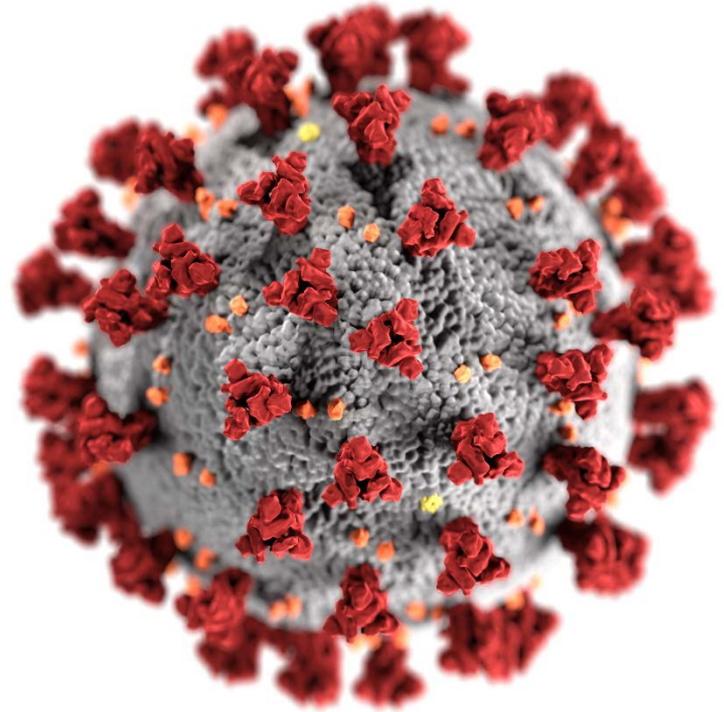


The CDC Import Permit Program's Response to the COVID-19 Pandemic Caused by SARS-CoV-2

**Centers for Disease Control and Prevention (CDC)
Division of Select Agents and Toxins (DSAT)
Import Permit Program (IPP)**

2020 Import Permit Regulations Webinar

December 3, 2020



cdc.gov/coronavirus

CDC's Import Permit Program

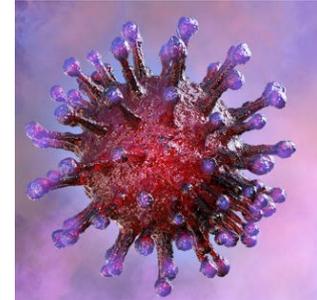
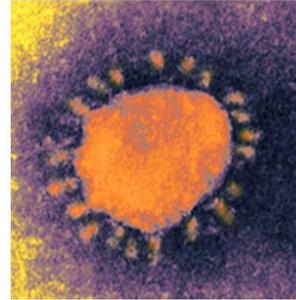
- Regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S.
- Authority is from The Public Health Service Act and regulations are found in 42 CFR 71.54



Coronavirus Importation Regulated by CDC

- Common human coronaviruses

- 229E (alpha coronavirus)
- NL63 (alpha coronavirus)
- OC43 (beta coronavirus)
- HKU1 (beta coronavirus)
- Routinely used in BSL-2 containment



- **Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) – 2003**

- Prior to becoming a select agent in December 2012, CDC permits were issued with a condition restricting distribution without additional permits
- Generally restricted to at least BSL-3 containment

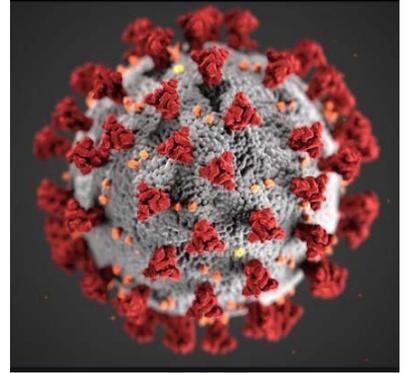
- **Middle East Respiratory Syndrome Coronavirus (MERS-CoV) – 2012**

- CDC permits have a condition restricting distribution of this agent without additional permits
- Generally isolated at BSL-3 containment; limited diagnostics in BSL-2 containment

- All coronaviruses have a positive stranded RNA genome, so complete RNA genome is regulated and subsequent distribution requires additional permits

Coronavirus Importation Regulated by CDC

- 2019 Novel Coronavirus - Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
 - Not a select agent
 - <https://www.selectagents.gov/resources/sagrms/2020.htm>
 - BSL-3 recommended for virus isolation and work with cultures
 - BSL-2 recommended for limited diagnostic testing
 - <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>
 - IPP permits have a condition restricting distribution without additional permits



Preview of selected conditions for permit:

THE SUBSEQUENT DISTRIBUTION OF SARS-COV-2 WILL REQUIRE AN ADDITIONAL SEPARATE PERMIT. WORK SHOULD BE CONDUCTED IN ACCORDANCE WITH THE INTERIM RISK ASSESSMENT, [HTTPS://WWW.CDC.GOV/CORONAVIRUS/2019-NCOV/LAB/LAB-BIOSAFETY-GUIDELINES.HTML](https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html)



When is SARS-CoV-2 regulated and when is SARS-CoV-2 not regulated by CDC IPP?

- SARS-CoV-2 that has been imported and any subsequent transfers of the imported SARS-CoV-2 are regulated
- 42 CFR 71.54 is limited to the act of importing. Therefore, materials containing SARS-CoV-2 that were obtained from domestic cases are not subject to this requirement <https://www.cdc.gov/cpr/ipp/index.htm>



COVID-19 Update:

Requesting permits to import Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) requires a CDC Import Permit application to be submitted electronically using the eIPP system (<https://eipp.cdc.gov/>). Subsequent transfers of previously imported material containing SARS-CoV-2 within the United States also require a CDC import permit.

Permit Required

- Import isolates or cultures of SARS-CoV-2.
- Import infectious substances (e.g., blood, bodily fluids, tissues) that are reasonably expected to contain SARS-CoV-2.
- Import nucleic acids capable of producing SARS-CoV-2 (i.e., full-length genomic RNA extracted from SARS-CoV-2).

A permit is required to transfer SARS-CoV-2 materials described above within the United States.

Permit Not Required

- Specimens or isolates/cultures of SARS-CoV-2 within the United States or its territories that were not generated from imported material.
- Nucleic acids encoding partial sections or fragments of SARS-CoV-2 incapable of producing infectious virus (i.e., partial or degraded SARS-CoV-2 genomic RNA).
- Diagnostic samples not known or suspected of containing SARS-CoV-2. See FAQ "Do I need an import permit" <https://www.cdc.gov/cpr/ipp/faq.htm>



Applications to Import SARS-CoV-2

- All requests must be submitted in:
<https://eipp.cdc.gov/>
- A Secure Access Management Services (SAMS) account is required
 - <https://www.cdc.gov/cpr/ipp/support.htm>
- Currently, all SARS-CoV-2 applications are given expedited status

The CDC Import Permit Program, or IPP, regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S.

Materials requiring import permits include infectious biological agents capable of causing illness in humans, materials known or reasonably expected to contain an infectious biological agent, vectors of human disease.

A SAMS account is required to access electronic IPP.

DSAT Contact Information

Help and Support

Centers for Disease Control and Prevention
Import Permit Program
1600 Clifton Road, NE, Mailstop H21-7
Atlanta, GA 30329

eIPP Customer Support Request Form
eIPP Resource Center
Telephone: (833) 271-8310
Email: eIPPSupport@cdc.gov

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Application Type: Agents vs Human Remains



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Import Permit Program (IPP)

[New Agents Form](#) [New Bats Form](#) [New Human Remains Form](#)

Agents Application

Isolates/cultures of SARS-CoV-2 or diagnostic/environmental materials known or reasonably expected to contain SARS-CoV-2

Generally intended for laboratories

Diagnostic, research, production, education, or other valid purpose of use

Human Remains Application (New)

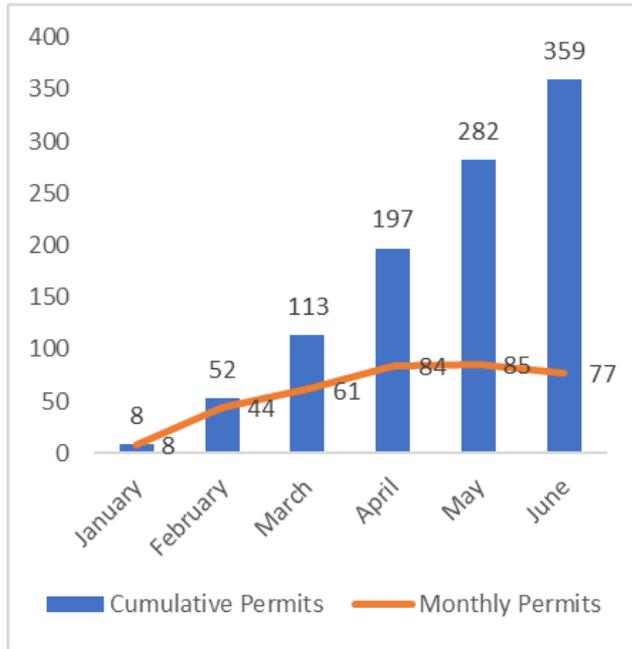
Unembalmed human remains where the individual was known or reasonably expected to be infected with SARS-CoV-2

Generally intended for funeral homes

Intended use is burial or cremation



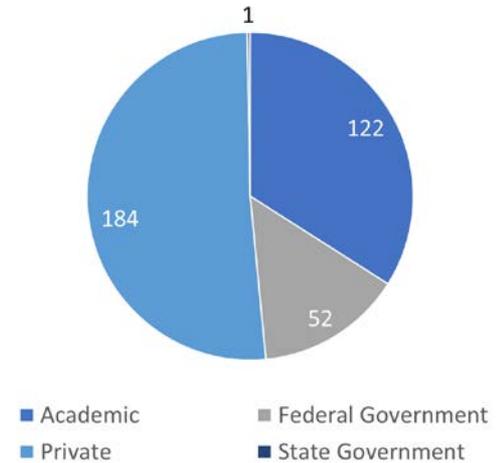
SARS-CoV-2 Permit Requests January – June 2020



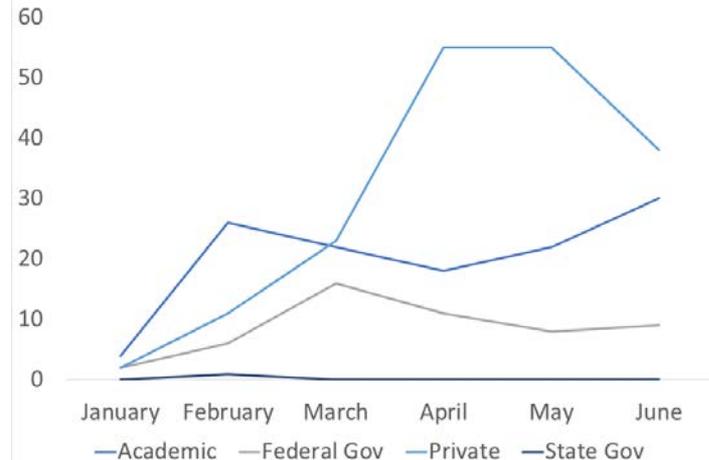
~22% increase in total issued permits over
quarters 1 & 2 of 2019



Permits Issued By Organization Type



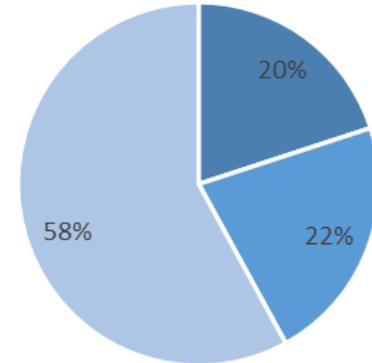
Permits Issued For SARS-CoV-2



SARS-CoV-2 Permit Overlap with Federal Select Agent Program (FSAP) Registrations

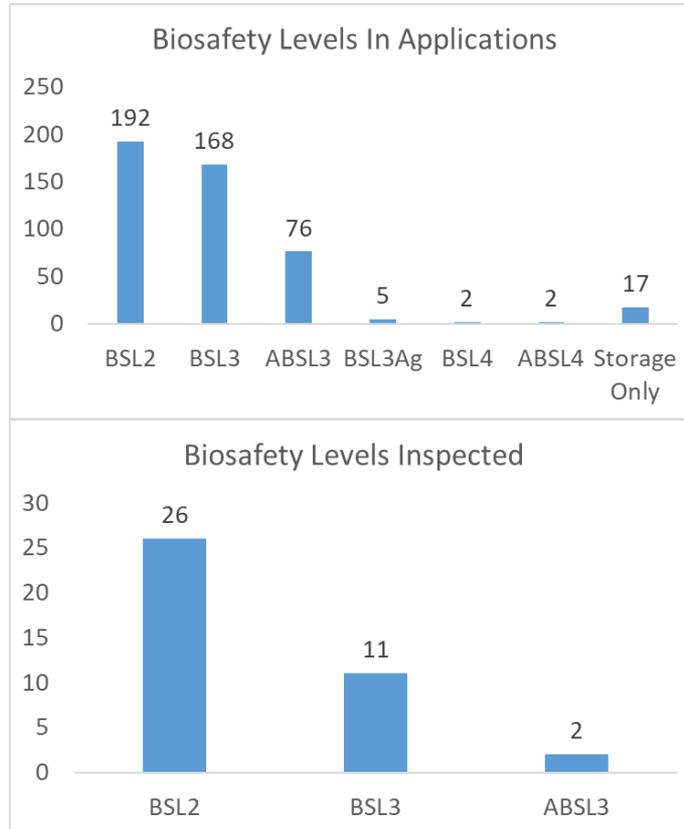
- Registration status was used for collaboration and prioritization of inspections with FSAP
- FSAP and IPP inspectors are cross-trained
- Again, SARS-CoV-2 is not a select agent, but DSAT can leverage resources between IPP and FSAP to avoid duplications in effort and direct resources to the most pressing public health needs

Laboratories With FSAP Registration



- FSAP Registered Entity With Registered Laboratory
- FSAP Registered Entity With Non-Registered Laboratory
- Non-FSAP Registered

Biosafety Levels (BSL) in Approved Applications Requesting SARS-CoV-2



Applications may have 1 or more safety levels



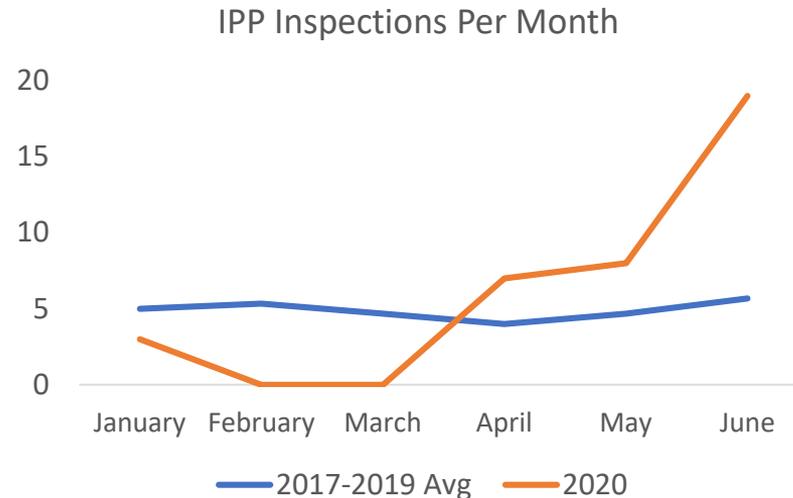
Application Metrics from January – June 2020

- **359** active permits issued, of which **11** were for human remains
- **9** applications were administratively closed
- **4** applications were withdrawn
- **0** applications were denied
- **14** permits were revoked



Change in Inspection Model Due to the Pandemic

- DSAT suspended all on-site inspections in March 2020
- 100% virtual inspections started on April 1, 2020
- DSAT resumed limited on-site inspections in September 2020



Inspection Metrics from January – June 2020

- 34 virtual inspections were conducted
 - Average number of Departures (Requires Corrective Action) = 2.9 (Range 0 – 9)
 - 5-year average (2013 – 2017) = 6.5 (Range 0 – 33)
- While infrequent, lapses in certification of Biological Safety Cabinets or HEPA filters were identified in some inspections

Instances	BMBL	Most Common Departures at BSL-2
14	A11	Training and information on personal health status
11	A9	Laboratory signage with entry and exit procedures
9	B1	Advising personnel of hazards and entry requirements
6	C3	Use of eye protection and decontamination
3	B10	Limiting procedures to a BSC or containment device
3	C1a	Properly maintained BSC usage for infectious aerosols



Notable Application Review and Inspection Findings from January – June 2020

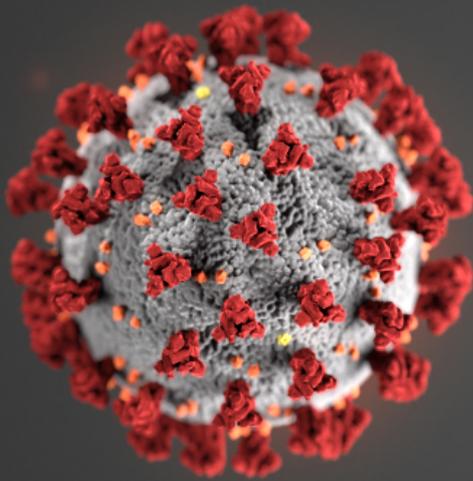
- Prior to issuance of a permit - Examples of withdrawn requests
 - 1 applicant requested to work with SARS-CoV-2 materials at BSL-1
 - 1 applicant requested to culture/propagate SARS-CoV-2 at BSL-2
 - Containment was not consistent with CDC recommendations, <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>, and the permittees eventually withdrew these requests
- After issuance of a permit – Examples of revocations
 - 3 permits did not have BSL-3 capabilities as claimed
 - 2 were undertaking renovations to convert from BSL-2 to BSL-3
 - 1 did not have appropriate infrastructure in place to meet BSL-3
 - 10 applicants requested revocation in lieu of inspection
 - 1 applicant requested revocation after the inspection in lieu of responding to observations from the virtual inspection
 - Obtained confirmation that the permits were not used, materials obtained under the permit were destroyed, or that the scope of work was revised to be consistent with current CDC recommendations



Next Steps

- IPP continues to expedite all requests for SARS-CoV-2
- Virtual inspections will remain a tool for ensuring compliance and appropriate biosafety measures
- A hybrid model of virtual and on-site inspection is being pursued by CDC IPP to optimize resources





For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

