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
  - BSL-3 recommended for virus isolation and work with cultures
  - BSL-2 recommended for limited diagnostic testing
  - IPP permits have a condition restricting distribution without additional permits

Preview of selected conditions for permit:

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](https://www.cdc.gov/cpr/ipp/index.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
# Application Type: Agents vs Human Remains

<table>
<thead>
<tr>
<th>Agents Application</th>
<th>Human Remains Application (New)</th>
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<tbody>
<tr>
<td>Isolates/cultures of SARS-CoV-2 or diagnostic/environmental materials known or reasonably expected to contain SARS-CoV-2</td>
<td>Unembalmed human remains where the individual was known or reasonably expected to be infected with SARS-CoV-2</td>
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<td>Generally intended for laboratories</td>
<td>Generally intended for funeral homes</td>
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<tr>
<td>Diagnostic, research, production, education, or other valid purpose of use</td>
<td>Intended use is burial or cremation</td>
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SARS-CoV-2 Permit Requests
January – June 2020

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

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

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.