date and signature of the individual(s)
approving the validation and where ap-
propriate the major equipment vali-
dated, shall be documented.

(b) Each manufacturer shall establish
and maintain procedures for moni-
toring and control of process param-
ceters for validated processes to ensure
that the specified requirements con-
tinue to be met.

(1) Each manufacturer shall ensure
that validated processes are performed
by qualified individual(s).

(2) For validated processes, the moni-
toring and control methods and data,
the date performed, and, where appro-
priate, the individual(s) performing the
process or the major equipment used
shall be documented.

(c) When changes or process devi-
ations occur, the manufacturer shall
review and evaluate the process and
perform revalidation where appro-
priate. These activities shall be docu-
mented.

Subpart H—Acceptance Activities

§ 820.80 Receiving, in-process, and fin-
ished device acceptance.

(a) General. Each manufacturer shall
establish and maintain procedures for
acceptance activities. Acceptance ac-
tivities include inspections, tests, or
other verification activities.

(b) Receiving acceptance activities.
Each manufacturer shall establish and
maintain procedures for acceptance of
incoming product. Incoming product
shall be inspected, tested, or otherwise
verified as conforming to specified re-
quirements. Acceptance or rejection
shall be documented.

(c) In-process acceptance activities.
Each manufacturer shall establish and
maintain acceptance procedures, where
appropriate, to ensure that specified
requirements for in-process product are
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 main-
tain procedures for finished device ac-
teptance to ensure that each produc-
tion run, lot, or batch of finished de-

§ 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 ac-
ceptance criteria. The identification of
acceptance status shall be maintained
throughout manufacturing, packaging,
labeling, installation, and servicing of
the product to ensure that only prod-
uct which has passed the required ac-
ceptance activities is distributed, used,
or installed.

Subpart I—Nonconforming
Product

§ 820.90 Nonconforming product.

(a) Control of nonconforming product.
Each manufacturer shall establish and
maintain procedures to control product
that does not conform to specified re-
quirements. The procedures shall ad-
dress the identification, documenta-
tion, evaluation, segregation, and dis-
position of nonconforming product.

The evaluation of nonconformance
shall include a determination of the