



DHS SCIENCE AND TECHNOLOGY

DHS CAPO-Federal Select Agent Program Joint Inspection Overview

July 24, 2019



**Homeland
Security**

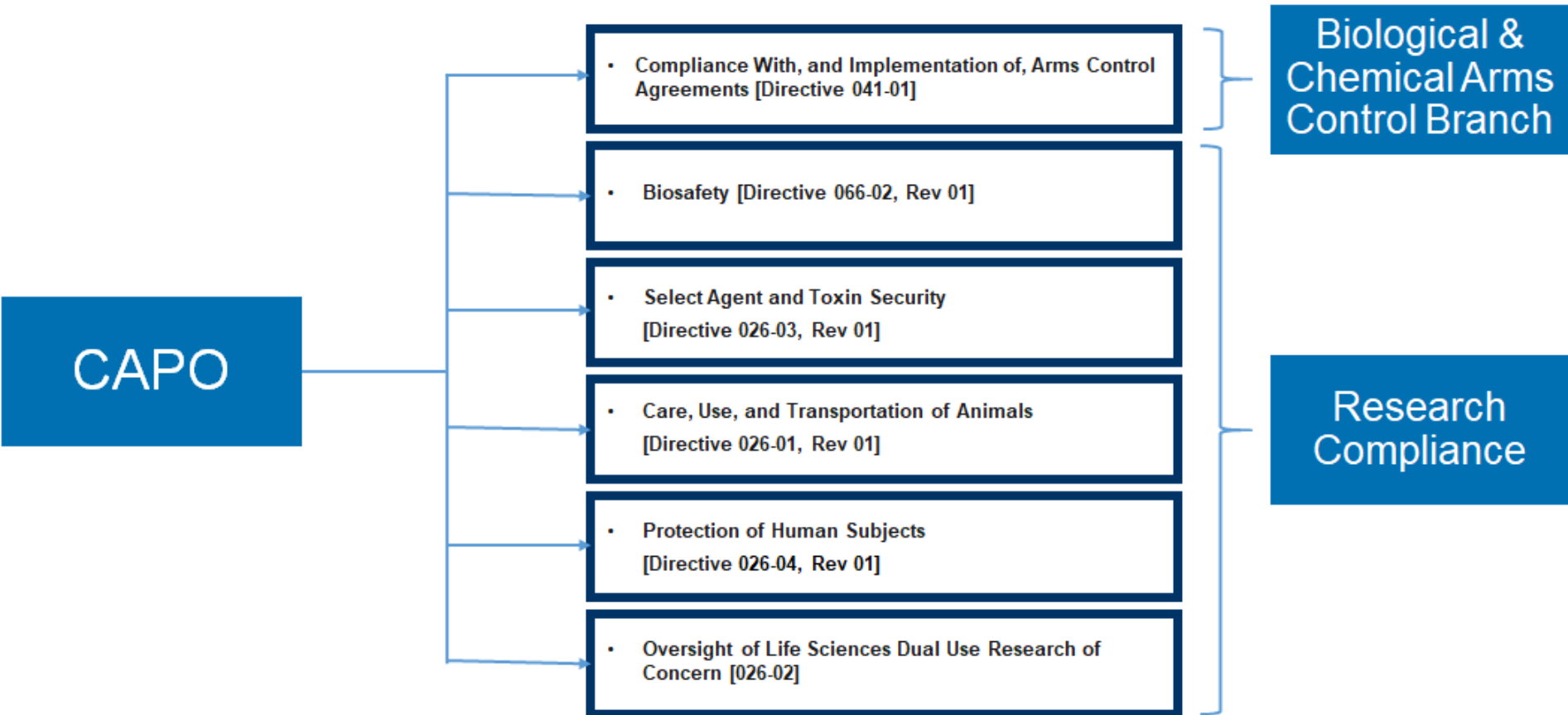
Science and Technology

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DHS Compliance Assurance Program Office (CAPO)

- CAPO operates within the DHS Science and Technology Directorate (S&T).
- However, CAPO responsibilities are DHS-wide, and its services are available to all DHS Components and performers.
- CAPO performs compliance support and oversight functions to ensure DHS-funded/-sponsored/-conducted activities are compliant with:
 - Federal regulations, policies, and guidelines
 - Applicable international agreements
 - Internal DHS Directives and Instructions
- CAPO performs compliance assurance and oversight in eight areas:
 - Treaty (Biological Weapons and Toxins Convention and Chemical Weapons Convention)
 - Biosafety
 - Biological select agents and toxins (BSAT)
 - Animal care and use
 - Human subjects research
 - Dual Use Research of Concern (DURC)
 - Export Controls
 - Committee on Foreign Investments in the U.S. (CFIUS)

DHS Directives (Department-Wide)



Regulatory Compliance Requirements for DHS

All DHS efforts must be conducted in accordance with relevant Federal regulations and guidelines, including:

DHS Directives

066-02 Rev 01,
Biosafety

026-03 Rev 01, *Select Agent and Toxin Security*

026-01 Rev 01, *Care and Use of Animals in Research*

026-04 Rev 01,
Protection of Human Subjects

and 026-02, *Oversight of Life Sciences Dual Use Research of Concern*

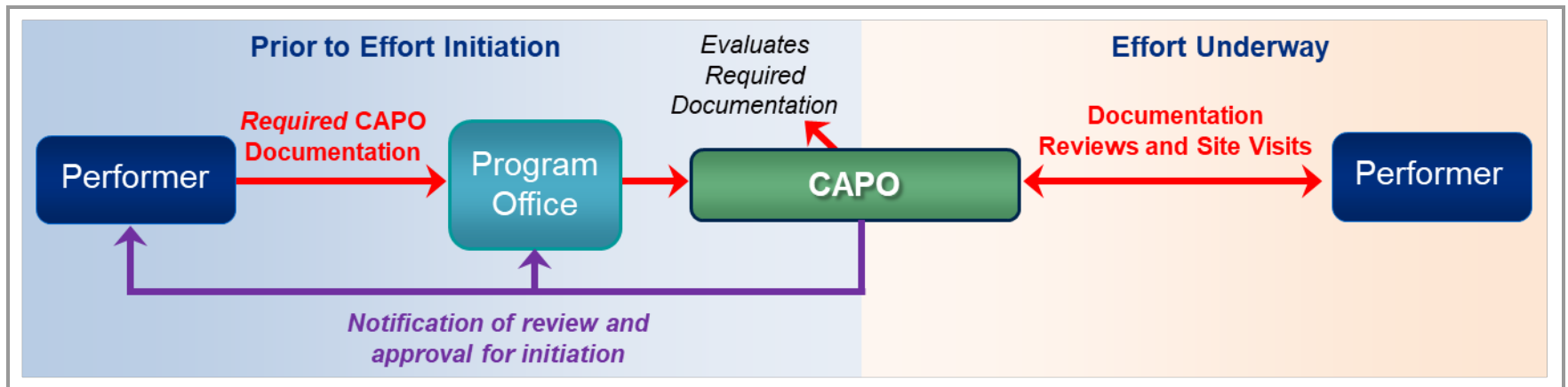
- CDC and USDA Regulations for Biological Select Agents and Toxins (BSAT)
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- USDA Implementation of the Animal Welfare Act (9 CFR Chapter 1)
- White House Policies on Life Sciences Dual Use Research of Concern
- Public Health Service Policy for Humane Care and Use of Laboratory Animals
- Federal Policy for the Protection of Human Subjects (aka "The Common Rule")
- United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012)
- United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern (September 2014)

CAPO BSAT Project Review

- DHS-sponsored projects involving BSAT must be reviewed and cleared by CAPO prior to the initiation of work, even if that work uses exempt quantities.
- CAPO conducts an initial documentation review, which is coordinated with the DHS Program Manager and registered entity, prior to clearance.
 - Statement of work
 - Biosafety manual
 - Copy of current FSAP certificate of registration
 - Project specific protocols/research plans/etc.
- Upon completion of review, CAPO sends the registered entity a memo approving the initiation of work.
- DHS performers who work with BSAT must comply with all aspects of the Select Agent Regulations (i.e. no additional requirements).

CAPO Ongoing Oversight

Following project initiation, CAPO conducts periodic documentation reviews and site visits as part of an ongoing effort to ensure regulatory compliance



DHS CAPO-FSAP Joint Inspections

- DHS S&T has a Memorandum of Understanding (MOU) with CDC and APHIS (first signed in October 2011) to participate in joint select agent inspections at entities conducting DHS-sponsored research activities involving BSAT.
- CAPO routinely participates in joint inspections of DHS performers working with BSAT with the FSAP.
- Benefits:
 - Coordinated inspections to reduce time and resource burdens for registered entities.
 - Improved transparency and information sharing.
 - Increased dialogue and collaboration in addressing compliance issues.

Coordination of Joint Inspections

- Joint inspection schedules are set by DSAT and/or AgSAS, not CAPO
- CAPO shares a list of registered entities conducting DHS-sponsored BSAT work with DSAT/AgSAS .
- DSAT/AgSAS inform CAPO of upcoming select agent inspections at those entities.
- CAPO coordinates with DSAT/AgSAS for upcoming inspections (i.e. inspection plan, logistics, tentative schedule, entry requirements, etc.)
- Initial agenda established by DSAT and/or AgSAS leads. CAPO may request documentation or accommodations.
- CAPO inspectors participate in inspections alongside DSAT and/or AgSAS inspectors (i.e. inspection of registered spaces, documentation review, interviews, etc.).
- CAPO does not write an independent inspection report.

DHS CAPO-FSAP Inspection History

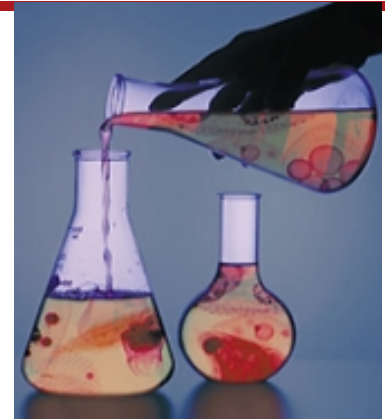
	FY14	FY15	FY16	FY17	FY18	FY19	<u>Total</u>
Number of Joint Inspections	7	11	8	5	10	6	47

Questions?

Questions and/or requests for more information may be directed to:

- **Treaty Compliance:**
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- **Regulatory and DURC Compliance:**
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