

components, dietary ingredients, dietary supplements, or contact surfaces. The design and construction must include, but not be limited to:

(1) Floors, walls, and ceilings that are of smooth and hard surfaces that can be adequately cleaned and kept clean and in good repair;

(2) Fixtures, ducts, and pipes that do not contaminate components, dietary ingredients, dietary supplements, or contact surfaces by dripping or condensate;

(3) Adequate ventilation or environmental control equipment such as air flow systems, including filters, fans, and other air-blowing equipment, that minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate components, dietary ingredients, dietary supplements, or contact surfaces;

(4) Fans and other air-blowing equipment located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary ingredients, dietary supplements, or contact surfaces;

(5) Equipment that controls temperature and humidity; and

(6) Aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces with clothing or personal contact.

(e) Provide adequate light in:

(1) All areas where components, dietary ingredients, or dietary supplements are examined, processed, or held;

(2) All areas where contact surfaces are cleaned; and

(3) Hand-washing areas, dressing and locker rooms, and bathrooms.

(f) Use safety-type light bulbs, fixtures, skylights, or other glass that is suspended over exposed components, dietary ingredients, or dietary supplements in any step of preparation, unless otherwise constructed in a manner that will protect against contamination of components, dietary ingredients, or dietary supplements in case of glass breakage.

(g) Provide protection by any effective means against contamination of components, dietary ingredients, and dietary supplements in bulk fermentation vessels, including consideration of:

(1) Use of protective coverings;

(2) Placement in areas where you can eliminate harborages for pests over and around the vessels;

(3) Placement in areas where you can check regularly for pests, pest infestation, filth or any other extraneous materials; and

(4) Use of skimming equipment.

(h) Use adequate screening or other protection against pests, where necessary.

6. Add new subpart D to part 111 to read as follows:

#### **Subpart D—Equipment and Utensils**

Sec.

111.25 What requirements apply to the equipment and utensils you use?

111.30 What requirements apply to automatic, mechanical, or electronic equipment?

#### **Subpart D—Equipment and Utensils**

##### **§ 111.25 What requirements apply to the equipment and utensils you use?**

(a)(1) You must use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained. Equipment and utensils include, but are not limited to, the following:

(i) Equipment used to hold or convey;

(ii) Equipment used to measure;

(iii) Equipment using compressed air or gas;

(iv) Equipment used to carry out processes in closed pipes and vessels; and

(v) Equipment used in automatic, mechanical, or electronic systems.

(2) You must use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components, dietary ingredients, or dietary supplements with:

(i) Lubricants;

(ii) Fuel;

(iii) Coolants;

(iv) Metal or glass fragments;

(v) Filth or any other extraneous material;

(vi) Contaminated water; or

(vii) Any other contaminants.

(3) All equipment and utensils you use must be:

(i) Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces;

(ii) Corrosion-resistant if the equipment or utensils contact components, dietary ingredients, or dietary supplements;

(iii) Made of nontoxic materials;

(iv) Designed and constructed to withstand the environment of their intended use, the action of components, dietary ingredients, or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and

(v) Maintained to protect components, dietary ingredients, and dietary supplements from being contaminated by any source.

(4) Equipment and utensils you use must have seams that are smoothly bonded or maintained to minimize accumulation of component, dietary ingredient, or dietary supplement particles, dirt, filth, organic material, or any other extraneous materials or contaminants to minimize the opportunity for growth of microorganisms.

(5) Each freezer and cold storage compartment you use to hold components, dietary ingredients, or dietary supplements:

(i) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that shows the temperature accurately within the compartment; and

(ii) Must have an automatic device for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation.

(6) Instruments or controls used in the manufacturing, packaging, or holding of a dietary ingredient or dietary supplement, including but not limited to, instruments or controls you use to measure, regulate, or record temperatures, hydrogen ion concentration (pH), water activity, or other conditions that control or prevent the growth of microorganisms or other contamination must be:

(i) Accurate and precise;

(ii) Adequately maintained; and

(iii) Adequate in number for their designated uses.

(7) Compressed air or other gases you introduce mechanically into or onto a component, dietary ingredient, dietary supplement, or contact surface or that you use to clean any contact surface must be treated in such a way that the component, dietary ingredient, dietary supplement, or contact surface is not contaminated.

(b)(1) You must calibrate instruments and controls you use in manufacturing or testing a component, dietary ingredient, or dietary supplement.

(2) You must calibrate before first use; and

(i) As specified in writing by the manufacturer of the instrument and control, or

(ii) At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.

(c) You must:

(1) Establish a written procedure for calibrating instruments and controls you use in manufacturing or testing a