

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR-2014-0001]

Availability of Toxicological Profiles for Tetrachloroethylene and Trichloroethylene

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), within the Department of Health and Human Services (HHS), announces the release of the final Toxicological Profiles for Tetrachloroethylene and Trichloroethylene. The present profiles supersede any previously released drafts.

FOR FURTHER INFORMATION CONTACT: Susan Ingber, Agency for Toxic Substances and Disease Registry, Division of Toxicology and Human Health Sciences, 1600 Clifton Rd., NE, Mail Stop S102-1, Atlanta, GA, 30329-4027, Email: ATSDRToxProfileFRNs@cdc.gov; Phone: 1-800-232-4636.

SUPPLEMENTARY INFORMATION:

Legislative Background

The Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*] amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) [42 U.S.C. 9601 *et seq.*] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) regarding hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances [also called the Substance Priority List (SPL)]. This list identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant potential threat to human health. The SPL is available online at www.atsdr.cdc.gov/spl.

In addition, CERCLA provides ATSDR with the authority to prepare toxicological profiles for substances not found on the SPL. CERCLA authorizes ATSDR to establish and maintain an inventory of literature, research, and

studies on the health effects of toxic substances (CERCLA Section 104(i)(1)(B); 42 U.S.C. 9604(i)(1)(B)); to respond to requests for health consultations (CERCLA Section 104(i)(4)); 42 U.S.C. 9604(i)(4)); and to support the site-specific response actions conducted by the agency.

Public Comment

ATSDR released the draft Toxicological Profiles for Tetrachloroethylene and Trichloroethylene for public comment December 15, 2014 (79 FR 74093). The comment period ended on March 16, 2015. ATSDR received multiple comments on the draft Tetrachloroethylene profile from a professional association and multiple comments on the draft Trichloroethylene profile from three professional associations and one law firm. ATSDR carefully reviewed and considered all comments in the preparation of the final profiles.

The Toxicological Profile for Tetrachloroethylene received comments related to the use of specific studies for the profile, potential omission of studies, and derivation of the minimal risk level (MRL). ATSDR addressed these comments by correcting, clarifying, or updating data in the final toxicological profiles.

The Toxicological Profile for Trichloroethylene received comments centered on the methods and data used for deriving the MRLs, as well as suggestions for inclusion of additional studies. ATSDR clarified areas of scientific uncertainty and modeling techniques used to derive the MRLs. ATSDR updated the profile with several additional studies.

For both profiles, ATSDR also conducted a second peer review of the epidemiological carcinogenicity sections of the profile by external peer reviewers. A list of peer reviewers and the peer review comments are available at ATSDR's Peer Review Agenda web page at (https://www.atsdr.cdc.gov/sites/peer_review/index.html).

Availability

The Final Toxicological Profiles for Tetrachloroethylene and Trichloroethylene are available online at www.regulations.gov, Docket No. ATSDR-2014-0001 and <http://www.atsdr.cdc.gov/ToxProfiles>.

Pamela I. Protzel Berman,

Director, Office of Policy, Partnerships and Planning, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Partnership Opportunity To Develop New Designs of Powered Air-Purifying Respirators for Healthcare Workers

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC), announces the opportunity for inventors, researchers, and/or respirator manufacturers to participate, through a collaborative agreement, in a project titled "New Generation Powered Air-Purifying Respirators," to develop new designs of powered air-purifying respirators (PAPRs) for healthcare workers.

DATES: Interested parties must submit a letter of intent, electronically or written, by July 31, 2019.

FOR FURTHER INFORMATION AND TO SUBMIT A LETTER OF INTENT CONTACT: Dr. Ziqing Zhuang, NIOSH National Personal Protective Technology Laboratory, 626 Cochran Mill Road, Pittsburgh, PA 15236, 412-386-4055 (not a toll-free number), zaz3@cdc.gov.

Letters of intent should be sent electronically to Dr. Zhuang at the email address listed.

SUPPLEMENTARY INFORMATION:

Additional Information: The National Institute for Occupational Safety and Health (NIOSH) is seeking to identify inventors, researchers, and/or respirator manufacturers with the respirator design and manufacturing capabilities to construct a new respirator prototype, based on the characteristics included in this notice.

This research endeavor grew from recommendations issued by the National Academies, Institute of Medicine's (now known as the National Academy of Medicine) 2008 report, "Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers;" 2011 report, "Respiratory Diseases: Personal Protective Equipment for Healthcare Workers: Update 2010;" and 2015 report, "The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary." These reports outline the next steps

toward better respiratory protection for healthcare workers.

This project aims to create and develop new concepts in PAPR design targeted for healthcare workers using a government-private partnership development model.

During the first phase of the project, a team of researchers from NIOSH's National Personal Protective Technology Laboratory will develop a set of consensus recommendations for this project, that, if implemented, are expected to improve the function and utility of respiratory protective devices used by healthcare workers. The consensus recommendations for respirator design will be comprised of desirable characteristics of the PAPR and respiratory protection programs, which fall into one of four actionable categories:

- Respirators should perform their intended functions effectively and safely.
- Respirators should support, not interfere with, healthcare worker activities.
- Respirators should be comfortable and tolerable.
- Respirators should support healthcare system policies and practices.

The following presents the plan for this phase of the study:

- The consensus recommendations developed by the National Personal Protective Technology Laboratory will be shared during partnership meetings.
- The candidate organizations will then use the guidance to build the respirator prototype(s).
- NIOSH researchers will evaluate, to the extent possible, the respirator prototype(s), to determine whether the respirator(s) under evaluation meets or exceeds the performance requirements identified in the consensus recommendations.
- NIOSH researchers will seek the collective expertise of related stakeholders regarding optimal product development.
- NIOSH researchers will pursue, to the extent possible, field evaluation of resulting respirator prototype(s), including feedback from healthcare workers.

Collaborative efforts may be made via a Cooperative Research and Development Agreement (CRADA) under the authority of the Federal Technology Transfer Act, 15 U.S.C. 3710a, or another appropriate agreement. No federal funds will be provided under this project.

NIOSH may select one or more partnering candidates with respirator

design and commercial manufacturing capabilities using the following criteria:

- The candidate organization has adequate and sustained resources and/or funding, as appropriate, to develop a new PAPR prototype(s) or modify existing PAPR models.
- The candidate organization has scientific advisors and staff with a demonstrated record of new product development and knowledge to construct the desired new respirator prototype(s) within 24 months of the effective date of the CRADA or other appropriate agreement.
- The candidate organization is capable of providing up to five units of the prototype for laboratory and limited field-testing.

Note: Preference is for substantial U.S. manufacture of resultant product.

- A candidate organization who has prior experience with respiratory protection products is preferred, but this experience is not required.
- A candidate organization who has the capacity to transform a proof-of-concept prototype into a commercially viable model is preferred, but such capacity is not required.

Candidate organizations will be evaluated against the selection criteria above, which indicate an organization's capability to incorporate the consensus recommendations, when they are developed, into the prototype(s). The partnership also requires the candidate organization to (a) abide by HHS policies regarding testing in human subjects, as applicable, and (b) support the advancement of scientific research, as evidenced by a written agreement to publish jointly research results in a prompt manner.

This announcement does not obligate HHS, CDC, or NIOSH to enter into a contractual or collaborative agreement with any respondents.

Background: The 2003 severe acute respiratory syndrome (SARS), 2009 H1N1 influenza, and 2014 Ebola outbreaks highlighted the ongoing need for effective respiratory protective devices for healthcare workers. Powered air-purifying respirators are an important type of respiratory protection to defend against high-level respiratory hazards and infectious body fluids. Challenges that have limited widespread utilization of PAPRs in healthcare settings remain.

PAPRs were originally developed to protect industrial workers (primarily in mining) for a typical 8-hour work shift. Changes in PAPR design can be made to better meet the needs in the healthcare environment. Compared to industrial settings, ambient particulate and toxic gas/vapor levels in typical U.S.

healthcare environments are lower. As a result, the silica dust test, which was designed for a mining or other dusty environment, may not apply to healthcare settings. Additionally, because the typical work rates of healthcare workers are significantly lower than those of industrial workers, a lower PAPR air flow rate may be justified to provide a sufficient level of protection.

Potential issues related to the protection, performance, and usability of PAPRs include particle leakage during strenuous activity, noise, overall bulkiness, visual impairment, interference with tasks, and issues related to decontamination, among other problems associated with their use.

Beginning in 2006, NIOSH requested the Institute of Medicine (now the National Academy of Medicine) review, and a follow-up review, of personal protective equipment (PPE) with the explicit purpose of recommending how to best protect healthcare workers during an influenza pandemic (IOM, 2007, 2011). In the reports, "*Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*" and "*Respiratory Diseases: Personal Protective Equipment for Healthcare Workers: Update 2010*", the Institute of Medicine noted a lack of evidence behind respirator protective measures, including minimal attention placed on the development of equipment meeting the unique needs of the healthcare workforce. The Institute of Medicine recommended revisiting elemental aspects of respirator design and development, including distinct attention to respirators tailored to the jobs performed by healthcare workers, and pursuing an evidence-based approach for equipment design to the extent possible.

In 2014, at NIOSH's request, the Institute of Medicine convened a workshop, titled, "*The Use and Effectiveness of Powered Air-Purifying Respirators in Health Care*", to help prioritize and accelerate NIOSH activities to update certification requirements for PAPRs. The proceedings of the workshop are available on the IOM website (linked above).

Some of the research over the past 10 years at NIOSH's National Personal Protective Technology Laboratory has focused on breathing patterns of healthcare workers, barriers and usability of PAPRs in healthcare settings, and development of new testing methods for evaluating protective performance. The National Personal Protective Technology Laboratory previously developed a set of

consensus recommendations, under the *Better Respiratory Equipment using Advanced Technologies for Healthcare Employees* project (Project BREATHE), to improve respiratory protective equipment used by healthcare workers. These earlier consensus recommendations will be modified as NIOSH develops the consensus recommendations for the project New Generation PAPRs.

This project seeks to improve respirator tolerability, comfort, and other functional characteristics, while maintaining a level of protection equivalent to or greater than current standards. The design changes contemplated in this project could increase compliance with respiratory protection guidelines and standards among healthcare workers.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Intent To Issue One OPDIV-Initiated Supplement to BCFS Health and Human Services Under the Standing Announcement for Residential (Shelter) Services for Unaccompanied Alien Children, HHS-2017-ACF-ORR-ZU-1132

AGENCY: Unaccompanied Alien Children's (UAC) Program, Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of intent to issue one OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, Texas under the UAC Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the intent to issue one OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, Texas in the amount of up to \$300,800,000. ORR announces the issuance of the first installment for 60 days in the amount of up to \$50,000,000.

ORR has been identifying additional capacity to provide shelter for potential increases in apprehensions of Unaccompanied Alien Children at the

U.S. Southern Border. Planning for increased shelter capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter for Unaccompanied Alien Children referred to its care by the Department of Homeland Security (DHS).

To ensure sufficient capacity to provide shelter to unaccompanied alien children referred to HHS, ORR is requesting that BCFS provide up to 1,300 temporary shelter beds at Carrizo Springs, Texas over a graduated timeframe.

DATES: Supplemental award funds will support activities until January 31, 2020. The first installment will support activities for 60 days.

FOR FURTHER INFORMATION CONTACT: Stephen Antkowiak, Office of Refugee Resettlement, Division of Unaccompanied Alien Children Operations, 330 C Street SW, Washington, DC 20201. Phone: 202-260-6165. Email: stephen.antkowiak@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: ORR is continuously monitoring its capacity to shelter the unaccompanied alien children referred to HHS, as well as the information received from interagency partners, to inform any future decisions or actions.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing program and its services through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility to provide shelter for Unaccompanied Alien Children referred to its care by DHS and so that the U.S. Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85-4544RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110-457), which authorizes post release services under certain

conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85-4544-RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Karen Shields,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement for the National Center for Benefits Outreach and Enrollment

ACTION: Notice.

The Administration for Community Living (ACL) announces the intent to award a single-source supplemental to the current cooperative agreement held by the National Council on Aging (NCOA) for the National Center for Benefits Outreach and Enrollment (NCBOE). The purpose of the NCBOE is to provide technical assistance to states, area agencies on aging, and service providers to provide outreach and low-income benefits enrollment assistance, particularly to older individuals with greatest economic need for federal and state programs. The administrative supplement for FY 2019 will be for \$390,861, bringing the total award for FY 2019 to \$11,390,861. With this supplemental funding, NCOA will develop specialized training and tools around integrated care models that can be used by SHIPs, MIPPA grantees, and other partners of ACL like Centers for Independent Living (CILs) and the Aging and Disability Resource Centers (ADRCs) to expand the NCBOE's outreach and education efforts targeting older adults with the greatest economic need. This includes reaching out to current MIPPA grantees to evaluate their needs and to determine what the grantees believe would be helpful and conducting other stakeholder group meeting(s) to discuss what should be created around these integrated care models. Stakeholders could include MIPPA and other ACL grantees, health plans, CMS, and other non-federal partners. Additionally, NCOA will continue, expand, and complete the work they are currently undertaking with the NCBOE award without disrupting services.