

needed, in all areas where water is necessary for:

(i) Manufacturing dietary ingredients or dietary supplements;

(ii) Making ice that comes in contact with components, dietary ingredients, dietary supplements, or contact surfaces;

(iii) Cleaning any surface; and

(iv) Employee bathrooms and hand-washing facilities.

(2) Water that contacts components, dietary ingredients, dietary supplements, or any contact surface must at a minimum comply with the National Primary Drinking Water regulations prescribed by the Environmental Protection Agency under 40 CFR part 141 and any state and local government requirements;

(3) You must have documentation or otherwise be able to show that water that contacts components, dietary ingredients, dietary supplements, or any contact surface meets the requirements in paragraph (d)(2) of this section.

(e) *Plumbing.* The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from your physical plant;

(3) Avoid being a source of contamination to components, dietary ingredients, dietary supplements, water supplies, or any contact surface, 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; and

(5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary ingredients or dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

(f) *Sewage disposal.* You must dispose of sewage into an adequate sewage system or through other adequate means.

(g) *Bathrooms.* You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not become a potential source of contamination to components, dietary ingredients, dietary supplements, or contact surfaces. You must:

(1) Keep the bathrooms in good repair at all times;

(2) Provide self-closing doors; and

(3) Provide doors that do not open into areas where components, dietary ingredients, dietary supplements, or contact surfaces are exposed to airborne contamination except where alternate means have been taken to protect against contamination (such as double doors or positive airflow systems).

(h) *Hand-washing facilities.* You must provide hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature. You must do this by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in your physical plant where good hygienic practices require employees to wash or to sanitize or both wash and sanitize their hands;

(2) Effective hand-cleaning and sanitizing preparations;

(3) Air driers, sanitary towel service, such as disposable paper towels, or other suitable drying devices;

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

(5) Signs that are easy to understand and are posted throughout the physical plant that direct employees handling components, dietary ingredients, dietary supplements, or contact surfaces to wash and, where appropriate, to sanitize their hands before they start work, after each absence from their duty station, and when their hands may have become soiled or contaminated; and

(6) Trash bins that are constructed and maintained in a manner to protect against recontamination of hands and contamination of components, dietary ingredients, dietary supplements, or any contact surface.

(i) *Trash disposal.* You must convey, store, and dispose of trash to:

(1) Minimize the development of odor;

(2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;

(3) Protect against contamination of components, dietary ingredients, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and

(4) Control hazardous waste to prevent contamination of components, dietary ingredients, dietary supplements, and contact surfaces.

(j) *Sanitation supervisors.* You must assign one or more employees to supervise overall sanitation. These supervisors must be qualified by training and experience to develop and supervise sanitation procedures.

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

Any physical plant you use in the manufacture, packaging, or holding of dietary ingredients or dietary supplements must:

(a) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations;

(b) Have adequate space for the orderly placement of equipment and holding materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components, dietary ingredients, and dietary supplements during manufacturing, packaging, or holding;

(c) Permit the use of proper precautions to reduce the potential for mixups or contamination of components, dietary ingredients, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. Your physical plant must have and you must use separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mixups of components, dietary ingredients, and dietary supplements during the following operations:

(1) Receiving, identifying, holding, and withholding from use, components, dietary ingredients, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, or holding of dietary ingredients and dietary supplements;

(2) Separating, as necessary, components, dietary ingredients, dietary supplements, packaging, and labels that are to be used from components, dietary ingredients, dietary supplements, packaging, or labels that are awaiting material review and disposition decision, reprocessing, or are awaiting disposal after rejection;

(3) Separating the manufacturing, packaging, and holding of different product types including, but not limited to, different types of dietary ingredients, dietary supplements and other foods, cosmetics, and pharmaceutical products;

(4) Performing laboratory analyses and holding laboratory supplies and samples;

(5) Cleaning and sanitizing contact surfaces;

(6) Packaging and label operations; and

(7) Holding dietary ingredients or dietary supplements.

(d) Be designed and constructed in a manner that prevents contamination of