

42 C.F.R. § 73.9

Responsible Official.

(a) An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must:

- (1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General,
- (2) Be familiar with the requirements of this part,
- (3) Have authority and responsibility to act on behalf of the entity,
- (4) Ensure compliance with the requirements of this part,
- (5) Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan, and
- (6) Ensure that annual inspections are conducted for each registered space where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented.

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