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# EPA PERSPECTIVE ON INDIVIDUAL PROTECTION APPROACHES FOR 40 CFR PART 197

Kenneth Czyscinski, U.S. Environmental Protection Agency (EPA)/Radiation Protection Division; 501 Third Street NW, Washington, D.C. 20460
John Bartlett, Sandy Cohen & Associates, 6858 Old Dominion Drive, Suite 301, McLean, Va 22101

## ABSTRACT

In the process of developing site-specific standards for the Yucca Mountain geologic repository, the EPA examined two alternate approaches for framing the individual radiation protection standard. One alternative, the Critical Group approach, focuses on a dispersed group of individuals as the exposed population for regulatory compliance assessments. The other approach uses a hypothetical representative individual for the dose assessments. In examining these alternatives for the site-specific conditions of the Yucca Mountain, Nevada, candidate repository site, the Agency evaluated them in terms of: (1) consistency with site-specific information; (2) most direct application of a "cautious but reasonable" approach to framing the standard, and (3) the approach that would minimize regulatory ambiguity relative to implementing the intent of the standard. The Agency determined that the representative individual approach offered the best application for the considerations listed, and defined the representative individual as the "Reasonably Maximally Exposed Individual" in the final standards for the Yucca Mountain site.

## INTRODUCTION

The Energy Policy Act of 1992 (1) directed EPA to develop site-specific radiation protection standards for the candidate Yucca Mountain repository, with specific reference to establishing an individual radiation exposure limit. In developing the exposure limits and performing dose assessments, two basic approaches have been used in radioactive waste disposal applications as well as site-specific assessments for the Yucca Mountain site, one approach involves characterizing an exposed group of individuals (commonly called a Critical Group). In contrast, the other approach involves defining a representative individual for the dose assessments. Both of these approaches were examined by the Agency during the standards development process in terms of; (1) consistency with site-specific information; (2) a "cautious but reasonable" approach to radiation protection and; (3) minimizing regulatory ambiguity for implementation. The considerations examined during the process of developing the standards are discussed below.

The proposed and final rules (2, 3) define a representative individual, called the Reasonably Maximally Exposed Individual (RMEI) as the receptor for dose assessments. The RMEI is characterized as a rural residential person with lifestyle and dietary parameters consistent with the current residents in the town of Amargosa Valley. The RMEI approach offers the best combination of consistency with site-specific information, a "cautious but reasonable" approach to radiation protection, and unambiguous implementation for regulatory purposes.

## CRITICAL GROUP AND REPRESENTATIVE INDIVIDUAL CHARACTERISTICS

In a generic sense, the Critical Group (CG) is typically described as representative of those individuals in a larger population who are expected to receive the highest dose equivalent from a specific source of radiation exposure. The CG should be small in number (tens to hundreds of people) and relatively homogeneous in terms of the characteristics that determine the actual dose levels, so that there is not a wide disparity between the doses to individual group members. In contrast, the representative individual approach defines a hypothetical individual for dose assessments, whose characteristics are determined by consideration of various factors for an actual population, such as food consumption patterns. To assure that the representative individual represents a high-end exposure level, the values of one or more of the parameters known to contribute heavily to the total dose are set to high-end values. These choices could be made to define a "maximally exposed" individual, or in the site-specific application discussed here a "reasonably maximally exposed" individual (RMEI). Both the CG and representative individual approaches can be considered as conservative estimates of expected exposure levels since the choices made for parameter values in both approaches are intended to bias dose assessments toward the high-end of exposure estimates.

The CG approach involves potentially more variation in dose values, since multiple individuals are involved. Since a group is involved, some degree of variation in the location of the exposed individuals can be justified which may give additional variations in estimated doses, adding another source of variance to the group characterization which already must consider diverse lifestyles in a population and the consequent pathway variations. The number and distribution of individuals in a CG can be defined any number of ways, some of which could be quite arbitrary and potentially not consistent with actual conditions at a specific site. In contrast, the representative individual approach would show less variation since only a single hypothetical individual is involved in the assessments at a fixed location where the dose assessments are made, and one or more of the dominating parameter values are fixed to high-end values with the remainder set to mean values derived from surveys of the local population (3). Variations in dose estimates for the representative individual as well as the CG also reflect variations in the contamination levels within the ground water, as a function of repository releases and radionuclide retardation along the transport paths to the downgradient receptors. In a particular site-specific application, parameter value choices can be made such that the actual doses estimates for either approach would give very similar results. The challenge lies in selecting a "cautious but reasonable" approach consistent with site-specific information and the characteristics of assumed releases from the repository projected in the downgradient direction.

Both the CG and representative individual approaches are accepted methods used in dose assessments for radioactive waste management and disposal activities. The CG approach has been examined by international radiation protection authorities (4), and incorporated into radioactive waste programs abroad (5). The representative individual approach has been used in other Agency standards for geologic disposal of radioactive wastes (6, 7). The CG approach is attractive when a specific population of exposed, or potentially exposed, individuals can be

identified for a specific contamination source, such as a population exposed from an ongoing industrial activity generating contamination or an existing waste disposal site. For the geologic repository application where projections of exposures are made for times in the distant future (thousands of years), defining an actual exposed population is speculative and potentially contentious in a regulatory decision making process. For this application, there is potential overlap between the two approaches in that a CG approach could be distilled into a hypothetical individual whose characteristics are defined to be representative of a hypothesized future exposed population (8, 9, 10), for convenience or for the case where a critical group is difficult or impossible to define concretely.

## REGULATORY CONCERNS IN SELECTING AN APPROACH FOR DOSE ASSESSMENTS

For geologic disposal of radioactive wastes, projections of the repository natural and engineered barrier system's performance require the extrapolation of relevant disposal system features, process and events over unprecedented time frames. Significant scientific uncertainties are involved in these extrapolations, which must be considered in developing regulatory standards as well as in decision making about compliance demonstrations for those standards. In making dose assessments over time frames of thousands of years, the uncertainties in the performance projections are added to the additional question of projecting human characteristics and activities far in the future. Attempting to combine both the uncertainties in projecting disposal system performance, with uncertainties in human characteristics and activities, leads to a situation where any number of alternate "futures" can be proposed which can have dramatically different dose projections. Because it is impossible to reliably forecast human characteristics and activities far into the future, the diverse alternate "futures" cannot be reliably weighted or ranked in a regulatory decision making process, resulting in a difficult and potentially unworkable situation for both the applicant and regulatory authority.

The question of uncertainty in predicting future human characteristics and activities has been examined by the Agency in previous rulemakings (6, 7). To address this issue, the Agency adopted an approach described in 40 CFR Part 194.25, i.e., the "future states assumption". For the purposes of dose assessments to potentially exposed individuals under this approach, human characteristics, levels of technology, and future activities are assumed to be as they presently exist. Therefore, dose assessments need only consider present population demographics for a specific location where the assessments are to be made, rather than include speculative predictions concerning changes in demographic information, health risks from exposures, etc. Although the current population is used as a baseline for formulating details of the standard, a rigid interpretation is not reasonable in that the population's characteristics should not be considered as frozen at a particular time, such as when the standard was finalized. Some consideration of near-term population growth and land use planning should be included if such near-term planning has a high probability of occurring in the next decade or two. Incorporating a relatively short "look ahead" would avoid the situation where the characteristics of the exposed population at the time of licensing a geologic repository could be significantly different than those existing when the standards were finalized. The assumption of current conditions does not

extend to climatic, hydrologic and geologic changes projected to occur at the repository site over the course of the regulatory time period however, and these changes are factored into repository performance assessments to develop a comprehensive source term for the dose assessments through the biosphere.

For the purpose of developing site-specific standards for the Yucca Mountain site, the Agency retained the future states assumption for the reasons described. To do otherwise would result in a situation where totally speculative parameters for dose assessments would result, making conducting dose assessments by DOE, or any other party, a highly speculative exercise and presenting the licensing authority with the difficulty of making a compliance decision on purely speculative dose scenarios.

With the "future states" assumptions as a foundation, developing a site-specific approach to setting the individual protection standard considered three other guiding considerations. The approach should; (1) be consistent with site-specific information, (2) be a "cautious but reasonable" approach and; (3) reduce regulatory ambiguity to the extent possible.
The first consideration is self-evident in that a site-specific standard should take into consideration the unique features of the candidate site. The second consideration stems from past Agency guidance on waste disposal standards (Appendix C in (6)), and recommendations from the National Academy of Science (NAS) (11) to adopt "cautious but reasonable" approaches to framing components of the standards. The third consideration is also closely tied to the intent of the future states assumption in terms of avoiding approaches which would result in widely differing scenarios for dose assessments, but for which it would be difficult to impossible to distinguish between the alternative scenarios conclusively. This situation would tend to make the licensing decision potentially arbitrary and therefore contentious in a legal arena. How each of these three considerations was evaluated in developing the site-specific standard for individual protection is described in the sections below.

## Site-Specific Information

The Yucca Mountain candidate site has been intensively studied since 1988 when detailed site characterization plans for the investigations were published (11). Results of geological studies, as well as environmental studies and population demographic studies, have been published in a myriad of documents since that time. Periodically total system performance assessments for the site have been published with supporting documentation, most recently in support of the site recommendation process (13), and previously to support an earlier evaluation of the viability of the site as a candidate for site recommendation (14). Information about the Yucca Mountain site used by the Agency to develop the standards is summarized in the final EPA standard (15), which also summarizes the total system performance assessments for the site.

There are some particularly important site-specific information and insights about the site's projected performance that played a significant role in framing the approach to the individual protection standard (13, 14, 15). The primary pathway for repository releases to reach potential receptors is through ground water movement. Ground water movement from the repository

location is anticipated to be vertically downward from the repository through the unsaturated zone, with some eastward displacement along the gently eastwardly dipping contacts between the volcanic rock units. The most rapid movement of ground water through the unsaturated zone is through nearly vertical fractures in the rock and eastwardly along the unit contacts. On entering the saturated zone, ground water flow is generally southward downgradient. In the saturated zone, flow is also dominated by fractures in the rocks.

Contamination transport plumes in such fracture-flow dominated systems will exhibit significantly less lateral dispersion along the transport path than in more porous flow dominated regimes, and will therefore remain comparatively narrow in width as the movement downgradient continues. Figure 1 (modified from (14)) is an illustration of particle track projected flow paths from across the repository. The ground waters in the unsaturated zone are diverted eastward along rock unit contacts before entering the saturated zone. The narrow flow path southward from the repository reflects the details of the flow system in that direction as well as the characteristics of fracture-flow dominated hydrologic regime. Fractures in these rocks are generally nearly vertical, with prominent fracturing (as indicated by the orientation of faults in the area) is in a north-south direction. Hydrologic data over the entire flow path is sparse. Consequently there is some uncertainty in projected flow paths well down gradient from the repository. However, these modeling projections represent the result of a decade of characterization studies and little refinement of these projections is likely.

Downgradient of the site the current population center is the town of Amargosa Valley, an area characterized by a relatively small widely dispersed population on the order of 1,000 people distributed over approximately 500 sq. miles. Currently, the closest residents to the repository site are located approximately 20 km south of the site (about ten people), in an area called Lathrop Wells. Plans for land development between Lathrop Wells and northward to the Nevada Test Site (NTS) boundary, at a distance of approximately 18 km from the repository, indicate that a science museum and industrial park are to be built within the next decade, considerably increasing land use in this area and the potential pool of exposed individuals. Demographic information for the Amargosa Valley area indicates that agriculture is a significant component of the economic base, but full-time farming only employs about one-tenth of the population. Part-time farming is more typical of the agricultural activities, with other occupations, often involving commuting outside the immediate community, constituting the majority of the population's daily activities. Alfalfa farming is the most water intensive and geographically widespread agricultural activity in the area, with an average farm size of approximately 255 acres under cultivation.

With this site-specific information, some conclusions can be made relative to framing the approach for the individual radiation exposure standard. Contamination plumes from repository releases will be narrow, rather than exhibiting wide dispersion of the contamination that would be expected in other flow systems. The potentially exposed population is not exclusively a farming community and is geographically dispersed. This fact combined with the expectation for narrow contamination plumes suggests that defining a CG for the potentially exposed population would be difficult. Exposures for the CG should be relatively homogeneous, i.e.,

they should not vary markedly within the group. Actual exposures to individuals in the population would probably vary significantly, determined by whether or not a given individual is located close to the plume centerline or not, since that determines drinking water concentrations and the source term for other pathway exposures. For a CG of tens to hundreds of individuals with relatively uniform dose distribution, an assumed distribution of individuals may be needed that is inconsistent with the reality of the area's widely dispersed population distribution. This observation argues for the use of a representative individual rather than a CG to avoid the speculative assumptions about the size and distribution of a critical group for the dose assessments. The diverse nature of lifestyle for the Amargosa Valley community also suggests that a truly representative CG may be difficult to define. For a representative individual, averaged parameter values for the variables that control the dose can be determined from surveys of the existing population, and values chosen to give the individual an "average" dose, or any other dose desired (a "maximum" dose or a "reasonably maximal" dose for example).

Another variation on the representative individual has been proposed for the dose receptor, a "subsistence" farmer approach (11). The Agency considered this alternative but did not adopt it for two major reasons. There are no current residents in Amargosa Valley corresponding to a subsistence farmer lifestyle, making this alternative inconsistent with site-specific information. Adopting the subsistence farmer approach would therefore be highly speculative and in conflict with the future states assumption. Considering the harsh conditions in the area, it appears unlikely that a subsistence farming lifestyle is feasible. The other reason is that the subsistence farmer would be a maximally exposed individual, and for reasons discussed below, the Agency has chosen to avoid extreme assumptions for the individual exposure scenario.

A variation on the CG approach has also been recommended (11), called a "probabilistic critical group". This approach was not selected for the standards because its fundamental premise of a geographically varying population (CG) distribution over the course of the regulatory time frame in the dose assessments is inconsistent with the future states assumption described above. Such an approach would present serious difficulties for regulatory decision making relative to justifying any particular CG geographic distribution. While the statistical nature of the assessments to the population, and the large number of dose assessments necessary in this approach, in part provide some rationale for the approach, it is more direct and easier to implement an approach that places the dose receptor in the direct path of projected releases. The representative individual approach in this regard is undoubtedly a conservative approach, and the text below discusses how it is also "cautious but reasonable".

## A "Cautious but Reasonable" Approach

In considering alternative framing of the individual protection standard, we agree with the NAS recommendation to adopt a "cautious but reasonable" approach to framing the standard (11), i.e., to avoid extreme assumptions that would drive the dose assessments to consider only worst case assumptions. This approach actually runs through all the decisions to be made in framing the

individual exposure standard. The choice of an RMEI vs. a CG partially reflects the cautious but reasonable consideration, but is more strongly influenced by the consideration of reducing regulatory ambiguity as discussed in more detail below.

As mentioned above, the Agency did not elect to characterize the representative individual as a subsistence farmer because that choice would go to the extreme end of the possible alternatives - i.e., beyond a "cautious" approach since the assumptions incorporated in a subsistence farmer approach would maximize the hypothetical dose to the individual and would therefore be extreme rather than simply "cautious". The subsistence farmer could also be considered unreasonable since the assumption that a subsistence farmer exists is not consistent with the current population information downgradient from the repository.

The RMEI approach is also consistent with the "cautious but reasonable" consideration. An RMEI represents a middle ground between two competing alternatives - a critical group (with the difficulties of making a representative group with the site-specific constraints of actual population characteristics), and a hypothetical individual with characteristics that maximize the hypothetical dose. A CG for the Amargosa Valley community is difficult to define because of the varied occupations and widespread geographic distribution of the population. While a farming community CG can be proposed, it is not representative of the majority of the population and as such could be considered extreme rather than simply cautious and reasonable. A representative individual, the RMEI, could be characterized to be an amalgam of lifestyles for the existing population. The "rural residential" RMEI described in the proposed and final rules (2, 3) is exemplary of such a middle ground between extreme and more representative assumptions.

Framing the individual protection standard in a "cautious but reasonable" fashion using a representative individual as the dose receptor involves making some specific requirements to assure that the approach is "cautious", biased toward high-end exposure estimates, but still "reasonable" - not an extreme case. Two specifications that can be used are, the location for the exposed individual, and one or more values for parameters that drive the dose calculations for particular pathways.

As mentioned in the previous section, the closest current residents are located approximately 20 km from the repository, but near-term development plans indicate that the area northward from Lathrop Wells to the NTS will be utilized and potentially exposed individuals will be in this area. As shown in Fig.1, a "cautious" approach to locating the RMEI would also consider the planned land use between the 18-20 km locations to avoid the situation where the RMEI for regulatory compliance calculations is not where the first potentially exposed individuals will be located. As a cautious measure, the RMEI's location was set at the accessible environment boundary (boundary of the controlled area) where the highest radionuclide concentrations in the projected contamination plume crosses the boundary. As Fig. 1 illustrates, the southernmost allowable

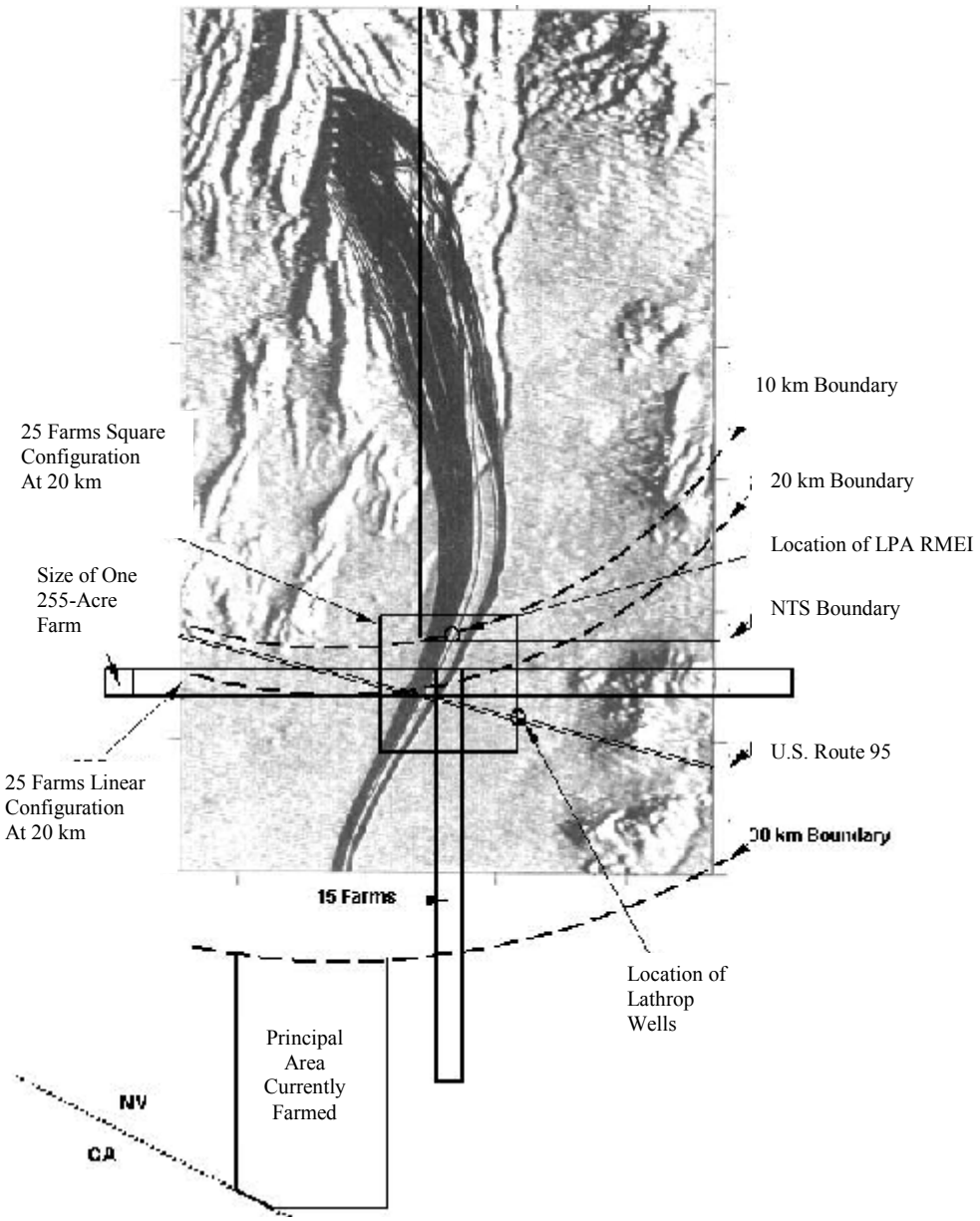


Fig. 1 Map showing particle-track ground water flow paths from Yucca Mountain and farm configurations (modified from (14)).

extent of the controlled area, which delineates the beginning of the "accessible environment" as defined in the standard (section 197.12 in (3))., correlates with the southwestern border of the (NTS). As a "cautious" approach, this location is conservative in that it is the northernmost location where individuals may locate since the NTS is currently, and most likely will remain, a restricted area for residential development. The location is also a conservative choice since the concentrations of radionuclides in any contamination plume should increase closer to the release source.

To assure that the representative individual is "reasonably maximally exposed", one or more parameters that strongly influence the dose assessments should be set at a value that pushes the dose assessment to the high end of the possible dose distribution. Since drinking water is a major source of potential exposure, if the amount of drinking water consumed by the RMEI is set at a fixed value (2 liters/day, see section 197.21 in (3)) toward the high end of possible consumption rates, the RMEI dose assessments will be biased toward the high end also.

By setting two parameters at high end values, the RMEI location and daily drinking water consumption, dose assessments will be biased to high-end values, but will still show a distribution since the values of other parameters affecting dose are to be representative of the characteristics of the potentially exposed community. Dose assessments for the RMEI will still vary as a function of variations in ground water radionuclide concentrations reflecting variations in repository performance. The receptor does not experience the maximum conceivable dose, but rather a sufficiently conservative high-end exposure consistent with a "reasonably maximally exposed" individual.

**Reducing Regulatory Ambiguity for Implementation**

The final consideration in framing the individual protection standard is reducing the potential for regulatory ambiguity and consequent uncertainties in implementing it. The intent here is to avoid the situation where a number of different exposure scenarios could be reasonably proposed that would differ widely in the level of projected exposure to the individual, but which lack clearly usable ranking or weighting criteria to distinguish between them. In such a situation, it would be impossible for the regulatory decision makers to rank or weigh the various exposure scenarios defensibly, making the compliance decision rely on arbitrary decisions. This consideration can also be seen as a conscious effort to assure that the standard can be successfully implemented for the site. Although the Agency is not the licensing authority for the Yucca Mountain site, the regulatory authority (the Nuclear Regulatory Commission) must be able to implement the standard through an open licensing process, where alternative performance scenarios representing alternative interpretations of the standard can be proposed. To avoid ambiguity over the intent of the standard, it should be defined specifically enough to minimize the potential for misinterpretation of the Agency's intent.

Figure 1 illustrates how this potentially contentious situation could arise. If a CG approach were used for the downgradient receptors and defined as consisting of farm families, the placement of farms becomes a determining factor in the dose assessments. The size and characteristics of the

farms and the number of exposed persons become critical issues in the assessments. Previous dose assessments for the Yucca Mountain site published by DOE (13, 14) have proposed farming critical groups consisting of 15-25 farms. Does assessments for such a group require that assumptions be made about the type of farming, location of the farms, number of individuals per farm, water use rates, etc.. All of these assumptions require decisions be made, many of which may not be consistent with site-specific information and could be considered arbitrary.

To illustrate the point, Fig.1 shows the placement of alfalfa farms of average size (255 acres as per information in (15)), the most water-intensive farming activity in Amargosa Valley. Fifteen to twenty five farms are arranged in square and linear arrangements across the particle-track path of projected ground water flow from the repository into Amargosa Valley. The placement of farms, combined with the relatively narrow width of the projected flow-path, indicates that dose assessments for the CG individuals will vary significantly depending on whether a particular farm is directly across the flow-path or on its perimeter. Some farms in these arrays would have no exposure at all. For the linear arrangement, only a small number of farms actually intercept the flow-path, even with a wider plume width from dispersion effects (which will remain relatively small in the fracture-flow dominated flow system however). Dose assessments for these arrangements of farms would vary from little to no exposure for individuals using water from the edges, and outside, of the projected contamination plumes, to much higher doses for individuals tapping the center of the plumes. Calculating the critical group dose assessments would be a contentious exercise, since some form of relative weighting would be needed, which compounds the uncertainties already present in defining the characteristics of the farms and their locations.

To have a CG where the dose distribution does not vary widely within the group, as required by the common understanding of the concept, would require that the farms be aligned along the flow path or only a small number of farms selected. For these arrangements, the actual doses would be almost identical since only dilution along the travel path would decrease concentrations of $^{129}I$ and $^{99}Tc$, (the important radionuclides within the regulatory time period of 10,000 yrs (13, 14)), and relatively little dilution with distance would be expected in these narrow contamination plumes. In either case the number of farms selected and their placement are fundamentally arbitrary decisions which would be difficult to defend by the applicant in preparing a compliance demonstration, and difficult for the regulatory authority to defend in making a compliance decision. This type of regulatory ambiguity is best avoided if an alternative "cautious but reasonable" approach to framing the exposure standard can be applied.

In this sense, the use of an RMEI reduces regulatory ambiguity significantly, while clearly preserving the intent of the standard. The location of the RMEI is easily defended since it is conservatively placed on the border of the NTS (the southernmost border of the controlled area) and closer to the repository than current or projected population distributions. The exact location is then simply where the projected plume of contaminated ground water from the repository crosses the NTS boundary, a calculation that is fundamental to repository performance

projections. Using a representative individual avoids the problems associated with defending selections of farm size, type, location and numbers of individuals, water use and pumping effects for multiple farms, etc., necessary if a CG farming community approach is applied.

The use of a representative individual, whose important characteristics are based upon those of the existing downgradient population, is also a defensible approach. It is actually a variation on the critical group approach described above for the situation where a critical group is difficult to define.

## SUMMARY

The use of an RMEI approach to framing the individual protection standard for the Yucca Mountain site is the best alternative for the site-specific situation. The RMEI approach as framed in the final standard (3) necessarily reflects the "future states" assumptions inherent in EPA's approach to standards for radioactive waste disposal, i.e., that speculation about human characteristics and activities in the distant future should not play a role in standards development. The RMEI approach is also consistent with other considerations examined in the process of developing the standard, particularly, consistency with site-specific information, a "cautious but reasonable" approach, and an conscious attempt to reduce regulatory ambiguities in framing the standard.
The RMEI approach is consistent with the population characteristics in the Amargosa Valley area downgradient from the repository, i.e. characterizing the RMEI as a "rural residential" individual whose characteristics are defined to be representative of the local population. Setting the RMEI location on the border of the controlled area (with the NTS boundary as the southernmost boundary) above the highest projected contamination levels in the ground water and setting the RMEI drinking water consumption at a high-end fixed value, will assure the dose assessment is for a "reasonably" but not maximally exposed individual. These two specifications for the RMEI also make the approach a "cautious but reasonable" one.

A major advantage in the use of a representative individual rather than a CG for the individual protection standard is the removal of the ambiguity that would follow if a CG approach were used instead, while preserving the intent of the standard. The narrow contamination plumes expected in fracture-flow dominated ground water systems, and the widely dispersed nature of the downgradient population, makes defining a CG in sufficient detail for dose assessments an exercise involving many decisions that would be arbitrary in nature and difficult to defend with site-specific information. Simply using a representative individual removes the ambiguity for implementation, but leaves flexibility for implementation in terms of defining the remaining parameters needed for dose assessments.

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