

Much of CDC’s health communication takes place within campaigns that have fairly lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This request includes studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced. This request also includes collection of information from public

health programs to assess needs related to initiation of a new program activity, or expansion or changes in scope, or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to identified needs.

Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: (1) Structured and qualitative interviewing for surveillance, research, interventions and material development, (2) cognitive interviewing for development of specific data collection instruments, (3) methodological research, (4) usability

testing of technology-based instruments and materials, (5) field testing of new methodologies and materials, (6) investigation of mental models for health decision-making, to inform health communication messages, and (7) organizational needs assessments to support development of capacity.

Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements. In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. The total burden hours for this collection is 46,516. Participation of respondents is voluntary. There is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response
General public	Screener	56,840	1	10/60
Health care providers	Screener	24,360	1	10/60
General public	Consent Forms	28,420	1	5/60
Health care providers	Consent Forms	12,180	1	5/60
General public	Individual Interview	4,620	1	1
Health care providers	Individual Interview	1,980	1	1
General public	Focus Group Interview	2,800	1	2
Health care providers	Focus Group Interview	1,200	1	2
General public	Survey of Individual	21,000	1	30/60
Health care providers	Survey of Individual	9,000	1	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2016–0001; Docket Number NIOSH 260–A]

Revised Draft NIOSH Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease

Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft document available for public comment and online public meeting.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment titled *Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials*. To view the notice, document and related materials, visit <https://www.regulations.gov> and enter CDC–2016–0001 in the search field and click “Search”.

DATES: The public online meeting will be held on October 30, 2018, 1 p.m.–4:30 p.m., Eastern Time, or until the last public commenter has spoken,

whichever occurs first. The public online meeting will be a web-based event available only by remote access. Members of the public who wish to provide public comments should plan to login to the meeting at the start time listed. Members of the public who register with the NIOSH Docket Office, niocindocket@cdc.gov to attend the public meeting will be provided the login information prior to the meeting.

ADDRESSES: Written comments submitted to the docket must be received by November 30, 2018. Written comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

FOR FURTHER INFORMATION CONTACT: Charles Geraci, NIOSH/EID/NTRC, Robert A. Taft Laboratories, 1090

Tusculum Avenue, Cincinnati, OH 45226, (513) 533-8339 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background: In response to public and peer review comments on the NIOSH draft document titled *Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials*, NIOSH has developed a revised draft document and released it for public comment [<https://www.regulations.gov>]. Regarding the previous draft document, notices of a public meeting and comment period were published on January 21, 2016 [81 FR 342], and February 10, 2016 [81 FR 7124]. A public meeting was held on March 23, 2016, and members of the public, stakeholders, and scientific peers were given the opportunity to provide comments by April 22, 2016. In the interest of completeness and transparency, NIOSH is making available the public and peer reviewer comments received on the previous draft document and the NIOSH responses to those comments at [<https://www.regulations.gov>]. NIOSH has carefully considered the review comments on the previous draft in developing the current draft document. For the current review, NIOSH is requesting comments on the August 2018 draft NIOSH document only.

This revised draft document provides an updated scientific literature review of information pertaining to occupational exposure to silver nanomaterials. This literature review includes studies on the toxicological effects of exposure to silver nanomaterials in experimental animal and cellular systems, the effect of particle size and other properties on the toxicological effects of silver, and NIOSH recommendations on the measurement and control of occupational exposures to silver and silver nanomaterials. NIOSH assessed the potential health risks of occupational exposure to silver nanomaterials by evaluating the scientific literature. Studies in animals have shown adverse lung and liver effects associated with exposure to silver nanoparticles. Based on an assessment of these data, NIOSH developed a recommended exposure limit (REL) for silver nanomaterials. This new draft REL applies to processes that produce or use silver nanomaterials. In addition, NIOSH continues to recommend its existing REL for total silver (metal dust and soluble compounds, as Ag) [www.cdc.gov/niosh/npg/npgd0557.html].

NIOSH further recommends the use of workplace exposure assessments, engineering controls, safe work procedures, training and education, and established medical surveillance approaches to prevent potential adverse health effects from exposure to silver nanomaterials. NIOSH proposes research needs to fill remaining data gaps on the potential adverse health effects of occupational exposure to silver nanomaterials.

The purpose of the public review of the draft document is to obtain comments on whether the proposed NIOSH draft document (1) adequately and clearly describes the scientific literature on the potential adverse health effects of silver nanomaterials, and (2) demonstrates that the NIOSH recommendations on occupational exposure to silver nanomaterials are consistent with current scientific knowledge.

Purpose of Public Meeting

To discuss and obtain comments on the revised August 2018 draft NIOSH document, "*Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials*". Special emphasis will be placed on discussion of the following questions for reviewers:

- (1) Does the draft document accurately identify and characterize the health hazards of exposures to silver and silver nanomaterials based on the available scientific literature?
- (2) Are the risk assessment and dosimetry modeling methods presented in the draft document consistent with current scientific knowledge and practice?
- (3) Is the relationship between exposure to silver nanomaterials and biological activity (toxicity) accurately portrayed in the draft document?
- (4) Is the available scientific evidence fully described regarding the human health relevance of the adverse health endpoints observed in rats associated with exposure to silver nanomaterials?
- (5) Is the proposed recommended exposure limit (REL) well-supported by the scientific data presented in the document?
- (6) Are the sampling and analytical methods proposed for silver nanomaterials adequate to measure worker exposure?
- (7) Are the recommended strategies for controlling exposure to silver and silver nanomaterials (*e.g.*, engineering controls, work practices, personal protective equipment) reasonable?
- (8) Are the important data gaps and future research needs complete and clearly described?

Online Public Meeting

The meeting is open to the public, limited only by the number of logins available. The Adobe Connect license accommodates approximately 500 people. In addition, there will be an audio conference for those who cannot login through a computer. There is no registration fee to attend this public online meeting. However, those wishing to attend are encouraged to register via email to NIOSH Docket Office niocindocket@cdc.gov by October 23, 2018. Registrants will be provided with the public meeting login information prior to the meeting. Individuals wishing to speak during the meeting may sign up when registering. Those who have not signed up to present in advance may be allowed to present at the meeting if time allows. Persons wanting to provide oral comments will be permitted up to 20 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting may also be submitted to the docket in writing to assure they are accurately recorded by the Agency.

Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved attendees will be admitted as login space allows.

Instructions: All material submitted to the Agency should reference the agency name and docket number [CDC-2016-0001; NIOSH 260-A]. Each person making a comment will be asked to give his or her name and affiliation, and all comments (including their name and affiliation) will be posted without change to <https://www.regulations.gov>. All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 155, 1150 Tusculum Avenue, Cincinnati, Ohio 45226-1998.

Dated: September 12, 2018.

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Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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