§ 820.86 Met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.

(d) Final acceptance activities. Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

(1) The activities required in the DMR are completed;
(2) the associated data and documentation is reviewed;
(3) the release is authorized by the signature of a designated individual(s); and
(4) the authorization is dated.

(e) Acceptance records. Each manufacturer shall document acceptance activities required by this part. These records shall include:

(1) The acceptance activities performed;
(2) the dates acceptance activities are performed;
(3) the results;
(4) the signature of the individual(s) conducting the acceptance activities; and
(5) where appropriate the equipment used. These records shall be part of the DHR.

§ 820.86 Acceptance status.

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.