

Justification for Change

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)

(OMB Control No. 0920-0576) Expiration 12/31/2018

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

Lori Bane
(404) 718-2006
(404) 718-2097 FAX
zoz1@cdc.gov

January 26, 2017

**Nonmaterial/non-substantive change to an OMB approved information collection
 “Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)”
 OMB Control No. 0920-0576, Expiration 12/31/2018**

Justification

This is a request for nonmaterial/non-substantive changes to clarify the meaning/intent of selected questions on approved forms. The nonmaterial/non-substantive changes do not affect the purpose, content, or burden of completing the forms.

The proposed changes are summarized in the table below:

Form	Current Item	Requested Change	Justification
APHIS/CDC Form 1, Section 6A – Building and Suite/Room Specific Security, Question #2	Perimeter security measures outside the building (check all that apply)	What security features are present outside of the building(s) where select agents and/or toxins are used or stored? (Check all that apply)	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Section 6A – Building and Suite/Room Specific Security, Question #3	Access to the building(s) or other area(s) housing the suite/room is controlled by (check all that apply)	How is access to building(s) or other area(s) housing registered room(s)/suite(s) controlled? (Check all that apply)	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Section 6A – Building and Suite/Room Specific Security, Question #4	Additional security measures present in the interior of the building where select agent and/or toxin is stored or used (check all that apply)	What additional security features are present in the interior of the building(s) where select agents and/or toxins are used or stored? (Check all that apply)	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Section 7A – Principal Investigator (PI) Information and Select Agent and Toxin Locations	List Suites/Rooms with Suite Legend (if applicable)	List rooms; follow up question: Are any of the rooms grouped as a suite? If yes, list rooms in suite	This change clarifies the meaning/intent of the question.

Form	Current Item	Requested Change	Justification
APHIS/CDC Form 1, Attachment C – Work with Animals, Question #3	Describe the waste stream: A. Are animal carcasses, cages, and waste (e.g. sewage, bedding) treated prior to disposal by an approved method? Choices: yes or no Check all that apply. Choices: incineration, tissue digester, autoclave, chemical, other B. Waste Handling Procedures. Choices: Waste decontaminated inside the containment area or waste transported outside of the containment area for decontamination. Describe when and how waste is treated before transport out of the containment area.	Is the entity waste stream treated prior to disposal? Choices: yes or no If no, explain. If yes, follow up questions A-D, each with the same choices: incineration, tissue digester, autoclave, chemical, other A. What is the method of treating carcasses? B. What is the method of treating infectious waste (e.g., cell cultures, infected arthropods, other biohazardous waste)? C. What is the method of treating disposable material (e.g. PPE)? D. What is the method of treating disposable caging (e.g. rodent/mosquito caging)?	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Attachment C – Work with Animals, Question #4	Describe any inactivation (e.g. formalin fixation, lysis of cells for nucleic acid extraction, irradiation) of samples collected from infected animals that will be manipulated at a lower biosafety level. Include concentration or dosage and contact/exposure time, as applicable.	Are samples (tissue, blood, nucleic acids, etc.) from exposed or infected animals manipulated at a lower biosafety level? If answer yes, follow up question: Describe the inactivation process (e.g. formalin fixation, lysis of cells for nucleic acid extraction, irradiation) for the samples. Include concentration or dosage and contact/exposure time, as applicable.	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Attachment C – Work with Animals, Question #9	Are experimentally infected animals monitored (e.g., daily checks)?	Are animals intentionally or accidentally infected with select agents monitored (e.g. daily checks)?	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Attachment E – Work with Arthropods, Question #9	Arthropods are prevented from release into suite/room. Choices: yes or no If yes, do procedures include protocol for accidental escape? Choices: yes or no	Are arthropods, including those experimentally infected, housed and manipulated in a suite/room such that accidental contact and release is prevented? Choices: yes or no	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Attachment E – Work with Arthropods, Question #10	Experimentally infected arthropods are housed and manipulated in a suite/room such that accidental contact and release is prevented. Choices: yes or no	Do protocols account for accidental escape? Choices: yes or no	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 1, Attachment F – Attachment F - BSL3Ag Laboratories, Question #10	Necropsy rooms are sized and equipped to accommodate large animals. Choice: yes or no If yes, describe	Are necropsy rooms sized and equipped appropriately to accommodate animals? Choices: yes or no If yes, describe.	This change clarifies the meaning/intent of the question.