

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting for Software Developers on the Common Formats for Patient Safety Data Collection

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The purpose of this notice is to announce a meeting to discuss implementation of the Common Formats with software developers and other interested parties. This meeting is designed as an interactive forum where software developers can provide input on use of the formats. AHRQ especially requests participation by and input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the Common Formats electronically.

DATES: The meeting will be held from 1:00 to 2:30 p.m. Eastern on Thursday, March 31st, 2022.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Medical Officer, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: AHRQ coordinates the development of sets of standardized definitions and formats (Common Formats) that make it possible to collect, aggregate, and analyze uniformly structured information about health care quality and patient safety for local, regional, and national learning. The Common Formats include technical specifications to facilitate the collection of electronically comparable data by Patient Safety Organizations (PSOs) and other entities. Additional information about the Common Formats can be obtained through AHRQ's PSO website at <https://psa.ahrq.gov/common-formats> and the PSO Privacy Protection Center's website at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to 299b-26 (Patient Safety Act), and the related Patient Safety and Quality Improvement Final Rule, 42

CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70731-70814, provide for the Federal listing of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information (patient safety work product) regarding the quality and safety of health care delivery.

The Patient Safety Act requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers. (42 U.S.C. 299b-24(b)(1)(F)). 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).

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.

Agenda, Registration, and Other Information About the Meeting

The March 31 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. To encourage stakeholder feedback, this meeting will feature a panel of representatives from two PSOs who will share insights from their experiences and challenges with incorporating Common Formats into the work of their PSOs and reporting providers. Sheila Rossi will represent the ECRI and ISMP PSO and Mike Personett will represent the Press Ganey

PSO on the panel. Time will be allocated during the panel presentation to engage meeting participants and foster active discussion. 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.

Dated: March 14, 2022.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-22-0060; Docket No. ATSDR-2022-0002]

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 Assessment of Environmental Health and Land Reuse Certification Training. This certification is a joint collaboration between ATSDR and the National Environmental Health Association (NEHA) that is designed to increase participant awareness and knowledge, skills and feedback on environmental health and land reuse.

DATES: ATSDR must receive written comments on or before May 17, 2022.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2022-0002 by either 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*.

Please note: Submit all comments through the Federal eRulemaking portal (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

Assessment of Environmental Health and Land Reuse Certification Training (OMB Control No. 0923–0060, Exp. 08/31/2022)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a Revision of an information collection request (ICR) titled Environmental Health and Land Reuse Certification Training (OMB Control No. 0923–0060, Exp. Date 08/31/2022).

This certification is a joint collaboration between ATSDR and the National Environmental Health Association (NEHA) under a cooperative agreement. ATSDR and NEHA are co-producing the certification, which is geared toward NEHA members and ATSDR stakeholders who are environmental professionals, primarily local and state health agency employees, but also planners, environmental consultants, environmental non-profits, and students in environmental science, environmental/public health, and planning. The certification goals and course objectives are:

- To increase participant awareness and knowledge of environmental health and land reuse,
- To increase skills and capacity of participants to engage in environmental health and land reuse work, and
- To assess participant feedback and assessment of their own increased awareness, skills, and knowledge in environmental health and land reuse.

Due to the prevalence of potentially contaminated land reuse sites such as brownfields, the certificate program and training modules focus on increasing skills in land reuse and redevelopment through the integration of epidemiology, risk assessment, risk communication, and toxicology concepts and resources. The certification is offered in two modes. The certificate registration and training is hosted on NEHA's existing online Learning Management System, which hosts a variety of certificate and credentialing courses. In addition, ATSDR's National Land Reuse Health Program offers registration and maintains a classroom version of the training for learners who prefer virtual/classroom instruction or who may have limited broadband. NEHA will verify and issue continuing education (CE) credits for the EHLR Certificate for both online and classroom courses.

ATSDR plans to eliminate the currently approved one-time collection

of feedback within 6–12 months after participation as of 08/31/2022. This follow-up survey was designed to evaluate the subsequent use of the certificate program training materials and resources to build capacity, and skills in environmental health and land reuse (EHLR). The follow-up survey will be discontinued because the training course content has been successfully established based on the feedback received to date.

Additional revisions are also needed. Initially, the training was to be administered under the CDC Training and Continuing Education Online (TCEO) system (see “Application for Training” [OMB Control No. 0920–0017, Exp. Date 04/30/2022]). ATSDR has decided to transition the administration of the online course to NEHA. This revision ICR will add the following information collections: Online and classroom registration, and pre- and post-tests and self-assessments for each of the five modules: Engaging with Your Community, Evaluating Environmental and Health Risks, Communicating Environmental and Health Risks to the Community, Redesigning with Health in Mind, and Measuring Success. In addition, course evaluations for each module will be added for online training only. ATSDR and NEHA will share this information to make improvements to both the online and the classroom modules.

In the past 16 months, ATSDR and NEHA have enrolled 1,135 online participants (n=71 per month). Extrapolating this average over 12 months yields an estimated annual enrollment of 852 online participants. Likewise, ATSDR has enrolled approximately 100 participants per year for classroom learning. For burden hour estimation, we make a simplifying assumption that all students have completed all modules, pre- and post-tests, self-assessments, and evaluations (for online participants). In reality, the certification is self-paced, and participants are in varying stages of completion toward certification.

ATSDR and NEHA are also planning a third mode of instruction for supplemental “EHLR Immersive Training” in three new modules: Community engagement, evaluation of environmental and health risks, and risk communication. This training will be offered as a face-to-face classroom course at environmental conferences to those who have completed the prerequisite EHLR online or classroom certification. Should COVID-19 affect live training, ATSDR may consider delivering the immersive training virtually.

Regarding the supplemental immersive training, ATSDR estimates that 125 conference attendees will meet the prerequisite certification requirement and will register for the training through a conference portal. They will be asked to complete a self-

assessment for each module to be submitted toward additional CE credits and to receive the supplemental certification.

ATSDR plans an annual enrollment of 1,077 participants, which is an increase of 877 participants over the previously

approved 200 participants. Participation in this information collection is voluntary and there is no cost to respondents other than their time. CDC requests OMB for an estimated 2,424 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)	
Environmental Health Professionals and Affiliates.	EHLR Registration (online)	852	1	3/60	43	
	Module 1 Pre-Test (online)	852	1	10/60	142	
	Module 1 Post-Test and Self-assessment (online).	852	1	15/60	213	
	Module 1 Evaluation (online)	852	1	5/60	71	
	Module 2 Pre-Test (online)	852	1	10/60	142	
	Module 2 Post-Test and Self-assessment (online).	852	1	15/60	213	
	Module 2 Evaluation (online)	852	1	5/60	71	
	Module 3 Pre-Test (online)	852	1	10/60	142	
	Module 3 Post-Test and Self-assessment (online).	852	1	15/60	213	
	Module 3 Evaluation (online)	852	1	5/60	71	
	Module 4 Pre-Test (online)	852	1	10/60	142	
	Module 4 Post-Test and Self-assessment (online).	852	1	15/60	213	
	Module 4 Evaluation (online)	852	1	5/60	71	
	Module 5 Pre-Test (online)	852	1	10/60	142	
	Module 5 Post-Test and Self-assessment (online).	852	1	15/60	213	
	Module 5 Evaluation (online)	852	1	5/60	71	
	EHLR Registration (classroom)	100	1	3/60	5	
	Module 1 Pre-Test (classroom)	100	1	10/60	17	
	Module 1 Post-Test and Self-assessment (classroom).	100	1	15/60	25	
	Module 2 Pre-Test (classroom)	100	1	10/60	17	
	Module 2 Post-Test and Self-assessment (classroom).	100	1	15/60	25	
	Module 3 Pre-Test (classroom)	100	1	10/60	17	
	Module 3 Post-Test and Self-assessment (classroom).	100	1	15/60	25	
	Module 4 Pre-Test (classroom)	100	1	10/60	17	
	Module 4 Post-Test and Self-assessment (classroom).	100	1	15/60	25	
	Module 5 Pre-Test (classroom)	100	1	10/60	17	
	Module 5 Post-Test and Self-assessment (classroom).	100	1	15/60	25	
	Immersive Training Registration (conference).	125	1	3/60	6	
	Module 1 Self-assessment (conference).	125	1	15/60	10	
	Module 2 Self-assessment (conference).	125	1	15/60	10	
	Module 3 Self-assessment (conference).	125	1	15/60	10	
	Total	2,424

Jeffrey M. Zirger,
 Lead, Information Collection Review Office,
 Office of Scientific Integrity, Office of Science,
 Centers for Disease Control and Prevention.

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