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## PURPOSE

This procedure describes the processes used by Retail Food Program staff for review of initial variance requests and for variance from code renewal requests.

## SCOPE

This procedure pertains to retail food establishments and covers initial variance requests from code provisions permitted and initiated under MN Rule 4626.1690, and variance renewals according to MN Rule 4626.0710 and 4626.1715. MN Rule 1550.3230 allows retail food establishments that bottle water using a noncommunity public water supply to request a variance from source water testing requirements.

## BACKGROUND

The Minnesota Food Code part 4626.1690 allows for retail food establishments to submit variance requests to the regulatory authority when they seek to deviate from certain code requirements. Types and use of equipment, facility construction requirements, as well as food handling processes or practices that differ from code provisions require a variance from code to ensure conformance with health standards and conditions in order to protect the food supply and public health. MN Rules parts 4626.1695 through 4626.1715 establish requirements for the regulatory authority to follow when deciding to grant or deny a variance request during the initial review and renewal processes.

Minnesota Statute 14 establishes requirements for Provisions Applicable to All Rules including variances.

Additionally, MN Rule 1550.3230 allows retail food establishments that bottle water to request a variance to reduce the frequency of source water testing when the source water is a noncommunity public water supply.

## RESPONSIBILITY

**Food Process Supervisor:** The Food Process Supervisor is a Retail Food Supervisor who assigns a lead reviewer, establishes work groups (when applicable), provides final decision of food process variance requests as required, and reviews denials, revocations, and refusals to renew letters prior to being sent to the Retail Food Program Manager.

**Inspector:** The inspector will provide information to retail food establishments expressing interest in applying for a variance. The inspector will also conduct a routine inspection within the applicable period of the other variances and communicate any concerns related to the implementation of the other variances to the supervisor. The inspector will conduct existing common specialized process variance reviews and common specialized process variance renewals in the field.

**Lead Reviewer:** The Lead Reviewer will coordinate the review of the variance request to include setting meetings, communicating with the retail food establishment/applicant as needed, and providing a recommendation to Food Inspection or Plan Review Supervisors upon completion of the review, when applicable.

**Plan Review Officer:** The Plan Review Officer will provide information to retail food establishments expressing interest in applying for a variance.

**Plan Review Supervisor:** The Plan Review Supervisor conducts initial review of equipment & facility variance applications, assigns a lead reviewer, establishes work groups (when applicable), provides final decision of equipment & facility variance requests as required, and reviews denials, revocations, and refusals to renew letters prior to being sent to the Retail Food Program Manager.

**Retail Food Program Manager:** The Retail Food Program Manager will refer decisions to deny variance requests, or to revoke or refuse to renew variance from code requests for legal review and will provide oversight for the appeals process.

**Retail Plans and Licensing Administrator:** The Retail Plans and Licensing Administrator will identify variance applications that are received, will conduct the initial review of Variances, and upload the application and supporting documents to SharePoint, assist in sending any necessary communications to the applicant, and upload final decision documentation to SharePoint and the USAFS facility file.

**Work Group:** The Work Group will participate in the evaluations of submitted variance request applications as assigned by the Food Inspection or Plan Review Supervisors and respond with requested information within defined time-frames.

## DEFINITIONS

**Common Specialized Process Variance:** certain types of commonly occurring Specialized Processes that did not require a variance under the 1998 Food Code. These types are: 1) acidification of rice; 2) fermenting cabbage; 3) curing meats, poultry, wild game animals, or fish; 4) reduced oxygen packaging meats cured at retail, and 5) custom processing wild game animals. This does not include: 1) smoking as a method of food preservation rather than as a method of flavor enhancement; 2) all other methods of using food additives or adding components, such as vinegar; 3) all other methods of packaging TCS food using a reduced oxygen packaging method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled as specified in part 4626.0420; 4) sprouting seeds or beans; 5) Operating a molluscan shellfish life-support system under 4626.0610; and 6) preparing food by any other method that is not in compliance with the Food Code.

**Equipment & Facility Variance:** a variance from code involving the installation and use of equipment or finish materials that deviate from code requirements and construction guidelines, but is necessary for the operation based on the facility’s menu, processes and/or construction.

**Existing Common Specialized Process:** Common Specialized Process associated with a haccp plan that was approved by the Food or Retail Inspection Program prior to 1/1/2019 and that is currently being conducted in the retail food establishment, but for which an initial variance from code has not been approved.

**Food Process Variance:** a variance from code that may include a haccp plan as a condition of the variance and directly involves food handling practices and/or food products.

**Retail Food Establishment**: any individual, person, firm, corporation, company, association, cooperative, or partnership who sells food directly to a consumer (as defined in the MN Rule 4626.0020 Subp. 35) and holds any classification of food handler license per MN Statute 28A.05 and 28A.06.

**Hazard Analysis Critical Control Point (HACCP) Plan: “**HACCP plan" is defined in MN 4626.0020 Subp. 40 and further means a written document that delineates the formal procedures for following the hazard analysis critical control point principles developed by the National Advisory Committee on Microbiological Criteria for Foods where required by the MN Food Code (MN Rules chapter 4626) in a retail food establishment.

**Initial or Revised Common Specialized Process:** Common Specialized Process that is associated with a newly submitted haccp plan or one that has to be resubmitted due to having major changes to the plan.

**Initial or Revised Other Variance:** Is a type of other variance that is associated with a newly submitted variance request or one that has be resubmitted due to having a material change to the variance from code.

**Other Variances:** every variance from code except common specialized process variances.

**Specialized Process:** Foods produced as described under Minnesota Rules part 4626.0415 (Specialized Processing Variance Requirements).

**Variance from Code:** is a dispensation by the regulatory authority for a retail food establishment to vary or deviate from certain regulatory requirements as described in MN Rule 4626.1690-4626.1715, or MN Rules 1550.3230. This includes common specialized process variances and other variances.

## PROCEDURES

* 1. **Variance from Code Application Guidance and Submission – Inspector, Plan Review Officer, Supervisor Role**
		1. If a retail food establishment intends or requests to conduct operations which require a variance from code, provide guidance to the owner or manager, provide guidance (and document as applicable) to a retail food establishment owner or manager to complete and submit the *Variance Request Application AG-02436* along with any other relevant supporting documents.
		2. Submission allowances
			1. The retail food establishment applying for a variance from code may submit a *Variance from Code Request Application* and other relevant supporting documents (plan review, construction, food process, etc.).
			2. A parent company may submit an application on behalf of several stores, provided all stores are under the jurisdiction of MDA; store locations under the jurisdiction of another regulatory authority must submit those to the appropriate MDA Delegated Agency(s).
			3. Application may be submitted via email at mda.haccp.variance@state.mn.us or via hard copy to MDA-FFSD sent by mail to MDA-DFID 625 Robert Street N, St. Paul, MN 55155.

## Variance from Code Application Processing – Retail Plans and Licensing Administrator Role

* + 1. Scan and email all new variance applications received by mail to MDA.HACCP.Variance@state.mn.us within three (3) business days of receipt. The applicable Retail Food Supervisors and Plan Review Supervisor are set up to receive emails to this address.
		2. other variance - Upload the *Variance Request Application* and other relevant documents to the Variance SharePoint site so they are readily accessible to others. Refer to the current guidance regarding use of the Variance SharePoint site.
		3. specialized process variance - Upload the *Variance Request Application* and other relevant documents to the HACCP Review SharePoint site so they are readily accessible to others. Refer to the current guidance regarding use of the HACCP Review SharePoint site.
		4. existing common specialized process variance or renewal common specialized process variance where it is not associated with HACCP review – Immediately assign the Retail Inspector assigned to the zip code of the retail food establishment. Scan and email all new variance applications received by mail to the Inspector and cc-their supervisor within three (3) business days of receipt. Refer to Section 6.15 for the remaining process.
	1. **Other Variance and Initial or Revised Common Specialized Process Variance Preliminary Review - Retail Plans and Licensing Administrator Role**
		1. Conduct an initial review of the application and supporting documents that were submitted by the retail food establishment and ensure that legal requirements are met per MN Rule 4626.1690 and 4626.1695 including the following within three (3) business days of receipt:
			1. The issue is one for which is allowed to vary for by law (MN Rule 4626.1690 A and MN Rule 4626.1695 E).
			2. The applicant is the party to whom the rule applies.
			3. The application is complete and contains all required information.
			4. The variance was requested in the manner as described in the rule.
			5. The type of variance being requested. See definitions of equipment & facility variance and food process variance.
		2. If plan submission is deemed complete, send the *Notice of Variance from Code Application Received Letter* to the establishment and update the electronic tracking system within three (3) business days of conducting the initial review.
		3. If plan submission is deemed incomplete, send the *Notice of* *Incomplete Variance from Code Request Application Letter* to the establishment and update the electronic tracking system within three (3) business days of conducting the initial review.
	2. **Other Variance and Initial or Revised Common Specialized Process Variance Lead Reviewer Assignment** - **Food Process Supervisor or Plan Review Supervisor Role**
		1. Assign a Lead Reviewer to the variance based on the type of variance (equipment & facility variance or food process variance), inspector training, experience, geography, workload, specialization, and availability, as well as the complexity of the submitted materials within five (5) business days of notification from the electronic tracking system.
		2. Establish a workgroup to review the variance from code if deemed appropriate within five (5) business days of notification from the electronic tracking system.

## Initial or Revised Other Variance Preliminary Review– Lead Reviewer Role

* + 1. Evaluate the variance application and supporting documentation within 30 days of assignment to determine if it meets regulatory requirements, including the following:
			1. The variance will have no potential adverse effect on public health, safety, or the environment;
			2. The alternative measures to be taken, if any, are equivalent to or superior to those prescribed by the MN Food Code;
			3. Strict compliance with the MN Food Code will impose an undue burden on the applicant;
			4. The variance has only future effect; e.g. a variance cannot excuse previously cited violations of the MN Food Code;
			5. Application of the rule for which the variance is requested would not serve any of the purposes of the rule (M.S.14.055 Subd 3).
		2. Review the variance requests within 30 days of assignment to determine if the retail food establishment’s proposed alternate measures are adequate, to include information in the variance application and other additional relevant support information. Additional documentation may include the following:
			1. Environmental, ingredient or finished product testing by a certified laboratory with official results provided to MDA
			2. Published scientific journal articles
			3. Letters from process authorities
			4. Process control, HACCP, or other records
			5. Supplier letters of guarantee
			6. haccp plan (new or revision of existing plan)
			7. Equipment specifications (cut sheets/spec sheets)
			8. Room finish material specifications
			9. Other documentation to demonstrate or support that their proposed alternate measures are adequate.
		3. If the application submission is deemed inadequate and a determination cannot be made whether or not to approve or deny the variance request, send a letter to the establishment using the *Retail Variance Review-On Hold letter (Lead Reviewer)* and update the electronic tracking system.
		4. Contact the area inspector(s) and supervisor(s) by phone, email or in person to determine whether there are any current regulatory issues with the facility that would prevent approval of the variance. This could include licensing, compliance, or enforcement issues. Any issues noted that impact the approval of the variance must be noted in the draft letter of response to the retail food establishment.
		5. Consult entities inside or outside of MDA when additional technical expertise or scientific competencies are needed to adequately evaluate the request. This may include DMID (Dairy and Meat Inspection Division), other state or local regulatory agencies, FDA Regional Food Specialists, process authorities, professional associations, or academia. Additionally, if a variance request is received from a national or regional chain business, FDA and/or local regulatory agencies may be consulted to enhance consistency of variance request evaluations.
		6. Grant a variance for a period of two (2) months longer than the inspection frequency for the risk category per *FOOD.30.16 – Retail Risk Category SOP*. This allows the agency an opportunity to verify the implementation of the variance during routine inspections.
			1. Under certain circumstances, variances may be granted approval for a six (6) month period with an additional review at that time. An example may be when a retail food establishment is requesting to do extended cooling, but has a history of inadequate documentation of cooling.
			2. A different period may be granted when conditions are unlikely to change, such as equipment, facility, or construction material variances.

## Initial or Revised Other Variance Decision and Recommendation – Lead Reviewer Role

* + 1. Formulate a recommendation for denial of a variance that is linked to criteria specified in MN Rules parts 4626.1690 and 4626.1695 based on the following reasons:
			1. Insufficient or missing information,
			2. Lack of or invalid scientific documentation,
			3. Adverse impact on public health,
			4. Lack of or inadequate environmental or product sample results,
			5. Lack of an adequate haccp plan, Standard Operating Procedure (SOP), or non-renewal of the Specialized Process Variance – if applicable,
			6. Significant violations found during inspections, either directly related to the terms of the variance from code, other risk factors or food code interventions, especially repeat violations,
			7. Sample results that indicate that the environment or food products contain pathogenic bacteria and the retail food establishment has not made sufficient progress to correct or address the concern,
			8. Changes to statutes or rules that would prohibit the variance from code, or
			9. Enforcement or legal actions against the retail food establishment.
		2. Upon completion of the variance request review, report the decision and recommendation to the Food Process Supervisor or Plan Review Supervisor based on the type of variance from code. In the instance where the variance involves new technology or science, the Retail Food Program Manager will make the final decision.
		3. If the variance request is recommended for approval, draft a letter to the retail food establishment using the *Notice of Approved* *Variance Request Letter* template and upload it to the electronic tracking system. The letter should include the following:
			1. Referencing details of the specific request, a summary of, or references to, any additional information submitted with the application
			2. any conditions or on-going testing or analysis that is required (including any requirements the retail food establishment had self-identified as being conditional for the variance from code)
			3. the scope or limitations of the variance from code
			4. recommendations for length of the variance from code; a specific expiration date will be added based on the date the letter is issued
			5. supporting documentation that will need to be submitted with a renewal of the variance from code.
			6. other information needed by the retail food establishment to comply with the requirements
		4. If the variance from code request is recommended for denial, draft a letter of response to the retail food establishment /applicant using the *Notice of Variance from Code Request Denial Letter* template and upload to the electronic tracking system.
			1. If the variance from code is denied, revoked, or renewal is refused because of insufficient information, the letter should include the following:
				1. A description of the deficiency, agency interpretation, information that is lacking in the application, or that they failed to respond to any previous request for information.
				2. That they may re-apply with the appropriate information, documentation, etc.
			2. If the variance from code is denied, revoked, or renewal is refused because of any of the reasons documented in 6.6.1. the specific reasons shall be documented in the letter and linked to criteria specified in MN Rules 4626.1690 or 4626.1695.

## Initial or Revised Other Variance Final Approval, Denial, Revocation, Refusal to Renew & Appeals – Food Process Supervisors or Plan Review Supervisor and Retail Food Program Manager Roles

* + 1. Thoroughly review the draft letter and the documentation as needed and make the final decision on the variance from code request.
		2. Upon the final decision, finalize the letter of approval or denial to the retail food establishment /applicant based on the draft submitted by the Lead Reviewer. Denial letters will be signed by Retail Food Program Manager.
		3. Evaluate any information regarding a retail food establishment’s unsuccessful implementation of the variance from code, infectiveness of alternative measures, or other concerns regarding food safety as a result of the variance from code when discovered during the variance from code period to determine if the variance must be revoked.
		4. Review any appeals received from an applicant for a variance from code that is denied. Refer to *FFSD.SOP.30.14 – Industry Appeals SOP* for further information about appeal receipt and review. The appeal must be requested in writing within **30 days** of receipt of the notice, and must include the basis for the appeal.

## Initial or Revised Other Variance Communication of Decision – Retail Plans and Licensing Administrator Role

* + 1. Send an electronic copy by e-mail or mail a hard copy of the final letter to the address listed on the application. If it is a denial, revocation, or refusal to renew, it will need to also be sent via certified mail.
			1. If the variance from code is issued to a person who owns multiple retail food establishments within MDAs jurisdiction, those stores should be referenced in the letter; however it is the applicant’s responsibility to provide the outcome and conditions to the individual stores.
			2. Copy applicable inspectors, their supervisors, the Food Process Supervisor or Plan Review Supervisor, and the Retail Food Program Manager on the letter (email notification acceptable).
			3. Provide The Minnesota Department of Health and Local Health Agencies an electronic copy of the approval letter if the outcome of the variance has impact on their regulatory programs.

## Renewal of Other Variances

## Retail Plans and Licensing Administrator Role

* + 1. Send out the *Notice of Variance from Code Renewal Required Letter* at least 60 days prior to expiration date and update the electronic tracking system. Include a copy of the original approval letter with the renewal notice.
		2. Conduct initial review of submitted variance from code renewal information when received according to 6.3.1.

Food Process Supervisors or Equipment & Facility Plan Review Supervisor Role

* + 1. Determine if a lead reviewer will be assigned to the variance from code renewal or if the renewal will be reviewed by the assigned supervisor.
		2. Determine if there is a material change in the condition upon which the variance from code was granted:
			1. If there is a change, review according to Section 6.5; or
			2. If there is no change, review and determine if the retail food establishment continues to satisfy the criteria specified in 4626.1695 and demonstrates compliance with the alternative measures or conditions outlined at the time the original variance from code was approved.
		3. If it satisfies MN Rule 4626.1695 and demonstrates conformance with the alternative measures or conditions and is found to be adequate, recommend approval. Refer to Section 6.4.3 for more information.
		4. If it does not conform with MN Rule 4626.1695 or the alternative stipulations outlined in the original approval letter, or is found inadequate, recommend probationary approval or denial, revocation, or non-renewal. Refer to Section 6.5.

## Initial or Revised Common Specialized Process Variance Review – Lead Reviewer Role

## The lead reviewer will be the same individual assigned as the Lead Reviewer for the common specialized process haccp plan that is associated with the variance.

* + 1. Evaluate the variance application and supporting documentation within the timeline associated with the corresponding HACCP review according to *FOOD.30.28* to determine if it meets regulatory requirements, including the following:
			1. The variance will have no potential adverse effect on public health, safety, or the environment;
			2. The alternative measures to be taken, if any, are equivalent to or superior to those prescribed by the MN Food Code;
			3. Strict compliance with the MN Food Code will impose an undue burden on the applicant;
			4. The variance has only future effect; e.g. a variance cannot excuse previously cited violations of the MN Food Code;
			5. Application of the rule for which the variance is requested would not serve any of the purposes of the rule.
		2. Review the variance request within the timeline associated with the corresponding haccp plan review according to *FOOD.30.28-HACCP Plan Review-Retail Food SOP* to determine if the retail food establishment’s proposed alternate measures are adequate, to include information in the variance application and other additional relevant support information. Additional documentation may include the following:
			1. Environmental, ingredient or finished product testing by a certified laboratory with official results provided to MDA
			2. Published scientific journal articles
			3. Letters from process authorities
			4. Process control, HACCP, or other records
			5. Supplier letters of guarantee
			6. haccp plan (new or revision of existing plan)
			7. Equipment specifications (cut sheets/spec sheets)
			8. Room finish material specifications
			9. Other documentation to demonstrate or support that their proposed alternate measures are adequate.
		3. If the variance application submission is deemed inadequate and a determination cannot be made whether or not to approve or deny the variance request, send a letter to the establishment using the *Retail Variance Review-On Hold letter (Lead Reviewer)* and update the electronic tracking system.
		4. Contact the area inspector(s) and supervisor(s) by phone, email or in person to determine whether there are any current regulatory issues with the facility that would prevent approval of the variance. This could include licensing, compliance, or enforcement issues. Any issues noted that impact the approval of the variance must be noted in the draft letter of response to the retail food establishment.
		5. Consult entities inside or outside of MDA when additional technical expertise or scientific competencies are needed to adequately evaluate the request. This may include DMID (Dairy and Meat Inspection Division), other state or local regulatory agencies, FDA Regional Food Specialists, process authorities, professional associations, or academia. Additionally, if a variance request is received from a national or regional chain business, FDA and/or local regulatory agencies may be consulted to enhance consistency of variance from code request evaluations.
		6. Grant a variance for a period two (2) months longer than the inspection frequency for the risk category per *FOOD.30.16 – Retail Risk Category SOP*. This allows the agency an opportunity to verify the implementation of the common specialized process variance during routine inspections.
			1. Under certain circumstances, variances may be granted approval for a six month period with an additional review at that time. An example may be when a retail food establishment is requesting to do extended cooling, but has a history of inadequate documentation of cooling.
			2. A different period may be granted in certain situations.
		7. Formulate a recommendation for denial of a variance that is linked to criteria specified in MN Rules parts 4626.1690 and 4626.1695 based on the following reasons:
			1. Insufficient or missing information,
			2. Lack of or invalid scientific documentation,
			3. Adverse impact on public health,
			4. Lack of or inadequate environmental or product sample results,
			5. Lack of an adequate haccp plan, Standard Operating Procedure (SOP), or non-renewal of the specialized process variance – if applicable,
			6. Significant violations found during inspections, either directly related to the terms of the variance, other risk factors or food code interventions, especially repeat violations,
			7. Sample results that indicate that the environment or food products contain pathogenic bacteria and the retail food establishment has not made sufficient progress to correct or address the concern,
			8. Changes to statutes or rules that would prohibit the variance, or
			9. Enforcement or legal actions against the retail food establishment.
		8. Upon completion of the variance request review, report the decision to the Food Inspection Supervisor for any input.
		9. If the variance request will be approved or renewed, draft a letter to the retail food establishment using the *Notice of Approval for Common Specialized Process Variance Request Letter or Notice of Renewal for Common Specialized Process Variance Request Letter* template and upload it to the electronic tracking system. The letter should include the following:
			1. Referencing details of the specific request, a summary of, or references to, any additional information submitted with the application
			2. any conditions or on-going testing or analysis that is required (including any requirements the retail food establishment had self-identified as being conditional for the variance)
			3. the scope or limitations of the variance
			4. recommendations for length of the variance; a specific expiration date will be added based on the date the letter is issued
			5. supporting documentation that will need to be submitted with a renewal of the variance from code.
			6. other information needed by the retail food establishment to comply with the requirements
		10. If the variance from code request is recommended for denial, revocation, or refusal to renew, draft a letter of response to the retail food establishment /applicant using the *Notice of Variance from Code Request Denial Letter* template and upload to the electronic tracking system.
			1. If the variance from code is denied, revoked, or renewal is refused because of insufficient information, the letter should include the following:
				1. A description of the deficiency, agency interpretation, information that is lacking in the application, or that they failed to respond to any previous request for information.
				2. That they may re-apply with the appropriate information, documentation, etc.
			2. If the variance from code is denied, revoked, or renewal is refused because of any of the reasons documented in 6.6.1. the specific reasons shall be documented in the letter and linked to criteria specified in MN Rules 4626.1690 or 4626.1695.

## Initial or Revised Common Specialized Process Variance - Final Approval, Denial, & Appeals – Lead Reviewer, Food Process Supervisor, and Retail Food Program Manager Roles

* + 1. Thoroughly review the draft letter and the documentation as needed and make the final decision on the variance request.
		2. Upon the final decision, finalize the letter of approval or denial to the retail food establishment /applicant based on the draft submitted by the Lead Reviewer. Approvals will be signed by the Lead Reviewer. Denial letters will be signed by Retail Food Program Manager.
		3. Evaluate any information regarding a retail food establishment’s unsuccessful implementation of the variance from code, infectiveness of alternative measures, or other concerns regarding food safety as a result of the variance from code when discovered during the variance period to determine if the variance from code must be revoked.
		4. Review any appeals received from an applicant for a variance from code that is denied. Refer to *FFSD.SOP.30.14 – Industry Appeals SOP* for further information about appeal receipt and review. The appeal must be requested in writing within **30 days** of receipt of the notice, and must include the basis for the appeal.

## Initial or Revised Common Specialized Process - Communication of Decision – Retail Plans and Licensing Administrator Role

* + 1. Send an electronic copy by e-mail or mail a hard copy of the final letter to the address listed on the application. If it is a denial, revocation, or refusal to renew, it will need to also be sent via certified mail.
			1. If the variance is for a corporate entity representing multiple stores within MDAs jurisdiction, those stores should be referenced in the letter; however it is the applicant’s responsibility to provide the outcome and conditions to the individual stores.
			2. Copy applicable inspectors, their supervisors, the Food Process Supervisor or Plan Review Supervisor, and the Retail Food Program Manager on the letter (email notification acceptable).
			3. Provide The Minnesota Department of Health and Local Health Agencies an electronic copy of the approval letter if the outcome of the variance from code has impact on their regulatory programs.

## Initial or Revised Common Specialized Process and Other Variance Records and Documentation – Retail Plans and Licensing Administrator Role

* + 1. Retain the variance application, supporting documentation, retail food establishment correspondence, final letters, etc. on the designated location on the SharePoint Site.
		2. Attach final letters in USA Food Safety for each affected establishment. Additionally, a copy of the final letter will be added to the Approved Variances library on the Variance SharePoint site.

## Other Variance Inspection Procedures

## Inspector

* + 1. Conduct a full routine inspection within the applicable period of the variance from code to ensure compliance with the terms of the variance from code. This includes a complete inspection of the establishment, as well as any other terms specific to the variance from code. This could include additional records, sample results, etc.
		2. Conduct additional visits or inspections at the retail food establishment to collect further information or documentation during the variance review (initial or renewal) process as requested.

Inspector, or Supervisor

* + 1. If information is observed or received regarding a retail food establishment’s unsuccessful implementation of the variance, or other concerns regarding food safety as a result of the variance, notify the applicable supervisor and consider referring to Compliance.
		2. If there are concerns about the safety of alternative measures or conditions of the variance as initially approved by the Lead Reviewer, send an email to the HACCP and Variance Team.
	1. **Common Specialized Process Variance Field Renewal and Existing Common Specialized Process Field Review**

## Inspector

* + 1. In order to conduct a field renewal of a variance from code or an initial review of an existing common specialized process, the process must be a common specialized process.
		2. Variance applications provide to the inspector outside of the inspection or where the inspector has been assigned an Existing Common Specialized Process Variance or a Common Specialized Process Variance Field Renewal, conduct an inspection within 30 days for the purposes of reviewing or renewing the variance.
		3. Conduct a HACCP Audit according to *FOOD.30.30 – HACCP Plan Audit-Retail Food SOP*.
		4. Existing Common Specialized Process Field Review
			1. Based on the HACCP Audit and Routine Inspection:
				1. If the inspection identifies that the current haccp plan is unapproved by the MDA Food Inspection Program, do not approve the variance application. Provide the retail food establishment with a *Variance Request Form* and have them submit the form and their haccp plan to the HACCP /Variance email or mailing address (see 6.1). This submission will be treated as an **initial common specialized process variance**. Example scenario: The retail food establishment is using a haccp plan where there is no marking on the haccp plan showing its previous review, no approval in SharePoint and no other documentation showing approval,
				2. If the inspection identified that the retail food establishment has an approved haccp plan, but the plan requires major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, do not approve the variance application. Provide the retail food establishment with a *Variance Request Form* and have them submit the form and their haccp plan to the HACCP /Variance email or mailing address (see 6.1). This submission will be treated as an **initial common specialized process variance**. Example scenario: The retail food establishment has an approved haccp plan, but they are actually using different critical limits such as alternative cooling temperatures under Appendix B and do not which to revert to their approved critical limits. .
				3. If the inspection identified that the retail food establishment has an approved haccp plan, and the plan does not require major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, but a Cease and Desist is issued on the common specialized process under field review, do not approve the Variance application. Approving the variance can be reconsidered after the Cease and Desist is lifted. If the firm did not already submit a Variance application, provide the retail food establishment with a *Variance Request Form* and have them submit the form to the HACCP /Variance email or mailing address (see 6.1) or have them submit it directly to the inspector. Example scenario: The retail food establishment does not have control of their processes and cannot get there processes under control during the inspection.
				4. If the inspection identified that the retail food establishment has an approved haccp plan, and the plan does not require major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, but there are issues with the variance application or concerns about what the retail food establishment is requesting, do not approve the variance. Provide the retail food establishment with a *Variance Request Form* and have them submit the form and their haccp plan to the HACCP /Variance email or mailing address (see 6.1) or have them submit it directly to the inspector. This submission will continue to be treated as an **existing common specialized process (**see 6.2.4**)**. Example scenario: The retail food establishment is not prepared or able to fill out the *Variance Request Form* or the inspector is concerned that an Other Variance from Code is necessary.
				5. If the inspection identified that the retail food establishment has an approved haccp plan, and the plan does not require major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, there are no issues with the application, but follow-on action is needed due to the non-compliance of the common specialized process, approve the variance with an expiration date just after the latest possible follow-on action date. Example scenario: The retail food establishment knows the critical limit and is in compliance or can get in compliance, but the retail food establishment is not keeping records.
				6. If the inspection identified that the retail food establishment has an approved haccp plan, and the plan does not require major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, there are no issues with the application, and no follow-on action is needed due to the common specialized process, approve the variance for a period two (2) months longer than the inspection frequency for the risk category per *FOOD.30.16 – Retail Risk Category SOP*. This allows the agency an opportunity to verify the implementation of the variance from code during routine inspections. Example scenario: The retail food establishment has some missing records and is not recording TMD verification.
		5. Common Specialized Process Variance Field Renewal
			1. Conduct a full routine inspection within the applicable period of the variance from code to ensure compliance with any other conditions of of the original variance from code.
			2. Based on the HACCP Audit, Routine Inspection, and review of Variance conformance:
				1. If the inspection identifies that the current haccp plan is unapproved by the MDA Food Inspection Program, do not renew the variance. Provide the retail food establishment with a *Variance Request Form* and have them submit the form and their haccp plan to the HACCP /Variance email or mailing address (see 6.1). This submission will be treated as a **revised common specialized process variance**. Example scenario: The retail food establishment is using a haccp plan where there is no marking on the haccp plan showing its previous review, no approval in SharePoint and no other documentation showing approval.
				2. If the inspection identified that the retail food establishment has an approved haccp plan, but the plan requires major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, do not renew the variance. Provide the retail food establishment with a *Variance Request Form* and have them submit the form and their haccp plan to the HACCP /Variance email or mailing address (see 6.1). This submission will be treated as a **revised common specialized process variance**. Example scenario: The retail food establishment has an approved haccp plan, but they are actually using different critical limits such as alternative cooling temperatures under Appendix B and do not revert to their approved critical limits.
				3. If the inspection identified that the retail food establishment has an approved haccp plan, and the plan does not require major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, but a Cease and Desist is issued on the common specialized process under field review, do not renew the variance. Renewing the variance can be reconsidered after the Cease and Desist is lifted. Consider the possibility of a revocation or refusal to renew in conjunction with your supervisor and/or Compliance. If the firm did not already submit a Variance application, provide the retail food establishment with a *Variance Request Form* and have them submit the form to the HACCP /Variance email or mailing address (see 6.1) or have them submit it directly to the inspector. Example scenario: The retail food establishment does not have control of their processes and cannot get there processes under control during the inspection.
				4. If the inspection identified that the retail food establishment has an approved haccp plan, and the plan does not require major changes to correct issues in the plan or how well the plan reflects the processes in the retail food establishment, but follow-up action is needed due to the non-compliance of the common specialized process, renew the variance with an expiration date just after the latest possible follow-on action date. Example scenario: The retail food establishment knows the critical limit and is in compliance or can get in compliance, but the retail food establishment is not keeping records.
				5. If no follow-on action is needed due to the common specialized process, renew the variance for a period two (2) months longer than the inspection frequency for the risk category per *FOOD.30.16 – Retail Risk Category SOP*. This allows the agency an opportunity to verify the implementation of the variance from code during routine inspections. Example scenario: The retail food establishment has some missing records and is not recording TMD verification.
		6. Under certain circumstances, variance requests may be granted approval/renewal for a six month period with an additional review at that time. An example may be when a retail food establishment is requesting to do extended cooling, but has a history of inadequate documentation of cooling.
		7. A different period may be granted when conditions are unlikely to change. The retail food establishment must complete the *Variance Request Form.*
		8. If the variance application was completed adequately and the process or processes were Approved or Renewed:
			1. Generate a *Notice of Approval for Common Specialized Process Variance* *Request Letter* or *Notice of Renewal for Common Specialized Process Variance Request Letter*. Upload the approval to the Facility Maintenance Page and use the following naming convention CSPV\_Approval (or) Renewal Request Letter\_Establishment Name. Email a copy of the application and the approval or renewal letter to the mda.haccp.variance@state.mn.us.
			2. Provide a copy of the letter to the retail food establishment with the delivery of the inspection report.
			3. Add the predefined comment about variance approval/renewal to the comment section on the Retail Inspection Report.
		9. If follow-up action will be taken and a shorter variance approval time period issued, ensure that the retail food establishment receives a follow-up inspection, haccp plan Audit, variance renewal review as specified from 6.15.4.
		10. Conduct additional visits or inspections at the retail food establishment to collect further information or documentation during the variance from code review (initial or renewal) process as requested by a supervisor or Compliance.

Inspector or Supervisor

* + 1. If information is observed or received regarding a retail food establishment’s unsuccessful implementation of the variance from code, or other concerns regarding food safety as a result of the variance from code, notify the applicable supervisor and consider referring to Compliance.
		2. If there are concerns about the safety of alternative measures or conditions of the variance from code as initially approved by the Lead Reviewer, send an email to the HACCP and Variance Team and their supervisor.

## RELATED DOCUMENTS (includes References, Attachments)

FOOD.30.16 – Retail Risk Category SOP

FFSD.SOP.30.14 – Industry Appeals SOP

FOOD.30.30 – HACCP Plan Audit-Retail Food SOP

Guidance – Variance for Cooling of Large Muscle Meats

Minnesota Food Code

Notice of Approved Variance from Code Request Letter

Notice of Incomplete Variance from Code Request Application Letter

Notice of Variance from Code Application Received Letter

Notice of Variance from Code Renewal Required Letter

Notice of Variance from Code Request Denial Letter

Notice of Approval for Common Specialized Process Variance Request Letter

Notice of Renewal for Common Specialized Process Variance Request Letter

Notice of Unnecessary Variance from Code Request Letter

Retail Variance from Code Review-On Hold letter (Lead Reviewer)

Variance Request Application (AG-02436)

## EQUIPMENT/MATERIALS NEEDED

N/A

## SAFETY

N/A

## CIRCULATION

This document is circulated to the following: Retail Food Program Staff, and the Retail Plans and Licensing Administrator. The current version will be stored electronically on the FFSD document control site.