controlled by precision, automatic, mechanical, or electronic equipment, provision shall be made to adequately check its performance.

(b) All containers to be used for undiluted drugs, drug components, intermediate mixtures, and finished feeds shall be received, adequately identified and properly stored and handled in a manner adequate to prevent mixups or contamination.

(c) Equipment, including dust-control and other equipment, such as that used for holding and returning recovered or flush-out materials back into production, shall be maintained and operated in such a manner as to prevent unsafe contamination of the medicated feed.

(d) The steps used to prevent unsafe contamination of medicated feed include one or more of the following, or other equally effective procedures:

(1) Cleaning of those parts of storage, mixing, conveying, and any other equipment coming in contact with the drug component of the medicated feed for the purpose of cleaning out of the equipment any drug, drug component, or medicated feed prior to the use of the same equipment for the production of a different medicated feed.

(2) The cleaning of the equipment as required in subparagraph (1) of this paragraph, may be achieved by flushing all feed-contacting surfaces of such equipment used in the production of a medicated feed with a quantity of an appropriate drug-free feedstuff that has been found sufficient to remove any significant quantity of a drug component or an intermediate mix or complete medicated feed prior to the production of a different medicated feed. The yield from any such flushing operation may be incorporated in appropriate amounts in the subsequent production of a medicated feed intended to contain the same drug component (or components) to produce a complete medicated feed conforming to its composition and labeling specifications.

(e) If there is sequential production of batches of a medicated feed containing the same drug component (or components) at the same or lower levels, there shall be sufficient safeguards to avoid any buildup above the specified levels of the drug components in any of the batches of the complete feed.

(f) A sampling and assay schedule on the finished medicated feed, or a schedule at least as reliable, for checking on the composition of the finished article shall be applied as follows:

(1) In the case of a medicated feed that requires an approved new-drug application or antibiotic form 10 for its manufacture and marketing, the schedule of assays established in such application shall be used.

(2) In the case of a medicated feed that does not require an approved new-drug application or antibiotic form 10 for its marketing, three appropriately drawn samples from each 400 tons of such medicated feeds produced shall be taken at appropriately spaced intervals over the production period, and, in any event, not less than three such samples of each particular medicated feed during any 1 year shall be collected and analyzed. For the purposes of this subparagraph, the term "each particular medicated feed" shall be construed to include all feeds containing the same drug component (or the same mixture of components) at different levels. The collection and analysis of samples shall be from the medicated feed containing the highest level of the drug component (or mixture of components).

(3) A medicated feed covered by subparagraph (2) of this paragraph shall be exempt from the prescribed sampling and analytical schedule under the following conditions:

(i) The manufacturing practices used in the production of the medicated feed were consistent with the regulations of this part; and

(ii) The manufacturer of the medicated feed has produced at least 3 batches of such feed conforming to composition and labeling specifications during the 1-year period immediately preceding the date of manufacture of the feed and during that period has not been notified by the Food and Drug Administration or any State regulatory official that his manufacturing practices were in conflict with section 501(a)(2)(B) of the act or the regulations of this part and has not distributed a medicated feed during that period which has been proceeded against under the act because of failure of such feed to comply with its composition or labeling requirements or which has been analyzed by any State official and found to be deficient: and

(iii) The medicated feed contains only, as the drug component (or components), a low-level growth-promotion antibiotic (or antibiotics) as provided by and in accordance with the regulations in Part 121 of this chapter; it was