An Audit Report on

Manufactured Foods Program Inspection Processes at the Department of State Health Services

January 2020

Report No. 20-021

State Auditor's Office reports are available on the Internet at http://www.sao.texas.gov/.

An Audit Report on

Manufactured Foods Program Inspection Processes at the Department of State Health Services

SAO Report No. 20-021
January 2020

Overall Conclusion

The Department of State Health Services (Department) has implemented a risk-based process to prioritize inspections of food facilities monitored by its Manufactured Foods Program (Program). The goal of that risk-based process is to ensure that the facilities with the highest risk ratings are inspected on a more frequent basis. During the period audited, the Department ensured that the inspections it conducted complied with the targeted timelines established in its policies.

However, the Department's processes were not sufficient to ensure that all facilities requiring inspections were included in its process for assigning inspections. As a result, the Department had not inspected some facilities for at least 58 months, some of which it had assigned a risk rating of High. Additionally, the Department developed processes designed to ensure that it assigned correct risk ratings to its Program facilities. However, those manual and automated processes did not always work as intended. As a result, some facilities were not assigned a risk rating or were assigned an incorrect one.

Background Information

The Department of State Health Services' (Department) Manufactured Foods Program (Program) is within the Department's Consumer Protection Division. That division is responsible for overseeing licensing, oversight, and compliance of consumer health goods and service providers to ensure public safety.

The Program licenses, inspects, and investigates consumer complaints for food facilities, such as manufacturers, wholesale operators, and warehouse operators.

The Program is divided into five geographic regions—Coastal, East, North, South, and West—and each region assigns inspections of food facilities in its respective region.

The Program had 50 inspector positions during fiscal year 2019, 6 of which were vacant.

Source: The Department.

While the Department consistently followed its enforcement processes, it did not ensure that it consistently updated the enforcement status in its licensing and enforcement system, VERSA Regulation (VERSA), accurately or within the required time frames. Additionally, the Department developed and documented policies and procedures for investigating complaints that it receives related to food safety, and it generally ensured that investigators complied with those procedures. However, it should strengthen its procedures for conducting complaint investigations within the required time frames and maintaining its central complaint tracking spreadsheet.

While the Department has established documented policies and controls for the use of its information systems, it also should improve its (1) user access controls and (2) processes for deleting inspection records and complaint records.

This audit was conducted in accordance with Texas Government Code, Section 321.0132.

For more information regarding this report, please contact James Timberlake, Audit Manager, or Lisa Collier, First Assistant State Auditor, at (512) 936-9500.

Table 1 presents a summary of the findings in this report and the related issue ratings. (See Appendix 2 for more information about the issue rating classifications and descriptions.)

Table 1

Summary of Chapters/Subchapters and Related Issue Ratings		
Chapter/ Subchapter	**Title**	**Issue Rating [a]**
1-A	While the Department Performed Inspections for a Majority of Manufactured Foods Program Facilities Within Targeted Time Frames, It Did Not Identify All Facilities Required to Be Inspected	High
1-B	The Department Established Manual and Automated Processes to Help Assign Risk Ratings; However, Those Processes Did Not Consistently Work as Intended	Medium
2	The Department Followed Its Enforcement Processes Related to the Violations That It Identified	Low
3	While the Department Followed Its Complaint Investigation Policies, It Should Strengthen Its Documentation of Complaints	Medium
4	The Department Should Improve Its Information Technology Controls	Medium

[a] A chapter/subchapter is rated **Priority** if the issues identified present risks or effects that if not addressed could critically affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Immediate action is required to address the noted concern and reduce risks to the audited entity.

A chapter/subchapter is rated **High** if the issues identified present risks or effects that if not addressed could substantially affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Prompt action is essential to address the noted concern and reduce risks to the audited entity.

A chapter/subchapter is rated **Medium** if the issues identified present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer program(s)/function(s) audited. Action is needed to address the noted concern and reduce risks to a more desirable level.

A chapter/subchapter is rated **Low** if the audit identified strengths that support the audited entity's ability to administer the program(s)/function(s) audited or the issues identified do not present significant risks or effects that would negatively affect the audited entity's ability to effectively administer the program(s)/function(s) audited.

Auditors communicated other, less significant issues separately in writing to the Department's management.

Summary of Management's Response

At the end of each chapter in this report, auditors made recommendations to address the issues identified during this audit. The Department agreed with the recommendations in this report.

Audit Objectives and Scope

The objectives of this audit were to determine (1) whether the Department's risk-based approach to prioritizing inspections of food facilities by the Manufactured Foods Program (Program) helps ensure the public's safety from the greatest health risks and (2) whether the Department is administering select functions according to requirements applicable to the Department's Program.

The scope of this audit covered the Program facilities that had a license status of current according to Department records as of June 30, 2019. For data analysis of inspection records, the audit scope covered inspection data for September 1, 2014, through June 30, 2019. For the testing of facility risk rating assignments, enforcement actions, and complaint records, the audit scope covered the period from September 1, 2017, through June 30, 2019.

Contents

Detailed Results

Appendices

Detailed Results

Chapter 1

While the Department Followed Its Risk-based Process for Prioritizing Inspections, It Should Improve Controls Over Its Food Facilities Inspection Assignment Processes and Calculation of Risk Ratings

Program Facilities

The Program is responsible for licensing and registering (when applicable), inspecting, and monitoring the following facility types:

- **Food Manufacturer** – A facility that manufactures food for sale to the public, such as bakeries, bottling and canning plants, ice plants, seafood processors, and vended water.
- **Food Wholesaler** – A facility that (1) sells any type of food product to any entity other than the final customer, (2) holds food that will be sold or distributed, (3) sells bulk raw materials (flour, sugar) to any entity other than the final customer.
- **Food Warehouse** – A facility that stores food products for a limited time for distribution.
- **Salvage Broker** – A facility that routinely handles distressed food merchandise, such as adulterated or misbranded merchandise.

Source: The Department.

The Department of State Health Services (Department) has implemented a risk-based process to prioritize inspections of food facilities monitored by its Manufactured Foods Program (Program) (see text box for information about the types of facilities inspected). The goal of that risk-based process is to ensure that the facilities with the highest risk ratings are inspected on a more frequent basis. The Department also ensured that the inspections it conducted complied with the targeted timelines established in its policies.

However, the Department's processes were not sufficient to ensure that all facilities requiring inspections were included in its processes for assigning inspections. As a result, the Department had not inspected some facilities for at least 58 months, some of which were assigned a risk rating of High.

Additionally, the Department developed processes to ensure that it assigned correct risk ratings to its Program facilities. However, those manual and automated processes did not always work as intended.

Chapter 1-A

While the Department Performed Inspections for a Majority of Manufactured Foods Program Facilities Within Targeted Time Frames, It Did Not Identify All Facilities Required to Be Inspected

Chapter 1-A Rating:

High [1]

The Department developed and implemented processes to ensure that it identifies and performs inspections for Program facilities. In addition, nearly all of the inspections it conducted from September 1, 2014, through June 30, 2019, complied with the established time frames. However, the Department did not identify all facilities that should be inspected and, as a result, it did not perform all required inspections. This was caused in part by weaknesses

[1] The risk related to the issues discussed in Chapter 1-A is rated as High because they present risks or effects that if not addressed could substantially affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Prompt action is essential to address the noted concern and reduce risks to the audited entity.

in the Department's controls over facility records in its licensing and enforcement system, VERSA Regulation (VERSA).

Risk-based Inspection Process

The Department developed and implemented processes for prioritizing inspections of food facilities by the Program designed to ensure that the facilities with the highest risk ratings are inspected on a more frequent basis. The Department established a process to assign a risk rating to each facility, and it established targeted time frames for inspecting those facilities based on the risk ratings. (See text box for the Department's current target inspection time frames.)

Program Inspection Frequencies

The Department assigns risk ratings to the Program facilities based on its formalized calculations. Additionally, the Department's policies require the following target inspection frequencies for those risk ratings:

- High Risk – 12 Months
- Medium Risk – 42 Months
- Low Risk – 48 Months

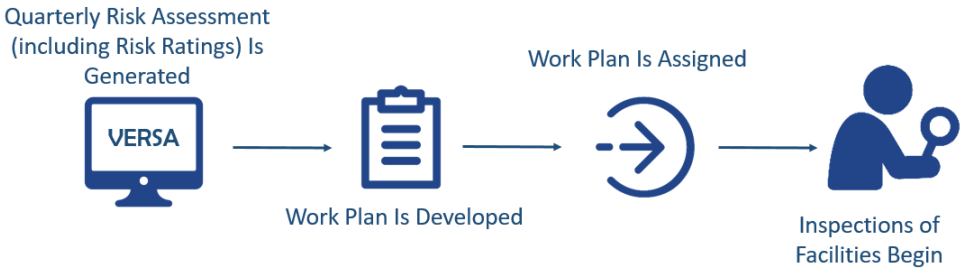
Source: The Departments' *Foods Procedures Manual*.

Under the Department's inspection processes, each of its five Program regions completes a quarterly risk assessment of Program facilities, develops a work plan, assigns and completes inspections, and conducts reviews of the inspection results. Figure 1 shows the inspection process.

Figure 1

The Department's Risk Assessment and Inspection Assignment Process

Each of the Department's five Program regions–Coastal, East, North, South, and West—complete the following process to assign inspections of facilities.



Source: Information from the Department.

Inspections Conducted

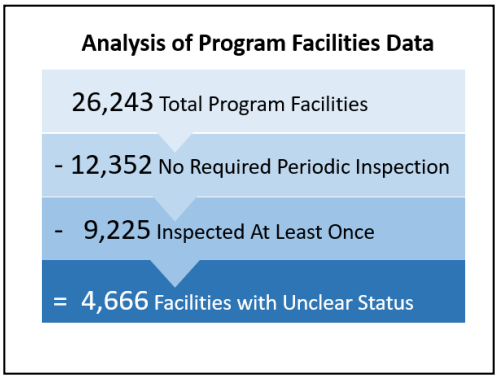
The Department had documentation showing that its Program regions followed its risk-based process for the time period reviewed. In addition, the Department inspected 9,225 Program facilities at least once from September 1, 2014, through June 30, 2019. The Department inspected 9,174 (99 percent) of those facilities within the target timelines. All of the other 51 facilities had been assigned a risk rating of High, and those inspections exceeded the Department's target time frame from 30 days to 20 months.

Delinquent Inspections

While the Department ensured that it complied with targeted timelines for the inspections it conducted, it did not include all facilities requiring an inspection in its risk-assessment process. As a result, it did not inspect certain facilities for at least 58 months. Not identifying all facilities that should be inspected according to the Department's policies increases the risk of not detecting food safety violations.

Data Analysis. As of June 30, 2019, there were 4,666 facilities with a current status in VERSA that had not been inspected at any time from September 1, 2014, through June 30, 2019 (see Figure 2 for more information about the data analysis of the Department's facilities information). Of the 4,666 facilities, 15 were assigned a High risk rating, 3,273 were assigned a Medium risk rating, and 1,088 were assigned a Low risk rating. In addition, 290 facilities did not have a risk rating assigned (see Chapter 1-B for more information).

Figure 2



Source: Data in VERSA.

Due to the manner in which the Department documented information for the 4,666 facilities in VERSA, each individual record must be reviewed to determine whether they should have been included in the Department's process for assigning inspections. As discussed below, testing of a sample of those facilities identified that some were (1) active and should have been inspected and (2) active and not subject to its recurring inspection requirements.

Sample Testing Results. The Department should have inspected at least some of the facilities discussed above according to its policies, including some facilities that had an assigned risk rating of High. Specifically, of the 75 facility records tested (see text box for information about that sample):

Sample of Facilities Tested

To determine the risk related to the 4,666 facilities discussed above, auditors selected the following for further review:

- All 15 facilities with a high-risk rating.
- A random sample of 60 additional facilities.

- Eight (53 percent) of the 15 high-risk rated facilities should have been inspected in accordance with Department time frame policies. In addition, the Department had never inspected 1 of those 8 facilities. As of June 30, 2019, that facility had been licensed by the Department for 19 months.

- Twenty-three (38 percent) of the 60 randomly selected facilities should have been inspected in accordance with Department time frame policies. In addition, the Department had never inspected 12 of those 23 facilities.[2] As of June 30, 2019, those 12 facilities had been licensed or registered by the Department for about 2 years to 12 years.

The remaining 44 facilities tested were either closed, newly created facilities, or did not require periodic inspections[3] (see text box for more information about those facilities). The records in VERSA for those 44 facilities did not contain readily identifiable fields to distinguish them from the population of facilities that require recurring inspections. By not having an efficient and accurate process to distinguish facilities that do not require recurring inspections from those that do, and not updating and correcting its data records in VERSA, the Department increases the risk of not inspecting all facilities as required.

Facilities That Do Not Require Periodic Inspections

Certain types of Program facilities do not require periodic inspections according to Department policy. For example, vended water, vended ice, and retail only facilities that are under additional local jurisdiction are required to have an initial inspection and are not subject to additional periodic inspections by the Department. The Department will conduct subsequent inspections of these facilities if the Department receives a complaint about them.

Source: The Department.

While the Department's policies prescribe a quarterly process to generate reports and analyze the Program facilities to determine whether they need to be inspected, the Department should strengthen its oversight to ensure that all facilities are included in the Program's risk assessments and work plans. For example, the Department does not perform reviews of the quarterly risk assessments and work plans prepared by each of the regions to verify that all required facilities are being assigned for inspection.

[2] As of October 2019, the Department had inspected 6 of the facilities subsequent to June 30, 2019: 4 were included in the high-risk rated facilities tested and 2 were included in the randomly selected sample tested.

[3] Of the 44 facilities that did not require recurring inspections, 37 were included in the random sample of 60 and 7 were included in the high-risk rated facilities tested.

Recommendations

The Department should:

- Develop and implement procedures to ensure that all required Program inspections are identified, planned, and conducted in compliance with its policies for frequency time frames. The Department should consider developing and implementing:
  - A process for Department review and approval of the quarterly work plans produced by the Program's regions.
  - Procedures to review, update, and correct Program facility records in VERSA to ensure that accurate and timely information is used during its quarterly processes for scheduling inspections.
- Implement a process to help identify which facilities are not subject to recurring inspections from facilities that do require those inspections. This could include the creation of a data flag or implementing standard and consistent data entry and naming conventions in VERSA.

Management's Response

The Department of State Health Services (Department) agrees with the findings and associated recommendations and offers the following responses. The Department is committed to performing timely and sufficient inspections of food facilities to the extent that resources allow.

The foods program (Program) will re-evaluate and implement updated quality assurance and work planning policies and procedures to ensure inspections are identified, planned, conducted, and in compliance with Department policies. This will entail determining the scope of policies and procedures required to address the audit recommendations; determining the level of effort and resources required to implement updated policies and procedures; and, ensure there are no unintended consequences to the new processes and policies.

The following steps will be considered to address audit recommendations (not all may be included):

- *The Program will conduct a review of the Department's risk ratings and inspection timeframes in comparison to the Food and Drug Administration's risk ratings and inspection timeframes for similar programs.*

- *The Program will consider the use of a "cover-by" date or due date column that automatically populates in the list used to develop the Program work plan.*

- *An annual work plan will be created and approved based on the cover-by date and risk. There will be a quarterly review of the work plan for any additions or deletions that may occur during the year.*

- *The Program will evaluate the current (VERSA) database (as resources permit) to ensure facility records are accurate and up-to-date when work planning is conducted.*

- *The Program will review all existing license modifiers and determine if new license modifiers or other identifiers are necessary to help facilitate the work planning process.*

- *The Program will work with the Business Filing and Verification Section to determine if modifications can be made to food license applications to identify firm products/processes to help ensure inspections of new facilities are prioritized.*

- *The Program will conduct a thorough review of the Foods Group Procedure Manual and other documented processes to ensure they are written in a clear and concise manner and policies are consistent and in line with the Program objectives/standards.*

- *All new and revised policies and procedures will be incorporated into the Foods Group Procedure Manual and fully reviewed with staff.*

Implementation Date:

Completion 3/31/2021.

Interim milestones will be identified once the scope of the project is fully defined and other factors such as required resources, level of effort and implementation are determined. The Surveillance Section will coordinate regular meetings with appropriate staff through project completion.

Responsible Persons:

- *Surveillance Food and Drug Unit Manager*

- *Manager, Foods Unit*

Chapter 1-B Rating:

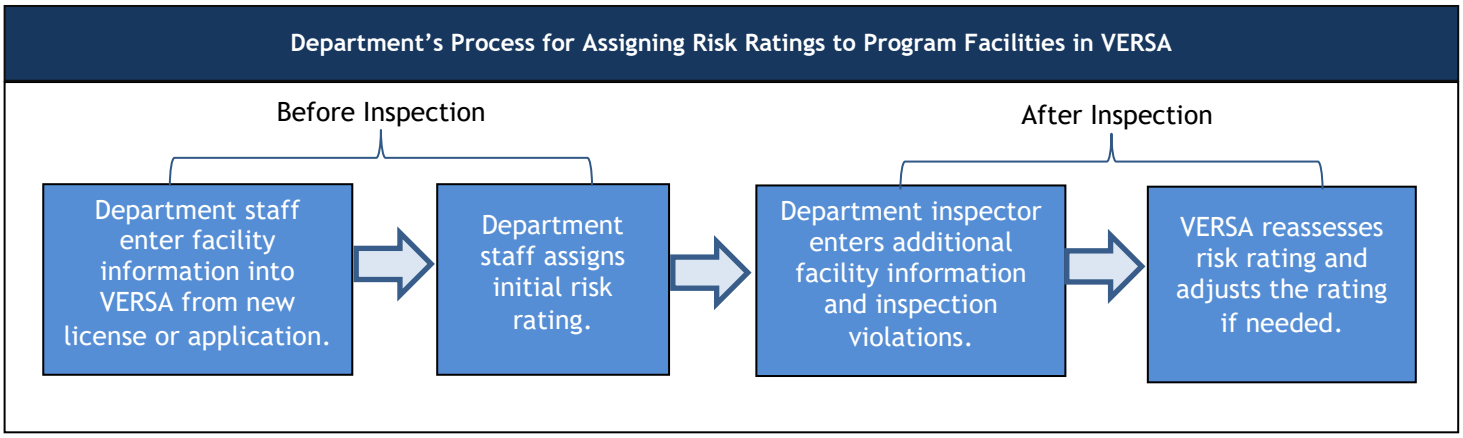
Medium [4]

Chapter 1-B

The Department Established Manual and Automated Processes to Help Assign Risk Ratings; However, Those Processes Did Not Consistently Work as Intended

The Department developed manual and automated processes to ensure that correct risk ratings are assigned to Program facilities. As Figure 3 shows, part of that process is automated.

Figure 3



Source: Based on information from the Department.

The Department's staff consistently entered facility information into VERSA as required, including information related to violations identified during inspections, such as the type of food and processes used, water source, and any violations identified. However, the Department staff did not always assign initial risk ratings and the automated program the Department developed did not always correctly reassess and adjust the risk rating. Specifically, an incorrect risk rating was assigned for 17 (28 percent) of 60 facility records tested. Of those 17 incorrect ratings:

- Fifteen facilities should have been assigned a lower risk rating.
- Two facilities should have been assigned a Medium risk rating but were incorrectly assigned a Low risk rating.

In addition, 2,781 facilities did not have any risk rating assigned in VERSA. The Department attributed the missing ratings for those records to its processes not working as intended. The Department's policy is to assign a Medium risk rating to all facilities that have not had an inspection. For 290 (10 percent) of those facilities, the Department had not conducted any

[4] The risk related to the issues discussed in Chapter 1-B is rated as Medium because they present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer program(s)/function(s) audited. Action is needed to address the noted concern and reduce the risks to a more desirable level.

inspections from September 1, 2014, through June 30, 2019.[5] The Department had conducted at least one inspection of the other facilities during that time period.

The Department did not sufficiently monitor its assignment of initial risk ratings and it did not test the risk-rating program in VERSA to verify that it would work as intended prior to implementation. In addition, it did not have procedures to monitor the program on an ongoing basis to verify that it continues to operate as intended.

The Department uses the assigned risk ratings to determine the frequency of inspections. By not assigning the correct ratings, the Department has an increased risk that it may (1) not inspect food facilities within the established time frames and (2) misalign its resources to inspect facilities at a higher frequency than it should.

Recommendations

The Department should:

- Identify and address the causes for the assignment of incorrect risk ratings, and recalculate the risk ratings for all facilities, including assigning at least a Medium risk rating for facilities that it had not yet inspected.
- Develop procedures to monitor Program facilities' risk rating assignments to ensure that they comply with the requirements in Department policy and that the automated program is working as intended.

Management's Response

The Department agrees with the findings and associated recommendations and offers the following responses.

- *The Department has addressed the possible cause(s) for the computerized program issues. Corrections to the computerized program have already been implemented. The Department generated work plans on November 13, 2019 and December 13, 2019 to verify the automated risk update job was operating as intended.*
- *The Department will develop a procedure and designate a responsible party to conduct a quarterly check of the automated risk assessment job to ensure the risk is accurately updated to include completed inspections*

[5] Those 290 facilities were included in the 4,666 facilities without a recorded inspection during the approximately 5-year period discussed in Chapter 1-A.

and newly created license records missing the Medium default risk modifier. The procedure will be added to the Foods Group Procedure Manual.

Implementation Date:

March 31, 2020

Responsible Person:

Food Safety Officer/MFRPS Coordinator

Chapter 2

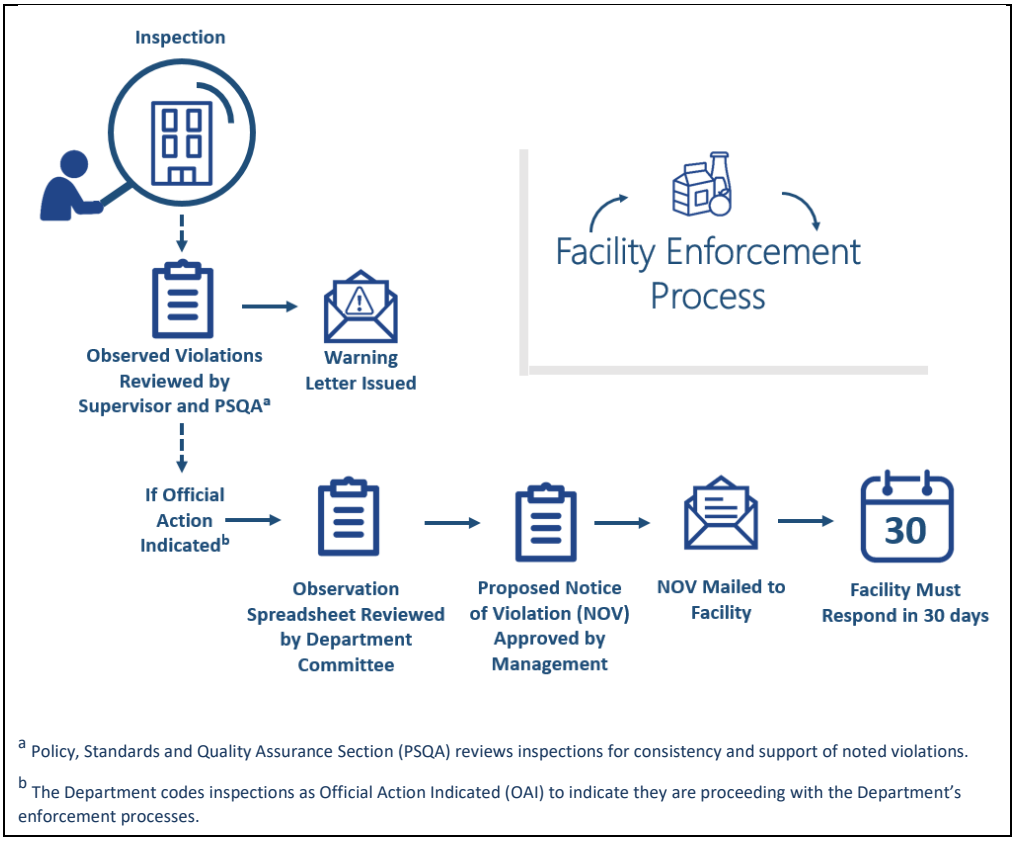
The Department Followed Its Enforcement Processes Related to the Violations That It Identified

Chapter 2 Rating:

Low [6]

The Department developed policies and procedures that describe and define the various enforcement actions that should be taken for violations identified during inspections of Program facilities. Based on the severity of the issues identified during an inspection, the Department may issue a Warning Letter to the facility or a Notice of Violation, which can result in fines and other penalties. Figure 4 shows the Department's enforcement process.

Figure 4



[a] Policy, Standards and Quality Assurance Section (PSQA) reviews inspections for consistency and support of noted violations.

[b] The Department codes inspections as Official Action Indicated (OAI) to indicate they are proceeding with the Department's enforcement processes.

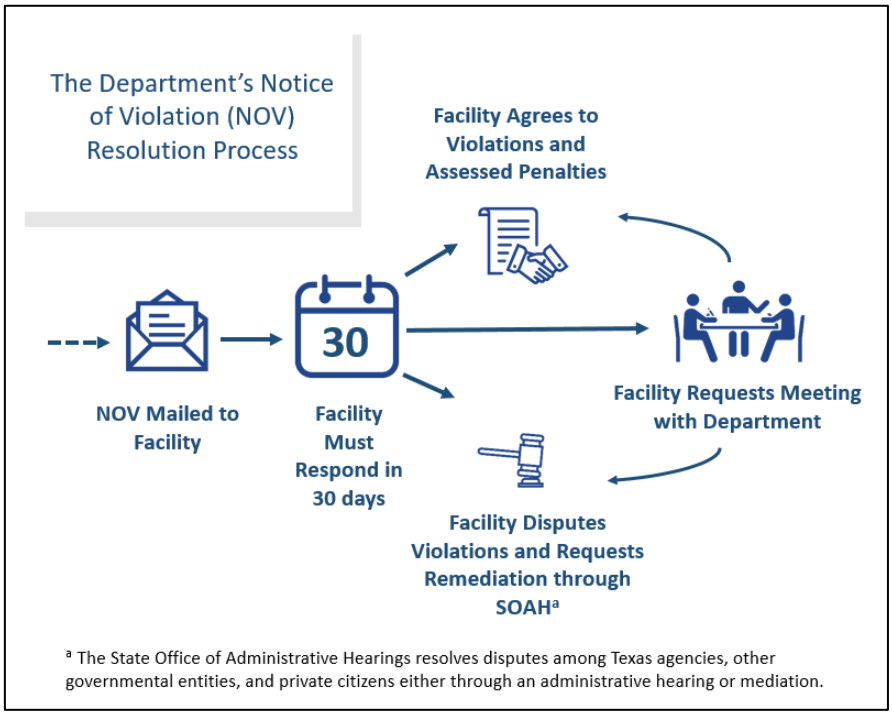
Source: Information from the Department.

[6] The risk related to the issues discussed in Chapter 2 is rated as Low because the audit identified strengths that support the audited entity's ability to administer the program(s)/function(s) audited or the issues identified do not present significant risks or effects that would negatively affect the audited entity's ability to effectively administer the program(s)/function(s) audited.

The Department complied with the criteria established in its policies for all 60 inspections tested. Specifically, for those inspections, the violations that the inspectors identified were classified correctly according to the Department's policies. That classification determines whether enforcement actions are required. In addition, for all 36 enforcement cases tested, the Department appropriately categorized the identified violations as Official Action Indicated (OAI), initiated the appropriate enforcement actions, and assessed penalties in accordance with its policies. In addition, 35 (97 percent) of the 36 enforcement cases tested complied with the Department's process. The Department closed one case before completing the process without documenting its justification for doing so.

The Department ensured that it entered all 36 enforcement cases in VERSA and followed-up on penalty payments when applicable; however, it did not always update case status correctly and in a timely manner. Specifically, the Department did not consistently update the case status in VERSA for certain events occurring subsequent to mailing out the Notice of Violation, such as when a meeting or hearing is rescheduled (see Figure 5 for information about the post-notification process). Specifically, for 11 (31 percent) of 36 cases tested, the case status was either not updated in a timely manner or updated with an incorrect status code. As of June 30, 2019, the case status progression had gone unrecorded for 6 of those 11 cases by 11 days to 22 months. The Department asserted that those six cases were not updated because the assigned enforcement officer left the Department and it did not ensure that the cases were transferred to another enforcement officer for processing.

Figure 5



Source: Information from the Department.

By not ensuring the enforcement actions are updated correctly and in a timely manner in VERSA, Department management may not have current information when making enforcement decisions.

Recommendation

The Department should ensure that the enforcement status of inspection violations are updated in VERSA correctly and in a timely manner, including ensuring that cases are transferred when an employee separates from the Department.

Management's Response

The Department agrees with the findings and associated recommendations and offers the following responses.

- *The following actions have been taken to enhance processes to update enforcement status in VERSA. The Unit has worked with the Regulatory Automation System (RAS) application personnel. The action step activity codes now mimic the Unit's current business practices and protocols. All actions taken can now be chronologically noted and easily tracked. Additionally, cases are now closed with succinct and thorough notes (when deemed) of action steps taken, detailing events warranting deviation in decision from protocol and parties involved with the decision.*

- *Additionally, the following steps have been taken to increase the monitoring of cases to ensure timeframes are being met and that cases are monitored after the separation of an employee from the Department. All cases are now proactively monitored by all Food and Drug Compliance personnel, so the separation of one employee will not result in the case not being monitored. Also, a system of adapting time frames in Microsoft Outlook for pre and post informal conference activities has been implemented.*

Implementation Date:

July 1, 2019

Responsible Person:

Unit Manager

Chapter 3

While the Department Followed Its Complaint Investigation Policies, It Should Strengthen Its Documentation of Complaints

Chapter 3 Rating:
Medium [7]

The Department's Program developed and documented policies and procedures for investigating complaints that it receives related to food safety, and it generally ensured that investigators complied with those procedures. However, it should strengthen its procedures for conducting complaint investigations within the required time frames, documenting non-jurisdictional complaints, and maintaining its central complaint tracking spreadsheet. It should also ensure that its documented policies are consistent and match its processes.

Complaint Investigations. For the 27 complaints tested, the Department completed investigations for all 26 complaints within its jurisdiction and appropriately referred 1 complaint to another jurisdiction. In addition, the Department conducted the investigations within the required time frames for 20 (77 percent) of the 26 complaints tested, and it correctly recorded that the investigation status was closed in VERSA for all 26 complaints.

Six complaint investigations, 5 of which were low-priority, were completed from 3 days to 10 months after the required time frame. For one complaint, the Department did not have any record of assigning the priority level rating. Additionally, for those 6 complaint investigations, the Department did not consistently document explanations for not completing the investigations within the required time frames.

Non-jurisdictional Complaints. For the 6 non-jurisdictional complaints tested, the Department's justifications for deeming complaints to be non-jurisdictional were reasonable. However, it could not provide documentation showing that 1 complaint tested was referred to the appropriate responsible party for investigation. While the Department enters complaint information into VERSA for jurisdictional complaints, it does not enter that information for complaints it refers to other entities. Consistently documenting the receipt and disposition of all complaints would help the Department ensure that complaints are appropriately investigated or referred to an appropriate entity for resolution.

Complaint Tracking Spreadsheet. The Department's policies require its (1) Policy, Standards, and Quality Assurance (PSQA) Section staff to enter complaints into VERSA and (2) Surveillance Section to maintain a central complaint

[7] The risk related to the issues discussed in Chapter 3 is rated as Medium because they present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.

tracking spreadsheet to document the complaints received and the results of the related investigations. While the PSQA and Surveillance sections entered complaints into VERSA and maintained the central complaint tracking spreadsheet, they did not consistently ensure that the spreadsheet was complete and up-to-date. Specifically, based on a reconciliation with the listings of complaints that each of the five Program regions maintained, the central complaint tracking spreadsheet as of June 30, 2019, did not include 16 (12 percent) of the 132 complaints that had been referred to its Program regions. The Department asserted that the Surveillance Section uses the central complaint tracking spreadsheet as a management tool for the complaints it receives.

Additionally, significant information, such as the dates the investigations were completed and the results of those investigations, was missing for some records. Specifically, as of June 30, 2019, the results for 6 (25 percent) of 24 completed complaint investigations tested had not been entered into the central complaint tracking spreadsheet. Those investigations had been completed from 3 months to 20 months prior to July 1, 2019.

The Department asserted that it does not reconcile the information in VERSA and the central complaint tracking spreadsheet to verify completeness and accuracy. Without accurate and current complaint investigation information, there is an increased risk that the Department may not follow-up on complaints in a timely manner.

Documented Policies and Procedures. The Department's documented policies and procedures contain inconsistent information related to the time frames for completing investigations of complaints. Specifically, the Department's current processes follow the time frames established in Chapter 5 of its *Foods Procedures Manual*. However, Chapter 17 of that manual contains different, and at times accelerated, time frames for certain types of complaints (see Table 2 on the next page). Ensuring that documented policies are internally consistent and match its processes could help the Department minimize the risk of confusion among its staff and ensure that complaints are investigated within the established time frames.

Table 2

Foods Procedures Manual Complaint Investigation Requirements			
Chapter 5 (Department's Current Process)		**Chapter 17 Time Frames**	
Complaint Category	**Investigation Time Frames**	**Complaint Category**	**Investigation Time Frames**
High Priority	2 weeks from date complaint receipt.	Foodborne illness	24 to 48 hours from complaint receipt.
Low Priority	1 month from date complaint receipt.	Injury	10 days from complaint receipt.
		Serious Allegations [a]	As soon as possible after complaint receipt.
		Less Serious Allegations	Next regular inspection.
[a] Serious allegations are defined as "conditions where the situation is likely to lead to adulteration or misbranding of a food commodity."			

Source: The Department's *Foods Procedures Manual*.

Recommendations

The Department should:

- Develop procedures to ensure that complaints are investigated within the required time frames.
- Develop and implement a process to receive, document, and track complaints it determines should be referred to other entities for investigation.
- Develop and implement procedures to verify that its VERSA complaint records and management tracking tools, such as its central complaint tracking spreadsheet, are complete and accurate.
- Update its *Foods Procedures Manual* to ensure the complaint categories and the time frames for investigating those complaint categories are consistently defined and align with the Department's actual processes.

Management's Response

The Department agrees with the findings and associated recommendations and offers the following responses. The Department is committed to performing timely and sufficient complaint investigations of food facilities to ensure the public's safety from the greatest health risks.

The Program will re-evaluate and implement updated complaint documentation policies and procedures to ensure complaint investigations

are correctly identified, referred when necessary, planned, conducted, and in compliance with Department policies.

The following processes will be analyzed and incorporated where appropriate:

- *The Program will explore the feasibility of utilizing alternative complaint investigation techniques to ensure that all complaints within its jurisdiction are investigated sufficiently and timely.*
- *The Program will review its process on how it receives, documents, and tracks complaints (deemed under the Program's purview) to ensure all complaints are investigated within the required timeframes and data is complete and accurate.*
- *The Program will review and update the complaint investigations section in the Foods Group Procedure Manual to ensure all complaint procedures (to include non-jurisdictional complaints) are in one chapter and are consistently defined.*

All new and revised policies and procedures will be incorporated into the Foods Group Procedure Manual and fully reviewed with staff.

Implementation Date:

July 31, 2020

Responsible Persons:

Surveillance Food and Drug Unit Manager

Manager, Foods Unit

Chapter 4

The Department Should Improve Its Information Technology Controls

Chapter 4 Rating:

Medium [8]

The Department established documented policies and controls for the use of its information systems. However, the Department should improve its user access controls and processes for deleting inspection and complaint records.

The Department's policies require it to disable user accounts when they are no longer needed and to conduct user access reviews. The Department also obtained a System and Organization Controls (SOC) Report[9] for the third-party vendor that maintains VERSA. That report did not identify any issues related to change management, policies and procedures, and backup and recovery. Additionally, the Department established password rules and settings that complied with its policies.

User Access. While the Department removed network access for separating employees, it did not consistently disable those users' access to VERSA in a timely manner. In addition, the Department should improve its reviews of user access. While the Department asserted that it had conducted a user access review in November 2018, it did not have sufficient documentation supporting that review, and that review did not identify some of the former employees who still had active access accounts. Effective user access reviews would help ensure that access to its inspection data is restricted to minimize the risk of unauthorized changes to that information. The Department's internal auditors also identified the weaknesses in the Department's user access controls in 2015.

Deletion of Records. The Department did not have adequate controls over the deletion of inspection and complaint records. Specifically, some users have the ability to delete records without any required review or approvals. The Department also does not have processes for monitoring its inspection and complaint records to identify deletions and verify that they are authorized. Monitoring inspection and complaint records for deletions, such as reviewing for gaps in record numbers, requiring deletions to be logged and reviewed, or reconciling VERSA records with other Department listings, would help the Department minimize the risk of inappropriate deletion of records.

[8] The risk related to the issues discussed in Chapter 4 is rated as Medium because they present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer program(s)/function(s) audited. Action is needed to address the noted concern and reduce risks to a more desirable level.

[9] A System and Organization Controls Report discusses the sufficiency of a vendor's controls that are relevant to the contracting entities' internal controls.

Recommendations

The Department should:

- Ensure that all user access accounts are disabled upon an employee's separation from the Department.
- Conduct periodic access reviews and ensure those reviews are effective and documented.
- Develop and implement controls over the deletion of records to reduce the risk of inappropriate deletions.

Management's Response

The Department generally agrees with the rating for this chapter; however, the Department believes that the risk of security breach is minimal. Even though the user accounts were still active in VERSA Regulation, the user agency network access was terminated according to policy. As a result of the disabled network access, the separated employees would not have the ability to log into VERSA Regulation.

The Department supports the audit recommendations and offers the following responses.

- *The program in conjunction with IT will review the current procedures and controls to ensure employee user accounts are disabled timely and appropriately upon an employee's separation. The Department will also develop a scheduled and documented review of user accounts by all sections with access to VERSA Regulation to ensure only authorized users have access to the system.*
- *Division management in conjunction with IT will review the current process for deletion of records in VERSA Regulation to ensure individual users who have rights to delete records are appropriate and also each section who utilizes this function has their process documented to ensure records are not inadvertently deleted.*

Implementation Date:

February 28, 2020

Responsible Persons:

Surveillance Section Director

Policy Standards and Quality Assurance Section Director

Compliance Section Director

Business Filing and Verification Section Director

Branch Manager Supporting CFO, Consumer Protection and Regional & Local Health Operation

Appendices

Appendix 1

Objectives, Scope, and Methodology

Objectives

The objectives of this audit were to determine (1) whether the Department of State Health Services' (Department) risk-based approach to prioritizing inspections of food facilities by the Manufactured Foods Program (Program) helps ensure the public's safety from the greatest health risks and (2) whether the Department is administering select functions according to requirements applicable to the Department's Program.

Scope

The scope of this audit covered the Program facilities that had a license status of current according to Department records as of June 30, 2019. For data analysis of inspection records, the audit scope covered inspection data for September 1, 2014, through June 30, 2019. For the testing of facility risk rating assignments, enforcement actions, and complaint records, the audit scope covered the time period from September 1, 2017, through June 30, 2019.

Methodology

The audit methodology included conducting interviews with Department management and staff; reviewing statutes, rules, and Department policies and procedures; collecting information and documentation on inspection, enforcement, and complaint processes; analyzing inspections data; performing selected tests and procedures on the information obtained; and analyzing and evaluating the results of those tests.

Data Reliability and Completeness

Licensing, inspection, and enforcement data. To test the Department's processes, auditors used data from the Department's licensing and enforcement system, VERSA Regulation (VERSA), related to Program facilities' licenses and inspections from September 1, 2014, through June 30, 2019. Auditors performed certain data analyses and reviewed queries of the data. Auditors also reviewed independent assessment reports of System and Organization Controls for the Department's third-party information service provider, and tested user access and password rules for VERSA. While the data contained some weaknesses (discussed in Chapter 1-A), auditors determined that

licensing, inspection, and enforcement data was sufficiently reliable for the purposes of this audit.

Complaints data. To test the Department's complaint process, auditors used complaints data and determined that it was unreliable because the Department could not provide a complete and comprehensive listing of all complaints related to Program facilities that it received (see Chapter 3 for more information). While auditors determined that the completeness of the complaints data was not sufficiently reliable for purposes of this audit, that data was the most complete population of complaints available; therefore, auditors used that data for testing and analysis.

Sampling Methodology

Auditors selected random and non-random samples of the Program's facilities, inspection records, enforcement actions, and complaints. Specifically:

- To test whether the Department was meeting its targeted timelines for facilities inspections, auditors performed data analysis on the population of facilities in VERSA and identified all facilities with a current status that did not have inspections within the time frames the Department established.

  Of the 4,666 facilities without an inspection from September 1, 2014, through June 30, 2019 identified through the data analysis described above, auditors tested all 15 facilities to which the Department assigned a risk rating of High, as well as an additional random sample of 60 other facilities. The random sample of 60 facilities was designed to be representative of the population and the test results may be projected to the population, but the accuracy of the projection cannot be measured.

- To test the Department's processes for assigning facilities risk ratings and enforcing inspection observations, auditors selected non-random samples of 60 facilities. Auditors selected records to ensure comprehensive coverage of each geographic area managed by the Department's five Program regions, as well as the types of facilities licensed and inspected. The sample items were not necessarily representative of the population; therefore it would not be appropriate to project the test results to the population.

- To test the Department's complaint processes, auditors selected a random sample of 27 complaints. The sample was designed to be representative of the population and the test results may be projected to the population, but the accuracy of the projection cannot be measured.

- To test the Department's non-jurisdictional complaint processes, auditors selected a non-random sample of 6 non-jurisdictional complaints. Auditors selected records to ensure comprehensive coverage of complaints throughout the time period from September 1, 2018, through June 30, 2019. Those sample items were not necessarily representative of the population; therefore, it would not be appropriate to project the test results to the population.

Information collected and reviewed included the following:

- Department policies and procedures.
- Department data from VERSA related to licenses, inspections, enforcement actions, and complaints.
- Department's Program Risk Assessment Tool.
- The Department's organizational charts.
- Inspection work plans developed in coordination between the Department's Policy, Standards, and Quality Assurance section and Surveillance section.
- The Department's user access data, password parameters policy, and password change log related to VERSA.
- Food letters, Notices of Violation, Agreed Orders, Enforcement Case Summaries, and other supporting documentation related to the Department's enforcement actions against facilities cited for violations observed during inspections.
- Complaint tracking logs, quarterly reports related to the status of complaints, and other supporting documentation related to the Department's complaint investigations of Program facilities.
- The Health and Human Services Commission's *Information Security Controls*, Version 1.0.

Procedures and tests conducted included the following:

- Interviewed the Department's management and staff.
- Observed selected inspections of Program facilities performed by Department staff.

- Tested inspection records to determine whether the Department calculated and assigned the correct risk ratings in accordance with the Department's Program Risk Assessment Tool.
- Analyzed inspection records to identify the number of facilities that were not assigned a risk rating.
- Identified and analyzed facilities that did not have an inspection during the period of September 1, 2014, through June 30, 2019.
- Tested enforcement actions for consistency with the severity of the identified violations.
- Tested complaints to determine whether they were investigated and processed in accordance with Department policies and procedures.

Criteria used included the following:

- Texas Health and Safety Code, Chapters 431 and 432.
- Title 25, Texas Administrative Code, Chapter 229.
- The Department's policies and procedures.
- The Health and Human Services Commission's *Information Security Controls*, Version 1.0.

Project Information

Audit fieldwork was conducted from May 2019 through October 2019. We conducted this performance audit in accordance with generally accepted government auditing standards.[10] Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The following members of the State Auditor's staff performed the audit:

- Robert G. Kiker, CGAP (Project Manager)
- Sherry Sewell, CGAP (Assistant Project Manager)
- Lindsay Escalante, MPSA
- Derek Lopez, MBA
- William J. Morris, CPA
- Jenna Perez, MAcy
- Jordan Skinner, CFE
- Dana Musgrave, MBA (Quality Control Reviewer)
- James Timberlake, CIA, CFE (Audit Manager)

[10] United States Government Accountability Office's *Government Auditing Standards*, 2011 Revision.

Appendix 2

Issue Rating Classifications and Descriptions

Auditors used professional judgment and rated the audit findings identified in this report. Those issue ratings are summarized in the report chapters/sub-chapters. The issue ratings were determined based on the degree of risk or effect of the findings in relation to the audit objective(s).

In determining the ratings of audit findings, auditors considered factors such as financial impact; potential failure to meet program/function objectives; noncompliance with state statute(s), rules, regulations, and other requirements or criteria; and the inadequacy of the design and/or operating effectiveness of internal controls. In addition, evidence of potential fraud, waste, or abuse; significant control environment issues; and little to no corrective action for issues previously identified could increase the ratings for audit findings. Auditors also identified and considered other factors when appropriate.

Table 3 provides a description of the issue ratings presented in this report.

Table 3

Summary of Issue Ratings	
Issue Rating	**Description of Rating**
Low	The audit identified strengths that support the audited entity's ability to administer the program(s)/function(s) audited or the issues identified do not present significant risks or effects that would negatively affect the audited entity's ability to effectively administer the program(s)/function(s) audited.
Medium	Issues identified present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.
High	Issues identified present risks or effects that if not addressed could substantially affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Prompt action is essential to address the noted concern(s) and reduce risks to the audited entity.
Priority	Issues identified present risks or effects that if not addressed could critically affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Immediate action is required to address the noted concern(s) and reduce risks to the audited entity.

Copies of this report have been distributed to the following:

Legislative Audit Committee

The Honorable Dan Patrick, Lieutenant Governor, Joint Chair
The Honorable Dennis Bonnen, Speaker of the House, Joint Chair
The Honorable Jane Nelson, Senate Finance Committee
The Honorable Robert Nichols, Member, Texas Senate
The Honorable Dustin Burrows, House Ways and Means Committee

Office of the Governor

The Honorable Greg Abbott, Governor

Health and Human Services Commission

Dr. Courtney Phillips, Executive Commissioner

Department of State Health Services

Dr. John Hellerstedt, Commissioner