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DISCLAIMER

Physiological Basis for Prompt Health Effects

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Abstract

As input to design considerations precluding worker radiological exposure that could lead to an acute health effect from a postulated accident condition, an assessment of the short term health effects was performed. To assure that the impact of the accident scenario on the individual is appropriately considered, both external and internal exposures are included in the evaluation. The focus of this evaluation was to develop a quantitative basis from which to consider the level of exposure postulated in an accident that could lead to a defined physiological impact for short term health effects. This paper does not assess latent health effects of radiological exposure associated with normal operations or emergency response guidelines as these are clearly articulated in existing regulations and ICRP documents. The intent of this paper is to facilitate a dialogue on the appropriate meaning of currently undefined terms such as "significant" exposure and "high-hazard material" in DSA development.

Purpose

The purpose of this paper is to develop a physiological basis from which to better guide those interpreting the intent of a "significant" exposure as used in DOE-STD-3009, CN3[i] for hazard analysis and "high hazard materials" as used in DOE-G-420.1-2[ii]. Specifically, the parameters of interest are those that would lead to selection of safety significant controls for worker protection and to define "high hazard materials" associated with considering PC-3 design for confinement of those materials. Although the requirements for selecting safety significant controls for worker protection are based on qualitative judgments, definitive values are appropriate from which to guide use of these terms. Significant exposure for example is considered between a few millirem to $LD_{50/30}$, depending on the individual and site questioned. Obviously, neither extreme is appropriate. Therefore, guidance is needed to achieve a measure of consistency across a large site, such as Savannah River, Hanford, or Nevada, and across the complex. The values developed should be considered as input to an "informed qualitative" decision making process and not as threshold values that require detailed analysis or as values not to be challenged. However, it is recognized that in the process of assessing consequences to the public for the various accident scenarios, it is often cost effective to analytically assess the potential consequences to co-located workers that are not in the immediate area of the hazard.

As the DOE standards, guides, orders, and rules are silent on the meaning of a "significant" exposure as used in DOE-STD-3009, CN3 or in defining "high hazard material" as used in DOE-G-420.1-2 interpretations vary significantly across the complex and between contractors, regulators, DNFSB, OA, etc. The intent of this paper is to lay the groundwork for a meaningful dialogue on the meaning of these terms and rather than an emotionally based "more or less conservative" argument. To begin the discussion this paper provides physiological data that may be used to frame the discussion and, as a minimum, should be used as a benchmark against which the discussion proceeds.

Whether specifically analyzed or assessed on a purely qualitative basis, the values developed in this paper provide a physiological basis guiding interpretation of "significant" exposure and "high-hazard materials."

This paper does not address radiological exposure associated with normal operations or emergency response guidelines, as these are clearly articulated in existing regulations. The focus is only on the criteria associated with accident conditions and the associated parameters that should drive specific design requirements for the more significant events. This paper therefore discusses the existing DOE guidance and implementation, assesses the physiological basis of various levels of significant radiological exposure, and the appropriate measures to assess potential prompt health effects. Based on these considerations, parameters that are associated with "significant" exposure and "high-hazard material" are presented as a means to initiate the dialogue to appropriately define these terms.

DOE Guidance:

DOE-STD-3009, CN2[i], "Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analysis" states:

> *As a general rule of thumb, safety-significant SSC designations based on worker safety are limited to those systems, structures, or components whose failure is estimated to result in a prompt worker fatality or serious injuries or significant radiological or chemical exposures to workers. The term, serious injuries, as used in this definition, refers to medical treatment for immediately life-threatening or permanently disabling injuries (e.g., loss of eye, loss of limb).*
>
> *The general rule of thumb cited above is neither an evaluation guideline nor a quantitative criterion. It represents a lower threshold of concern for which safety-significant SSC designation may be warranted. Estimates of worker consequences for the purpose of safety-significant SSC designation are not intended to require detailed analytical modeling. Considerations should be based on engineering judgment of possible effects and the potential added value of safety-significant SSC designation.*

DOE-STD-1021-2002[iii], "Natural Phenomena Hazards Performance Categorization Guidelines for Structures, Systems, and Components" provides:

> Figure 2-1 "Basic Guidelines for Preliminary NPH Performance Categorization of Structures, Systems, and Components" links SSCs required to function for the NPH events that have been functionally classified as safety significant to PC-2 and SSCs that have been functionally classified as safety class to PC-3.

DOE-G-420.1-2[ii], "Guide for the Mitigation of Natural Phenomena Hazards for DOE Nuclear Facilities and Nonnuclear Facilities" states:

> *When safety analyses determine that local confinement of high-hazard materials is required for worker safety, PC-3 designation may be appropriate for the SSCs involved. PC-3 NPH provisions are consistent with those used for reevaluation of commercial plutonium facilities with conservatism in between that of model building code requirements for essential facilities and civilian nuclear power plant requirements.*

Title 10 of the Code of Federal Regulations, Part 835 (10CFR835[iv]) in addition to prescribing the application of the ALARA occupational exposure process, provides the following exposure criteria:

> *The design objectives for exposure rates for potential exposure to a radiological worker where occupancy differs from the above shall be ALARA and shall not exceed 20 percent of the applicable standards in §835.202.*
>
> 835.202 Occupational dose limits for general employees.
>
> (a) Except for planned special exposures conducted consistent with §835.204 and emergency exposures authorized in accordance with §835.1302, the occupational dose received by general employees shall be controlled such that the following limits are not exceeded in a year:
>
> (1) A total effective dose equivalent of 5 rems (0.05 sievert);
>
> (2) The sum of the deep dose equivalent for external exposures and the committed dose equivalent to any organ or tissue other than the lens of the eye of 50 rems (0.5 sievert);
>
> (3) A lens of the eye dose equivalent of 15 rems (0.15 sievert); and
>
> (4) A shallow dose equivalent of 50 rems (0.5 sievert) to the skin or to any extremity.
>
> (b) All occupational doses received during the current year, except doses resulting from planned special exposures conducted in compliance with §835.204 and emergency exposures authorized in accordance with §835.1302, shall be included when demonstrating compliance with §§835.202(a) and 835.207.

> (c) Doses from background, therapeutic and diagnostic medical radiation, and participation as a subject in medical research programs shall not be included in dose records or in the assessment of compliance with the occupational dose limits.

Implementation of DOE Guidance:

Safety Significant controls are chosen to protect workers from postulated accident scenarios which could cause prompt significant health effects to those workers (fatality or serious injury) or which could lead to a significant radiological or chemical exposure to those workers. Prior to DOE-STD-3009, CN2, the standard included a statement that the safety significant control consideration did not include latent health effects such as cancers.

> *It specifically excludes potential latent effects (e.g., potential carcinogenic effects of radiological exposure or uptake.*

Deletion of this statement muddied the water as to what a "significant" exposure was. Since latent health effects come into play, in addition to prompt health effects which is the focus of this paper, latent health effects must be considered in control selection. The international community has developed standards for latent health effects. The ICRP limitations for annual exposure is the standard that is generally accepted as appropriately limiting worker's risk of developing latent health effects for annual exposures of 2 rem TEDE. For some radionuclides that have long biological clearance times, the result of the exposure from the postulated accident is essentially the same as an annual exposure each year over the life of the individual. Thus, a worker exposed to 100 rem TEDE would essentially be receiving a dose of 2 rem each year. As noted later in this paper, there are issues with this comparison. These issues are shown in recent studies of exposed workers from the early days of the weapons program. These workers have significantly higher committed doses from early uptakes of radionuclides with long biological clearance times, but do not show any deleterious effects from this continued exposure. A second issue is that this same 100 rem TEDE exposure for a radionuclide with a short (for this example assume less than 1 year) biological clearance time would have a more significant prompt health impact, which could include prompt health effects (although some of these may require medical treatment, they would not lead to near term death). However, when assessed using the TEDE measure, both of these exposures are identical.

Another benchmark is the emergency response programs both within DOE and the commercial nuclear reactors program that permit emergency workers involved in lifesaving activities to receive over 25 rem exposure to perform the task. Most current programs do not define an upper limit, however, several identified 75 rem as the limit for this lifesaving task. Note that this exposure would primarily be a prompt exposure and not be spread over 50 years. It is expected that PPE would be worn to perform the task.

Another look at a significant exposure would be the level of exposure warranting special attention because it could result in immediate health effects rather than those lower level exposures that may lead to latent health effects such as an increased risk of developing cancer. In general the focus is on accident scenarios of lower frequency events. Normal

operational exposures are protected by 10CFR835 exposure design and operational limits, as well as the associated ALARA requirements. Additionally, the emergency response requirements for these facilities as driven by DOE-O-451.1C[v] and it associated guide[vi] provide additional measures assuring that exposures to workers in the event of an accident are much less than the values used for selecting safety significant controls and determining the need for designing at the PC-3 NPH level.

Recognizing the DOE-STD-3009[i] guidance, which states that estimates of worker consequences for the purpose of safety significant SSC designation are not intended to require detailed analytical modeling and that considerations should be based on engineering judgment of possible effects and the potential added value of safety significant SSC designation, the values presented must be placed in context. The lack of specificity in defining the need for safety significant protection for workers or requiring PC-3 design for confinement of hazardous material can lead to inconsistencies across the complex or between facilities at a single site. This condition leads to the associated implementation challenges and questions from external agencies such as the OA or DNFSB. Thus, the values developed herein are intended to be a guide for making an informed qualitative decision on the need for controls or the need to elevate the NPH design requirements for confinement of hazardous materials.

Restated, the functional classification process and the selection of NPH higher performance categories is to guide selection of SSCs and design criteria which can provide assurance that workers will be protected from the more significant postulated accident scenarios and is not intended to define acceptable or expected worker exposures. Additionally, since appropriate conservatism is built into the values selected, they can be used as threshold or trigger points, rather than values that should not be challenged or for which one must be well below.

Levels of Exposure:

To properly evaluate worker risk in a postulated accident scenario, the actual physiological response to a postulated level of radiological exposure should be a basis of the evaluation. It is recognized that the physiological response is not exact; exposure at just above a decision threshold value does not automatically assure that the individual would suffer the identified impacts. It is important to note that the data which forms that basis for projected physiological responses are for the general population, including healthy adults, children, the aged, and the infirm and not on the less susceptible healthy adult DOE worker. However, little formal consideration is generally given to the *in utero* period, with exception of a declared pregnancy.

These values have been conservatively evaluated and the response to the "insult" to the body due to the radiological exposure is unique to the individual based on an evaluation of a range of documents assessing radiological consequences, of which the key references are presented in the Reference section of this paper [vii,viii,ix,x,xi,xii]. It is recognized that other dose values have been reported in the literature. The values chosen in this evaluation, based on a crosscutting evaluation of the open literature, appear to represent a general consensus within the Health Physics community. Note that the personnel of concern at a DOE site are the

normal healthy worker population. To the extent that the data developed in clinical studies looks at the general population, an additional level of conservatism is provided for the selected trip points.

It is recognized that prompt exposure is more appropriately evaluated in terms of absorbed dose, expressed in rad or gray, rather than dose equivalent (or equivalent dose) expressed in rem or sievert. It is also recognized that the use of dose equivalent (here after referred to as equivalent dose) is based on considerations of increased risk of latent health effects. As the majority of the accident scenarios involved in DOE facilities are associated with airborne releases of radiological material, the dose is made up of an external irradiation from the airborne material and the internal irradiation from intake of material by the exposed individual. Internal dose consequences are assessed by the health physics community based on impact to the affected organs on a radionuclide by radionuclide basis. Recent literature[xii] which assesses the potential prompt health effects of an internal exposure indeally based on the absorbed dose to the individual organs and to some extent the effective dose (E). It is recognized that this approach provides a more accurate assessment of a postulated accident, however approved accident assessment tools, such as MACCS[xiii], are limited to equivalent dose (rem or sievert). Thus, the conservative approach provided herein has been selected as an appropriate tool for selecting safety significant controls and for enhancing the design for more significant accident scenarios. Additionally, the values provided in this assessment do not account for intervention by health officials in reducing the actual dose that an individual could receive from an uptake of radiological material.

It is recognized that a few radionuclides may result in organ equivalent doses much greater than the effective dose. However, in general these radionuclides (e.g., Iodine) are not of significant concern for non reactor DOE accident scenarios. Additionally, by selecting appropriately conservative dose limits and methodologies, differences in potential permanent health effect dose considerations can be accounted for or minimized.

Table 1 presents the radiological exposure range and the associated potential physiological response to that level of exposure for the postulated DOE worker.

Table 1: Physiological Response vs. Radiological Dose (Healthy Adults).

Identifier	Prompt Exposure Level (rem)	Physiological Response Description
A	$0 \leq \text{Dose} \leq 25$	Below level of detectable blood chemistry changes
B	$25 < \text{Dose} \leq 100$	Range of detectable physiological response (beginning of blood chemistry changes)
C	$100 < \text{Dose} \leq 300$	Range of immediate physiological response, but below level of life threatening conditions (Note that below 200 rem people in general do not immediately become sick or feel ill.[x])
D	$300 > \text{Dose}$	Onset of life threatening physiological damage
E	$450 \approx \text{Dose}$	LD-50 designation (50 percent of people exposed at this level would die within 30 days)[ix]

TEDE vs One Year Effective Dose Equivalent[*]:

The data on physiological response has been derived from evaluating subject responses to a prompt dose. Many of the current guidelines for radiological response to an exposure (direct prompt exposure or long term exposure due to an intake of the radionuclide) are based on the calculated total dose that the individual may receive during his working lifetime. This is typically designated as TEDE (Total Effective Dose Equivalent).

> *TEDE: Total Effective Dose Equivalent (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).*[xiv]

TEDE was developed to provide a long term risk evaluation tool to gauge the risk or dose to an individual resulting from an exposure and attributes the dose to the year of the event. As the primary focus of these considerations was establishing regulatory acceptance limits and determining exposure levels that increase the recipient's risk of latent stochastic health effects (such as cancers), TEDE provided a reasonable mechanism for assessing the stochastic risk and establishing regulatory limits and action levels. Additionally, within this regulatory framework, assigning the total dose in the year of exposure eliminated the cumbersome task of keeping up with an individual's past internal exposures in order to track the exposure that the individual received in the current year (previously identified as AEDE or annual effective dose equivalent). It is noted however that this later issue is associated with tracking actual exposures to an individual and is not of concern in postulated accident

[*] One year effective dose equivalent (EDE-1) is defined as the sum of the external dose from the accident and the internal dose assessed at one year from the incident.

analysis and in determining exposures that should lead to specific design solutions or enhanced protective actions in the facility safety basis.

However, in assessing accident scenarios for DSAs or the potential short term health effects from a postulated accident scenario, TEDE may not be a useful measure of the immediate physiological response of the exposed individual since it is formulated to address latent health effects for chronic exposures such as normal work activities (and anticipated off normal conditions), included radiation weighting factors (quality factors) based on latent health effects, and it ignores dose and dose rate effects. The physiological response of an individual exposed to a radionuclide with a long biological clearance time from an internal exposure will be different from an individual that receives the same effective dose from a prompt exposure. Additionally, as noted in the previous section whole-body equivalent dose does not accurately account for the potential impact from an intake to each affected organ. Therefore, past attempts to establish appropriate accident scenario dose limits for defining the need for safety significant equipment have met with difficulty. For example an individual that is postulated to receive a 100 rem TEDE exposure to a radionuclide with a long biological clearance time will have a significantly different physiological response than the same individual receiving a 100 rem exposure either as an acute external exposure or the intake of a radionuclide with a short biological clearance time. Those radionuclides with a short biological clearance time results in a response that is more characteristic of a prompt dose than a radionuclide with a long biological clearance time, which essentially provides a slowly declining annual dose for the lifetime of the individual. Thus, the same TEDE level of exposure from the quickly clearing radionuclide would have a more significant physiological insult to the body than one in which the exposure was spread over many years. As such, an internal exposure of a long lived radionuclide measured as a TEDE significantly overstates the potential immediate health consequences and forces an alternative approach to determine an appropriate basis from which to assess these potential health effects.

As the focus of selecting safety significant controls for worker protection is based on significant exposures, includes exposures which could cause an immediate consequence to workers, TEDE does not provide a useful measure from all radionuclides. The reason for the difference in health effects has not been completely explained, but impairment of organ function (early deterministic effects) are believed to arise when the body's repair mechanisms can not response to the rate that damage occurs. As such, a limited time measure is more appropriate than the 50 year integrated dose provided by the TEDE measure in assessing these immediate health effects. Since a prompt dose from an uptake of a radionuclide does not have a clear definition, it is important to select a conservative, yet physiologically meaningful measure. As such the, One Year Effective Dose Equivalent (EDE-1) is recommended as an appropriate measure. A clinical response evaluation to significant radiological exposure is typically assessed in terms of days and weeks (to a few months) and not in years.[xv] Thus, the one year dose evaluated as a prompt dose provides a conservative, yet meaningful measure when assessing the physiological response to an exposure to radiation or radiological material. The values selected as trigger points have therefore been compared to limiting organ doses to prevent severe deterministic health effects from an acute intake of radioactive material[xii].

It is important to note that this consideration is only for determining significant exposure and determining when more robust design measures are appropriate for actual worker protection and not appropriate for defining regulatory acceptance levels for worker exposures. No form of the TEDE should be used in any retrospective evaluation of a significant radiological exposure (e.g., doses beyond the normal regulatory limits). Selection of safety significant controls is just one part of an overall protection posture within the DOE regulations to assure appropriate protection for workers, the public, and the environment. For example the emergency response requirements establish the protective actions needed in response to an off normal condition within the facility. Additionally, these credited controls are the top level of an overall defense in depth safety position for DOE non-reactor nuclear facilities.

Significant Exposure and High-Hazard Material Considerations

Two definitions are appropriate to address the two terms that are promulgated within DOE regulations. First is the DOE-STD-3009[i] term used to determine when safety significant controls are warranted – significant exposure. Second is the guidance that NPH PC-3 designation may be appropriate when safety analyses determine that local confinement of "high-hazard materials" is required for worker safety. As the second definition is obviously an additional level of robustness above that which would be required to just meet the DOE-STD-3009 significant control requirement, it is appropriate that the two levels be different. In both cases, it is appropriate to assess the appropriate physiological response to the radiological exposure and then select a dose value that corresponds to that level of biological response for the typical DOE facility worker.

The level of prompt exposure (whole body irradiation) at which blood chemistry changes can be easily measured is between 25 rem and 100 rem and the onset of prompt health effects is between 100 rem and 300 rem. These values provide an appropriate starting point for considering the definition of a significant exposure that is not associated with long term or latent health consequences. As such, the lowest definition of such an exposure would be 25 rem EDE-1 and the lowest definition for a dose consequence that would align with high-hazard materials warranting additional NPH robustness would be 100 rem EDE-1.

One could argue easily that since the prompt health affects do not begin until approximately 100 rem prompt whole body or effective dose that this is a better measure of significance. However, rather than use terms such as "not challenging" or "much less than" in assessing dose consequences, implementation will be more effectively and consistently applied if the measure is to not exceed 25 rem EDE-1 for determining significance when evaluating design decisions.

Likewise, one could argue that since the onset of life threatening conditions due to prompt radiological exposure is 300 rem, this level of exposure poses a more appropriate measure for warranting PC-3 design for confinement of high-hazard materials. However, using the same philosophy as in selecting safety significant controls above, using 100 rem EDE-1 as a threshold value leaves an appropriate measure of conservatism between the onset of immediate (non-life threatening) health effects and life threatening exposures.

Additionally, by using the dose consequence at EDE-1 significant conservatism is built in to the dose assessment. The immediate health affects ranges were established based on prompt exposures (exposures that occurred in the range of an hour) and thus integrating the total dose over a year and treating it as a prompt exposure does not account for medial intervention or for the body's natural defense mechanisms to accommodate the exposure. Therefore the approach is clearly very conservative.

These values should be used by the DOE community as the starting point for a dialogue on definitions in informing the qualitative control selection process within safety analysis, design, and functional classification of safety equipment for worker protection. It is important to repeat that these values are not considered acceptable doses nor permitted doses. They are only dose levels that warrant significant additional measures beyond that which is driven by 10CFR835 worker exposure levels for emergency response actions.

Conclusion

Without specificity in the meaning or intent of "significant exposure" or "high hazard material" the DOE community will continue to be second guessed and the cost of operating our facilities will continue to escalate. Healthy dialogue on these two terms should be sought and the outcome captured within the DOE directives system.

Acronyms/Definitions:

ALARA	As Low As Reasonably Achievable
DNFSB	Defense Nuclear Facility Safety Board
$LD_{50/30}$	Radiological dose that is expected to be lethal to 50 percent of the exposed population within 30 days
NPH	Natural Phenomena Hazard
OA	DOE Office of Assessment
PC	Performance Category for NPH design
SSC	Structure, System, and Component
TEDE	Total Effective Dose Equivalent or the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (50 year committed dose for internal exposures)
EDE-1	One year effective dose equivalent (EDE-1) is defined as the sum of the deep-dose equivalent for external radiation from the accident and the internal dose assessed at one year from the incident

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