contaminating components or dietary supplements.

(5) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be:
   (i) Stored in appropriate containers; and
   (ii) Handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary supplements, or any contact surface.

(6) Cleaning compounds and sanitizing agents must be adequate for their intended use and safe under their conditions of use;

(7) You must store cleaned and sanitized portable equipment and utensils that have contact surfaces in a location and manner that protects them from contamination.

§ 111.35 Under this subpart D, what records must you make and keep?

(a) You must make and keep records required under this subpart D in accordance with subpart P of this part.

(b) You must make and keep the following records:
   (1) Written procedures for fulfilling the requirements of this subpart, including written procedures for:
      (i) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement;
      (ii) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and
      (iii) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements;
   (2) Documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment, unless such documentation is kept with the batch record;
   (3) Documentation of any calibration, each time the calibration is performed, for instruments and controls that you use in manufacturing or testing a component or dietary supplement. In your documentation, you must:
      (i) Identify the instrument or control calibrated;
      (ii) Provide the date of calibration;
      (iii) Identify the reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy;
      (iv) Identify the calibration method used, including appropriate limits for accuracy and precision of instruments and controls when calibrating;
      (v) Provide the calibration reading or readings found;
      (vi) Identify the recalibration method used, and reading or readings found, if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and
      (vii) Include the initials of the person who performed the calibration and any recalibration.
   (4) Written records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment;