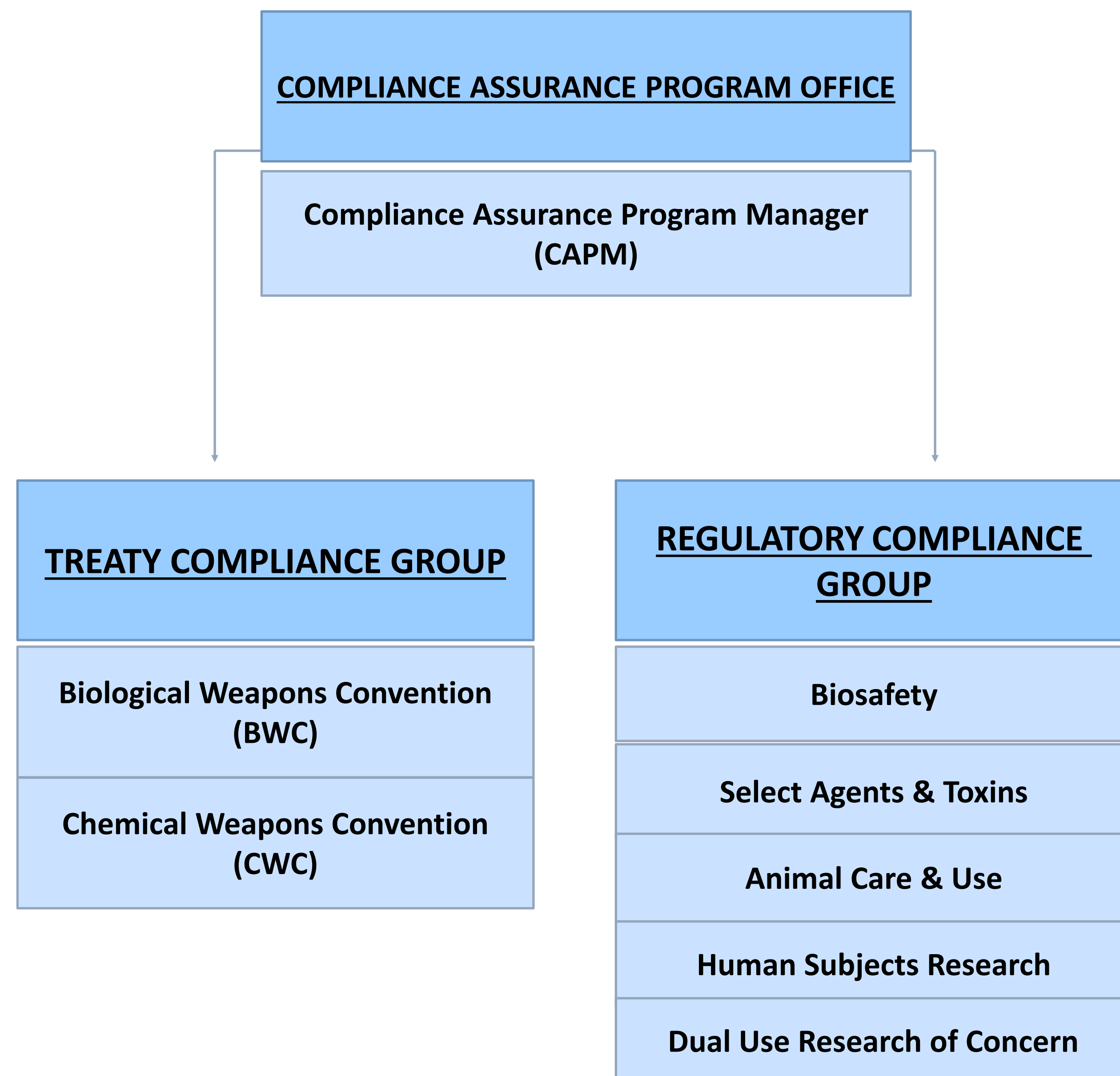


Department of Homeland Security Compliance Assurance Program Office

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Summary

The Compliance Assurance Program Office (CAPO) within the DHS Science and Technology Directorate (S&T) performs compliance support and oversight functions to ensure DHS-funded activities are compliant with relevant international agreements, federal regulations, DHS policies, and related standards and guidance. CAPO is divided into the Regulatory Compliance Group (RCG) and the Treaty Compliance Group (TCG).

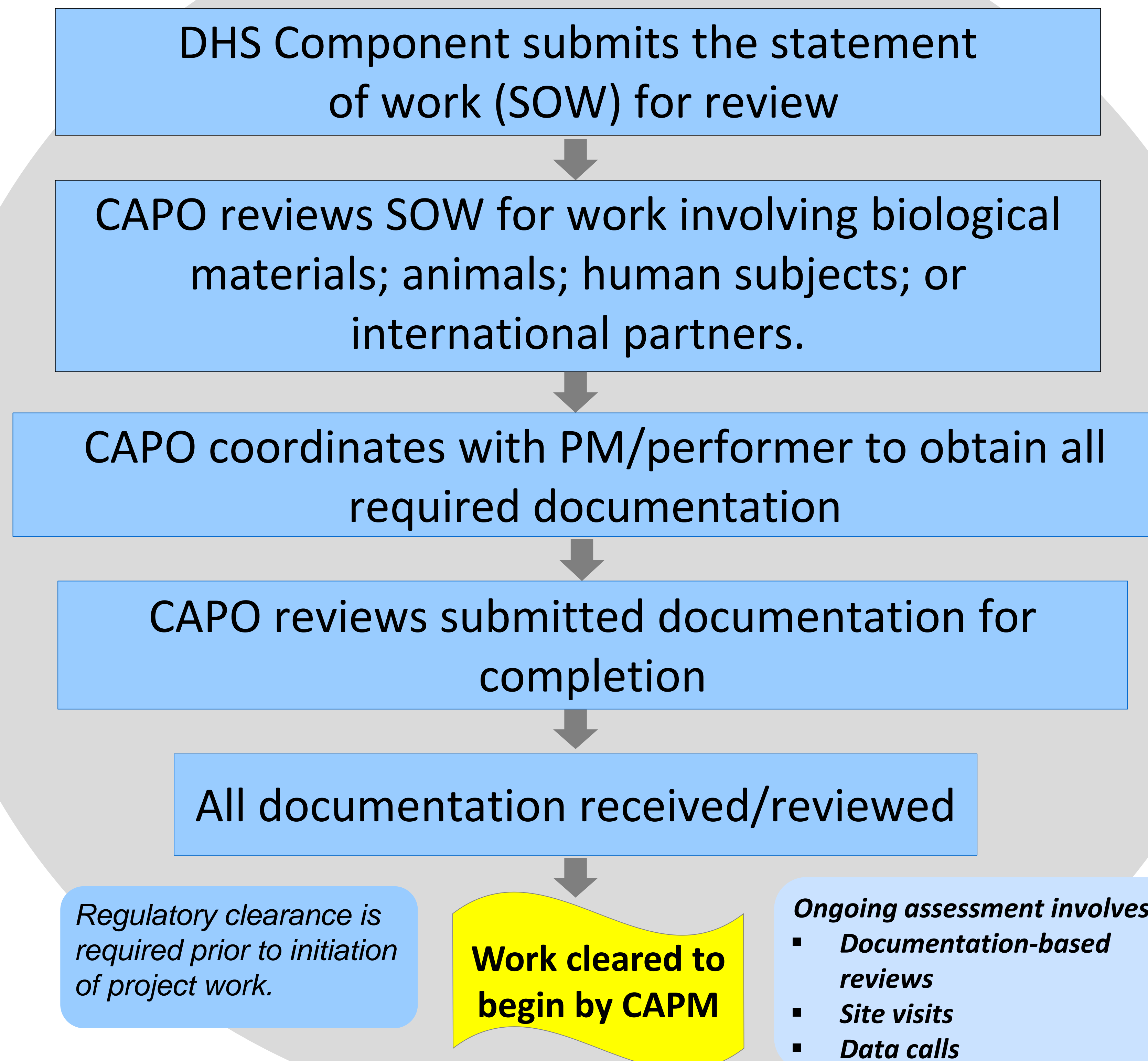


DHS Compliance Assurance Structure

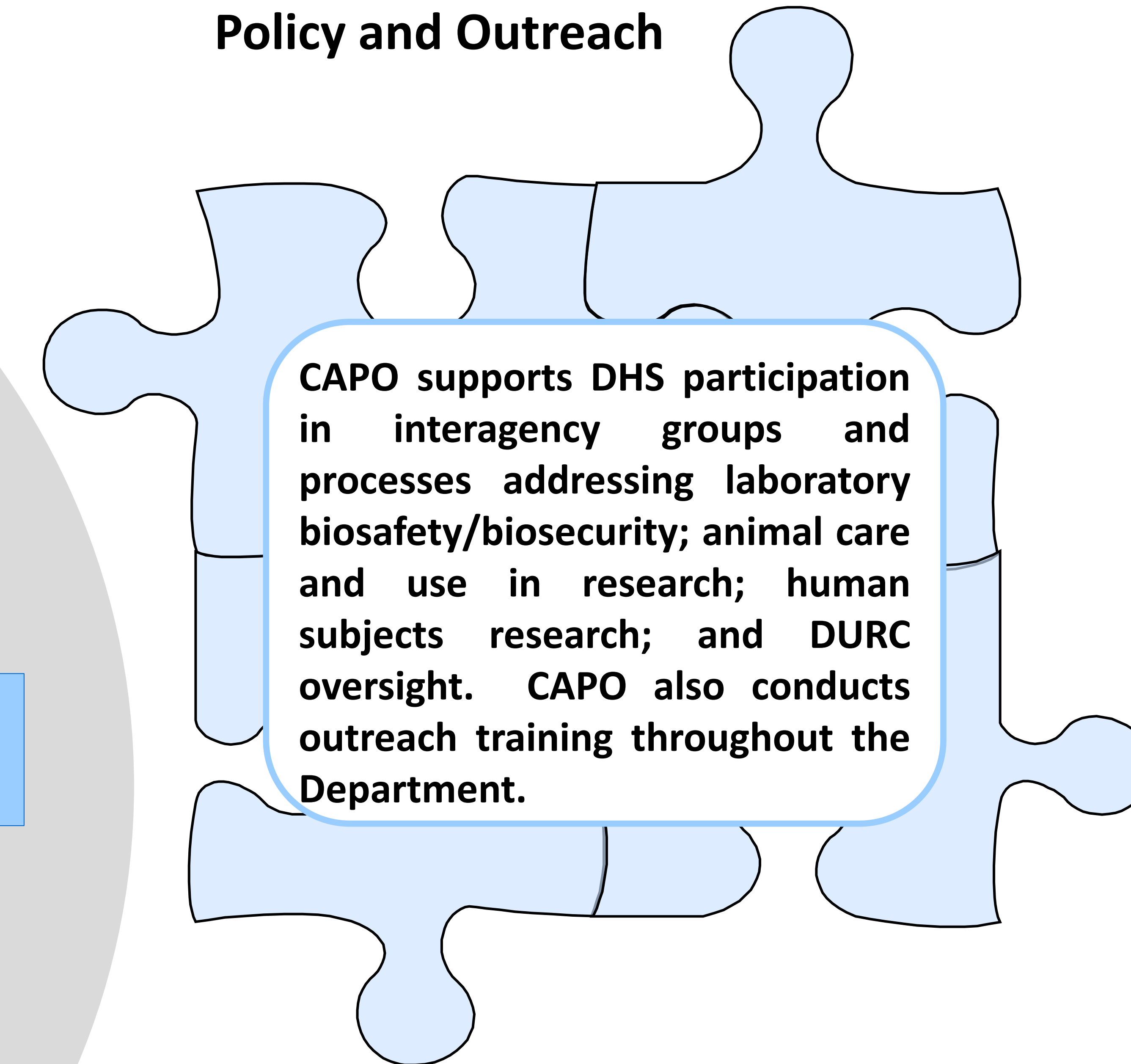
CAPO conducts regulatory assessments of new projects, performs documentation-based reviews of existing programs, participates in joint inspections of select agent-registered entities with CDC and APHIS, and represents DHS in interagency discussions pertaining to oversight of biosafety and biosecurity policy. Areas of oversight include biosafety, select agent and toxin security, research involving recombinant and/or synthetic nucleic acid molecules, human subjects or animals, and compliance with the Biological and Chemical Weapons Conventions. CAPO also leads DHS efforts pertaining to life sciences dual use research of concern (DURC) and institutional DURC (iDURC).

The CAPO also provides input and analysis to the Compliance Review Group (CRG), which monitors DHS activities for biological and chemical treaty compliance, renders compliance determinations, and provides guidance on compliance issues.

CAPO Regulatory Review Process



Policy and Outreach



The DHS CAPO:

- Relies on existing compliance-related materials and oversight mechanisms to ensure that all DHS-funded biological activities are conducted in safe and secure environments, and in compliance with applicable federal requirements and DHS policies.
- Proactively addresses and ensures DHS awareness of biological compliance issues and concerns that arise at institutions performing DHS-funded biological laboratory work.
- Garners input from DHS-funded performers to promote the implementation of best practices.
- Utilizes insight generated from stakeholder interactions to contribute to ongoing biosafety and biosecurity enhancement efforts.

RCG Review assures compliance with relevant federal regulations and guidelines

- ❖ CDC/USDA Select Agent Regulations
- ❖ CDC/NIH BMBL 5th edition
- ❖ NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- ❖ USA Implementation of the Animal Welfare Act
- ❖ Public Health Service Policy for Humane Care and Use of Lab Animals
- ❖ Federal Policy for the Protection of Human Subjects ("The Common Rule")

DHS Directives

- ❖ 066-02, Biosafety
- ❖ 026-03, Select Agent and Toxin Security
- ❖ 026-01, Care and Use of Animals in Research
- ❖ 026-04, Protection of Human Subjects