

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 260. GOOD MANUFACTURING PRACTICE REGULATIONS**

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Subchapter 1. General Provisions

310:260-1-1. Purpose; citation [AMENDED]

310:260-1-2. Scope [AMENDED]

310:260-1-3. Incorporation by reference [AMENDED]

310:260-1-6. Definitions [AMENDED]

Subchapter 3. Manufacturing, Processing, Packing or Holding Human Food

310:260-3-1. Personnel [AMENDED]

310:260-3-2. Grounds and plants [AMENDED]

310:260-3-3. Sanitary operations [AMENDED]

310:260-3-4. Sanitary facilities and controls [AMENDED]

310:260-3-5. Equipment and utensils [AMENDED]

310:260-3-6. Processes and controls [AMENDED]

Subchapter 5. Tree Nut ~~Peanut~~ Processing [AMENDED]

310:260-5-1. Tree Nut ~~Peanut~~ crackers/shellers [AMENDED]

310:260-5-2. Custom Tree Nut ~~peanut~~ crackers [AMENDED]

Subchapter 7. Salvageable and Salvaged Merchandise

310:260-7-1. Merchandise protection [AMENDED]

310:260-7-2. Movement of distressed merchandise [AMENDED]

310:260-7-3. Reconditioning [AMENDED]

310:260-7-4. Labeling [AMENDED]

310:260-7-5. Handling of nonsalvageable merchandise [AMENDED]

310:260-7-6. Record keeping [AMENDED]

310:260-7-7. Salvage processors and distributors out-of-state [AMENDED]

Subchapter 9. Food Storage Warehouses

310:260-9-1.1. Warehousing and distribution [NEW]

310:260-9-1. Lighting and ventilation [AMENDED]

310:260-9-2. Dry storage [AMENDED]

310:260-9-3. Cold and Frozen storage [AMENDED]

310:260-9-4. Protection of stored food [AMENDED]

310:260-9-5. Morgue [AMENDED]

310:260-9-6. Restroom Toilet and handwashing facilities [AMENDED]

310:260-9-7. Waste storage and disposal [AMENDED]

310:260-9-8. Exterior construction [AMENDED]

310:260-9-9. Surroundings

310:260-9-10. Transportation and storage [AMENDED]

310:260-9-11. Exemptions [AMENDED]

Subchapter 11 - Licensing, Inspections and Plan Review [REVOKED]

310:260-11-1. Licensing [REVOKED]

310:260-11-2. Inspections [REVOKED]

310:260-11-3. Examination and condemnation of food [REVOKED]

310:260-11-4. Plan review [REVOKED]

Subchapter 13 - Special Risk Situations [REVOKED]

310:260-13-1. Emergency occurrences [REVOKED]

- 310:260-13-2. Infection [REVOKED]
- Subchapter 15 – Compliance and Enforcement [NEW]
- 310:260-15-1. License Required [NEW]
- 310:260-15-2. Examination and condemnation of food [NEW]
- 310:260-15-3. Variance [NEW]
- 310:260-15-4. Documentation of proposed variance and justification [NEW]
- 310:260-15-5. When Plans are required [NEW]
- 310:260-15-6. Contents of the Plans and Specifications [NEW]
- 310:260-15-7. Preoperational inspections
- 310:260-15-8. Form of submission [NEW]
- 310:260-15-9. Qualifications and responsibilities of applicants [NEW]
- 310:260-15-10. Contents of the application [NEW]
- 310:260-15-11. New, converted, or remodeled establishments [NEW]
- 310:260-15-12. Issuance of license [NEW]
- 310:260-15-13. Denial of application for license, notice [NEW]
- 310:260-15-14. Responsibilities of the license holder [NEW]
- 310:260-15-15. Licenses not transferable [NEW]
- 310:260-15-16. Competency of inspectors [NEW]
- 310:260-15-17. Allowed at reasonable times after due notice [NEW]
- 310:260-15-18. Refusal, notification of right to access, and final request for access [NEW]
- 310:260-15-19. Refusal, reporting [NEW]
- 310:260-15-20. Inspection order to gain access [NEW]
- 310:260-15-21. Documenting information and observations [NEW]
- 310:260-15-22. Specifying time frame for corrections [NEW]
- 310:260-15-23. Issuing report and obtaining acknowledgment of receipt [NEW]
- 310:260-15-24. Refusal to sign acknowledgment [NEW]
- 310:260-15-25. Ceasing operations and reporting [NEW]
- 310:260-15-26. Resumption of operations [NEW]
- 310:260-15-27. Obtaining information: personal history of illness, medical examination, and specimen analysis [NEW]
- 310:260-15-28. Restriction or exclusion of employee with infection [NEW]

SUMMARY:

A brief summary of the contents and purpose of the rule are provided here.

310:260-1-1. Purpose; citation: The current rule declares a need to regulate food manufacturing to provide uniformity of inspections to protect consumers from adulterated or misbranded foods. The proposed rule implements 63 O.S. Section 1-1101 et seq to protect consumers from adulterated or misbranded foods, and establish definitions, set standards, provides for food establishment plan review, license issuance, inspection, employee restriction, and license suspension.

310:260-1-2. Scope: The current rule sets the criteria in subchapter 3 to determine if facilities, methods, and controls used to manufacture food products are in conformance with good manufacturing practices to ensure that food for human consumption is safe and has been prepared, packaged, salvaged, or held under sanitary conditions. The proposed rule states all criteria in the chapter shall apply to all food manufacturing, processing, packing, holding, transporting, or salvage operations conducted within the State of Oklahoma.

310:260-1-3. Incorporation by reference: The current rule incorporates CFR 21 part 70 through 73A, 74A, 80 through 82B, 100 through 197, 1210, 1220, and 1250, Code of Federal Regulations (CFR), as of April 1, 1991, issued under the Federal Food, Drug and Cosmetic Act of April 1, 1986 are hereby incorporated by reference into this regulation, except: Parts 104.19, 109.5, 170.15, and 171. The proposed rule incorporates by reference, as published on July 1, 2019, a detailed list of CFRs.

310:260-1-6. Definitions: The current rule has a list of definitions established in 1990. The proposed rule adds multiple definitions from the industry, the retail food code, and 21, CFR 110.

310:260-3-1. Personnel: The current rule addresses employee personal hygiene. The proposed rule adds descriptions of open wounds, use of gloves, and protection against allergen cross-contact.

310:260-3-2. Grounds and plants: The current rule provides basic construction standards for a food manufacturing plant. The proposed rule also addresses allergen cross-contact and clarifies shatter-resisting lighting.

310:260-3-3. Sanitary operations: The current rule addresses general sanitary operations, cleaning, use of toxics, pest control, sanitation and storage of food contact surfaces. The proposed rule clarifies language and also addresses allergen cross-contact and sanitation of non-food contact surfaces.

310:260-3-4. Sanitary facilities and controls: The current rule addresses approved water supply, plumbing, sewage disposal, toilet facilities, and trash disposal. The proposed rule clarifies language in regards to each topic.

310:260-3-5. Equipment and utensils: The current rule addresses equipment construction, installation, and use. The proposed rule clarifies language and addresses allergen cross-contact.

310:260-3-6. Processes and controls: The current rule addresses the general sanitation, raw materials, and food manufacturing operations. The proposed rule simplifies and clarifies language, and addresses allergen cross-contact.

Subchapter 5 – Tree Nut ~~Pecan~~ Processing: The current rule describes pecan processors. The proposed rule describes tree nut processors.

310:260-5-1. Tree Nut ~~Pecan~~ crackers/shellers: The current rule addresses the physical facilities of a pecan cracker establishment and the cleaning, sanitizing, and drying of pecans. The proposed rule allows for all tree nuts, corrects grammar, and eliminates redundant language.

310:260-5-2. Custom Tree Nut ~~pecan~~ crackers: The current rule describes signage and sales tickets required of a custom pecan cracker. The proposed rule expands the rule to custom tree nut processors and corrects language.

310:260-7-1. Merchandise protection: The current rule describes methods of protection from contamination for salvaged foods. The proposed rule corrects language and updates terminology.

310:260-7-2. Movement of distressed merchandise: The current rule addresses the notice to department of the creation or movement of salvaged food. The proposed rule corrects and simplifies language.

310:260-7-3. Reconditioning: The current rule describes what non-salvageable food items are. The proposed rule corrects and simplifies language.

310:260-7-4. Labeling: The current rule describes the label removal and relabeling process. The proposed rule simplifies and clarifies language.

310:260-7-5. Handling of nonsalvageable merchandise: The current rule describes non-salvageable food items and how they must be disposed of. The proposed rule removes the requirement for the Department to supervise the disposal.

310:260-7-6. Record keeping: The current rule describes the records retention process for the salvaged food establishments. The proposed rule changes the time limit from two years from the completion of transactions involving the products to 2 years from receipt of the product.

310:260-7-7. Salvage processors and distributors out-of-state: The current rule describes the requirements of out of state food salvage processors and distributors and requires a permit to be issued from the Department. The proposed rule removes the requirement of a permit from the Department.

310:260-9-1.1. Warehousing and distribution: There is no current rule. The proposed rule addresses the protection of food during storage and transportation against allergen cross-contact, biological, chemical, and physical contamination.

310:260-9-1. Lighting and ventilation: The current rule describes the lighting and ventilation requirements of a warehouse. The proposed rule corrects language.

310:260-9-2. Dry storage: The current rule describes the characteristics of the floors, walls, and ceilings of a dry storage area. The proposed rule corrects language.

310:260-9-3. Cold and Frozen storage: The current rule describes storage requirements for frozen and refrigerated foods. The proposed rule corrects language and updates terminology.

310:260-9-4. Protection of stored food: The current rule addresses pest control, use of rodenticides, storage of toxics, and storage of food items. The proposed rule removes approval of rodenticides and clarifies the storage of foods and toxics.

310:260-9-5. Morgue: The current rule describes the storage and disposal of returned wholesale food items. The proposed rule corrects language.

310:260-9-6. Restroom Toilet and handwashing facilities: The current rule describes the restroom and hand sink requirements of a warehouse establishment. The proposed rule corrects language.

310:260-9-7. Waste storage and disposal: The current rule describes the removal of liquid and physical waste from a warehouse facility. The proposed rule corrects language.

310:260-9-8. Exterior construction: The current rule describes the exterior construction of a warehouse establishment. The proposed rule corrects language.

310:260-9-9. Surroundings: The current rule describes the requirements for the outer premises of a warehouse facility. The proposed rule corrects language.

310:260-9-10. Transportation and storage:
The current rule describes the sanitation and food protection requirements of transport vehicles. The proposed rule corrects language.

310:260-9-11. Exemptions: The current rule exempts bin warehouses from restroom requirements. The proposed rule corrects language.

Subchapter 11 - Licensing, Inspections and Plan Review: The current rule outlines the plan review, licensing, and inspection process. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

310:260-11-1. Licensing: The current rule outlines the application process, license expiration, and suspension process. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

310:260-11-2. Inspections: The current rule outlines the inspection process. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

310:260-11-3. Examination and condemnation of food: The current rule allows the Department to sample and test food products. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

310:260-11-4. Plan review: The current rule outlines the plan review process. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

Subchapter 13 - Special Risk Situations: The current rule defines what is an emergency occurrence or infection of staff. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

310:260-13-1. Emergency occurrences: The current rule defines an emergency occurrence, what the owner must do, and what the Department must do. There is no proposed rule as this section is revoked and replaced by Subchapter 15. 310:260-13-2. Infection:

The current rule defines what an establishment must do when they determine an employee is infectious. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

Subchapter 15 – Compliance and Enforcement: There is no current rule. The proposed rule sets forth plan review, licensing, inspection, enforcement, and variance requirements.

310:260-15-1. License Required: There is no current rule. The proposed rule sets forth the statutory requirement for possession of a license to manufacture or wholesale food and the expiration of the license.

310:260-15-2. Examination and condemnation of food: There is no current rule. The proposed rule allows the Department to sample and test food products.

310:260-15-3. Variance: There is no current rule. The proposed rule allows for a variance to be granted in regards to a section of this chapter.

310:260-15-4. Documentation of proposed variance and justification: There is no current rule. The proposed rule defines what is required in a variance application.

310:260-15-5. When Plans are required: There is no current rule. The proposed rule defines the stages at which a plan review must be conducted.

310:260-15-6. Contents of the Plans and Specifications: There is no current rule. The proposed rule describes what is to be included in a plan review application.

310:260-15-7. Preoperational inspections: There is no current rule. The proposed rule allows the Department to make preoperational inspections.

310:260-15-8. Form of submission: There is no current rule. The proposed rule defines how a prospective business owner must apply for a license.

310:260-15-9. Qualifications and responsibilities of applicants: There is no current rule. The proposed rule defines who may own an establishment regulated under this chapter.

310:260-15-10. Contents of the application: There is no current rule. The proposed rule describes what must be on the license application.

310:260-15-11. New, converted, or remodeled establishments: There is no current rule. The proposed rule describes what is required for a new, converted, or remodeled establishment to obtain a license.

310:260-15-12. Issuance of license: There is no current rule. The proposed rule describes who the Department will issue the license to.

310:260-15-13. Denial of application for license, notice: There is no current rule. The proposed rule describes how the Department will notify the applicant.

310:260-15-14. Responsibilities of the license holder: There is no current rule. The proposed rule describes what a license holder must do to remain in good standing.

310:260-15-15. Licenses not transferable: There is no current rule. The proposed rule forbids the transfer of a license between owners.

310:260-15-16. Competency of inspectors: There is no current rule. The proposed rule defines the professional licensing requirements of inspectors.

310:260-15-17. Allowed at reasonable times after due notice: There is no current rule. The proposed rule defines the times at which an inspection may be conducted.

310:260-15-18. Refusal, notification of right to access, and final request for access: There is no current rule. The proposed rule describes the process that begins when an inspection is denied.

310:260-15-19. Refusal, reporting: There is no current rule. The proposed rule describes how the inspector shall report the refusal of an inspection.

310:260-15-20. Inspection order to gain access: There is no current rule. The proposed rule allows the Department to issue an order to allow inspection.

310:260-15-21. Documenting information and observations: There is no current rule. The proposed rule describes what is recorded on the inspection sheet.

310:260-15-22. Specifying time frame for corrections: There is no current rule. The proposed rule allows the Department to specify a time frame for correction.

310:260-15-23. Issuing report and obtaining acknowledgment of receipt: There is no current rule. The proposed rule describes providing the establishment with a copy of the inspection.

310:260-15-24. Refusal to sign acknowledgment: There is no current rule. The proposed rule describes what happens when the person in charge refuses to sign the inspection sheet.

310:260-15-25. Ceasing operations and reporting: There is no current rule. The proposed rule defines situations in which an establishment shall cease food preparation activities.

310:260-15-26. Resumption of operations: There is no current rule. The proposed rule describes what the business owner must do prior to reopening after an imminent health hazard.

310:260-15-27. Obtaining information: personal history of illness, medical examination, and specimen analysis: There is no current rule. The proposed rule allows the Department to request information if an employee is suspected of being contagious.

310:260-15-28. Restriction or exclusion of employee with infection: There is no current rule. The proposed rule allows the Department to restrict the work activities of an employee who is contagious.

AUTHORITY:

Oklahoma State Commissioner of Health, Title 63 O.S. §1-104, Title 63 O.S. § 1-1101 et seq., and Title 63 O.S. § 1-1119.

COMMENT PERIOD:

February 3, 2020, through March 7, 2020. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through March 7, 2020, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on March 6, 2020, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 from 9AM to noon. The alternate date and time in the event of an office closure due to inclement weather is March 10, 2020, in room 1102, from 9AM to noon. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through March 7, 2020, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSONS:

Kim Bailey, General Counsel, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6017, e-mail KimB@health.ok.gov or Audrey C. Talley, Rule Liaison, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 260. GOOD MANUFACTURING PRACTICE REGULATIONS

1. **DESCRIPTION:**

A brief summary of the contents and purpose of the rule are provided here.

310:260-1-1. Purpose; citation: The current rule declares a need to regulate food manufacturing to provide uniformity of inspections to protect consumers from adulterated or misbranded foods. The proposed rule implements 63 O.S. Section 1-1101 et seq to protect consumers from adulterated or misbranded foods, and establish definitions, set standards, provides for food establishment plan review, license issuance, inspection, employee restriction, and license suspension.

310:260-1-2. Scope: The current rule sets the criteria in subchapter 3 to determine if facilities, methods, and controls used to manufacture food products are in conformance with good manufacturing practices to ensure that food for human consumption is safe and has been prepared, packaged, salvaged, or held under sanitary conditions. The proposed rule states all criteria in the chapter shall apply to all food manufacturing, processing, packing, holding, transporting, or salvage operations conducted within the State of Oklahoma.

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310:260-11-4. Plan review: The current rule outlines the plan review process. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

Subchapter 13 - Special Risk Situations: The current rule defines what is an emergency occurrence or infection of staff. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

310:260-13-1. Emergency occurrences: The current rule defines an emergency occurrence, what the owner must do, and what the Department must do. There is no proposed rule as this section is revoked and replaced by Subchapter 15.

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Subchapter 15 – Compliance and Enforcement: There is no current rule. The proposed rule sets forth plan review, licensing, inspection, enforcement, and variance requirements.

310:260-15-1. License Required: There is no current rule. The proposed rule sets forth the statutory requirement for possession of a license to manufacture or wholesale food and the expiration of the license.

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310:260-15-6. Contents of the Plans and Specifications: There is no current rule. The proposed rule describes what is to be included in a plan review application.

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310:260-15-8. Form of submission: There is no current rule. The proposed rule defines how a prospective business owner must apply for a license.

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310:260-15-13. Denial of application for license, notice: There is no current rule. The proposed rule describes how the Department will notify the applicant.

310:260-15-14. Responsibilities of the license holder: There is no current rule. The proposed rule describes what a license holder must do to remain in good standing.

310:260-15-15. Licenses not transferable: There is no current rule. The proposed rule forbids the transfer of a license between owners.

310:260-15-16. Competency of inspectors: There is no current rule. The proposed rule defines the professional licensing requirements of inspectors.

310:260-15-17. Allowed at reasonable times after due notice: There is no current rule. The proposed rule defines the times at which an inspection may be conducted.

310:260-15-18. Refusal, notification of right to access, and final request for access: There is no current rule. The proposed rule describes the process that begins when an inspection is denied.

310:260-15-19. Refusal, reporting: There is no current rule. The proposed rule describes how the inspector shall report the refusal of an inspection.

310:260-15-20. Inspection order to gain access: There is no current rule. The proposed rule allows the Department to issue an order to allow inspection.

310:260-15-21. Documenting information and observations: There is no current rule. The proposed rule describes what is recorded on the inspection sheet.

310:260-15-22. Specifying time frame for corrections: There is no current rule. The proposed rule allows the Department to specify a time frame for correction.

310:260-15-23. Issuing report and obtaining acknowledgment of receipt: There is no current rule. The proposed rule describes providing the establishment with a copy of the inspection.

310:260-15-24. Refusal to sign acknowledgment: There is no current rule. The proposed rule describes what happens when the person in charge refuses to sign the inspection sheet.

310:260-15-25. Ceasing operations and reporting: There is no current rule. The proposed rule defines situations in which an establishment shall cease food preparation activities.

310:260-15-26. Resumption of operations: There is no current rule. The proposed rule describes what the business owner must do prior to reopening after an imminent health hazard.

310:260-15-27. Obtaining information: personal history of illness, medical examination, and specimen analysis: There is no current rule. The proposed rule allows the Department to request information if an employee is suspected of being contagious.

310:260-15-28. Restriction or exclusion of employee with infection: There is no current rule. The proposed rule allows the Department to restrict the work activities of an employee who is contagious.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

Persons potentially affected are those who operate a food manufacturing, wholesale, salvage, or tree nut processing establishment, the state employees who inspect and regulate these establishments, and the general public who purchases product made at these establishments.

- Potential costs to the regulated industry will be minimal as the FDA already imposes these rules on any establishment who sells their product across state lines.

3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**

Businesses will benefit from this rule due to the increased ability to sell products outside of Oklahoma.

- The general public will benefit by the increased food safety measures applied to manufactured foods.

4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**

There is no fiscal impact.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**

There is no fiscal impact.

- The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

6. **IMPACT ON POLITICAL SUBDIVISIONS:**

There is no anticipated impact.

7. **ADVERSE EFFECT ON SMALL BUSINESS:**

There is no anticipated adverse effect..

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**

This rule is adapted from the current 21 CFR 110 used by the FDA.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**

This rule will have a positive effect on public health due to the increased food safety measures applied to manufactured foods.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

This rule has no known detrimental effect on public health and safety if not adopted.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on Monday, January 06, 2020.

Title 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
Chapter 260. GOOD MANUFACTURING PRACTICE REGULATIONS

SUBCHAPTER 1. GENERAL PROVISIONS

310:260-1-1. Purpose; citation

- (a) The rules in this Chapter implement 63 O.S. Section 1-1101 et seq. The purpose of this Chapter is to safeguard public health and provide to consumers food that is safe, unadulterated, and honestly presented. This Chapter establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food establishment plan review, license issuance, inspection, employee restriction, and license suspension ~~The Oklahoma State Board of Health finds and declares that a uniform statewide code is needed to regulate all food manufacturing, processing, packing, holding, transporting or salvaging operations conducting business within the State of Oklahoma, to provide for uniformity in inspecting of such establishments, and to protect the health of consumers by preventing the sale or distribution of foods which have become adulterated or misbranded.~~
- (b) These rules and regulations may be cited as the Human Foods Good Manufacturing Practice Regulations.

310:260-1-2. Scope

~~The criteria in this chapter subchapter 3 shall apply to all food manufacturing, processing, packing, holding, transporting, or salvage operations conducted within the State of Oklahoma in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, salvaging or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to ensure that food for human consumption is safe and has been prepared, packaged, salvaged, or held under sanitary conditions.~~

310:260-1-3. Incorporation by reference

- (a) The following Code of Federal Regulation (CFR) provisions are incorporated by reference as published on July 1, 2019 ~~Title 21, Parts:~~

- (1) Title 21 CFR, Part 70 COLOR ADDITIVES;
- (2) Title 21 CFR, Part 73 LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION, Subpart A-Foods;
- (3) Title 21 CFR, Part 82 LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS, Subpart A-General Provisions and Subpart B-Foods, Drugs, and Cosmetics;
- (4) Title 21 CFR, Part 100 GENERAL;
- (5) Title 21 CFR, Part 101 FOOD LABELING;
- (6) Title 21 CFR, Part 102 COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS;
- (7) Title 21 CFR, Part 104 NUTRITIONAL QUALITY GUIDELINES FOR FOODS;
- (8) Title 21 CFR, Part 105 FOODS FOR SPECIAL DIETARY USE;
- (9) Title 21 CFR, Part 106 INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS;
- (10) Title 21 CFR, Part 107 INFANT FORMULA;
- (11) Title 21 CFR, Part 109 UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL, Subpart A-General Provisions and Subpart B-Tolerances for Unavoidable Poisonous or Deleterious Substances;
- (12) Title 21 CFR, Part 110 CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD;
- (13) Title 21 CFR, Part 111 CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS;

- (14) Title 21 CFR, Part 113 THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS;
- (15) Title 21 CFR, Part 114 ACIDIFIED FOODS;
- (16) Title 21 CFR, Part 120 HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS;
- (17) Title 21 CFR, Part 123 FISH AND FISHERY PRODUCTS;
- (18) Title 21 CFR, Part 129 PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER;
- (19) Title 21 CFR, Part 136 BAKERY PRODUCTS;
- (20) Title 21 CFR, Part 137 CEREAL FLOURS AND RELATED PRODUCTS;
- (21) Title 21 CFR, Part 139 MACARONI AND NOODLE PRODUCTS;
- (22) Title 21 CFR, Part 145 CANNED FRUITS;
- (23) Title 21 CFR, Part 146 CANNED FRUIT JUICES;
- (24) Title 21 CFR, Part 150 FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS;
- (25) Title 21 CFR, Part 152 FRUIT PIES;
- (26) Title 21 CFR, Part 155 CANNED VEGETABLES;
- (27) Title 21 CFR, Part 156 VEGETABLE JUICES;
- (28) Title 21 CFR, Part 158 FROZEN VEGETABLES;
- (29) Title 21 CFR, Part 160 EGGS AND EGG PRODUCTS;
- (30) Title 21 CFR, Part 161 FISH AND SHELLFISH;
- (31) Title 21 CFR, Part 163 CACAO PRODUCTS;
- (32) Title 21 CFR, Part 164 TREE NUT AND PEANUT PRODUCTS;
- (33) Title 21 CFR, Part 166 MARGARINE;
- (34) Title 21 CFR, Part 168 SWEETENERS AND TABLE SIRUPS;
- (35) Title 21 CFR, Part 169 FOOD DRESSINGS AND FLAVORINGS;
- (36) Title 21 CFR, Part 170 FOOD ADDITIVES;
- (37) Title 21 CFR, Part 172 FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION;
- (38) Title 21 CFR, Part 173 SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION;
- (39) Title 21 CFR, Part 174 INDIRECT FOOD ADDITIVES: GENERAL;
- (40) Title 21 CFR, Part 175 INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS;
- (41) Title 21 CFR, Part 176 INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS;
- (42) Title 21 CFR, Part 177 INDIRECT FOOD ADDITIVES: POLYMERS;
- (43) Title 21 CFR, Part 178 INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS;
- (44) Title 21 CFR, Part 179 IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD;
- (45) Title 21 CFR, Part 180 FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY;
- (46) Title 21 CFR, Part 181 PRIOR-SANCTIONED FOOD INGREDIENTS;
- (47) Title 21 CFR, Part 182 SUBSTANCES GENERALLY RECOGNIZED AS SAFE;
- (48) Title 21 CFR, Part 184 DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE;
- (49) Title 21 CFR, Part 186 INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE;
- (50) Title 21 CFR, Part 189 SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

~~70 through 73A, 74A, 80 through 82B, 100 through 197, 1210, 1220, and 1250, Code of Federal Regulations (CFR), as of April 1, 1991, issued under the Federal Food, Drug and Cosmetic Act of April 1, 1986 are hereby incorporated by reference into this regulation, except: Parts 104.19, 109.5, 170.15, and 171.~~

(b) For purposes of the provisions adopted by reference, references to the "Secretary" or "Commissioner" shall be deemed to mean the Commissioner of Health for the State of Oklahoma, and "Department" shall be deemed to mean the Oklahoma State Department of Health.

(c) When a provision of the Code of Federal Regulations is incorporated by reference, all citations contained therein are also incorporated by reference, and the definitions contained therein shall apply.

(d) In the event that there are inconsistencies or duplications in the requirements of those provisions incorporated by reference from the CFR, and the requirements otherwise set forth herein, the provisions incorporated from the CFR shall prevail except where the regulations set forth herein are more stringent.

310:260-1-6. Definitions

The following words or terms, when used in this chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Acid food or acidified food" means foods that have an equilibrium pH of 4.6 or below.

~~"Act" means Article 11 (Food) of the Oklahoma Public Health Code, Title 63 O.S. 1-1101 et.seq., as amended.~~

"Additive" as used in this Chapter shall have the same meaning for the following terms:

(1) "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 321(t) and 21 CFR, Part 70.

(2) "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 321(s) and 21 CFR, Part 170.

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

"Adulterated" means the definition in 63 O.S. Section 1-1109.

"Approved" means acceptable to the Department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

"Batter" means a semi-fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

"Beverage" means a liquid for drinking, including water.

"Bin warehouse" means any building where pre-packaged food is stored, the operator or his employee is present no more than two hours daily, and no other operations are conducted.

"Blanching", except for tree nuts and peanuts, means a prepackaging heat treatment of food stuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or bio-chemical changes in food.

"CFR" means Code of Federal Regulations. Citations in this Chapter to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR, 178.1010 refers to Title 21, Part 178, Section 1010.

"Code of Federal Regulations" means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which is published annually by the U.S. Government Printing Office; and contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40 CFR, and Wildlife and Fisheries rules in 50 CFR.

"Control measure" means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

"Corrosion-resistant" means capable of maintaining original surface characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and bactericidal solutions, and other conditions-of-use.

"Critical control point" means a point or procedure in a specific food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or filth in the final food or decomposition of the final food.

"Custom tree nut pecan cracking" means the cracking of whole tree nuts pecans for individual customers. The tree nuts pecans may be brought by the customer from off the premises or may be purchased from the cracker. Tree nuts Pecans may not be cracked for resale.

"Department" means the Oklahoma State Department of Health, and its duly designated representatives, and a health department designated in writing by the State Commissioner of Health to perform official duties or other acts authorized under the Oklahoma Public Health Code and this Chapter.

"Distressed merchandise" means any food which has been subjected to improper storage; loss of label or identity; smoke, water, fumes, extreme temperatures, pressure or radiation which are due to natural disasters or otherwise; or which may have been rendered unsafe or unsuitable for human or animal consumption or use for any other reason.

"Easily cleanable" means that surfaces are readily accessible and made of such materials and finish and so fabricated that residue may be effectively removed by normal cleaning methods.

"Employee" means the license holder, person in charge, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in an establishment ~~any individual having supervisory or management duties and any other person working in a food establishment.~~

"Equipment" means an article that is used in the operation of an establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine. It does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids ~~stoves, ovens, ranges, hoods, slicers, mixers, meatblocks, tables, counters, refrigerators, sinks, dishwashing machines, steam tables, and similar items other than utensils, used in the operation of a food establishment.~~

"Food" means any raw, cooked, or processed edible substance, ice, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption.

"Food contact surfaces" means those surfaces of equipment and utensils with which food normally comes in contact, and those surfaces from which food may contact drain, drip, or splash back onto surfaces normally in contact with food.

"Food hazard" means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

"Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and provides food for sale or distribution to other business entities such as food processing plants or food establishments.

"Food storage warehouse" means any building, establishment or place where food is stored as a commercial venture or business, or is stored in connection with or as a part of a business.

"Tree nut grower Grower" means a person who sells only whole tree nuts pecans grown on his property.

"HACCP" means Hazard Analysis Critical Control Point.

"HACCP plan" 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.

"Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a plumbing fixture especially placed for use in personal hygiene and designed for washing of the hands.

"Hazardous substance" means any substance or mixture of substances which is toxic, corrosive, an irritant, strong sanitizer, flammable or which generates pressure through decomposition.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

"Imminent public health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury means a situation wherein the evidence is sufficient to show that a product or practice, posing a significant threat or danger to health, creates a public health situation that should be corrected immediately to prevent injury and that should not be permitted to continue while a hearing or other formal proceeding is pending.

"Impermeable" means incapable of allowing liquids to pass through the covering.

"License" means the document issued by the Department that authorizes a person to operate an establishment.

"License holder" means the entity that is legally responsible for the operation of the establishment such as the owner, the owner's agent, or other person; and possesses a valid license to operate an establishment.

"Lot" means the food produced during a period of time indicated by a specific code.

"Major food allergen" means milk, egg, fish (such as bass, flounder, cod, and including crustacean such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or a food ingredient that contains protein derived from a food specified above.

(1) Major food allergen does not include: Any highly refined oil derived from a food specified in Major Food Allergen definition and any ingredient derived from such highly refined oil; or

(2) Any ingredient that is exempt under the petition or notification process specified in the Federal Food, Drugs, and Cosmetics Act, 21 U.S.C. Section 343

"Manufacture" means the process of combining or purifying articles of food and packing same for sale to the consumer, either by wholesale or retail. Any firm, person, or corporation who represents itself as responsible for the purity and the proper labeling of any article of food by placing or having placed its name and address on the label of any food shall be deemed a manufacturer and shall be included within the meaning of these rules.

"Microorganism" means yeasts, molds, bacteria and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

"Misbranding" means the definition contained in 63 O.S. Section 1-1110.

"Monitor" means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

"Non-food contact surfaces" means surfaces of equipment not intended for contact with food, but which are being exposed to splash or food debris or which otherwise require frequent cleaning. These surfaces shall be designed and fabricated to be smooth, washable, free of unnecessary ledges, projections, or crevices, and readily accessible for cleaning, and shall be of such material and in such repair as to be easily maintained in a clean and sanitary condition.

"Non-salvageable merchandise" means distressed merchandise which cannot be safely or practically reconditioned.

~~"Operator" means any person, partnership, corporation, association, cooperative or other business unit having the direct and primary responsibility for the construction, maintenance and operation of a food storage or food manufacturing plant or warehouse.~~

"Packaging" means any covering, wrapper, or container in which a product is placed for retail or wholesale distribution, either before or after sale, to a consumer. Packaging shall not be construed to include the inner wrapper.

"Tree nut Pecan cracker/sheller" means a commercial establishment in which tree nuts pecans are processed and/or packaged for human consumption, other than custom tree nut pecan cracking.

"Perishable foods" means any food of such type or in such condition or physical state that it may spoil or otherwise become unfit for human consumption.

"Person" means an individual, corporation, business trust, estate, trust, partnership, association, or any other public or private legal entity.

"Personnel" means all persons employed by a food manufacturer, salvage establishment or salvage broker who do or may in any manner handle or come in contact with the handling, storage, transporting, selling or distributing of food, salvageable or salvaged merchandise.

"Pest" means any objectionable animal or insect including, but not limited to, birds, rodents, flies and larvae.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

"Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling or holding of human food.

"Potentially hazardous food" means any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustaceans, or other ingredients, including synthetic ingredients, in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. The term does not include foods which have a pH level of 4.6 or below a water activity (a) value of 0.85 or less.

"Plumbing fixture" means a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

"Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Potable water" means water obtained from an approved source that is:

- (1) A public water system, or
- (2) A nonpublic water system that is constructed, maintained, and operated according to law.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 4 categories:

- (1) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (2) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;
- (3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and
- (4) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

"Processing" means the preparing of a food in a manner which changes the food from its original state.

"Processor" means anyone processing food under the authority of this chapter.

"Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

"Reconditioning" means any appropriate process or procedure by which distressed merchandise can be brought into compliance with the standards of the Department for consumption or use by the public.

"Refuse" means all garbage, trash, and rubbish not intended for reuse as salvaged merchandise.

"Regulatory authority" means the Oklahoma State Department of Health, a health department designated in writing by the State Commissioner of Health to perform official duties or other acts authorized under the Oklahoma Public Health Code and this Chapter, or a representative thereof.

"Rework" means clean, unadulterated food that has been removed from processing for reasons other than ~~unsanitary~~ ~~insanitary~~ conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

"Safe moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage and distribution. The maximum safe moisture level for a food is based on its water activity (~~aw~~ ~~aw~~). An ~~aw~~ ~~aw~~ will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

"Safe temperatures" as applied to Time/Temperature Control for Safety Food ~~potentially hazardous food~~ means food temperature of 45°F or below 140°F or above.

"Sale or distribution" means the act of selling or distributing, whether for compensation or not, and includes delivery, holding or offering for sale, transfer, or other means of handling or trafficking.

"Salvage distributor or broker" means a person who engages in the business of selling, distributing, or otherwise trafficking in any distressed or salvaged merchandise who does not operate a salvage establishment.

"Salvage establishment" means any place of business engaged in reconditioning or by other means the salvaging of distressed merchandise or that sells, buys or distributes for human use any salvaged merchandise.

"Salvage operator" means a person who is engaged in the business of operating a salvage establishment.

"Salvage processing plant" means any establishment primarily engaged in the business of reconditioning or by other means the salvaging of distressed merchandise and which sells or distributes such merchandise for human use.

"Salvage warehouse" means a separate storage facility used by a salvage broker or salvage establishment for the purpose of holding distressed or salvaged merchandise. A salvage warehouse may not be used for the purpose of reconditioning or selling to consumers.

"Salvageable merchandise" means any distressed merchandise, as defined in this section, which can be reconditioned to the satisfaction of the Department.

"Salvaged merchandise" means any distressed merchandise that has been reconditioned to the satisfaction of the Department.

"Sanitize ~~Sanitization~~" means adequately treat food-contact ~~adequate treatment of surfaces~~ by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing the number of other microorganisms but without. ~~Such treatments shall not adversely affecting affect the product or its safety and shall be safe to the consumer.~~

"Shall" is used to state mandatory requirements.

"Shelf-stable product" means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

"Should" is used to state recommended or advisory procedures or to identify recommended equipment.

"Single-service articles" means cups, containers, lids, closures, plates, knives, forks, spoons, stirrers, paddles, straws, placemats, napkins, doilies, wrapping materials, toothpicks and similar articles, intended to be discarded after one use.

"Standard operating procedure (SOP)" means a set of step-by-step instructions compiled by the establishment to instruct employees in the proper method to perform complex routine operations. SOPs aim to achieve efficiency and quality control, while reducing miscommunication, and documenting failures to enable better process to be developed.

"Time/Temperature Control for Safety Food" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

"**Utensil**" means any implement used in the storage, preparation, transportation, or service of food.

"**Variance**" means a written document issued by the Department that authorizes a modification or waiver of one or more requirements of this Chapter, if, in the opinion of the Department, a health hazard or nuisance will not result from the modification or waiver.

"**Vehicle**" means any car, truck, bus or other means by which food or distressed, salvageable or salvaged merchandise is transported from one location to another.

"**Water activity**" (~~aw~~ ~~aw~~) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

"**Wholesome**" means in sound condition, clean, free from adulteration and otherwise suitable for human consumption.

SUBCHAPTER 3. MANUFACTURING, PROCESSING, PACKING OR HOLDING HUMAN FOOD

310:260-3-1. Personnel

(a) **Disease control.** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packing materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report such health conditions to their supervisors.

(b) **Cleanliness.** All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- (1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.
- (2) Maintaining adequate personal cleanliness.
- (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work station, and at any other time when hands may have become soiled or contaminated.
- (4) Removing all ~~insecure~~ unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
- (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. ~~The gloves should be of an impermeable material, and intended for use in handling food.~~
- (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
- (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
- (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
- (9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packing materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

- (c) Education and training.** Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.
- (d) Supervision.** Responsibility for assuring compliance by all personnel with all requirements of this Chapter shall be clearly assigned to competent supervisory personnel.
- (e) Implementation.** The plant management shall take all reasonable measures and precautions to ensure that the provisions of the above subsections are achieved.

310:260-3-2. Grounds and plants

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

- (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
- (2) Maintaining roads, yards, and parking lots, including dust and flying debris, so that they do not constitute a source of contamination in areas where food is exposed.
- (3) Adequately draining areas that may contribute contamination to food by seepage, food-borne filth, or providing a breeding place for pests.
- (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
- (5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes (i.e., manufacturing, processing, packing, and holding). The plant and facilities shall:

- (1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
- (2) Permit the taking adequate of proper precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packing materials with microorganisms, chemicals, filth, or other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which for allergen cross-contact and contamination are is likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.
- (3) Permit the taking of proper precautions to protect food in installed outdoor bulk fermentation vessels by any effective means, including:
 - (A) Using protective coverings.
 - (B) Controlling areas over and around the vessels to eliminate harborage for pests.
 - (C) Checking on a regular basis for pests and pest infestation.
 - (D) Skimming the fermentation vessels, as necessary.
- (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food packing materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, packed or held ~~or stored~~ and where equipment or utensils are cleaned.

(6) Provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage safety type light bulbs or protective shielding of artificial lighting fixtures located over, by, or within food storage or preparation areas and facilities where utensils and equipment are cleaned or stored, or otherwise protect against food contamination by broken glass.

(7) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(8) Provide, where necessary, adequate screening or other protection against pests.

(9) Provide adequate protection, from contamination, of food products, while being transported by vehicles.

310:260-3-3. Sanitary operations

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated ~~within the meaning of the Act.~~ Cleaning and sanitizing of utensils and equipment operations shall be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Cleaning and sanitizing substances. ~~Cleaning~~ Approved cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a letter of supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials ~~that are required to maintain sanitary conditions~~ may be used or stored in a plant where food is processed or exposed:

- (1) Those required to maintain clean and sanitary conditions;
- (2) Those necessary for use in laboratory testing procedures;
- (3) Those necessary for plant and equipment maintenance and operation; and
- (4) Those necessary for use in the plant's operations.

(c) Storage of toxic materials. Toxic cleaning compounds, ~~approved~~ sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packing materials. ~~All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products shall be followed.~~

(d) Pest control. No pests or animals shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packing materials. Effective measures shall be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant ~~insecticides or rodenticides~~ is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(e) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing/~~processing, packing,~~ or holding low-moisture food shall be in a dry, sanitary condition before at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

~~(3) Non-food contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.~~

(34) Single-service articles (such as utensils for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against allergen cross-contact and against contamination of food or food-contact surfaces, or food-packing materials.

~~(45)~~ Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be approved, effective and safe under conditions of use. The wash solution for multi-use beverage containers must contain at least 3% caustic and must be maintained to at least 140 ~~degrees~~ °F temperature. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(f) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(gf) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

310:260-3-4. Sanitary facilities and controls

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate, approved source in compliance with applicable water supply regulations adopted by the State Board of Health. Any water that contacts food, ~~or food-contact surfaces, or food-packaging materials~~ shall be safe and of adequate sanitary quality. Running Hot and cold running water at a suitable temperature, and under pressure as needed shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be permanently attached, of adequate size and design and adequately installed and maintained to:

(1) Carry ~~adequate sufficient~~ quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is no backflow from, or cross-connection between, piping systems that discharge-waste water or sewage and piping systems that carry ~~potable water for food or food manufacturing or for equipment and utensil cleaning.~~

(c) Sewage disposal. Sewage ~~shall be disposed of~~ disposal shall be made into an adequate and approved sewerage system ~~or disposed of through other adequate means through permanently attached plumbing which is in compliance with applicable wastewater disposal regulations adopted by the State Board of Health.~~

(d) Toilet facilities. ~~Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials. The plant shall be provided with conveniently located toilets which shall be kept clean and in good repair. The toilet room shall be completely enclosed, well lighted vented to the outside, and equipped with a tight self-closing door. Any window opening shall be screened to prevent entrance of insects.~~

(e) Hand-washing facilities. ~~Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. Hand-washing facilities shall be adequate and convenient and shall be furnished with hot and cold running water at a suitable temperature.~~ Compliance with this requirement includes:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

~~(2) Effective hand-cleaning and sanitizing preparations.~~

~~(3) Sanitary towel service or suitable drying devices.~~

~~(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.~~

~~(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs should be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces and toilet facilities.~~

~~(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food, equipment or hands.~~

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

~~(g) Adequacy of facilities. Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, (a) through (f) of this section.~~

310:260-3-5. Equipment and utensils

(a) Design, fabrication, installation and maintenance.

(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

~~All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, shall meet NSF Standards, or equivalent, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food contact surfaces shall be corrosion resistant and shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.~~

(b) Seams. Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Non-food contact equipment. Equipment that is in the areas where food is manufactured, processed, packed, or held ~~manufacturing or food handling area~~ and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying and manufacturing systems. Holding conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Thermometers. Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately to within $\pm 3^{\circ}\text{F}$ inside the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change during manual operation.

(f) Instruments and controls. Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate, precise, and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

310:260-3-6. Processes and controls

(a) ~~General sanitation requirements.~~

(1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

~~All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, processing and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the Act shall be rejected, or if permissible, treated or processed to eliminate the contamination.~~

(b) Raw materials and other ingredients.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect allergen cross-contact and against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary potable quality. Water may ~~shall not~~ be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or if it increases the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may render the food injurious to the health of ~~produce food poisoning or other disease~~ in humans, or they shall be pasteurized or otherwise be treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated ~~within the meaning of the Act.~~

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins, ~~pesticides or herbicides,~~ shall comply with current FDA Food and Drug Administration regulations, ~~guidelines, and action levels~~ for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable FDA Food and Drug Administration regulations, ~~guidelines, and defect action levels~~ for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated ~~within the meaning of the Act.~~ Material scheduled for rework shall be identified as such and separated from other foods.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated ~~within the meaning of the Act.~~

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) Manufacturing operations.

(1) Equipment and utensils and finished food containers shall be maintained in an adequate ~~acceptable~~ condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

- (2) All food manufacturing, ~~processing, packing, and hold~~ including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms allergen cross-contact, ~~or for the contamination of food. This may include careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.~~
- (3) Food that can support the rapid growth of undesirable microorganisms, ~~particularly those of public health significance,~~ shall be held at temperatures in a manner that will prevent ~~prevents~~ the food from becoming adulterated during manufacturing, processing, packing, and holding. ~~Compliance with this requirement may be accomplished by any effective means, including:~~
- (A) ~~Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved.~~
 - (B) ~~Maintaining frozen foods in a frozen state.~~
 - (C) ~~Maintaining hot foods at 140°F (60°C) or above.~~
 - (D) ~~Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.~~
- (4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, ~~particularly those of public health significance,~~ shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated ~~within the meaning of the Act.~~
- (5) Work-in-process and rework shall be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
- (6) Effective measures shall be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by ~~conveyor~~ conveyer shall be protected against allergen cross-contact and against contamination as necessary.
- (7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework or other food shall be constructed, handled, and maintained during manufacturing processing, packing, and holding ~~or storage~~ in a manner that protects against allergen cross-contact and against contamination.
- (8) ~~Adequate~~ Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. ~~Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.~~
- (9) Food, raw materials, and other ingredients that are adulterated:
- (A) ~~Shall~~ shall be disposed in a manner that protects against the contamination of other food; ~~or-~~
 - (B) If the adulterated food is capable of being reconditioned, it shall be:
 - (i) Reconditioned (if appropriate) ~~reconditioned~~ using a method that has been proven to be effective; or
 - (ii) Reconditioned (if appropriate) and it shall be reexamined and subsequently found not to be adulterated before being incorporated into other food.
- (10) ~~Steps~~ Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against allergen cross-contact and against contamination. ~~Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food contact surfaces, and by using time and temperature controls at and between each manufacturing step.~~

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth Thermophilic growth and contamination by thermophilic microorganisms in blanchers blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary. ~~Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.~~

(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time shall be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms. ~~Compliance with this requirement may be accomplished by any effective means, including the following:~~

~~(A) Using ingredients free of contamination.~~

~~(B) Employing adequate heat processes where applicable.~~

~~(C) Using adequate time and temperature controls.~~

~~(D) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.~~

~~(E) Cooling to an adequate temperature during manufacturing.~~

~~(F) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.~~

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against allergen cross-contact, contamination, and growth of undesirable microorganisms. ~~Compliance with this requirement may be accomplished by any effective means, including:~~

~~(A) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.~~

~~(B) Adequate cleaning and sanitizing of all food contact surfaces and food containers.~~

~~(C) Using materials for food containers and food packaging materials that are safe and suitable.~~

~~(D) Providing physical protection from contamination, particularly airborne contamination.~~

~~(E) Using sanitary handling procedures.~~

(14) Food such as, but not limited to, dry mixes, nuts, immediate moisture food, and dehydrated food, that relies on the control of a_w ~~aw~~ for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. ~~Compliance with this requirement may be accomplished by an effective means, including employment of one or more of the following practices as appropriate:~~

~~(A) Monitoring the pH of raw materials, food in process, and finished food.~~

~~(B) Controlling the soluble solids water ratio in finished food.~~

~~(C) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.~~

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. ~~Compliance with this requirement may be accomplished by an effective means, including employment of one or more of the following practices as appropriate:~~

~~(A) Monitoring the pH of raw materials, food in process, and finished food.~~

~~(B) Controlling the amount of acid or acidified food added to low acid food.~~

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality in accordance with 310 260-3-4(a), ~~from a source in compliance with applicable water supply regulations adopted by the State Board of Health~~ and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in these regulations, ~~and provisions shall be made for drainage of water produced by melting ice.~~

(17) Food-manufacturing areas and equipment used for manufacturing human food shall not be used to manufacture nonhuman food grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

(18) Food manufacturing shall not be performed in places of human residence nor shall manufacturing areas open directly into rooms occupied as residence or sleeping quarters.

(19) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than two (2) years.

SUBCHAPTER 5. TREE NUT PECAN PROCESSING

310:260-5-1. Tree Nut Pecan crackers/shellers

(a) **Physical facilities.** The physical facilities of a pecan cracker/sheller shall comply with Sections 310:260-3-2 through 310:260-3-5.

(a) **Cleaning and sanitizing.** All tree nuts pecans shall be thoroughly cleaned to remove all foreign matter before sanitizing. After cleaning, tree nuts pecans shall be subjected to a bactericidal process with:

(1) Immersion ~~immersion~~ in hot water at 170⁰ degrees F- or more for at least two (2) minutes or exposed to a flow of hot water at 170⁰ degrees F- or more for at least five (5) minutes, or exposed to hot air at a temperature of 180⁰ degrees F- for at least twenty (20) minutes in a properly constructed oven or hot air cabinet equipped with an indicating thermometer located in the coldest zone, or

(2) A ~~a~~ 1000 PPM chlorine equivalent and a flotation process solution of 200 PPM chlorine equivalent, or

(3) Exposure ~~exposure~~ to steam in a properly designed cabinet for at least fifteen (15) minutes at 170⁰ degrees F-, or for at least five (5) minutes at 200⁰ degrees F-, or

(4) Exposure ~~exposure~~ of a jet of live steam for at least One (1) minute, or

(5) Any ~~any~~ other bactericidal treatment which has been proven by laboratory tests to effectively sanitize tree nuts pecans and which has been approved by the Department.

(b) **Holding and drying.** Folding, soaking, or tempering, tree nuts pecans must not be subjected to contamination. Drying of tree nuts pecans must be done in such a manner as to prevent recontamination of moist tree nuts pecans.

(c) **Sanitizing of equipment.** All equipment used for handling, storing, and transporting sanitized tree nuts pecans and/or tree nuts pecans meats shall be subjected to a bactericidal process approved by the Department. Approved processes shall include:

(1) Exposure ~~exposure~~ to steam in a properly constructed cabinet for at least fifteen (15) minutes at 170⁰ degrees F-, or for at least five (5) minutes to at least 200⁰ degrees F-, or

(2) Exposure ~~exposure~~ to a jet of live steam for at least one (1) minute, or

(3) Immersion ~~immersion~~ in or exposure to a flow of chlorine solution of not less than 200 PPM strength for at least two (2) minutes, or

(4) Immersion ~~immersion~~ in hot water at 170⁰ degrees F- or more for at least two (2) minutes or exposure to a flow of hot water at 170⁰ degrees F- or more (at the outlet) for at least five (5) minutes, or

(5) Exposure ~~exposure~~ to hot air at a temperature of 180⁰ degrees F-, for at least twenty (20) minutes in a properly constructed oven or hot air cabinet equipped with an indicating thermometer located in the coldest zone, or

(6) Any ~~any~~ other bactericidal treatment which has been proven by laboratory tests to effectively sanitize equipment and which has been approved by the Department.

(e) **Other requirements.** Additionally, all All commercial tree nut pecan crackers/shellers shall be subject to all applicable portions of this code Sections 310:260-3-1 and 310:260-3-6.

310:260-5-2. Custom Tree Nut ~~pecan~~ crackers

(a) Signage.

(1) The custom ~~tree nut pecan~~ cracking facility must publicly display an easily readable sign which states: "Custom Tree Nut Pecan Operations are Exempt from ~~Board of Health Department~~ Regulations Pertaining to Cleaning and Sanitizing of tree nuts pecans /Processing Equipment. Tree nuts Pecans Cannot be Cracked for Resale" or words to that effect.

(2) A customer's own Tree Nuts pecans left on the premises for custom Tree Nut pecan cracking must be separately labeled before and after custom cracking with the customer's name and contact information address.

(3) Custom Tree Nut pecan crackers shall affix ~~the a~~ statement "Custom Tree Nut Operations are Exempt from Health Department Regulations Pertaining to Cleaning and Sanitizing of Tree Nuts /Processing Equipment. Tree Nuts Cannot be Cracked for Resale" or words to that effect on the label, bill of sale, receipt, etc., presented to the customer upon payment to all custom cracked pecans which states: "Custom Pecan Cracking Operations are Exempt from Health regulations on Cleaning and Sanitizing of Pecans/Processing Equipment. Pecans Cannot Be Cracked for Resale" or words to that effect.

(b) **Other requirements.** Custom ~~tree nut pecan~~ crackers shall not be subject to licensure Sections 310:260-3-3 and 310:260-3-6.

SUBCHAPTER 7. SALVAGEABLE AND SALVAGED MERCHANDISE

310:260-7-1. Merchandise protection

(a) Protection from contamination.

(1) All salvageable and salvaged merchandise, while being stored or processed at a salvage processing plant, or during transportation, shall be protected from contamination.

(2) All perishable foods shall be kept at such temperature as will protect against spoilage.

(3) ~~Time temperature Control for Safety~~ All ~~potentially hazardous~~ food shall be maintained at safe temperature (45 ~~degrees~~⁰F- or below; 140 ~~degrees~~⁰F- or above).

(4) Poisonous and toxic materials shall be identified, and handled under such conditions as will not contaminate other salvageable or salvaged merchandise or constitute a hazard to personnel.

(b) **Segregation of non-salvageable materials.** All salvageable articles shall be promptly sorted and segregated from non-salvageable materials to prevent further contamination of goods to be salvaged or offered for sale or distribution.

310:260-7-2. Movement of distressed merchandise

(a) Notice to department.

(1) When merchandise becomes distressed as the result of ~~a train, automotive, airline, marine, or other~~ conveyance accident; flood, wind, fire, sewer backup, or such other unforeseen catastrophe, ~~it shall be the duty of the owner or claimant of such distressed merchandise~~ shall to make personal contact with the Department within twenty-four (24) hours after the merchandise becomes distressed and prior to removal from the place at which it was located when it became distressed merchandise.

(2) If emergency removal of such distressed merchandise is required, such notice to the Department shall be made as soon thereafter as possible.

(3) It shall be the duty of the owner or manager of the salvage processing plant to make contact with the Department within forty-eight (48) hours whenever distressed merchandise subject to the provisions of this regulation is obtained.

(b) Movement of distressed merchandise.

(1) Distressed merchandise shall be moved from the site where it became distressed ~~of a fire, flood, sewer backup, wreck or other cause~~ as expeditiously as possible after compliance with (a) of

this section so as ~~not to become putrid, to protect against spoilage, prevent~~ rodent or insect harborage, or otherwise a menace to the public health.

(2) All distressed and salvageable merchandise of a perishable nature shall, prior to product reconditioning, be transported only in vehicles provided with adequate refrigeration for maintenance.

(3) No interstate movement of distressed or salvageable merchandise from or into Oklahoma shall be made without prior approval of the Department. Concurrence shall also be obtained from the U.S. Food and Drug Administration or U.S. Department of Agriculture, Animal and Plant Health Inspection Service (meat and poultry products), and as required by State law of the State to or from which such merchandise is being shipped, prior to such anticipated interstate movement.

310:260-7-3. Reconditioning

(a) **Salvageable merchandise.** All salvageable merchandise shall be reconditioned prior to sale or distribution.

(b) **Distressed or nonsalvageable merchandise.** The following items shall be deemed unfit for sale or distribution:

(1) ~~Metal~~ All metal cans of food offered for sale or distribution shall be which are essentially free from rust (pitting) and dents (especially at rim, end double seams and/or side seams).

(2) Leakers, springers, flippers, and swellers ~~shall be deemed unfit for sale or distribution.~~

(3) Containers, including metal and glass containers with press caps, screw caps, pull rings or other types of openings which have been in contact with non-potable water, liquid foam, or other deleterious substances, as a result of fire fighting efforts, flood, sewer backups or similar mishaps shall be deemed unfit for sale or distribution, i.e., nonsalvageable merchandise.

(c) **Metal containers of food.**

All metal containers of food, other than those mentioned in (b) of this section whose integrity has not been compromised and whose integrity would not be compromised by the reconditioning, and which have been partially or totally submerged in water, liquid foam, or other deleterious substance as the result of flood, sewer backup or other reasons shall, after thorough cleaning, be subjected to sanitizing rinse of a concentration of 200 ppm available chlorine for a minimum period of one minute, or shall be sanitized by another method approved by the Department. They shall subsequently be treated to inhibit rust formation. All other types of containers so damaged shall be deemed unfit for use or sale.

310:260-7-4. Labeling

~~(a) Label removal.~~

~~(1) Any cans or tins showing surface rust shall have labels removed, the outer surface cleaned by buffing, a protective coating applied where necessary, and shall be relabeled.~~

~~(2) Relabeling of other salvageable nonmetal (glass, plastic, etc.) containers shall be required when original labels are missing or illegible.~~

~~(b) Relabeling.~~

(1) Relabeling of other salvageable nonmetal (glass, plastic, etc.) containers shall be required when original labels are missing or illegible.

~~(2) All salvaged merchandise shall be labeled to indicate that the merchandise has been salvaged. All salvaged merchandise in containers is to be provided with labels meeting the requirement of Oklahoma statutes.~~

~~(3) Where original labels are removed from containers which are to be resold or redistributed, the replacement labels must show the name and address of the salvage establishment.~~

310:260-7-5. Handling of nonsalvageable merchandise

(a) **Nonsalvageable merchandise.** Food deemed to be nonsalvageable merchandise are:

(1) Foods contaminated and/or adulterated by pesticides or other chemicals;

- (2) Potentially hazardous foods (frozen or those requiring refrigeration) which have been exposed to a temperature above 45° F (7.2° C) for a period exceeding 4 hours;
- (3) Foods packaged in paper or other porous materials which have been subjected to contamination.

(4) Those described in Section 310:260-7-3 as nonsalvageable.

(b) Distribution of nonsalvageable merchandise. Nonsalvageable merchandise shall not be sold or distributed as food, but shall be disposed of in a manner approved by ~~and under the supervision of the~~ Department.

310:260-7-6. Record keeping

(a) Inspection by the Department. A written record of receipt of distressed, salvageable and salvaged merchandise shall be kept by the salvage establishment or salvage broker for inspection by the Department during business hours.

(b) Content of records. The records shall include a general description of distressed merchandise received, source of the distressed merchandise, the date received and the type of damage (fire, flood, etc.)

(c) Retention of records. These records shall be kept on the premises of the salvage establishment or salvage broker for a period of two (2) years following the receipt of completion of transactions involving a lot of merchandise.

310:260-7-7. Salvage processors and distributors out-of-state

Salvaged merchandise from salvage processing plants and distributors located outside the jurisdiction of the State of Oklahoma may be sold or distributed within the State, if such plants and distributors conform to the provisions of this regulation or to substantially equivalent provisions ~~and have a valid permit, for such sale or distribution, from the Department.~~ To determine the extent of compliance with such provisions, the Department may accept reports from responsible authorities in other jurisdictions where such plants and distributors are located.

SUBCHAPTER 9. FOOD STORAGE WAREHOUSES

310:260-9-1.1. Warehousing and distribution

Storage and transportation of food shall be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

310:260-9-1. Lighting and ventilation

(a) Lighting.

(1) All parts of the food storage warehouse shall be lighted so as to permit the activity for which the premises are used to be carried on safely and to permit effective cleaning and inspection of the premises.

(2) Safety shields on lights or safety type lights shall be used where needed for the protection of food storage.

(b) Ventilation.

Where needed, rooms shall have sufficient ventilation to prevent any undue condensation or water vapor or objectionable odors, or temperature extremes.

310:260-9-2. Dry storage

(a) Floors.

(1) Floors shall be constructed of easily cleanable and reasonably smooth material.

(2) Floors ~~They~~ shall be kept clean and in good repair.

(b) Walls and ceiling.

Walls and ceiling shall be of sound construction, easily cleanable and kept reasonably free of dirt, dust and cobwebs and in good repair.

310:260-9-3. Cold and Frozen storage

(a) Thermometers.

Each cold storage unit shall be equipped with an accurate and easily visible thermometer with the sensing element at least five feet above the floor.

(b) Storage temperatures.

Perishable and Time/Temperature Control for Safety ~~potentially hazardous~~ foods shall be stored at 45° F or below.

(c) Frozen foods.

All frozen food shall be stored at a temperature of 0° F or below except for defrost cycles, loading or unloading, or for other temporary conditions beyond the immediate control of the person or company under whose care or supervision the frozen food is stored. However, the internal temperature of all frozen food shall be maintained at 0° F or below except when the product is subjected to the above-mentioned conditions; at such times the internal product temperature shall not exceed 10° F and such product shall be returned to 0° F as quickly as possible.

(d) Floors, Walls, and Ceilings.

(1) Floors shall be constructed of material that can be easily kept clean, sanitary and in good repair.

(2) Walls and ceiling shall be reasonably smooth, and kept clean and in good repair.

~~(e) Walls and ceilings. Walls and ceiling shall be reasonably smooth, and kept clean and in good repair.~~

(ef) Defrosting.

During defrosting of overhead coils in cold storage rooms, stored food shall be effectively protected from contamination by condensation, drip or leakage.

310:260-9-4. Protection of stored food

(a) Pests.

The operator shall take all reasonable measures to protect the area where food is kept or stored in a food storage warehouse against the entrance into the establishment, and the breeding or presence on the premises of rodents, birds, flies, roaches, weevils and other vermin.

(b) Animals.

No dogs, cats, fowl, birds or any other type animal shall be permitted in a food storage warehouse, except that patrol dogs or guide dogs accompanying blind or deaf persons shall not be excluded.

(c) Use of rodenticides.

When in use, rodenticides shall be placed in covered bait boxes where necessary to prevent spillage or possible contamination of stored food and danger to employees. All rodenticide baits shall be applied in such a manner as to prevent contamination of stored food products.

~~(d) Approval and application of pesticides and rodenticides. All pesticides and rodenticides used for control of vermin shall be in compliance with the Federal Insecticide, Fungicide and Rodenticide Act, and shall be applied in such a manner as to protect stored foods from contamination and in accordance with labeled instructions.~~

(de) Storage and Labeling of toxics.

(1) Cleaning materials, pesticides, rodenticides, and any other such hazardous substances used in the operation of the warehouse shall be stored:

(A) In in properly labeled containers in a closed closet or cabinet in a separate area from food products.

(B) An adequate distance from stored food and single service articles to prevent contamination caused by leakage or spillage.

(2) Where multiple level storage methods are used, all such substances shall be stored below food or single service articles.

(ef) Pest control services.

(1) When a licensed pest control service is employed, it shall file at the warehouse a diagram of the bait station locations and the rodenticide in use.

(2) The operator should designate an employee to be responsible for the pest control program being used.

~~(g) Storage of toxics.~~ Storage methods shall be used to minimize deterioration and prevent contamination of stored food products. Cleaning materials, pesticides, rodenticides, and any other hazardous substances shall be stored an adequate distance from stored food and single service articles to prevent contamination caused by leakage or spillage. Where multiple level storage methods are used, all such substances shall be stored below food or single service articles. Shelves, cabinets, dunnage and pallets shall be used where necessary to protect stored food products.

(fh) Product Storage on floors.

(1) Skids or pallets shall provide a minimum of 6" clearance above the floor to facilitate cleaning, protection of the product, and for movement of air in refrigerated storage areas.

~~(2i) Space around walls.~~ Merchandise stored on skids or pallets shall be at least 18" away from any wall.

~~(3j) Access for cleaning.~~ Construction of shelving, cabinets, and storage methods used shall be such as to permit ready access for cleaning and sanitary inspection.

~~(4k) Overhead piping.~~ No overhead waste drain pipes or other overhead piping shall be used which presents a risk of contamination to foods stored below due to excess condensation or leakage. Protective shields may be used to eliminate this risk.

~~(5l) Animal feeds.~~ Bagged animal feeds shall be stored so as not to be intermingled with the storage of human food products. Storage on separate pallets is acceptable.

310:260-9-5. Morgue

(a) ~~Holding of damaged foods.~~ The operator of a food storage warehouse shall provide an area for the accumulation and holding of all damaged foods or foods which may be unwholesome.

(b) ~~Disposal of unwholesome foods.~~ The operator shall maintain a program of timely and proper disposal of unwholesome food to prevent development of unsanitary conditions or vermin breeding places and rodent harborage.

310:260-9-6. Restroom Toilet and handwashing facilities

(a) Toilets.

(1) The warehouse shall be provided with conveniently located toilets and shall be kept clean and in good repair.

(2) The toilet room shall be completely enclosed, well lighted, vented, and equipped with a tight, self-closing door.

(3) Window Any window opening shall be screened to prevent entrance of insects.

(b) Handwashing facilities.

(1) Handwashing facilities shall be adequate and conveniently located in relation to toilet areas.

(2) Handwashing facilities shall be equipped with hot and cold water, under pressure.

(3) Soap or detergent and paper towels or other single use drying devices shall be provided at all times.

(4) Handwashing facilities shall be kept clean and in good repair.

~~(5e) Sign.~~ Signage A sign directing employees to wash their hands before returning to work shall be posted in all toilet rooms.

310:260-9-7. Waste storage and disposal

(a) ~~Liquid waste.~~ All liquid waste resulting from cleaning floors, equipment, flushing toilets, handwashing facilities, refrigeration equipment and air conditioners shall be disposed of in a sanitary manner per standards established and regulated by the Oklahoma Department of Environmental Quality

~~(ODEQ). Where wastes cannot be discharged into a sanitary sewer, all wastes shall be discharged into a system which meets or exceeds the minimum standards for waste disposal, as approved by the Department.~~

- ~~(b) Waste containers. Containers shall be provided for trash or rubbish.~~
- (c) **Maintenance.** The warehouse shall be free of unnecessary litter and rubbish, such as paper, empty containers, or other material that might serve as a place for harborage of rodents or other vermin.
- (d) **Storage.** All garbage and waste shall be stored in covered containers.
 - (1) Reusable containers shall be non-absorbent, easily washable receptacles which are covered with close-fitting lids, pending removal.
 - (2) Disposable containers or liners may be used.
 - (3) Removal of garbage and waste shall be frequent and the holding area shall be kept clean.
- (e) **Disposal.** All garbage and rubbish shall be disposed of at regular intervals of sufficient frequency and in such manner as to prevent the creation of unsanitary conditions.

310:260-9-8. Exterior construction

- (a) ~~**Outer openings.**~~ The exterior of a food storage warehouse shall be so designed, fabricated and finished to minimize the entrance of insects, birds and rodents.
- (b) ~~**Screening.**~~ All necessary ventilation louvers or openings into food storage warehouses shall be effectively screened against insects, birds and rodents.
- (c) ~~**Service connections.**~~ All service connections through the exterior wall of the establishment, including water, gas, electrical and refrigeration connections shall be ~~grommets~~ or sealed to prevent the entrance of insects, birds and rodents.

310:260-9-9. Surroundings

The outer premises of the food storage warehouse shall be reasonably clean, and well drained, free from any material or condition that creates rodent, bird and/or insect harborage and free from other nuisances and sources of contamination.

310:260-9-10. Transportation and storage

- (a) ~~**Sanitation.**~~ All cars, trucks or other vehicles used in the transportation of processed food products shall be kept in a clean condition at all times. Refuse, dirt and waste products subject to decomposition shall be removed daily. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.
- (b) ~~**Food protection.**~~ Food products shall be handled in such a manner so as to protect all food from deterioration while in transit. Foods, while in transit, shall be protected in such a manner as to preclude being contaminated by hazardous substances, microbial contamination, and against the deterioration of the food and the container.
- (c) Vehicles transporting Time/Temperature Control for Safety ~~potentially hazardous~~ food shall be equipped to maintain safe temperatures at all times. An accurate and easily visible thermometer shall be provided for monitoring the temperature of frozen and refrigerated storage areas while food is being held or transported.

310:260-9-11. Exemptions

Bin warehouses, as defined, shall be exempt from the regulations pertaining to providing ~~toilet and handwashing~~ restroom facilities, and water under pressure ~~provisions. However, this exemption applies only to these provisions and all other regulations are applicable.~~

SUBCHAPTER 11. — LICENSING, INSPECTIONS AND PLAN REVIEW [REVOKED]

310:260-11-1. Licensing [REVOKED]

~~(a) General.~~ No person shall operate a food manufacturing establishment, food storage warehouse, or a salvage establishment, who does not have a valid license issued to such person by the Oklahoma State Department of Health pursuant to Title 63 O.S. 1981, Section 1-1101 and following. Only a person who is in virtual compliance with the requirements of these rules and regulations shall be entitled to receive or retain such a license.

~~(b) Applications.~~ Any person desiring to operate a food manufacturing establishment, food storage warehouse or salvage establishment, shall make written application for a license on forms provided by the Oklahoma State Department of Health. The applicant shall be the legal owner of the business. Such application shall include the name and address of each applicant, the location and type of proposed establishment, and the signature of each applicant or his authorized agent.

~~(c) Expiration of license.~~ A license shall expire one year from the date of its issuance unless canceled or revoked prior to its expiration. For purposes in determining the expiration date of all licenses under this section, the date of issuance shall be deemed to be the date that an approved application for licensure is first issued by a duly authorized representative of the Health Department.

~~(d) License revocation and suspension.~~ Procedures for revocation and suspension of licenses are stated in the Oklahoma Administrative Procedures Act. These procedures provide for the licensee to be notified of his alleged violations of the Public Health Code and any of these rules. The procedures also provide for the licensee to have the opportunity to be present at a hearing and to present evidence in his defense. The Commissioner of Health's representative makes a recommendation or proposed order to the Commissioner of Health or Deputy Commissioner of Health in his or her stead. The Commissioner of Health or Deputy Commissioner of Health promulgates a final order revoking or suspending the license, dismissing the matter, or providing for other relief as allowed by statute. This final order is appealable to District Court if it is contrary to law or evidence. At any time after the action is filed against the licensee, the State Department of Health and the licensee may dispose of the matter by consent order or stipulation.

310:260-11-2. Inspections—[REVOKED]

~~Representatives of the regulatory authority, after proper identification, shall be permitted to enter any food manufacturing establishment, food storage warehouse or salvage establishment at any reasonable time for the purpose of making inspections to determine compliance with these regulations. The representative shall be permitted to examine records maintained in the food manufacturing establishment, food storage warehouse or salvage establishment (or other location) to obtain information pertaining to the source of food and supplies in the establishment when deemed necessary for the enforcement of these regulations~~

310:260-11-3. Examination and condemnation of food—[REVOKED]

~~Food may be examined or sampled by the Oklahoma State Department of Health as often as necessary for enforcement of these rules and regulations. The Oklahoma State Department of Health may place an embargo on food in accordance with the provisions of Title 63 O.S. 1981, Section 1-1105.~~

310:260-11-4. Plan review—[REVOKED]

~~(a) Submission.~~ Prior to commencing construction of a facility not previously licensed, or extensive remodeling of an existing structure, or hereafter substantial alteration of an existing facility for use as a manufacturing, processing, packing or holding plant, food storage or food salvage establishment, adequately prepared plans and specifications should be submitted to the Oklahoma State Department of Health, Food Protection Service, P.O. Box 53551, Oklahoma City, Oklahoma 73152.

~~(b) Deficiencies.~~ If the Department deems such plans and specifications to not conform to the requirements or additional material information is required, the Department shall, within ten (10) days after the receipt thereof, notify by certified mail, the person who submitted them of its objections or its need for additional information.

~~(c) **Criteria.** The decision to submit a formal plan when extensive remodeling or substantial alteration is contemplated, shall be determined as follows:~~

- ~~(1) if change prompts the preparation of a plan by an architect, or~~
- ~~(2) if change prompts the preparation of a plan by food processing or food equipment consultants.~~

~~(d) **Content.** Plans for new construction shall include:~~

- ~~(1) installation layout of processing equipment to be installed on the food processing floor.~~
- ~~(2) location of handwashing facilities, toilets, and employees locker rooms.~~
- ~~(3) construction material to be used on floors, walls, and ceiling.~~
- ~~(4) location of removable filters.~~
- ~~(5) ventilation system design.~~
- ~~(6) type of waste disposal systems to be used.~~
- ~~(7) any air quality equipment to be used.~~

SUBCHAPTER 13. — SPECIAL RISK SITUATIONS — [REVOKED]

310:260-13-1. Emergency occurrences — [REVOKED]

~~The person in charge of a food establishment that is affected by a fire, flood, extended power outage, or a similar significant occurrence that creates a reasonable probability that food in the food establishment may have been contaminated or that the temperature level of the food which is in a potentially hazardous form may have caused that food to have become hazardous to health, shall take such action as is necessary to protect the public health and shall promptly notify the Oklahoma State Department of Health of the emergency. Upon receiving such notice of this occurrence, the regulatory agency shall take action deemed necessary to protect the public health.~~

310:260-13-2. Infection — [REVOKED]

~~When the Oklahoma State Department of Health has reasonable cause to suspect possible disease transmission by an employee of a food establishment, the Department may secure a morbidity history of the employee or make any other investigation as indicated and shall take appropriate action. The Oklahoma State Department of Health may require at a minimum any or all of the following measures:~~

- ~~(1) The immediate exclusion of the employee from employment in food establishments;~~
- ~~(2) The immediate closing of the food establishment concerned until no further danger of disease outbreak exists.~~
- ~~(3) Restriction of the employee's services to some area of the establishment where there would be no danger of transmitting disease;~~
- ~~(4) Adequate medical laboratory examination of the employee and other employees and of his and their body discharges.~~

SUBCHAPTER 15. — COMPLIANCE AND ENFORCEMENT

310:260-15-1. License Required

- ~~(a) No person shall operate a food manufacturing establishment, food storage warehouse, or a salvage establishment, who does not have a valid license issued to such person by the Department pursuant to O.S. §63-1-1119. Only a person who is in virtual compliance with the requirements of these rules and regulations shall be entitled to receive or retain such a license.~~
- ~~(b) A license shall expire one year from the date of its issuance unless canceled or revoked prior to its expiration. For purposes in determining the expiration date of all licenses under this section, the date of issuance shall be deemed to be the date that an approved application for licensure is first issued by a duly authorized representative of the Health Department.~~

310:260-15-2. Examination and condemnation of food

Food may be examined or sampled by the Department as often as necessary for enforcement of these rules and regulations. The Department may place an embargo on food in accordance with the provisions of Title 63 O.S. 1-1105.

310:260-15-3. Variance

(a) Whenever the Department adopts new rules or amends existing language in this Chapter, the owner of a food establishment may request that a variance be granted on any nonconforming use that may then exist, on or before the effective date of the rule change, at the license holder's place of operation.

(b) Variances requested pursuant to this Subchapter are subject to approval by the Department. In order to have the variance approved, a license holder must submit a written application on a form provided by the Department. Any variance request shall be deemed denied unless the license holder subsequently receives notice of approval from the Department.

(c) If the license holder replaces the equipment or reconstructs the portion of the facility that is the subject of the variance, the new equipment or construction must conform to the rules of this Chapter.

(d) Variances are not considered to be part of the license and may be revoked at any time, for any reason, by the Department.

310:260-15-4. Documentation of proposed variance and justification

(a) Variance requests are subject to review by the Department. During this process, the inspector must confirm the following:

(1) The nature and extent of the nonconforming use;

(2) That the equipment or portion of the facility in question is in an operable and sanitary condition, and can be maintained in satisfactory condition during the term of the variance;

(3) That no public health threats or food-related illness will result if the variance is granted.

310:260-15-5. When Plans are required

(a) A license applicant or license holder shall submit to the Department properly prepared plans and specifications for review and approval before:

(1) The construction of an establishment;

(2) The conversion of an existing structure for use as an establishment; or

(3) The extensive remodeling of an establishment or a change of operation.

(b) If the Department deems such plans and specifications to not conform to the requirements or additional material information is required, the Department shall notify the person who submitted them of its objections or its need for additional information.

310:260-15-6. Contents of the Plans and Specifications

The plans and specifications for an establishment shall include the following information to demonstrate conformance with Code provisions:

(1) Food items intended to be produced;

(2) Anticipated volume of food to be prepared, held, and transported;

(3) Proposed equipment types, manufacturer and model numbers (if available);

(4) Proposed floor plan;

(5) Installation layout of processing equipment to be installed on the food processing floor;

(6) Location of handwashing facilities, restrooms, and employees locker rooms;

(7) Other information as required by the Department.

310:260-15-7. Preoperational inspections

The Department may conduct one or more preoperational inspections to verify that the establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, and is in compliance with law and this Chapter.

310:260-15-8. Form of submission

A person desiring to operate an establishment shall submit to the regulatory authority a written application for a license on a form provided by the regulatory authority.

310:260-15-9. Qualifications and responsibilities of applicants

To qualify for a license, an applicant shall:

- (1) Be an owner of the food establishment or an officer of the legal ownership;
- (2) Comply with the requirements of this Chapter;
- (3) As specified under OAC 310:260-15-17, agree to allow access to the food establishment and to provide required information; and
- (4) Pay the applicable license fees at the time the application is submitted.

310:260-15-10. Contents of the application

The application shall include:

- (1) The name, mailing address, telephone number, and signature of the person applying for the license and the name, mailing address, and location, of the establishment;
- (2) Information specifying whether the establishment is owned by an association, corporation, individual, partnership, or other legal entity.

310:260-15-11. New, converted, or remodeled establishments

For establishments that are required to submit plans as specified under OAC 310:260-15-5 the Commissioner of Health shall issue a license to the applicant after:

- (1) A properly completed application is submitted;
- (2) The required fee is submitted;
- (3) The required plans, specifications, and information are reviewed and approved; and
- (4) An inspection shows that the establishment is built or remodeled in accordance with the approved plans and specifications and that the establishment is in compliance with this Chapter.

310:260-15-12. Issuance of license

The Department may issue a license to a new owner of an existing food establishment after a properly completed application is submitted, reviewed, and approved, the fees are paid, and an inspection shows that the establishment is in compliance with this Chapter.

310:260-15-13. Denial of application for license, notice

If an application for a license to operate is denied, the regulatory authority shall provide the applicant with a notice that includes:

- (1) The specific reasons and Chapter citations for the license denial;
- (2) The actions, if any, that the applicant must take to qualify for a license; and
- (3) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law.

310:260-15-14. Responsibilities of the license holder

Upon acceptance of the license issued by the Commissioner of Health, the license holder in order to retain the license shall:

- (1) Post the license in a location in the establishment that is conspicuous to visitors;
- (2) Comply with the provisions of this Chapter;
- (3) Immediately discontinue operations and notify the Department if an imminent health hazard may exist as specified under OAC 310:260-15-25;
- (4) Allow representatives of the Department access to the establishment as specified under OAC 310:260-15-17;

(5) Replace existing facilities and equipment with facilities and equipment that comply with this Chapter if:

(A) The Department directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted,

(B) The Department directs the replacement of the facilities and equipment because of a change of ownership, or

(C) The facilities and equipment are replaced in the normal course of operation;

(6) Comply with directives of the Department including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the Department in regard to the license holder's establishment or in response to community emergencies;

(7) Accept notices issued and served by the Department according to law;

(8) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Chapter or a directive of the Department, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives; and

(9) If applicable, submit the annual renewal application and pay all renewal license and late fees.

310:260-15-15. Licenses not transferable

A license may not be transferred from one person to another person, from one establishment to another, from one physical address to another, from one corporation to another, from one limited liability company or corporation to another, from one partnership to another, or from one type of operation to another if the food operation changes from the type of operation specified in the application under OAC 310:260-15-6 and the change in operation is not approved.

310:260-15-16. Competency of inspectors

An authorized representative of the Department who inspects an establishment or conducts plan review for compliance with this Chapter shall have the knowledge, skills, and ability to adequately perform the required duties, and be licensed pursuant to Title 59 O.S. §, 59-1150.1 et seq.

310:260-15-17. Allowed at reasonable times after due notice

After the Department presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the Department to determine if the establishment is in compliance with this Chapter by allowing access to the establishment, allowing inspection, and providing information and records specified in this Chapter and to which the Department is entitled according to law, during the establishment's hours of operation and other reasonable times.

310:260-15-18. Refusal, notification of right to access, and final request for access

If a person denies access to the Department, the Department shall:

(1) Inform the person that:

(A) The license holder is required to allow access to the Department as specified under OAC 310:260-15-17 of this Chapter,

(B) Access is a condition of the acceptance and retention of an establishment license to operate as specified under OAC 310:260-15-14(4), and

(C) If access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to law; and

(2) Make a final request for access.

310:260-15-19. Refusal, reporting

If after the regulatory authority presents credentials and provides notice as specified under OAC 310:260-15-17, explains the authority upon which access is requested, and makes a final request for access as specified in OAC 310:260-15-18, the person in charge continues to refuse access, the regulatory authority shall provide details of the denial of access on an inspection report form.

310:260-15-20. Inspection order to gain access

If denied access to a food establishment for an authorized purpose and after complying with OAC 310:260-15-18, the Department may issue, or apply for the issuance of an order to gain access as provided in law.

310:260-15-21. Documenting information and observations

The Department shall document on an inspection report form:

- (1) Administrative information about the establishment's legal identity, street and mailing addresses, type of establishment and operation as specified, inspection date, and other information such as type of water supply and sewage disposal, status of the license, and personnel certificates that may be required; and
- (2) Specific factual observations of violative conditions or other deviations from this Chapter that require correction by the license holder.

310:260-15-22. Specifying time frame for corrections

The regulatory authority may specify on the inspection report form the time frame for correction of the violations.

310:260-15-23. Issuing report and obtaining acknowledgment of receipt

At the conclusion of the inspection the regulatory authority shall provide a copy of the completed inspection report and the notice to correct violations to the license holder or to the person in charge, and request a signed acknowledgment of receipt.

310:260-15-24. Refusal to sign acknowledgment

The Department shall:

- (1) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified under OAC 310:260-15-23:
 - (A) An acknowledgment of receipt is not an agreement with findings,
 - (B) Refusal to sign an acknowledgment of receipt will not affect the license holder's obligation to correct the violations noted in the inspection report within the timeframes specified, and
 - (C) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the Department's historical record for the food establishment; and
- (2) Make a final request that the person in charge sign an acknowledgment receipt of inspectional findings.

310:260-15-25. Ceasing operations and reporting

(a) Except as specified in (b) of this Section, a license holder shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard exists because of an emergency such as a fire, flood, sewage backup, no water in the facility, insufficient refrigeration and/or hot food storage facilities available, substantial evidence or presence of a large number of insects or evidence of rodents in food or on food preparation surfaces, interruption of safe potable water supply to the facility, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, interruption of electrical service for more than 4 hours, severe structural damage in the facility, an employee working with a Salmonella, Shigella, E. coli 0157:H7 or Hepatitis A infection, gross unsanitary occurrence or condition,

or other circumstance as determined by the Commissioner of Health, or his designee, that shall endanger public health.

(b) A license holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

310:260-15-26. Resumption of operations

If operations are discontinued as specified under OAC 310:260-15-32 or otherwise according to law, the license holder shall notify the regulatory authority before resuming operations.

310:260-15-27. Obtaining information: personal history of illness, medical examination, and specimen analysis

The regulatory authority shall act when it has reasonable cause to believe that a food employee has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound, or acute respiratory infection, by:

- (1) Securing a confidential medical history of the employee suspected of transmitting disease or making other investigations as deemed appropriate; and
- (2) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected employee and other employees.

310:260-15-28. Restriction or exclusion of employee with infection

When the Department has reasonable cause to suspect possible disease transmission by an employee of a food establishment, the Department may secure a morbidity history of the employee or make any other investigation as indicated and shall take appropriate action. The Department may require at a minimum any or all of the following measures:

- (1) The immediate exclusion of the employee from employment in food establishments;
- (2) The immediate closing of the food establishment concerned until no further danger of disease outbreak exists.
- (3) Restriction of the employee's services to some area of the establishment where there would be no danger of transmitting disease;
- (4) Adequate medical laboratory examination of the employee and other employees and of his and their body discharges.