

Analysis of FSAP Inspection Report Departures

September 21, 2023



Agenda

- Background information
 - Inspection analysis, purpose, and methodology
- Results
 - Most common regulatory departures
- Discussion



A close-up photograph of a scientist in a laboratory. The scientist is wearing a white lab coat over a blue shirt and a dark tie. They are also wearing clear safety glasses and a white surgical mask. The scientist is holding a clipboard and a pen, looking down at the clipboard. The background is a blurred laboratory setting with various pieces of equipment.

Background Information

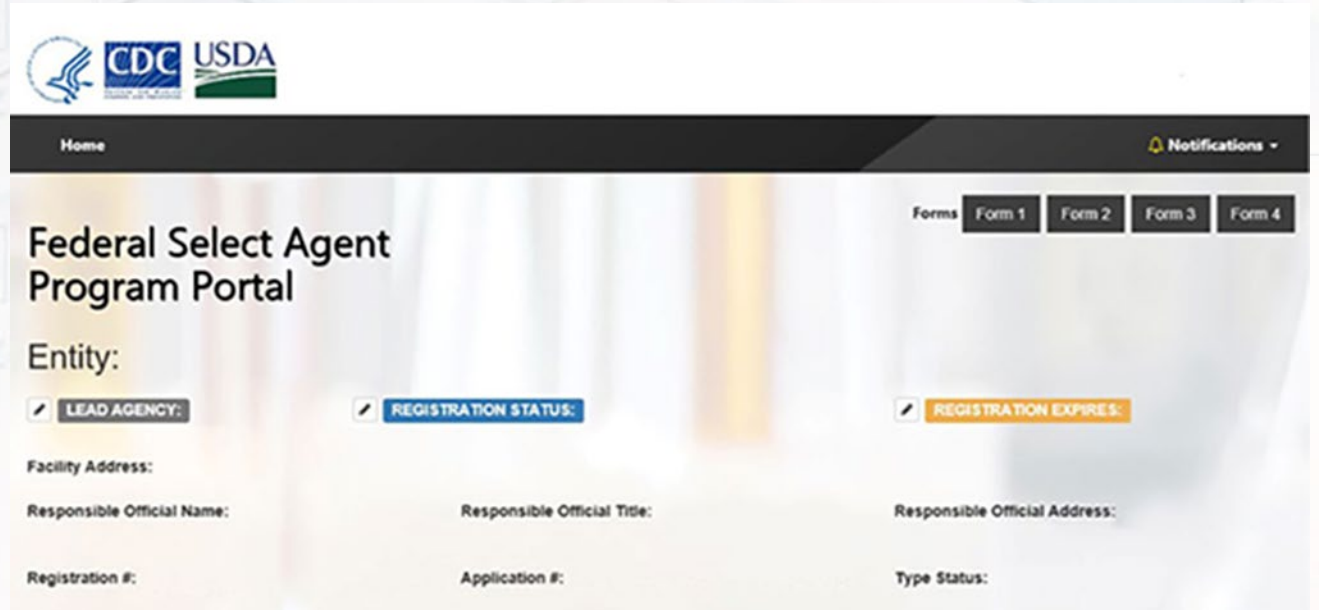
Background information (1 of 3)

- FSAP regulates the possession of and work with biological select agents and toxins (BSAT) to help ensure that it is conducted as safely and securely as possible
- This is accomplished in part by inspecting entities registered with FSAP to ensure adherence to the select agent and toxin regulations
- Entities are subject to announced and unannounced inspections
- Either CDC or USDA leads the inspection: CDC DSAT for HHS-only BSAT, USDA DASAT for USDA-only BSAT. Entities registered for both HHS and USDA BSAT are normally inspected jointly



Background information (2 of 3)

- FSAP uses the electronic Federal Select Agent Program (eFSAP) Information System for inspection processes, including:
 - Scheduling inspections
 - Previewing items that will be assessed during the inspection
 - Notifying entity responsible staff when inspection findings are released
 - Enabling entities to directly respond to the inspection findings by uploading documentation of their corrective actions



The screenshot shows the Federal Select Agent Program Portal website. At the top, there are logos for CDC and USDA. Below the logos is a navigation bar with "Home" and "Notifications" (with a dropdown arrow). The main content area is titled "Federal Select Agent Program Portal" and includes a "Forms" section with buttons for "Form 1", "Form 2", "Form 3", and "Form 4". The "Entity:" section contains three dropdown menus: "LEAD AGENCY:", "REGISTRATION STATUS:", and "REGISTRATION EXPIRES:". Below these are several input fields: "Facility Address:", "Responsible Official Name:", "Responsible Official Title:", "Responsible Official Address:", "Registration #:", "Application #:", and "Type Status:".



Background information (3 of 3)

- Due to travel restrictions related to the COVID-19 pandemic, FSAP developed and implemented remote and hybrid (i.e., a combination of remote and on-site) inspections
- Remote inspections focus primarily on:
 - Review of documentation aspects of the regulations
 - Employee interviews
 - Review of plans and training requirements
- On-site inspection key to investigate compliance problems or complex facility issues
- Document review is now conducted remotely, when possible, to minimize time at the entity



Purpose of Evaluating FSAP Inspections



- Follow up to June 2020 Responsible Official Webinar Presentation
- Entities use inspection reports (particularly departures) to monitor and improve their biosafety and security of facilities, practices, and training
- eFSAP-compiled data provides ample resources for entities to evaluate potential vulnerabilities and gauge likely focus areas during upcoming inspections



Methodology of Analyzing 2019-2022 FSAP Reports

- 742 inspections from 2019 to 2022 were tabulated directly from the eFSAP information system
- 2676 regulatory departures, 1046 general concerns, and 203 other compliance determinations were identified in these inspections
 - Average of 3.6 regulatory departures per inspection (over all 4 years)
- Data analyzed and graphs generated in Excel

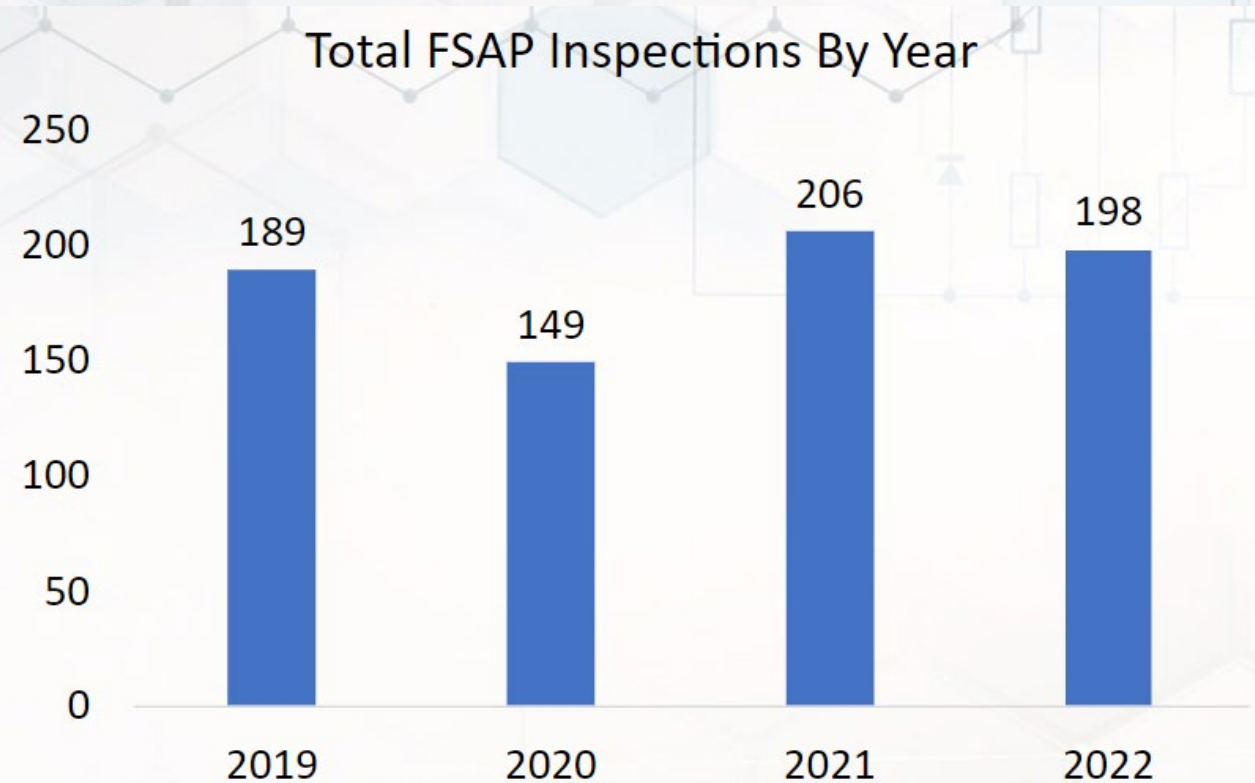


Results



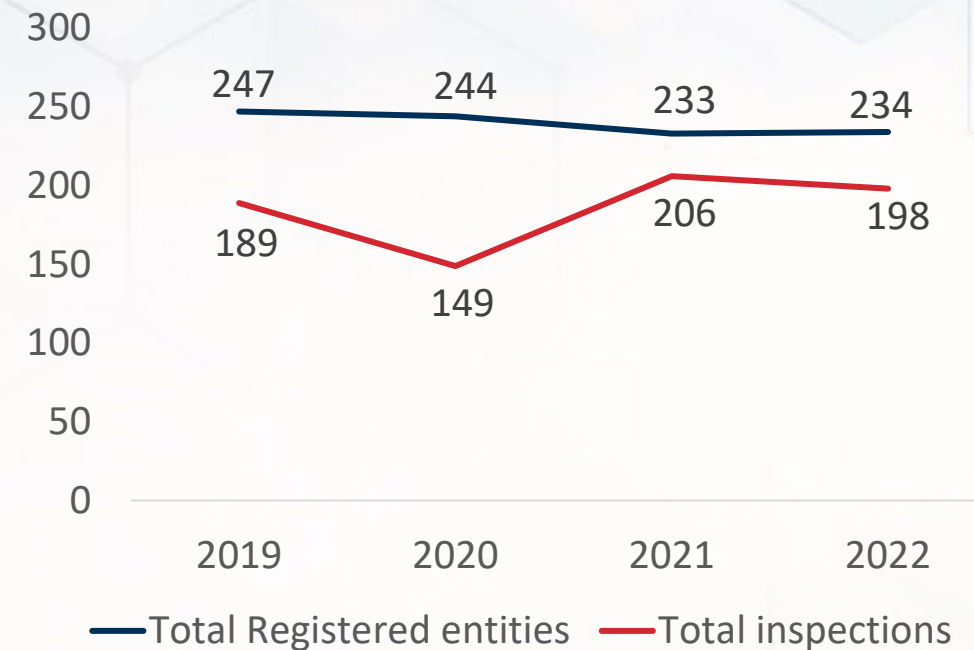
FSAP Inspections By Year, 2019 - 2022

- 2020 presented logistical challenges with inspections, which spurred development of the “remote” inspection and a minor decrease in total inspections
- 2021 re-introduced onsite inspections and hybrid inspections, which continued through 2022



Total Inspections In Relation to Total Registered Entities, 2019 - 2022

- The number of registered entities has remained relatively stable
- The number of inspections relative to the number of entities decreased in 2020, but increased over pre-pandemic levels in 2021 and 2022

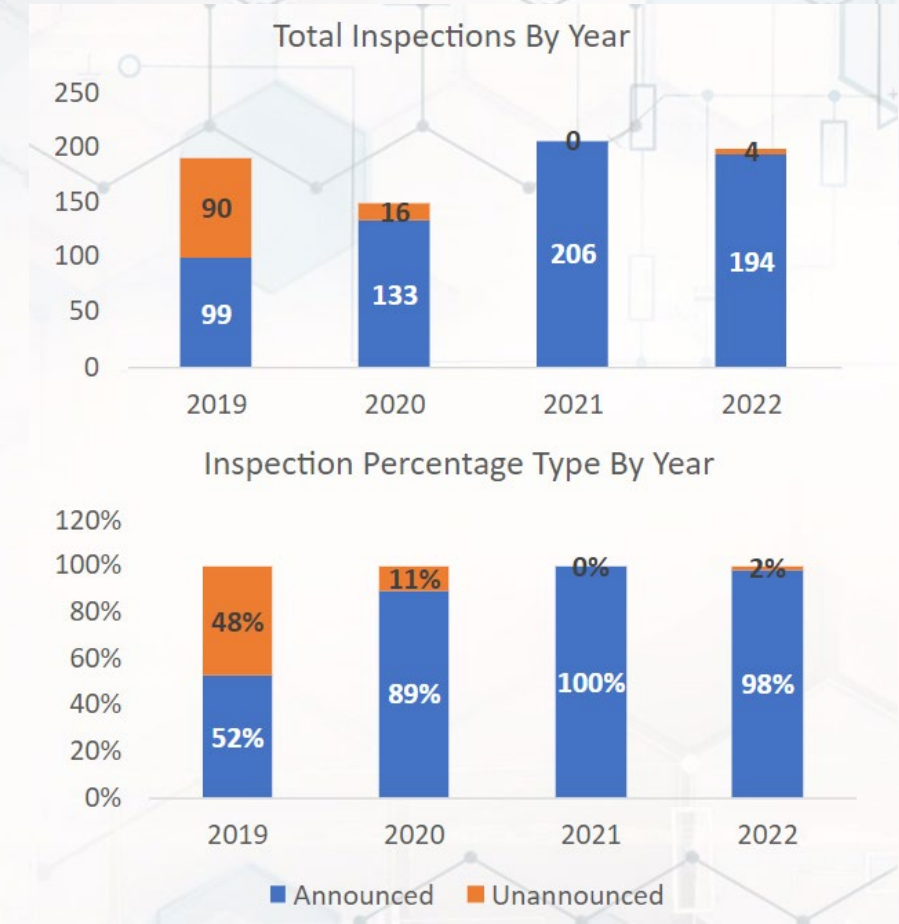


Inspections as a % of Total Entities	77%	61%	88%	85%



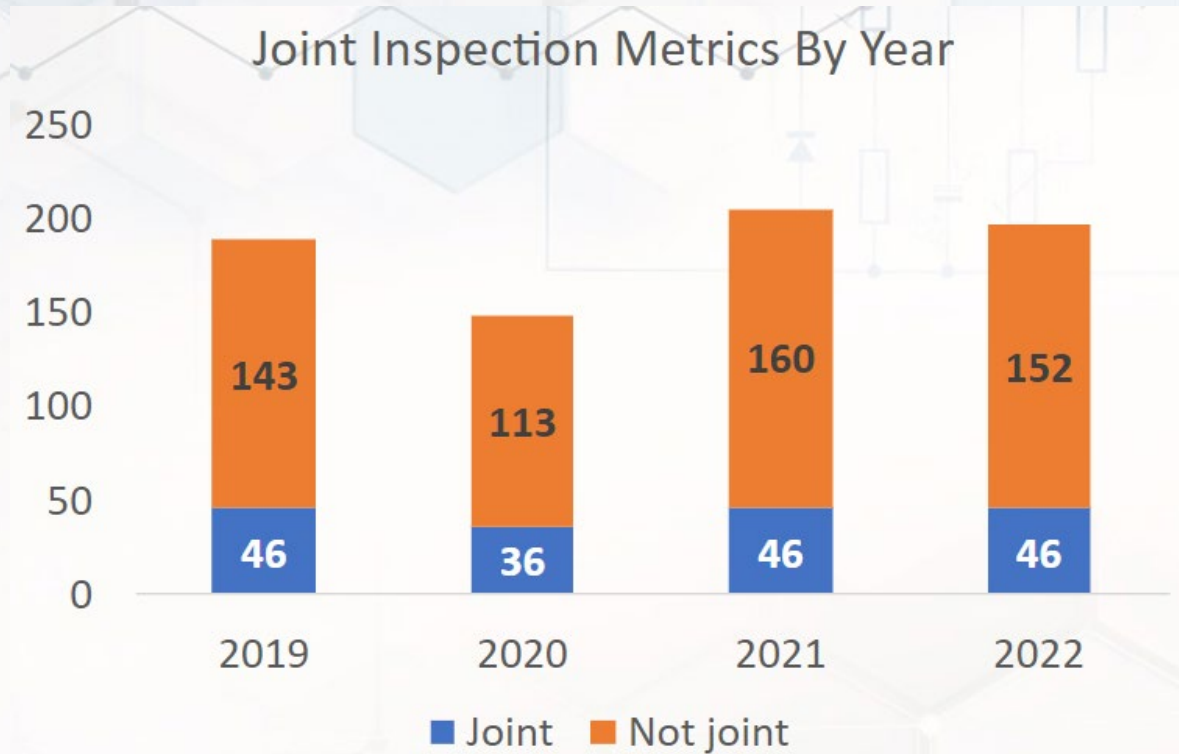
Announced vs Unannounced FSAP Inspections By Year, 2019 - 2022

- Unannounced inspections were common prior to the start of the COVID-19 pandemic in 2020
- All inspections were announced after the start of the pandemic through 2021
- In 2022, re-introduced unannounced inspections but were limited as most entities were due for renewal inspection in 2022
- 2023 (Jan-May): 20% of all inspections were unannounced, including inspections of BSL-4 facilities



Joint Inspections by Year, 2019 - 2022

- Joint Inspections with CDC and USDA inspectors are conducted when entities possess both HHS-only and USDA-only BSAT
- Most inspections are by a single agency and there is a consistent number of joint inspections

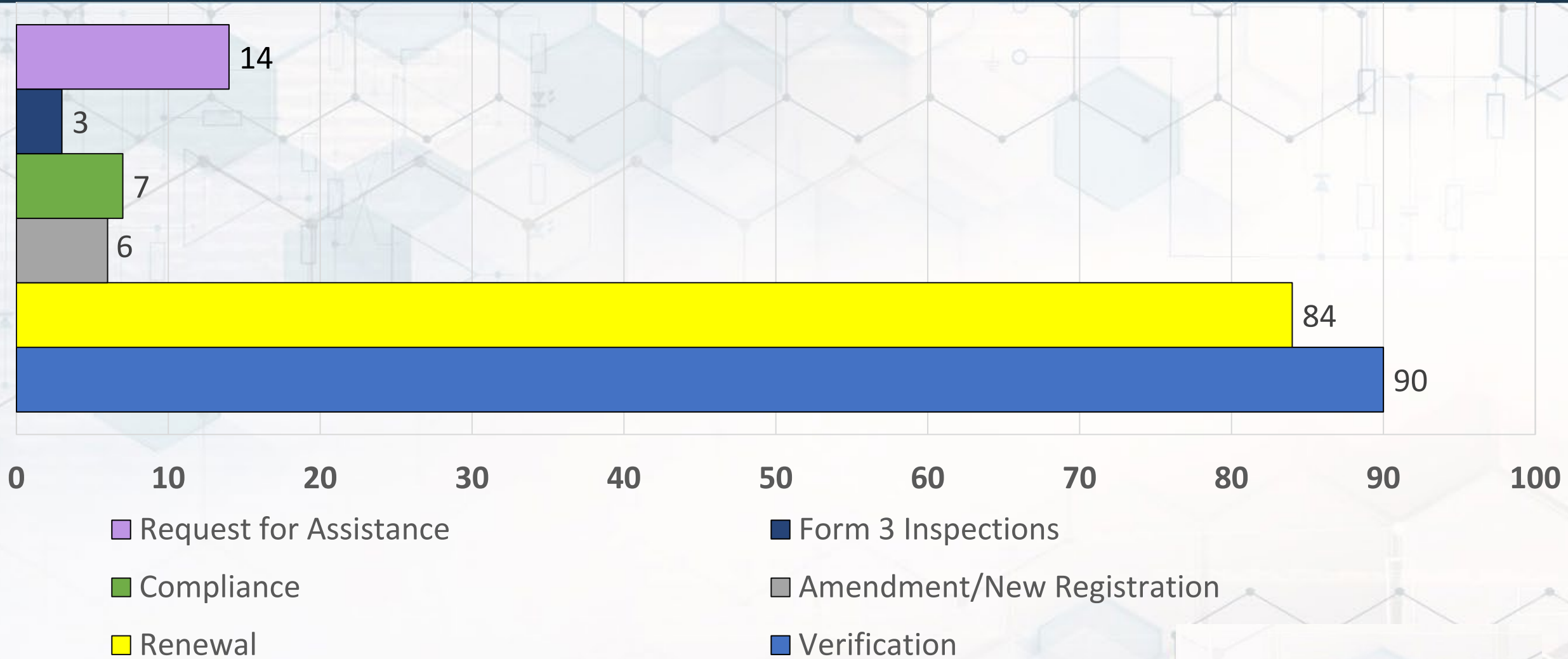


Inspection Categories

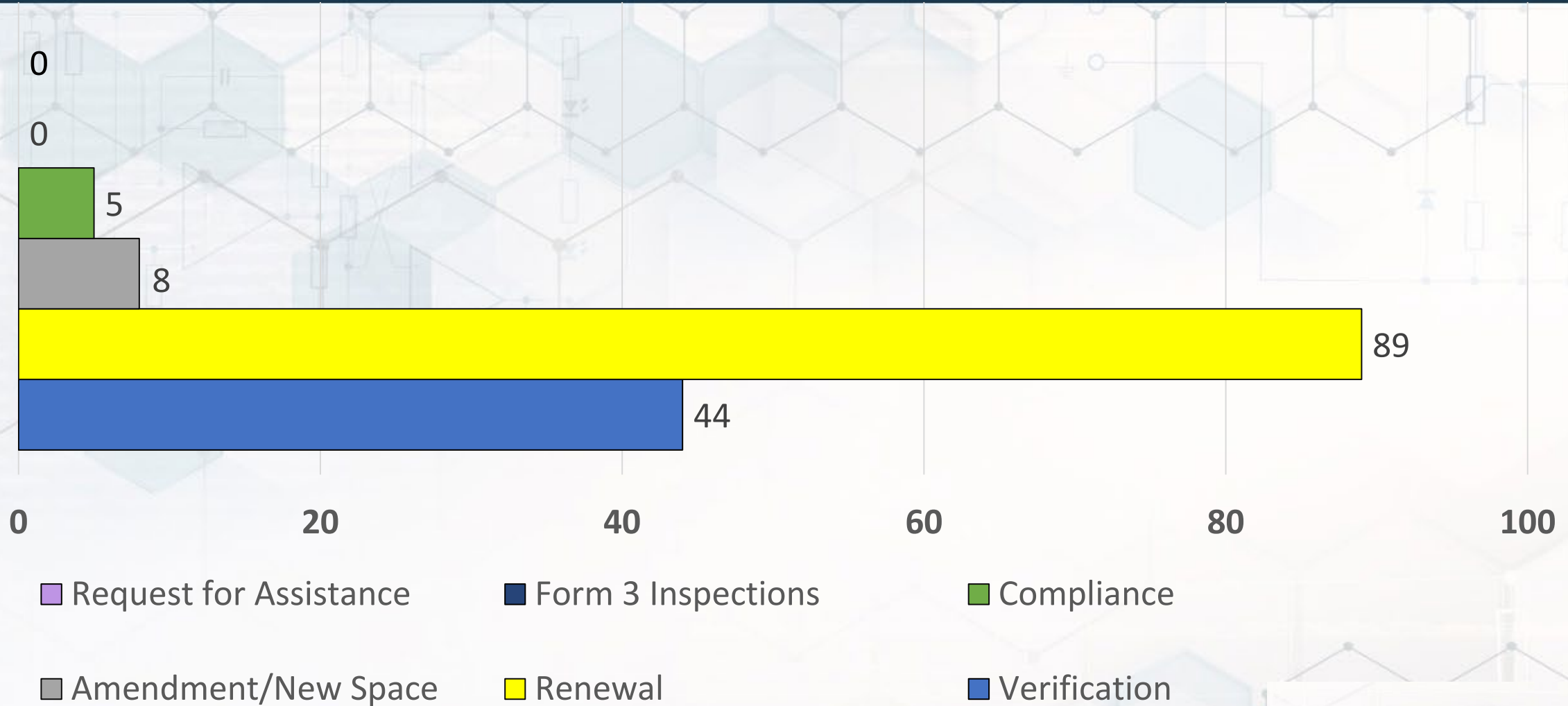
- **Renewal inspections** that generally occur once every 3 years preceding the registration expiration
- Generally, 1-2 **Verification inspections** occur during the 3-year approval
- **Compliance** or **Form 3 inspections** are generally triggered by an event
- **Amendment, New Registration, or Request for Assistance** inspections are generally initiated by the entity
- Multiple categories can be assigned to a single inspection



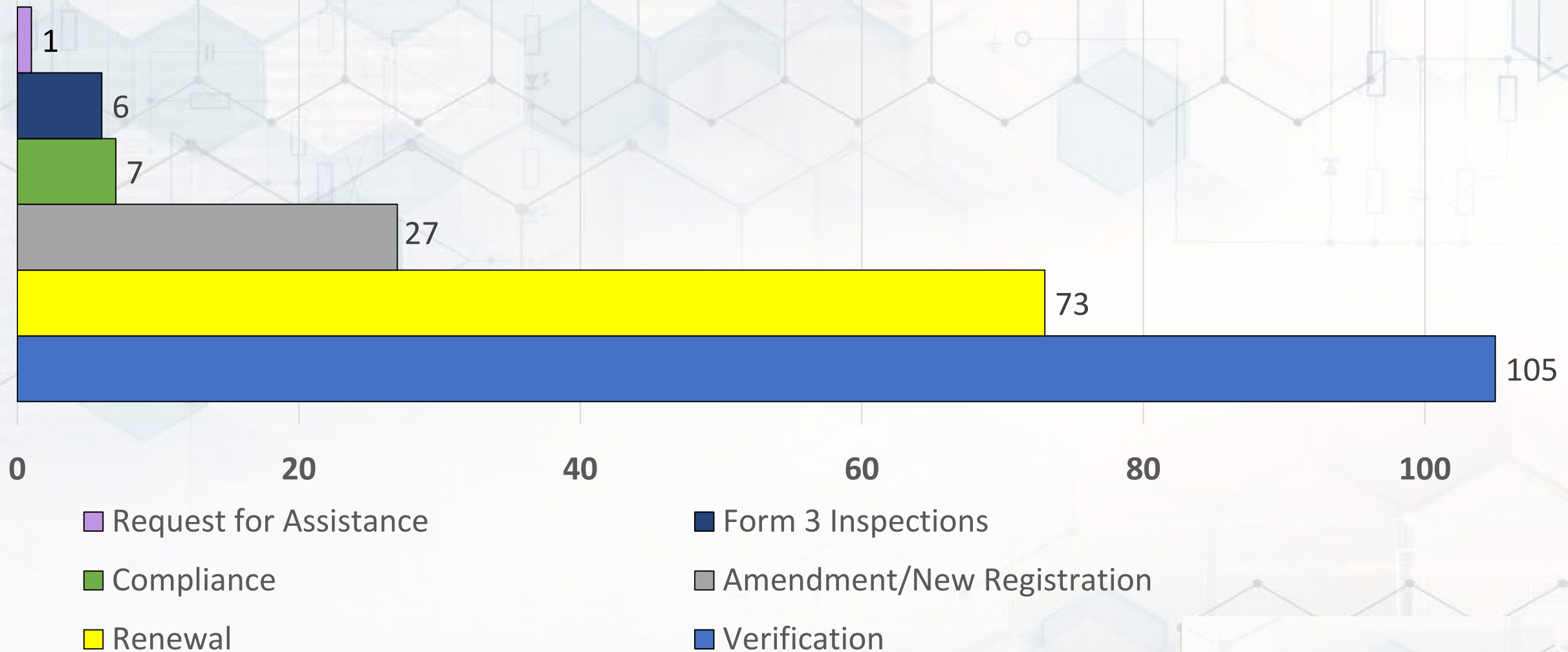
Inspection Numbers by Category, 2019



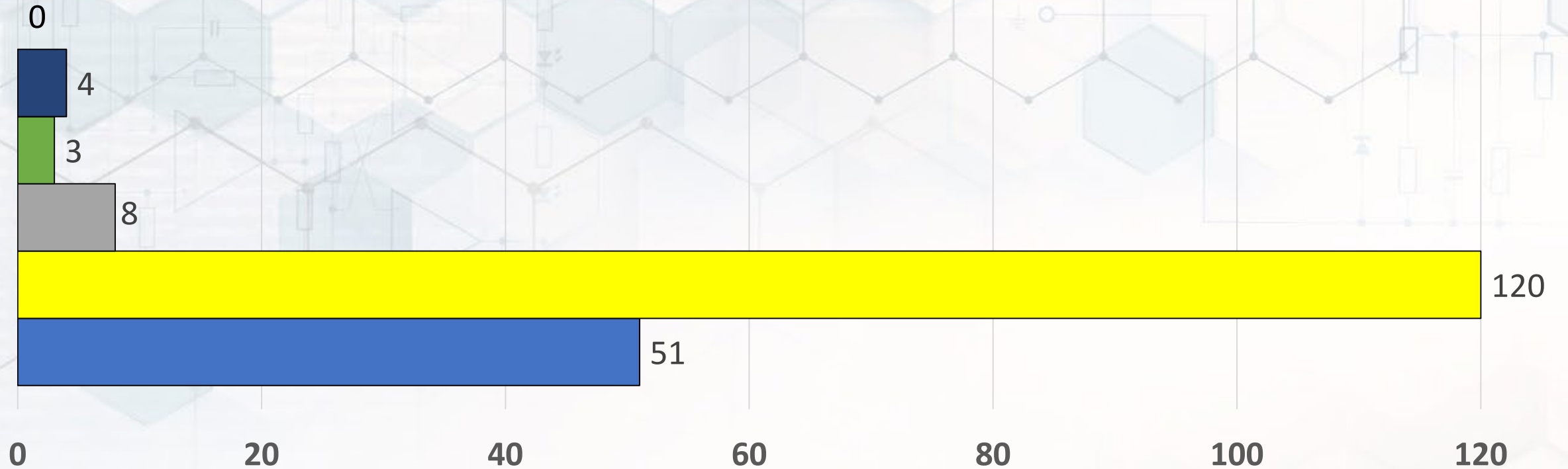
Inspection Numbers by Category, 2020



Inspection Numbers by Category, 2021



Inspection Numbers by Category, 2022



Request for Assistance

Compliance

Renewal

Form 3 Inspections

Amendment/New Registration

Verification

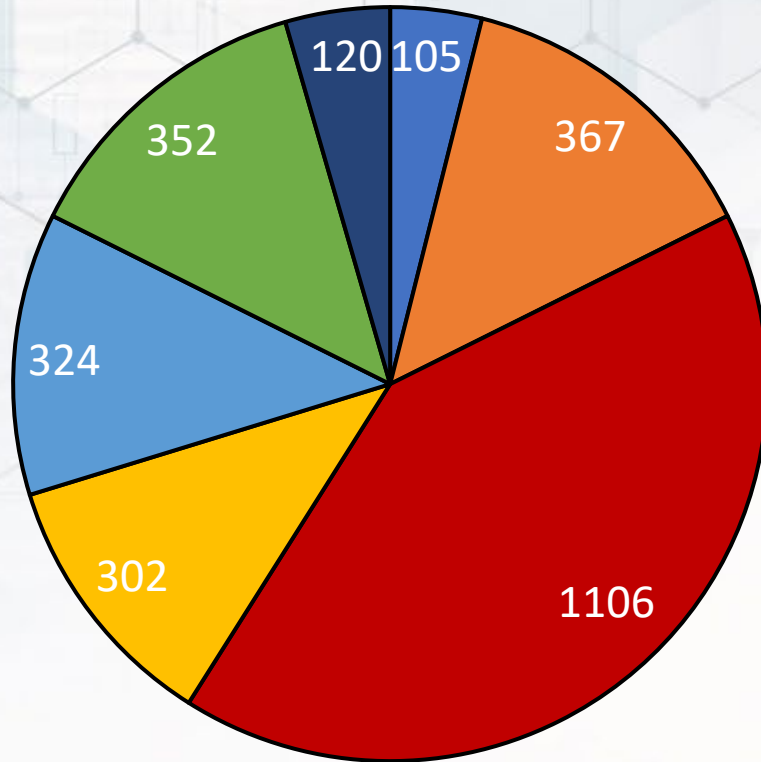


Summary for Inspection Categories, 2019 - 2022

- The pandemic affected the types of inspections FSAP conducted
 - 2020 focused on renewal inspections, where most were strictly remote
 - Renewal and verification inspections were balanced pre-pandemic
 - Renewal and verification inspections had alternating highs and lows due to shorter renewal period
 - Requests for assistance (“Outreach visits”) decreased during the pandemic but are growing in 2023
 - When onsite visits resumed in 2021, FSAP incorporated remote elements (“hybrid inspection”)
- Compliance inspections or Form 3 inspections remained rare events throughout this time period



Overall Departures, 2019 – 2022



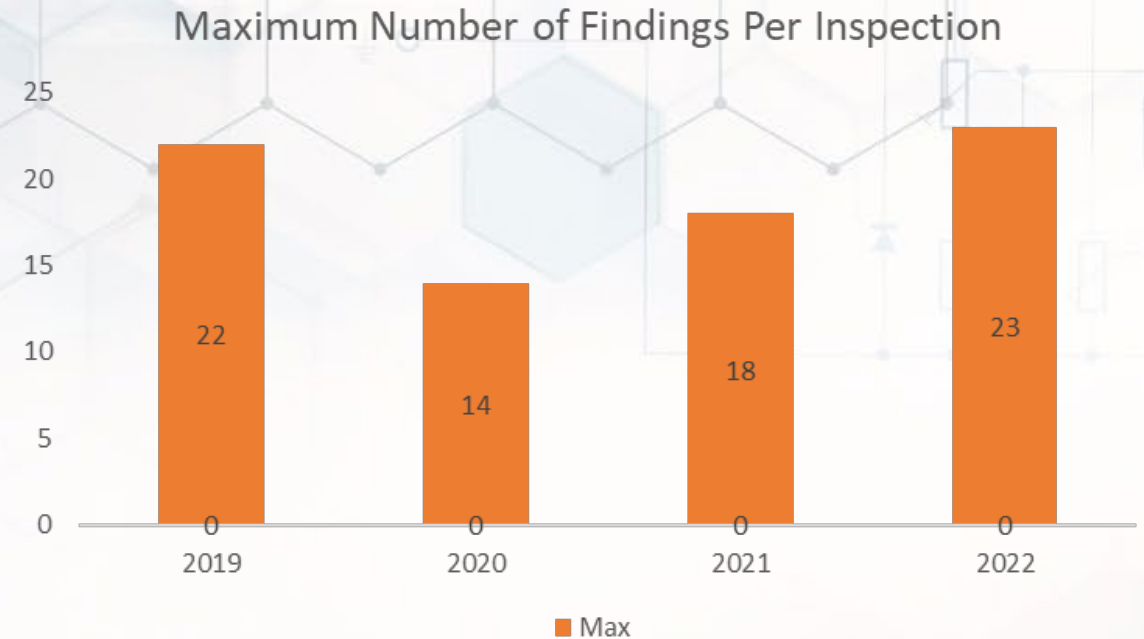
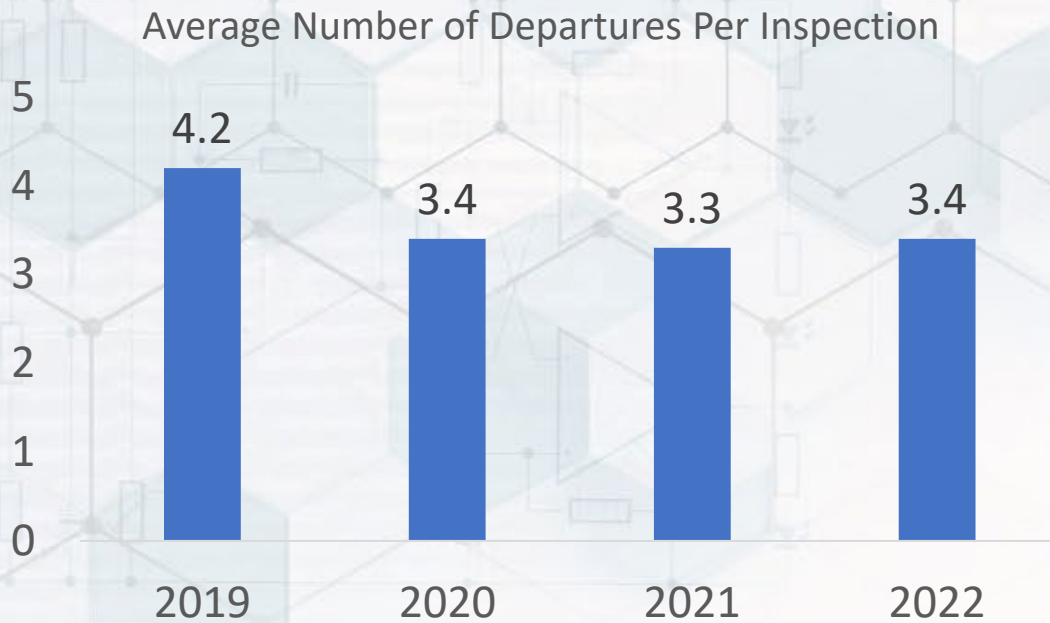
- Section 9 - Responsible Official (4%)
- Section 11 - Security (14%)
- Section 12 - Biosafety (41%)
- Section 14 - Incident Response (11%)
- Section 15 - Training (12%)
- Section 17 - Records (13%)
- Other - Registration, SRA, TLR (5%)

SRA = Security Risk Assessment
TLR = Theft, Loss, Release

- 2676 Total Departures



Inspection Finding Average and Range, 2019 – 2022



- 2020 had mostly remote inspections
 - The average number of findings was comparable to other years
 - The maximum number of findings per report was notably lower



Inspection Finding Severity (1 of 2)

- From 2019-2022, FSAP has assigned every regulatory departure a severity score from an established matrix
- 3-point scale
 - Low
 - Moderate
 - Serious



The screenshot shows the website for the Federal Select Agent Program (FSAP). The header includes the CDC and USDA logos and the text 'FEDERAL SELECT AGENT PROGRAM'. A search bar is located in the top right corner. The navigation menu includes 'Overview', 'Select Agents & Toxins', 'Compliance', 'Regulations & Policies', 'Forms', 'Resources', and 'eFSAP'. The current page is 'Select Agents > Compliance'. The main heading is 'Severity Spectrum of Inspection Departures and Enforcement Actions'. Below the heading is a 'Download PDF' link with a PDF icon and the text '[PDF - 383 KB]'. The main text describes the FSAP's spreadsheet, which outlines categories of inspection regulatory departures grouped by severity level (low, moderate, serious) and related enforcement options. It notes that the information is intended to provide awareness of how FSAP considers the severity of findings and provides visibility to enforcement options. A disclaimer states that the list is not all-inclusive but conveys FSAP's risk view at a large scale.

<https://www.selectagents.gov/compliance/enforcement.htm>



Inspection Finding Severity (2 of 2)

Severity Spectrum: Departures from the select agent and toxin regulations are communicated through an inspection report. Departures may include findings of low risk as well as findings that may lead to an immediate stoppage of some or all activities. **The intention of this document is to provide awareness of how FSAP considers severity of inspection findings and provide visibility to the application of enforcement options to these findings.**

Serious: Departures that are an **immediate threat to human, plant, or animal health**, animal or plant products, and/or security of biological select agents and toxins (BSAT) and those that **indicate a need for systemic improvements**. In selected cases **an Immediate Action Report will be submitted** within 10 days from the Monday following the last day of the inspection. Required **corrective action may include ceasing work or addressing departures within a shortened period of time**. Other departures will be reported in the routine inspection report submitted within 30 days from the Monday following the last day of the inspection.

Moderate: Departures that have the **potential to be a threat to human, plant, or animal health**, animal or plant products, and/or security of BSAT. If not corrected, such **departures will likely impact the safety of** humans, animals, and/or plants, animal or plant products, and/or security of BSAT and increase **the risk of more serious departures**. A routine inspection report will be submitted within 30 days from the Monday following the last day of the inspection.

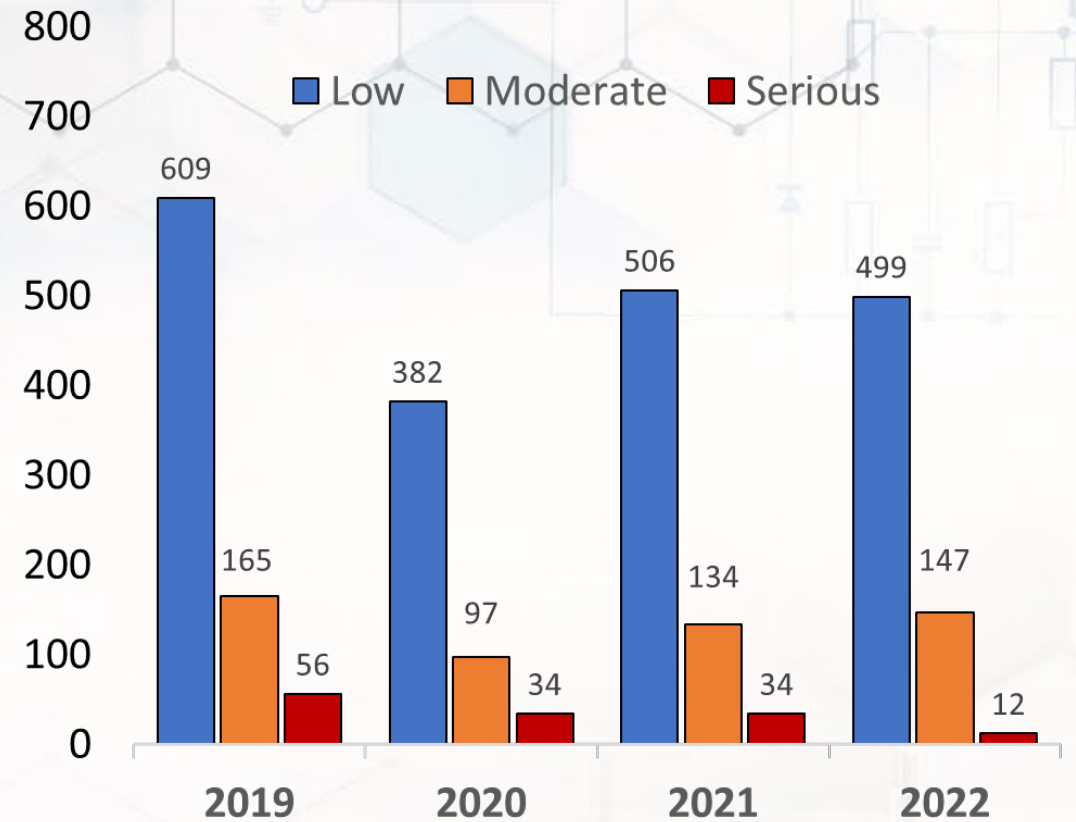
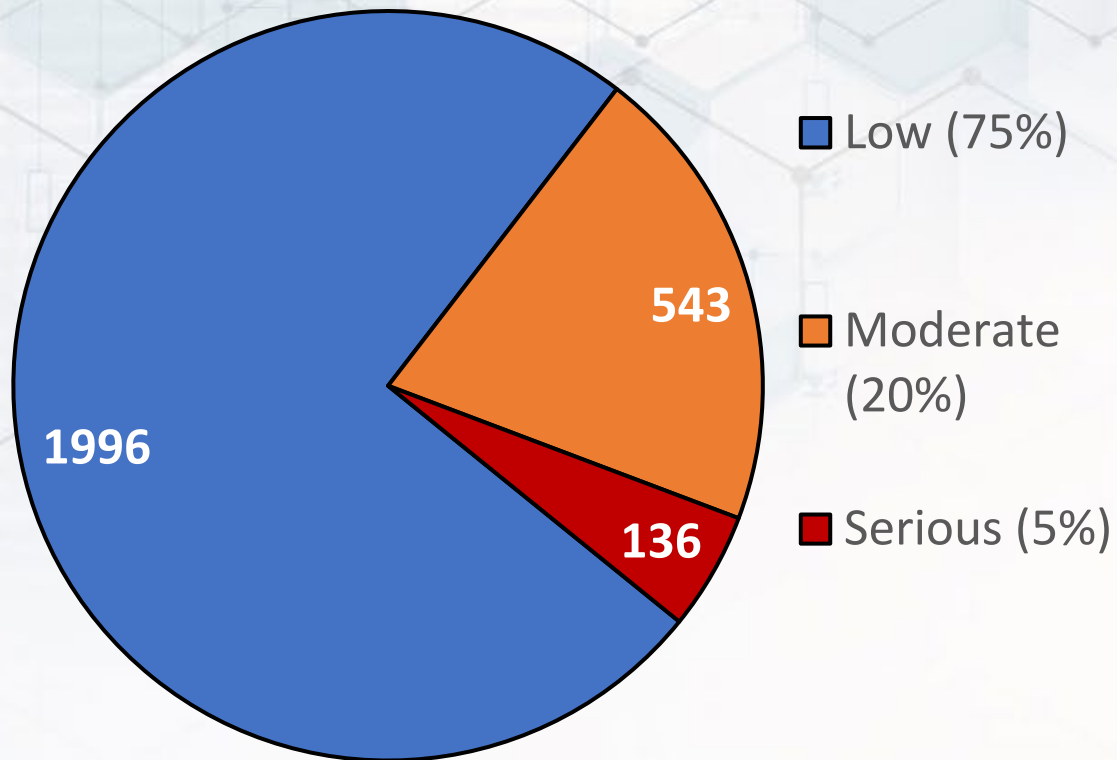
Low: Departures that are **unlikely to pose an immediate threat to human, plant, or animal health** animal or plant products, and/or security of BSAT but are not consistent with safe and secure standards of practice. **If not corrected, such departures degrade the culture of safety and security**. Repetition of departures may be considered more serious and lead to enforcement actions. A routine inspection report will be submitted within 30 days from the Monday following the last day of the inspection.

<https://www.selectagents.gov/compliance/enforcement.htm>



Departures by Severity, 2019 - 2022

Overall



• 2676 Total Departures



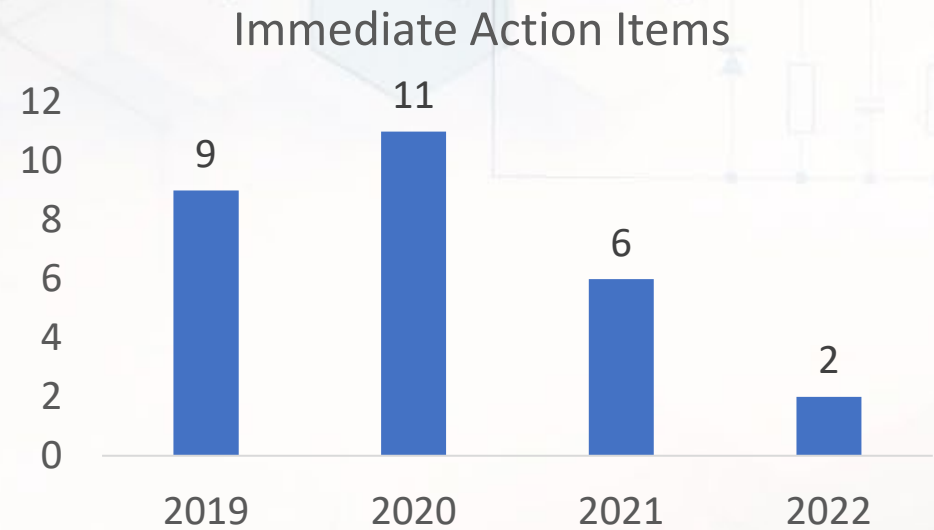
Inspection Finding Severity Summary

- Most inspection departures (75%) are classified as low severity.
- Serious departures are very rare and have been trending down since 2019 (56 to 12)

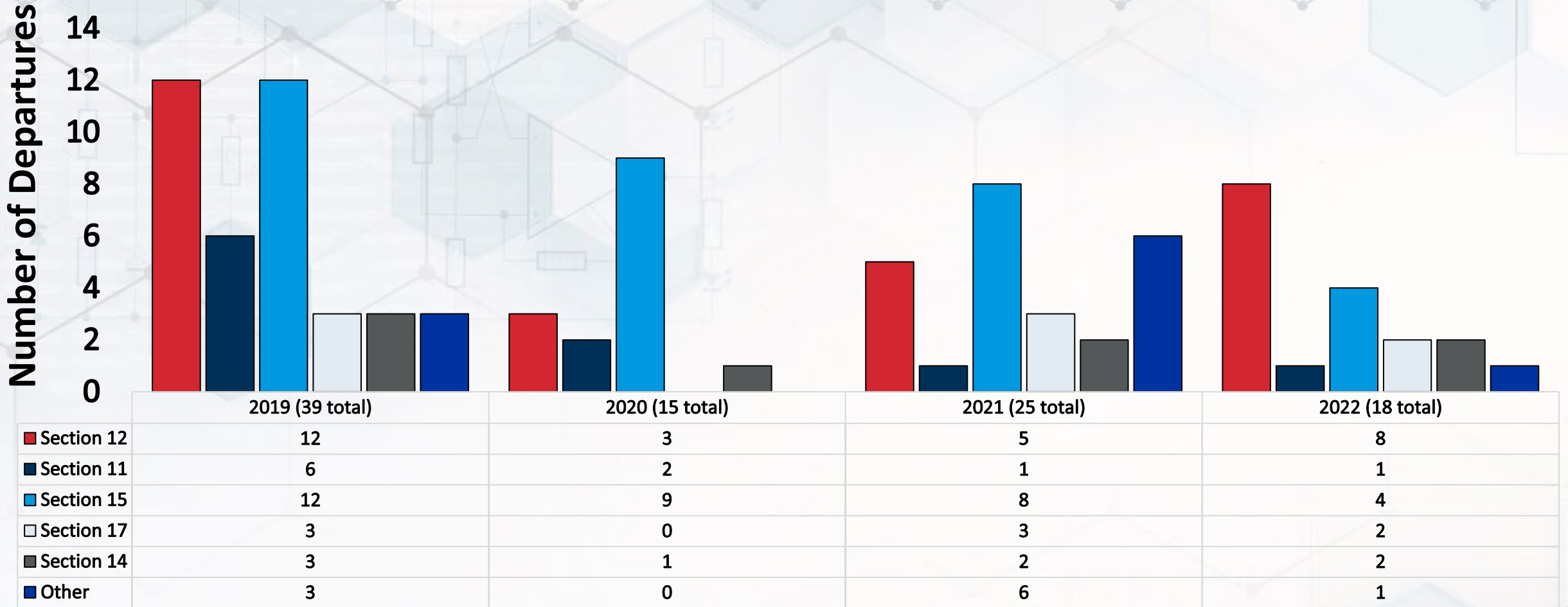


Immediate Action Items, 2019 - 2022

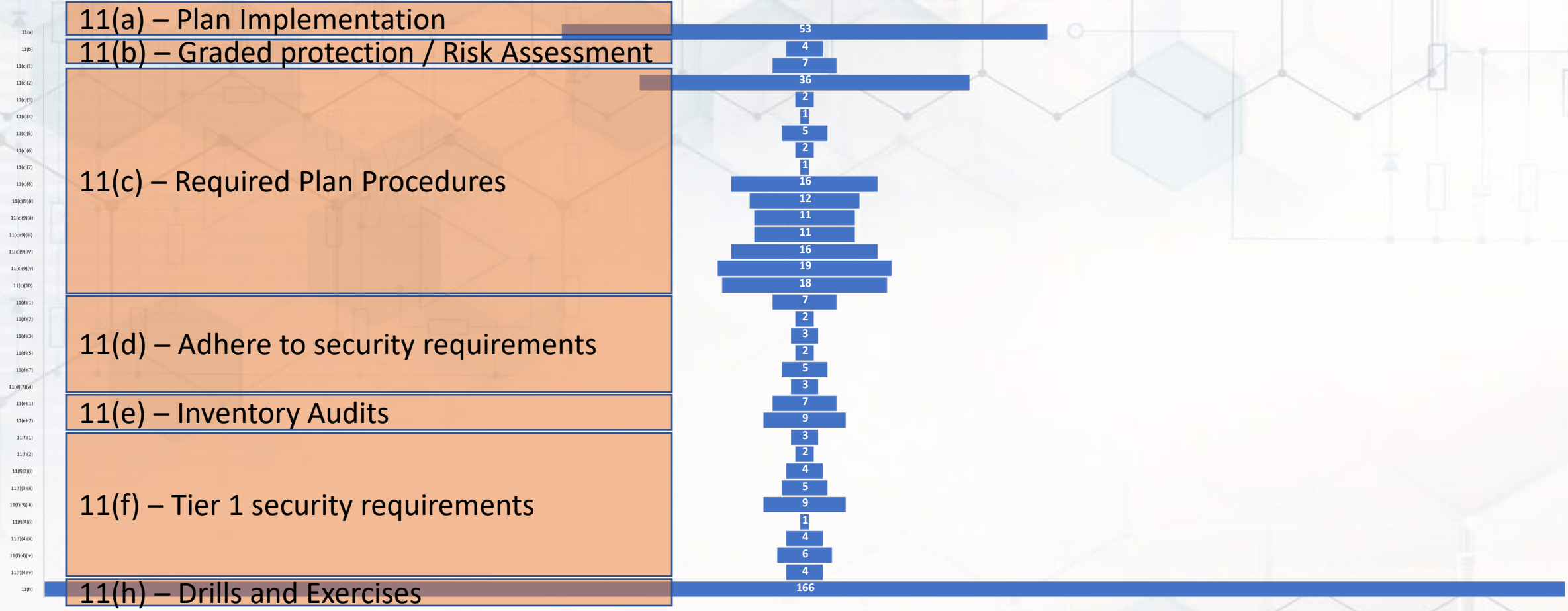
- Serious departures may be marked as requiring “immediate action”
 - “Immediate action” findings are issued in 10 business days and require a response in 10 business days
 - “Immediate action” may include a limited suspension to stop the problematic activity



Repeat Departures, 2019 - 2022



Section 11 Security Departures, 2019 - 2022



Section 12 Biosafety Departures, 2019 - 2022



“Closed” and “Conditionally Closed” Inspection Findings

- A departure remains open in the inspection module until the entity provides an adequate response to the requested corrective action and it is marked as **“Closed”**
- **“Conditionally closed”** applies to a specific item that has not been adequately addressed, but further action is not required at this time. It can be changed to “closed” in the future when fully addressed
- From 2019 – 2022 this action has been used **5** times or **< 1%** of inspections during this time. Examples:
 - There are significant time delays for repairs; work has been suspended until the issue can be resolved and/or a mitigation plan is in place to manage the issue
 - The entity has been revoked and did not resolve all departures

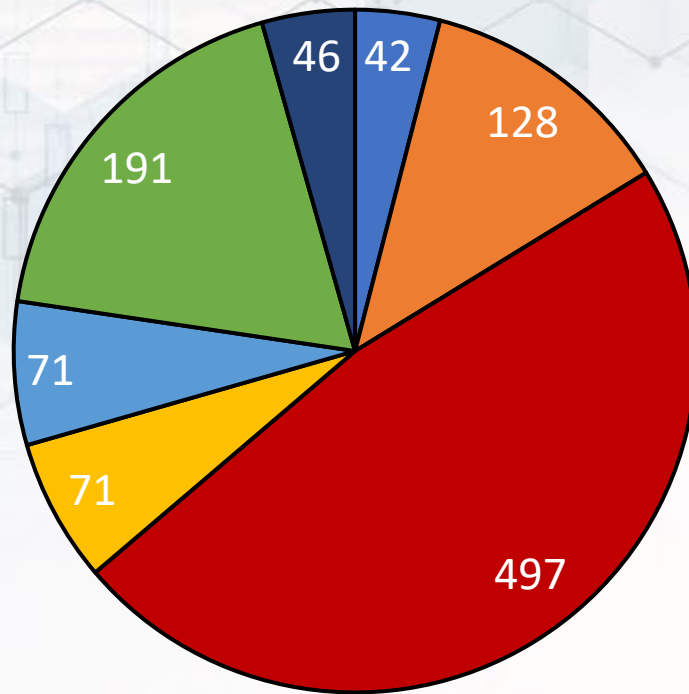


General Concerns

- General concerns have been issued during this entire time period
- These are observations that are not departures at that time but could lead to future regulatory departures
- No response is required by the entity



Overall General Concerns, 2019 - 2022



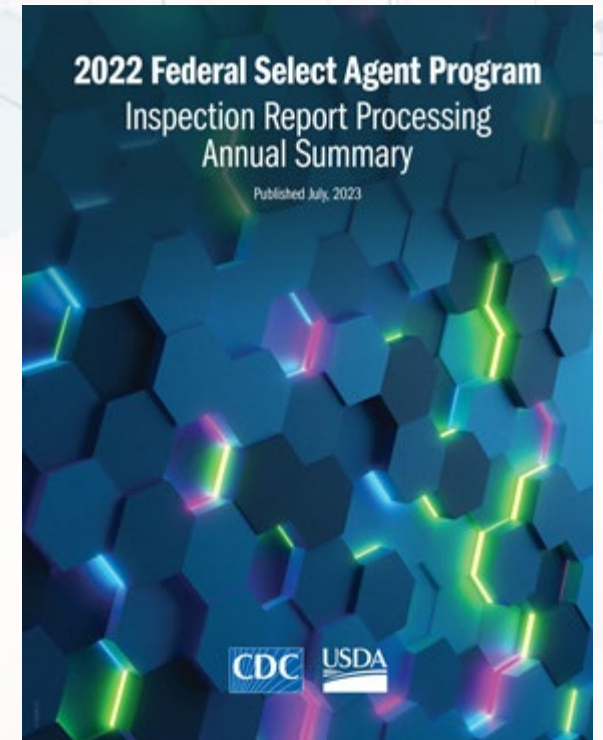
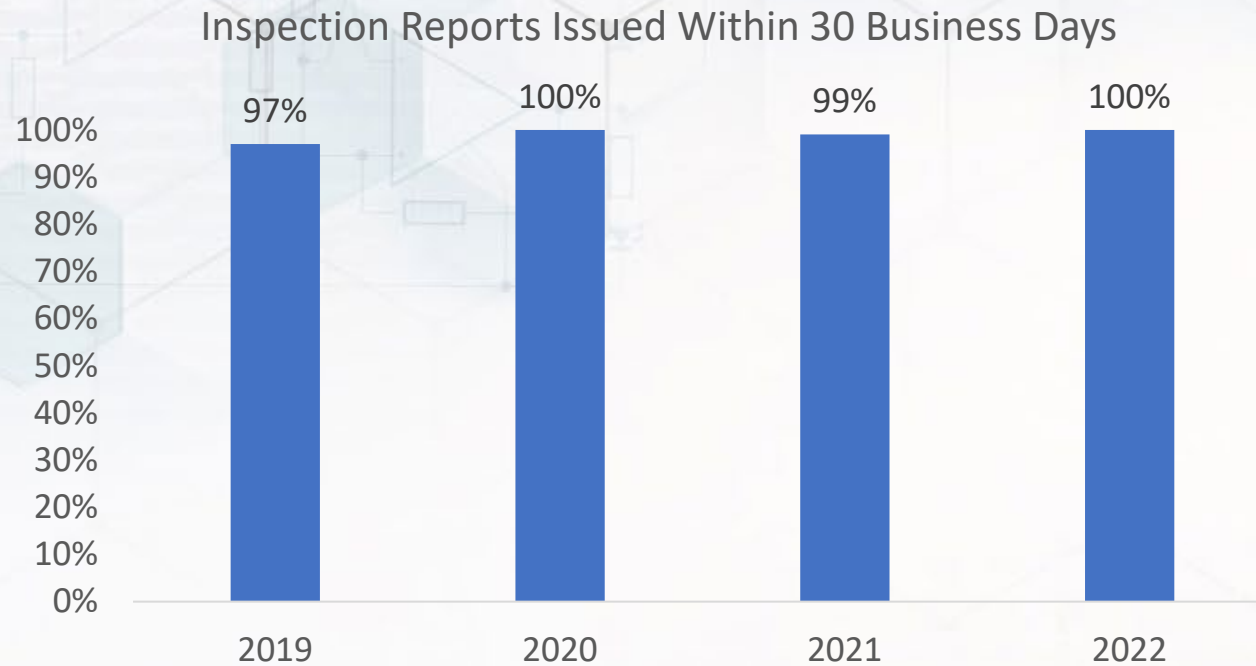
- Section 9 - Responsible Official (4%)
- Section 11 - Security (12%)
- Section 12 - Biosafety (48%)
- Section 14 - Incident Response (7%)
- Section 15 - Training (7%)
- Section 17 - Records (18%)
- Other - Registration (4%)

- 1046 Total General Concerns



Inspection Report Timeliness

- Nearly all inspection reports are issued within 30 business days



<https://www.selectagents.gov/resources/publications/index.htm>



Discussion



Highlights in 2019 – 2022 Inspection Findings

- The pandemic required innovation in how FSAP conducted inspections
- Biosafety departures (Section 12) continue to predominate, followed by security (Section 11) and records (Section 17). General Concerns show a similar trend
- The average number of inspection findings have slightly decreased (4.2 down to 3.3) during this time
- “Serious” departures have significantly decreased (56 in 2019 to 12 in 2022; a 79% decrease)
- Repeat departures primarily occur with deficiencies in training and biosafety



Notable Observations That Can Be Avoided

- Make sure inactivation procedures are validated and documented. They must be reviewed annually (even when not currently used)
- Validate your maximum load size if you are autoclaving carcasses
- Use a freezer log (or similar) if storing carcasses prior to destruction
- Make sure donning and doffing procedures are posted where these activities occur and updated when changes occur
- Post your spill procedures in the laboratory (BMBL 6th Edition updates)
- Check for expired disinfectants
- Review your Form 1 registration in the eFSAP information system to reflect changes to work, strains/serotypes, and visitor entry requirements



Drivers of Change

- The pandemic and the shift to remote inspections caused inspection time to be weighted towards items that can be assessed from afar (i.e., increased attention on plans and records)
 - Changes in departure frequency may reflect sampling and not real trends
- At the same time, real impacts were seen in many ways
 - Missed/late biosafety cabinet certifications due to difficulties in scheduling certifiers
 - Missed/late training due to staff being away or directed to other priorities



www.selectagents.gov

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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 or the Animal and Plant Health Inspection Service.

