2018 MFRPS Assessment Data
Document Control Findings
Chronic Observations

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U.S. FOOD & DRUG ADMINISTRATION

Assessment Work Plan

FY-2017	
Interval 1 -	2
Interval 2 -	0
Interval 3 -	15
Interval 4 -	5
Interval 5 -	0
Total	22

FY-2018	
Interval 1 -	**0**
Interval 2 -	2
Interval 3 -	4
Interval 4 -	8
Interval 5 -	5
Total	**19**

FY-2019	
Interval 1 -	*2*
Interval 2 -	*1*
Interval 3 -	*0*
Interval 4 -	*14*
Interval 5 -	*5*
Total	*21*

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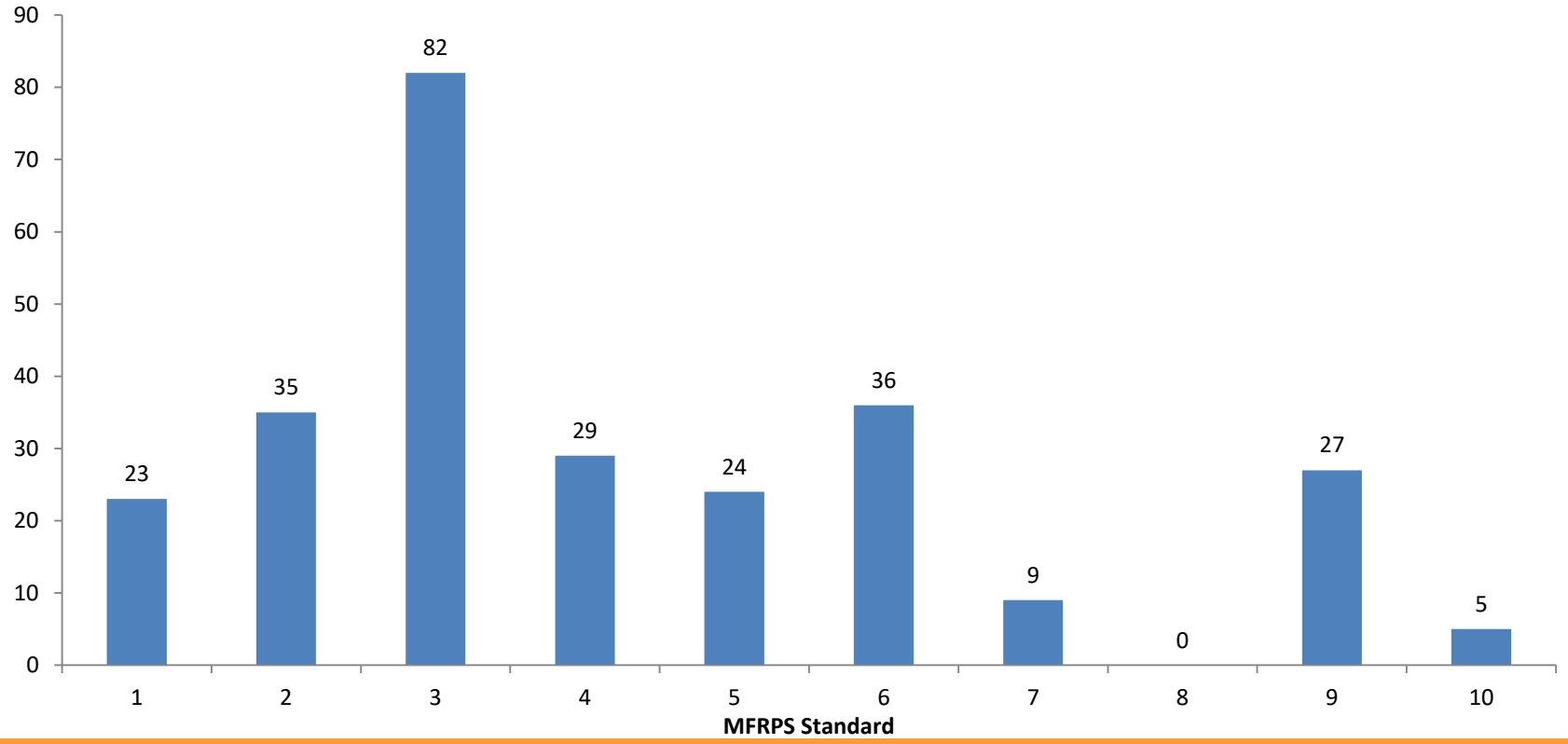
Total Findings FY-18

(270 Total Observations)



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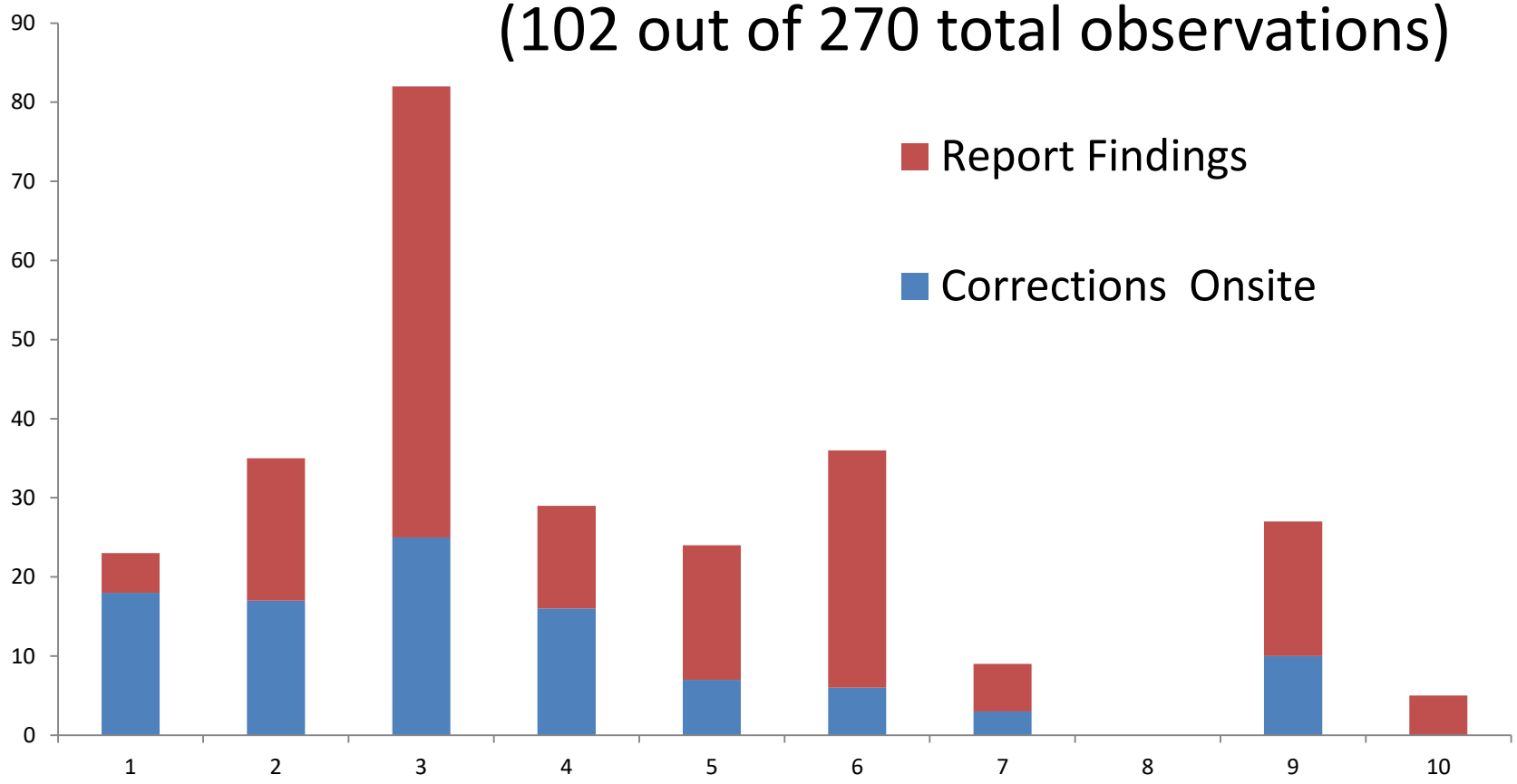
Findings Corrected Onsite

(102 out of 270 total observations)



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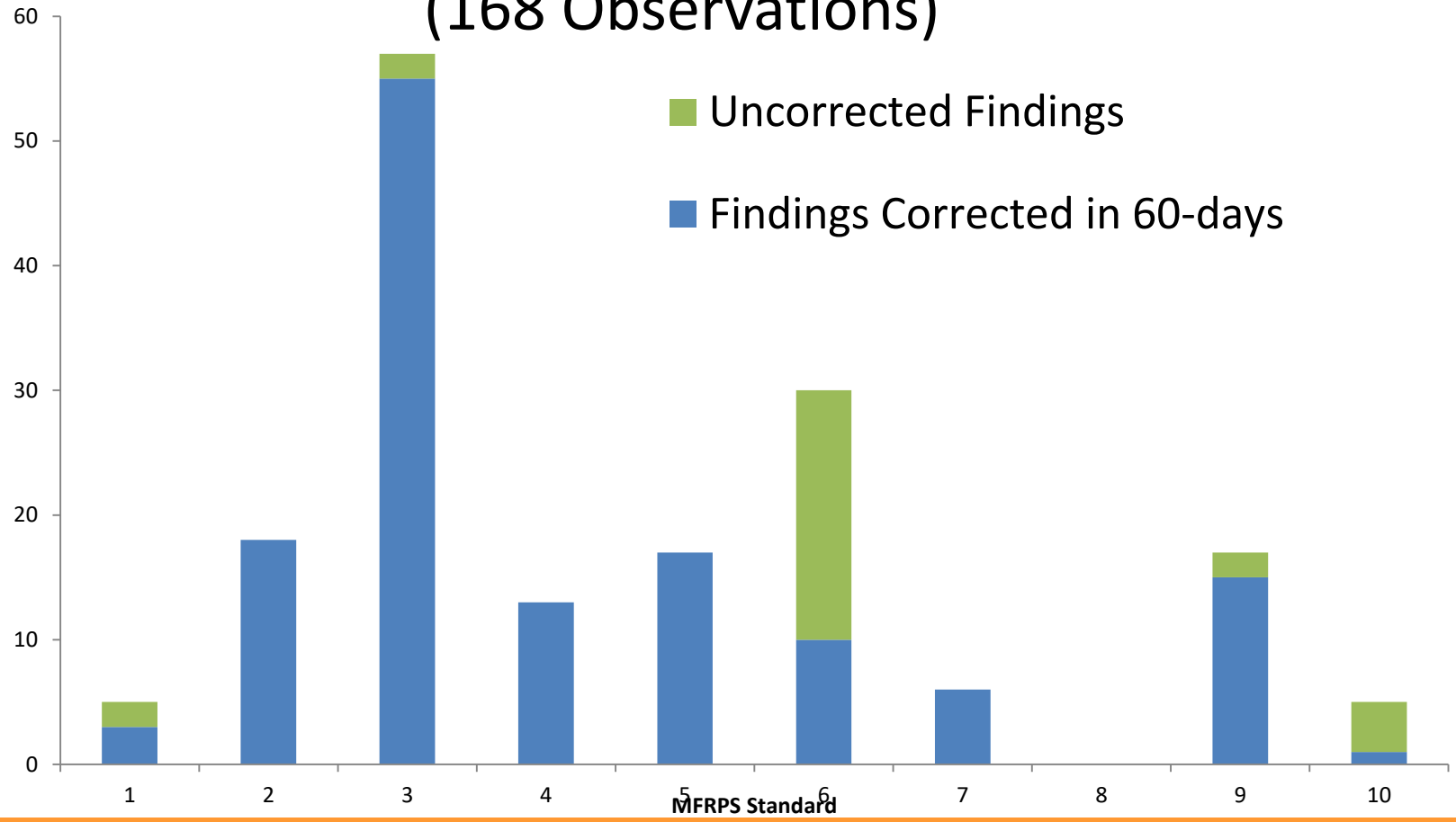
60 Day Corrections

(168 Observations)



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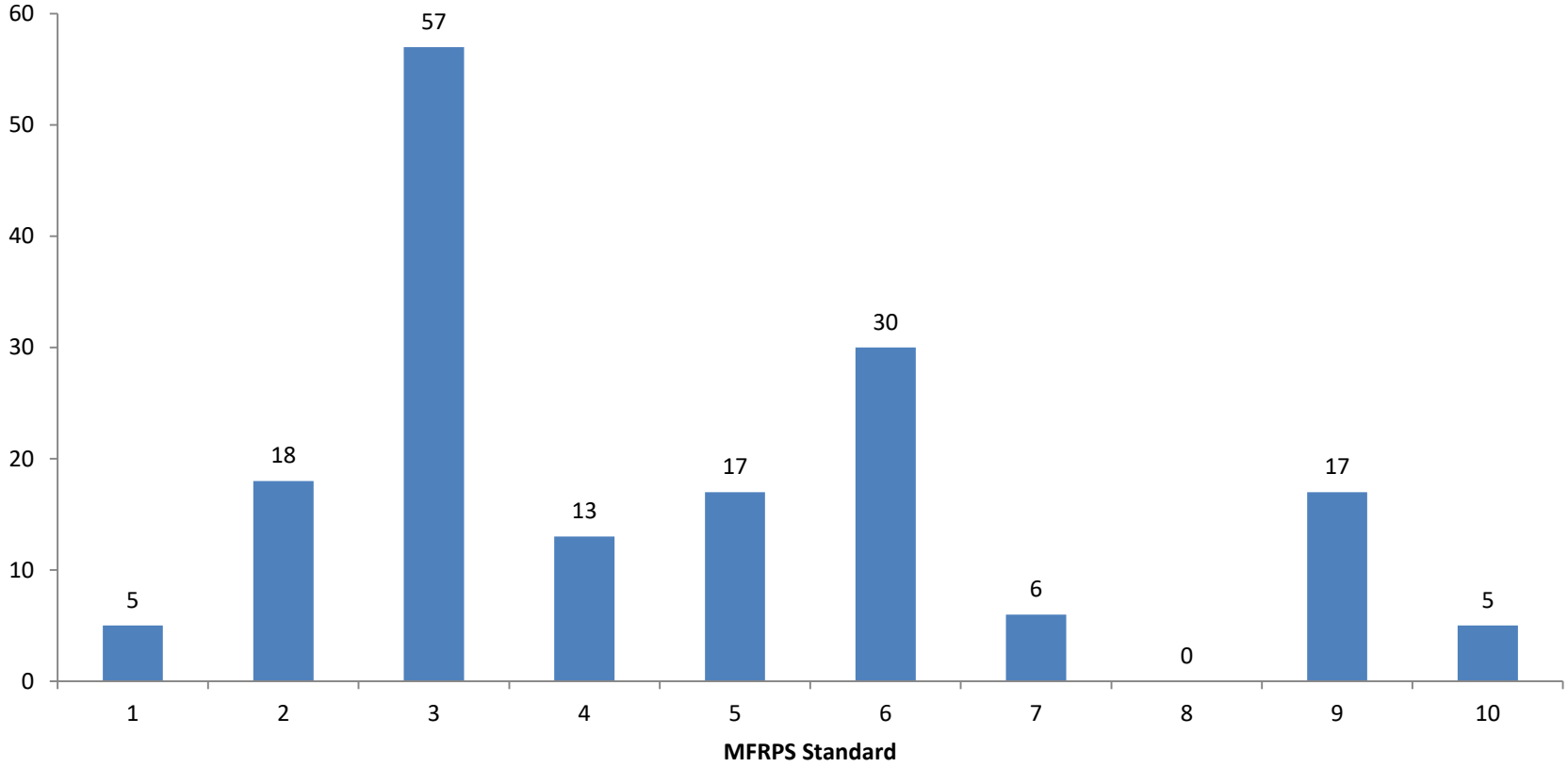
Final Report Findings
(168 Observations)



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30 Total Final Report Findings

Standard	Report Findings	Corrections Onsite	Findings Corrected in 60-days	Uncorrected Findings	FY- 18 Total Findings
1	5	18	3	2	23
2	18	17	18	0	35
3	57	25	55	2	82
4	13	16	13	0	29
5	17	7	17	0	24
6	30	6	10	20	36
7	6	3	6	0	9
8	0	0	0	0	0
9	17	10	15	2	27
10	5	0	1	4	5
	168	**102**	**138**	30	**270**

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FY-18 Chronic Program Elements

Program Element and % Corrected	Number of FY18 Observations	Element Description / Notes
9.3.2 & 9.3.2.1 92% corrected	24 total -10 @ 9.3.2.1 -14 @ 9.3.2	**The state program must have a written DOCUMENT CONTROL procedure that ensures the information contained in the appendices and supporting documents for program elements are CURRENT AND FIT-FOR-USE.**

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FY-18 Chronic Program Elements

DEFINITION of Document Control: document control ensures that documents are reviewed for adequacy, approved for release by authorized personnel and distributed to and used at the location where the prescribed activity is performed.

FY-18 Chronic Program Elements

DEFINITION of Current and Fit for Use: "current" indicates that documentation is signed and dated in accordance with program policies and procedures that meet criteria in the most current standard.

"**Fit-for-use"** is a quality term used to indicate that a product or service fits the customer's defined purpose for that product or service. Documentation may be electronic or hard copy.

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FY-18 Chronic Program Elements

9.3.2 The State program must…

9.3.2.1 Have a written Document Control procedure……

9.3.2.2 Retain records or procedures required under x.5 of each standard for the three previous years, or per the State program's record retention policy, whichever is longer. Records or procedures can be maintained either electronically or in hardcopy.

FY-18 Chronic Program Elements

9.3.2.1 Document Control: and 9.3.2 The State program must:

- 4 Observations for written procedure deficiencies
- 20 Observations were **conformance** to definitions to "Document Control" and "Current and- Fit-for-Use":
  - ✓ Identifying authorized personal to review and approve
  - ✓ Not having control over distribution
  - ✓ Not controlling supporting documents used to meet program elements including internal and external documents such as FERPS, MFRPS, Juice and Seafood Hazards Guides, or original templates.
- All but 2 Observations were corrected. (92% corrected)

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FY-18 Chronic Program Elements

Program Element and % Corrected	Number of FY18 Observations	Element Description / Notes
1.3.2.1 100% corrected	12 total	**REGULATORY FOUNDATION Assessment The State program must complete Appendix 1 or equivalent form. The State program conducts a baseline self-assessment to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to sections of the current Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) Title 21 specified in Appendix 1.**

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FY-18 Chronic Program Elements

- 12 Observations @1.3.2.1

REGULATORY FOUNDATION Assessment
The State program must complete Appendix 1 or equivalent form. The State program conducts a baseline self-assessment to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to sections of the current Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) Title 21 specified in Appendix 1.

FY-18 Chronic Program Elements

Equivalent: means that the State law **directly references** the relevant provision or regulation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Title 21 Code of Federal Regulations (CFR). The State program **specifies the Federal statute or regulation that is incorporated into the State law,** including **the revision date** of the State statutory provision or regulation, the **date the Federal statutory provision** or regulation **was incorporated into the State law,** and whether that statutory or regulatory provision is included in whole, in part, or modified from the original.

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FY-18 Chronic Program Elements

- **Equivalent in Effect:** means that the State law has the same regulatory effect as the relevant FD&C Act provision or CFR regulation. A State law may have the same regulatory effect as the Federal law or regulation if either a single State law or rule has the same regulatory effect as the Federal law or regulation, or when multiple laws of that State are combined and deemed equivalent to a single Federal law or regulation. In conducting such self-assessment, the State program may need to consult with its legal counsel when a provision is determined to be Equivalent in effect.

FY-18 Chronic Program Elements

- **Appendix 1: Self-Assessment Worksheet *Instructions:***

  Determine if State laws and regulations are "EQUIVALENT," "EQUIVALENT IN EFFECT," or "NOT EQUIVALENT" to Federal statutes and regulations.
  1*-If there is no State law or regulation that is EQUIVALENT or EQUIVALENT IN EFFECT, mark the NOT EQUIVALENT box;* ***otherwise*** *list the State law or regulation citation and complete the columns for* ***either*** *EQUIVALENT or EQUIVALENT IN EFFECT as appropriate.*

  2-The Notes section shall be used in part to detail differences between State and Federal laws and regulations.

  3-If regulatory responsibility for a FD&C-CFR falls under the jurisdiction of another agency, that particular FD&C-CFR row should be left blank – with documentation provided in the notes section of which agency has the jurisdiction. -

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FY-18 Chronic Program Elements

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
110[18]	Current good manufacturing practice in manufacturing, packing, or holding human food							
111	Current good manufacturing practice for dietary supplements							
113	Thermally processed low-acid foods packaged in hermetically sealed containers							

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FY-18 Chronic Program Elements

Program Element and % Corrected	Number of FY18 Observations	Element Description / Notes
6.3.1.2.2 92% corrected	6 total	The State program has a written compliance and enforcement program that: Describes the procedure to monitor chronic violations**.** **All 6 observations lacked procedures to describe monitoring Chronic Violations**
4.3.5.1 100% corrected	6 total	Corrective Action Plan Required When: An individual receives an overall rating of "needs improvement**" Three observations written for not performing a CA when an individual received an overall field audit rating of "Needs Improvement" and 3 for the QAP not requiring a CA when an individual field audit rating was "Needs Improvement"**

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FY-18 Chronic Program Elements

Program Element and % Corrected	Number of FY18 Observations	Element Description / Notes
5.3.5.3 100% corrected	6 total	**Post Response** Distributes recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach. **Written procedures did not identifying or addressing what agency is responsible for distributing the final program investigation reports, including and environmental assessment if completed to relevant agencies responsible for reporting contributing factors and antecedent to CDC.**

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FY-18 Chronic Program Elements

Program Element and % Corrected	Number of FY18 Observations	Element Description / Notes
3.3.2.14	5 total	Inspection Procedure Use **current versions of applicable hazard guides** or other guidance, to identify and evaluate the HAZARDS associated with product(s) and process(es) when conducting inspections of specialized food and processes.
4.3.2.1	5 total	Field Inspection Audit; Frequency. The QAP requires a minimum of two FIELD INSPECTION AUDITS of each inspector be conducted every 36 months. **Three observations for not conducting at least 2/36 months and 2 for not including that in the QAP. Implementation and Conformation Observations**

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