FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products

2013

This guidance document is designed to help establishments that manufacture mechanically tenderized beef products:

- Identify the minimum components of validated cooking instructions;
- Identify the two elements to validating cooking instructions:
  - Scientific and technical support (design) and
  - In-plant demonstration data (execution)

To help establishments meet the first element of validation, this document contains attachments establishments can use as supporting documentation for cooking instructions.

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What is the purpose of this Compliance Guideline?

The purpose of this guidance document is to help establishments develop validated cooking instructions to use on the labels of mechanically tenderized beef products. Specifically, it articulates:

- The minimum components validated cooking instructions should contain;
- The two elements to validating cooking instructions:
    - Scientific and technical support (design) and
    - In-plant demonstration data (execution)

This document contains attachments that establishments can use as supporting documentation to meet the first element of validation.

It is important to note that this Guideline represents FSIS's current thinking on this topic. The guideline will be updated in response to comments, as necessary, and to be consistent with any changes made to the rule should it become final.

Who is this Compliance Guideline designed for?

This guidance is designed for all official FSIS regulated establishments that produce raw or partially cooked mechanically tenderized beef products. Such products include raw or partially cooked needle or blade tenderized beef products, including mechanically tenderized beef products that have also been injected with marinade or solution. This guidance is not intended for establishments that produce mechanically tenderized product that will be fully cooked at an official establishment.

How can I comment on this Compliance Guideline?

This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). More information can be found on the FSIS Web page:

www.fsis.usda.gov/Significant_Guidance/index.asp

Request for comments:

FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The document will be updated in response to comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments

directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0013. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to http://www.regulations.gov.

Why should mechanically tenderized beef products be labeled with validated cooking instructions?

Consumers often request restaurants to cook steaks "rare" or "medium-rare". Generally, intact cuts of muscle such as steaks are rendered free of pathogenic bacteria if cooked to these desired levels of doneness provided the steaks are seared according to the recommendations in the Food Code. According to the 2009 Food Code §3-401.11(C)(3), a raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if among other things, "the steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces." Seared intact steaks may be considered a ready-to-eat food because contamination with pathogenic bacteria such as *Escherichia coli* O157:H7 (*E. coli* O157:H7) and other Shiga-toxin producing *E. coli* (STEC) organisms, if present, would only occur on the surface of the product. As long as the external surfaces are exposed to lethality temperatures, the product can be rendered safe without thoroughly cooking the product through the interior (NACMCF, 1997).

In some cases, however, intact cuts of muscle such as steaks are made non-intact through methods of mechanical tenderization, such as needle and blade tenderization. In these cases, any contamination on the outside of the steak may be carried to the inside through penetration by needles and other devices. As a result, it is important that mechanically tenderized beef products be cooked thoroughly as opposed to "rare" or "medium rare".

Despite the safe handling instructions to "cook thoroughly," recent outbreak data indicate that for needle or blade tenderized raw beef products, consumers, restaurants, and retail stores do not always thoroughly cook these products to a temperature and time combination sufficient to destroy harmful bacteria, such as *E. coli* O157:H7, in the product. Indeed, in many cases, patients associated with outbreaks reported preparing or ordering steaks as "rare" or "medium-rare." Since 2003, the Centers for Disease Control and Prevention has received reports of five outbreaks attributable to needle or

blade tenderized beef products prepared in restaurants and consumers' homes. Among these outbreaks, there were a total of 157 *E. coli* O157:H7 cases that resulted in 34 hospitalizations and 4 cases of hemolytic uremic syndrome (HUS). Failure to thoroughly cook a mechanically tenderized raw or partially cooked beef product was a significant contributing factor in all of these outbreaks (Culpepper et al., 2009; Swanson et al., 2005).

Cooking instructions for these products should inform consumers that these products need to be cooked to a specified minimum internal temperature, and should identify whether they need to be held at that minimum temperature for a specified time before consumption, i.e., rest or dwell time, to ensure that they are thoroughly cooked. This document provides guidance on how to validate such cooking instructions.

What are the minimum components of validated cooking instructions that should be on the label?

The cooking instructions should include, at a minimum:

(1) The method of cooking;

(2) A minimum internal temperature validated to ensure that potential pathogens are destroyed throughout the product;

(3) Whether the product needs to be held for a specified time at that temperature or higher before consumption; and

(4) Instruction that the internal temperature should be measured by the use of a thermometer.

The cooking instructions included on the label should be practical and likely to be followed by consumers.

To the right is an example of cooking instructions which meet these minimum components. Note that these instructions are in addition to the Safe Handling instructions required on raw beef products in 9 CFR 317.2(l)(1).

For Food Safety and Quality Follow These Cooking Instructions:
Grill:
1) Heat grill on Medium-High.
2) Cook for 3 minutes, flip and cook for another 3 minutes to an internal temperature of 145°F as measured with a food thermometer.
3) After removing from the grill, allow meat to rest for at least three minutes before serving.

In this example, to meet requirements, an establishment would need to validate that the cooking instructions will achieve the time and temperature combination on the label (i.e., 145°F for 3 minutes). Once it validates the cooking instructions, the establishment would not need any additional supporting documentation to meet the first element of validation. No additional documentation would be needed

because the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks supports that adequate reduction of pathogens would be achieved with a desired endpoint temperature of 145°F and a rest time of 3 minutes.

How can an establishment validate their cooking instructions?

There are two main elements to validation which also apply to the process of validating cooking instructions.

ELEMENT 1: Scientific or Technical Support (Design)

The first part to validating cooking instructions is providing scientific or technical support for the judgments made in designing the cooking instructions. The scientific support should demonstrate that:

- The cooking instructions provided can repeatedly achieve the desired minimum internal temperature and, if applicable, rest time and
- The minimum internal temperature and, if applicable, rest time achieved by the instructions will ensure that the product is thoroughly cooked to destroy potential pathogens throughout the product.

To collect the first type of support, demonstrating that the cooking instructions can repeatedly achieve the desired minimum internal temperature and, if applicable, rest time, the cooking instructions are generally repeated under actual consumer cooking conditions to ensure the desired endpoint temperature and rest time can consistently be met. For example, if an establishment has instructions which state to cook a mechanically tenderized steak on a grill for 7 minutes in order to heat the steak to 160°F then, put simply, the establishment would need to heat the steak on different types of grills several times to ensure that it actually takes 7 minutes to heat the steak to 160°F under different consumer cooking conditions. As a result, **this first type of supporting documentation does not need to consist of microbiological data but rather should contain data demonstrating the cooking instructions consistently achieve the desired endpoint temperature under worst-case scenario conditions**.

It is the responsibility of the establishment to identify supporting documentation that demonstrates consumers can achieve the endpoint temperature and rest time by following the cooking instructions. This type of documentation generally consists of a scientific article from a peer-reviewed journal, a published processing guideline, or data gathered in-plant or at a test kitchen. Data can be gathered anywhere the consumer cooking equipment is available.

A number of journal articles have been published in which researchers have already validated cooking instructions for mechanically tenderized beef products. To assist establishments with developing cooking instructions, Attachment 1 of this guideline contains a summary of published supporting documentation for cooking instructions that

have been found to achieve a sufficient endpoint temperature and rest time, along with the critical operational parameters included in each study. Establishments may utilize these cooking instructions on the labels of their products provided that the actual product being produced and labeled is similar to the product the instructions were developed for. For example, if an establishment produced a 1 inch thick needle tenderized steak, the following instructions could be used as they have been validated according to the research conducted by Luchansky et al (2012) provided in Attachment 1:

For Food Safety and Quality Follow These Cooking Instructions:
Grill:
1) Heat grill on Medium-High.
2) Cook for 5 minutes, flip and cook for another 5 minutes to an internal temperature of 160°F as measured with a food thermometer.

These instructions are provided for a gas grill method of cooking which has been found to be the preferred method for cooking steaks (Savell et al., 1999). In the research, provided in Attachment 1, the study authors determined the amount of time it would take on a gas-grill to reach different desired endpoint temperatures for steaks of different thicknesses. Only products which reached endpoint temperatures sufficient to produce a ready-to-eat product (that is one in which at least a 5-$\log_{10}$ reduction of *Salmonella* and shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) organisms such as *E. coli* O157:H7 is achieved) are included in Attachment 1.

Establishments using cooking instructions from Attachment 1 would not need to provide the original journal articles used to develop the instructions because all of the critical operational parameters have been provided in the Attachment. Therefore, if establishments utilize instructions from Attachment 1, no further supporting documentation is needed to meet the first element of validation.

NOTE: The list of references provided in Attachment 1 is not exhaustive. Establishments may identify other articles published in peer-reviewed

KEY QUESTION

Question: If I use Attachment 1 as the scientific support for my cooking instructions, do I need additional supporting documentation to meet the first element of validation?

Answer: No, Attachment 1 has been developed using published research. All critical operational parameters an establishment would be expected to meet are included in the Attachment. Therefore, the establishment does not need to maintain the original journal articles the instructions were developed from on file. In addition, only cooking instructions which achieve a minimum internal temperature and, if applicable, rest time needed to ensure that the product is thoroughly cooked to destroy potential pathogens were selected. Therefore, the establishment also does not need to maintain additional supporting documentation for the internal temperature and, if applicable, rest time chosen.

journals or other supporting documentation that can be used to support that cooking instructions have been validated.

When selecting supporting documentation for cooking instructions, **it is important that an establishment identifies supporting documentation that closely matches its actual process**. In order to determine that the supporting documentation closely matches the actual process and the cooking instructions on the label, establishments should ensure that the documentation was developed for a product that is similar in terms of the:

- Cut of beef,
- Method of tenderization
- Thickness
- Cooking method and
- Desired endpoint temperature and rest time (if applicable)

that will be referenced in the cooking instructions on the label.

It is important for establishments to ensure that the actual product being labeled is similar to the product studied because differences in the cut of beef, method of tenderization, thickness, and cooking method all have an impact on heat transfer and as a result, the amount of time it takes to reach the desired endpoint temperature. Therefore, if any of these parameters in the actual product or process differ from those used in the supporting documentation, the establishments should provide documentation as part of their validation records supporting why the desired endpoint temperature will still be reached. Such a justification could include reference to previously conducted research or scientific principles which would support that the desired endpoint temperature will still be reached. This justification is needed because the establishment can't be sure that the desired endpoint temperature will be met if different critical operational parameters are used. If a justification cannot be provided, then additional support may be needed. For example, if an establishment produces a 2-inch thick steak and the only available cooking instructions that have been validated are for a 1 inch steak, then the cooking instructions should not be used because it will take significantly longer to reach the desired endpoint temperature with a thicker steak (Luchansky, 2012). The next section discusses how an establishment can validate their own cooking instructions if none are available in the literature for a similar product.

In addition to identifying scientific or technical support demonstrating that the cooking instructions can repeatedly achieve the desired endpoint temperature, an establishment should also identify supporting documentation that demonstrates the expected level of bacterial pathogen reduction achieved when the desired endpoint temperature is reached. Such scientific supporting documentation should demonstrate that the minimum internal temperature and, if applicable, rest time in the instructions (for example 160°F instantaneously) has been validated to ensure that potential pathogens are destroyed throughout the product. This means that if the product reaches the desired minimum internal temperature for the applicable rest time, that at least a 5-$\log_{10}$

reduction of *Salmonella* and STEC organisms such as *E. coli* O157:H7 will be achieved. **As a result, the supporting documentation for the endpoint temperature and rest time should consist of or be developed from microbiological data demonstrating an adequate reduction in pathogens is achieved.**

> **NOTE:** The cooking instructions provided in Attachment 1 of this guideline were developed to reach minimum internal temperature and rest time combinations found to achieve at least a 5-$\log_{10}$ reduction of *Salmonella* and shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) organisms such as *E. coli* O157:H7. Therefore, these instructions were developed from microbiological data demonstrating an adequate reduction in pathogens is achieved and no further supporting documentation is needed.

It is also the responsibility of the establishment to identify supporting documentation for the endpoint temperature and, if applicable, rest time used for a product's cooking instructions. This type of documentation generally consists of a scientific article from a peer-reviewed journal, a published processing guideline, a challenge or inoculated pack study, or a regulatory performance standard. It is important to consider that not all cooking instructions have been developed to achieve a sufficient endpoint temperature, and if applicable, rest time. Often cooking instructions are developed to achieve a desired doneness of a product (i.e., "medium", "medium-well", or "well-done"). Cooking instructions for mechanically tenderized beef products should be developed to achieve desired endpoint temperatures in order to ensure a safe product.
According to the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks from April 2009 (See Attachment 2 of this guideline), products cooked to 150°F should be held or allowed to rest for at least 52 seconds to achieve at least a 5-$\log_{10}$ reduction of *Salmonella* and *E. coli* O157:H7. Products cooked above 160°F achieve a 5-$\log_{10}$ reduction in these pathogens instantaneously without any additional rest time. **The FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks also supports that adequate reduction of pathogens would be achieved with a desired endpoint temperature of 145°F and a rest time of 3 minutes. If establishments can validate that their cooking instructions will achieve that time and temperature combination, they would meet requirements and no additional supporting documentation would be needed to meet the first element of validation.**

Establishment's may utilize the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks provided in Attachment 2 of this guideline as support for the endpoint temperature and rest time or they may provide their own supporting documentation for other time and temperature combinations. If they use other time and temperature combinations, establishments would have to demonstrate that those other combinations achieve the same results as the time and temperature combinations in the table. This is because the time and temperature combinations in the FSIS Guidance were developed from microbiological data demonstrating an adequate reduction in pathogens is achieved. Although the FSIS Guidance was developed using microbiological data for *Salmonella*, the guidance can be used to support an adequate

reduction of STEC such as *E. coli* O157:H7is also achieved because *Salmonella* is considered an indicator for lethality. *Salmonella* is used as an indicator for lethality because it is more heat resistant than other pathogens such as *E. coli* O157:H7. Therefore, if a 5-$\log_{10}$ reduction of *Salmonella* is achieved, at least a 5-$\log_{10}$ reduction of *E. coli* O157:H7 should be achieved as well (Goodfellow and Grown, 1978; Line et al., 1991). In addition to the FSIS guidance, establishments may also utilize the endpoint time and temperature combinations provided in the 2009 FDA Food Code for mechanically tenderized meats in § 3-401.11(A)(2). As with the FSIS guidance, although the Food Code does not contain actual microbiological data, the time and temperature combinations were developed from microbiological data demonstrating an adequate reduction in pathogens is achieved.

How can an establishment develop its own supporting documentation for its cooking instructions if a product doesn't match one of those in Attachment 1 of this guideline?

If an establishment produces a product for which supporting documentation for cooking instructions is not readily available (for example, the product is of a different thickness or cut than one that has been studied or is partially cooked at the establishment), or if an establishment wants to provide cooking instructions for a cooking method that has not been studied, then additional supporting documentation will be needed. Such supporting documentation may be developed by collecting data in a test kitchen or other location where the cooking method (i.e., gas grill, broiler, stove top, etc.) is available for testing. Data may be collected by establishment employees, a third party, or establishments may elect to conduct and to document trials with consumers to monitor how well they are able to follow labeled cooking instructions.

To develop supporting documentation for cooking instructions, the establishment should determine the temperature of the product after it is cooked following the instructions on the label. If instructions have not already been developed, the establishment can collect data during cooking to determine the length of time it takes to reach the desired endpoint temperature. As previously discussed, the endpoint temperature and if applicable, rest time should be selected to ensure at least a 5-$\log_{10}$ reduction of *Salmonella* and shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) organisms such as *E. coli* O157:H7. The appropriate validation study should at least consider conditions likely to result in the lowest endpoint temperature or worst-case scenario (NACMCF, 2006). In order to ensure the validation study represents the worst-case scenario, the following product and testing variables should be considered.

Product variables

- **Method of tenderization:** The method of tenderization - either needle/blade tenderized or injected - appears to affect the amount of cooking time needed to reach a desired endpoint temperature (Luchansky, et al 2011). Therefore, the product studied should be prepared using the same method of

tenderization (ideally under actual in-plant conditions) as the product for which the cooking instructions are being developed.

- **Thickness of the product:** The thickness of the product is a critical factor for heat transfer. The thicker a product, the longer it will take for the core of the product to reach the desired endpoint temperature. Therefore, it is recommended that the thickness of products from at least three lots be measured. The validation study should be conducted using a product that represents the thickest product measured. If the establishment has a quality specification for thickness, the maximum thickness could also be used to select the thickest product to study.

- **Type of cut (i.e., steak or roast):** Related to the thickness of the product, the type of cut can also affect heat transfer due to differences in size, shape, presence or absence of a bone, and fat content. To account for these differences, cooking instructions for each cut should be validated separately.

Testing variables

- **Method of cooking:** Cooking instructions may be provided for multiple cooking methods/devices. Common methods of cooking for mechanically tenderized beef products such as steaks and roasts include cooking by conventional oven, gas grill, or stove top. When testing cooking instructions for conventional ovens, testing should be done on electric, gas, as well as convection ovens if possible to determine that the instructions work on all types of ovens. Prior to beginning the validation study, a cold spot determination should be conducted to ensure that even in the coldest spot the desired endpoint temperature is reached. FSIS does not recommend that cooking instructions be developed for microwave ovens due to difficulty in applying heat uniformly. For more considerations related to different cooking methods, see the Grocery Manufacturer's Association (GMA) 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products available at: http://www.gmaonline.org/downloads/wygwam/121894_1.pdf.

- **State of the product at the start of cooking, e.g., frozen versus refrigerated, or room temperature:** The initial temperature of the tested product should be the lowest expected temperature at the start of cooking. As recommended in GMA's 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products, even if the instructions require thawing before cooking, it may be worthwhile to consider additional tests to assess the impact on cooking adequacy if the consumer does not fully thaw the product prior to cooking. Alternatively, two sets of validated cooking instructions could be provided: one for preparation of thawed product and one for preparation of frozen product.

- **Multiple units:** The amount of product cooked at the same time needs to be considered, particularly for products cooked in a conventional oven. The cooking instructions may need to be extended if multiple servings are cooked at once. If cooking instructions are written for cooking multiple units (for example two steaks), the instructions should be validated for the same number of units.

- **Type of pan or cooking container:** Establishments may also need to consider the type of pan/cooking container during the design of the validation study. Darker metals tend to heat more quickly than lighter ones. If the type of pan is not included in the cooking instructions than the establishment should consider using a lighter pan during the validation study to represent a worst-case scenario.

- **Number and location of temperature measurement sites during testing:** Testing of the endpoint temperature should occur in the thickest part of the product. If possible, at least two temperature measurements should be taken per product.

- **Number of replicates:** In order to determine variability in the time it takes to reach the desired endpoint temperature, at least three replicates should be conducted for each type of cooking method studied. Conducting replicates is one of the main principles of the scientific method and involves repeating the entire trial over again under the same conditions multiple times to determine the reproducibility of the results. Guidance is provided later in this document on how to evaluate the results from the different replicates.

KEY POINT: REPLICATES

There is often confusion surrounding the principle of conducting replicates. Often times, multiple products will be tested under the same conditions at the same time (for example, multiple steaks may be placed in the same oven and cooked together); however, these would not be considered true replicates because variability in the oven conditions is not being measured. In order to determine variability in cooking, the steaks would need to be tested separately, under the same conditions, multiple times. For example, one steak would need to be cooked in the oven under the trial conditions. After the results are measured and the oven is cooled, the trial would need to be repeated again with another steak. Each piece of steak tested should be from a different lot so that variability within the product is measured as well.

- **Rest or dwell time after cooking:** If the supporting documentation for the minimal internal endpoint temperature indicates a rest time is needed in order to achieve adequate reduction in pathogens, then this should be noted in the trial design so that the instructions are developed appropriately. A "rest or dwell time" is the amount of time the product remains at the final temperature,

after it has been removed from a grill, oven, or other heat source. During the time after meat is removed from the heat source, its temperature remains constant or continues to rise, which destroys pathogens. If the product is covered during the rest time to help maintain the final temperature, this should be noted as well.

- **Rotation of product:** If the product is flipped part way during cooking, this should be documented in the testing and included in the instructions.

Testing methodology

After the establishment has identified the product and testing variables, the testing methodology should be determined. If cooking instructions are already available for the product, the establishment can repeatedly prepare the product following the instructions and determine whether the desired endpoint temperature is consistently met.

If instructions are not available, the establishment can collect data during cooking to determine the length of time it takes to reach the desired endpoint temperature. To do this, a stainless steel thermocouple can be inserted from one end into the center of the product to measure the internal temperature during cooking. To ensure more accurate measurement, another stainless steel theromocouple can be inserted in the center of the product from the opposite end. The temperature can be continuously monitored with thermocouple data logger at 5 second intervals. The product can then be cooked using the desired cooking method until the desired endpoint temperature is reached, at which point the amount of time it took to reach the temperature can be recorded. If two thermocouples are used, the time recorded should be the time it takes for both thermocouples to reach the desired endpoint temperature. See Luchansky et al., 2011 and 2012 for an example of this testing methodology.

In either case, the product should be prepared under the same conditions at least three separate times (i.e., three replicates should be conducted) to ensure the results are repeatable by consumers. Establishments may determine to conduct additional replicates after consulting with a statistician.

An example of a trial that could be used to validate cooking instructions that takes these product and testing variables into account is provided in Attachment 3.

How to evaluate the results

If labeling instructions were developed prior to the study and the goal of the study was to validate whether these instructions achieved the desired endpoint temperature, then when evaluating the data, if all of the temperatures taken following the instructions met or exceeded the target temperature, then the cooking instructions can be considered adequate. When not all data are at or above the target temperature a statistical analysis of the data points is recommended. As recommended in GMA's 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat

(NRTE) Products, one approach is to calculate the z-value for the data. The Z-value formula is:

Z = (average temperature – target temperature)/standard deviation

The average temperature is calculated from all data for products cooked using the instructions being tested. The target temperature is the temperature that the instructions are designed to achieve. The standard deviation is a calculation representing the variability or spread in the data for products cooked using the instructions being tested.

The calculated Z-value is used to determine the probability that a random temperature value would be less than the target temperature by comparing it with Z-values from a statistical table (see Attachment 4). For example, using the Table in Attachment 4, a Z-value equal to or greater than 2.33 means that 99% of the time, when the product is cooked using the instructions, the temperature will be at or above the target temperature. This also means that 1% of the time (or about 1 in 100 times) the temperature will be below the target. From a public health perspective, establishments should try to achieve a Z-value greater than 2.33 to have a high degree of confidence, that when followed, the cooking instructions will result in a temperature at or above the target temperature.

If instructions were not available prior to the study, and the study was used to determine the time it takes to reach the endpoint temperature, then the establishment should use the worst-case scenario result from all of the replicates as the cooking instructions. This means that if there was variability in the length of time it took to reach the endpoint temperature, the cooking instructions should be developed using the longest amount of time needed to achieve the desired endpoint temperature.

In some cases, the establishment may need to conduct statistical analyses to determine whether significant differences were found between testing scenarios. For example, if an establishment wants to provide a single set of instructions for both electric and gas ovens, the instructions should be validated using both types of cooking. Then statistical analyses should be conducted to determine whether there were any significant differences in the time it took to reach the desired endpoint temperature using the two methodologies. If no significant differences are found, then the establishment can conclude that a single set of instructions would be sufficient.

If cooking instructions are changed for product quality reasons or if the product or testing variables are changed (e.g., the thickness of the steak increases), the new instructions should be validated to ensure safety. In addition, establishments should closely monitor calls to their toll free numbers and other consumer complaints for signs that the cooking instructions are not easily followed or, when followed, do not adequately cook the product.

ELEMENT 2: Initial In-plant Demonstration Data (Execution)

Once an establishment has identified supporting documentation for the cooking instructions chosen, it then needs to implement the same critical operational parameters from the supporting documentation that were used to develop the cooking instructions. The critical operational parameters related to the product that should be implemented in the actual process include the:

- Cut of beef,
- Method of tenderization, and
- Thickness.

In order to meet the second element of validation, the establishment needs to ensure that it produces the product that meets these critical operating parameters.
To gather data demonstrating the process produces products meeting the critical operational parameters used to develop the cooking instructions. This means the establishment needs to collect in-plant data supporting that the cut of beef, method of tenderization, and thickness of product that bears the cooking instructions match those of the product the cooking instructions were developed for.

After collecting the initial execution data, the establishment should verify on an on-going basis that the critical operational parameters continue to be met and match those used in the supporting documentation. It is up to the establishment to support the frequency with which the critical operational parameters are verified on an ongoing basis. This data may already be collected by establishments on an ongoing basis as part of quality specifications.

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Attachment 1: Summary of Published Supporting Documentation for Cooking Instructions

Cut of Meat	Method of Tenderization	Thickness	Cooking Method	Endpoint Temperature	Validated Cooking Instructions	Reference
Top butt steak	Brine injection	1 in	Open-flame gas grill (380°F)	160°F	*For a 1 inch steak:* Cook on a gas grill for 10 minutes, flip and cook for another 10 minutes until the steak reaches 160°F.	Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. 2011. Journal of Food Protection. 74(7): 1054-1064.
Top butt steak	Needle tenderized	1 in 1.5	Open-flame gas grill (380°F)	150°F	*For a 1 inch steak:* Cook on a gas grill for 3 ½ minutes, flip and cook for another 3 ½ minutes until the steak reaches 150°F. Allow the steak to rest for 1 minute*****. *For a 1½ inch steak:* Cook on a gas grill for 8.5 minutes, flip and cook for another 8.5 minutes until medium doneness until the steak reaches 150°F. Allow the steak to rest for 1 minute*****.	Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. 2012. Journal of Food Protection. 75(1): 62-70.
				160°F	*For a 1 inch steak:* Cook on a gas grill for 5 minutes, flip and cook for another 5 minutes until medium-well doneness until the steak reaches 160°F. *For a 1½ inch steak:* Cook on a gas grill for 8 minutes, flip and cook for another 8 minutes until medium-well doneness until the steak reaches 160°F.	

*Initial research did not include a rest or dwell time, however, in order to achieve a 5-$\log_{10}$ reduction of *Salmonella* and *E. coli* O157:H7 a rest time should be included (see Attachment 2 of this guidance document for support).

Attachment 2: FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks April 2009

Temp °F	Temp °C	Time for 5.0-log_{10}Reduction	Unit Time
130	54.4	86	min.
131	55.0	69	min.
132	55.6	55	min.
133	56.1	44	min.
134	56.7	35	min.
135	57.2	28	min.
136	57.8	22	min.
137	58.4	18	min.
138	58.9	14	min.
139	59.5	11	min.
140	60.0	9	min.
141	60.6	7	min.
142	61.1	6	min.
143	61.7	5	min.
144	62.2	4	min.
145	62.8	3	min.
146	63.3	130	sec.
147	63.9	103	sec.
148	64.4	82	sec.
149	65.0	65	sec.
150	65.6	52	sec.
151	66.1	41	sec.
152	66.7	33	sec.
153	67.2	26	sec.
154	67.8	21	sec.
155	68.3	17	sec.
156	68.9	14	sec.
157	69.4	11	sec.
158	70.0	0	sec.
159	70.6	0	sec.
160	71.1	0	sec.

The required lethalities are achieved instantly when the internal temperature of a cooked meat product reaches 158°F or above.

This Time/Temperature table is based on Thermal Death Curve for *Salmonella* in Beef Emulsions in tubes derived from Goodfellow & Brown, 1978[1,2].

[1] Goodfellow, S. J. and W. L. Brown. 1978. Fate of *Salmonella* Inoculated into Beef for Cooking. Journal of Food Protection. 41: 598-605.

[2] All times that were a fraction of a minute or second was rounded up to the next whole number (e.g., 16.2 seconds for 155 °F was round up to 17 seconds.

Attachment 3: Example Validation of Conventional Oven Cooking Instructions for a Needle Tenderized Roast

Validation Trial Product Summary Sheet	
Date: 12/5/2012	
Product Name: Roast #456	
Product variables	
Method of tenderization	Needle Tenderized
Thickness of the product	5 inches
Type of cut	Eye-round roast (3 lbs)
Testing variables	
Method of cooking	Both ovens were preheated to 350°F Electric oven – KitchenAid Model #: 5678 Serial #: LMN5678 Gas oven – LG Model #: 12345 Serial #: ABC12345
State of the product at the start of cooking, e.g., frozen versus refrigerated, or room temperature	Refrigerated
Multiple units	Only one roast was tested at a time because this is how the consumer would ordinarily prepare the product
Type of pan/cooking container	The roast was cooked in a light pan (uncovered) to represent worst case scenario
Number and location of temperature measurement sites during testing	Two temperature measurements were taken in the center of the roast (the thermocouples were inserted into opposite ends of the roast)
Number of replicates	The testing methodology was repeated three times for each method of cooking (electric and gas)
Endpoint temperature	150°F
Rest time after cooking	1 minute
Rotation of product	None

Test methodology:

First, a cold spot determination was conducted for each type of oven in which oven temperatures were taken in five different locations (front left, front right, back left, back right, and center) on each rack in the oven.

After the cold spot determination was complete, the oven was heated to 350°F. Then product (at refrigeration temperature) was placed in the oven on a light colored pan in the location previously identified to be the coldest. Two calibrated, stainless steel thermocouples were inserted from opposite ends of the product into the center of the roast to measure the internal temperature of the roast during cooking. The temperature of the roast was continuously monitored with an eight-channel thermocouple data logger at 5 second intervals. The roast was removed from the oven when both thermocouples within the roast reached 150°F. Time was recorded at this point. The temperature of the roast was measured after the 1 minute rest time to ensure that the product temperature remained at 150°F while it was uncovered.[3]

This entire procedure, beginning after the cold spot determination, was repeated three times. Results were recorded on the charts below.

Results:

Electric oven preheated to 350°F

	Time to reach 150°F
Trial 1	91 minutes
Trial 2	97 minutes
Trial 3	90 minutes

Gas oven preheated to 350°F

	Time to reach 150°F
Trial 1	98 minutes
Trial 2	89 minutes
Trial 3	93 minutes

A two-sample t-test was conducted and it was determined that the difference in the mean time to reach 150°F using the gas and electric oven was not statistically significant.

Conclusions:

A single set of instructions can be created for electric and gas ovens since the difference in time it took to reach the desired endpoint temperature was not statistically significant. Since the longest amount of time it took to reach 150°F was 98 minutes, this value will be rounded up for the instructions so that consumers are instructed to cook

[3] This method was adapted from Luchansky et al. 2011 and 2012.

the product for 1 hour and 40 minutes (or 100 minutes). Consumers will also be instructed to allow the product to rest for 1 minute. An example of the final validated cooking instructions are provided below.

For Food Safety and Quality Follow These Cooking Instructions:
Electric or gas oven:
1) Heat oven to 350°F.
2) Cook for 1 hour and 40 minutes to an internal temperature of 150°F as measured with a food thermometer.
3) Remove from oven and allow meat to rest for 1 minute.

Attachment 4: Z-Table (Cumulative Probabilities of the Standard Normal Distribution Entry)

Z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
-3.5	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
-3.4	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0002
-3.3	0.0005	0.0005	0.0005	0.0004	0.0004	0.0004	0.0004	0.0004	0.0004	0.0003
-3.2	0.0007	0.0007	0.0006	0.0006	0.0006	0.0006	0.0006	0.0005	0.0005	0.0005
-3.1	0.0010	0.0009	0.0009	0.0009	0.0008	0.0008	0.0008	0.0008	0.0007	0.0007
-3.0	0.0013	0.0013	0.0013	0.0012	0.0012	0.0011	0.0011	0.0011	0.0010	0.0010
-2.9	0.0019	0.0018	0.0018	0.0017	0.0016	0.0016	0.0015	0.0015	0.0014	0.0014
-2.8	0.0026	0.0025	0.0024	0.0023	0.0023	0.0022	0.0021	0.0021	0.0020	0.0019
-2.7	0.0035	0.0034	0.0033	0.0032	0.0031	0.0030	0.0029	0.0028	0.0027	0.0026
-2.6	0.0047	0.0045	0.0044	0.0043	0.0041	0.0040	0.0039	0.0038	0.0037	0.0036
-2.5	0.0062	0.0060	0.0059	0.0057	0.0055	0.0054	0.0052	0.0051	0.0049	0.0048
-2.4	0.0082	0.0080	0.0078	0.0075	0.0073	0.0071	0.0069	0.0068	0.0066	0.0064
-2.3	0.0107	0.0104	0.0102	0.0099	0.0096	0.0094	0.0091	0.0089	0.0087	0.0084
-2.2	0.0139	0.0136	0.0132	0.0129	0.0125	0.0122	0.0119	0.0116	0.0113	0.0110
-2.1	0.0179	0.0174	0.0170	0.0166	0.0162	0.0158	0.0154	0.0150	0.0146	0.0143
-2.0	0.0228	0.0222	0.0217	0.0212	0.0207	0.0202	0.0197	0.0192	0.0188	0.0183
-1.9	0.0287	0.0281	0.0274	0.0268	0.0262	0.0256	0.0250	0.0244	0.0239	0.0233
-1.8	0.0359	0.0351	0.0344	0.0336	0.0329	0.0322	0.0314	0.0307	0.0301	0.0294
-1.7	0.0446	0.0436	0.0427	0.0418	0.0409	0.0401	0.0392	0.0384	0.0375	0.0367
-1.6	0.0548	0.0537	0.0526	0.0516	0.0505	0.0495	0.0485	0.0475	0.0465	0.0455
-1.5	0.0668	0.0655	0.0643	0.0630	0.0618	0.0606	0.0594	0.0582	0.0571	0.0559
-1.4	0.0808	0.0793	0.0778	0.0764	0.0749	0.0735	0.0721	0.0708	0.0694	0.0681
-1.3	0.0968	0.0951	0.0934	0.0918	0.0901	0.0885	0.0869	0.0853	0.0838	0.0823
-1.2	0.1151	0.1131	0.1112	0.1093	0.1075	0.1056	0.1038	0.1020	0.1003	0.0985
-1.1	0.1357	0.1335	0.1314	0.1292	0.1271	0.1251	0.1230	0.1210	0.1190	0.1170
-1.0	0.1587	0.1562	0.1539	0.1515	0.1492	0.1469	0.1446	0.1423	0.1401	0.1379
-0.9	0.1841	0.1814	0.1788	0.1762	0.1736	0.1711	0.1685	0.1660	0.1635	0.1611
-0.8	0.2119	0.2090	0.2061	0.2033	0.2005	0.1977	0.1949	0.1922	0.1894	0.1867
-0.7	0.2420	0.2389	0.2358	0.2327	0.2296	0.2266	0.2236	0.2206	0.2177	0.2148
-0.6	0.2743	0.2709	0.2676	0.2643	0.2611	0.2578	0.2546	0.2514	0.2483	0.2451
-0.5	0.3085	0.3050	0.3015	0.2981	0.2946	0.2912	0.2877	0.2843	0.2810	0.2776
-0.4	0.3446	0.3409	0.3372	0.3336	0.3300	0.3264	0.3228	0.3192	0.3156	0.3121
-0.3	0.3821	0.3783	0.3745	0.3707	0.3669	0.3632	0.3594	0.3557	0.3520	0.3483
-0.2	0.4207	0.4168	0.4129	0.4090	0.4052	0.4013	0.3974	0.3936	0.3897	0.3859
-0.1	0.4602	0.4562	0.4522	0.4483	0.4443	0.4404	0.4364	0.4325	0.4286	0.4247
-0	0.5000	0.4960	0.4920	0.4880	0.4840	0.4801	0.4761	0.4721	0.4681	0.4641
+0	0.5000	0.5040	0.5080	0.5120	0.5160	0.5199	0.5239	0.5279	0.5319	0.5359
0.1	0.5398	0.5438	0.5478	0.5517	0.5557	0.5596	0.5636	0.5675	0.5714	0.5753
0.2	0.5793	0.5832	0.5871	0.5910	0.5948	0.5987	0.6026	0.6064	0.6103	0.6141
0.3	0.6179	0.6217	0.6255	0.6293	0.6331	0.6368	0.6406	0.6443	0.6480	0.6517
0.4	0.6554	0.6591	0.6628	0.6664	0.6700	0.6736	0.6772	0.6808	0.6844	0.6879
0.5	0.6915	0.6950	0.6985	0.7019	0.7054	0.7088	0.7123	0.7157	0.7190	0.7224
0.6	0.7257	0.7291	0.7324	0.7357	0.7389	0.7422	0.7454	0.7486	0.7517	0.7549
0.7	0.7580	0.7611	0.7642	0.7673	0.7704	0.7734	0.7764	0.7794	0.7823	0.7852
0.8	0.7881	0.7910	0.7939	0.7967	0.7995	0.8023	0.8051	0.8078	0.8106	0.8133
0.9	0.8159	0.8186	0.8212	0.8238	0.8264	0.8289	0.8315	0.8340	0.8365	0.8389
1.0	0.8413	0.8438	0.8461	0.8485	0.8508	0.8531	0.8554	0.8577	0.8599	0.8621
1.1	0.8643	0.8665	0.8686	0.8708	0.8729	0.8749	0.8770	0.8790	0.8810	0.8830
1.2	0.8849	0.8869	0.8888	0.8907	0.8925	0.8944	0.8962	0.8980	0.8997	0.9015
1.3	0.9032	0.9049	0.9066	0.9082	0.9099	0.9115	0.9131	0.9147	0.9162	0.9177
1.4	0.9192	0.9207	0.9222	0.9236	0.9251	0.9265	0.9279	0.9292	0.9306	0.9319
1.5	0.9332	0.9345	0.9357	0.9370	0.9382	0.9394	0.9406	0.9418	0.9429	0.9441
1.6	0.9452	0.9463	0.9474	0.9484	0.9495	0.9505	0.9515	0.9525	0.9535	0.9545
1.7	0.9554	0.9564	0.9573	0.9582	0.9591	0.9599	0.9608	0.9616	0.9625	0.9633
1.8	0.9641	0.9649	0.9656	0.9664	0.9671	0.9678	0.9686	0.9693	0.9699	0.9706
1.9	0.9713	0.9719	0.9726	0.9732	0.9738	0.9744	0.9750	0.9756	0.9761	0.9767
2.0	0.9772	0.9778	0.9783	0.9788	0.9793	0.9798	0.9803	0.9808	0.9812	0.9817
2.1	0.9821	0.9826	0.9830	0.9834	0.9838	0.9842	0.9846	0.9850	0.9854	0.9857
2.2	0.9861	0.9864	0.9868	0.9871	0.9875	0.9878	0.9881	0.9884	0.9887	0.9890
2.3	0.9893	0.9896	0.9898	0.9901	0.9904	0.9906	0.9909	0.9911	0.9913	0.9916
2.4	0.9918	0.9920	0.9922	0.9925	0.9927	0.9929	0.9931	0.9932	0.9934	0.9936
2.5	0.9938	0.9940	0.9941	0.9943	0.9945	0.9946	0.9948	0.9949	0.9951	0.9952
2.6	0.9953	0.9955	0.9956	0.9957	0.9959	0.9960	0.9961	0.9962	0.9963	0.9964
2.7	0.9965	0.9966	0.9967	0.9968	0.9969	0.9970	0.9971	0.9972	0.9973	0.9974
2.8	0.9974	0.9975	0.9976	0.9977	0.9977	0.9978	0.9979	0.9979	0.9980	0.9981
2.9	0.9981	0.9982	0.9982	0.9983	0.9984	0.9984	0.9985	0.9985	0.9986	0.9986
3.0	0.9987	0.9987	0.9987	0.9988	0.9988	0.9989	0.9989	0.9989	0.9990	0.9990
3.1	0.9990	0.9991	0.9991	0.9991	0.9992	0.9992	0.9992	0.9992	0.9993	0.9993
3.2	0.9993	0.9993	0.9994	0.9994	0.9994	0.9994	0.9994	0.9995	0.9995	0.9995
3.3	0.9995	0.9995	0.9995	0.9996	0.9996	0.9996	0.9996	0.9996	0.9996	0.9997