

**Responses to Major Comments on  
Technical Support Document**

**Public Health Goal  
For  
Radium-226 and Radium-228  
in Drinking Water**

**Prepared by**

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## **INTRODUCTION**

The following are the combined responses to major comments received by the Office of Environmental Health Hazard Assessment (OEHHA) on the public health goal (PHG) technical support document for radium-226 and radium-228, based on the pre-release review draft. Changes have already been made in response to these comments, and have been incorporated into the draft posted on the OEHHA website. For the sake of brevity, we have selected the more important or representative comments for responses. Comments appear in quotation marks where they are directly quoted from the submission; paraphrased comments are in italics.

These comments and responses are provided in the spirit of the open dialogue among scientists that is part of the process under Health and Safety Code Section 57003. For further information about the PHG process or to obtain copies of PHG documents, visit the OEHHA Web site at [www.oehha.ca.gov](http://www.oehha.ca.gov). OEHHA may also be contacted at:

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## **RESPONSES TO MAJOR COMMENTS RECEIVED**

### **Comments from University of California, Davis**

Comment 1. “In general, the amount and quality of work performed by the authors in drafting these documents was very impressive. They covered enough topics regarding the properties and hazards of the contaminants in a manner that was comprehensive and accurate.”

Response 1. Comments noted.

Comment 2. “The data discussed on Development and Reproductive Toxicity (page 14) is not applicable because it involved radium as an external radiation source (not ingestion or internal exposure). Other information presented on toxicity, toxicokinetics, metabolism, mode(s) of action and exposure, and potential for carcinogenicity was accurate and comprehensive.”

Response 2. The document contains data relevant to the potential toxicity of radium, but not all of it, such as the data mentioned above, can be used for development of a PHG for drinking water.

Comment 3. “The approach used in developing the draft PHG was appropriate and consistent. The general methods used for determination of PHG for non-cancer health effects limitation and cancer risk limitation were appropriate. The authors used the cancer risk coefficients published by the U.S. EPA (U.S. EPA, 1999) to determine the draft PHG, and should state that this document and its references should be reviewed to understand their interpretation of carcinogenicity data and mechanisms.”

Response 3. Yes; the document has been revised accordingly.

Comment 4. “The authors covered key studies and the usefulness of data for the dose-response assessment in good detail for determining the non-cancer health effects PHG. For the cancer risk limitation PHG, the authors did not elaborate on animal and human data to independently develop the dose-response assessment for determining it. Their use of the U.S. EPA cancer risk coefficients is a reasonable way to determine cancer risk limitation PHGs.”

Response 4. Comment noted.

Comment 5. “The risk assessment methodologies used were appropriate and other methods would not likely be as technically supportable.”

Response 5. Comment noted.

Comment 6. *The commenter recommends that the de minimis lifetime cancer risk be scrutinized thoroughly. Also, the commenter suggests that an explanation or discussion on the rationale for the lower de minimis chosen by Cal/EPA ( $1 \times 10^{-6}$ ) compared to the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection ( $5 \times 10^{-5}$ ) be given. “Cal/EPA needs to justify the development of a 50 fold lower de minimis cancer risk recommendation.”*

Response 6. OEHHA has used a *de minimis* cancer risk of  $1 \times 10^{-6}$  for development of PHGs for carcinogens since the inception of the drinking water risk assessment program. This is now stated in the Risk Characterization section. The approach was intended as an alternative to the U.S. EPA use of zero as the acceptable level for exposure to carcinogens in development of maximum contaminant level goals (MCLGs), which is the federal counterpart to the California PHG program. It was felt that there was adequate legal precedent for declaring a one in a million risk to be below the level of regulatory significance. Higher risk levels used in regulatory programs tend to be based on risk/benefit or cost and feasibility considerations, whereas PHGs are by law based only on consideration of public health. For perspective, we also provide the concentration (or pCi/L) values for risk levels of  $10^{-4}$  and  $10^{-5}$  in our PHG documents

Comment 7. “More specific data is needed on the levels of  $^{226}\text{Ra}$  and  $^{228}\text{Ra}$  that have already been found in California drinking water supplies. This will allow the reader to get a better perspective on how the proposed PHG compares to what is currently in our water supplies.”

Response 7. The readily available information on drinking water levels of the combined radium isotopes in California is described in the PHG document.

Comment 8. “The authors have handled the uncertainties appropriately in the data interpretation and calculations that derived the non-cancer and cancer risk PHGs. The cancer risk calculation that they have used to develop the draft PHG has substantial conservatism built into it and provides more than adequate protection for members of the public.”

Response 8. We agree; no changes have been made in response to this comment.

Comment 9. *Several editorial comments were provided.*

Response 9. Changes were made to the document, where appropriate.

### **Comments from University of California, San Diego**

Comment 1. “The document is both detailed and scientifically, state of the art. The calculations are done competently.”

Response 1. Comment noted.

Comment 2. “The text abruptly ends after the Section: **Other regulatory standards**. I recommend that a **Concluding Summary** should be given following page 26, before page 27. The **SUMMARY** at the beginning of the document should be moved here.”

Response 2. The document layout is part of our standardized format; no revision will be made in response to this comment.

Comment 3. *Several editorial comments were provided.*

Response 3. Changes were made to the document, where appropriate.

### **Comments from U.S. Environmental Protection Agency, Office of Water**

Comment 1. “The documents are well done and easy to follow and understand.”

Response 1. Comment noted.

Comment 2. “It would be useful to know how [the RSC for radium was] derived. Just giving these numbers, does not convey much information. Also, EPA does not use RSC for calculating health-based numbers for chemicals listed as carcinogens. RSC is only used for non-carcinogenic chemicals.”

Response 2. The RSC was only used to calculate our public-health protective concentration for the non-carcinogen effects. The RSC was based on the estimated contribution from the average adult dietary intake of <sup>226</sup>Ra and <sup>228</sup>Ra compared to drinking water. The estimated drinking water intake would contribute less than 50 percent of the total intake. Text was revised to reflect how the RSC was derived.

Comment 3. “Based on a review of these documents (although I have not reviewed their supporting references), the process used to develop these PHGs appears reasonable and the documents themselves present information in a reasonably transparent format. The documents have calculated the health protective concentrations based on carcinogenic end-point as well as noncarcinogenic end-points and as the values from carcinogenic end points are lower, the values chosen for all the PHGs are those based on carcinogenic end-point.”

Response 3. Comment noted.

Comment 4. *Several editorial comments were provided.*

Response 4. Changes were made to the document, where appropriate.

## **Comments from U.S. Environmental Protection Agency, Radiation Protection Division**

Comment 1. “Provide additional background information on the purpose of the PHGs and their relationship to the USEPA maximum contaminant level goals (MCLGs).”

Response 1. The Preface of the document contains background information on the PHG program; this has been slightly expanded in the revised document. Additional perspective is provided in the Risk Characterization and Other Regulatory Standards sections.

Comment 2. “Present radioactivity concentrations in either conventional units (e.g., pCi/L) or SI units (e.g., Bq/L), but not both simultaneously.”

Response 2. Because most of our audience is not intimately familiar with the radiation terminology, we think it makes more sense to keep both units. We acknowledge that this makes it read more awkwardly for experts who are familiar with both terms.

Comment 3. “Ensure that the *general* discussions on radiation exposures, doses, and potential human health effects are identical in all three documents. Use the current ICRP Publication 60 definitions for absorbed dose, equivalent dose, and effective equivalent dose, and consult UNSCEAR 2000 for summary information on radiation-related health effects.”

Response 3. Every effort will be made to ensure consistency across the three radionuclide PHG documents (radium, strontium, and tritium) that are being finalized at this time. We have considered the suggested references, and decided to retain the existing definitions and descriptions to maintain consistency with the U.S. EPA source documents. We thank the commenter for pointing out these important references.

Comment 4. *Several editorial comments were provided.*

Response 4. Changes were made to the document, where appropriate.

## **Comments from Larry Grimm, Personal Opinion, Environmental Health and Safety, University of California, Los Angeles**

Comment 1. “There is no derivation of the NOAEL in the proposal. A reviewer cannot analyze the proposal without this derivation. The derived NOAEL is critical to the determination of the PHG. Please provide me with the derivation.”

Response 1. Derivation of the NOAEL was presented in the Subchronic Toxicity section (page 16) of the document.

Comment 2. “The prime study supporting the NOAEL non-stochastic effects (Keane, et al) is a case study of workers in two separate factories. Only women (no men) ingesting a particular chemical form of Ra-226 and Ra-228 are studied. Such chemical forms are unlikely to be found in drinking water. Although the study attempts to determine a specific negative change (bone density changes), it does not determine if there was an overall positive/negative change on the overall health of the subjects. Nor does the study exclude other potentially mitigating factors, e.g. older women routinely have bone density issues based on menopause and the use of hormones. The Keane study, although well designed, uses a somewhat arbitrary method of analyzing non-stochastic changes via examination of radiographs of bone. This leaves a lot of questions as to the validity of the study. Additionally, applying a case study to the setting of PHG’s is not a normal epidemiological practice and is open to criticism.”

Response 2. Comment noted. The weaknesses of the Keane *et al.* (1983) article were considered prior to our determination of the non-cancer health-protective values. However, we find the study to be appropriate for our use.

Comment 3. “The potential beneficial effects of low dose radiation are dismissed in the proposal. There are thousands of studies demonstrating the beneficial effects of low dose radiation. By decreasing a human’s intake of natural radiation, there is a distinct possibility that it could cause an increase in non-stochastic and stochastic effects, i.e. increase the death/illness rate in the population. From the scientific literature and my calculations, it appears there is at least a  $1 \times 10^6$  probability that a person may get a non-stochastic/stochastic effect from lowering the natural ingestion rate. Therefore the OEHHA must give equal consideration to the potential harm from reducing natural radiation, as well as the potential benefits from reducing natural radiation. By not giving equal consideration to both sides of the low dose debate, in effect the OEHHA is saying that they do not care if more people get ill or die.”

Response 3. Potential hormetic effects were discussed in the document, and rejected as a potential basis for regulatory consideration. This is based on the recommendations of the National Council on Radiation Protection and Measurements (NCRP, 2001), which concluded that there is no strong support for a hormesis interpretation of the radiation epidemiological literature. They conclude that all epidemiological evidence implicating hormesis was either a statistical anomaly that disappeared as more and better data became available, or was due to confounding factors such as better health for radiation workers. The NCRP also concluded that low-dose cancer studies are equivocal because of the intrinsic limitations in their precision and statistical power. Because of these limitations there is a danger in over-interpreting either individual negative studies or individual highly positive studies. The hypothesis that there could be low-dose positive effects from exposure to radium does not provide a quantitative basis for setting a PHG.

Comment 4. “The proposal does not discuss the risk valuation conflict between the US Nuclear Regulatory Commission (NRC) and the US Environmental Protection Agency. There is considerable disagreement between the two agencies that should be discussed in a proposal such as this. As the NRC is the prime regulator of radioactive materials in this

country, it is important that the public be aware of the conflict between the two agencies and the basis for the risk evaluation.”

Response 4. Although discussion around the risk valuation for radionuclides may be desirable, this issue was not addressed or evaluated in this document because of the decision to base the risk estimates on the risk coefficients developed by the U.S. EPA Office of Radiation and Indoor Air as listed in Federal Guidance Report No. 13 (U.S. EPA, 1999). In this case, we believe the risk valuation questions should be resolved at the national level.

Comment 5. “The proposal does not discuss dose, nor dose response, in the detail necessary for a full understanding of the issue. As dose plays a critical role in determining the risk, the report should convert ingestion values to dose/dose-rate values.”

Response 5. The complex issues related to dose-rate effects are discussed in Federal Guidance Report No. 13 (U.S. EPA, 1999) and other basic support documents. However, OEHHA saw no need to discuss the details for this document, considering the decision to adopt the federal risk coefficients.

Comment 6. *Several editorial comments were provided.*

Response 6. Changes were made to the document, where appropriate.

### **Comments from Daniel Hirsch, Committee to Bridge the Gap**

Comment 1. *Recent data suggest that much older individuals are as sensitive as the young child to the carcinogenic effects of low-level ionizing radiation. The commenter feels that the PHG document does not consider the potential increased risk older adults may experience if they were to be exposed to radium.*

Response 1. Although there is a suggested greater sensitivity in older individuals to low-level ionizing radiation in a couple of papers, no extra consideration was made regarding this potential effect because radium specifically deposits in and affects growing bones, which would make children the most sensitive population. Changes to the document were made to reflect this point and provide more perspective.

Comment 2. “The TSDs [Technical Support Documents] at times treat the various assumptions leading, step by step, to their risk estimates as those these were absolute values rather t[h]an somewhat controversial estimates with substantial uncertainties associated with them. To get to a risk estimate, numerous steps are required, and the uncertainties about each increase when taken together. The concentrating effect in various organs, the biological half-life, the relative biological effectiveness (RBE), the effect of age, and the conversion between dose and risk – each should have large error margins around them and the cumulative effective of those error margins taken into

account. It is not clear that the resulting PHGs are appropriately conservative, given these large uncertainties.”

Response 2. We acknowledge the presence of large uncertainties in our assumptions and calculations. The uncertainties extend in both directions, toward lesser as well as toward greater risks, as should be evident in our responses to other commenters. However, it should be noted that there is a considerable amount of *certainty* in key areas of the risk assessment of radium, including the mode of action, inter- and intra-species extrapolation, and relative source contribution (RSC). A substantial body of information exists on the carcinogenic effects of radionuclides, including radium, on human subjects. In addition, several agencies have developed and are refining models to estimate human body exposures to radionuclides, which have also added to the certainty of the estimations. OEHHA considers that basing the PHG value on an estimated lifetime cancer risk of one in one million adequately addresses the uncertainties and is appropriately health-protective.

Comment 3. “The draft TSDs frankly bear a sign of bias or tilt that is unfortunate. For example, they discuss a number of factors that nuclear advocates have put forward for their premise that low-dose radiation is less harmful than generally assumed, or perhaps even health protective. The TSDs discuss arguments about adaptive response and hormesis – and properly dismiss them. There is no discussion, however, of biological phenomena that might result in the standard risk estimates being low, such as bystander effects and genomic instability. Additionally, there is no assessment of epidemiological factors that could similarly result in estimates derived from population studies also being low, for example, the healthy survivor effect which some epidemiologists have demonstrated skews the A-bomb survivor data, the current gold standard from which risk estimates are derived. There is also significant evidence that the current assumption of a Dose and Dose-Rate Reduction Factor is inappropriate and thus understates true risks by a factor of 2 or more.”

Response 3. All relevant arguments have been considered in the development of a public-health protective concentration by OEHHA, but were addressed in part by accepting the risk coefficients provided for this purpose in Federal Guidance Report No. 13 (U.S. EPA, 1999). Risk coefficients and assumptions used in this development tend to be conservative and thus generate a public-health protective concentration.

Comment 4. “The TSDs end with a listing of radiation standards from different agencies. However, the choice of the standards included is weighted toward the more lax standards in existence (e.g., 100 mrem/yr NRC standard that has been criticized by US EPA as ‘non-protective of public health’. Other standards that are more protective have been left out. For examples, US EPA’s Preliminary Remediation Goals for CERCLA cleanups – beginning at  $10^{-6}$  risk and falling back to no more than  $10^{-4}$ , or roughly .05 millirem/yr to 5 millirem/yr if one can’t meet the more protective standard and can demonstrate compliance with the 9 balancing criteria in CERCLA –are left out. EPA’s 10 mrem/yr NESHAP standard are left out. NRC’s 10 CFR 50 Appendix I 5 mrem/yr criteria are left out. Furthermore, if one is to include such a table, one should discuss the contradiction

between the risk levels associated with many radiation standards and those considered acceptable for all other carcinogens – many radiation standards carry with them associated risk levels far outside the acceptable risk range for chemical carcinogens.”

Response 4. Standards listed in the summary table at the end of the document provide an overview of the range of available radionuclide standards. There has been no attempt to present a comprehensive list, nor to bias the list in one direction or another. OEHHA feels that the large disparity between the PHG values, based on a  $10^{-6}$  risk level, and the federal and state MCLs is an adequate reminder of the theoretical risk involved, if drinking water were to contain the radionuclides at the MCL levels, over a lifetime. We have more explicitly pointed out elsewhere the substantive issues involved in the tolerated risks at the gross alpha and beta screening levels used for the primary screening for radiation hazards in drinking water (see <http://www.oehha.ca.gov/water/reports/grossab.html>).

Comment 5. “The TSDs simply use EPA Federal Radiation Guidance document with no consideration whether other risk estimates are more appropriate and no consideration of the numerous studies showing it understates true risks. A series of relatively recent studies all demonstrate radiation risks about an order of magnitude greater than that assumed in the TSDs. These include the Hanford, Oak Ridge, and SSFL studies mentioned above, and the Canadian Radiation Workers study, among others. The draft PHGs may thus be too lax by an order of magnitude or more.”

Response 5. In the development of our public-health protective concentrations, an extensive literature search was done, pertinent articles were reviewed, and all arguments judged to be relevant were considered. The decision to utilize the federal radiation guidance was not taken lightly, and we acknowledge the strong opinions on both sides of the issues (too lax versus too strict). The risk coefficients and assumptions used in Federal Guidance Report No. 13 (U.S. EPA, 1999) are judged to be most defensible at this time. OEHHA therefore considers the public-health protective concentration to be appropriate.

Comment 6. *Several editorial comments were provided.*

Response 6. Changes were made to the document, where appropriate.

## REFERENCES

Keane AT, Kirsh IE, Lucas HF, *et al.* (1983). Non-stochastic effects of <sup>226</sup>Ra and <sup>228</sup>Ra in the human skeleton. In: *Biological Effects of Low-Level Radiation*. International Atomic Energy Agency, Vienna, Austria, pp. 329-350.

NCRP (2001). *Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation*. National Council on Radiation Protection and Measurements. Washington, D.C. Report No. 136.

U.S. EPA (1999). Cancer Risk Coefficients for Environmental Exposures to Radionuclides. Federal Guidance Report No. 13. U.S. Environmental Protection Agency, Washington, D.C. September 1999. EPA 402-R-99-001.