U.S. FOOD & DRUG ADMINISTRATION

Advanced Bootcamp
February 21, 2024

FDA Food Code Requirements for ROP

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FDA, Office of State Cooperative Programs

Food Code Requires Variance & HACCP Plan for Specialized Processing Methods

- Smoking food for preservation (not flavor)
- Curing food
- Using food additives or adding components such as vinegar
  - As a method of food preservation
  - To render a food non-TCS

3-502.11, 8-201.13

Food Code Requires Variance & HACCP Plan for Specialized Processing Methods

- Operating a molluscan shellfish display tank.
- Custom processing animals for personal use.
- Sprouting seeds or beans.
- Any method determined by the RA to require a variance.

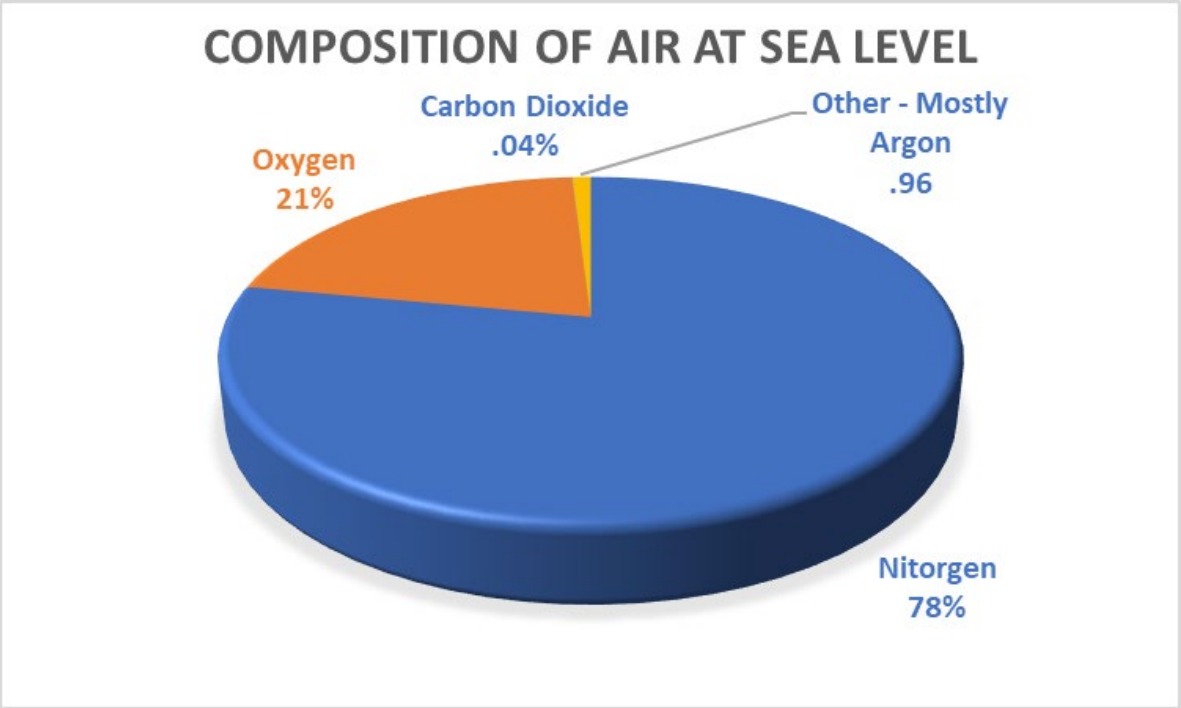
- Packaging TCS food using a ROP method ***except where C. bot. and L. mono. are controlled under § 3-502.12***.

3-502.11, 8-201.13

ROP Food Code Definition

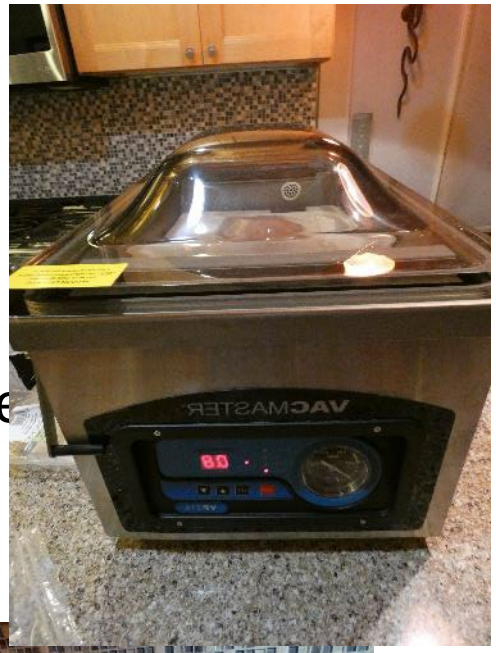
The reduction of the amount of oxygen in a package by:

- Removing oxygen
- Displacing and replacing oxygen with other gas or gasses, or
- Otherwise controlling the oxygen content to < normal at sea level (21%) and
- Involves food for which the hazards *C. bot.* or *L. mono.* Require control in the final packaged form.



Vacuum Packaging

- Vacuum packaging
  - Air is removed from a package
  - The package is hermetically sealed so that a vacuum remains inside the package.



Modified Atmosphere (MAP) & Controlled Atmosphere Packaging (CAP)

- Modified atmosphere packaging (MAP)
  - Atmosphere of a package of food is modified so that its composition is different from air.
  - **Atmosphere may change over time**
    - permeability of the packaging
    - respiration of the food.
  - MAP includes
    - Reduction in the % of oxygen
    - Total replacement of oxygen, or
    - Increase in the proportion of other gases (carbon dioxide, nitrogen)
- Controlled atmosphere packaging (CAP)
  - Modified so that until the package is opened, its composition is different from air, **and continuously controlled**
    - Using oxygen scavengers or
    - a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

Typical MAP Equipment

Typical MAP Equipment

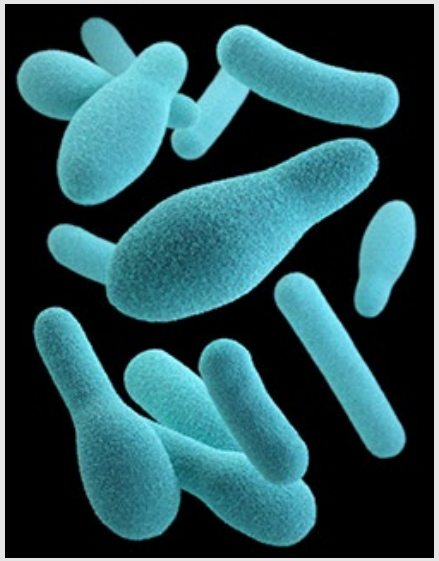
Cook Chill Packaging

- **<u>Cook-chill packaging</u>**, in **which cooked food is hot filled** into impermeable bags that are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Sous Vide Packaging:

- in which raw or partially cooked food is **vacuum packaged** in an impermeable bag**, cooked in the bag**, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Why the Fuss?



- *Listeria monocytogenes*
  - Facultative anaerobe
  - Growth at refrigerated temperatures
  - Ubiquitous: Air, soil, water, food products, animals
  - Serious illness in elderly, young, immunocompromised, and pregnant women
- *Clostridium botulinum*
  - Anaerobe
  - Some types grow at refrigerator temps – Types E and non-proteolytic B&F (38F), found in marine/aquatic environments.
  - Vegetative cells relatively easy to kill with heat, but organism produces spores which are very heat resistant and survive normal cooking temperatures
  - Produces a neurotoxin, one of the deadliest naturally occurring substances known.

ROP without a variance: 3-502.12 HACCP Plan Required

Foods with 2 barriers

- AW of 0.91 or less
- PH of 4.6 or less
- MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA
- FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables

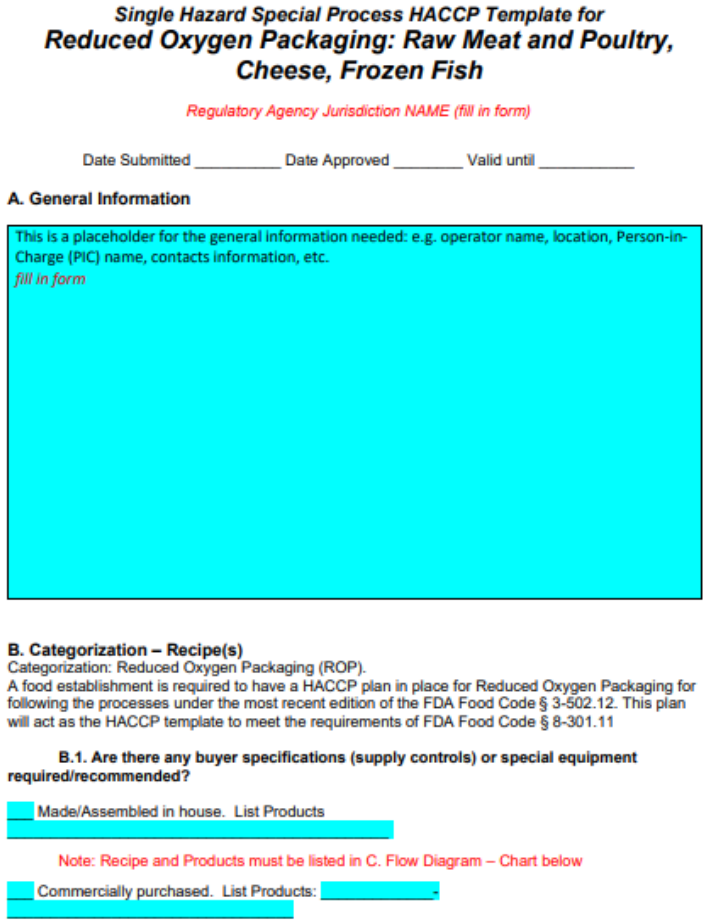
Cheeses: commercially manufactured in a food processing plant with no ingredients added

Fish: must be frozen before, during, and after ROP. Otherwise, variance is always needed.

Cook-chill & sous vide

Cook-Chill & Sous Vide Without a Variance

- The following excludes FISH
- Provide a HACCP plan to RA prior to processing Ensures food is:
  - Prepared and consumed **on the premises** (or off premises within same business entity).
  - No sales to other businesses or directly to consumers.



Single Hazard Special Process HACCP Template for
Reduced Oxygen Packaging: Raw Meat and Poultry, Cheese, Frozen Fish

Regulatory Agency Jurisdiction NAME (fill in form)

Date Submitted _____ Date Approved _____ Valid until _____

A. General Information

This is a placeholder for the general information needed: e.g. operator name, location, Person-in-Charge (PIC) name, contacts information, etc.
fill in form

B. Categorization – Recipe(s)
Categorization: Reduced Oxygen Packaging (ROP).
A food establishment is required to have a HACCP plan in place for Reduced Oxygen Packaging for following the processes under the most recent edition of the FDA Food Code § 3-502.12. This plan will act as the HACCP template to meet the requirements of FDA Food Code § 8-301.11

B.1. Are there any buyer specifications (supply controls) or special equipment required/recommended?

___ Made/Assembled in house. List Products

Note: Recipe and Products must be listed in C. Flow Diagram – Chart below

___ Commercially purchased. List Products: _____

6

3-502.12 (D)

http://www.foodprotect.org/guides-documents/single-hazard-special-process-haccp-template-guidance-document-and-sample-templates/

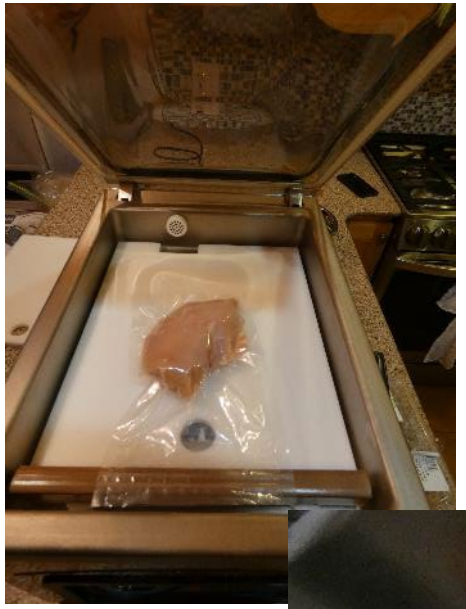
Cook-Chill & Sous Vide Without a Variance

– Cooked in accordance with 3-401.11 (A), (B), and (C).

3-502.12 (D)

Cook-Chill & Sous Vide Without a Variance

- Protected from contamination before and after cooking
- Placed in a package with an oxygen barrier and sealed
  - before cooking, or
  - placed in a PACKAGE and sealed immediately after cooking and before reaching a 135°F



3-502.12 (D)

Cook-Chill & Sous Vide Without a Variance

- Cooled to 5°C (41°F) in the sealed package per the Code and:
  - Held at 41°F ≤7 days and consumed or discarded; or
  - Cooled to 34°F within 48 hrs. of reaching 41°F = 30-day shelf life;
  - Cooled to 34°F within 48 hours of reaching 41°F, removed from 34ºF, and maintained at 41°F ≤ 7 days (can't exceed 30 days);
  - Held frozen with no shelf-life restriction while frozen.

3-502.12 (D)

Cook-Chill & Sous Vide Without a Variance

- Held in a refrigeration unit that is equipped with an **electronic system that continuously monitors** time and temperature and is **visually examined** for proper operation **twice daily.**
- If transported offsite: verifiable electronic monitoring

3-502.12 (D)

Other Requirements

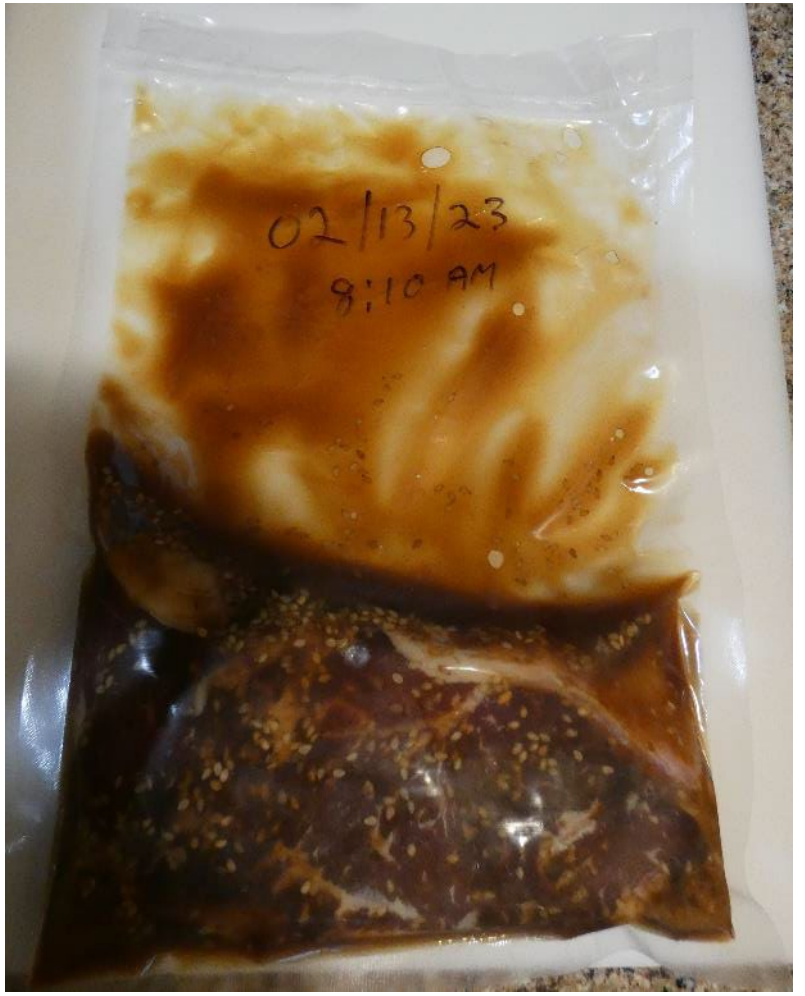
- Labeled with product name & date packaged.
- Maintain cooling and cold holding records for 6 mos. for regulatory review.

3-502.12 (D)

- Operational procedures:
  - Prohibit BHC with RTE
  - Designated work area
  - Cleaning/sanitizing procedures
- Training program
  - Concepts for safe operation
  - Equipment use & operational procedures

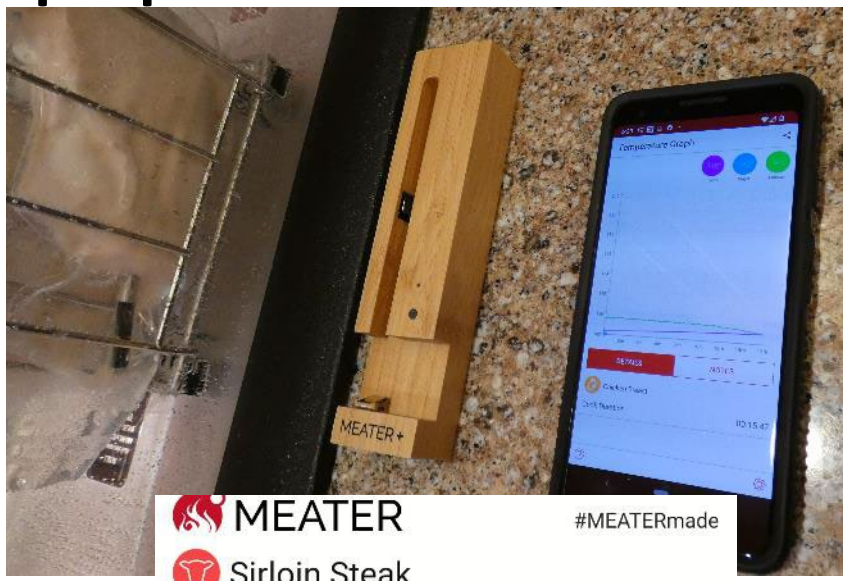
ROP Methods Without a Variance or HACCP Plan

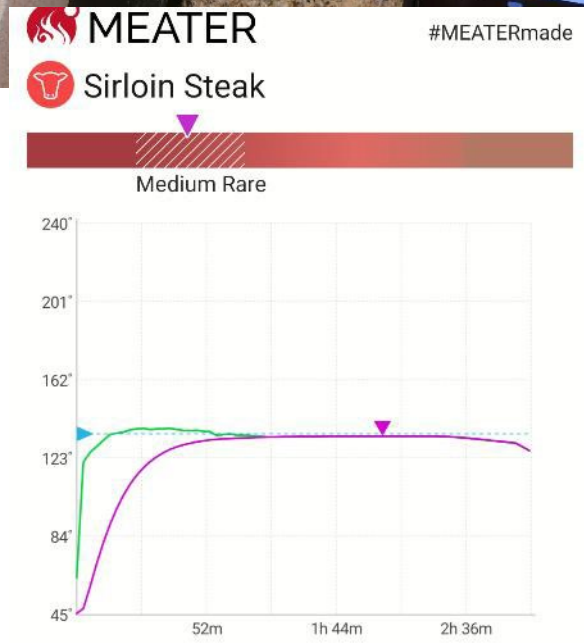
- A HACCP Plan is not required for ROP packaging methods to package TCS food that is always:
  - (1) Labeled with the production **time and date**,
  - (2) Held at 5°C (41°F) or less during refrigerated storage, and
  - (3) Removed from its package in the food establishment **within 48 hours** after packaging.
- Not FISH



3-502.11 (F)

Possible Additional Sous Vide Equipment





Question 1

With this type of ROP, cooked food is hot filled into impermeable bags that are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated.

A) Vacuum Packaging
B) Cook chill
C) Sous vide
D) Controlled atmosphere packaging (CAP)

Question 2

With this type of ROP method, air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package.

A) Vacuum Packaging
B) Cook chill
C) Sous vide
D) Modified atmosphere packaging (MAP)

Question 3

In this type of ROP packaging, raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated.

A) Vacuum Packaging
B) Cook chill
C) Sous vide
D) Modified atmosphere packaging (MAP)

Question 4

Retail establishments may use ROP methods on TCS foods without a variance if the provisions of 3-502.12 (B) are followed exactly as written and it is a food with a high level of competing organisms such as raw meat, raw poultry, raw vegetables, or fresh raw fish.

- True
- False

Question 5

For preparation without a variance, Cook-chill and sous vide products must be cooked according to time/temperatures as specified under 3-401.11 (A), (B), and (C) unless a consumer advisory is provided as detailed in 3-603.11.

- True
- False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HACCP Plan Validation, Review and Approval

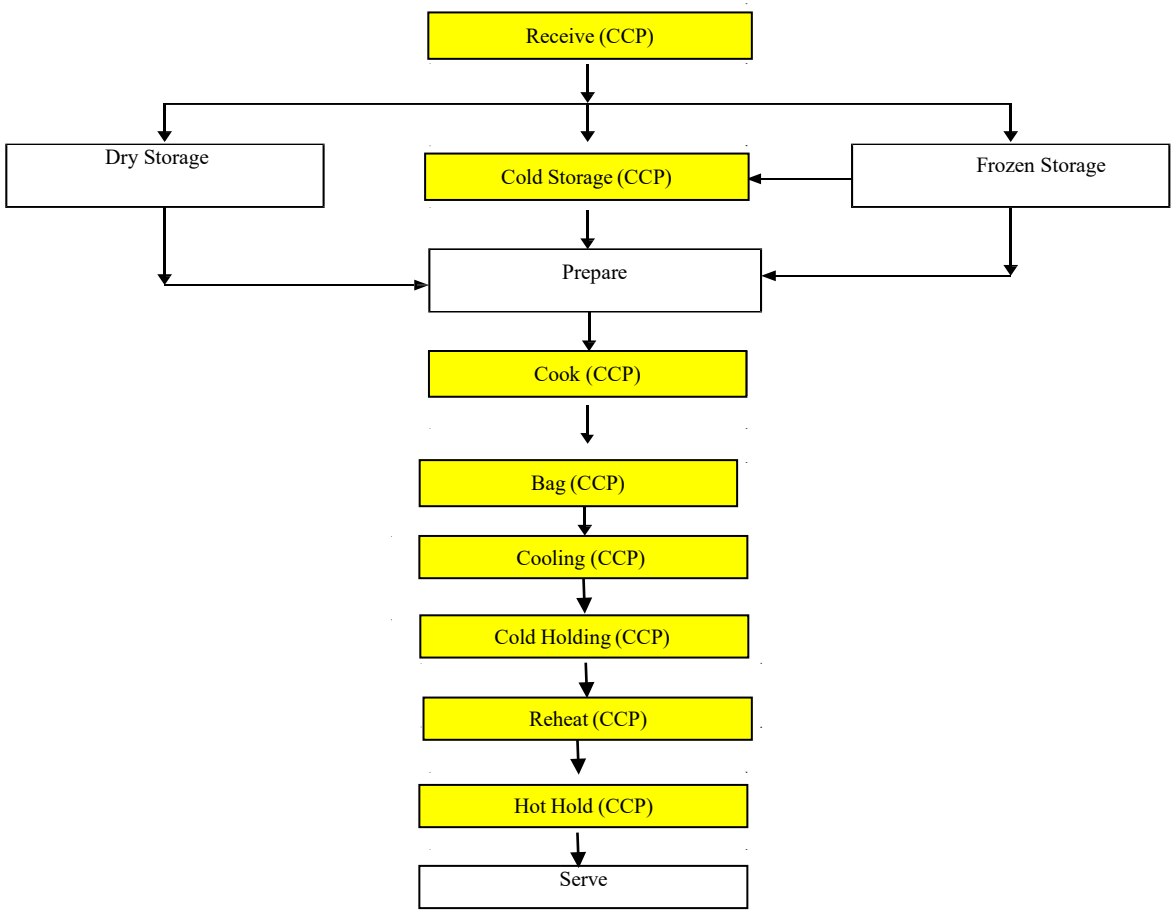
Veronica Bryant, North Carolina Department of Health and Human Services

HACCP Plan Basics

- Food Flow
- Hazard Analysis
- Critical Control Point
- Critical Limits
- Monitoring Procedures
- SOPs/Prerequisite Programs

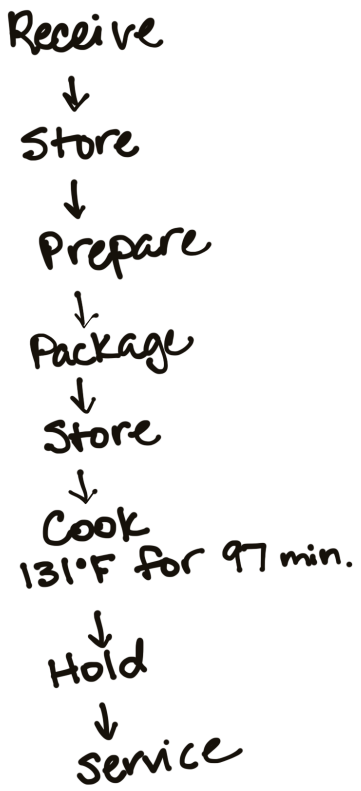
This is the easy part!

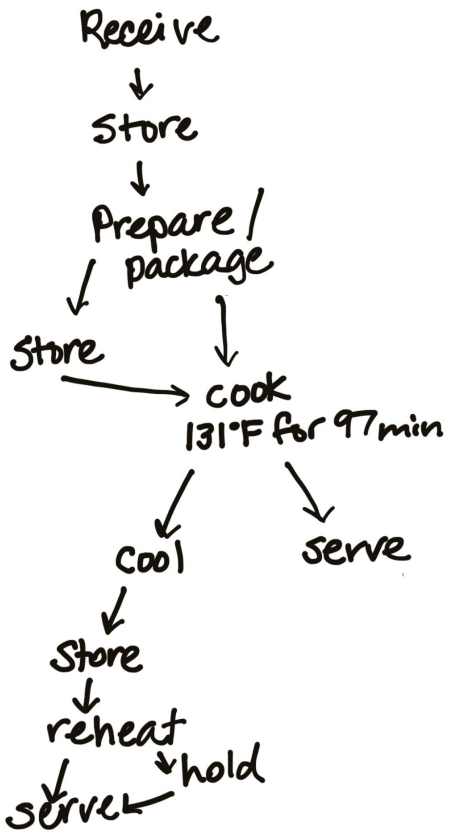
What Would You Do?



Food Flow Examples

Sous vide – steak





Food Flow Examples

Receive → Store → Prepare→ Package → Store → Cook → Hold → Serve

First, we receive the produce from our supplier. Then we store the product in our walk-in cooler. Then we prepare the product. Then the package the product in ROP. We store the product in ROP packaging and then we cook the product to 131F for 91 minutes. We hold the product in a steam table above 135F and then we serve it.

1. Receive
2. Store
3. Prepare
4. Package
5. Store
6. Cook
7. Hold
8. Serve

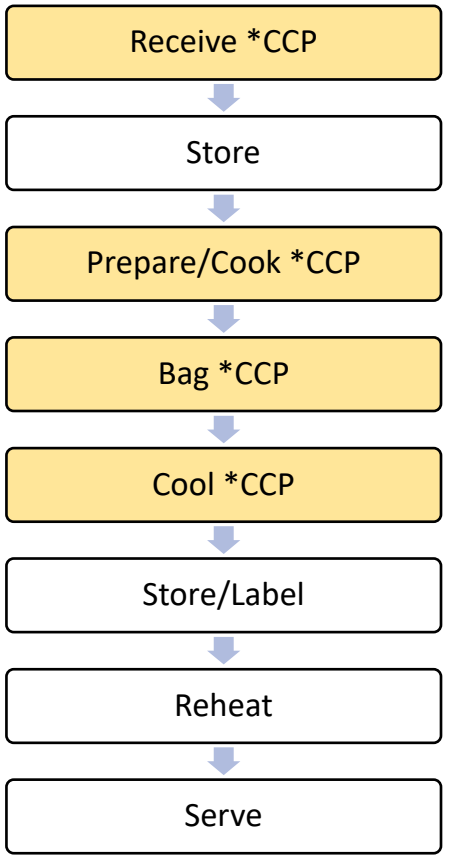
Poll Question – Determining CCPs

Canned Spaghetti Sauce
Ground Beef
Onions, Garlic
Parmesan Cheese
Herbs (Oregano, Basil)
Sugar
Red Wine

1. Add ground beef to steam kettle, cook until meat reaches 155F. Drain
2. Add onions and garlic. Sauté.
3. Add spaghetti sauce, salt, herbs, sugars, red wine, cheese. Stir.
4. Heat to 190F, then simmer while stirring
5. Portion into bags
6. Seal bags
7. Place in ice bath to cool
8. Remove and place in cooler
9. Refrigerate and store
10. Reheat and serve

- Poll Question #1 Which of the following is a primary hazard of concern for this process?
  - –A Salmonella
  - –B Bacillus Cereus
  - –C Clostridium Botulinum
- Poll Question #2 Which steps are the CCPs
  - A 1 and 4
  - B 6 and 9
  - C 4 and 7

Poll Question – Food Flow



- Could you approve a HACCP plan with this food flow diagram?
  - Yes
  - No

Correct Answer – No, store/label CCP is missing, and you cannot approve a plan if there are missing CCPs.

What is Validation?

- Validation –Will the process control the hazards as designed?
  - –Completed by operator
    - Sometimes done informally, operator has validated once they have turned it in
  - –Completed by regulator
    - Regulatory authority agrees or disagrees with operators' validation

Validation	Before
Monitoring	During
Verification	After

ROP Validation Considerations

- Compliance with Food Code Section 3-502.12
  - Time/temperature requirements
  - Final cook temperatures
  - Cook/chill or sous vide not sold in package to consumer
  - Labeling for raw meat ROP

- Is additional science being used?
  - Equivalent Lethality
  - Alternate Monitoring Procedures

Monitoring and Equivalent Lethality

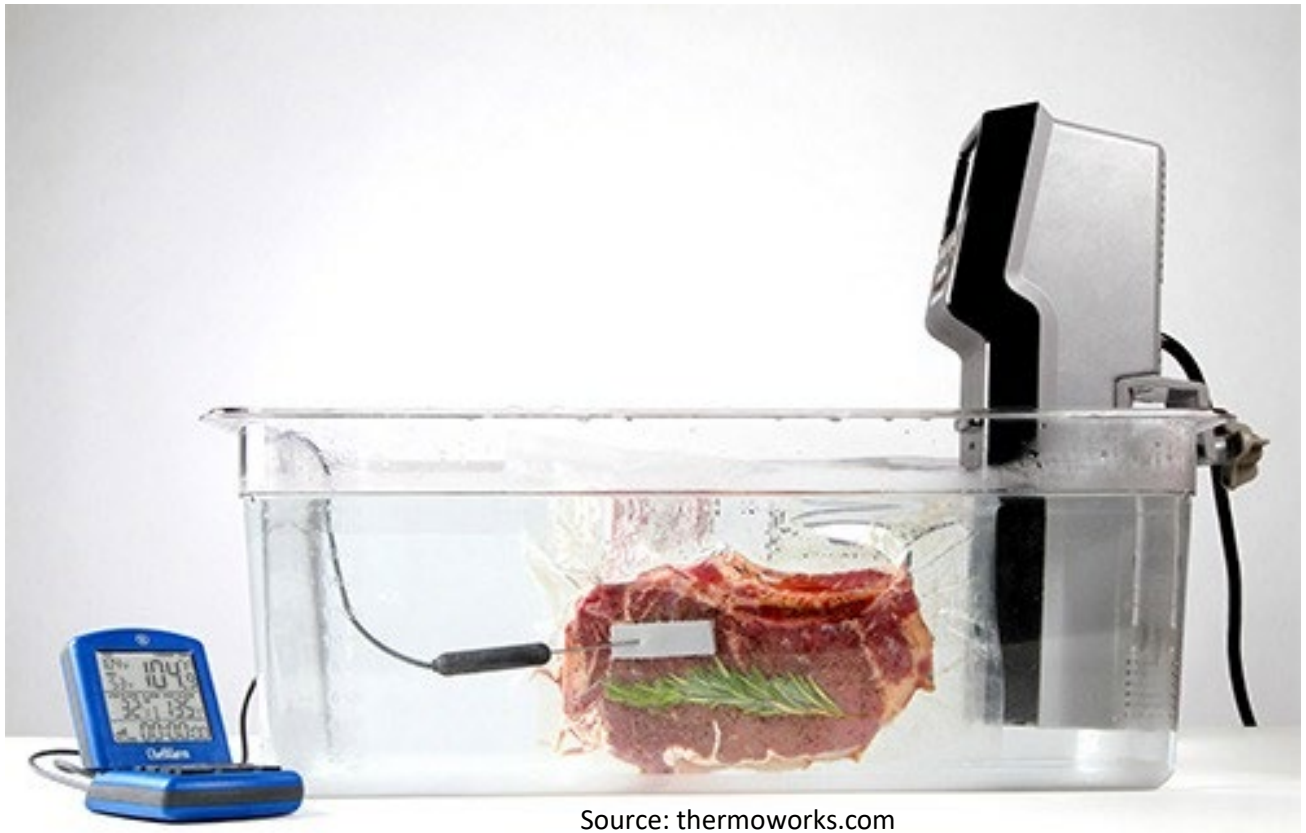
- Using FSIS Appendix A, will not reach FDA Food Code Final Cook Temps
- Cannot meet 3-502.12, will need a variance
- Most commonly used alternate validation used
- Will need to monitor both time and temperature
- Not instantaneous cooking temperature like food code cooking temperature

Table 2. Time-Temperature Combinations for Meat Products to Achieve Lethality

Temperatures stated are the minimum internal temperatures that must be met in all parts of the meat product for the total dwell time listed.[5] An establishment must ensure both time and temperature parameters are met to use this table to support its process achieves the Log reduction target. **Relative humidity**[6] and heating **come-up-time (CUT)**[7] are also **critical operating parameters** when using this table. (See pages 37 and 38 for poultry endpoint time-temperature tables).

Degrees Fahrenheit	*Degrees Centigrade*	*6.5-log $_{10}$ Lethality*	*7-log $_{10}$ Lethality*
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.

HACCP Monitoring Procedures



Source: thermoworks.com

Validated Monitoring Procedures

- Other monitoring methods exist
- Internal temperature is “easy button”
- Operators can use other validated methods

Validated Monitoring Procedures

Douglas E. Baldwin, Sous vide cooking: A review, International Journal of Gastronomy and Food Science, Volume 1, Issue 1, 2012, Pages 15-30.

- Measuring thickness instead of internal temperature
- ”Come up time” included

Table 2
Time sufficient to pasteurize meat, fish, or poultry in water baths from 55 °C/131 °F to 66 °C/150.8 °F. This table is based on the internationally accepted and generally conservative 2 min at 70 °C/158 °F with $z = 7.5$ °C/13.5 °F for a million to one reduction in *Listeria monocytogenes* and applies to all foods (FDA, 2011). For less conservative pasteurization times, see Baldwin (2008) and Fig. 5. This calculation uses a thermal diffusivity of 1.11×10^{-7} m^2/s, a surface heat transfer coefficient of 95 W/m^2-K, and $\beta = 0$ up to 30 mm and $\beta = 0.28$ above 30 mm in (*).

Thickness (mm)	55 °C 131 °F	56 °C 132.8 °F	57 °C 134.6 °F	58 °C 136.4 °F	59 °C 138.2 °F	60 °C 140 °F
5	3:33	2:41	2:00	1:30	1:08	0:51
10	3:35	2:43	2:04	1:36	1:15	1:00
15	3:46	2:55	2:16	1:48	1:28	1:13
20	4:03	3:11	2:32	2:04	1:44	1:28
25	4:17	3:25	2:46	2:18	1:57	1:41
30	4:29	3:38	3:00	2:32	2:11	1:55
35	4:45	3:53	3:15	2:46	2:25	2:09
40	4:59	4:07	3:29	3:00	2:39	2:22
45	5:21	4:29	3:50	3:22	3:00	2:42
50	5:45	4:53	4:14	3:44	3:21	3:03
55	6:10	5:18	4:39	4:08	3:45	3:26
60	6:38	5:45	5:06	4:35	4:10	3:50
65	7:07	6:15	5:34	5:02	4:36	4:15
70	7:40	6:45	6:03	5:30	5:04	4:42

Validated Monitoring Procedures

- Different equipment used
- Additional SOPs
- Monitoring procedure must match validated process

Poll Question -

- When monitoring sous vide cooking temperatures, recording the temperatures of the water bath is sufficient for monitoring procedures
  - True
  - False

File Review and HACCP Approval

- Previous inspections are part of approving HACCP Plan
- What documentation is available?
- Active Managerial Control
- Cooling/Space considerations

Remember

- Retail HACCP Builds on Food Code
- Look for unique hazards or processes outside the code
- Operators can have extra items in plan
- Cannot leave out critical items

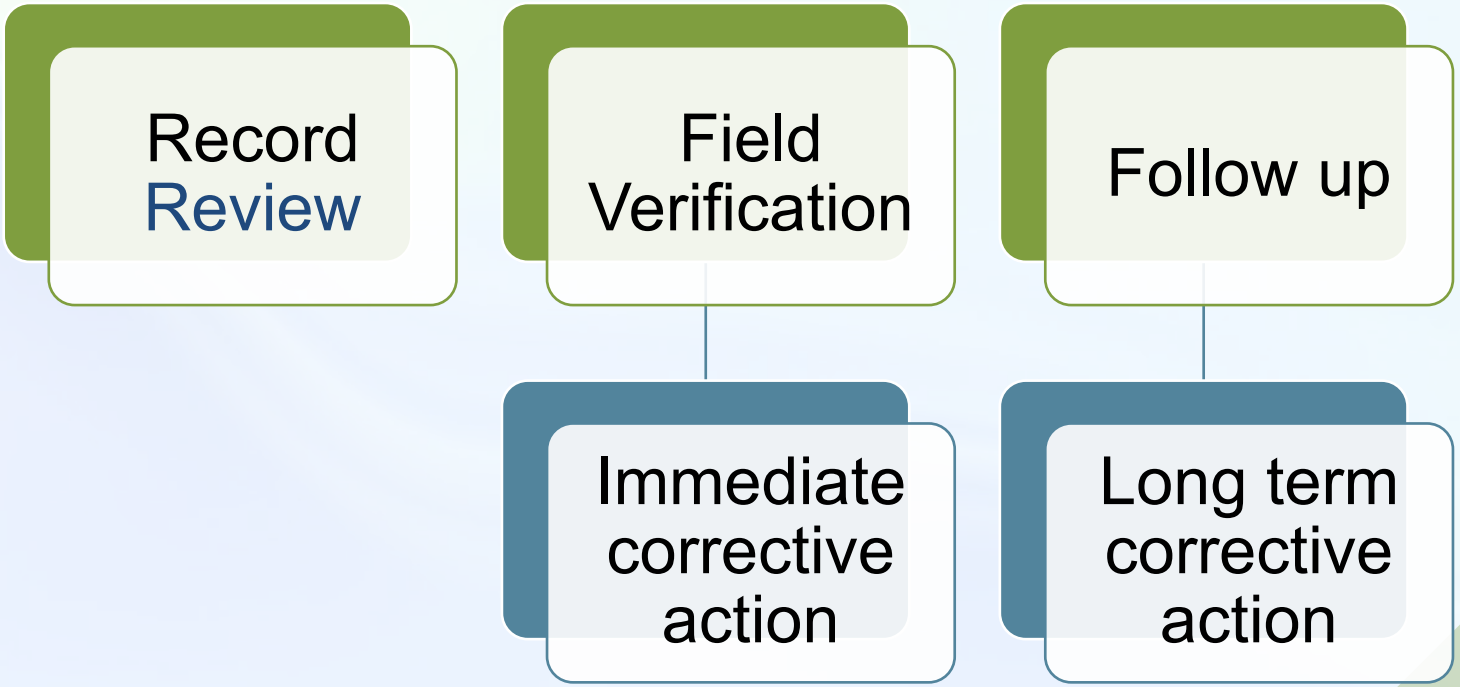
Advanced Bootcamp
February 21, 2024

HACCP Field Verifications

Tara Edwards
Senior Environmental Health Specialist
Southern Nevada Health District

Overview

- **Purpose of a field verification?**
  - **VERIFY that the plan is being followed as written**
- **Do you currently conduct field verifications?**



Southern Nevada Health District

File Review

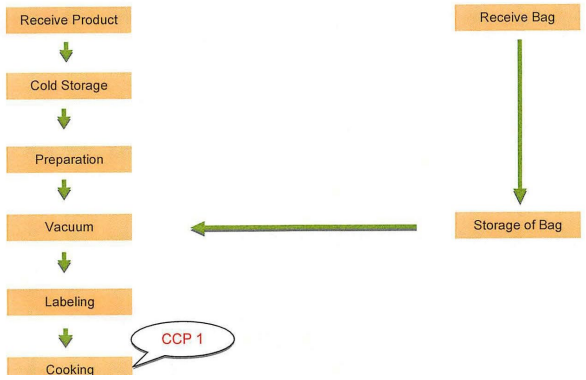
- Products
- Process Flow
- CCP Summary
- Logs
- Previous compliance issues

Cooling Temperature Log

Instructions: Record temperatures at 2 hours, 6 hours and every 12 hours thereafter uring the cooling cycle. Record corrective actions, if applicable. The foodservice manager will verify that the foodservice staff is cooling food properly by visually monitoring foodservice employees during the shift and reviewing, initialing, and dating this log daily. Maintain this log for a minimum of 6 months.

Date	Food Item	Time/ Temp	Time/ Temp	Time/ Temp	Time/ Temp	Time/ Temp	Time/ Temp	Corrective Actions Taken	Initials	Verified By/ Date

Chicken For Cold Preparation - Sous Vide Cooking Flowchart



Proteins - Sous Vide Worksheet

Food Flow	CCP	Hazard (B)Biological (P) Physical (C)Chemical	Critical Limits	
Cooking	CCP # 1	Vegetative Bacteria: Listeria Monocytogenes, Campylobacter Jejuni, Yersinia Enterocolitica, Salmonela Spore Forming/Toxin Producing Bacteria: Bacilius Cereus, Clostridium Perfringens, Staphylococcus Aureus, Clostridium Botulinum Fecal/OralRoute Hazards: Escherichia Coli O 157:H7, ShigellaSPP Viruses: Norovirus, Hepatitis A Parasites: Trichinella Chemical Hazards: Naturally Occurring Chemical Toxins: Aditives etc	-Water temperature for (Beef & Lamb) 138.0 F -Core Temperature 138.0 F for at least 18 minutes -Water temperature for (Pork) 145.0 F -Core Temperature 145.0 F for at least 4 minutes -Water temperature for (Poultry) 147.2 F -Core Temperature 147.2 F for at least 3 minutes	Food Prepare temperatures record in Cool will be checke Logger Therm DUO) K Type a needle probe part of the me the Core temp time of the co secure the pu avoid any likir approved foa for Specs. If cl manually, the monitor temp each batch by sous vide tape
Chilling	CCP # 2	Vegetative Bacteria: Listeria Monocytogenes, Campylobacter Jejuni, Yersinia Enterocolitica, Salmonela Spore Forming/Toxin Producing Bacteria: Bacilius Cereus, Clostridium Perfringens, Staphylococcus Aureus, Clostridium Botulinum Fecal/OralRoute Hazards: Escherichia Coli O 157:H7, ShigellaSPP Viruses: Norovirus, Hepatitis A Parasites: Trichinella Chemical Hazards: Naturally Occurring Chemical Toxins: Aditives etc	After cooking all proteins to the desire core temperature and time. Chill down each bags immediately in a bath of ice and water 33.8 F. The final Core temperature of 41.0 F should be reach following the FDA requirement : 135 F - 70 F in 2 hours 70 F - 41 F within additional 4 hours (not to exceed 6 hours) Cool to 34F within 48 hours of reaching 41F	Food Prepare temperatures record in elec Temperature a Data Logger (BLUETHERM Hypodermic r the thickest p able to check during the all process. To se the bag and a use a FDA app Appendix for manually tem checked at le hour, and eve

APPROVED

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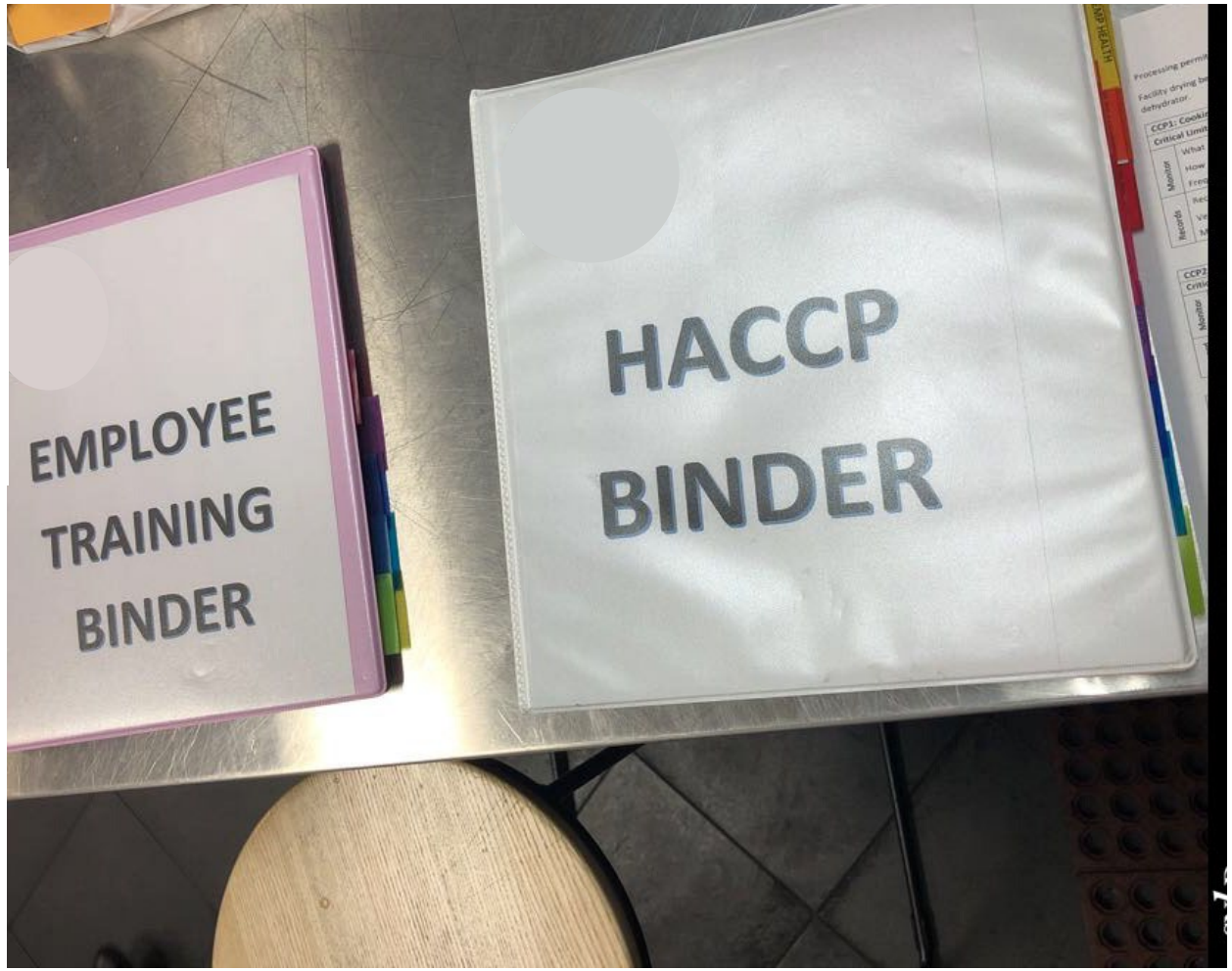


Verify Knowledge/ Training

- When is the best time to verify knowledge/training?
- Observe processing
  - Following described procedures
- Ask questions throughout field verification/inspection
  - Open ended questions
    - Critical limits
    - Monitoring procedures
- Training Records

Ingredients

BEEF

Black Angus Choice Fillet 8 oz.

Black Angus Choice Fillet 9 oz.

Black Angus Choice Fillet 12 oz.

Black Angus Choice Fillet 20 oz.

Choice New York 12 oz.

Prime Block Cut Sirloin 6 oz.

Prime Rib-eye 20-22 oz.

Tender Chuck Roll LB

Prime Porterhouse 40 oz.

Steak Ends LB

Triangles LB

Tenderloin Tips LB

PORK

Chop 14 oz.

CHICKEN

Breast Sliced LB

Verify Product Description

HACCP FLOW CHART Soups Stews Sauces, Pumpable Protein

Receive Product

TCS @41°F or below	Non TCS

↓

Hold ingredients TCS @ 41°or below - Hold Non TCS in Dry Storage

↓

Assemble Product Ingredients and Cook in Kettle CCP1

Soups stews and sauces 194° 10 min	Cheese Sauce, Mac & Cheese 14

↓

Pump product 135°F bag and label CCP 2

↓

Tumble Chill 135-70° in 2 hours; 70-41° in 4 additional hours CCP 3

↓

Transfer to 34° Walk in Chill and Veify 34° within 48 hours CCP3B

↓

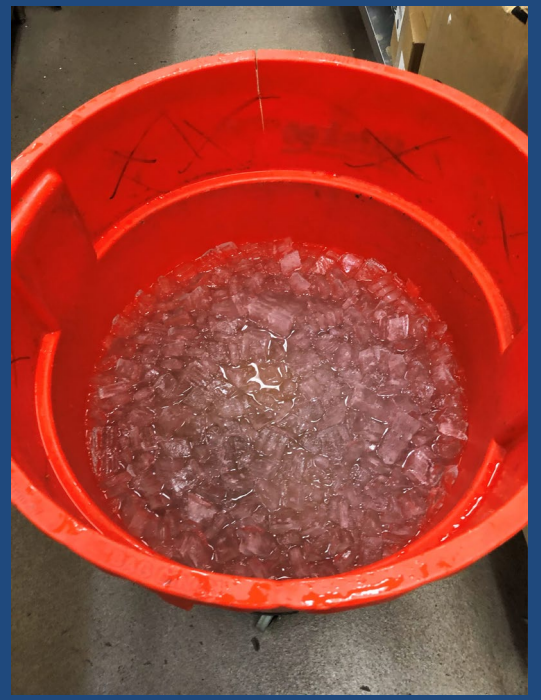
Hold Cold 34° not longer than 30 days CCP 4

↓

Remove from Bag

↓

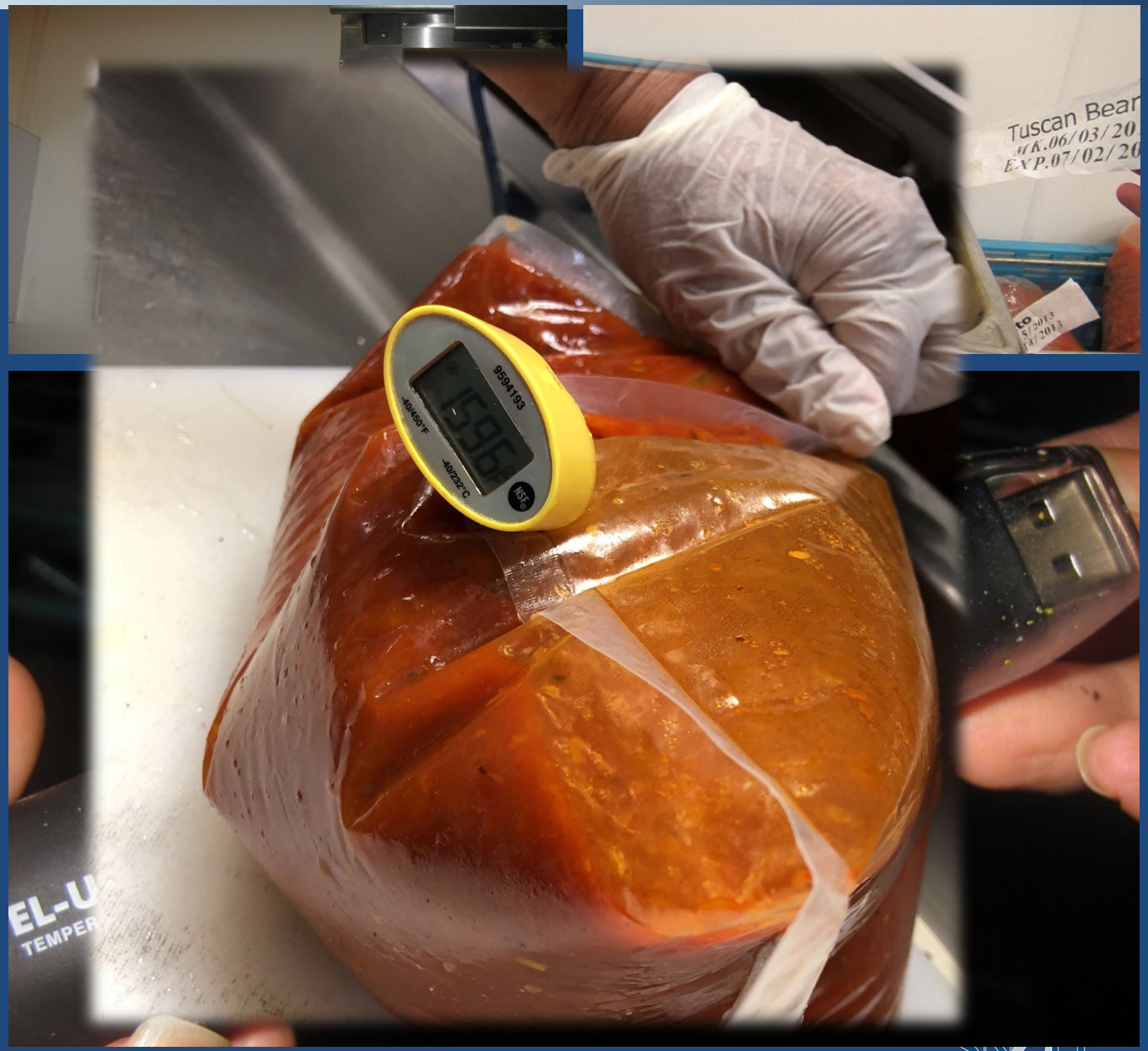
Reheat to 165° within 2 hours and Serve



Verify Process Flow

Verify Critical Limits are met

- Specified in the plan



Verify Monitoring Procedures

- What
- How
- Frequency

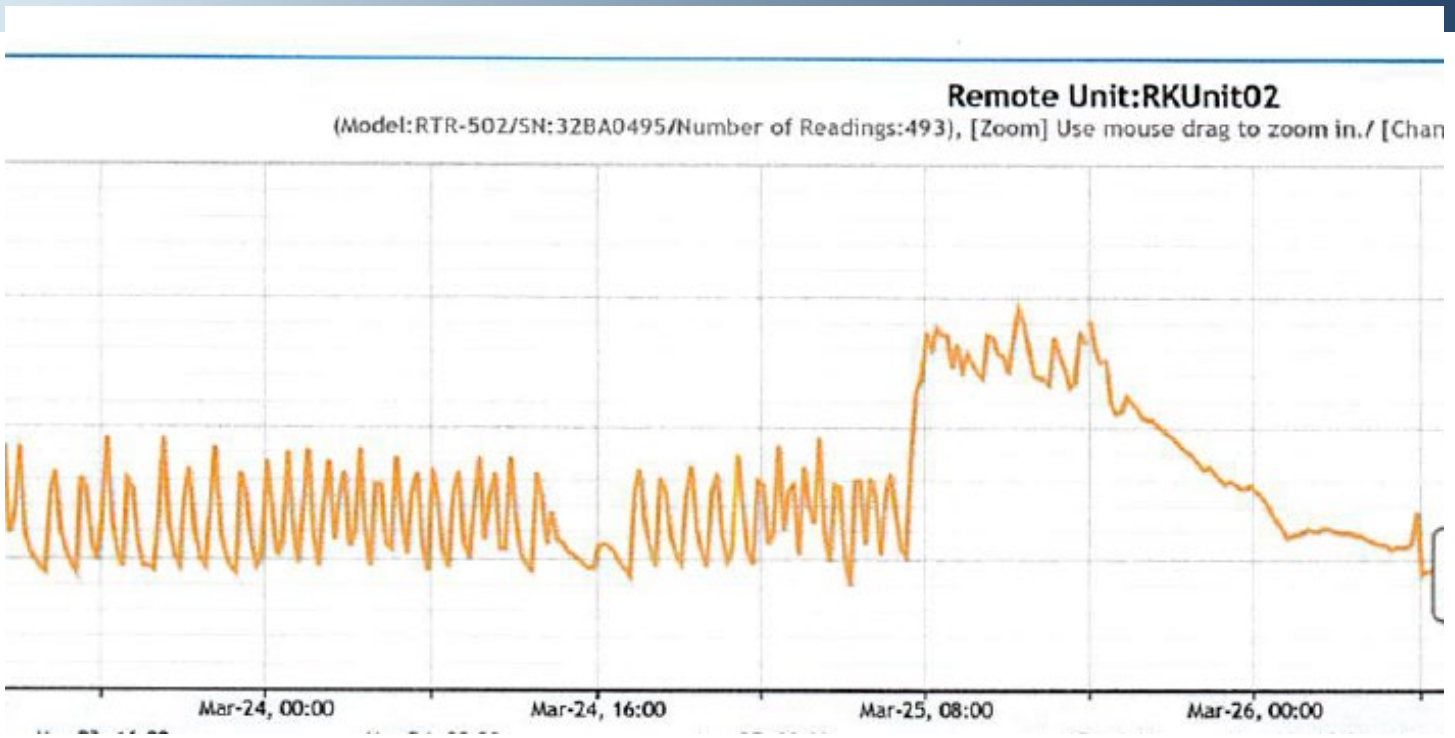
Verify Immediate Corrective Action

- **Verify that the written Corrective Actions are followed for out of compliance issues**

Long Term Corrective Action

When should the HACCP approval be revoked?

Level of Non-compliance	Corrective Action
Missed Critical Limit	Immediate correction, including discarding of food if justified, follow up within 10 days to ensure continuing compliance
Missed monitoring of critical limit	Immediate correction, have employees begin monitoring during visit, follow-up within 10 days to ensure continuing compliance
Other areas of non-compliance	Follow-up within 30 days to make sure either the plan has been changed or procedure has changed



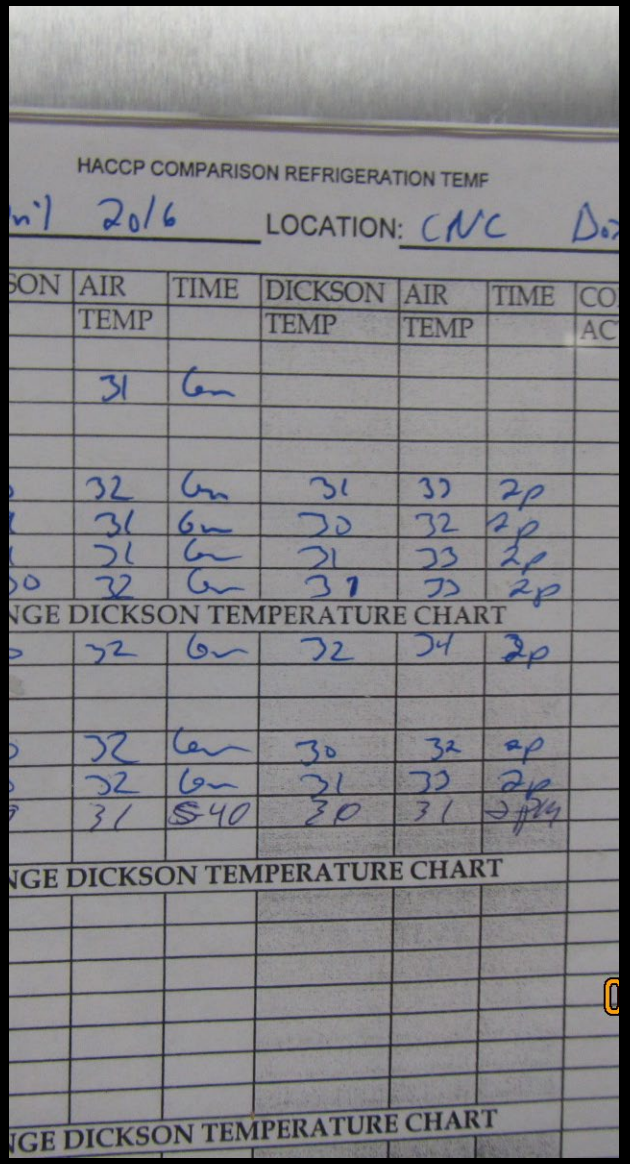
Verify Record Keeping and Person in Charge Verification

- Documentation
  - HACCP Plan and approval
  - Records
    - CCPs
  - Corrective actions
  - Prerequisites (e.g., calibration records)

Verify Record Keeping and Person in Charge Verification

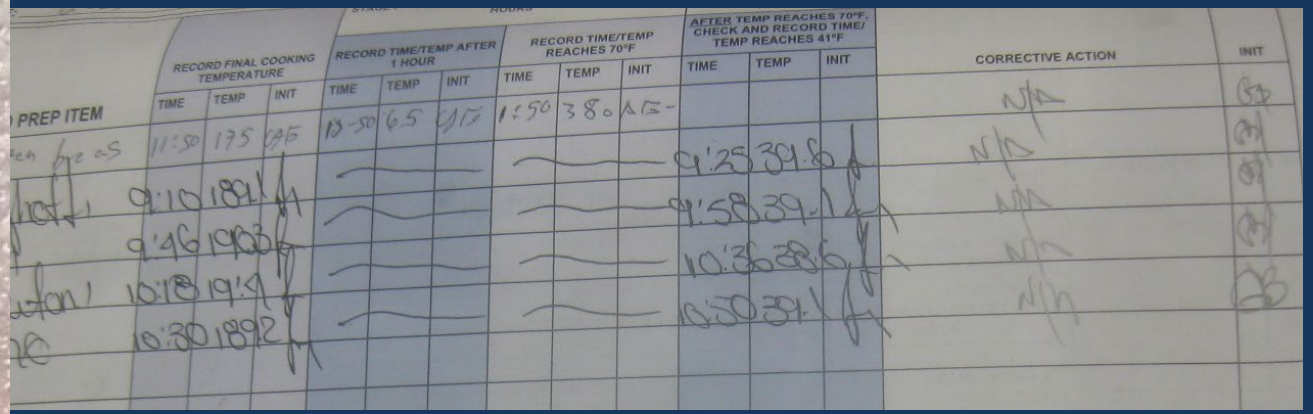
- Records complete?
- Monitoring
- Corrective actions
- Verification
- Min of 3 batches/products

- Record maintained per plan?



Verify Record Keeping and Person in Charge Verification

- Are the records accurate/realistic



Verify Prerequisites

- Proper calibration of equipment
  - Method
  - Frequency
  - Documentation
- Other Prerequisites

Any Questions