

ORDER FOR SUPPLIES OR SERVICES
SCHEDULE - CONTINUATION

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 09/07/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0401
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0001	Admin Office: CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001 Period of Performance: 09/07/2021 to 03/06/2023 New Task Order Request under NAS Contract #68HERC19D0011. Funding for New NAS Task Order - Title: "NAS Independent External Peer Review of EPA's Draft Assessment Product - 2021" Total New Task Order Request Amount: \$389,857.54 NAS Contract: 68HERC19D0011 TO No.: TBD TOCOR: Vicki Soto ALTOCOR: Dahnish Shams CO: Mark Cranley CS: William Yates Acquisition Division: CAD Exemption Code (5170 Conference Process): ME262600 CL COR: Glennis Reslock ALT CL COR: Jorge Rangel NO IT Codes or FTTARA necessary Product/Service Code: R499 Accounting Info: 21-22-C-26D1000-000FK9-2532-26A5C-2126 D1C012-001 BFY: 21 EFY: 22 Fund: C Budget Org: 26D1000 Program (PRC): 000FK9 Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 2126D1C012-001 Funding Flag: Complete Funded: \$300,000.00 Accounting Info: 21-22-C-26D1000-000FK8-2532-26A5C-2126 D1C012-002 BFY: 21 EFY: 22 Fund: C Budget Org: 26D1000 Program (PRC): 000FK8 Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 2126D1C012-002 Funding Flag: Complete Funded: \$312,809.00 Continued ...				612,809.00	
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))					\$612,809.00	

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TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

PERFORMANCE WORK STATEMENT

National Academy of Sciences (NAS)

Contract #68HERC19D0011

PR-ORD-21-01009

Task Order #68HERC21F0401

I. TITLE: NAS Independent External Peer Review of EPA’s Draft Assessment Product – 2021

II. Task Order Contracting Officer Representative(s):

<p>Task Order Contracting Officer Representative (TOCOR) Name: Vicki Soto Office: ORD/CPHEA/CPAD William Jefferson Clinton Building 1200 Pennsylvania Avenue, N.W. Mail Code: 8602R, Room No. 71205 Washington, DC 20460</p> <p>Phone: (202) 564-3077 Email: soto.vicki@epa.gov</p>	<p>Alternate Task Order Contracting Officer Representative (Alt. TOCOR) Name: Dahnish Shams Office: ORD/CPHEA/CPAD William Jefferson Clinton Building 1200 Pennsylvania Avenue, N.W. Mail Code: 8602R, Room No. 71204 Washington, DC 20460</p> <p>Phone: (202) 564-2758 Email: shams.dahnish@epa.gov</p>
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III. PERIOD OF PERFORMANCE: Date of Task Order award through 18 months following award.

IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to engage with the scientific community to address key science issues pertinent to the development of human health assessments. This TO will provide one (1) expert peer review of a formaldehyde draft assessment document.

V. BACKGROUND

EPA’s Center for Public Health and Environmental Assessment (CPHEA) is a leader in the science of human health and environmental risk assessments. CPHEA champions the development and use of health and environmental assessments by interacting with other agencies, the scientific community, industry, policymakers, and the public. The NAS is widely viewed as an impartial, knowledgeable, and respected organization, capable of ensuring audience acceptance of products with which it is associated. The NAS is also able to provide EPA access to a wide range of scientific, expert reviewers and can independently vet such experts for conflicts of interests and a lack of impartiality.

VI. SCOPE OF WORK

The NAS shall recruit subject-matter experts to provide external peer review of an EPA draft assessment document. NAS’ identified peer reviewers shall conduct a peer-review of the draft EPA assessment of formaldehyde. EPA is seeking NAS’ advice on the clarity and scientific underpinnings of the overall EPA assessment. EPA’s draft assessment includes a hazard identification analysis, which summarizes the chemical properties, toxicokinetics, and health effects associated with exposure, and dose-response analysis, which characterizes the quantitative relationship between chemical exposure and each credible

health hazard. These quantitative relationships are then used to derive cancer and noncancer toxicity values (e.g., inhalation unit risk, reference concentration). The NAS peer review committee is charged by EPA to consider whether the conclusions presented in the draft assessment are clearly presented and scientifically supported. NAS shall develop a peer review report summarizing its findings on the conclusions presented by EPA and recommend ways in which the EPA assessment may be strengthened. NAS shall not assess the human health effects of formaldehyde separately from the IRIS assessment. The NAS previously conducted a peer review of the IRIS assessment of formaldehyde in 2010-2011. While the 2010 draft is of similar length, the current assessment represents an entirely new draft developed de novo using systematic review methods and in a manner responsive to NAS comments on the prior draft. More information on the assessment and its history can be found on the IRIS website: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614.

Task 1 - Review of EPA's Draft Assessment Document (Contract Level PWS Task Area 1 and Task Area 5)

EPA requests that NAS perform an expert external peer review on one (1) draft CPHEA assessment (i.e., Integrated Risk Information System (IRIS) Toxicological Review of Formaldehyde plus supplemental appendices) evaluating whether the scientific literature was adequately evaluated by EPA, and whether appropriate methods were used to synthesize the current state-of-the science. In all cases, the project shall operate in a manner consistent with the NAS consensus study process (see: <https://www.nationalacademies.org/about/our-study-process>). The NAS expert peer review committee shall evaluate the assessment's conclusions using the charge questions set forth by EPA and shall not conduct an independent assessment separately from the IRIS document nor shall the NAS comment on the broader aspects of the IRIS Program. Comments provided by the NAS committee shall be limited to responding to the materials provided by the EPA. EPA will provide all documentation (e.g., toxicological review, supplemental documents) in PDF format and grant any access to tools relevant for the review to the peer review panel. Additional background information may be provided to the committee. These materials shall not be reviewed by the NAS, but may be informative as the committee deliberates. Assessment documents will be found via the IRIS website at https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614. If necessary, EPA will provide a one-pager with the necessary background information. NAS shall coordinate with the EPA prior to initiating Task 1 and notify EPA prior to any public notifications and/or actions. Task 1 will consist of three (3) subtasks.

Subtask 1.1. – Establish expert panel

Prior to the initiation of the peer review and immediately upon award of this task order, NAS shall establish an expert panel of up to 12 experts following their procedures on committee composition, balance, and conflict of interest. NAS shall take public nominations for panel members and solicit comments on the panel. The NAS shall form a committee of experts approximately 3 months from the award of this task order. Recommended areas of expertise include the following:

- Public health risk assessment expertise, especially current experience supporting regulatory decisions in the context of the available scientific information for public health and environmental protection (e.g., international or state risk assessors). It would be preferable if this expert(s) has demonstrated experience with systematic review methods for environmental exposures;

- Environmental/occupational epidemiology, especially in the areas of cancer, reproductive, asthma and other immunological effects, and respiratory effects (i.e., multiple experts are needed);
- Toxicology, especially in the areas of cancer, respiratory effects, neurotoxicology, and/or reproductive/developmental toxicology. At least one of these experts should have experience with biological modeling (e.g., toxicokinetic/dosimetric modeling);
- Exposure measures for observational epidemiology studies of environmental and occupational exposures; and
- Dose-response analysis of environmental chemicals, especially current experience with data analysis for human exposure studies, including observational studies.

Subtask 1.2. – Conduct an independent external peer review and convene public meeting(s)

EPA requests that NAS conduct an independent external peer review of the draft CPHEA assessment or assessment materials. In coordination with NAS, EPA will transmit charge questions, along with the external peer review draft assessment materials and public comments received, prior to the peer review. NAS shall commence the peer review upon receipt of the assessment materials. EPA will also provide to NAS the public comments submitted on the draft assessment for the committee to consider as background information during their review. EPA also requests that NAS organize a public external peer review meeting(s) for the peer review panel to discuss the draft assessment with EPA. The public peer review meeting(s) shall not exceed 8 total hours and shall include an opportunity for written and oral public comments to the external peer review committee.

Subtask 1.3. – Prepare Panel Report Based upon listed Tier Levels

The NAS expert peer review committee shall develop a final report on their review and evaluation of the EPA document. The pre-publication report must be delivered no later than eleven (11) months upon initiation of the peer review (approximately 8 month study development, approximately 3 month quality peer review). Committee formation shall occur separately under subtask 1.1. Within the peer review report, the NAS shall promote clarity and the timely completion of the draft CPHEA assessment materials (e.g., Toxicological Review) by prioritizing and/or tiering recommendations provided to EPA under the following system:

Tier 1: Recommended Revisions– Important revisions for EPA to consider and address in order to improve the critical scientific concepts, issues, and/or narrative within the assessment.

Tier 2: Suggested Revisions – Revisions that are encouraged to strengthen or clarify the scientific concepts, issues, and/or narrative within the assessment but are not critical. Other factors (e.g., Agency practice and resources) may need to be considered by EPA before undertaking these revisions.

Tier 3: Future Considerations– Useful and potentially informative scientific exploration that may inform future evaluations of key science issues and/or inform the development of future assessments. These recommendations are likely outside the immediate scope and/or needs of the assessment under review.

VIII. Deliverables

The products of the NAS tasks for activity are as follows:

- a) EPA requests that written progress reports be provided to the Contracting Officer (CO), Contract Level Contracting Officer Representative (CL COR), and Task Order Contracting Officer Representative (TOCOR) quarterly and include updates on meetings and project milestones.
- b) Task 1, Subtask 1.2. - For all public meetings requested, the CO, CL COR, and TOCOR shall be informed via email of the time, location, and agenda of the meeting 45 days, or as early as practicable, prior to the meeting. All communications regarding public meetings should go through the CO, CL COR, and TOCOR. The NAS shall provide EPA with a final list of all meeting attendees and public commenters within five (5) business days after the meeting. If necessary, arrangement and provision of transportation, lodging, and any other logistical support for the experts' participation shall be provided. If public websites or similar means are used to disseminate information to the public during the course of this task, the CO and TOCOR shall be notified of the location of such information (e.g., websites), as well as relevant changes to them.
- c) Task 1, Subtask 1.3. - The primary products for each review are expected to be: (a) proposed and final lists of experts including biographical sketches, (b) written confirmation that review of potential COI and partiality issues for each expert was completed in accordance with NAS procedures, (c) any submitted public comments, and (d) a final peer review report.

IX. ACCEPTANCE CRITERIA

The Contractor shall prepare high quality products that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums and should be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow, as well as, technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonably complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016, Adobe Acrobat or compatible format. Deliverables will be accepted upon review and approval by the TOCOR.