistic estimate for LCF.~~The LNT model and data inputs used in MACCS are not consistent with NRC regulations in that models and dose coefficients recommended by ICRP since 1990 have been incorporated into the health consequence analysis.

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- The current LNT model may underestimate LCF because low dose exposures are corrected by a conservative dose, dose rate effectiveness factor (DDREF) that may be appropriate for regulatory purposes, but may not be representative of actual health assessments. The National Academies recommends a smaller DDREF of 1.5 than is used by MACCS.

- The alternative does not recognize the uncertainties in this given area.

(3) Estimate the number of ~~detectable~~ LCF using a LNT model with single 5 rem per year, 10 rem lifetime ~~the t~~dose truncation value~~hresholds.~~ ~~proposed by the HPS~~

This option has the following advantages:

- It would reduce cost and support the existing schedule.
- It ~~c~~would ~~improve~~ promote a common understanding among stakeholders by providing a single consequence ~~number~~ for each scenario analyzed.
- ~~It is consistent with new (draft) ICRP recommendations which state that the computation of cancer deaths based on collective effective doses involving trivial exposures to large populations is not reasonable and should be avoided.~~

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- It ~~is~~ could be viewed as consistent with ICRP statements on the use of collective dose and the position of the HPS. ~~the official position statement of the Health Physics Society (HPS) entitled, "Radiation Risk in Perspective," (PS010-1, August 2004) which recommends not assessing risk below 5 rem per year or 10 rem lifetime exposures.~~
- ~~It avoids the issue of a threshold for LCF induction.~~
- It focuses policy attention where health effects may be more likely to ~~occur~~be observed~~.~~, and the area in which differences in scenarios occur.
- ~~It focuses attention on optimum mitigative action preparedness.~~

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This option has the following disadvantages:

- It is not consistent with SECY 05-0233 or the previous practice of using LNT to estimate LCF, hence comparison of offsite consequences with previous studies will not be possible.

- It is not consistent with NCRP recommendations using collective dose to assess latent health effects (NCRP Report 121) because it uses a single dose (i.e., 5 rem) to truncate collective effective dose calculation.

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- This alternative may be perceived as advocating a threshold for LCF induction, even though it is intended only to facilitate the presentation of the most meaningful offsite consequences.
- Most of the collective dose is excluded from consideration. Few, if any, health effects will be observed beyond the 50 mile emergency planning zone for the ingestion pathway, hence, this alternative may be perceived as not providing "complete" information.
- The truncation of dose results in a step function whereby exposure to 4.9 rem per year or 9.95 rem per lifetime is considered safe, but small increments above these values are unsafe.
- The alternative does not recognize the uncertainties in this given area.

(4) Estimate the number of LCF using a LNT model with single 10 mrem per year dose truncation value. The ICRP in Report 104, Scope of Radiological Protection Control Measures, observed that an individual radiation dose is likely to be regarded as trivial if it is of the order of some tens of microsieverts per year. Similarly, the International Atomic Energy Agency observed that the level of trivial effective dose equivalent would be in the range of 10 to 100 μSv (1 to 10 mrem) per year.

This option has the following advantages:

- It would reduce cost and support the existing schedule.
- It could promote a common understanding among stakeholders by providing a single consequence for each scenario analyzed.
- It is consistent with new (draft) ICRP recommendations which state that the computation of cancer deaths based on collective effective doses involving trivial exposures to large populations is not reasonable and should be avoided.
- It could be viewed as consistent with ICRP and IAEA statements on use of trivial exposures.
- It focuses policy attention where health effects may be more likely to be observed, and the area in which differences in scenarios occur.

This option has the following disadvantages:

- It is not consistent with SECY 05-0233 or the previous practice of using LNT to estimate LCF, hence comparison of offsite consequences with previous studies will not be possible.
- It is not consistent with NCRP recommendations using collective dose to assess latent health effects (NCRP Report 121) because it uses a single dose (i.e., 10 mrem) to truncate collective effective dose calculation.
- It is not consistent with the HPS position that health effects attributable to radiation exposure should not be considered below 5 rem in a year.
- A significant amount of the collective dose is excluded from consideration.
- The truncation of dose results in a step function whereby exposure to 10 mrem per year is considered safe, but small increments above these values are unsafe.

CONCLUSION~~The staff considered the use of expert elicitation panels for determination of a cancer induction threshold and the dose threshold for detectable LCF. The staff did not pursue these methods as they were not likely to resolve the issue, could not support the schedule and the reporting of SOARCA results do not require determination of a cancer induction threshold.~~

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~~RECOMMENDATION~~:

~~The staff recommends that the Commission approve the following as the staff's approach for communicating SOARCA LCF results:~~
The inputs into the MACCS model have vastly improved the estimate of latent health effects and reflect a more realistic estimate of the deposition of radioactive material and the associated dose received from radioactive materials.

For the purpose of radiation protection regulation, the NRC uses a LNT model to estimate radiation-induced cancer and hereditary effects. The staff continues to support this approach for regulatory purposes. However, the staff is divided on how to best estimate latent cancer fatalities after exposure to low doses of ionizing radiation. Some staff members believe that the establishment of a dose threshold for reporting LCFs is more appropriate because they believe that the use of a LNT dose response model significantly overestimates the number of LCF. These staff members believe that exclusion of small radiation exposures to members of the public (e.g., < 5 rem) is appropriate because SOARCA is not a regulatory analysis, but rather an effort to model offsite health consequences more realistically. Therefore, some staff believes that the use of collective dose and LNT for predicting LCF is neither appropriate nor required. ~~The staff believes that using the HPS dose threshold (option 3) for estimation of health risk provides the best approach for reporting SOARCA results. This is consistent with the SOARCA strategy of using "best estimate" analyses to identify likely consequences. Further it would focus attention on optimum mitigative action preparedness. This approach~~

The staff recognizes that a calculation of LCF using all doses will be done, if not by ourselves, and that significant resources may need to be expended in an attempt to explain what is being provided, and why this is the most appropriate presentation. The staff will have to make clear that the presentation is not a complete estimate of LCF, but rather a tool to facilitate understanding and decision making. The staff also recognizes that the selected value is not supported by any specific scientific information regarding the induction of cancer. Where the ~~would also facilitate risk communication by fostering a common understanding of the staff's estimate of potential severe accident consequences. The staff also believes that this approach comports with the Commission's use of LNT for regulatory processes because the usage here is only for the purposes of reporting analysis results. Where the threshold~~ dose truncation is used in final SOARCA report, a discussion of the reasoning behind the ~~threshold~~ value selected would be included.

Note that in the October 1, 2007, Commissioner Technical Assistant briefing, the SOARCA project team reported initial results using ~~the HPS thresholda~~ a 5 rem in a year, 10 rem lifetime truncation dose. These results reflect only one of the alternatives describe herein. T~~However,~~ the staff is prepared to modify analyses in accordance with any additional Commission direction.

RESOURCES:

The activities described in this paper were anticipated by the SOARCA project and the resources needed to support this effort are budgeted.

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COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

Luis A. Reyes
Executive Director
for Operations

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