

SUPPLEMENTARY INFORMATION:

Title: New Source Performance Standards for Secondary Lead Smelters (40 CFR Part 60, Subpart L), Reporting and Recordkeeping Requirements OMB Control No: 2060-0080, EPA ICR No: 1128.05.

This information collection is a reinstatement, without change, of a previously approved collection for which approval has expired.

Abstract: New Source Performance Standards for Secondary Lead Smelters were developed to ensure that air emissions from these facilities do not cause ambient concentrations of lead and non-lead particulate matter to exceed levels that may reasonably be anticipated to endanger public health and the environment. Owners or operators of secondary lead smelters subject to NSPS must notify EPA of construction, reconstruction, modification, anticipated and actual startup dates, and results of performance tests. These facilities must also maintain records of performance test results, startups, shutdowns, and malfunctions. In order to ensure compliance with the standards, adequate recordkeeping and reporting is necessary. This information enables the Agency to: (1) Identify the sources subject to the standard; (2) ensure initial compliance with emission limits; and (3) verify continuous compliance with the standard. Responses are mandatory under 40 CFR Part 60. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15. The Federal Register Notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on June 11, 1996 [61 FR 29551].

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1.5 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able

to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: 23.

Estimated Number of Responses: 23.

Frequency of Response: 1/yr/ respondent.

Estimated Total Annual Hour Burden: 35 hours.

Estimated Total Annualized Cost Burden: \$1,225.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 1128.05 and OMB Control No. 2060-0080 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460 and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

Dated: November 27, 1996.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 96-31125 Filed 12-5-96; 8:45 am]

BILLING CODE 6560-50-P

[FRL-5660-5]

Investigator-Initiated Grants on Health Effects of Arsenic

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The purpose of this notice is to solicit public comment on the four research topics in the draft Request for Applications (RFA) on the health effects of low levels of arsenic in drinking water. EPA staff and academic researchers identified these arsenic research topics as important for reducing the uncertainty regarding the health risks of ingested arsenic at low levels. The Safe Drinking Water Act Amendments of 1996 directed EPA to develop a plan for study to support arsenic rulemaking that would reduce the uncertainty of health risks of arsenic. Congress directed EPA to consult with Federal Agencies and interested public and private entities in conducting the study and authorized

EPA to work with interested parties to carry out the study plan. At a later date, EPA will hold a public meeting(s) on the arsenic study plan.

DATES: Comments are requested on the wording, scope of the topics, and the appropriateness of the research topics presented in this draft RFA. Comments must be received on or before January 6, 1997. EPA plans to issue the RFA a month after the close of the comment period.

ADDRESSES: Comments must be submitted to Dr. Sheila Rosenthal at EPA, (8723), 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: For questions or comments regarding the solicitation process, contact Dr. Sheila Rosenthal, telephone number (202) 260-7334, EPA (8723), 401 M Street, SW., Washington, DC 20460, electronic mail address:

rosenthal.sheila@epamail.epa.gov. For questions or comments regarding the arsenic research topics, contact Ms. Irene Dooley, telephone number (202) 260-9531, EPA (4607), 401 M Street, SW., Washington, DC 20460, electronic mail address: dooley.irene@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA's National Center for Environmental Research and Quality Assurance (NCERQA) is preparing to issue a joint solicitation for research on the health effects of low levels of arsenic in drinking water. Funding for this joint solicitation will be provided by EPA, the American Water Works Association Research Foundation (AWWARF), and the Association of California Water Agencies (ACWA) for a total of approximately \$3 million. Any proposal submitted will be considered for an EPA grant or AWWARF contract, unless the proposal stipulates otherwise. EPA will fund approximately \$2 million worth of grants, and AWWARF/ACWA will fund approximately \$1 million worth of contracts. It is expected that three to six applications, each with a project period of up to 3 years, will be funded under this joint solicitation.

NCERQA will receive, process, and distribute the proposals to the peer reviewers; convene the peer review sessions in conformance with existing EPA and AWWARF guidelines; and record the review discussion for each proposal. No EPA or ACWA or AWWARF employees will serve as peer reviewers. The funding parties will discuss their respective research agendas for the sole purpose of ensuring that any one proposal is not funded by both EPA and AWWARF. The funding parties will ensure annual review of

projects being funded separately by the parties, and promote dissemination of results and communication of research findings to appropriate regulatory bodies and other stakeholders.

The description of the request for applications is as follows:

ARSENIC HEALTH EFFECTS RESEARCH

Background

Risk management policies for arsenic in the United States (U.S.) have changed with increases in knowledge, as evidenced by the U.S. Environmental Protection Agency's (EPA's) divergent guidance for arsenic under the Safe Drinking Water Act and the Clean Water Act. EPA's drinking water standard, or maximum contaminant level (MCL), of 50 µg/l was developed by the Public Health Service in the mid-1940s. In 1980, EPA established a human health water quality criterion for arsenic at 0.018 µg/l for a one in a million (10^{-6}) cancer risk level under the Clean Water Act. Researchers have since developed a substantial amount of data (toxicologic, epidemiologic, and some mechanistic) about the potential human health effects of arsenic (As) following ingestion.

The existing information has been used to develop a risk assessment. EPA's 1988 arsenic risk assessment (Special Report on Ingested Inorganic Arsenic: Skin Cancer; Nutritional Essentiality EPA/625/3-87/013) has undergone peer review, inside and outside the Agency. The risk assessment has led to the identification of several areas of uncertainty. Given the high costs associated with reducing the level of arsenic in drinking water systems, it has been decided that research to reduce the uncertainty in the risk assessment is warranted.

The EPA, American Water Works Association Research Foundation (AWWARF), and Association of California Water Agencies (ACWA) are jointly requesting grant and contract applications for research on human health effects associated with low level arsenic exposure via ingestion.

While there are several possible approaches to improving our understanding of the molecular basis of the carcinogenicity of arsenic, additional data on the baseline exposure, metabolism of arsenic, and role of arsenic in carcinogenesis are critical research priorities. Exposure data on arsenic from dietary sources other than drinking water would help determine the relative significance of arsenic from drinking water. This would be important information in future risk assessments for arsenic in drinking water and provide much needed

exposure information for future epidemiological studies. Furthermore, on-going epidemiological feasibility studies being funded by EPA and AWWARF plus several studies in Mexico, South America, and Asia should provide needed health effects data and improve future epidemiological study designs. This is the reason epidemiological studies are not requested as a part of this RFA. Understanding the mechanism of arsenic carcinogenesis and the variability in arsenic metabolism may ultimately be used to determine the shape and slope of dose response curves, including possible threshold effects, and reduce the uncertainty in these curves. Research proposals in the following four topic areas are invited. Proposals may address one or more than one topic area.

1. Contribution of Arsenic From Dietary Sources

In order to understand the possible health impacts of exposure to arsenic from drinking water ingestion, it is essential to know the relative contributions from different media. Since air exposures typically are low, the amount and variability of exposures from food and beverages need to be quantified for various populations, taking into account demographic variabilities. This could be done by using market-basket surveys for U.S. populations, as well as analyses of dietary intakes for specific individuals. In conducting these studies it is also essential to address availability of arsenic absorption from ingested foods, as well as arsenic speciation (chemical form and oxidation state). Information on specific food sources should be determined in addition to total dietary contributions.

2. Determinants of Variability in Arsenic Metabolism

Given the critical role of methylation in the disposition of arsenic, further characterization of the enzymatic basis of arsenic methylation is required. To date, human arsenic methyltransferase has not been isolated, but transferases are generally polymorphic. Understanding the factors affecting human sensitivity would improve the arsenic risk assessment. The objective of this section is to evaluate variations in arsenic metabolism as reflected in variations in urinary metabolites or other biomarkers of exposure as associated with the exposure level, nutritional status, genetic factors, and other variables. Included in this area are studies to improve mass balance data on typical human metabolism of arsenic at

various doses and chemical forms. There is a need for the development and refinement of assay procedures to characterize arsenic methyltransferases in human tissues. In addition, these studies would compare biomarkers of arsenic metabolism in individuals exposed to varying levels of arsenic with differences that include, but are not limited to, nutritional status, age, sex, and genetic variations.

3. Development of Animal Models for Determining Mechanisms for Arsenic Carcinogenesis

Currently, EPA's cancer risk assessment is based on a low-dose linearity and multistage extrapolation model, because there is not enough information on the mechanism of arsenic to do otherwise. In order to understand how arsenic causes cancer, it is first necessary to have a model system in laboratory animals. This model system can then be dissected to determine the molecular mechanism of the carcinogenesis. Understanding of the mechanism can often be used to identify biomarkers that would be useful for developing dose-response relationships, including possible threshold effects, and for detecting human populations sensitive to arsenic.

4. Biologically Based Quantitative Models

Quantitative models are key to extrapolation issues. They are critical not only to the description of experimental results but also in the generation of additional research. Physiologically based pharmacokinetic (PBPK) models, which incorporate measurable physiological and biochemical parameters, can be used to describe the bioavailability, uptake, tissue distribution, metabolism, and excretion of a chemical. By varying the biological parameters, one can predict across routes, exposure scenarios, high-to-low doses, and even species. The relationships among readily measured endpoints (e.g., blood levels, urinary metabolites, etc.) can be described. PBPK models can be linked to response models to predict how a specific tissue concentration can result in biological effect.

A major question in arsenic health effects is the relationship among exposure, dose, and response. PBPK models should be developed using either animal or human data and appropriately validated. Exposure via one route should be modeled and validated for another route. The ability to back-predict exposure, as well as tissue concentration, from readily

measured surrogates should be investigated.

Funding

Funding for this joint solicitation is provided by the U.S. EPA, AWWARF, and ACWA for a total of approximately \$3 million. Any proposal submitted will be considered for an EPA grant or AWWARF contract, unless the proposal stipulates otherwise. EPA will fund approximately \$2 million worth of grants, and AWWARF/ACWA will fund approximately \$1 million worth of contracts. It is expected that three to six applications, each with a project period of up to 3 years, will be funded under this joint solicitation.

Eligibility

Academic and not-for-profit institutions located in the U.S. and state or local governments are eligible under all existing EPA authorizations. Profit-making firms are not eligible to receive assistance from EPA under this program, but are eligible to receive funding from AWWARF. Researchers in federal agencies other than EPA may submit applications, but federal employees may not request salary reimbursement. Federal employees may cooperate or collaborate with other eligible applicants within the limits imposed by applicable legislation and regulations.

Researchers who are late in any ongoing AWWARF sponsored studies without an approved no cost extension will not be eligible for funding by AWWARF; however, they may be eligible for funding by EPA. Potential applicants who are uncertain of their eligibility for an AWWARF contract should contact their AWWARF project manager.

AWWARF and EPA have a policy of non-discrimination and abide by all laws, rules, and executive orders governing equal employment opportunity. All entities receiving funding under this solicitation will be required to agree not to discriminate on the basis of age, sex, race, religion, color, national origin, handicap or veteran status. AWWARF expects its contractors to be equal opportunity employers who accept the goal of having a workforce that generally reflects the minority composition of the community in which it is located. It is the policy of AWWARF to encourage proposals from qualified minority owned or directed institutions.

Funding Mechanism

The funding mechanism for all awards issued under this solicitation will consist of grants from EPA and

contracts from AWWARF and depends on the availability of funds. In accordance with Public Law 95-224, the primary purpose of a grant is to accomplish a public purpose of support or stimulation authorized by Federal statute rather than acquisition for the direct benefit of the Agency. In issuing a grant agreement, EPA anticipates that there will be no substantial EPA involvement in the design, implementation, or conduct of the research funded by the grant. However, EPA will monitor research progress, based in part on annual reports provided by awardees. ACWA and AWWARF will receive the annual progress reports for the EPA grants.

The mission of AWWARF is to "advance the science of water to improve the quality of life." Contracts with AWWARF are managed by an assigned AWWARF project manager and a volunteer Project Advisory Committee (PAC). PACs are organized by AWWARF for each funded project to provide guidance, review all reports and significant materials, and generally monitor project performance on behalf of AWWARF and the water utility industry. EPA will appoint a member to each AWWARF project advisory committee funded from this joint solicitation. Periodic reports for AWWARF are required every four months. In addition, a final report and intellectual property rights as outlined in the "Standard AWWARF Funding Agreement" are required under all AWWARF contracts. The "Standard AWWARF Funding Agreement" is available on the AWWARF home page at <http://www.awwarf.com>. For general information regarding the "Standard AWWARF Funding Agreement," contact Kathy Garretson at 303-347-6118 or by E-mail at kgarretson@awwarf.com.

The final RFA will also include instructions to potential applicants on the specific format to be used for applications. These instructions will be similar to such instructions found in other EPA/ORD solicitations which may be reviewed on the Internet at <http://www.epa.gov/ncerqa>.

Dated: November 27, 1996.

Approved for publication:

Joseph K. Alexander,
Acting Assistant Administrator for Research and Development.

[FR Doc. 96-31058 Filed 12-05-96; 8:45 am]

BILLING CODE 6560-50-P

[ER-FRL-5475-6]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared November 11, 1996 Through November 15, 1996 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564-7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the Federal Register dated April 5, 1996 (61 FR 15251).

Draft EISs

ERP No. D-AFS-L65271-AK Rating EO2, South Lindenberg Timber Sale(s), Timber Harvesting, Tongass National Forest, Stikine Area, Kupreanof Island, AK.

Summary: EPA expressed environmental objections due to potential impacts to water quality and fish habitat. EPA requested that more information and mitigation be provided in the final EIS.

ERP No. D-BLM-K65188-CA Rating EC2, Eagle Mountain Landfill and Recycling Center Project, Land Exchange, Right-of-Way Grants and COE Section 404 Permit Issuance, Riverside County, CA.

Summary: EPA expressed environmental concerns based on the need for more specific protection of resources on the offered lands as well as avoiding nighttime lighting, and a commitment to compensate for loss of bat habitat. EPA also requested additional information regarding management of the offered lands, the visibility analysis, and alternatives to reduce nighttime lighting impacts to the nearby Wilderness Area.

ERP No. D-COE-E90015-00 Rating EC2, Pearl River in the Vicinity of Walkiah Bluff, Wetland Restoration, Implementation, Picayune, Pearl River County, MS and St. Tammany Parish, LA.

Summary: EPA expressed environmental concerns about whether closure of the four distributaries will adversely affect wetlands in their present drainways and requested additional information regarding future hydrology.

ERP No. D-COE-K01008-CA Rating EO2, Santa Maria and Sisquoc Rivers Specific Plan, Mining and Reclamation Plans (MRPs), Coast Rock Site and S.P.