



Department of Energy

Argonne Site Office
9800 South Cass Avenue
Argonne, Illinois 60439

AUG 09 2013

Dr. Eric Isaacs
Director, Argonne National Laboratory
President, UChicago Argonne, LLC
9700 South Cass Avenue
Argonne, IL 60439

Dear Dr. Isaacs:

SUBJECT: NATIONAL ENVIRONMENTAL POLICY ACT (NEPA) DETERMINATION FOR ARGONNE NATIONAL LABORATORY (ARGONNE)

The Argonne Site Office (ASO) has approved the following as a categorical exclusion (CX) under the category of "B 3.6 Small-scale research and development, laboratory operations, and pilot projects."

- Bio Safety Level-1 and Bio Safety level-2 Research at Argonne (ASO-CX-298)

Therefore, no further NEPA review is required. However, if any modification or an expansion of the scope is made to the above project, additional NEPA review will be necessary.

Enclosed please find a copy of the approved Environmental Review Form (ERF) for the project. If you have any questions, please contact Kaushik Joshi of my staff at (630) 252-4226.

Sincerely,

A handwritten signature in black ink, appearing to read "Joanna M. Livengood".

Joanna M. Livengood
Site Manager

Enclosure:
As Stated

cc: J. Stauber, ANL, w/encl.
G. Dyrkacz, ANL, w/encl.
W. Brocker, ANL, w/encl.
K. Joshi, ASO, 201, w/encl.
M. McKown, DOE-CH, 201, w/encl.
P. Siebach, DOE-CH, 201, w/encl.

Environmental Review Form for Argonne National Laboratory

Click on the question mark for instructions, contacts, and additional information on specific line items (?)

Project/Activity Title: BSL - 1 and BSL - 2 Research at Argonne

ASO NEPA Tracking No. ASO CX-298 **Type of Funding:** DOE, WFO, or CRADA

B&R Code _____

Identifying number: _____ WFO proposal # _____ CRADA proposal # _____

Work Project # _____ ANL accounting # (item 3a in Field Work Proposal) _____

Other (explain) _____

Project Manager: _____ Signature: _____ Date: _____

NEPA Owner: Gary Dyrkacz Signature: Gary Dyrkacz Date: 7/17/2013

NEPA Owner: William Brocker Signature: William Brocker Date: 7/18/2013

ANL NEPA Reviewer: Joel Stauber Signature: Joel V. Stauber Date: 7/29/13

I. Description of Proposed Action: The scope of this ERF is bench scale Biosafety level (BSL)-1 and BSL-2 research in laboratories on the Argonne site. The NIH guidelines define bench scale as not production scale and using less than 10 liters of culture. The proposed research would be restricted to that which has been determined by the Argonne Institutional Biosafety Committee (IBC) to be unambiguously BSL-1 or BSL-2 and within the work scopes described below. The proposed research also must comply with the requirements outlined in the Argonne Biosafety Manual, Bloodborne Pathogens Occupational Exposure Control Plan, and LMS Procedures. Laboratories and equipment must also pass inspection by a Biological Safety Officer prior to initiation of research.

BSL-1 bench scale research is currently being performed in various laboratories at ANL, and has been determined to be an activity that does not individually or cumulatively have a significant effect on the human environment, and therefore is categorically excluded under B.3.6, operation of bench scale research laboratories. BSL-2 research currently performed at ANL has also been determined, on a case-by-case basis, to fall within the parameters of Categorical Exclusion B3.12, microbiological and biomedical diagnostic, treatment and research facilities excluding BSL-3 and BSL-4.

Scope of BSL-1 Research

Bench scale BSL-1 research would involve material or microorganisms that are not known to consistently cause disease in healthy human adults. A typical BSL-1 laboratory has a sink, eye wash station and chemical-resistant work surfaces. Work is done on the open bench, there is no specific recommendation that the laboratory be isolated from other parts of the building, and standard microbiological practices

are used. A variety of bench scale BSL-1 research will be conducted under the supervision of principal investigators and with the oversight of the Division ES&H Coordinators.

Scope of BSL-2 Research

Bench scale BSL-2 research would involve material or microorganisms listed below that are known to cause disease in healthy humans but that do not pose an inhalation hazard. The proposed bench scale BSL-2 research would be conducted by laboratory personnel who have specific training in the handling of the material under their control and are directed by competent scientists. All bench scale BSL-2 work under this ERF will be under an approved IBC protocol that establishes operational and engineering controls. Work areas in continuous laboratories will be inspected no less than annually. Temporary BSL-2 areas would be inspected by Biological Safety Officers prior to initiation of research.

BSL-2 laboratories are BSL-1 areas supplemented with engineering controls and physical containment equipment (such as biosafety cabinets (BSC) and sealed rotor heads) required by the IBC. Requirements for BSL-2 areas also include limited access to the room and agent/toxin storage areas. BSL-2 laboratories must have facility specific manuals or SOPs which include specific training for each agent and PPE requirements and other protocols to reduce the risk of accidental occupational exposure via inoculation through the skin or mucous membrane. Infectious or toxic waste must be decontaminated by treating with chemical disinfectants, steam autoclaving or offsite incineration.

BSL-2 research under this ERF would involve material in the following categories:

1. Human/non-human primate (NHP) material, i.e. blood, tissue or cells or any products derived from these types of materials, which poses a low level infectious hazard.
2. Biological toxins
3. Prions
4. Work involving Risk Group 2 human/NHP pathogens and material derived therefrom. Risk Group 2 agents are associated with human diseases which are rarely serious and for which preventive or therapeutic interventions are often available.
5. Other biological material which may pose either a zoonotic infection hazard such as animal or insect derived material or an environmental hazard such as parasitic plants, noxious weeds, animal or plant pathogens or insects.

Research not within the scope of this ERF includes activities which are:

- Assessed by the IBC as unambiguously BSL-3 or requiring BSL-3 containment, i.e. constitute an aerosol or splash hazards which cannot be readily handled by a certified BSC.
- Research activities that use more than 10 liters of culture or more than 5 gallons of hazardous liquid chemicals or 5 pounds of hazardous solid chemicals. See the storage and use requirements in the **Potential Environmental Effects Responses Section**.
- Research activities that require major building renovation or additions.
- Research activities that require modified Safety Assessment Document for accelerator facilities, i.e. APS.
- Research activities that generate "no path forward" wastes.

- Research activities that required new or modified regulatory permits.
- Research activities including sample collection that occurs outdoors that may have significant environmental impact.

II. Description of Proposed Action: BSL-1 bench scale research is being performed in various indoor laboratories at ANL. There are four operating BSL-2 laboratories on site within Building 202 and one continuously operating BSL-2 facility in 438 and 440. Temporary BSL-2 areas are set up periodically at the APS, primarily in sectors 2, 14, 18, 23. Proposed BSL-2 research would also be conducted at the Advanced Protein Crystallization Facility (under construction).

III. Potential Environmental Effects: (Attach explanation for each "yes" response. See Instructions for Completing Environmental Review Form)

A. Complete Section A for all projects.

- | | | |
|--|-----------------|----------------|
| 1. Project evaluated for Pollution Prevention and Waste Minimization opportunities and details provided under items 2, 4, 6, 7, 8, 16, and 20 below, as applicable | Yes <u>X</u> | No <u> </u> |
| 2. Air Pollutant Emissions | Yes <u>X</u> | No <u> </u> |
| 3. Noise | Yes <u> </u> | No <u>X</u> |
| 4. Chemical/Oil Storage/Use | Yes <u>X</u> | No <u> </u> |
| 5. Pesticide Use | Yes <u> </u> | No <u>X</u> |
| 6. Polychlorinated Biphenyls (PCBs) | Yes <u> </u> | No <u>X</u> |
| 7. Biohazards | Yes <u>X</u> | No <u> </u> |
| 8. Effluent/Wastewater (If yes, see question #12 and contact Gregg Kulma (FMS-SEP) at 2-9147 or gkulma@anl.gov | Yes <u>X</u> | No <u> </u> |
| 9. Waste Management | | |
| a) Construction or Demolition Waste | Yes <u> </u> | No <u>X</u> |
| b) Hazardous Waste | Yes <u>X</u> | No <u> </u> |
| c) Radioactive Mixed Waste | Yes <u> </u> | No <u>X</u> |
| d) Radioactive Waste | Yes <u> </u> | No <u>X</u> |
| e) PCB or Asbestos Waste | Yes <u> </u> | No <u>X</u> |
| f) Biological Waste | Yes <u>X</u> | No <u> </u> |
| g) No Path to Disposal Waste | Yes <u> </u> | No <u>X</u> |

- h) Nano-material Waste Yes ___ No X
10. Radiation Yes ___ No X
11. Threatened Violation of ES&H Regulations or Permit Requirements Yes ___ No X
12. New or Modified Federal or State Permits Yes ___ No X
13. Siting, Construction, or Major Modification of Facility to Recover, Treat, Store, or Dispose of Waste Yes ___ No X
14. Public Controversy Yes ___ No X
15. Historic Structures and Objects Yes ___ No X
16. Disturbance of Pre-existing Contamination Yes ___ No X
17. Energy Efficiency, Resource Conserving, and Sustainable Design Features Yes ___ No X
- B. For projects that will occur outdoors, complete Section B as well as Section A.**
18. Threatened or Endangered Species, Critical Habitats, and/or other Protected Species Yes ___ No ___
19. Wetlands Yes ___ No ___
20. Floodplain Yes ___ No ___
21. Landscaping Yes ___ No ___
22. Navigable Air Space Yes ___ No ___
23. Clearing or Excavation Yes ___ No ___
24. Archaeological Resources Yes ___ No ___
25. Underground Injection Yes ___ No ___
26. Underground Storage Tanks Yes ___ No ___
27. Public Utilities or Services Yes ___ No ___
28. Depletion of a Non-Renewable Resource Yes ___ No ___
- C. For projects occurring outside of ANL complete Section C as well as Sections A and B.**
29. Prime, Unique, or Locally Important Farmland Yes ___ No ___

30. Special Sources of Groundwater (such as sole source aquifer) Yes ___ No ___
31. Coastal Zones Yes ___ No ___
32. Areas with Special National Designations (such as National Forests, Parks, or Trails) Yes ___ No ___
33. Action of a State Agency in a State with NEPA-type Law Yes ___ No ___
34. Class I Air Quality Control Region Yes ___ No ___

IV. Subpart D Determination: (to be completed by DOE/ASO)

Are there any extraordinary circumstances related to the proposal that may affect the significance of the environmental effects of the proposal? Yes ___ No X

Is the project connected to other actions with potentially significant impacts or related to other proposed action with cumulatively significant impacts? Yes ___ No X

If yes, is a categorical exclusion determination precluded by 40 CFR 1506.1 or 10 CFR 1021.211? Yes ___ No ___

Can the project or activity be categorically excluded from preparation of an Environment Assessment or Environmental Impact Statement under Subpart D of the DOE NEPA Regulations? Yes X No ___

If yes, indicate the class or classes of action from Appendix A or B of Subpart D under which the project may be excluded. APPENDIX B - 3.6 Small-scale research and development, laboratory operations, and pilot projects.
 If no, indicate the NEPA recommendation and class(es) of action from Appendix C or D to Subpart D to Part 1021 of 10 CFR.

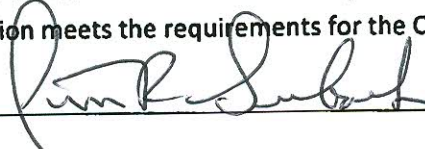
ASO NEPA Coordinator Review: Kaushik Joshi

Signature: Kaushik Joshi

Date: 8-6-2013

ASO NCO Approval of CX Determination:

The preceding pages are a record of documentation that an action may be categorically excluded from further NEPA review under DOE NEPA Regulation 10 CFR Part 1021.400. I have determined that the proposed action meets the requirements for the Categorical Exclusion identified above.

Signature: 

Date: 8/7/2013

Peter R. Siebach
Acting Argonne Site Office NCO

ASO NCO EA or EIS Recommendation:

Class of Action: _____

Signature: _____

Date: _____

Peter R. Siebach
Acting Argonne Site Office NCO

Concurrence with EA or EIS Recommendation:

CH GLD: _____

Signature: _____

Date: _____

ASO Manager Approval of EA or EIS Recommendation:

An ___ EA ___ EIS shall be prepared for the proposed _____ and
_____ shall serve as the document manager.

Signature: _____

Date: _____

Dr. Joanna M .Livengood
Manager

October 2011

Potential Environmental Effects Responses

Experiments will use the smallest cultures sizes as practical.

1. The IEPA requires that the autoclaves will have a monthly biological indicator testing procedure to ensure they are working properly.

For BSL-2 work, biological safety cabinets (BSC) will be used for all transfers and general manipulations of biohazardous materials which pose a splash or aerosol hazard. For IBC approved operations outside of a BSC, such materials will be moved in sealed secondary containers that will completely contain the material in the event of a failure of the primary container. Centrifugations will be carried out in sealed centrifuge rotors, specially vented centrifuges, or sealed safety cups or sealed buckets that fully contain the primary centrifuge tube.

4. The proposed activities may involve the use and storage of chemicals. The amount of chemicals used in a single experiment, measurement, or test will be limited to five gallons of hazardous liquid and five pounds of hazardous solid. The production, acquisition, storage, or use of chemicals will follow the requirements outlined in applicable LMS procedures. This includes following the import/export requirements under the TSCA procedures.
7. For BSL-2 work the biohazardous materials that fall under this ERF are described in Section I. Only small, non-production size quantities are allowed (i.e., below roller bottle or spinner bottle quantity or below 10 liters). All cultures, stocks and other regulated solid and liquid wastes are decontaminated by an OSHA, EPA, or CDC approved decontamination method, such as autoclaving, incineration, or chemical decontamination before disposal. An agent such as 1/10 freshly diluted bleach solution or Clidox are commonly used. These are processes which have been validated as effective at destroying any biological hazards that may be present.
8. Typical effluents for BSL-2 work will be from the steam autoclaves. Any discharge from the autoclaves after treatment will be to the sanitary sewer. All autoclaves will be tested monthly with biological indicators to ensure that they are working properly. Wastewater must be deactivated before it can be disposed into the sanitary sewer. Other effluents will be handled as waste according to the Waste Handling Procedures Manual and the LMS Procedures.
- 9b. Small quantities of hazardous waste such as acids, bases, oxidizers, carcinogens, inorganic salts and solvents will be generated typical to bench scale research activities and they will be stored and disposed according to the Waste Handling Procedures Manual and LMS Procedures.
- 9f. Biological waste from the cell lines and derived materials, proteins, or genetic material will be autoclaved at 121°C and 21 psi for one hour prior to disposal in the regular trash. Some materials may require disposal through Waste Management for off-site incineration.