

Division of Select Agents and Toxins

# 2017 Inspection Report Processing Annual Summary

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# 2017 DSAT Inspection Report Processing Annual Summary

January 1, 2017 – December 31, 2017

The *2017 DSAT Inspection Report Processing Annual Summary* presents timeliness data related to inspection reports issued by the Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT) to entities regulated by the Federal Select Agent Program (FSAP) during calendar year 2017 (CY2017). This analysis is used to improve the timeliness of inspection reports to ensure registered entities are provided timely feedback after an inspection.

## Section 1. Introduction

Biological select agents and toxins (BSAT), such as *Bacillus anthracis*, avian influenza viruses, *Ralstonia solanacearum*, and botulinum neurotoxin, have the potential to pose a severe threat to human, animal, or plant health, and to animal or plant products. Research to improve rapid detection of and medical countermeasures against BSAT is critical for the United States to be able to respond to incidents involving BSAT. FSAP, which includes DSAT and the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS)/Agriculture Select Agent Services (AgSAS), oversees the possession, use, and transfer of BSAT by laboratories working with these agents in accordance with regulatory requirements. The select agent regulations (SAR) include biosafety/biocontainment, security, and incident response requirements that registered entities must follow to ensure the safety and security of those working in laboratories and living in surrounding communities. An entity required to register with FSAP (i.e., an entity that possesses, transfers, or works with BSAT) is subject to the SAR and on-site inspections to review laboratory programs to ensure that appropriate biosafety/biocontainment and security measures are in place.

In October 2015, an internal CDC review of DSAT identified areas for improving biosafety and security oversight<sup>1</sup>. One recommendation was for DSAT to identify and publish the reasons for inspection reports being delayed. To address this, DSAT began analyzing inspection report processing data, and this is the third annual summary.

## Section 2. Methods

DSAT determined inspection report processing times by querying the National Select Agent Registry database, inspection team spreadsheets, and the Operations Branch Inspection Coordinator's spreadsheet to extract processing data for inspection reports issued in CY2017 for DSAT-only inspections and DSAT-led DSAT/AgSAS joint inspections. Inspection report processing typically involves, at minimum:

- A debrief with the DSAT Operations Branch Chief and Team Leads to discuss inspection observations;
- Review of observations and documents collected during the inspection;
- Determination of the severity level of the inspection observations; and
- Writing, editing, and reviewing the inspection report prior to sending the final report to the entity.

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<sup>1</sup> Division of Select Agents and Toxins: CDC 90-Day Internal Review (<https://www.cdc.gov/phpr/dsat/full-report.htm>)

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The overall target timeframe for final inspection reports is 30 business days. As in CY2016, processing times for CY2017 were defined as the number of federal government business days from the Monday following the last day of the inspection to the issuance of the inspection report. Final inspection reports were classified into two categories: 1) issued within 30 business days or 2) issued after 30 business days. Final reports that are issued after the 30 business day target are considered delayed. If inspection findings require the FSAP to immediately suspend activities within the registration or revoke an entity's registration, the entity is contacted immediately to ensure appropriate action is taken. The inspections were stratified by inspection type and the quarter the inspection report was issued. DSAT used the following four quarters based on the month the inspection report was issued:

- First quarter: January-March
- Second quarter: April-June
- Third quarter: July-September
- Fourth quarter: October-December

DSAT changed the processing day starting point in CY2016 from the number of federal government business days following the last day of the inspection to account for days in which inspectors would be unable to address inspection reports because of travel from an inspection. For all comparisons to data previously published in the *2015 Inspection Report Processing Annual Summary (2015 Annual Summary)*, DSAT recalculated the CY2015 processing times according to the CY2016 definition.

Inspection report processing times were analyzed by inspection types, which were classified into six categories:

- **Compliance** – Review of entity BSAT program focused on laboratory spaces and documents (e.g., plans, records, facility verification documentation) for compliance issues, including DSAT-identified issues or whistleblower reports.
- **Maximum Containment** – Review of entity program, including laboratory spaces and documents, for laboratories that work with agents requiring highest levels of containment [e.g., Biosafety Level (BSL) 3-Ag, Animal BSL-4, and BSL-4].
- **New Entity** – Review of all laboratory spaces and documents for entity submitting a new registration application to work with BSAT.
- **New Space** – Review of laboratory space and documents for adding new laboratory space to existing registration.
- **Renewal** – Review of entire entity program, including all registered laboratory spaces and documents, to renew existing registration; this typically occurs every 3 years.
- **Verification** – Review of selected portions of an entity program, including assessment of responses to previous inspection departures as well as selected laboratory spaces and documents.

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For each inspection report that was sent after the deadline, DSAT identified the reason(s) for the delay and grouped them into one or more of the following categories:

- **Severe Non-Compliance:** Delays due to other steps inspectors had to take to ensure the entity quickly addressed severe compliance issues discovered during an inspection. These steps can include generating an Immediate Action Report (discussed in the Results section) and additional discussion of the inspection findings with FSAP leadership. Severe compliance issues are those that may lead to a suspension, revocation, or an offer to participate in a voluntary Corrective Action Plan. The Corrective Action Plan Program was created to assist entities identified as having systemic deficiencies in achieving compliance with the SAR.
- **Workload:** Delays due to workload while processing inspection reports, such as: simultaneous processing of inspection reports, reduced staff, and competing priorities.
- **Administrative:** Delays due to administrative processes, such as: delays in review and delays due to inspection scheduling challenges.
- **Concurrence:** Delays in achieving concurrence between AgSAS and DSAT regarding the inspection report observations and corrective actions. These are only associated with joint inspections.

For the previous analysis, the *2016 Annual Summary*, three additional reasons for delay past 30 business days were available for selection: Inspection Scheduling, Extensive Revisions, and Competing Priorities. For this report, the reasons “Extensive Revisions” and “Inspection Scheduling” were moved into the Administrative category, while “Competing Priorities” was moved into the Workload category to streamline and simplify analysis of reasons for delay past 30 business days.

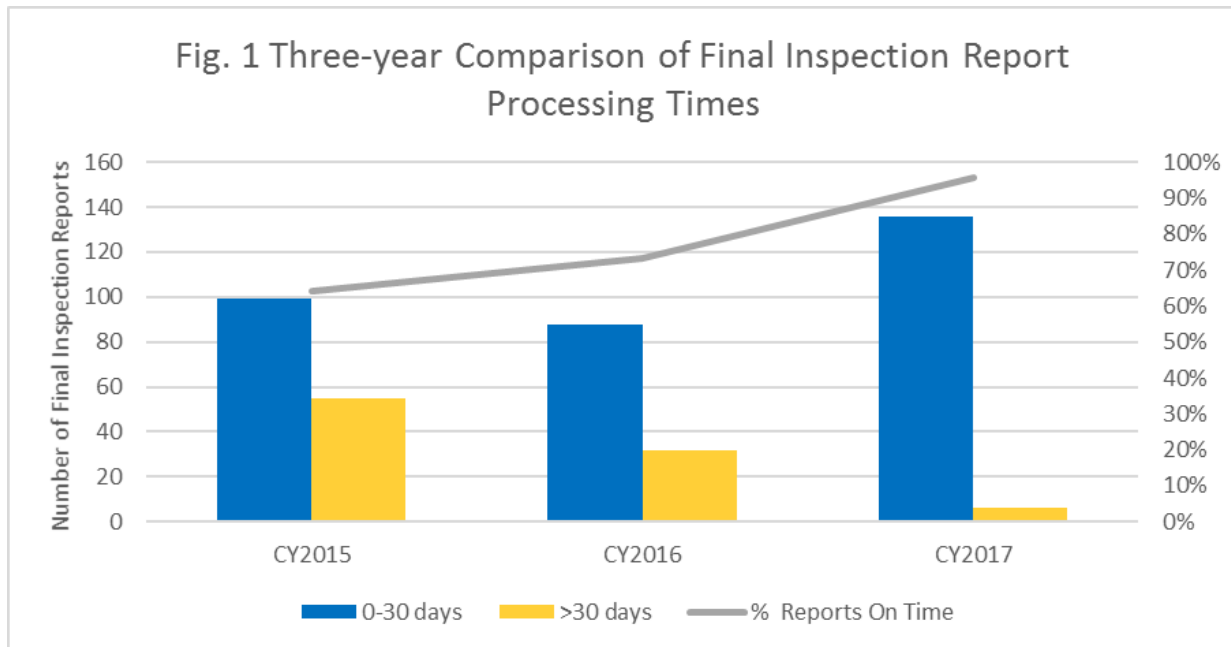
## Section 3. Results

As of December 31, 2017, DSAT issued a total of 142 final inspection reports in CY2017 for DSAT-only and DSAT-led joint inspections, which is 22 more reports than in CY2016. Ninety-six percent (136/142) of the CY2017 final reports were issued within 30 business days, compared with 73% (88/120) of the reports in CY2016 and the adjusted 64% (99/154) of reports in CY2015 (Figure 1). There were eight final inspection reports pending as of December 31, 2017 (and therefore not included in the analysis for 2017) for inspections performed in the fourth quarter of CY2017 (Q4 CY2017), and all reports were issued within 30 business days during the first quarter of CY2018. This data will be captured in the CY2018 *Inspection Report Processing Annual Summary*. No final inspection reports were pending at the time of writing this report for inspections performed in previous quarters in CY2016.



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**Figure 1. Three-year Comparison of Final Inspection Report Processing Times.** The graph shows the number of final inspection reports sent either within or after 30 business days for CY2015, CY2016, and CY2017. The line shows the percent of final inspection reports sent within 30 business days for each year. The percent of reports sent within 30 business days increased from 64% in CY2015 to 73% in CY2016 to 96% in CY2017.

In CY2016 the FSAP began issuing interim inspection reports when a final inspection report would not be completed within the goal of 30 business days, or when immediate notification was required. There are two types of interim reports:

- **A preliminary report** is issued to provide inspection feedback only if the final report will not be sent within the goal of 30 business days. This report should be sent within 20 business days. The final report should be sent within 30 business days after the issuance of the preliminary report (for a total of 50 business days).
- **An immediate action report** is sent when an inspection identifies serious regulatory violations requiring urgent action by an entity. This report is sent within 10 business days. The final report should still be sent within 30 business days.

In CY2017, only one preliminary report was sent (1/142, 0.7%) before the final report was issued (Table 1). The preliminary report's processing time was 20 business days, and the associated final report was sent at 29 business days after the issuance of the preliminary report (Table 1). The six final reports that were delayed past 30 business days did not have preliminary reports issued to the entities. Four of the six final reports were over 30 business days, but under 37 days. Only two of the six final reports were over 40 business days but fewer than 60 days. These two reports were issued early in CY2017 for inspections that occurred in CY2016, and since that time period the issuance of inspection reports has improved.

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**Table 1. Final Inspection Report Processing Time by Preliminary Report, CY2017**

Final Report Type	Total Number of Reports	Number of Final Reports Sent Within Processing Target	Processing Time to Final Report (in Federal Government Business Days): Average	Processing Time to Final Report (in Federal Government Business Days): Range
No Preliminary Report	141	135	20.3	1-53
With Preliminary Report	1	1	N/A	29* (49 business days after inspection)

\*The final report associated with a preliminary report should be sent within 30 business days after the issuance of the preliminary report for a total of 50 business days.

Immediate action reports were introduced in CY2016 to ensure that serious departures are communicated quickly and that an entity takes action for these departures immediately. The target for issuance of these reports is 10 business days. However, if an immediate threat to safety or security is found during an inspection, these findings are immediately communicated to the entity at the inspection instead of waiting the 10 business days. In CY2017, immediate action reports were issued in 2.1% of inspections (3/142) and the average processing time for these reports was 8.67 business days (Table 2). For immediate action reports in CY2017, 100% (3/3) were sent within the 10 business day time frame and ranged from 8 to 9 business days.

**Table 2. Immediate Action Inspection Report Processing Time, CY2017**

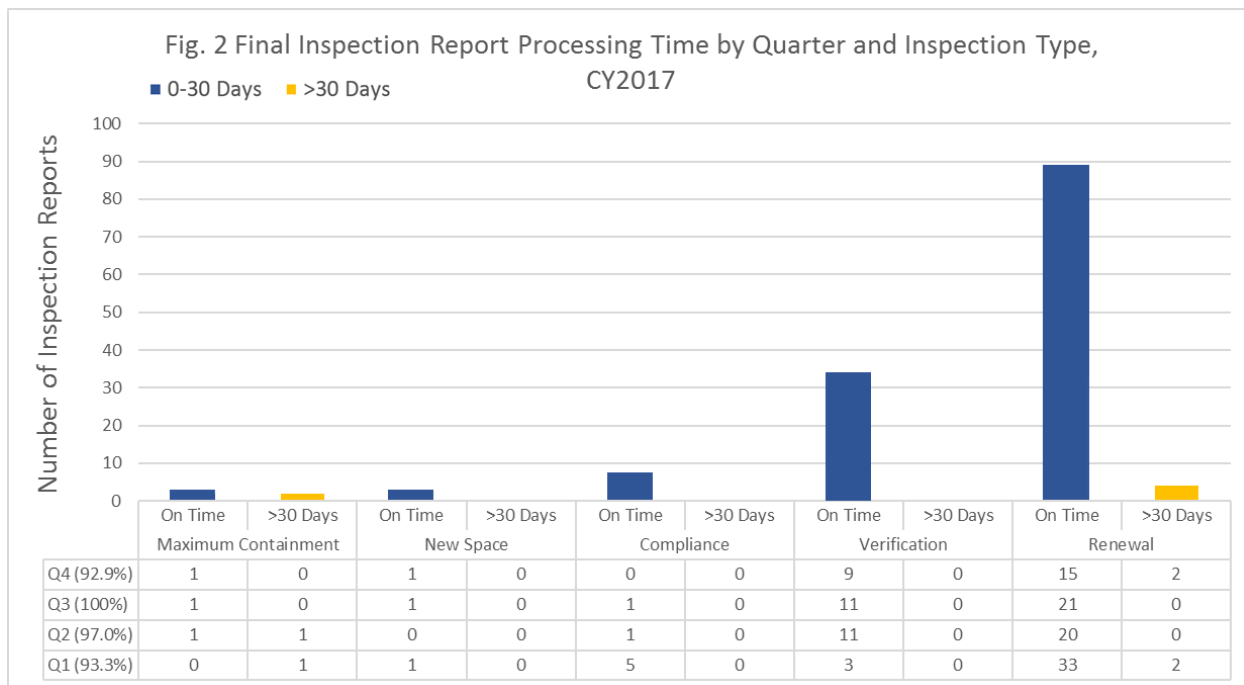
Report Type	Number of Reports	Number of Reports Sent Within Processing Target	Processing Time (in Federal Government Business Days): Average	Processing Time (in Federal Government Business Days): Range
Immediate Action Report	3	3	8.67	8-9

The 2015 and 2016 Annual Summaries reported that the type of inspection influenced inspection report processing times. The same was found for CY2017. Figure 2 shows CY2017 final inspection report processing times by quarter and inspection type. The quarterly percent of all final inspection reports sent within 30 business days was over 90% during the year, starting at 93.3% in Q1 CY2017, 97.0% in Q2 CY2017, 100% in Q3 CY2017, and finishing at 92.9% in Q4 CY2017. For inspection types, DSAT observed that, similar to CY2015 and CY2016, Renewal Inspections were the most common report sent in CY2017, followed by Verification and Compliance Inspections. Inspection report processing times for all inspection types improved in CY2017 from CY2016. Unlike CY2016 and CY2015, there were no New Entity Inspections in CY2017. Ninety-six percent of final reports for Renewal Inspections were sent within 30 business days in CY2017, compared with 78% in CY2016. In addition, the percent of final reports for Verification Inspections sent within 30 business days increased from 87% in CY2016 to 100% in CY2017; Compliance Inspections improved from 70% to 100%; New Space Inspections improved from 60% to 100%; and Maximum Containment Inspections improved from 10% to 60%.

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As in CY2016, analysis of CY2017 data indicated that entity type did not affect inspection report processing time. Therefore, inspection report processing data by entity type is not included in this summary.



**Figure 2. Final Inspection Report Processing Time by Quarter and Inspection Type, CY2017.** The graph shows the number of final inspection reports sent either within or after 30 business days by inspection type for CY2017. The table shows the number of final inspection reports sent either within or after 30 business days by inspection type for each quarter. The percentages for each quarter indicate the number of final inspection reports sent within 30 business days divided by the total number of final inspection reports sent during that quarter.

DSAT tracked the reasons for delays in issuing final inspection reports. Workload and Administrative were the only two reasons for delay in CY2017, cited four and five times, respectively. Because multiple reasons can be cited to explain the delay, this number is greater than the total number of delayed reports. No reports were delayed due to Severe Compliance or Concurrence.

## Section 4. Discussion

The number of final inspection reports issued on time increased by 32% in CY2017 as compared to CY2016, and there was an on-time increase of 50% as compared to CY2015 (Fig. 1). A reason for that improvement was a continued program-wide commitment to issuing final inspection reports within 30 business days. DSAT will continue to identify solutions to further improve inspection report processing times.

Starting in January 2016, DSAT introduced preliminary reports to improve timely communication of inspection findings for final reports that would not be issued within 30 business days. DSAT issued only one preliminary report during CY2017 (Table 1), in contrast to CY2016 when DSAT issued 14 preliminary

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reports. The decrease in preliminary reports was due to an effort to issue final inspection reports within 30 business days, negating the need for a preliminary report. However, none of the six delayed reports in CY2017 had a preliminary report issued to the entity. The two final reports that were over 40 but fewer than 60 business days were issued in the first quarter of CY2017 for inspections that occurred in CY2016. The remaining four final inspection reports were fewer than 7 business days late and showed improvement since the first quarter. For these four reports, it is likely that instead of issuing two inspection reports (preliminary and final) within days of each other, the choice was made to delay the final report by a few days. Going forward, DSAT will reinforce the requirement to issue preliminary reports when final reports may be delayed past 30 business days, and identify procedures to shorten the processing time in order to provide timely inspection feedback to entities.

CY2017 was the second year that FSAP issued immediate action reports, which communicate serious regulatory departures observed during an inspection as well as the remediation needed to address those departures. DSAT issued only three immediate action reports in CY2017 compared to thirteen immediate action reports in CY2016. DSAT observed that 100% of issued immediate action reports for CY2017 were sent within the 10 business day target (Table 2), which is an increase of 85% compared to CY2016. This significant increase was due to the lower number of immediate action reports generated in CY2017.

As reported in the *2015* and *2016 Annual Summaries*, the timeliness of inspection reports was affected by inspection type. With the exception of Maximum Containment Inspections, 97% (133/137) of final inspection reports were issued within 30 business days for all inspection types in CY2017 (Fig. 2). Maximum Containment Inspections are the most complex inspections performed by DSAT, requiring additional on-site inspection days to review the extensive engineering measures and documents required of these laboratories. During the first two quarters of CY2017, only two inspectors performed all Maximum Containment Inspections. During CY2017, several DSAT inspectors were trained to conduct Maximum Containment Inspections, and they began inspecting these complex laboratories in the third quarter of CY2017. This decreased the burden on the original two maximum containment inspectors which helped with the timely issuance of these reports. DSAT will continue to monitor Maximum Containment Inspection report processing time to identify additional processes that can improve the timeliness of these reports.

For CY2017, of the six final reports that had processing times past 30 business days, four were Renewal Inspections. Renewal Inspections require a comprehensive review of all entity documents and laboratory space in order to renew the entity's registration. Review of entity documents often continues after the inspection, which has caused delays in issuance of the reports. As part of the new eFSAP database system, entities will soon be able to upload many of their documents that would normally be reviewed on site during the inspection. This should reduce the review burden during and after the inspection, which will improve inspection report processing times.

CY2016 was the first year in which DSAT tracked reasons that reports were sent after 30 business days. In the *CY2016 Annual Summary*, the most cited reason for delay of the final report was Workload, followed by Severe Compliance and then Administrative. Since the reasons for delay were simplified in



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CY2017, as noted in the Methods section, for comparison, the second most cited reason for delay for CY2016 was adjusted to be Administrative, behind Workload. In CY2017, the most cited reason for final inspection report delay was Administrative, which was cited five times. DSAT will continue to track reasons for inspection report delays to identify processes that can improve the timeliness of all reports.

The *2015* and *2016 Annual Summaries* reported that DSAT inspector workload affected inspection report processing times. In CY2017, “Competing Priorities” was moved into the Workload category. If the same categorization had been used in CY2016 also, Workload would have been cited as the reason for delay for 15 final inspection reports. In CY2016, Workload was already the most cited reason, even without including the reason “Competing Priorities”. In CY2017, Workload was the second most cited reason for delay of inspection reports, observed in two quarters that had delayed reports (the first and second quarters). Some inspection teams were short-staffed at the beginning of the year, which increased the workload of these teams and affected the processing time for those inspection reports. In addition, DSAT spent a significant amount of time throughout CY2017 developing eFSAP, which meant that additional program priorities led to increased workload for many inspectors. As the burden on DSAT staff to adapt to eFSAP decreases, and as more features are added to the system that simplify entity oversight, there should be an increase in available time for processing of inspection reports. DSAT will continue to identify solutions to reduce workload in order to improve inspection report processing times.

The biggest change in cited reasons for final inspection report delays between CY2016 and CY2017 is the absence of instances where Severe Compliance issues resulted in inspection report delays. There were only three immediate action reports sent to entities in CY2017. Severe Compliance issues often cause delayed final inspection reports due to the requirement to write both the immediate action report and the final inspection report within 30 business days. In these cases, Severe Compliance is often cited as the reason for the delay. No reports were delayed due to this reason in CY2017, but it was the third most cited reason for delay in CY2016 (after adjusting the CY2016 numbers due to the consolidation of reasons). DSAT will continue to prioritize these Severe Compliance issues to ensure these reports are issued in a timely manner.

Inspection reports are important tools used by the program to get critical feedback to entities in order to continuously improve the safety and security of those working with BSAT as well as the communities that surround the entities. These reports contain the program’s findings from inspections and any corrective actions needed; therefore, the timely issuance of inspection reports allows each entity to address the observations expeditiously. DSAT continually strives to improve these processes. Data from these analyses are used throughout the year to modify processes and further train inspection staff to address the issues identified to continue to improve the timeliness of issuing inspection reports.

In summary, the timeliness of inspection reports improved, with only six final reports delayed in CY2017 as compared to 32 final reports in CY2016. We anticipate that the replacement of the traditional inspection report process with eFSAP will further improve our ability to meet timeliness metrics.

For questions or additional information, please contact DSAT at [LRSAT@cdc.gov](mailto:LRSAT@cdc.gov).