

Analysis of FSAP Inspection Report Departures

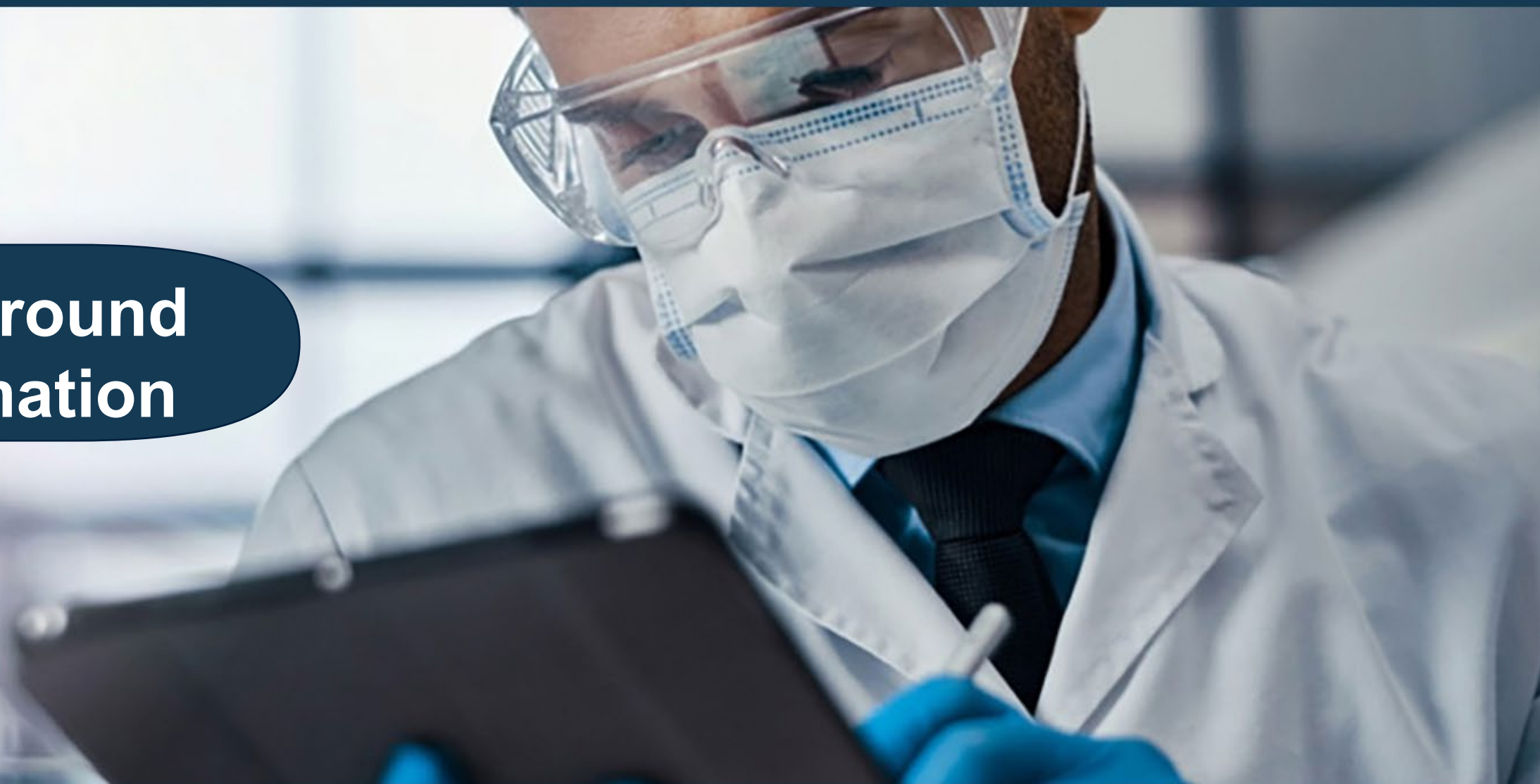


Agenda

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

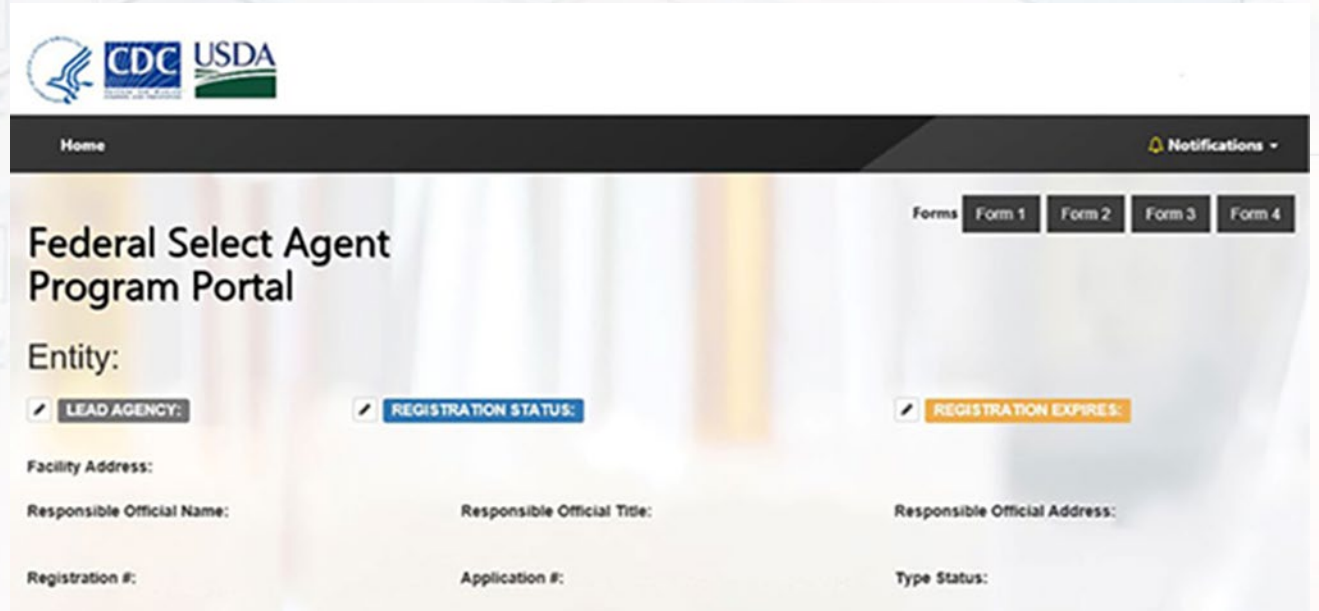


Background Information



Background Information

- 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 displays the Federal Select Agent Program Portal. At the top, there are logos for CDC and USDA. Below the logos is a navigation bar with a 'Home' link and a 'Notifications' dropdown menu. The main content area features the title 'Federal Select Agent Program Portal' and a 'Forms' section with buttons for 'Form 1', 'Form 2', 'Form 3', and 'Form 4'. The 'Entity:' section includes three status indicators: 'LEAD AGENCY:', 'REGISTRATION STATUS:', and 'REGISTRATION EXPIRES:'. Below this, there are input fields for 'Facility Address:', 'Responsible Official Name:', 'Responsible Official Title:', 'Responsible Official Address:', 'Registration #:', 'Application #:', and 'Type Status:'.



Purpose of Evaluating FSAP Inspections and Findings



- Follow-up to September 2023 Responsible Official Webinar presentation
- Entities use inspection reports (particularly departures) to monitor and improve their biosafety and security of facilities, practices, and training
- FSAP uses eFSAP-compiled data to serve as a resource to evaluate entities for potential vulnerabilities and gauge likely focus areas during upcoming inspections

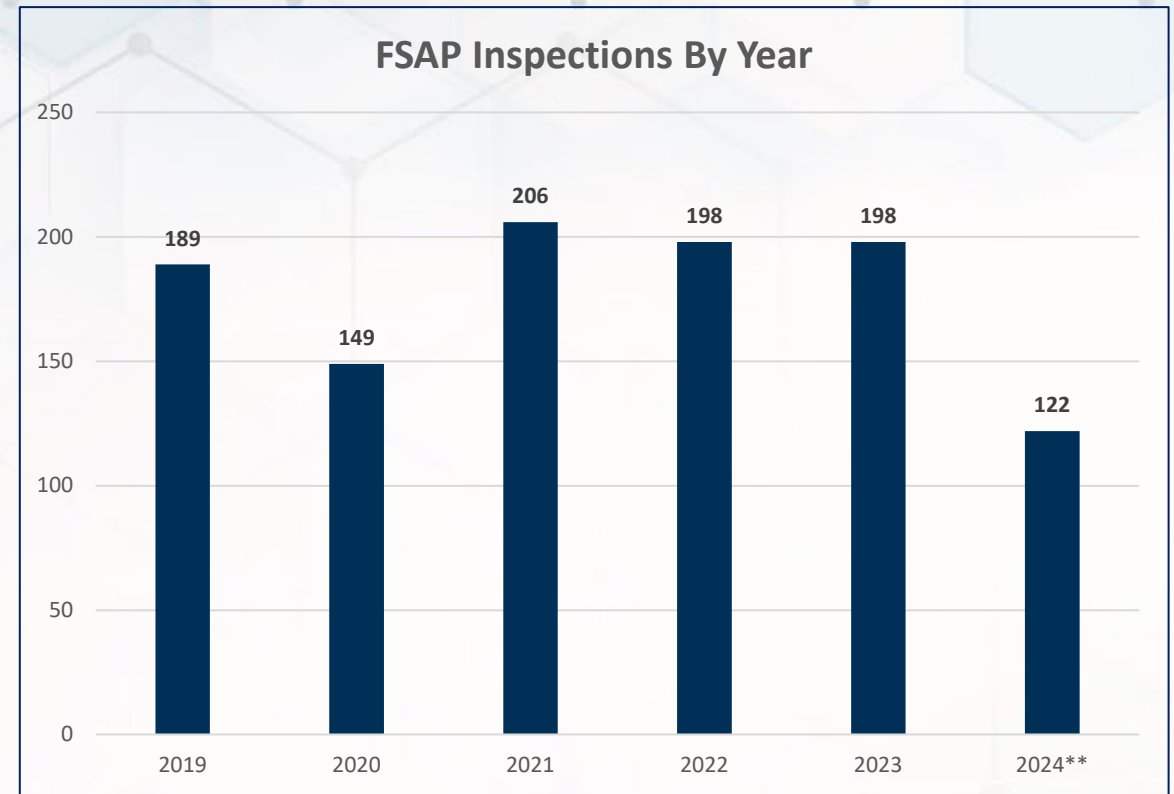


Inspection Data



FSAP Inspections By Year, 2019 - 2024

- 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 have continued thru 2024

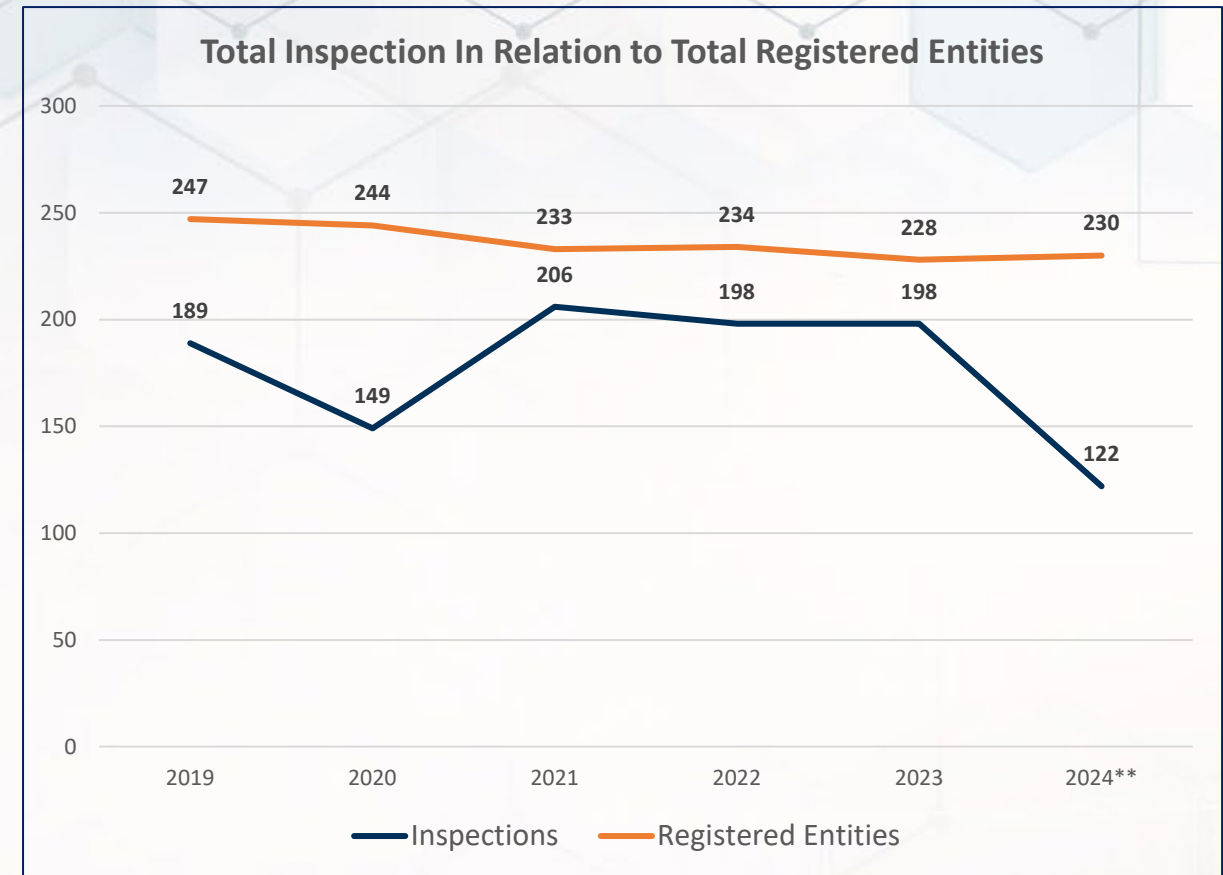


** Inspections to July 2024



Total Inspections in Relation to Total Registered Entities, 2019 - 2024

- The number of registered entities has remained relatively stable
- The number of inspections relative to the number of entities decreased in 2020 and increased to pre-pandemic levels in years 2021-2023.
- For 2024, the same relative number of inspections is maintained.



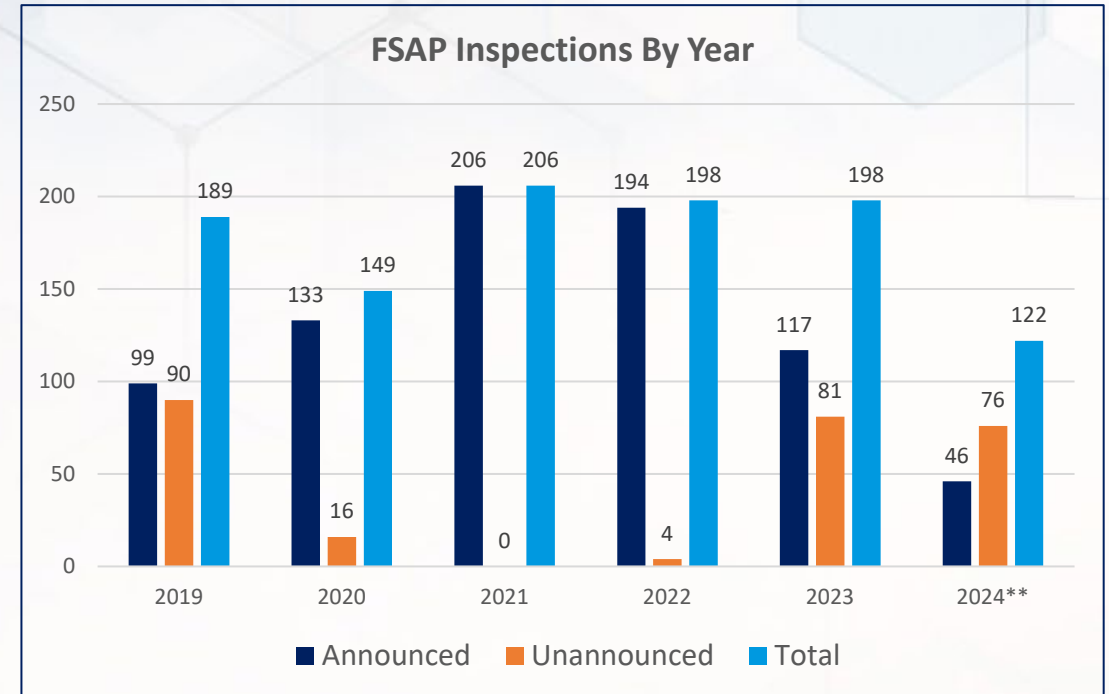
Inspections as a % of Total Entities	77%	61%	88%	85%	87%	53%**
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** Inspections to July 2024



Announced vs Unannounced FSAP Inspections by Year, 2019 - 2024

- 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: 41% of all inspections were unannounced, including inspections of BSL-4 facilities
- 2024 (Jan-July): 62% of all inspections were unannounced, including BSL-4 facilities

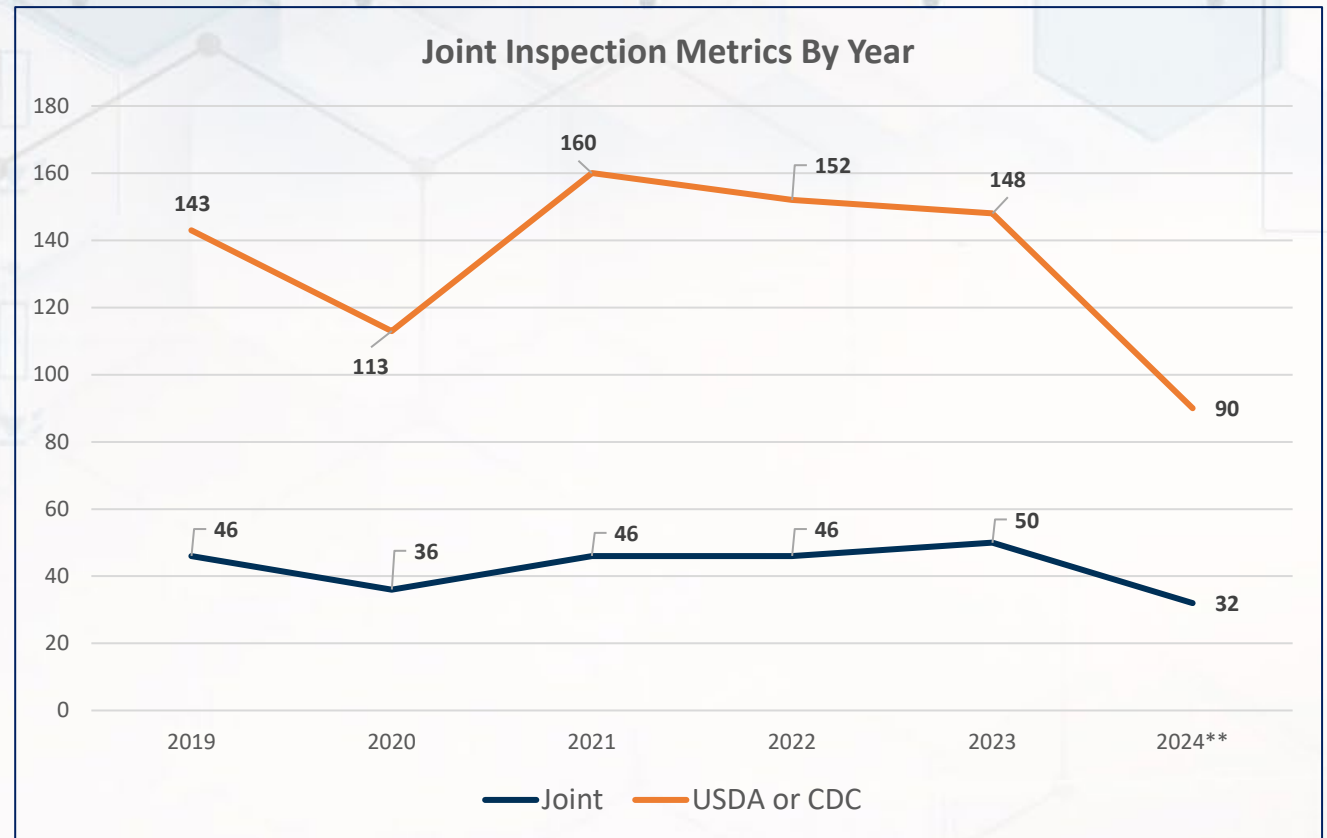


** Inspections to July 2024



Joint Inspections by Year, 2019 - 2024

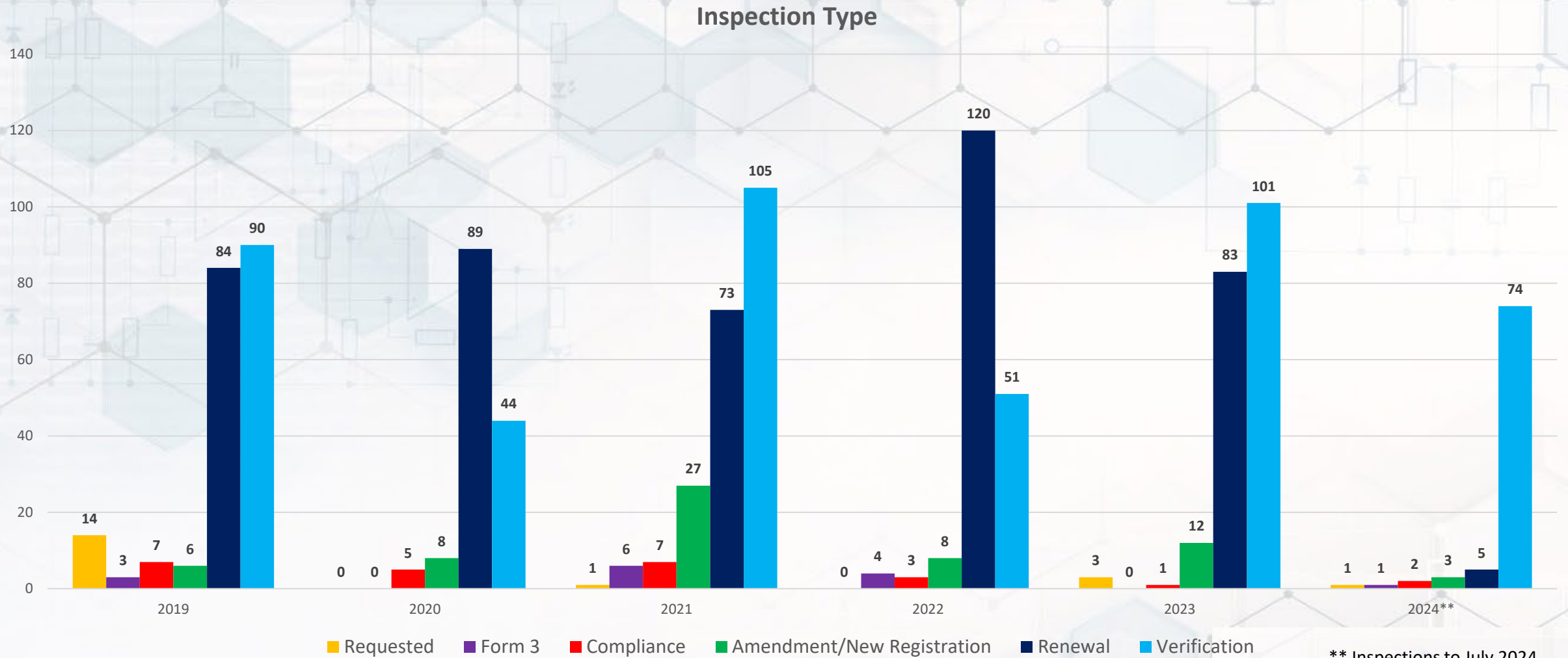
- Joint Inspections with CDC and APHIS inspectors are conducted when entities possess both HHS-only and USDA-only BSAT
- Most inspections are by a single agency and there is a relatively consistent number of joint inspections by year



** Inspections to July 2024



Inspection Numbers by Category, 2019 - 2024



Summary for Inspection Categories, 2019 – 2024 (1 of 2)

- 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 grew in 2023
 - When onsite visits resumed in 2021, FSAP incorporated remote elements (“hybrid inspection”)



Summary for Inspection Categories, 2019 – 2024 (2 of 2)

- The Future

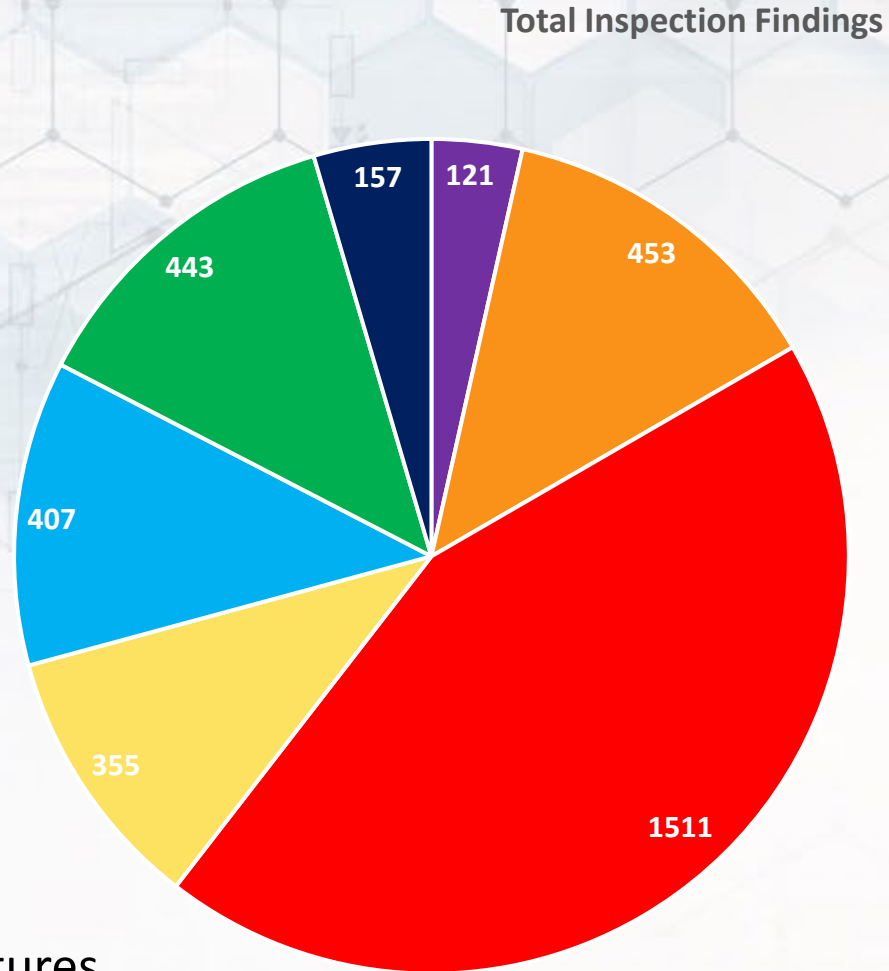
- Re-balancing and harmonizing verification and renewal inspections
- Further tailoring and updating remote and on-site inspections for the hybrid processes
- Expanding remote verification inspections for low complexity entities
- Continuing outreach visits for new space and complex amendments



Departure Data



Overall Departures, 2019 - 2023



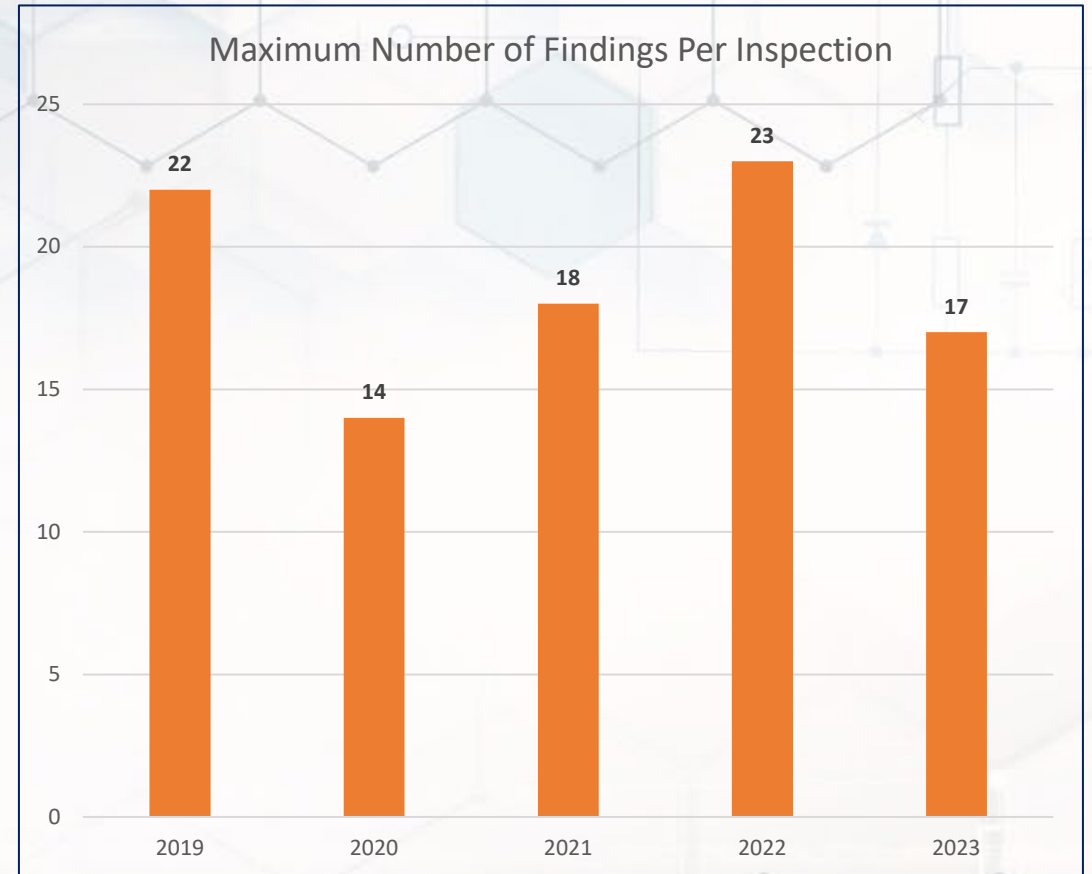
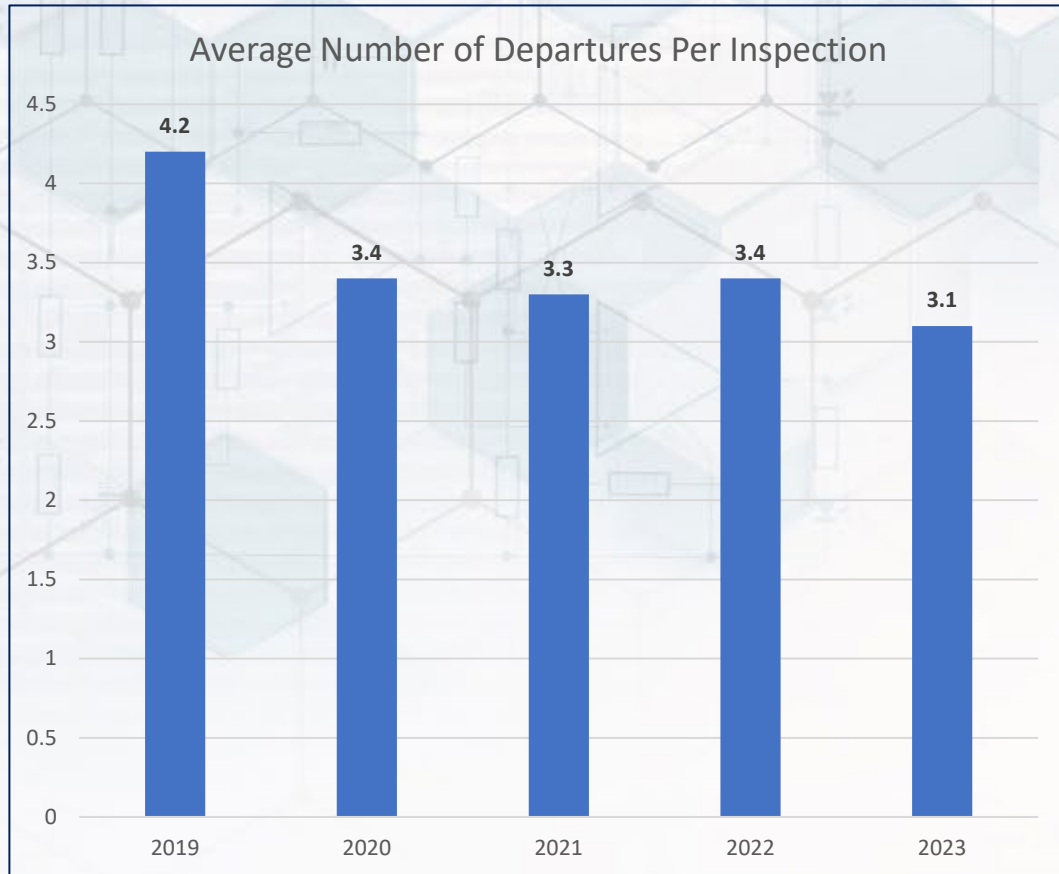
- Section 9
- Section 11
- Section 12
- Section 14
- Section 15
- Section 17
- Other - Registration, SRA, TLR

- 3447 Total Departures

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



Inspection Finding Average and Range, 2019 - 2023



Inspection Finding Severity (1 of 2)

- From 2019-2024, FSAP has assigned every regulatory departure a severity score from an established matrix
- Severity 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. 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 states: 'The Federal Select Agent Program (FSAP) has developed a spreadsheet that outlines categories of inspection regulatory departures grouped according to the level of severity, as well as related enforcement options that may be applied. The intention of this information is to provide awareness of how FSAP considers the severity of inspection findings and provide visibility to the application of enforcement options to these findings. Example violations are grouped into a three-tier risk scoring system in the categories of low, moderate, and serious severity levels.' A note at the bottom states: 'Departures may include findings of low risk as well as findings that may lead to an immediate stoppage of some or all activities. Please note that this is not meant to be an all-inclusive list of possible departures, but is meant to convey, at a large scale, how FSAP views risk.'

<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

- Immediate threat to human, plant, or animal health
- Need for systemic improvement
- Immediate Action
- Corrective action may include ceasing work or corrections in a shortened timeframe

Moderate

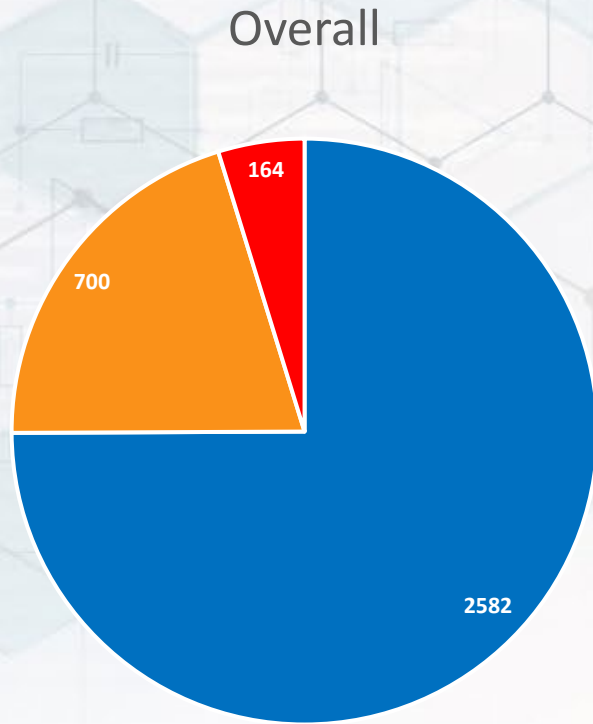
- Potential to be a threat to human, plant, or animal health
- Departures will likely impact safety and/or security of BSAT
- Risk of more serious departures

Low

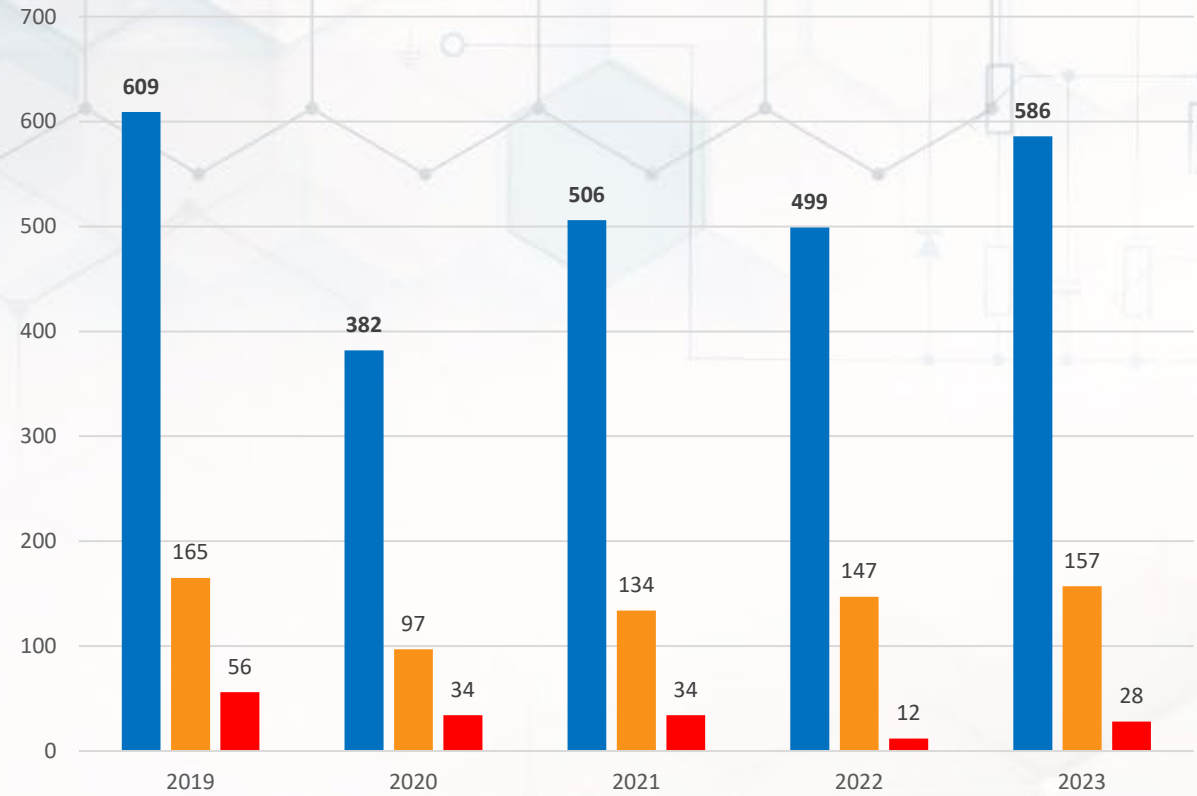
- Unlikely to pose an immediate threat to human, plant, or animal health
- Departures degrade the culture of safety and security
- Repetition may lead to enforcement actions



Departures by Severity, 2019 - 2023



■ Low ■ Moderate ■ Serious



■ Low ■ Moderate ■ Serious

- 3446 Total Departures



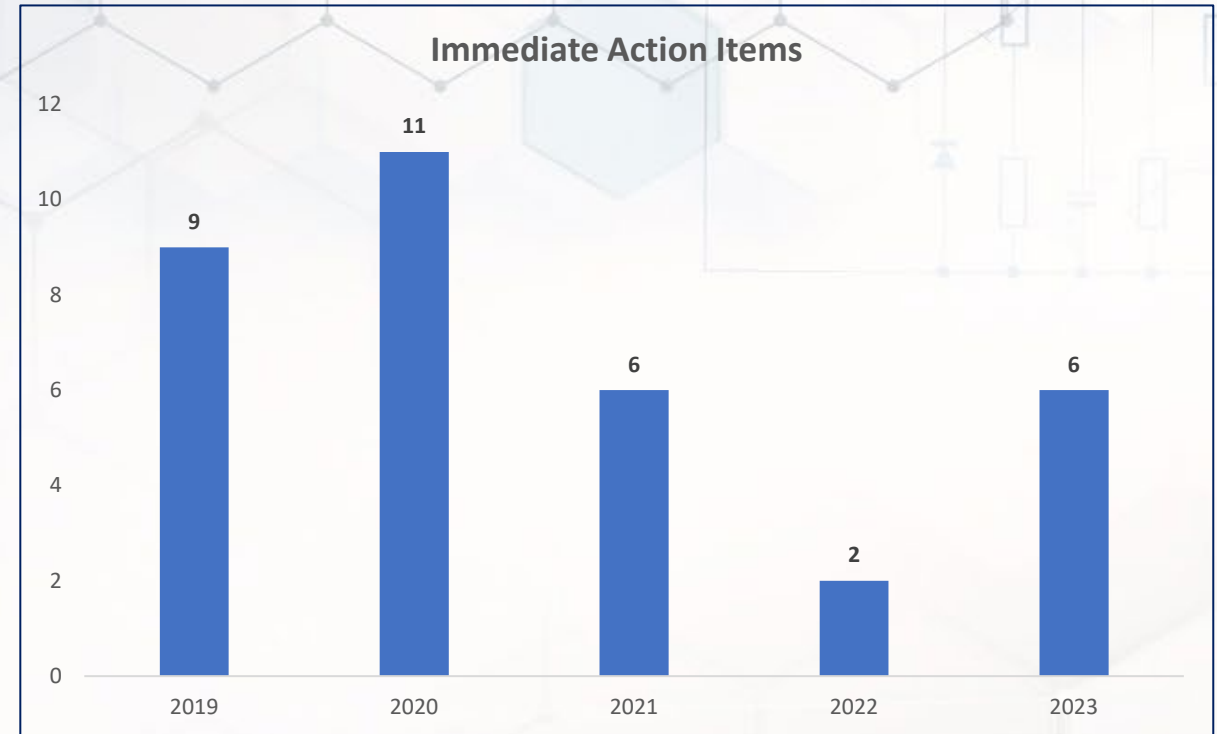
Inspection Finding Severity Summary

- Most inspection departures (75%) are classified as low severity
- Serious departures are rare and have remained few since 2019 (from 6.7% down to 3.6% of findings in 2023).



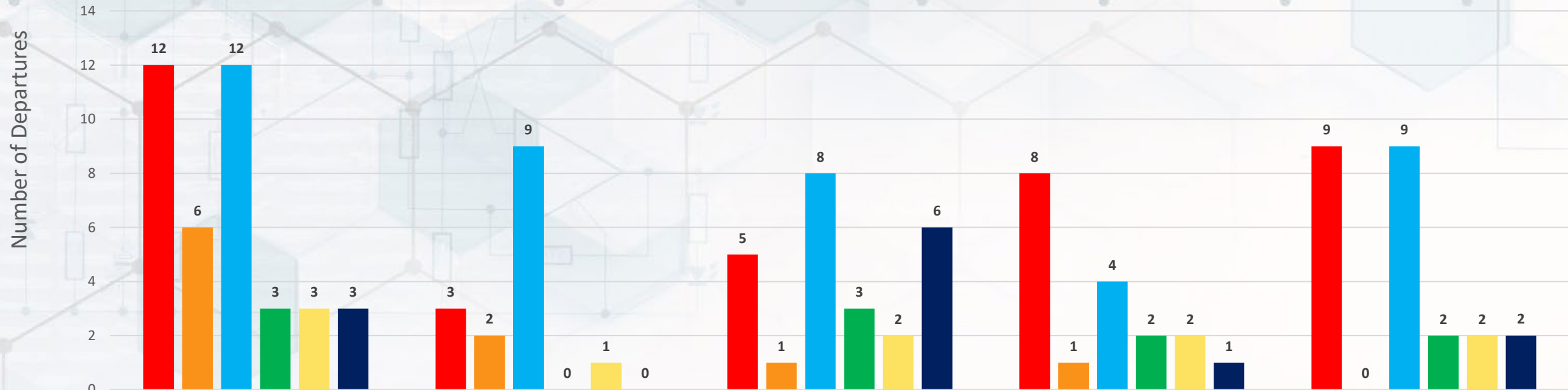
Immediate Action Items, 2019 - 2023

- Serious departures may be marked as requiring “immediate action”
 - “Immediate action” findings are issued within 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 - 2023

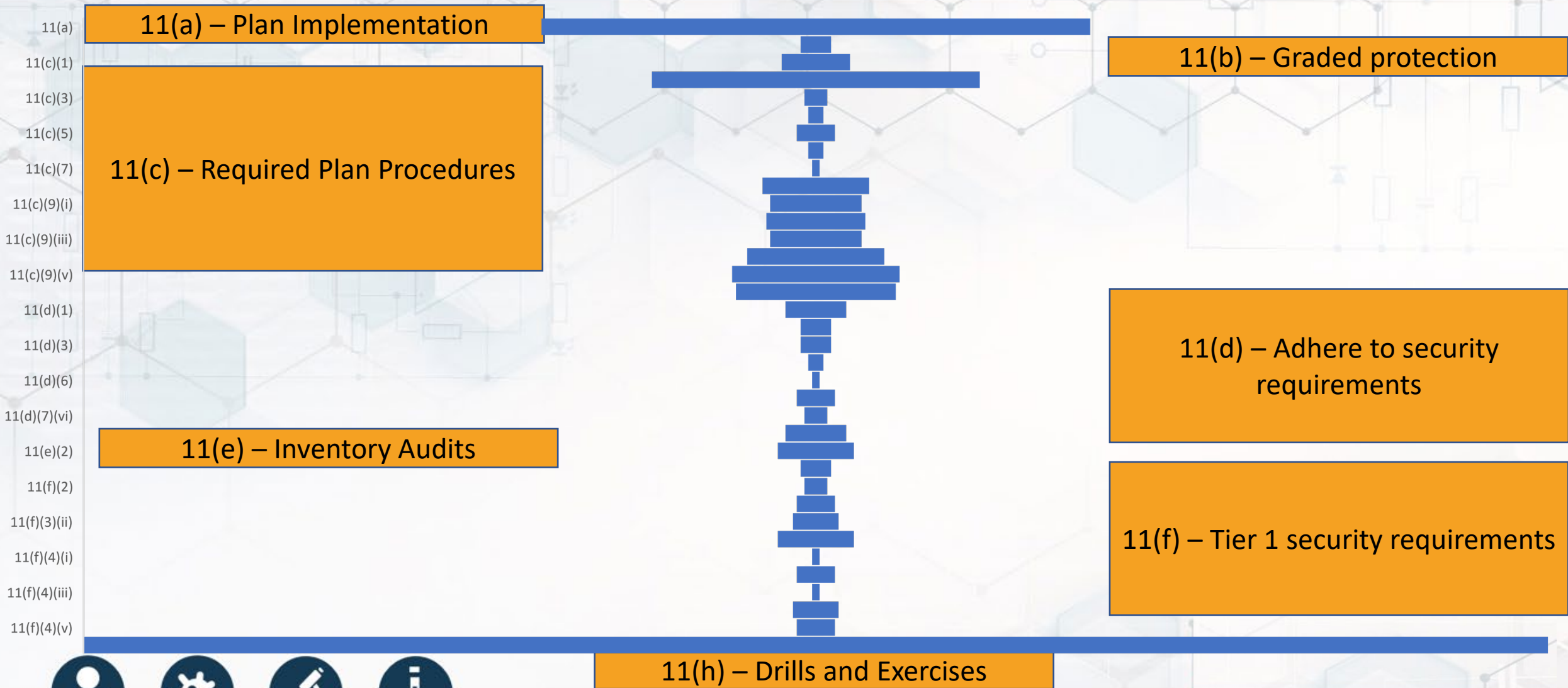
Repeat Departures by Year



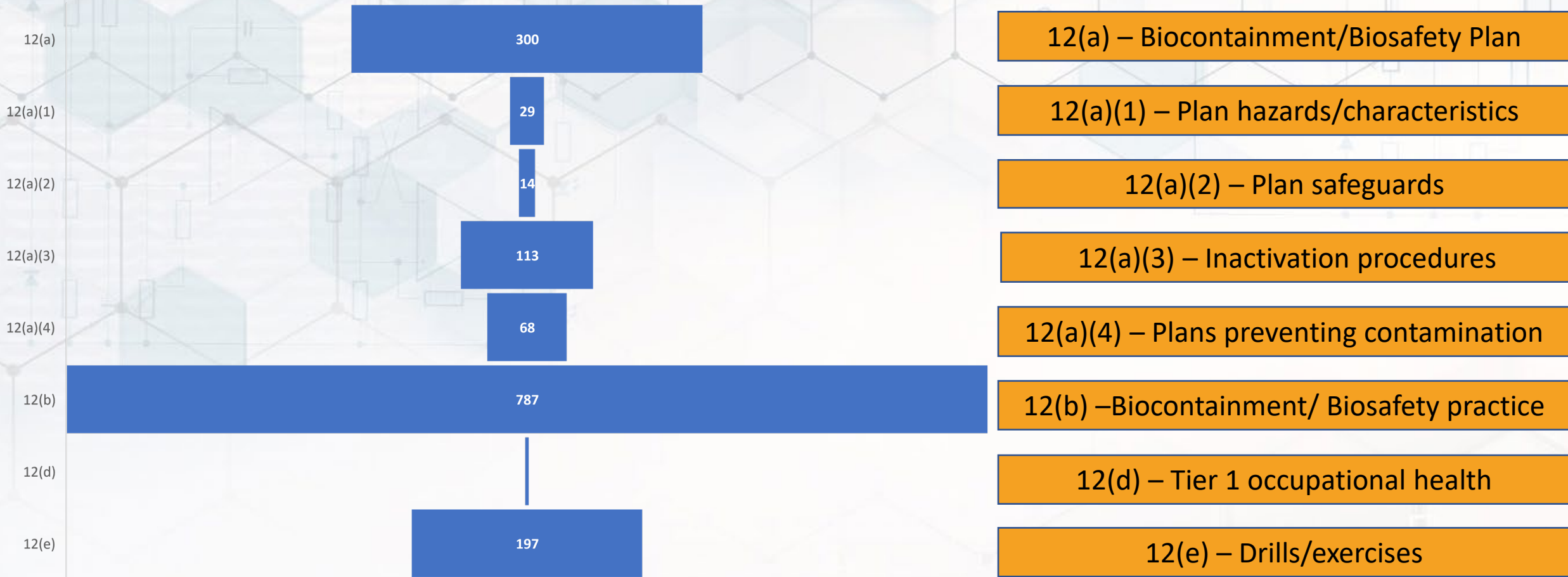
	2019 (39 total)	2020 (15 total)	2021 (25 total)	2022 (18 total)	2023 (22 total)
Section 12	12	3	5	8	9
Section 11	6	2	1	1	0
Section 15	12	9	8	4	9
Section 17	3	0	3	2	2
Section 14	3	1	2	2	2
Other	3	0	6	1	2



Section 11 Security Departures, 2019 - 2023



Section 12 Biosafety Departures, 2019 - 2023



“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

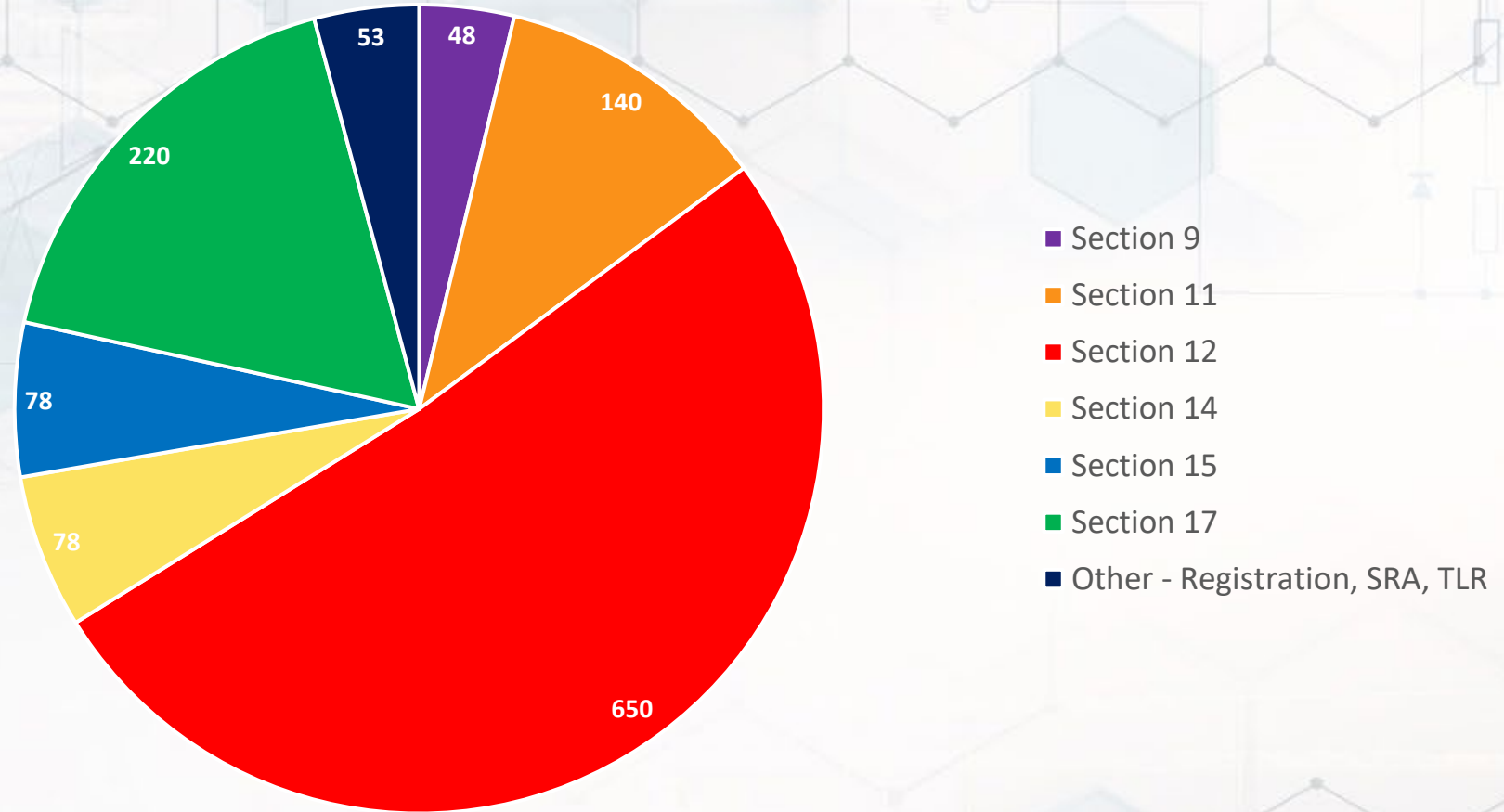


General Concerns

- 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 - 2023

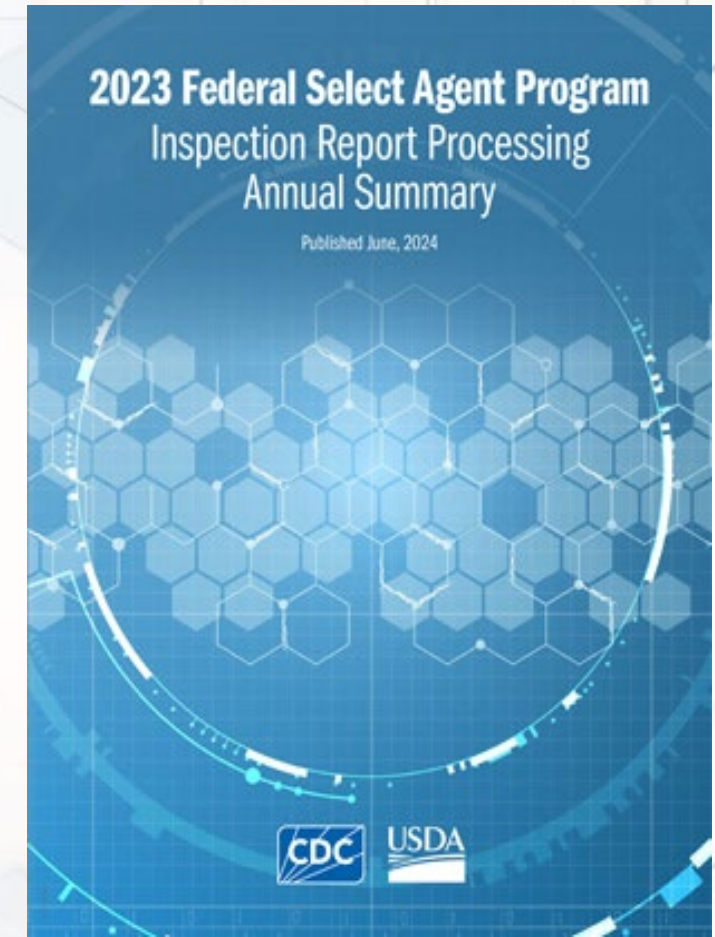
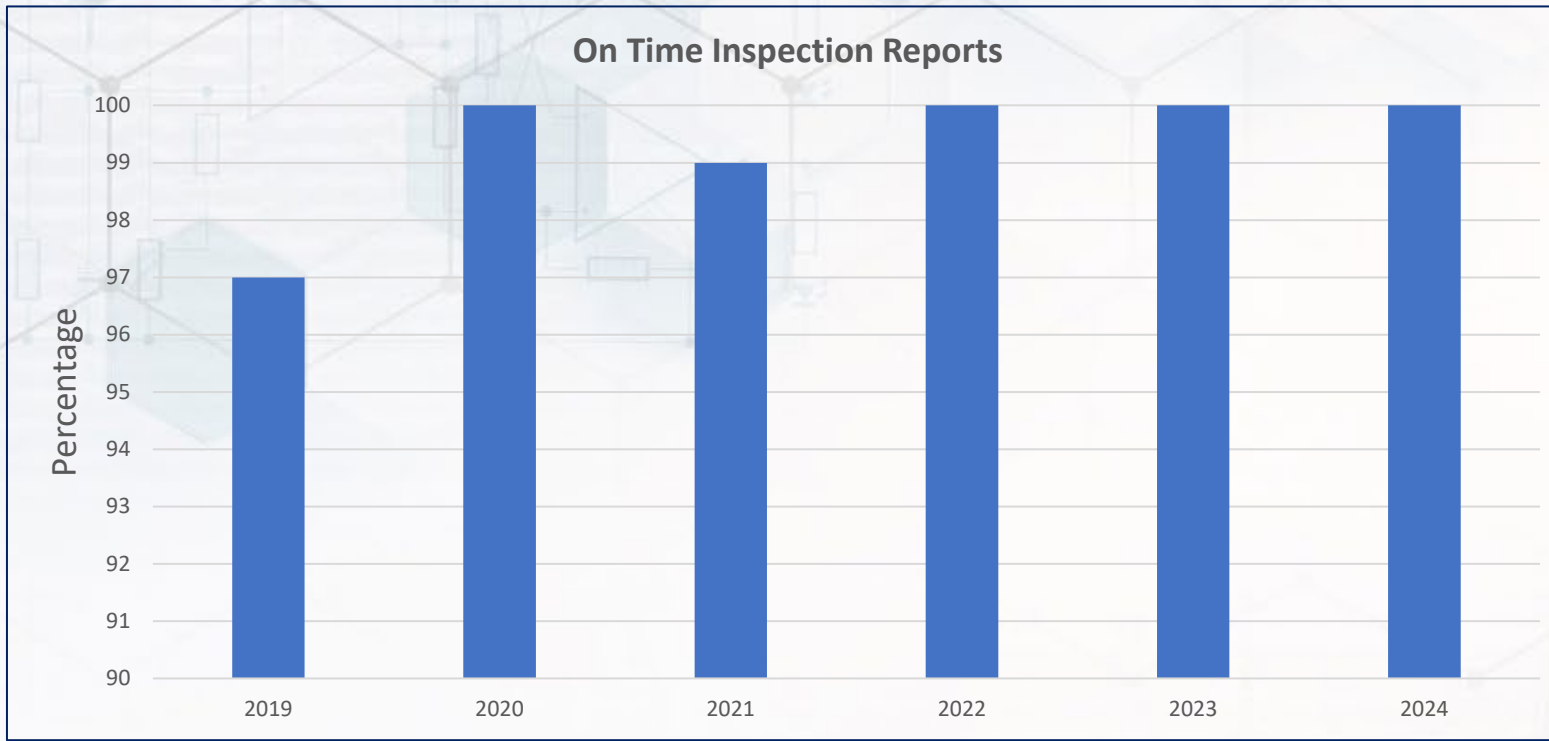


- 1267 Total General Concerns



Inspection Report Timeliness

- Recently, all inspection reports were issued within 30 business days



** Inspections to July 2024



Highlights in 2019 - 2024 Inspection Findings

- Biosafety departures (Section 12) 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 3.1 in 2023)
- “Serious” departures have significantly decreased (6.7% of findings in 2019 down to 3.6% in 2023)
- Repeat departures primarily occur with deficiencies in training and biosafety



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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.

