September 18, 1998

Ms. Carol M. Browner
Administrator
United States Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Administrator Browner:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel convened for EPA's rulemaking on the National Primary Drinking Water Regulation for Radon (Radon in Drinking Water Rule). The 1996 Safe Drinking Water Act (SDWA) amendments require that a radon in drinking water rule be proposed by August 1999 and that a final regulation be promulgated by August 2000. In addition, the statute requires that a Health Risk Reduction and Cost Analysis (HRRCA) be published by February 1999, six months in advance of the proposal. The statute also requires that the National Academy of Sciences (NAS) assess the risk of radon in drinking water and the health risk reduction benefits associated with measures to reduce radon in indoor air, and that these assessments be used in setting the standard.

On July 9, 1998, EPA's Small Business Advocacy Chairperson (Thomas E. Kelly) convened this Panel under section 609(b) of the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Director of the Standards and Risk Management Division of the Office of Ground Water and Drinking Water within EPA's Office of Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA).

It is important to note that the Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process as well as from public comment on the proposed rule. Any options the Panel identifies for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with the Safe Drinking Water Act.

Background

EPA expects that this regulation will predominately affect small public water systems (i.e., those serving less than 10,000 people) whose source water is ground water. In our 1991 proposal (which was never finalized, and which was withdrawn in August, 1997), we projected that 27,000 mostly small systems would be required to treat to achieve the proposed level of 300 picoCuries/Liter.

The structure of the SDWA radon provision is unique in that it provides for development of a maximum contaminant level (MCL) as well as an alternative maximum contaminant level (AMCL) pegged to the ambient outdoor air concentration and the air-to-water transfer factor. This structure reflects Congressional concerns that radon risk in air typically far exceeds that in water. However, the cancer risk from radon in water is higher than the cancer risk estimated to result from any other drinking water contaminant. Under the new SDWA requirements, States would have the option of requiring that their facilities meet either the MCL or the AMCL.

If States choose the AMCL, they must put in place a "multi-media mitigation (MMM) program" that achieves "equivalent or greater health risk reduction benefits" (than meeting the MCL). MMM programs could include elements such as building homes radon resistant, mitigating existing homes, and disseminating information about radon in air. (Individual utilities would have the option of meeting the AMCL and developing a MMM program, in the event their State chooses the MCL).

Stakeholder Meetings and Small Entity Outreach

To facilitate regulation development, EPA has actively involved stakeholders in the development of the proposed rule. As part of this effort, EPA sponsored three public meetings in 1997, in San Francisco, CA, Boston, MA, and Washington, D.C. An additional meeting is planned for October 1998, in Washington, D.C. The purpose of these meetings is to provide stakeholders with information on EPA's plans for activities to develop a proposed National Primary Drinking Water Regulation (NPDWR) for radon; solicit public input on major technical and implementation issues, and on preferred approaches for continued public involvement; and identify additional parties who may be interested in future meetings.

OGWDW believes that input from small entities is particularly important in the rulemaking process because so many systems are small. EPA, in consultation with OMB and SBA, invited 23 small entity representatives (SERs) for the Radon in Drinking Water SBREFA process. These entities represent a broad range of the entities potentially affected by the rule including small water utilities serving communities; representatives from home-owner associations, investor-owned systems,

purchased water systems, small local governments, and churches. The SERs were provided with background information on the Safe Drinking Water Act and brief information on the Radon in Drinking Water Rule at a meeting on March 4, 1998 at EPA Headquarters.

On May 11, 1998, EPA held a SER conference call from Washington D.C. to provide a forum for SER input on key issues related to the planned proposal of the radon in drinking water rule. These issues included, but were not limited to: (1) issues related to the rule development, such as radon health risks, occurrence of radon in drinking water, treatment technologies and costs, analytical methods, and monitoring; and (2) issues related to the development and implementation of the multi-media mitigation program guidelines. In a conference call convened by the Small Business Advocacy Review Panel (SBAR) on August 10, 1998, the SERs were asked to comment on four main areas, small systems variances, affordability of potential compliance technologies, communication with water customers, and the MMM program. A record of SER comments are provided in Section 8 of the Panel Report. OGWDW will consider the SER comments received along with the Panel's recommendations when developing the proposed rule. Summaries of the SER conference calls and a list of documents distributed to SERs are included in Appendix A and B of the Panel Report.

Panel Findings and Discussion

Under the RFA, the Panel is to consider four regulatory flexibility issues related to the potential impact of the rule on small entities: (1) the type and number of small entities to which the rule will apply; (2) record keeping**,** reporting and other compliance requirements applicable to small entities; (3) the rule's interaction with other Federal rules; and (4) regulatory alternatives that would minimize the impact on small entities consistent with the stated objectives of the statute authorizing the rule. The Panel's most significant findings and discussion with respect to each of these issues are summarized below.

Timing of the Panel

Two Panel members expressed concern that the Panel was convened too early in the rulemaking process to properly fulfill its responsibility to solicit input from SERs regarding "significant alternatives to the proposed rule ." These Panel members were concerned about the lack of a draft proposed rule for the SERs to comment on and the fact that the NAS report had not been completed on schedule and supported the request of two SERs for a three-week extension of the Panel process to allow consideration of the report. They also noted that the Panel Report will not be released to the general public for nearly a year following its completion, and they saw little practical reason why its completion could not have been delayed in order to allow consideration of the NAS report.

In denying the request to extend the Panel deliberative period, the Chair noted the importance of balancing the need for early input on the rulemaking process with the availability of data and information to inform small entity comments. The Chair assured the Panel that EPA would provide the NAS report to both the SERs and the Panel members for their review and comment whenever the NAS released it, even though the Panel itself might be formally concluded by that time.

Types and Number of Potentially Affected Small Entities

No commenters questioned the information provided by EPA on the number and types of small entities which may be impacted by the radon rule. The Panel believes that EPA has very good information about the number and types of small water systems, but noted that concerns have been raised about its estimates of the number of wells at affected ground water systems. The Panel recommends that EPA continue to refine its estimates of the number of affected wells.

Record Keeping, Reporting and Other Compliance Requirements

The Panel notes that a number of SERs are concerned about the frequency of monitoring after initial determination of compliance. The Panel recommends that EPA reduce the frequency of monitoring after initial determination of compliance and consider providing waivers from monitoring requirements when a system is not at risk of exceeding the MCL. The Panel recommends that EPA consider burden-reduction approaches while developing the radon monitoring requirements and ensure that requirements are simple and easy to interpret, to facilitate compliance by small systems.

Almost all SER commenters expressed concern over the potentially high costs of the rule. The Panel noted the discrepancies among the EPA and trade association (Association of California Water Agencies and American Water Works Association) cost estimates for compliance with an MCL of 300 pCi/L. EPA has taken a number of steps to better define these various assumptions including convening of a 'blue ribbon panel" of utility experts in December 1997. The Panel also understands that EPA is working with AWWA and ACWA to resolve the discrepancies in the various cost estimates and develop a set of estimates that EPA and water system operators agree are realistic. The Panel supports EPA's ongoing efforts to update these estimates to ensure that they are as complete and accurate as possible.

The SERs expressed concerns about potential costs, particularly treatment technology, and the Panel made a number of recommendations to address these concerns. In developing requirements and guidance concerning the appropriate use of aeration or granular activated carbon (GAC), EPA should consider and include in its regulatory cost estimates, to the extent possible, the complete burden estimate. The Panel understands that GAC treatment may be a cost effective treatment technology for a relatively small number of systems that meet certain site-specific conditions. However, to assist small

systems in making their treatment technology decisions, the Panel recommends that EPA provide clear guidance for when GAC treatment may be appropriate as a central or point-of-entry unit treatment technology.

The Panel also discussed issues related to affordability of the rule for small systems. EPA's preliminary assessment suggests that aeration technology will be adequate to achieve compliance with various possible MCL options and is likely to be affordable for all size categories of systems. EPA recently published a Federal Register notice in which it solicited comment on national affordability criteria under which compliance would be considered affordable if the ratio of median annual household water expenditures (nationally, for total drinking water system expenditures) to median household income (nationally) does not exceed 2.5%. Two Panel members were concerned that this approach does not account for the variability of treatment costs across systems, the variability of current water bills, and the variability of incomes among communities served by small systems. The Panel noted that there are mechanisms in SDWA through the Drinking Water State Revolving Loan Fund program that can reduce costs for these systems and the system. However, two Panel members questioned whether this would be adequate to meet the needs of disadvantaged small systems. The Panel decided that the affordability issues should be further addressed in a venue outside of the radon SBAR Panel process because they are relevant to all drinking water regulations.

Interaction with Other Federal Rules

In developing regulations or guidance related to aeration, the Panel recommends that EPA should carefully consider the interaction of treatment technology for radon with requirements for other current and developing rules (e.g., lead and copper, arsenic, ground water rule, disinfection by-products, etc.) and allow states and systems adequate flexibility to implement treatment in the most cost-effective manner. These interactions should also be appropriately accounted for in the Health Risk Reduction and Costs Analysis for the radon rule.

Regulatory Alternatives

The Panel discussed several regulatory alternatives in detail, including setting the MCL, regulatory protection for smokers, and guidelines for the multimedia mitigation program. Highlights are presented below.

Setting the MCL

Perhaps the most effective alternatives for minimizing any significant economic impact of the proposed rule on small entities involve the choice of the MCL. Because EPA has not yet determined

what specific concentration levels it will consider for the proposed rule, the Panel's discussion of this issue focused on the 300 pCi/L level that was proposed in 1991. Approximately half of the SERs commented on the proposed level of the 1991 MCL of 300 pCi/L, all believing it was unrealistically or unreasonably low. The Panel notes that the SDWA requires an incremental cost analysis of MCL options under consideration. EPA further notes that a host of risk management considerations will be evaluated and a full consideration of costs and benefits will be performed in order to determine a proposed MCL level.

Two Panel members recommend that EPA give serious consideration to setting an MCL at the AMCL level, or at least at a level substantially above 300 pCi/L. Under the statute, EPA must set the MCL as close to the MCLG as feasible (taking cost in consideration) unless it determines that the benefits of an MCL set at the feasible level do not justify its costs. These Panel members believe that the benefits of a relatively low MCL may not justify its costs, given the much lower costs of avoiding cancer cases through mitigation of radon in indoor air, which accounts for 95% of total cancer risk from radon. They recommend that EPA look closely at this question. The EPA Panel members are concerned that setting the MCL at the AMCL could effectively undermine Congressional intent with respect to the flexibility provided under this portion of the statute by the AMCL/multi-media mitigation program alternative.

Radon Risk to Smokers

The Panel discussed the issue of whether or not the fact that radon risk may be significantly greater for smokers than for non-smokers is relevant to the standard-setting process. The Panel noted that questions have arisen about the extent to which non-smoking water system customers should be responsible for reducing the higher risk smokers face as a result of a voluntary life style choice. At the same time, the Panel recognizes that smokers are also entitled to protection from harmful contaminants in their drinking water. Panel members agree that the significance of this issue will become clearer once the NAS estimates for incremental risks to smokers and non-smokers are available. EPA will also provide an analysis of risks to smokers and non-smokers separately, as well as together, in the HRRCA.

Multi-Media Mitigation Guidelines

The Panel discussed several issues related specifically to development of the multi-media mitigation (MMM) program guidelines required under the radon provision in SDWA if EPA promulgates an alternative maximum contaminant level (AMCL). There was agreement among the Panel members on several general principles that EPA should consider in the development of the guidelines. These are:

- That the guidelines should be “user-friendly,” that is, straight-forward and simple to understand and use by both States and by public water systems (PWSs).
- That the guidelines should provide a viable and realistic alternative to meeting the MCL, both for states and for PWSs, including small systems.
- That the guidelines should provide flexibility to States and PWSs in satisfying the statutory requirement that the health risk reduction benefits expected to be achieved by the program be equal to or greater than the health risk reduction benefits that would result from compliance with the MCL.
- That provision of information to the public is an important element of any program designed to achieve health risk reduction benefits through the mitigation of radon in indoor air, given that such a program will necessarily rely, to some extent, on voluntary actions by the public.
- That equity is an important consideration in the design of a MMM program, given the fact that the households which benefit from reductions of radon in indoor air will not necessarily be the same households that experience continued exposure to radon levels in drinking water above the MCL.

Within these broad areas of agreement, there were some specific issues where consensus was not reached. The Panel discussed the pros and cons of developing a model MMM program for small systems. Two Panel members supported this approach as a means of ensuring that compliance with the AMCL would be a viable option for small systems in states which do not adopt the AMCL statewide. While the Panel did not reach consensus on this issue, all Panel members agreed that the guidelines should facilitate development of credible programs by both states and water systems (including small systems), and recommended that EPA consider the best way to accomplish this.

Another issue on which the Panel did not reach consensus was the meaning of the statutory requirement for a MMM program to achieve "health risk reduction benefits" equal to or greater than the health risk reduction benefits that would be achieved by compliance with the MCL. EPA’s interpretation of the phrase "health risk reduction benefits" is synonymous with "health risk reduction" and refers to the actual risk reduction achieved through reduced exposure to radon in indoor air. The other Panel members suggested an alternative interpretation that would attribute some "health risk reduction benefit" to the provision of information itself, because it would support homeowners in making informed choices about what level of risk reduction, and at what cost, was appropriate for them and their families. The Panel did not agree on this point but did agree that provision of information is an important component of any risk reduction strategy.

The Panel also discussed the issue of the appropriate baseline against which to measure health risk reduction benefits achieved by a MMM program. For states which already have effective voluntary programs, the MMM guidelines will need to address how much "credit" these programs should get for health risk reduction benefits currently being produced, or expected to be produced in the future. The Panel agreed that some "credit" toward program approval should be given for some

existing measures that are incorporated into the MMM program.

The Panel believes EPA should carefully consider all comments received during this outreach process on these and other issues of concern to small entities. A full discussion of the comments received and Panel recommendations are included in the final report.

Sincerely,

/S/

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Small Business Advocacy
U.S. Environmental Protection Agency

/S/

Don Arbuckle, Acting Administrator
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Enclosure