

NECAFS
Preventive Controls
February 2021



Objectives

- FDA Program Alignment Overview
- OHAFO Structure
- PC Inspections Overview



FDA Program Alignment 2017

- Alignment by FDA Regulated Product
- Organization no longer based on Geography

Old Geographic Districts BLT-DO



Maryland

District of Columbia

Virginia

West Virginia



Old Geographic Districts

NWE-DO

Connecticut

Maine

Massachusetts

New Hampshire

Rhode Island

Vermont



Old Geographic Districts

NYK-DO – New York



NWJ-DO – New Jersey



Old Geographic Districts PHI-DO



Delaware

Pennsylvania



Program Division

Office of Human and Animal Food

HAFE-1

MA, ME, NH, NY, RI, VT

HAFE-2

DE, MD, NJ, PA, VA, WV,
District of Columbia



HAFE-1 Management

- Ronald Pace, Program Division Director
- Lori Holmquist, Director of Investigations
- CDR Catherine Beer, Director of Compliance



HAFE-2 Management

- Randy Pack, Program Division Director
- CDR Martin Guardia, Director of Investigations
- Vacant, Director of Compliance

Preventative Controls

21 CFR 117

Inspections



- Who Conducts FDA Inspections
- Number of Inspections Conducted
- Inspection Coverage



PC Inspections

Who conducts the Inspections

- FDA Inspections
- State Contract Inspections
- Training

FY19 and FY20 Preventative Control Inspection Counts

| Division | FY19 | | | FY20 | | |
|----------|-------|-----|------------|-------|-----|------------|
| | State | FDA | Total FY19 | State | FDA | Total FY20 |
| HAFE1 | 220 | 351 | 571 | 214 | 201 | 415 |
| HAFE2 | 364 | 489 | 853 | 402 | 176 | 578 |

Preventative Controls

21 CFR 117

- **Subpart A: General Provisions**
- **Subpart B: Current Good Manufacturing Practice (old part 110)**
- **Subpart C: Hazard Analysis and Risk-Based Preventive Controls**
- **Subpart D: Modified Requirements**
- **Subpart E: Withdrawal of a Qualified Facility Exemption**
- **Subpart F: Requirements Applying to Records That Must be Established and Maintained**
- **Subpart G: Supply-Chain Programs**

Limited Scope PC Inspection

- Subpart A Training Requirements
- Subpart B cGMP
- Subpart F

Limited Scope PC Inspection

A brief review and assessment of required preventive controls:

- Sanitation Controls
- Food Allergen Control
- Process Controls

Full PC Inspection

- All Subparts of 21 CFR 117
- Hazard Analysis

