Cold Hold Enforcement Strategies
Timeline of 41°F from FDA to North Carolina

- **1993**: FDA lowers the rate from 45°F to 41°F.
- **1997**: Stakeholders raise concern; CFP gives a 5 year phase in period for equipment.
- **2006**: Many states adopt the phase in period and NSF/ANSI revised standard 7 based on equipment design to meet 41°F under normal conditions in retail food.
- **2012**: NC adopts 2009 food code amending 41°F allowing NC food establishments to have 7 years to meet 41°F.
- **2019**: 45°F sunsets for cold holding.
## Where is North Carolina Retail?

Data compiled from County Risk Factor Studies

<table>
<thead>
<tr>
<th>Category</th>
<th>IN</th>
<th>OUT</th>
<th>Out Of Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seafood</td>
<td>41</td>
<td>18</td>
<td>31%</td>
</tr>
<tr>
<td>Produce</td>
<td>76</td>
<td>80</td>
<td>51%</td>
</tr>
<tr>
<td>Institution</td>
<td>90</td>
<td>75</td>
<td>45%</td>
</tr>
<tr>
<td>Meat Market</td>
<td>175</td>
<td>42</td>
<td>19%</td>
</tr>
<tr>
<td>Hospital</td>
<td>5</td>
<td>14</td>
<td>74%</td>
</tr>
<tr>
<td>Full Service</td>
<td>154</td>
<td>337</td>
<td>69%</td>
</tr>
<tr>
<td>Deli</td>
<td>70</td>
<td>143</td>
<td>67%</td>
</tr>
<tr>
<td>Elem. School</td>
<td>102</td>
<td>70</td>
<td>41%</td>
</tr>
<tr>
<td>Fast Food</td>
<td>122</td>
<td>216</td>
<td>64%</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>835</strong></td>
<td><strong>995</strong></td>
<td><strong>54%</strong></td>
</tr>
</tbody>
</table>
## State Cold Hold Study

<table>
<thead>
<tr>
<th>Basic Statistics</th>
<th>Out of Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluations Completed</td>
<td>68</td>
</tr>
<tr>
<td>Refrigerators Observed</td>
<td>199</td>
</tr>
<tr>
<td>Total Temperature Observations</td>
<td>424</td>
</tr>
<tr>
<td>% Non-compliance</td>
<td>79.1%</td>
</tr>
<tr>
<td>Average Temperature</td>
<td>45.2°F</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>4.3</td>
</tr>
<tr>
<td>Median Temperature</td>
<td>44.0°F</td>
</tr>
<tr>
<td>95% Confidence Interval</td>
<td>44.8°F – 45.0°F</td>
</tr>
</tbody>
</table>
% Non-compliance by Food Group

- RTE Foods: 28.9%
- Milk/Dairy: 16.2%
- Cooked Foods: 23.6%
- Sushi Fish: 2.1%
- Raw Eggs/Egg Products: 1.7%
- Cut Leafy Greens: 8.4%
- Cut Produce: 9.3%
- Raw Animal Proteins: 9.8%
How will Inspections be Marked with this Regulatory Change?

• Historically, we have marked OUT for non-compliance with no point deductions on the first inspection.

• How we address food safety is most important. Not point deductions.
  • Can the food be served safely?
Question: What rules are affected on this date?

Answer:

• Cold Holding Temperatures\(^P\) (#20, 3 pts)
• Date Marking\(^{PF,P}\) (#21, 3 pts)
• Cooling\(^P\) (#18, 3 pts)
• Time As A Public Health Control\(^{PF,P}\) (#22, 2 pts)
• Thawing\(^C\) (#33, 1 pt)
• Slacking\(^C\) (#33, 1 pt)
• Cooling Method\(^{PF}\) Capacities (#31, 1 pt)
What to do now..................

• Complete Cold Hold Assessment sheets.
• Educate the operator about what the specific issues are with their facility.
• Start pointing out ways establishments can get into compliance with their existing equipment.
• Encourage staff training and equipment maintenance (low-cost solutions)
• RCPs for behavioral based problems.
• Prepare operators for potential points losses/consequences of non-compliance.
Compliance Strategies

1. Assess equipment
2. Evaluate Menu
3. Active Managerial Control of cooling
4. Equipment intended use
5. Proper stacking of foods in units
6. Time as a Public Health Control (4-6 hours depending)
Corrective Action Options

• Education
• Voluntary Disposal
• Risk Control Plans (RCPs)
• Variance Alternative
Education

- Cold Hold Campaign Signage/Posters
- County-developed educational documents
- Utilize Cold Holding Assessment sheet (if not already used)
Voluntary Disposal

- Use for small batches of food when operator has no information about the product

- We do not have Embargo Authority for foods between 42°F-45°F when only concern is temperature

- When food isn’t date-marked and operator has no information about product, ask questions
Risk Control Plans (RCPs)

• These are best for behavior-focused solutions

• Teaching an employee the correct method for controlling risk factors

• **Example RCP:**
Requesting a RCP for proper ambient cooling in the 38°F walk-in cooler prior to placing food into a make unit (diced tomatoes).
Verification/Consultative Visits

• When/why the need of VR?
  • In-service training
  • Follow up on RCPs
  • Education didn’t feel sufficient based on problems observed during inspection
Long-Term Solutions

• Mark OUT on inspection sheet

• Use of RCPs

• Implementation of Standard Operating Procedures (SOPs)

• Issuance of Variances:
  • Date marking for 4 days at 42°F – 45°F
  • TPHC starting between 42°F – 45°F not to exceed 70 °F degrees
Reasoning

• The *Historical Record of Cold Holding Temperature Provisions* in the 2013 FDA Annex discusses how the FDA decided on 41°F and what they did to bridge the gap

• ‘Thus, there are mechanisms in place to allow industry flexibility in holding foods out of temperature control and the exemption for holding at 45°F was no longer necessary, given equipment capabilities, existing provisions of the Food Code that could be utilized (e.g., *variances, time as a public health control*), and the impact on public health.’
Variance Alternative

• Why the allowance of variances for these citations?
  • It is important to understand that the risk is being addressed.
  • LM cultures are equal when comparing RTE TCS foods kept at 42°F – 45°F for 4 days or 41°F at 7 days
  • 4-day date marking for foods held at 42°F-45°F
  • 24 hr date marking variance (42°F-45°F)
  • TPHC starting at 42°F – 45°F for 4 hours and kept at 70°F or below is equal to 41°F for 6 hours at 70°F or below

• NCDHHS will approve the variances with the county support
  • Templates have been developed to streamline the process
  • Templates will require equipment information
    • When the equipment is replaced, the variance would be removed
When to Issue an Intent to Suspend

• Cannot be based solely on cold holding between 42°F-45°F

• Too many risk factors to control (cooling, date marking, thawing, etc.)

• Needs to be well documented
  • Show progression on multiple inspections/visits

• NCDA cannot support embargo on temperature alone until it gets above 45°F.
Scenario 1: Cold Holding/Date Marking 42°F-45°F

• Prep-style cooler has TCS food items holding between 42°F-45°F

• What should the REHS do?
Scenario 1: Cold Holding/Date Marking 42°F-45°F

- 1st Offense

- REHS marks #20 and #21 OUT on Inspection Form, takes 0 credit
  - Discard RTE, TCS foods over 4 days old that are required to be date marked
  - Rule out behavioral issues (too much food, cooling, maintenance, etc.)
  - Have PIC contact refrigeration technician
  - Educate
  - Implement Risk Control Plan
  - Option of Time as a Public Health Control
  - Option of use of ice
Scenario 1: Cold Holding/Date Marking 42°F-45°F

• 2nd Offense

• REHS marks #20 and #21 OUT on Inspection Form, takes half credit
  - Review Risk Control Plan
  - Time as a Public Health Control
Scenario 1: Cold Holding/Date Marking 42°F-45°F

- 3rd Offense

- REHS marks #20 and #21 OUT on Inspection Form, takes full credit
  - Option of utilizing a Variance
  - Building the case to pursue Intent to Suspend
Scenario 2: Cooling with 42°F-45°F

- All mechanical refrigeration in the establishment is measuring 42°F-45°F
- Foods are found cooling in the walk in cooler
  (cut tomatoes @67°F, chili @135°F, potato salad @47°F)
- These foods are found in shallow portions, metal pans, loosely covered and are stored properly
- PIC states “this is how foods are cooled in establishment”
- You decide foods will not cool to 41°F due to mechanical refrigeration
- Potato salad was made from ambient ingredients, 3 hours ago

What should the REHS do?
Scenario 2: Cooling with 42°F-45°F

• 1st Offense

• REHS marks #18 OUT for potato salad, takes 0 credit
  • CDI of cooling is education if foods cool within 45°F rate (use calculations). Food can be kept. Educate on alternatives such as limited cooling of menu items.
  • Implement Risk Control Plan
  • Educate
  • Implement better cooling methods to achieve proper cooling parameters (i.e. use of ice as an ingredient, ice baths, ice wands, incorporating freezer, etc.)-TO PREVENT FURTHER VIOLATIONS
Scenario 2: Cooling with 42°F-45°F

- 2nd Offense
- Beginning taking points depending on the severity of the violations seen
- Discuss options of remediation
- Review Risk Control Plan
- Build case for intent to suspend
Summary

• No point deductions for first inspection only
• Education can be considered a CDI
• Determine the root cause-Why is the food above 41°F?
• Variance is an option
• **Cannot** take points under variance #27
• Not all scenarios can be addressed in the PS contact a Regional if you need assistance
• DOCUMENT DOCUMENT DOCUMENT
• Be reasonable
Questions?