**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket No. CDC–2018–0057]

**Notice of Intent To Prepare an Environmental Impact Statement, Public Scoping Meeting, and Request for Comments; Acquisition of Site for Development of a Replacement Underground Safety Research Program Facility for the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) in Mace, West Virginia**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

**ACTION:** Notice of intent; announcement of public meeting; and request for comments.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), in cooperation with the General Services Administration (GSA), announces its intent to prepare an Environmental Impact Statement (EIS) to analyze and assess the environmental impacts of the proposed acquisition of a site in Mace, West Virginia, and the development of this site into a replacement of the National Institute for Occupational Safety and Health (NIOSH) Underground Safety Research Program facility (Proposed Action). The current acquisition and development would replace the former Lake Lynn Experimental Mine in Fayette County, Pennsylvania and would support research programs focused on miner health and safety issues. The site being considered for acquisition and development includes 461.35 acres located off of U.S. Route 219 in Randolph and Pocahontas Counties near Mace, West Virginia.

This notice is pursuant to the requirements of the National Environmental Policy Act of 1969 (NEPA) as implemented by the Council on Environmental Quality (CEQ) Regulations (40 CFR parts 1500–1508). CDC, in cooperation with GSA, also intends to initiate consultation, as required by Section 106 of the National Historic Preservation Act (NHPA), to evaluate the potential effects, if any, of the Proposed Action on historic properties. Following the scoping meeting, a Draft EIS will be prepared and circulated for public comment. CDC is the lead federal agency for this Proposed Action.

**DATES:**

**Public Scoping Meeting:** A public scoping meeting in open house format will be held on June 26, 2018 in Slatyfork, West Virginia. The meeting will begin at 5:30 p.m. and end no later than 8:30 p.m.

**Written comments:** Written scoping comments must be submitted by 11:59 p.m. on July 14, 2018.

**Deadline for Requests for Special Accommodations:** Persons wishing to participate in the public scoping meeting who need special accommodations should contact Sam Tarr at 770–488–8170 by 5:00 p.m. Eastern Time, June 19, 2018.

**ADDRESSES:** The public scoping meeting will be held at the Linwood Community Library, 72 Snowshoe Drive, Slatyfork, West Virginia 26291.

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**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ’s health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Francis D. Chesley, Jr.,
Acting Deputy Director.
You may submit comments identified by Docket No. CDC–2018–0057 by either of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov (Follow the instructions for submitting comments).
- U.S. Mail: Sam Tarr, Office of Safety, Security, and Asset Management (OSSAM), Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–K80, Atlanta, Georgia 30329–4027.

Instructions: All submissions must include the agency name and Docket Number. All relevant comments received will be posted to http://www.regulations.gov (personally identifiable information, except for first and last names, will be redacted). For access to the docket to review background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Sam Tarr, Office of Safety, Security, and Asset Management (OSSAM), Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–K80, Atlanta, Georgia 30329–4027, phone: (770) 488–8170, or email: cdc-macewv-eis@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: CDC is dedicated to protecting health and promoting quality of life through the prevention and control of disease, injury, and disability. NIOSH, one of CDC’s Centers, Institutes, and Offices, was established by the Occupational Safety and Health Act of 1970. NIOSH plans, directs, and coordinates a national program to develop and establish recommended standards, conduct research and development, and perform related activities to ensure health and safety of workers. NIOSH is responsible for the protection and promotion of workers' health and safety in the United States.

In 1997, NIOSH assumed the lease for a facility referred to as the Lake Lynn Experimental Mine (LLEM) when the mine safety and health function was transferred from the Bureau of Mines (BOM) to NIOSH. The LLEM facility had been leased by BOM since 1982. The LLEM was located 60 miles south of Pittsburgh, Pennsylvania. The LLEM and above ground fire testing facility was primarily used for studies and research on mine explosions, mine seals, mine rescue, ventilation, diesel exhaust, new health and safety technologies, ground control, and fire suppression. After December 2012, the property was no longer available for long-term leasing. CDC attempted to purchase the LLEM underlying property, but LLEM was vacated by the Government after market-based purchase offers were rejected by the property owners.

In 2013, CDC completed a Project Development Study to outline a design solution for the replacement of the LLEM. The study presented the facility and site requirements and design concepts for the replacement facilities. In 2016, to identify potentially available locations that could accommodate the space requirements defined in the 2013 study, GSA issued (on behalf of CDC) two separate Request for Expressions of Interest (REOI) for a site, developed or undeveloped, that could be used for the new underground safety research facility. The first REOI, advertised in June 2016, contained a limited delineated area within a 200-mile radius of the LLEM. The REOI set forth criteria that would be used to evaluate the suitability of the submitted sites. One expression of interest that had the potential to meet the minimum criteria was received. After further evaluation, however, the site was found to be non-viable.

The second REOI was issued in October 2016 and expanded the delineated area to the contiguous United States. Three expressions of interest were received. One did not meet the minimum criteria, and a second expression of interest did not contain all necessary information to evaluate the offer. The offeror of the second site did not respond to subsequent GSA inquiries. The third potential site met the minimum criteria and was determined to be a viable site. The site is located near Mace, West Virginia, and straddles the Randolph and Pocahontas County lines. In accordance with NEPA, as implemented by the CEQ regulations (40 CFR parts 1500–1508), CDC is preparing the environmental impact statement for the action. Under NEPA, Federal agencies are required to evaluate the environmental effects of their proposed actions and a range of reasonable alternatives to the proposed action before making a decision. At a minimum, the EIS will evaluate the following two alternatives: The Proposed Action Alternative (acquisition of the Site and construction of a new underground safety research facility) and the No Action Alternative.

Scoping Process: In accordance with NEPA, a public scoping process will be conducted to establish the range of issues to be addressed during the preparation of the EIS. Scoping is an early and open process for determining the scope of issues to be addressed and identifying issues that should be taken into account in selecting an alternative for implementation. To that end, during the scoping process, CDC will actively seek input from interested people; organizations; federally recognized Native American tribes; and federal, state, and regional agencies.

The purpose of this Notice is to inform interested parties regarding CDC’s plan to prepare an EIS for the proposed Site acquisition in Mace, West Virginia, and the development of the Site into an underground safety research facility; to provide information on the nature of the Proposed Action; and to initiate the scoping process. The public scoping meeting will be held on June 26, 2018, at the Linwood Community Library, 72 Snowshoe Drive, Slatefork, West Virginia 26291, from 5:30 p.m. to 8:30 p.m. Eastern Time. The public scoping meeting will be in open house format. General information on the Site and the Proposed Action will be provided, and representatives of CDC and GSA will be available to answer one-on-one questions. There will be no formal presentation or question-and-answer session. Participants may arrive at any time between 5:30 p.m. and 8:30 p.m. Eastern Time. Comment forms will be provided for written comments, and a stenographer will be available to transcribe oral comments. Through the NEPA scoping process, CDC will also facilitate consultation with the public as required by Section 106 of the NHPA.

Dated: June 7, 2018.

Sandra Cashman,
Executive Secretary Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2018–D–1918]

Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for