

Guidance for Shared Use Kitchens

The purposes of this guidance document is to assure that foods processed in New York State in a Shared Use Kitchen, and offered for sale for human consumption, are safe and that the food processing establishments, in which such foods are manufactured or processed, conform to proper operating and sanitary standards. What makes Shared Use Kitchens unique is that the owner/lessor of the facility does not have to be an operator in the facility, although may be. This document defines the roles of the owner/lessor, the operators and their shared responsibilities in a Shared Use Kitchen.

The shared responsibilities will be unique to all such operations as no two facilities will be identical. They may include which party will be responsible for sanitation at the end of a shift, who is responsible for a pre-operational sanitation, as well as other functions.

I. Definitions:

- 1. The terms Incubator Kitchen, Shared Use Kitchen, Leased Commercial Kitchen (Shared Use Kitchen) are food preparation facilities that provide kitchen space and access to commercial equipment to prepare food on a lease or rental basis.
- 2. The terms Incubator Kitchen Owner, Lessor, Owner (Lessor) is the owner of the commercial kitchen location to be rented.
- 3. The term Shared Use Kitchen Operator (Operator) is a person or company licensed by the New York Department of Agriculture and Markets (DAM), to process food under Article 20-C, that rents space at the leased commercial kitchen location.

II. Article 20-C Food Processing License:

- 1. The Lessor of a Shared Use Kitchen shall not rent, lease, share or allow its use unless it has been approved to do so by DAM and has obtained a valid Article 20-C license from the DAM as is outlined in New York Agriculture an Markets Law §251-z-3, paid the appropriate fee and is subject to inspection and enforcement as a food processing establishment.
- 2. Each operator of a Shared Use Kitchen shall not prepare or manufacture food unless it has a valid Article 20-C license from DAM after paying the appropriate fee.

III. Responsibilities of Lessor

- 1. Complying with:
 - a. 1 NYCRR Parts 259-262, 276, 277, 279, 280
 - b. New York Agriculture and Markets Law Article 20-C

to ensure the kitchen and all operators are properly licensed and/or permitted with the appropriate agency and to maintain all records of the same for inspection.

- 2. Maintaining the building, property and equipment in an acceptable sanitary manner, and in compliance with Article 17 New York Agriculture and Markets Law and 1 NYCRR 260.1
- 3. Maintaining a facility schedule/calendar, including the date and time of processing, name of operator and to maintain and provide upon request, all scheduling/calendar records during inspection.



- 4. Limiting operations to only those which the facility has the appropriate equipment, space, and facilities for production and has been approved by DAM as acceptable in the space provided. When the scope of operations expands, DAM must be given prior notice and must give approval before those new operations begin.
- 5. Maintain a file for each operator, which must contain, but is not limited to:
 - a. The business contact information, including:
 - i. Name
 - ii. Phone number
 - iii. Address
 - b. Any scheduled processes.
 - c. The date and time of processing
 - d. Copies of or access to each processors' production records to include the product name, production codes and shipping dates.
- 6. Ensure that no more than one manufacturing or packing operation takes place per processing area, at one time.
- 7. Verify that all individuals using equipment are properly trained to use that equipment.
- 8. Have sufficient storage for operators' raw ingredients and finished product before shipping (such as correct environmental conditions for staging before shipping) and to store the raw ingredients and finished products separately or verify ingredients and finished products are being stored in a licensed warehouse.
- 9. Ensure that all finished products are shipped directly after they are manufactured. They must not be stored in the Shared Use Kitchen.
- 10. Ensure that all processing occurs at the Shared Use Kitchen. Product may not be moved to an unlicensed or uninspected facility for further processing. Products must be fully processed and packaged within the Shared Kitchen,
- 11. Have a master cleaning schedule and maintain all records of the same for inspection.
- 12. Have a preventative maintenance program for the building, grounds and equipment, including, but not limited to: refrigeration units, ovens, packaging equipment, metal detectors, filling equipment, cleaning equipment, and to maintain all records of the same for inspection.
- 13. Comply with Subpart B of 21 CFR 117.20(a) Grounds, 117.20(b) Plant Construction and Design, 117.35(a) General Maintenance, 117.35(b) Substances Used in Cleaning and Sanitizing; Storage of Toxic Materials, 117.35(c) Pest Control, 117.35(d) Sanitation of Food-Contact Surfaces, 117.35(e) Sanitation of Non-food Contact Surfaces, 117.35(f) Storage and Handling of Cleaned Portable Equipment and Utensils, 117.37 Sanitary Facilities and Controls, 117.40 Equipment and Utensils when equipment and Utensils are supplied by the Lessor

IV. Responsibilities of Operator

- The operator has all the same responsibilities as any other 20-C license holder, other than those responsibilities specific to the Lessor of the facility, which include payment of license fee (after two years of operating), maintaining all records as required by 21 CFR 117, Subpart F – Requirements Applying to Records That Must be Established and Maintained.
- 2. Maintain copies of all 20-C licenses and necessary certificates, such as Preventative Controls Qualified Individuals (PCQI) on file at the Shared Use Kitchen, or meet the



requirements of 21 CFR 117, Subpart D, <u>Modified requirements that apply to a qualified</u> <u>facility.</u>

- 3. Verify that all equipment is cleaned and sanitized before and after using.
- 4. Compliance with INYCRR Parts 260 Current good manufacturing practices (cGMP's).
- Maintain allergen controls to prevent cross contact contamination as outlined in 21 CFR 117.10 Personnel, 117.20 Plant and Grounds, 117.35 Sanitary Operations, 117.40 Equipment and Utensils, 117.80 Process and Controls, 117.93 Distribution
- 6. Ensure that proper temperatures are maintained as outlined in 21 CFR 117.80 Processes and Controls
- 7. Adherence to a process review conducted by a recognized process authority, when required.
- 8. Compliance with 1NYCRR Part 259.1 Packaging and Labeling of Food

V. Shared Responsibilities of Lessor and Operator

These responsibilities must be formalized in a written agreement between the lessor and each operator, before any operator may begin to manufacture any products.

- 1. Some of the shared responsibilities needed to determine include:
 - a. Pre-operational sanitation inspections
 - b. Post operational sanitation inspections
 - c. Sanitation verification activities and associated records
 - d. Performing corrective actions when sanitation is found to be insufficient
 - e. Writing preventative measures after corrective actions initiated
 - f. Implementing the preventative hazard control measures, such as:
 - i. Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure
 - ii. When appropriate, reanalyze the food safety plan in accordance with §117.170 to determine whether modification of the food safety plan is required.

VI. Resources

- 1. Basic Label Requirements
- 2. Obtain a Process/Schedule Process Review
- 3. https://www.nysenate.gov/legislation/laws/AGM/A20-C
- 4. Human Foods Preventive Control Rule
- 5. FSMA Final Rule for Preventative Controls for Human Food
- 6. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food
- 7. <u>Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive</u> <u>Controls for Human Food; Title 21 Part 117</u>
- 8. Subchapter C. Food and Food Products (Article 17 Agriculture and Markets Law)
- 9. Article 20-C Food Processor License