

techniques, and approaches dealing with occupational safety and health problems.

This research relates to the interplay of personal, organizational, and cultural influences on risk-taking and proactive decision-making behaviors among mine workers. The antecedents, or characteristics, that impact these behaviors are not well understood in mining. Understanding the degree to which antecedents influence decisions can inform the focus of future health and safety management interventions.

NIOSH proposes a project that seeks to empirically understand the following: What are the most important organizational antecedent characteristics needed to support worker health and safety (H&S) performance behaviors in the mining industry?

What are the most important personal antecedent characteristics needed to support worker health and safety (H&S) performance behaviors in the mining industry?

To answer the above questions, NIOSH researchers developed a psychometrically supported survey. Researchers identified seven worker perception-based ‘organizational values’ and four ‘personal characteristics’ that are presumed to be important in fostering H&S knowledge, motivation, proactive behaviors, and safety outcomes. Because these emergent, worker perception-based constructs have a theoretical and empirical history, psychometrically tested items exist for each of them.

NIOSH researchers will administer this survey at mine sites to as many participating mine workers as possible to answer the research questions. Upon data collection and analysis NIOSH researchers will revalidate each scale to ensure that measurement is valid. A quantitative approach, via a short survey, allows for prioritization, based on statistical significance, of the antecedents that have the most critical influence on proactive behaviors. Data collection will take place with approximately 1,200 mine workers over three years. The respondents targeted for this study include any active mine worker at a mine site, both surface and underground. All participants will be between the ages of 18 and 75, currently employed, and living in the United States. Participation will require no more than 20 minutes of workers’ time (5 minutes for consent and 15 minutes for the survey). There is no cost to respondents other than their time.

Upon collection of the data, it will be used to answer what organizational/ personal characteristics have the biggest impact on proactive and compliant health and safety behaviors. Dominance and relative weights analysis will be used as the data analysis method to statistically rank order the importance of predictors in numerous regression contexts. Safety proactive and safety compliance will serve as the dependent variables in these regression analyses, with the organizational and personal characteristics as independent variables.

Findings will be used to improve the safety and health organizational values and focus of mine organizations, as executed through their health and safety management system for mitigating health and safety risks at their mine site. Specifically, if organizations are lacking in values that are of high importance among employees, site leadership knows where to focus new, innovative methods, techniques, and approaches to dealing with their occupational safety and health problems. Finally, the data can be directly compared to data from other mine organizations that administered the same standardized methods to provide broader context for areas in which the mining industry can focus more attention if trying to encourage safer work behavior.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Safety/health Mine Operator .....	Mine Recruitment Script .....	10	1	5/60
Mine Worker .....	Individual Miner Recruitment Script .....	400	1	5/60
Mine Worker .....	Survey .....	400	1	15/60

**Leroy A. Richardson,**  
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Prevention.*  
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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Centers for Disease Control and  
Prevention**

**[30 Day–15–15VA]**

**Agency Forms Undergoing Paperwork  
Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request

to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written

comments should be received within 30 days of this notice.

### Proposed Project

National Disease Surveillance Program III—CDC Support for Case Investigation, Contact Tracing, and Case Reports—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

The international outbreak of Ebola virus disease (EVD) in West Africa began March 10, 2014. The initial cases were from southern Guinea, near its rural border with Liberia and Sierra Leone. Highly mobile populations contributed to increasing waves of person-to-person transmission of EVD that occurred in multiple countries in West Africa. The CDC activated its Emergency Operations Center on July 9,

2014 to help coordinate technical assistance and control activities with international partners and to deploy teams of public health experts to the affected countries.

The operations turned to the United States (U.S.) when the first imported case of EVD was diagnosed in Texas on September 30, 2014. In response, on October 11, 2014, the CDC Quarantine Stations and the Department of Homeland Security Customs and Border Patrol mobilized to screen, detect, and refer arriving travelers who were potential persons at risk for EVD to appropriate state, territorial, and local (STL) authorities. The CDC also increased its commitment to support STL public health authorities to combat and control the spread of EVD within their jurisdictions.

Thus in 2014, the CDC requested and received an expedited emergency review and approval from OMB of an

information collection request to initiate multiple urgently needed information collections in West Africa, at U.S. ports of entry, and within STL jurisdictions. These information collections allowed the agency to accomplish its primary mission on many fronts to quickly prevent public harm, illness, and death from the uncontrolled spread of EVD.

This new collection of information is designed to allow CDC to conduct active disease surveillance in support of and at the request of STL authorities among respondents that may include the general public, workers, and STL authorities. This should cut down on the need for multiple steps in emergency requests that were experienced in the first year of the 2014 Ebola virus response.

There are no costs to the respondents other than their time. The total annualized burden requested is 14,702 hours.

### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
General Public—Case .....	Ebola Virus Disease Case Investigation Form—United States.	15	1	30/60
General Public—Case .....	Symptom Monitoring Form .....	15	42	5/60
General Public—Person Under Investigation (PUI).	Ebola Virus Disease Person Under Investigation (PUI) Form.	300	1	10/60
General Public—Person Under Investigation (PUI).	Symptom Monitoring Form .....	300	42	5/60
General Public—Contact .....	Ebola Virus Disease Contact Tracing Form—United States.	105	1	10/60
General Public—Contact .....	Symptom Monitoring Form .....	105	42	5/60
Healthcare Workers .....	Ebola Virus Disease Tracking Form for Healthcare Workers with Direct Patient Contact.	600	15	10/60
Healthcare Workers .....	Symptom Monitoring Form .....	600	57	5/60
Laboratory Personnel .....	Ebola Tracking Form for Laboratory Personnel.	600	15	10/60
Laboratory Personnel .....	Symptom Monitoring Form .....	600	57	5/60
Environmental Services Personnel .....	Ebola Tracking Form for Environmental Services Personnel.	600	15	10/60
Environmental Services Personnel .....	Symptom Monitoring Form .....	600	57	5/60
State, Territorial, and Local Public Health Authorities and Their Delegates.	White House Evening Report .....	15	42	10/60
Total .....	.....	.....	.....	.....

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-2306]

### Testicular Toxicity: Evaluation During Drug Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Testicular Toxicity: Evaluation During Drug Development.” The draft guidance addresses nonclinical findings that may raise concerns of a drug-related adverse effect on the testes, clinical monitoring of adverse testicular effects early in clinical development, and the design and conduct of a safety clinical trial assessing drug-related testicular toxicity. The draft guidance is intended