

111.13 What supervisor requirements apply?

Subpart B—Personnel

§ 111.10 What microbial contamination and hygiene requirements apply?

(a) *Microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination of any material including components, dietary ingredients, dietary supplements, and contact surfaces used in the manufacture, packaging, or holding of a dietary ingredient or a dietary supplement. Such measures include, but are not limited to, the following:

(1) Excluding any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion, or any other abnormal source of microbial contamination, which may be expected to result in microbial contamination of components, dietary ingredients, dietary supplements, or contact surfaces, from working in any operations until the condition is corrected; and

(2) Instructing your employees to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could contaminate any components, dietary ingredients, dietary supplements, or any contact surface.

(b) *Hygienic practices.* If you work in operations during which adulteration of the component, dietary ingredients, dietary supplement, or contact surface may occur, you must use hygienic practices to the extent necessary to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces. These hygienic practices include, but are not limited to:

(1) Wearing outer garments in a manner that protects against the contamination of components, dietary ingredients, dietary supplements, or any contact surface;

(2) Maintaining adequate personal cleanliness;

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility:

(i) Before starting work; and
(ii) At any time when the hands may have become soiled or contaminated;

(4) Removing all unsecured jewelry and other objects that might fall into components, dietary ingredients, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot

be adequately sanitized during periods in which components, dietary ingredients, or dietary supplements are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of components, dietary ingredients, dietary supplements, or contact surfaces;

(5) Maintaining gloves used in handling components, dietary ingredients, or dietary supplements in an intact, clean, and sanitary condition. The gloves must be of an impermeable material;

(6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;

(7) Not storing clothing or other personal belongings in areas where components, dietary ingredients, or dietary supplements or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages and using tobacco products in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed; and

(9) Taking any other precautions necessary to protect against the contamination of components, dietary ingredients, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

§ 111.12 What personnel qualification requirements apply?

(a) You must have qualified employees to manufacture, package, or hold dietary ingredients or dietary supplements; and

(b) Each person engaged in manufacturing, packaging, or holding must have the training and experience to perform the person's duties.

§ 111.13 What supervisor requirements apply?

(a) You must assign qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients and dietary supplements.

(b) You and the supervisors you use must be qualified by training and experience to supervise.

5. Add new subpart C to part 111 to read as follows:

Subpart C—Physical Plant

Sec.

111.15 What sanitation requirements apply to your physical plant?

111.20 What design and construction requirements apply to your physical plant?

Subpart C—Physical Plant

§ 111.15 What sanitation requirements apply to your physical plant?

(a) *Physical plant facilities.* (1) You must maintain your physical plant in a clean and sanitary condition; and

(2) You must keep your physical plant in repair sufficient to prevent components, dietary ingredients, dietary supplements, or contact surfaces from becoming contaminated.

(b) *Cleaning compounds, sanitizing agents, and pesticides.* (1) You must use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and safe and adequate under the conditions of use.

(2) You must not use or hold toxic materials in a physical plant in which contact surfaces, components, dietary ingredients, or dietary supplements are manufactured or exposed, unless those materials are necessary:

(i) To maintain clean and sanitary conditions;

(ii) For use in laboratory testing procedures;

(iii) For maintaining or operating the physical plant or equipment; or

(iv) For use in the plant's operations.

(3) You must identify and hold toxic cleaning compounds, sanitizing agents, pesticides, and pesticide chemicals in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

(c) *Pest control.* (1) You must not allow animals or pests in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination of components, dietary ingredients, dietary supplements, or contact surfaces;

(2) You must take effective measures to exclude pests from the physical plant and to protect against contamination of components, dietary ingredients, dietary supplements, and contact surfaces on the premises by pests; and

(3) You must not use insecticides, fumigants, fungicides, or rodenticides, unless you take precautions to protect against the contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

(d) *Water supply.* (1) You must provide water that is safe and of adequate sanitary quality, at suitable temperatures, and under pressure as