

Division of Select Agents and Toxins

2015 Inspection Report Processing Annual Summary

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Centers for Disease
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Preparedness and Response

2015 DSAT Inspection Report Processing Annual Summary

January 1, 2015 – December 31, 2015

This 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 of the Federal Select Agent Program (FSAP) January 1, 2015 – December 31, 2015. This analysis will be used to monitor and 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) have the potential to pose severe threats to human, animal, or plant health or to animal or plant products. Research to improve rapid detection of and medical countermeasures against BSAT is critical to the ability of the United States to respond to attacks involving BSAT, such as *Bacillus anthracis*, Ebola virus, and botulinum neurotoxin. The FSAP, comprised of DSAT and the 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, but are not limited to, biosafety, 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. Entities required to register with the FSAP, i.e., entities that possess, transfer, or work with regulated BSAT, are subject to SAR requirements, including on-site inspections to review laboratory select agent programs to ensure that appropriate biosafety and biosecurity measures are in place.

Following high-profile laboratory incidents involving BSAT that occurred at federally-regulated laboratories in recent years, multiple groups within the federal government took a closer look at the biosafety and biosecurity practices involved in the conduct and oversight of work with BSAT. In October 2015, FSAP improvement recommendations were released from three independent reviews: CDC, Fast Track Action Committee on SAR, and Federal Experts Security Advisory Panel. These recommendations are designed to strengthen the federal government's biosafety and biosecurity regulatory practices and oversight, both through the FSAP and at a broader national level.

The CDC internal 90-day review of DSAT was ordered by CDC Director Dr. Tom Frieden to examine DSAT and make recommendations to improve the program. The resulting report produced recommendations in three main areas: inspections, incident reporting, and transparency and public understanding of FSAP (<http://www.cdc.gov/phpr/dsat/full-report.htm>). One recommendation specifically called for DSAT to review the timeliness of inspection reporting. This included conducting analysis of inspection report timeliness data to identify reasons for reports being delayed beyond 30 days and sharing those data with the regulated community annually.

To address this recommendation, DSAT has implemented a process to analyze inspection report processing data and publish an annual summary describing the timeliness of DSAT inspection reports. The 2015 DSAT Inspection Report Processing Annual Summary represents the first annual report of inspection report timeliness issued by DSAT in accordance with the CDC 90-day recommendations.

Section 2. Methods

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DSAT queried the National Select Agent Registry (NSAR) database for final and pending inspection reports for all DSAT-only and DSAT-led joint inspections with AgSAS performed in calendar year 2015 (CY2015). Queries were for entity type, inspection type, and to calculate processing times. Processing times were defined as the number of business days following the last day of the inspection to the issuance of the report, or December 31, 2015 for pending reports. Inspection report processing typically involves, at minimum, a debrief with the DSAT operations Branch Chief to discuss departures; review of observations and documents collected during the inspection; and writing and editing of the inspection report, including several levels of review prior to sending the final report to the entity.

In 2015, DSAT led 167 inspections of registered entities or entities applying for registration. DSAT generated 164 inspection reports based on the 167 inspections. One report of a DSAT-led joint inspection was written by AgSAS, and two entities had two separate inspections but the inspection findings were combined into one report for each entity. As of December 31, 2015, final reports were sent to 154 entities while 10 inspection reports were being processed and classified as pending.

Inspection report processing times were stratified by entity and inspection types. Entities self-report entity type as part of the application for registration, in accordance with the entity type definitions in the Instructions for the Completion of the APHIS/CDC Form 1 ([http://www.selectagents.gov/resources/APHIS-CDC Form 1 Guidance Document.pdf](http://www.selectagents.gov/resources/APHIS-CDC_Form_1_Guidance_Document.pdf)). To maintain consistency with previous DSAT publications, the entity type categories Academic (Private) and Academic (State) were combined into the single type named Academic. The Government (State/Local) entity type was re-named Non-Federal Government. Inspection report data are classified into the following entity types:

- Academic – A university that is neither owned nor controlled by any government entity, or is predominantly funded by public means through the government.
- Commercial – A privately owned for-profit company including partnerships and corporations either held privately or whose shares are traded on the open market.
- Government Federal – An entity that is part of an agency of the Federal government.
- Government Non-Federal – An entity that is part of an agency of a State or Local government.
- Private – A privately owned company including partnerships and corporations, where no part of the income is distributed to its owners, directors, officers, members or stockholders, and whose principle purpose is for charitable or benevolent purposes.

Inspection types are 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, ABSL-4, and BSL-4)

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- New Entity – review of all laboratory spaces and documents for entity submitting a new application to work with BSATs
- 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

To determine the percentage of CY2015 inspection reports processed within specific time frames for each inspection or entity type, inspection report processing duration was classified into four time periods: 0-15, 16-29, 30-59, and ≥60 business days. The number of final inspection reports by inspection type or entity type were counted for each time period.

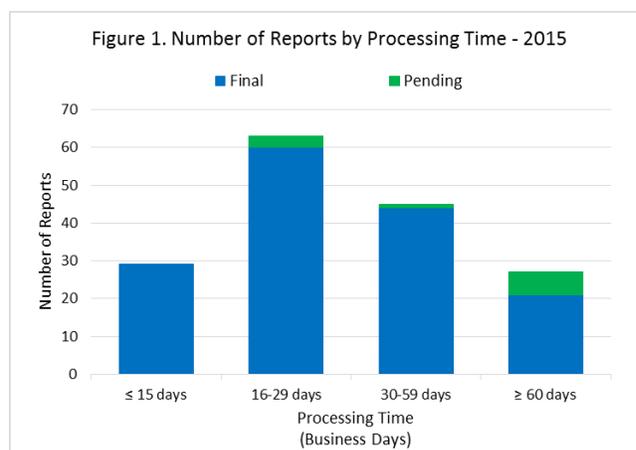
To compare the quarterly median processing time for all final inspection reports to final inspection reports by inspection type, all final inspection reports were stratified into the following four quarters based on the start date of each inspection:

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

After all inspections were classified by quarter, inspections were further stratified by inspection type. The median processing time for each inspection type by quarter was calculated as the number of business days between the completion of the inspection and the date the final report was sent to the entity. The number of inspection reports for each inspection type by quarter was counted and included in the analysis.

Section 3. Results

DSAT sent 54.2% (89/164) of the final reports from all inspections conducted in 2015 within 30 business days (Figure 1), which is the current DSAT target time frame to process inspection reports. The median of 26 business days and the processing time range of 3 to 205 business days indicate that a small number of inspections required substantially longer processing time than other inspections (Table 1).



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Table 1. BSAT Laboratory Inspection Report Processing Time (Business Days) by Inspection Type, CY 2015								
Total Number of Inspection Reports: 164								
Inspection Type	Number of Inspections	Inspections Without a Report	Final Reports			Pending Reports		
			Number of Reports	Processing Time		Number of Reports	Processing Time	
				Median	Range		Median	Range
Renewal	78	2	76	28	7-205	0	N/A	N/A
Verification	57	0	55	26	5-136	2	17	16-17
Compliance	16	1	15	21	3-106	0	N/A	N/A
New space	8	0	7	34	7-137	1	65	65
New entity	1	0	1	17	17	0	N/A	N/A
Maximum Containment	7	0	0	N/A	N/A	7	136	16-212
Total	167	3	154	26	3-205	10	82	16-212
DSAT Only	136	0	130	25	3-136	6	82	16-171
DSAT-Led Joint	31	3	24	37	8-205	4	86	16-212

Reports for Renewal inspections were the most common report sent in 2015, followed by Verification and Compliance inspections (Table 1). DSAT did not issue inspection reports for two Renewal inspections and one Compliance inspection. Of the two Renewal inspections without a report, one report was combined with that of another renewal inspection for the same entity, while the other report was written by AgSAS. For the Compliance inspection without a report, the results of the inspection were combined with another Compliance inspection of the same entity. The two Renewal inspections in which the results were combined occurred three months apart, while the two Compliance inspections were separated by two weeks.

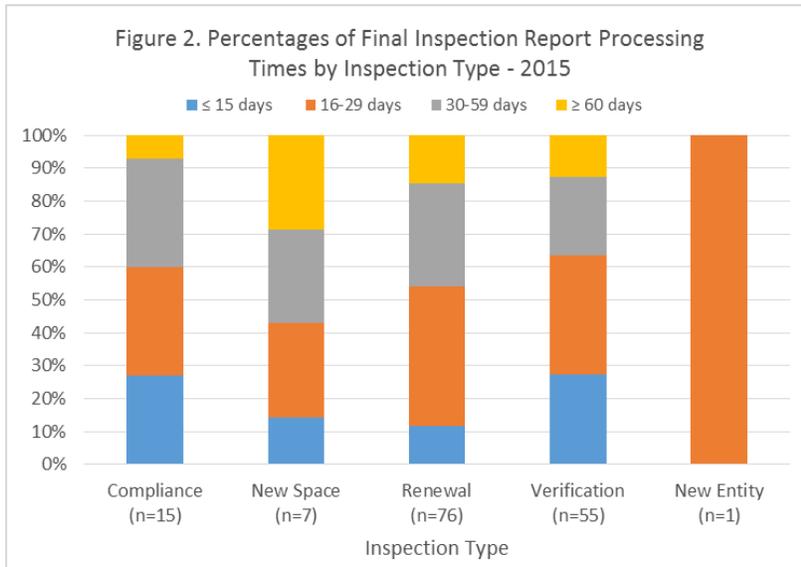
Three pending reports were for inspections (two Verification and one Maximum Containment) that occurred in December 2015 and were within the DSAT 30-day target to issue reports. Seven reports from Maximum Containment inspections in 2015 were not completed during the calendar year and had a median processing time of 136 business days while still pending at the end of the year. The median report processing time for final reports ranged from 17 business days for Compliance and New Entity inspections to 34 business days for New Space inspections. DSAT-issued reports for joint inspections with AgSAS required longer to process than inspections led by DSAT alone (Table 1).

Table 2. BSAT Laboratory Inspection Report Processing Time (Business Days) by Entity Type, CY 2015								
Total Number of Inspection Reports: 164								
Entity Type	Number of Inspections	Inspections Without a Report	Final Reports			Pending Reports		
			Number of Reports	Processing Time		Number of Reports	Processing Time	
				Median	Range		Median	Range
Academic	58	3	50	34	3-205	5	98	16-160
Government Non-Federal	46	0	46	18	5-136	0	N/A	N/A
Government Federal	27	0	24	27	7-92	3	35	16-212
Commercial	23	0	22	25	7-126	1	65	65
Private	13	0	12	27	16-83	1	171	171
Total	167	3	154	26	3-205	10	82	16-212

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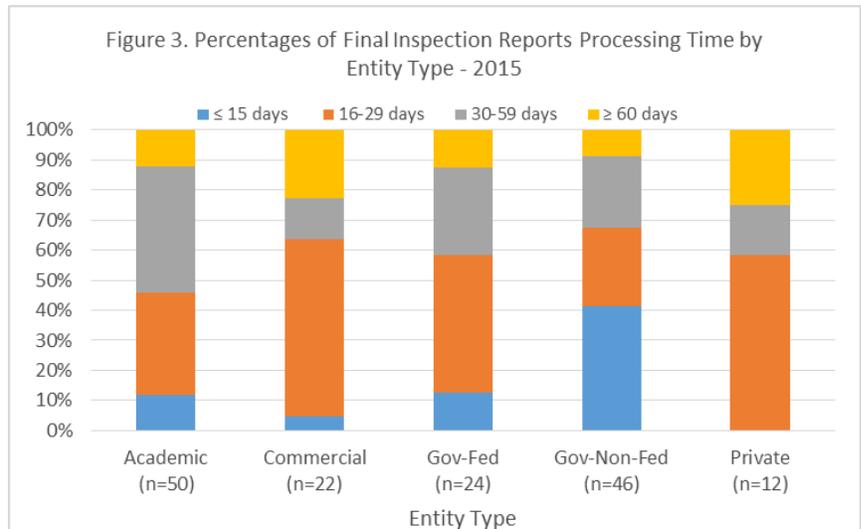
Reports for Academic inspections were the most common final inspection report sent in 2015 (Table 2). All three of the inspections for which a report was not issued were associated with inspections of academic entities. Median processing times ranged from 34 business days for academic entities to 18 for Governmental Non-Federal entities (e.g., state public health laboratories).



The timeliness of processing inspection reports differed between types of inspections (Figure 2), yet nearly half of inspections in each type were processed within 30 business days. DSAT performed only one new entity inspection in 2015. Some reports for Verification and Compliance inspections were processed more efficiently: nearly 30% of these inspection reports were processed in 15 days or less. Reports of inspections for New

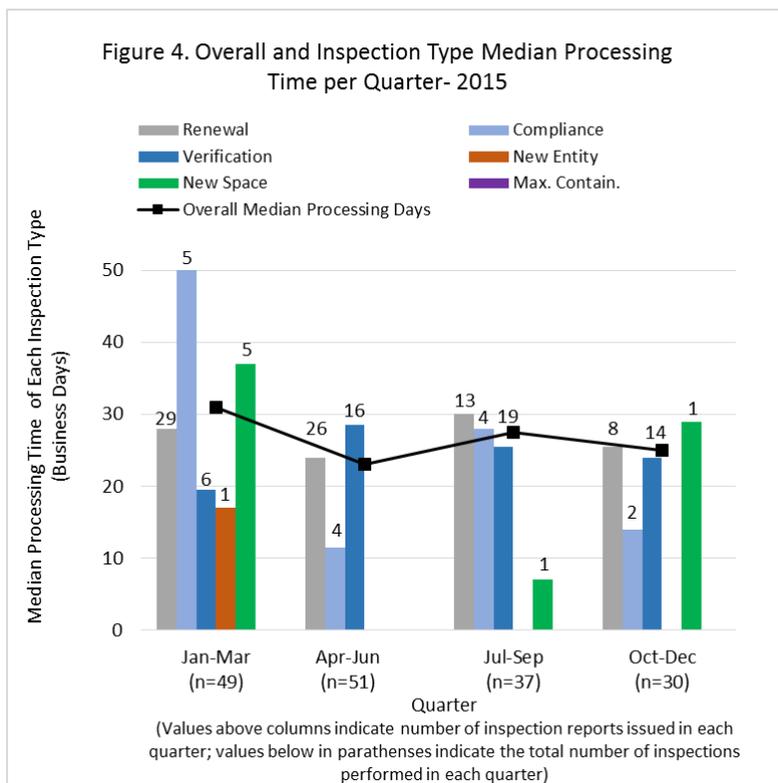
Space to existing laboratories required more processing time: 42% reports were processed within 30 business days. Only 70% of New Space inspections were processed within 59 days, compared to approximately 90% for the other inspection types.

The timeliness of processing inspection reports differed when analyzed by entity type (Figure 3). With the exception of Academic inspection reports, approximately 60% of all other entity-type inspection reports were sent within 30 business days. Inspection reports for Government Non-Federal entities were prepared more quickly: nearly 40% of these inspection reports were sent in less than 15 business days. Inspection reports for Academic entities required more processing time as approximately 40% of all academic inspection reports were sent within 30-59 business days.



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As shown in Figure 4, the number of inspections and median processing time for all inspection reports was highest early in 2015 and declined towards the end of the year. During the first quarter, the median report processing time for all inspection reports was 31 business days (black line), greater than the DSAT 30-day time frame for issuing inspection reports. Median processing times for Compliance and New Space inspections during the first quarter were 50 and 37 business days, respectively, representing the highest median processing times observed during the year. Reports from nine of the 46 inspections performed by DSAT in the first quarter required more than 60

business days to prepare. In contrast, the median processing time for reports from the 46 inspections conducted during the second quarter was the lowest of the year at 23 business days. The number of inspections performed declined in the final two quarters. During the final two quarters, the number of reports for renewal inspections dropped substantially and the median processing time remained below 30 business days.

Section 4. Discussion

Reports from over half of all inspections performed in CY 2015 were issued within 30 business days following the inspection, meeting the current DSAT performance target to prepare and issue inspection reports. Analysis of data on timeliness of inspection report preparation and issuance indicate that the timeliness of inspection reports is affected by workload, inspection type and entity type. This variation in timeliness of inspection report preparation is likely the result of complexity and comprehensiveness of inspections that differ according to inspection type and entity type.

Reports for DSAT-led joint inspections with AgSAS require longer processing times than reports for DSAT-only inspections. The processing time for joint inspection reports is longer, likely due to the increased communication required to obtain concurrence between the two agencies, but may also be related to the size and complexity of entities working with BSAT on both HHS and USDA select agent lists. DSAT and AgSAS continue to work on ways to reduce the processing time of joint inspection reports.

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In general, inspection report processing time depends on multiple factors including inspection type, entity type, and seriousness of observed regulatory departures. For example, Renewal and New Space inspections required the longest processing times of all inspection types in 2015. Renewal inspections are the most comprehensive inspection type, because inspectors perform staff interviews and review documentation of all SAR requirements. New Space inspections may require more processing time since DSAT has not previously inspected these laboratories. DSAT is continuing to investigate reasons why reports for New Space inspections require more processing time. Non-Federal Government entities are often state or local public health laboratories with small staffs and few laboratory rooms. Therefore, inspectors have fewer documents and rooms to review, leading to shorter processing times. Academic entities range from universities with one room and one Principal Investigator to universities with multiple Principal Investigators in multiple buildings. Academic inspections require more time as the size and complexity of each entity increases. In addition to these factors, processing of serious departures, observed for any inspection or entity type, may extend processing time as inspectors consult with DSAT leadership and subject matter experts prior to the release of the report. The median processing time for all inspection reports improved as the number of inspections and specific inspection types declined. Consistent with these observations, DSAT is re-evaluating inspector workload and staffing to improve the timeliness of inspection reports.

In addition, the FSAP has begun to issue preliminary reports to improve communications and ensure that the program is able to provide timely feedback after an inspection, particularly when a final inspection report will not be completed within 30 business days. Preliminary reports will provide inspection feedback while the final report is being prepared. Two types of preliminary reports are now being issued:

- **Immediate action preliminary reports** are sent when serious violations needing immediate action are observed during an inspection. These are sent within 10 business days from the Monday following the close of the inspection, consistent with the urgency of remediation needed.
- **Routine preliminary reports** are issued for an entity's information only while the final report is being prepared. These are sent within 20 business days from the Monday following the conclusion of the inspection.

As this is a new option for the program in 2016, no preliminary inspection reports of either type were issued during the time frame for this report.

For questions or additional information, please contact DSAT at LRSAT@cdc.gov.