Department of Energy
Washington, DC 20585

March 29, 2013

JM CHRONOLOGY
JM RECEIVED 3/29/13
OUT FOR REVIEW 4/4/13
DRB DISCUSSION 4/18/13

MEMORANDUM FOR: INGRID KOLB
DIRECTOR
OFFICE OF MANAGEMENT

THROUGH: KEVIN T. HAGERTY
DIRECTOR
OFFICE OF INFORMATION RESOURCES

FROM: GLENN S. PODONSKY
CHIEF HEALTH, SAFETY AND SECURITY OFFICE
OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT: Notice of Intent to Revise Department of Energy Policy 434.1, *Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites*, dated June 6, 2005

PURPOSE: This memorandum provides justification for the revision of Department of Energy (DOE) Policy (P) 434.1, *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 to address future policy needs for the operation, coordination, and oversight of these laboratories.

JUSTIFICATION:

Background: In March 2012, the National Institutes of Health issued a new Government Policy on Dual Use Research of Concern (DURC) calling for a systematic review of the potential risks associated with federally funded studies involving 15 select pathogens and toxins. The new policy requires all agencies to review both proposed projects and those already funded. If a review identifies the potential for dual use DURC, the agency and the lead scientist will need to develop a risk mitigation plan.

Summary of Development Process: Following the receipt of this new U.S. Government Policy, the Department's BioSurety Workgroup convened to discuss how the Department should respond to this new policy. Following a number of teleconferences with the working group, it was decided that only a minor revision to the existing BioSurety Policy (DOE P 434.1) would satisfy the need for DOE to appropriately address this new policy. A draft of a revised P 434.1 was developed to include a reference to DURC and a paragraph to consider this policy when undertaking select agent research. The draft Revised DOE policy was vetted with all members of the Departmental BioSurety workgroup. The workgroup agreed that the final draft should be submitted to the Directives Review Board (DRB) for approval and entered into the DOE RevCom process following the procedures in DOE O 251.1C, *Departmental Directives.*

CTirado rec'd 3/29/13

Applicability: No changes in applicability are planned.

Major Changes: No major changes are being made to the Policy; however, the following paragraph will be added:

> "All research activities involving Dual Use Research of Concern (DURC) must be reviewed with consideration of the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern."

In addition the following reference will be added to the Reference section of the Policy: United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern", http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf

IMPACT:
No conflicts with other directives are identified.
No impacts to departmental functions or operations are anticipated. However, adding this language will increase awareness of the U.S. Policy on Dual Use Research of Concern.

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OPI: Patricia R. Worthington, HS-10, 3-5926

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

Concur: _____ Nonconcur: _____ Date: 4-18-13

Unless determined otherwise by DRB, writers will have up to 60 days in which to develop their first draft and submit to the Office of Information Resources, MA-90

Timeline: Schedule for Directives Development

Standard Schedule for Directives Development	Days
Draft Development	10
Review and Comment (RevCom)	30
Comment Resolution	30
Final Review	30
Total	100

Risk Identification and Assessment

Revision of DOE P 434.1, "Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites"

Risk	Probability	Impact	Risk Level
People			
1. May provide knowledge of information, products or technology that could be misused for harmful purposes	Possible	High	Extreme
2. Personal injury or illness due to lack of Medical Counter measures	Possible	Medium	Significant
Mission			
3.			
Assets			
4.			
Financial			
5. Loss of funding for research	Possible	High	Extreme
Customer and Public Trust			
6. Loss of public trust in Departments ability to control hazards	Possible	Medium	Significant

Gap Analysis of Existing Risks and Controls

Laws	• *List controls as relevant*
External Regulation	• 7 CFR 331, Possession, Use, and Transfer of Select Agents and Toxins • 9 CFR 121, Possession, Use, and Transfer of Select Agents and Toxins • 42 CFR 73, Select Agents and Toxins • U.S. Policy on Dual Use Research of Concern (NIH)
DOE Regulation	• 10 CFR 851, Worker Safety and Health Program
DOE Orders	• DOE O 440.1B, Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees • DOE P 434.1, Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites
Contract Controls	• 48 CFR 970.5223-1, Integration of ESH into work planning and execution
External Assessments	• *List GAO, IG, and other assessments if relevant.*

Risk Mitigation Techniques

Risk Assessment for DOE P 434.1, "Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites"					
Risk/Opportunity	**Risk Level**	**Potential Cost/Benefit**	**External Control(s)**	**Proposed Mitigation Technique**	**Internal Control (if needed)**
May provide knowledge of information, products or technology that could be misused for harmful purposes	Extreme		U.S. Policy on Dual Use Research of Concern	Revise P-434.1	
Personal injury or illness due to lack of Medical Counter measures	Significant		U.S. Policy on Dual Use Research of Concern	Revise P-434.1	DOE O 440.1B 10 CFR 851
Loss of funding for research	Extreme	Failure to follow NIH U.S. Policy on Dual Use Research may lead to Federal funding being withheld	U.S. Policy on Dual Use Research of Concern	Revise P-434.1	
Loss of public trust in the Departments ability to control the hazard	Significant	Risk of funding being withheld	U.S. Policy on Dual Use Research of Concern	Revise P-434.1	