Minnesota Department of Agriculture
Dairy and Food Inspection Division

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Version #: **1**	Effective Date: 6/30/2015
Title: **Variance Request SOP**	

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1. PURPOSE

This procedure describes the review process for variance requests, as defined by the Minnesota Rules, to provide consistent review of all variance applications.

2. SCOPE

This procedure covers variance requests initiated under Minnesota Rule 4626.1690 of the Minnesota Food Code which pertain to Retail Food Establishments. It includes issues such as definitions, food handling, specialized process requirements, equipment and facilities as well as under MN Rule 1550.3230 regarding Source Water Testing Requirements.

3. BACKGROUND

The Minnesota Food Code, Minnesota Rule 4626.1690, allows for a variance request to be submitted by a Food Establishment (as defined below) in situations when a firm seeks a deviation from certain regulatory requirements. Equipment, facility construction requirements, food processes or practices that require a variance may represent a heightened risk for foodborne illness if not conducted under strict operational procedures. They may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. MN Rules 4626.1695 through 4626.1715 establishes the requirements for review, conditions, renewal; and denial, revocation or refusal to renew a variance.

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

Additionally, MN Rule 1550.3230 allows bottled water plants to request a variance to reduce the frequency of source water testing when the source water is a non-community public water supply.

4. RESPONSIBILITY

Food Program Manager –will review all policies and procedures and issue final approval of all food program policies and procedures and provide oversight for the appeals process.

Regulatory, Educational and Outreach Program Coordinator –will ensure that all staff is trained in carrying out the responsibilities of this SOP.

Science and Technology (S/T) Committee Chair: will conduct initial reviews of variance requests, establish work groups and work group leads, and provide final decision of variance requests as required.

Science and Technology (S/T) Committee – will evaluate food variance requests/applications at firms within Dairy and Food Inspection Division's regulatory authority.

Science and Technology Work Group –will evaluate a submitted variance request at the request of the Chair/ Work Group Lead and respond within defined time-frames.

Science and Technology Work Group Lead –will coordinate the review of the variance including setting meetings, communication to the chair, and communication to the firm for additional information.

Supervisor - will ensure all assigned staff in their respective program area receive the appropriate training and follow the procedures described.

Compliance Officer – will follow the procedures described as applicable to their position and notify their supervisor when the procedures cannot be followed.

Inspector –will follow the procedures described as applicable to their position and notify their supervisor when the procedures cannot be followed.

Office Support Staff (OSS) (designated to receive and distribute office mail) –will identify variance requests that are received and submit these requests, along with supporting documents, to the Science and Technology Committee Chair.

5. DEFINITIONS

Food Establishment: any individual, firm, corporation, company, association, cooperative, or partnership who sells food directly to a consumer (as defined in the MN Retail Food Code). Common names that are frequently interchanged are "retail food establishment" and "retailer".

Science and Technology Committee: A group of selected MDA DFID staff from all Program areas convened to review new technologies and variance requests (as allowed by the MN Rules). The Science and Technology Committee (S/T Committee) functions under a Charter which establishes procedures and guidelines for its operation. The current appointments for the Chair and Vice Chair of the S/T Committee can be found on the Committee SharePoint site)

Specialized Process: are foods produced as described under Minnesota Food Code 4626.0415 (Specialized Processing HACCP Requirements) and 4626.1730 (When a HACCP Plan is Required).

Variance: is a dispensation by the regulatory authority for a Food Establishment to vary or deviate from certain regulatory requirements as described in MN Rule 4626.1690-4626.1715.

6. PROCEDURES

6.1. Variance Application Guidance and Submission -

6.1.1. Inspectors, Compliance Officers and Supervisors: If a firm would like to vary from the current Minnesota Food Code, provide guidance (and issue orders as applicable) to a Food Establishment owner or manager to

complete and submit the *Variance Request Application AG- 02436* (either an initial or renewal application).

a. The firm applying for a variance may submit a *Variance Request Application* while working towards licensure (plan review, construction, etc.).
b. 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).

6.2. Application Processing and Work Group Assignment

6.2.1. OSS: Scan and email all new applications and renewals received by mail to MDA.HACCP.Variance@state.mn.us within 3 days of receipt. The Chair and Vice Chair of the S/T Committee are set up to receive emails to this address.

6.2.2. S/T Committee Chair or Vice Chair: Post the Variance Request Application and other relative documents to the S/T Committee SharePoint site so they are readily accessible to others. Refer to *FOOD.WI.30.15 - Variance Process Tracking Work Instruction*.

6.2.3. S/T Committee Chair or Vice Chair : Conduct an initial review of the application and supporting documents that were submitted by the firm and ensure that legal requirements are met per MN Rule 4626.1690 and 4626.1695 including the following:

a. The issue is one for which is allowed to vary for by law (4626.1690 A and 4626.1695 E.
b. The applicant is the party to whom the rule applies.
c. The application is complete and contains all required information.
d. The variance was requested in the manner as described in the rule.

6.2.4. S/T Committee Chair or Vice Chair: Establish a Work Group and Work Group Lead consisting of S/T Committee members based on training, expertise, education, experience, and work assignments relevant to the content of the application. The number of workgroup members will be dependent on the content of the request and availability of staff to ensure timely evaluation.

6.3. Evaluation Criteria

6.3.1. Work Group: Evaluate the variance application and supporting documentation to determine if it meets regulatory requirements, including the following:

a. The variance will have no potential adverse effect on public health, safety, or the environment;
b. The alternative measures to be taken, if any, are equivalent to or superior to those prescribed by the MN Food Code;
c. Strict compliance with the MN Food Code will impose an undue burden on the applicant;

d. The variance has only future effect; e.g. a variance cannot excuse previously cited violations of the MN Food Code;
e. 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).

6.3.2. Work Group: If the firm did not provide the appropriate information with the initial submission, request additional valid documentation from the applicant to support the variance request as needed to determine if the firm's proposed alternate measures are adequate. A variance may be denied if a firm fails to provide any requested information within **60 calendar days** of the request for additional information. Documentation may include the following:

a. Environmental, ingredient or finished product testing by a certified laboratory with official results provided to MDA
b. Published scientific journal articles
c. Letters from process authorities
d. Process control, HACCP, or other records
e. Supplier letters of guarantee
f. HACCP Plan (new or revision of existing plan)
g. Equipment specifications (cut sheets/spec sheets)
h. Room finish material specifications
i. Other documentation to demonstrate or support that their proposed alternate measures are adequate.

6.3.3. Work Group Lead: Contact the area inspector(s) and supervisor(s) by phone, email or in person to determine whether there are any current regulatory issues that would prevent the granting or renewal of the variance. This could include licensing, compliance or enforcement issues. Any issues noted that impact the granting of the variance must be noted in the draft letter of response to the firm. Consult the Plan Review Supervisor when an issue is related to equipment, facilities, or construction materials at a Food Establishment.

6.3.4. Work Group: Consult entities outside of MDA when additional technical expertise or scientific competencies are needed to adequately evaluate the request. This may include 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.

6.3.5. Work Group: Determine if specific conditions for the variance are needed to protect the public health, safety, or the environment. Examples include environmental monitoring for Listeria, data loggers for continuous temperature monitoring, restrictions on products to be produced, etc. Guidance for review of specific types of variance requests and required specific conditions for more frequently requested variances are included in the Related Documents.

6.3.6. Work Group: Grant variances for a period of one year unless another time frame is required based on the variance. This allows the agency an opportunity to verify the implementation of the variance during a routine inspection. Per *FOOD.30.16 Retail Risk Category SOP*, all Food Establishments with approved processes variances should be categorized as High Risk with a base inspection frequency of 12 months.

a. Under certain circumstances, variances may be granted provisional approval for a six month period with an additional workgroup review at that time.
b. A period of greater than one year may be granted when conditions are unlikely to change, such as equipment, facility, or construction material variances.

6.3.7. Work Group: A variance may be denied or revoked for any of the following reasons:

a. Insufficient or missing information,
b. Lack of or invalid scientific documentation,
c. Adverse impact on public health,
d. Lack of or inadequate environmental or product sample results,
e. Lack of an adequate HACCP plan or Standard Operating Procedure (SOP),
f. Significant violations found during inspections, either directly related to the terms of the variance, other risk factors or food code interventions, especially repeat violations,
g. Sample results that indicate that the environment or food products contain pathogenic bacteria and the firm has not made sufficient progress to correct or address the concern,
h. Changes to statutes or rules that would prohibit the variance, or
i. Enforcement or legal actions against the firm.

6.4. Work Group Decision and Recommendation

6.4.1. Work Group Lead: Upon completion of the variance request review, report the Work Group decision and recommendation to the S/T Chair or Vice Chair. In the instance where there is disagreement between work group members or reviewers, the Food Program Manager will make the final decision.

6.4.2. Work Group Lead (or designee): If the variance request is recommended for approval or renewal, draft a letter of response to the firm/applicant and post it on SharePoint. Draft /template letters are located on SharePoint. The letter should include the following:

a. a summary of, or references to, any additional information submitted with the application
b. any conditions or on-going testing or analysis that is required (including any requirements the firm had self-identified as being conditional for the variance)
c. the scope or limitations of the variance

d. recommendations for length of the variance; a specific expiration date will be added based on the date the letter is issued
e. other information needed by the firm to comply with the requirements

6.4.3. Work Group Lead (or designee): If the variance request is recommended for denial or revocation draft the letter of response to the firm/applicant and post it on SharePoint. Draft/template letters are located on SharePoint.

a. If the variance is denied or revoked because of insufficient information, the letter should include the following**:**
   i. A description of the information that is lacking in the application and that they failed to respond to previous request for that information.
   ii. That they may re-apply with the appropriate information, documentation, etc.
b. If the variance is denied or revoked because of any of the reasons documented in 6.3.7 b-i, the specific reasons shall be documented in the letter.

6.5. Variance Final Approval, Denial, Revocation & Appeals

6.5.1. S/T Committee Chair, Vice Chair, a Food Inspection Supervisor, or Food Program Manager: Thoroughly review the work group draft letter and the documentation as needed and make the final decision on the variance request.

6.5.2. S/T Committee Chair or Vice Chair: Upon the final decision, finalize the letter of approval or denial to the firm/applicant based on the draft submitted by the work group**.**

6.5.3. S/T Committee Chair, Vice Chair or Food Program Manager: Evaluate any information regarding a firm's unsuccessful implementation of the variance, infectiveness of alternative measures, or other concerns regarding food safety as a result of the variance when discovered during the variance period to determine if the variance must be revoked.

6.5.4. S/T Committee Chair, Vice Chair, or Food Program Manager: Refer any appeals received from an applicant for a variance that is denied, revoked or refused to be renewed to the Compliance Unit to schedule a contested case hearing. The appeal must be requested in writing within **30 days** of receipt of the notice, and must include the basis for the appeal.

6.6. Communication of Decision

6.6.1. S/T Committee Chair or Vice Chair (or designee): Mail a hard copy of the letter to the address listed on the application. An electronic copy may also be sent by email.

a. If the variance is 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.

b. Copy applicable Inspectors, Supervisors, and the Food Program manager on the letter (email notification acceptable).

c. 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.

6.7. Records and Documentation

6.7.1. S/T Committee Chair or Vice Chair: Retain the variance application, supporting documentation, firm correspondence, final letters, etc. on the Science and Technology Committee SharePoint site.

6.7.2. S/T Committee Chair or Vice Chair: Attach final letters in USA Food Safety for each affected establishment unless otherwise informed in the email. Additionally, a copy of the final letter will be added to the Approved Variances library on the S/T Committee SharePoint site.

6.8. Inspection Procedures

6.8.1. Inspector: When a variance has been granted, conduct a full routine inspection within the applicable period of the variance to ensure compliance with the terms of the variance. This includes a complete inspection of the establishment, including a HACCP Audit (when applicable as a condition of the variance), as well as any other terms specific to the variance. That could include additional records, sample results, etc. Preference for timing of the inspection and HACCP Audit would be within 2 months prior to the expiration date of the variance.

6.8.2. Inspector: As requested, conduct additional visits or inspections at the food establishment to collect further information or documentation during the variance review process.

6.8.3. Inspectors, Compliance Officers, Supervisor or Others: if there are concerns with information regarding a firms unsuccessful implementation of the variance, infectiveness of alternative measures, or other concerns regarding food safety as a result of the variance, notify the S/T Committee Chair/Vice Chair for further evaluation as noted in 6.5.

7. RELATED DOCUMENTS (includes References, Attachments)

- FOOD.30.16 Retail Risk Category SOP
- FOOD.WI.FOOD.30.15 – Variance Process Tracking Work Instruction
- Guidance – Variance for Cheese as Non-PHF
- Guidance - Variance for Cooling of Large Muscle Meats
- Guidance - Variance for Extend Shelf Life ROP Meats
- Guidelines for Retail Food Establishments - Environmental Sampling for Listeria
- Minnesota Food Code
- Variance Request Application (AG- 02436)

8. EQUIPMENT/MATERIALS NEEDED

- DFID SharePoint Site – Science & Technology Committee

9. SAFETY

N/A

10. CIRCULATION

This document is circulated to the following: food inspectors, food inspection supervisors, compliance officers, compliance supervisor, food program manager, and applicable support staff. An electronic version of this procedure is stored in the Food Program SOP Library.

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	**Status (I, R)**	**Change History**
1	**I**	**Initial Policy Drafting.**

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I = Initial document; R = Revised document