

The Patient Safety Act also authorizes the development of data standards, known as the Common Formats, to facilitate the aggregation and analysis of non-identifiable patient safety data collected by PSOs and reported to the network of patient safety databases (NPSD). (42 U.S.C. 299b–23(b)). The Patient Safety Act and Patient Safety Rule can be accessed at: <http://www.pso.ahrq.gov/legislation/>.

AHRQ has issued Common Formats for Event Reporting for three settings of care—hospitals, nursing homes, and community pharmacies. As part of the agency's efforts to improve diagnostic safety and quality in healthcare, AHRQ is in the process of developing Common Formats for Event Reporting—Diagnostic Safety (CFER–DS). The CFER–DS is intended to help healthcare providers identify and report missed opportunities in the diagnostic process in a standardized manner across healthcare settings and specialties. Widespread use of the CFER–DS will make it possible to collect, aggregate, and analyze diagnostic safety-related information from healthcare providers across the country, which in turn can accelerate learning in this vital area of patient safety. Public comment has been received on a version 0.1 of the CFER–DS, and an Expert Panel convened by the National Quality Forum (NQF) is currently in the process of reviewing the public comments and providing feedback to AHRQ.

Federally listed PSOs can meet the requirement to collect patient safety work product in a standardized manner to the extent practical and appropriate by using AHRQ's Common Formats. The Common Formats are also available in the public domain to encourage their widespread adoption. An entity does not need to be listed as a PSO or working with one to use the Common Formats. However, the Federal privilege and confidentiality protections only apply to information developed as patient safety work product by providers and PSOs working under the Patient Safety Act.

Each version of the Common Formats is released with accompanying technical specifications, intended to provide direction to software developers and to PSOs that plan to submit data to the Patient Safety Organization Privacy Protection Center (PSOPPC) to ensure non-identification for transmission to the NPSD. For existing Common Formats for Event Reporting, technical specifications include the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field

length, guide for use, etc.) included in Common Formats;

- Clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the data from the PSO to the PSOPPC using the Common Formats;

- Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSOPPC;

- Common Formats flow charts—diagrams the valid paths to complete the formats (a complete event report);

- Local specifications—provides specifications for processing, linking, and reporting on events and details specifications for reports; and

- Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations (*e.g.*, HL–7, International Standards Organization (ISO)).

Agenda, Registration, and Other Information About the Meeting

The December 16, 2021 meeting will be an interactive forum designed to allow meeting participants not only to provide input but also to respond to the input provided by others. The meeting agenda will include: An update of Federal efforts related to the PSO Program and Common Formats; discussion of the CFER–DS, including requesting feedback on planned technical support materials and general integration/implementation; and, planning for future meetings, including discussing potential topics of interest for regular future meetings with software developers. AHRQ requests that interested persons send an email to SDMeetings@infinityconferences.com for registration information. Before the meeting, an agenda and logistical information will be provided to registrants. Prior to the meeting, AHRQ invites review of the CFER–DS which can be accessed through NQF's website at https://www.qualityforum.org/Common_Formats_for_Patient_Safety_Data.aspx.

Dated: November 9, 2021.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60 Day–2–0059; Docket No. ATSDR–2021–0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs). This Revision information collection request (ICR) will allow ATSDR/NCEH to continue to conduct additional Exposure Assessments (EAs) that may be requested at military or non-military installations.

DATES: ATSDR must receive written comments on or before January 18, 2022.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2021–0008 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to [Regulations.gov](https://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office,

Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7118; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs) (OMB Control No. 0923-0059, Exp. 06/30/2022)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per-or-polyfluoroalkyl substances (PFAS) are contaminants that have gained national prominence over the last decade. PFAS are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, many remain in the environment and may impact people's health.

The Agency for Toxic Substances and Disease Registry (ATSDR) and the

National Center for Environmental Health (NCEH) are requesting a three-year revision information collection request (ICR) to continue to conduct PFAS exposure assessments (EAs) at both military or non-military locations known to have PFAS in drinking water, groundwater, or any other sources of water. Previously, ATSDR was approved to conduct up to five EAs per year, for which the agency completed a total of eight. Currently, ATSDR is seeking approval to conduct up to three EAs per year for a maximum of seven additional locations.

Originally authorized under the National Defense Authorization Act (NDAA) of 2018, ATSDR is also mandated under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances in the environment. NCEH can conduct EAs under the authority of Section 301 of the Public Health Service Act (42 U.S.C. 241).

The PFAS EAs are conducted using statistical sampling to produce unbiased estimates of exposure to PFAS in communities living on or near the chosen current or former military installations. The number of respondents per EA will vary, but we expect the number to be approximately 395, and to be determined by specific statistical methods.

The time burden associated with the EAs include the following collections:

- **Community Event Evaluation Survey:** ATSDR/NCEH will hold a public meeting prior to the start of the EA and attendees will be asked to complete a five minute Community Event Evaluation Survey. It is assumed that 163 of the 250 attendees will complete the survey at each EA site, resulting in a burden of 41 hours for three EAs.
- **Household Eligibility Screener:** ATSDR/NCEH anticipates asking approximately 269 adults in each household at each EA site to complete a five minute telephone script, resulting in a burden of 66 hours for three EAs.
- **Estimation of Number of EA Respondents by Age Group:** Based on the criteria in the Household Recruitment Phone Script, 149 households are assumed to provide the target sample size of 395 respondents at each EA site, with a total of 1,185 respondents for three EAs. Based on

2017 Census estimates of average household size (2.5), and number of adults (1.9), and children under 18 years of age (0.6) in the household, we are able to estimate the annual number of respondents by age group as the following for three EAs: 900 adults ≥ 18 years and 284 children (165 aged 3-11 years and 119 aged 12-17 years).

- **Biological Testing Tracking:** All of the EAs use biological sampling for PFAS (blood and urine). A biological testing tracking form for the testing event will be provided to ensure that all appropriate forms are completed and all biological samples are collected. The testing will take 20 minutes, resulting in a burden of 395 hours annually for three EAs.

- **Adult Consent for Biological Testing:** 300 adults at each EA site will be administered a 10-minute consent form for testing of blood and urine for PFAS, resulting in a burden of 150 hours annually for three EAs.

- **Parental Permission Form for Biological Testing:** A parental permission form will be administered to the parents of 284 children aged 3-17 years for testing of blood and urine. The parental permission form will take 10 minutes resulting in a burden of 47 hours annually for three EAs.

- **Child Assent Form for Biological Testing:** Children aged 12-17 years (119) will assent to the testing of blood and urine for PFAS. The child assent form will take approximately 10 minutes, resulting in a burden of 20 hours annually for three EAs.

- **Adult Exposure Questionnaire for Biological and Environmental Testing:** 300 adults at each EA site will be administered an exposure questionnaire. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes, resulting in a burden of 450 hours annually for three EAs.

- **Parent Proxy for Child Exposure Questionnaire for Biological Testing:** 165 parents will respond to the 15-minute questionnaire for their children, 3-11 years, resulting in a burden of 41 hours annually for three EAs.

- **Child Exposure Questionnaire for Biological Testing:** Annually, 119 children will respond to the 15-minute child questionnaire for themselves (age 12-17 years), resulting in a burden of 30 hours annually for three EAs.

- **Household Recruitment Script for Environmental Testing:** ATSDR/NCEH will administer a five minute environmental recruitment script to 69 heads of households, resulting in a burden of six hours annually for three EAs.

• *Consent for Environmental Testing:* ATSDR/NCEH will obtain consent to test 10% of EA households for tap water and indoor dust samples using a 10-minute consent form for an annual total of 45 households, resulting in burden of eight hours annually for three EAs.

Environmental Sample Collection: ATSDR/NCEH will complete sampling at 45 households for three EAs deemed eligible for the EA for testing of tap water and indoor dust samples. The sampling will take 30 minutes, for an

estimated burden of 23 hours annually for three EAs.

ATSDR estimates the annualized time burden is 1,277 hours. Participation is voluntary, and there are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|----------------------------------|--|-----------------------|------------------------------------|--|--------------------|
| EA Community Members | Community Event Evaluation Survey | 489 | 1 | 5/60 | 41 |
| EA Participants (all ages) | Biological Testing Tracking | 1,185 | 1 | 20/60 | 395 |
| EA Adults | Household Eligibility Screener | 807 | 1 | 5/60 | 66 |
| | Consent | 900 | 1 | 10/60 | 150 |
| | Exposure Questionnaire (Adult) for Biological and Environmental Testing. | 900 | 1 | 30/60 | 450 |
| EA Parents | Parental Permission | 284 | 1 | 10/60 | 47 |
| | Exposure Questionnaire (Child) for Biological Testing (Parent Proxy). | 165 | 1 | 15/60 | 41 |
| EA Children | Assent | 119 | 1 | 10/60 | 20 |
| | Exposure Questionnaire (Child) for Biological Testing (Child completed). | 119 | 1 | 15/60 | 30 |
| EA Heads-of-Households | Household Recruitment Script for Environmental Sampling. | 69 | 1 | 5/60 | 6 |
| | Environmental Sampling Consent Form | 45 | 1 | 10/60 | 8 |
| | Environmental Sample Collection Form | 45 | 1 | 30/60 | 23 |
| Total | | | | | 1,277 |

Jeffrey M. Zirger,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-22-0047]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on March 26, 2021, to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to

allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570.

Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control No. 0923-0047, Exp. 01/31/2022)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Federal government’s commitment to improving service delivery. By qualitative feedback we mean information that provides