



Department of Energy  
Washington, DC 20585

October 22, 2015

JM Chronology  
JM RECEIVED 10/22/15  
OUT FOR REVIEW 10/26/15  
DRB DISCUSSION 11/5/15

MEMORANDUM FOR: INGRID KOLB  
DIRECTOR, OFFICE OF MANAGEMENT

THROUGH: KEVIN T. HAGERTY  
DIRECTOR, OFFICE OF INFORMATION RESOURCES

FROM: MATTHEW B. MOURY  
ASSOCIATE UNDER SECRETARY FOR  
ENVIRONMENT, HEALTH, SAFETY AND SECURITY

SUBJECT: Notice of Intent to Revise Department of Energy Policy 434.1A,  
*Conduct and Approval of Select Agent and Toxin Work at Department  
of Energy Sites*, dated November 7, 2013

**PURPOSE:** This memorandum provides justification for the revision of Department of Energy (DOE) Policy (P) 434.1A, *Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites*. This directive provides the Department's expectations for the establishment and operation of DOE research laboratories utilizing select agents and toxins, as regulated by the United States Department of Health and Human Services, and addresses future policy needs for the operation, coordination, and oversight of these laboratories.

**JUSTIFICATION:** A new United States Government (USG) policy for institutional oversight of life sciences dual use research of concern (DURC) became effective September 24, 2015. This policy is complementary to the March 2012 USG Policy for DURC and addresses institutional oversight of DURC for federally funded studies that involve 15 select pathogens and toxins. Institutional oversight will include policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Institutional oversight of DURC is a critical component of a comprehensive oversight system since institutions are the most familiar with the life sciences research conducted in their facilities.

Revisions will include minor administrative changes, as well as an additional sentence to consider the 2015 USG DURC Policy and a reference to the new USG Policy in the references section. The USG Institutional DURC Oversight Policy is available at [www.phe.gov/s3/dualuse](http://www.phe.gov/s3/dualuse).

There are no valid external, consensus, or other standards (e.g., International Organization for Standardization, Voluntary Protection Program, etc.) available that can be used in place of the new content that will be added to this directive.

**IMPACT:** The proposed revision to DOE P 434.1A does not duplicate existing laws, regulations, or national standards; and it does not create undue burden on the Department. It will provide

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further expectations for complying with the new USG DURC Policy. Additional impacts of this proposed revision are provided in the completed risk analysis tool (attachment).

**WRITER:** Robin (Pickens) Keeler, (301) 903-9981, [robin.keeler@hq.doe.gov](mailto:robin.keeler@hq.doe.gov)

**OPI/OPI CONTACT:** Bill McArthur, PhD, DOE Responsible Manager, Office of Worker Safety and Health Policy, EHSS, (301) 903-9674, [bill.mcarthur@hq.doe.gov](mailto:bill.mcarthur@hq.doe.gov)

Ingrid Kolb, Director, Office of Management (MA-1):

Concur:  Nonconcur: \_\_\_\_\_ Date: 11-4-2015

<u>Standard Schedule for Directives Development</u>	<u>Days</u>
Draft Development	60 days
Review and Comment (RevCom)	30
Comment Resolution	30
Final Review	30
Total	150

Attachment