closure, in-process material, packaging material, or labeling in the production of a PET drug.

PET means positron emission tomography.

PET drug means a radioactive drug that exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for providing dual photon positron emission tomographic diagnostic images. The definition includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of a PET drug. ''PET drug'' includes a ''PET drug product'' as defined in this section.

PET drug product means a finished dosage form of a PET drug, whether or not in association with one or more other ingredients.

PET drug production facility means a facility that is engaged in the production of a PET drug.

Production means the manufacturing, compounding, processing, packaging, labeling, reprocessing, repacking, relabeling, and testing of a PET drug.

Quality assurance means a system for ensuring the quality of active ingredients, PET drugs, intermediates, components that yield an active pharmaceutical ingredient, analytical supplies, and other components, including container-closure systems and in-process materials, through procedures, tests, analytical methods, and acceptance criteria.

Receiving facility means any hospital, institution, nuclear pharmacy, imaging facility, or other entity or part of an entity that accepts a PET drug product that has been given final release, but does not include a common or contract carrier that transports a PET drug product from a PET production facility to a receiving facility.

Specifications means the tests, analytical procedures, and appropriate acceptance criteria to which a PET drug, PET drug product, component, container-closure system, in-process material, or other material used in PET drug production must conform to be considered acceptable for its intended use. Conformance to specifications means that a PET drug, PET drug product, component, container-closure system, in-process material, or other material used in PET drug production, when tested according to the described analytical procedures, meets the listed acceptance criteria.

Strength means the concentration of the active pharmaceutical ingredient (radioactivity amount per volume or weight at the time of calibration).

Sub-batch means a quantity of PET drug having uniform character and quality, within specified limits, that is produced during one succession of multiple irradiations, using a given synthesis and/or purification operation.

Verification means confirmation that an established method, process, or system meets predetermined acceptance criteria.

§ 212.2 What is current good manufacturing practice for PET drugs?

Current good manufacturing practice for PET drugs is the minimum requirements for the methods to be used in, and the facilities and controls used for, the production, quality assurance, holding, or distribution of PET drugs intended for human use. Current good manufacturing practice is intended to ensure that each PET drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

§ 212.5 To what drugs do the regulations in this part apply?

(a) *Application solely to PET drugs.* The regulations in this part apply only to the production, quality assurance, holding, and distribution of PET drugs. Any human drug that does not meet the definition of a PET drug must be manufactured in accordance with the current good manufacturing practice requirements in parts 210 and 211 of this chapter.

(b) *Investigational and research PET drugs.* For investigational PET drugs for human use produced under an investigational new drug application in accordance with part 312 of this chapter, and PET drugs produced with the approval of a Radioactive Drug Research Committee in accordance with part 361 of this chapter, the requirement under the act to follow current

good manufacturing practice is met by complying with the regulations in this part or by producing PET drugs in accordance with Chapter 823, ''Radiopharmaceuticals for Positron Emission Tomography—Compounding,'' May 1, 2009, pp. 365–369, 32d ed. of the United States Pharmacopeia (USP) National Formulary (NF) (USP 32/NF 27) (2009). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, Geeta M. Tirumalai, 301–816–8352, e-mail: *gt@usp.org*, Internet address: *http://www.usp.org/USPNF/notices*. You may inspect a copy at the Food and Drug Administration Biosciences Library, 10903 New Hampshire Ave., Silver Spring, MD, 20993–0002, 301–796–3504, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Subpart B—Personnel and Resources

§ 212.10 What personnel and resources must I have?

You must have a sufficient number of personnel with the necessary education, background, training, and experience to perform their assigned functions. You must have adequate resources, including facilities and equipment, to enable your personnel to perform their functions.

Subpart C—Quality Assurance

§ 212.20 What activities must I perform to ensure drug quality?

(a) *Production operations*. You must oversee production operations to ensure that each PET drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

(b) *Materials*. You must examine and approve or reject components, containers, closures, in-process materials, packaging materials, labeling, and finished dosage forms to ensure compliance with procedures and specifications affecting the identity, strength, quality, or purity of a PET drug.

(c) *Specifications and processes*. You must approve or reject, before implementation, any initial specifications, methods, processes, or procedures, and any proposed changes to existing specifications, methods, processes, or procedures, to ensure that they maintain the identity, strength, quality, and purity of a PET drug. You must demonstrate that any change does not adversely affect the identity, strength, quality, or purity of any PET drug.

(d) *Production records*. You must review production records to determine whether errors have occurred. If errors have occurred, or a production batch or any component of the batch fails to meet any of its specifications, you must determine the need for an investigation, conduct investigations when necessary, and take appropriate corrective actions.

(e) *Quality assurance*. You must establish and follow written quality assurance procedures.

Subpart D—Facilities and Equipment

§ 212.30 What requirements must my facilities and equipment meet?

(a) *Facilities*. You must provide adequate facilities to ensure the orderly handling of materials and equipment, the prevention of mix-ups, and the prevention of contamination of equipment or product by substances, personnel, or environmental conditions that could reasonably be expected to have an adverse effect on product quality.

(b) *Equipment procedures*. You must implement procedures to ensure that all equipment that could reasonably be expected to adversely affect the identity, strength, quality, or purity of a PET drug, or give erroneous or invalid test results when improperly used or maintained, is clean, suitable for its intended purposes, properly installed, maintained, and capable of repeatedly producing valid results. You must document your activities in accordance with these procedures.