

2019 Responsible Official Workshop

Inspections

23 July 2019



42 USC §262a (f) (Inspections)

7 USC §8401 (f) (Inspections)



- The [HHS] Secretary shall have the authority to inspect persons subject to regulations [related to the possession, use, and transfer of select agents and toxins] to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions [regarding safeguard and security requirements].
- The [USDA] Secretary shall have the authority to inspect persons subject to regulations [related to the possession, use, and transfer of select agents and toxins] to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions [regarding safeguard and security requirements].

42 USC §262a (f) (Inspections)
7 USC §8401 (f) (Inspections)



The Federal Select Agent Program inspectors have the legal authority to enter and inspect any registered entity at any time without any preconditions.

42 CFR §73.18 Inspections
9 CFR §121.18 Inspections
7 CFR §331.18 Inspections



(a) Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(a) Without prior notification, APHIS must be allowed to inspect any site at which activities regulated under this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by this part.

42 CFR §73.18 Inspections
9 CFR §121.18 Inspections
7 CFR §331.18 Inspections



Without prior notification, the Federal Select Agent Program inspectors must be allowed to inspect any registered entity and must be allowed to inspect and copy any records relating to the activities covered by the select agent regulations.

42 CFR § 73.8 Revocation or suspension of registration.
9 CFR § 121.8 Revocation, or suspension of registration.
7 CFR § 331.8 Revocation, or suspension of registration.



(a) [A] certificate of registration [may be] revoked or suspended if: (3) The individual or entity does not meet the requirements of [the select agents and toxins regulations].

42 CFR § 73.8 Revocation or suspension of registration.
9 CFR § 121.8 Revocation, or suspension of registration.
7 CFR § 331.8 Revocation, or suspension of registration.



A registered entity's failure to allow
Federal Select Agent Program
inspectors to inspect that entity is a
failure to meet a regulatory
requirement by that entity.

42 CFR § 73.7 Registration
9 CFR § 121.7 Registration
7 CFR § 331.7 Registration



- (a) Unless exempted under §73.5, an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary. Unless exempted under §73.6 or 9 CFR §121.6, an individual or entity shall not possess, use, or transfer overlap select agents or toxins, without a certificate of registration issued by the HHS Secretary and [APHIS] Administrator.
- (a) Unless exempted under §121.5, an individual or entity shall not possess, use, or transfer any VS select agent or toxin without a certificate of registration issued by the [APHIS] Administrator. Unless exempted under §121.6 or 42 CFR §73.6, an individual or entity shall not possess, use, or transfer any overlap select agent or toxin without a certificate of registration issued by the [APHIS] Administrator and the HHS Secretary.
- (a) Unless exempted under §331.5, an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by the [APHIS] Administrator.

42 CFR § 73.7 Registration
9 CFR § 121.7 Registration
7 CFR § 331.7 Registration



An entity whose registration is suspended or revoked may not possess, use, or transfer a select agent or toxin.

18 USC 175b(c)

Select agents



For HHS select agents and toxins: Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a select agent for which such person has not obtained a registration required by [HHS select agents and toxins] regulations . . . shall be fined under [the United States Criminal Code], or imprisoned for not more than 5 years, or both.

For USDA select agents and toxins: Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a [USDA] biological agent or toxin . . . for which such person has not obtained a registration required by [USDA select agents and toxins] regulations . . . shall be fined under [the United States Criminal Code], or imprisoned for not more than 5 years, or both.

18 USC 175b(c) Select agents



An entity that possesses a select agent or toxin without a valid registration is in violation of United States criminal law.

INSPECTIONS



The FSAP “inspector”
is not a “visitor.”



INSPECTIONS



All FSAP inspectors will, where required, have the appropriate security clearance for the entity to be inspected. For those entities requiring pre-access verification, FSAP will have shared with the entity confirmation of the security clearance prior to the beginning of the inspection.

INSPECTIONS

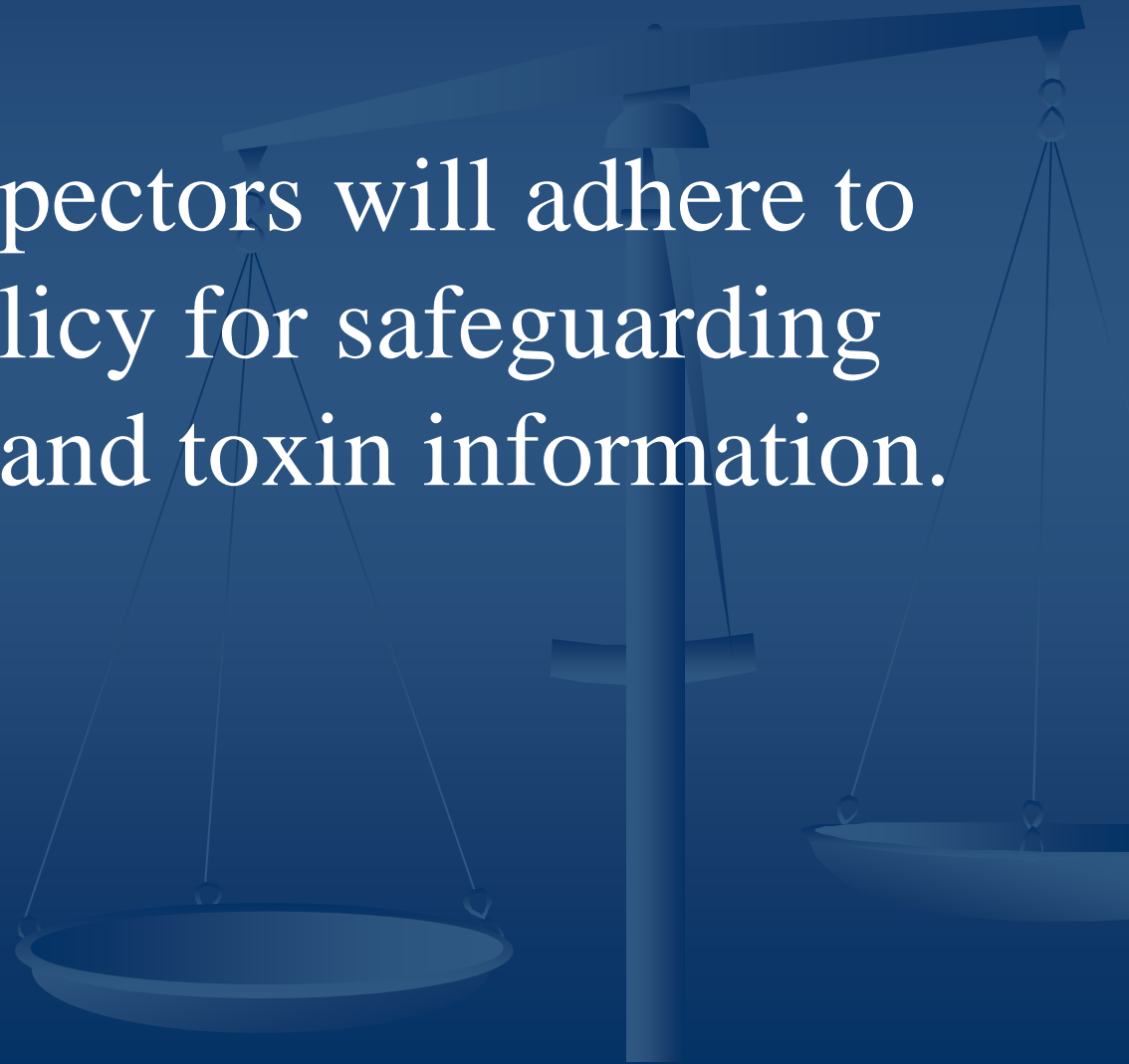


- All FSAP inspectors will have undergone the appropriate medical clearance for the entity to be inspected.
- Each inspector has been certified to not have any underlying medical conditions which would interfere with their performing his/her duties.
- Each individual also maintains a copy of his/her immunization records and his/her respirator fit testing card.
- The inspectors are not allowed to participate in any entity medical surveillance program.

INSPECTIONS



All FSAP inspectors will adhere to FSAP's policy for safeguarding select agent and toxin information.



INSPECTIONS



The FSAP inspector will identify himself or herself by their personal identity verification (PIV) card (his/her official government identification card).

INSPECTIONS

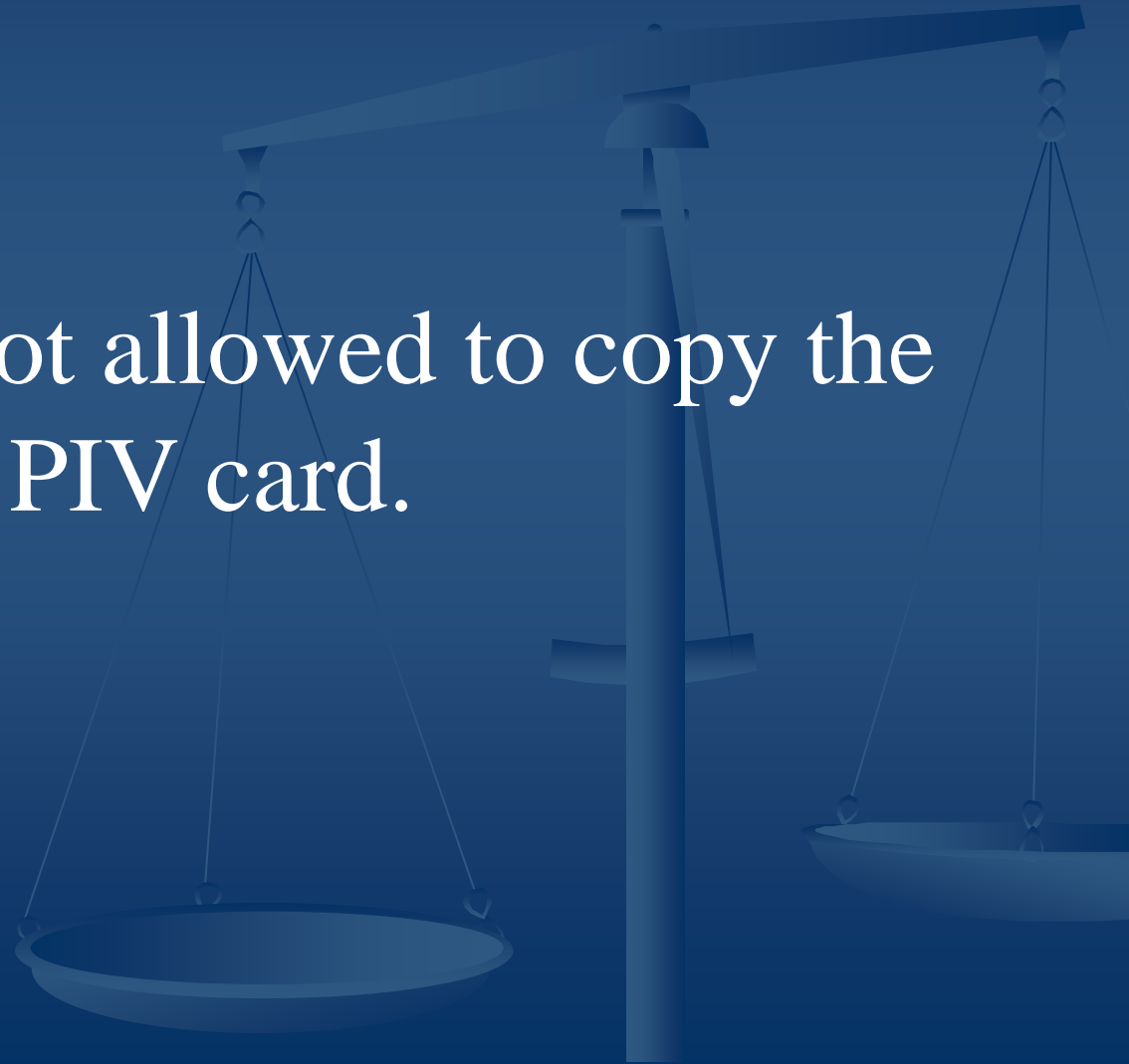


The FSAP inspector is not allowed to surrender his/her PIV card to the entity or exchange the PIV card for the entity's identification badge.

INSPECTIONS



An entity is not allowed to copy the PIV card.



INSPECTIONS



The FSAP inspector will not provide an entity with any personal identification (e.g., a driver's license, social security number).

INSPECTIONS



The FSAP inspector is not authorized to sign and will not sign any type of an entity confidentiality agreement.

INSPECTIONS



The FSAP inspector is not authorized to sign and will not sign any type of document releasing the entity from any liability.

INSPECTIONS



The FSAP inspector
cannot be required to submit to any
type of a health screening.

INSPECTIONS

Federal Select Agent Program: SA Gram

DATE: April 12, 2019

TO: Responsible Officials and Alternate Responsible
Officials

SUBJECT: Reminder regarding entity verification
requirements for FSAP inspectors performing site
visits of registered entities

Questions?

