



Division of Select Agents and Toxins

# 2016 Inspection Report Processing Annual Summary

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# 2016 DSAT Inspection Report Processing Annual Summary

January 1, 2016 – December 31, 2016

The *2016 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 regulated entities registered with the Federal Select Agent Program (FSAP) during calendar year 2016 (CY2016). This analysis is used to improve the issuance of inspection reports with the goal of ensuring registered entities are provided timely feedback after an inspection.

## Section 1. Introduction

Biological select agents and toxins (BSAT), such as *Bacillus anthracis*, Ebola virus, and botulinum neurotoxin, have the potential to pose a severe threat to human, animal, or plant health or to animal or plant products. Research to improve rapid detection of BSAT and medical countermeasures against BSAT is critical for the United States to be able to respond to incidents involving BSAT. FSAP, which is comprised of 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 the laboratories and living in the surrounding community. An entity required to register with FSAP (i.e., an entity that possesses, transfers, or works with BSAT) is subject to the SAR requirements and on-site inspections to review laboratory programs to ensure that appropriate biosafety/biocontainment and security measures are in place.

In October 2015, CDC published recommendations from an internal 90-day review of DSAT to identify areas for improving biosafety and security regulatory practices and oversight (<http://www.cdc.gov/phpr/dsat/full-report.htm>). One recommendation called for DSAT to analyze inspection report timeliness data to identify reasons for issued reports being delayed beyond 30 processing days, and share those data with the regulated community annually. To address this recommendation, in 2016, DSAT began analyzing inspection report processing data and published a summary describing the timeliness of BSAT inspection reports. The *2016 DSAT Inspection Report Processing Annual Summary* represents the second summary annual report issued by DSAT.

In response to the data from CY 2015, in CY2016, FSAP began issuing interim inspection reports to improve communication and ensure that the program provided timely feedback after an inspection, particularly when a final inspection report will not be completed within 30 processing days. Throughout 2016, two types of interim reports were issued:

- **Immediate action reports** are sent when serious violations requiring urgent action by the entity are observed during an inspection. These are sent within 10 business days from the Monday following the close of the inspection. Entities that require immediate suspension or revocation of registration are not issued immediate action reports but are instead contacted immediately to ensure swift action is taken.

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- **Preliminary reports** are issued to provide inspection feedback only if the final report will not be sent within 30 processing days. These are sent within 20 business days from the Monday following the close of the inspection.

## Section 2. Methods

To determine inspection report processing times, DSAT queried the National Select Agent Registry database to extract processing data for reports issued in CY2016 for DSAT-only inspections and DSAT-led joint inspections with AgSAS. Inspection report processing typically involves, at minimum: a debrief with the DSAT Operations Branch Chief and Team Leads to discuss departures; review of observations and documents collected during the inspection; determining the severity level of the departures; and, writing and editing of the inspection report, including several levels of review prior to sending the final report to the entity. Final inspection reports were classified into two categories: 1) issued within 30 processing days or 2) issued after 30 processing days. The inspections were stratified by inspection type and the quarter that the report was issued. DSAT used the following four quarters based on the month the report was issued:

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

For 2016, DSAT changed the processing day starting point from the number of federal government business days following the last day of the inspection to the number of federal government business days after the Monday following the last day of the inspection. The change in policy was implemented 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 \(2015 Summary\)](#), DSAT re-calculated the 2015 processing times according to the 2016 definition. Final reports that are issued after the 30 processing day target are considered delayed.

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 application to work with BSAT.

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- **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; typically occurs every 3 years.
- **Verification** – Review of selected portions of the entity program, including assessment of responses to previous inspection departures as well as selected laboratory spaces and documents.

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

- **Severe Compliance** – Delays due to the need for additional steps to be taken (simultaneous with the development of the report) in order to address severe compliance issues discovered during an inspection. Severe compliance issues are those that may lead to significant compliance actions such as suspensions, revocations, or voluntary Corrective Action Plans.
- **Workload** – Delays due to circumstances leading to increased workload while processing inspection reports, such as: simultaneous processing of multiple inspection reports, entity amendments to registrations, reduced staff, or inspectors on leave.
- **Administrative** – Delays due to administrative processes, such as delays between the completion of the report and the date the report is sent to the entity, delays in reviewers not reviewing the report in a timely manner, or delays in the completion of the initial draft report.
- **Concurrence** – Delays in DSAT receiving concurrence from AgSAS regarding the inspection report observations and corrective actions. These issues are only associated with joint inspections.
- **Inspection scheduling** – Delays due to inspections that are scheduled close to one another (e.g., two complex inspections scheduled one week apart).
- **Extensive revisions** – Delays due to reports that require multiple rounds of review and revisions prior to issuance.
- **Competing priorities** – Delays due to addressing other urgent DSAT needs and responsibilities.

## Section 3. Results

As of January 1, 2017, DSAT issued 120 final inspection reports in CY2016 for DSAT-only and DSAT-led joint inspections, which is 35 fewer reports than in CY2015. Seventy-three percent (88/120) of the CY2016 final reports were issued within 30 processing days, compared with the adjusted 64% (99/154) of reports in CY2015<sup>1</sup>. Of the 20 final reports pending for inspections performed in the fourth quarter of CY2016 (Q4CY2016), two were in process for more than 30 processing days. No final inspection reports were pending for inspections performed in previous quarters in CY2015 or CY2016.

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<sup>1</sup> The original data used in the *2015 Summary* indicated that 59% (91/154) of 2015 final reports were issued within 30 processing days.

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The *2015 Summary*, released in April, 2016, reported that 10 final inspection reports were pending, including: Seven Maximum Containment; Two Verification; and One New Space inspection. Two of the reported Maximum Containment inspections represented site visits where inspection reports were not issued. One Verification inspection report was issued within 30 processing days while five of the remaining seven reports were in process for more than 30 processing days before December 31, 2015. No reports remain pending from inspections performed in CY2015.

CY2016 was the first year DSAT issued interim reports, including immediate action and preliminary reports. Preliminary reports are issued only when the final report will exceed 30 processing days so that an entity can begin to address observations while the final report is being completed. Preliminary reports should be sent within 20 processing days and the final report should be sent within 30 processing days of the issuance of the preliminary report. Throughout CY2016, 12% (14/120) of all final reports had a preliminary report sent before the final report was issued (Table 1). The median preliminary report processing time was 19 days, and 79% (11/14) of the preliminary reports were sent within 20 processing days (data not shown). Eight-six percent (12/14) of the associated final reports were sent within 30 processing days of the issuance of the preliminary report (Table 1).

**Table 1. BSAT Final Inspection Report Processing Time by Preliminary Report, CY2016**

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): Median	Processing Time to Final Report (in Federal Government Business Days): Range
No Preliminary Report	106	76	25	4-224
With Preliminary Report <sup>2</sup>	14	12	16	4-38

The *2015 Summary* reported that serious regulatory departures influenced the processing time of inspection reports issued in CY2015. Immediate action reports were introduced in CY2016 to ensure that serious departures are communicated quickly and that entities take action for these departures immediately. The target for issuance of these reports is 10 processing days. In CY2016, immediate action reports were issued in 11% of inspections (13/120) and the median processing time for these reports was 10 processing days (Table 2). Fifty-four percent (7/13) of immediate action reports were sent within the 10 processing day time frame and ranged from three to 15 processing days. Thirty-three percent (2/6) of the delayed immediate action reports were sent in the last six months of CY2016 (data not shown). These immediate action reports were sent within 11 processing days, while the four delayed immediate action reports sent in the first six months averaged 14 processing days.

**Table 2. Immediate Action Inspection Report Processing Time, CY2016**

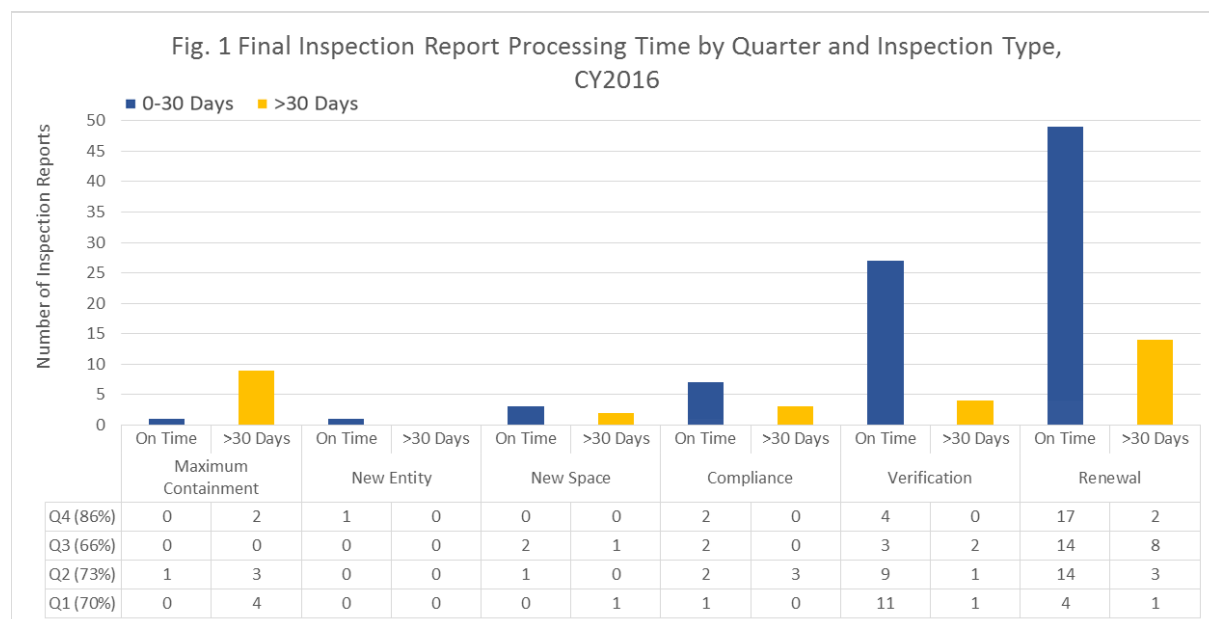
Report Type	Number of Reports	Number of Reports Sent Within Processing Target	Processing Time (in Federal Government Business Days): Median	Processing Time (in Federal Government Business Days): Range
Immediate Action Report	13	7	10	3-15

<sup>2</sup> For final reports in which a preliminary was sent, the 30 business day timeframe begins the day the preliminary report is issued.

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The 2015 Summary also reported that the type of inspection and entity type influenced inspection report processing time in CY2015. Figure 1 shows CY2016 final inspection report processing times by quarter and inspection type. The quarterly percent of all final inspection reports sent within 30 processing days fluctuated during the year, starting at 70% in Q1CY2016, 73% in Q2CY2016, 66% in Q3CY2016, and finishing at 86% in Q4CY2016. For inspection types, DSAT observed that, like 2015, Renewal inspections were the most common report sent in CY2016, followed by Verification and Compliance inspections. Inspection report processing times for nearly all inspection types improved in CY2016 from CY2015, with the exception of New Entity inspections, which continued to achieve the 30 processing day target in both years. Seventy-eight percent of final reports for Renewal inspections were sent within 30 processing days in CY2016, compared with the adjusted 59% in CY2015. In addition, the percent of final reports for Verification inspections sent within 30 processing days increased from 75% in CY2015 to 87% in CY2016; Compliance inspections improved from 60% to 70%; New Space inspections improved from 43% to 60%; and Maximum Containment inspections improved from zero to 10%. DSAT performed one New Entity inspection in both CY2015 and CY2016, and both final reports were issued within 30 processing days. Unlike CY2015, analysis of CY2016 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.



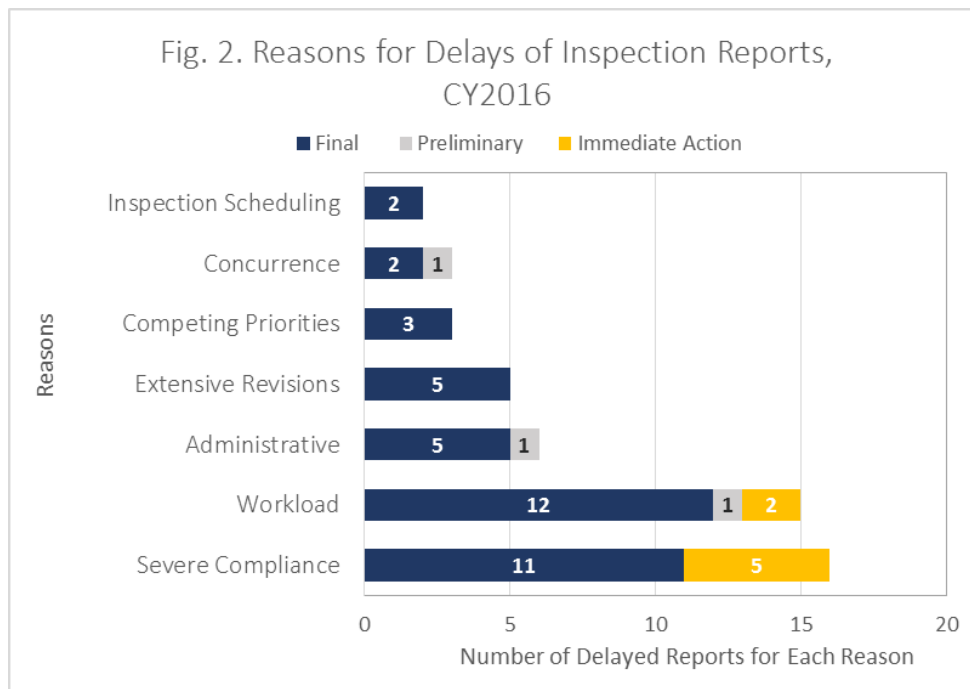
**Figure 1. Final Inspection Report Processing Time by Quarter and Inspection Type, CY2016.** The graph shows the number of final inspection reports sent either within or after 30 processing days by inspection type for CY2016. The table shows the number of final inspection reports sent either within or after 30 processing days by inspection type for each quarter. The percentages for each quarter indicate the number of final inspection reports sent within 30 processing days divided by the total number of final inspection reports sent during that quarter.

DSAT tracked the reasons for delays in issuing interim and final inspection reports (Fig. 2). Workload and Severe Compliance were cited 11 and 12 times as reasons for delayed final inspection reports, respectively. Together, these two reasons were cited as a delay for 56% (18/32) of the delayed final

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inspection reports. Workload or Severe Compliance were also cited in all delayed immediate action reports. Administrative and Extensive Revisions also contributed to delayed final inspection reports as these reasons contributed to 31% (10/32) of those reports.



**Figure 2. Reasons for Delays of Inspection Reports, CY2016.** The number of final, preliminary, and immediate action reports in which each reason was cited in CY2016. The number of reasons exceed the number of reports because several reports had multiple reasons for the delay.

## Section 4. Discussion

DSAT observed that the issuance of final inspection reports improved by almost 10% in CY2016. One reason for that improvement was a program-wide commitment to issuing final inspection reports within 30 processing days. The DSAT goal for issuing inspection reports has been 30 processing days for several years; however, DSAT had not rigorously tracked inspection report processing time. In light of the CDC 90-day internal review recommendation to improve inspection report timeliness, DSAT re-committed itself in January CY2016 to meeting that objective. DSAT will continue to identify solutions to improve inspection report processing times.

Starting in January 2016, FSAP introduced preliminary reports to improve timely communication of inspection findings for final reports that will not be issued within 30 processing days. However, DSAT issued only 14 preliminary reports during the year (Table 1). The median processing time to issue preliminary reports was 19 processing days, one day less than the 20 processing day target. DSAT will continue to increase issuing preliminary reports when final reports may be delayed, and identify procedures to shorten the processing time in order to provide timely inspection feedback to entities.

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CY2016 was also the first 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 observed that only 54% of issued immediate action reports were sent within the 10 processing day target (Table 2). DSAT investigated the reasons for this low percentage and discovered that inspectors were still adapting their procedures for the new report. To address this observation, DSAT trained staff on the new policy and made procedural changes to address the new requirements. As a result, immediate action report processing time improved over the course of the year, as two-thirds of the delayed immediate action reports in CY2016 were sent in the first six months of the year. DSAT will continue to identify solutions to ensure immediate action reports are issued within the processing target.

As reported in the *2015 Summary*, the timeliness of inspection reports was affected by inspection and entity type. DSAT did not include entity type data in this report because the analysis of the CY2016 processing data showed that inspection type is a more accurate predictor of processing time than entity type. With the exception of Maximum Containment inspections, 60% or more of final inspection reports were issued within 30 processing days for all inspection types in CY2016 (Fig. 1). Maximum Containment inspections are the most complex inspection performed by DSAT, requiring additional on-site inspection days to review the extensive engineering measures and documents required of these laboratories. Fifty percent of the Maximum Containment inspection reports issued in CY2016 were for inspections that took place in 2015 and were already past the 30 processing day target at the beginning of the year. Only two inspectors performed all of the Maximum Containment inspections for CY2016. To distribute the workload required by these inspections, DSAT has identified additional inspectors to perform Maximum Containment inspections who will begin inspecting these facilities in CY2017. DSAT will continue to monitor Maximum Containment inspection report processing time to identify processes that can improve the timeliness of these reports.

The *2015 Summary* also reported that DSAT inspector workload affected inspection report processing times. In CY2016, workload was one of the reasons most cited for delays of inspection reports, including 12 final, two immediate action, and one preliminary inspection reports (Figure 2). Even though DSAT performed 20% fewer inspections in CY2016, some inspection teams were short-staffed during the year, which increased the workload of these teams and affected the processing time for those inspection reports. DSAT will continue to identify solutions to reduce workload in order to improve inspection report processing times.

CY2016 was also the first year in which DSAT tracked reasons for reports that were sent after 30 processing days. Administrative reasons were associated with delayed reports only in the first two quarters of CY2016 (Fig. 2). Because these issues were identified and addressed as the issues arose, DSAT was able to prevent ongoing issues in these areas. Other reasons such as Concurrence, Competing Priorities, Extensive Revisions, Workload, and Severe Compliance were associated with delayed reports throughout the entire year. DSAT will continue to track reasons for inspection report delays to identify processes that can improve the timeliness of all reports.



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Severe Compliance was cited for 16 delayed interim and final inspection reports (Fig. 2). Severe Compliance issues require prompt attention and DSAT is committed to improving the timely reporting of these issues to ensure the safety and security of BSAT in these facilities and surrounding communities. As was indicated in the *2015 Summary*, CY2016 reports for inspections that identify serious regulatory departures often require additional processing time due to additional steps taken in order to address any significant issues discovered during an inspection. DSAT will continue to analyze the processing procedures for reports involving Severe Compliance issues to identify ways to reduce the processing time of these reports.

Inspection reports are critical because they contain the program's findings and corrective actions needed to ensure the safety and security of those working with BSAT as well as the communities surrounding entities. The timely issuance of inspection reports allows each entity to address the observations expeditiously. DSAT is continually striving 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 in order to further improve the timeliness of issuing inspection reports.

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