

reproduction of microorganisms and pests, and these microorganisms and pests may, in turn, contaminate your components, dietary ingredients, dietary supplements, and contact surfaces; and

- Include 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. For example, your employees will perform their duties more efficiently and more effectively if they have sufficient space to perform those duties. The clothing worn by your employees will be less likely to be a source of contamination if there is sufficient space between your employees and your components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.20(e) would require your physical plant to provide adequate light in all areas where components, dietary ingredients, or dietary supplements are examined, processed, or held and in all areas where contact surfaces are cleaned. Proposed § 111.20(e) also would require that you provide adequate lighting in hand washing areas, dressing and locker rooms, and bathrooms. Inadequate lighting in areas where components, dietary ingredients, or dietary supplements are examined, processed, or held may make it difficult to examine a component or read a label; as a result, incorrect ingredients may be used in a dietary supplement. Adequate lighting also is important in areas where contact surfaces are cleaned to ensure that the contact surfaces have been cleaned properly. Adequate lighting is important in hand-washing areas, dressing and locker rooms to ensure that personal cleanliness is maintained in accordance with proposed § 111.10(b).

Proposed § 111.20(f) would require your physical plant to 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 in case of glass breakage. These precautions are necessary because glass shards can be very small and difficult to see, and some lights may spread their contents if they burst or explode. So, to protect your components, dietary ingredients, and dietary supplements, the proposal would require your physical plant to take precautions concerning your lighting and other suspended glass.

Proposed § 111.20(g) would require that your physical plant provide protection by any effective means against contamination of components, dietary ingredients, and dietary supplements in bulk fermentation vessels. The proposal describes some means to consider, such as using protective coverings, placement in areas where you can eliminate harborages for pests over and around vessels, placing bulk fermentation vessels in areas where you can check regularly for pests, pest infestation, filth, or other extraneous material, and using skimming equipment. You must protect components, dietary ingredients, and dietary supplements held in bulk fermentation vessels because, if the contents of a bulk fermentation vessel are contaminated, those contaminated contents may be used to make many dietary ingredients or dietary supplements that, as a result, would be adulterated.

Proposed § 111.20(h) would require your physical plant to include adequate screening or other protection against pests, where necessary. This provision would be one measure to exclude certain pests from the physical plant that also may assist you in complying with proposed § 111.15(c). As we explained earlier in the discussion of proposed § 111.15(c), pests are a potential source of contamination because they may carry microorganisms, shed hair or feathers, leave droppings, or carry filth or dirt into your physical plant.

D. Equipment and Utensils (Proposed Subpart D)

Proposed subpart D consists of two provisions. These proposed provisions consist of general requirements for equipment and utensils and for automatic equipment, including computerized systems, hardware, and software.

1. What Requirements Apply to the Equipment and Utensils You Use? (Proposed § 111.25)

Proposed § 111.25 would establish general requirements pertaining to equipment design, construction, and sanitation. For example, proposed § 111.25(a)(1) would require that you use equipment and utensils of appropriate design, construction, and workmanship that would enable them to be suitable for their intended use, adequately cleaned, and properly maintained. The equipment and utensils covered under the proposal would include, but not be limited to:

- Equipment used to hold or convey;
- Equipment used to measure;

- Equipment using compressed air or gas;
- Equipment used to carry out processes in closed pipes and vessels; and

- Equipment used in automatic, mechanical, or electronic systems.

To show how proposed § 111.25(a)(1) might apply, assume that you use a mixer to blend powdered ingredients. If the mixer blade is too small, it might not mix the ingredients properly or thoroughly, and the resulting batches might be adulterated if the ingredients are not provided at the required levels throughout the batch. In this example, the mixer was not suited for its intended use. As another example, if your manufacturing equipment is so complex or designed in a way that makes cleaning difficult, any unclean surfaces on that equipment could become a source of contamination in the future. In this case, the equipment was not adequately cleaned and properly maintained or, alternatively, was not of appropriate design for its intended uses.

Proposed § 111.25(a)(2) would require that you use equipment and utensils of appropriate design and construction whose use will not result in the contamination of your components, dietary ingredients, or dietary supplements with lubricants, fuel, coolants, metal or glass fragments, filth or other extraneous material, contaminated water, or any other contaminants.

Proposed § 111.25(a)(3) would require your equipment and utensils to be:

- Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces;
- Corrosion-resistant if the equipment or utensils contact components, dietary ingredients, or dietary supplements;
- Made of nontoxic materials;
- 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
- Maintained to protect components, dietary ingredients, and dietary supplements from being contaminated by any source.

Deteriorating equipment can be a source of contamination. For example, repeated contact between metal surfaces in a grinding or tableting machine can result in metal fragments that can contaminate your dietary ingredients or dietary supplements. So, your equipment and utensils must be designed and constructed to withstand the environment of their intended use and you must maintain your equipment