the conditionally released batch, demonstrate that the conditionally released batch will likely meet the established specifications;
(ii) You determine that all other acceptance criteria are met;
(iii) You retain a reserve sample of the conditionally released batch of drug product;
(iv) You promptly correct the malfunction of analytical equipment, complete the omitted test using the reserve sample after the malfunction is corrected, and document that reasonable efforts have been made to prevent recurrence of the malfunction;
(v) If you obtain an out-of-specification result when testing the reserve sample, you immediately notify the receiving facility; and
(vi) You document all actions regarding the conditional final release of the drug product, including the justification for the release, all followup actions, results of completed testing, all notifications, and corrective actions to prevent recurrence of the malfunction involving analytical equipment.
(2) Even if the criteria in paragraph (f)(1) of this section are met, you may not approve the conditional final release of the product if the malfunction involving analytical equipment prevents the performance of a radiochemical identity/purity test or prevents the determination of the product’s specific activity.
(3) You may not release another batch of the PET drug product until you have corrected the problem concerning the malfunction of analytical equipment and completed the omitted finished-product test.

§ 212.71 What actions must I take if a batch of PET drug product does not conform to specifications?

(a) Rejection of nonconforming product. You must reject a batch of a PET drug product that does not conform to specifications. You must have and follow procedures to identify and segregate the product to avoid mix-ups. You must have and follow procedures to investigate the cause(s) of the nonconforming product. The investigation must include, but is not limited to, examination of processes, operations, records, complaints, and any other relevant sources of information concerning the nonconforming product.
(b) Investigation. You must document the investigation of a PET drug product that does not meet specifications, including the results of the investigation and what happened to the rejected PET drug product.
(c) Correction of problems. You must take action to correct any identified problems to prevent recurrence of a nonconforming product or other quality problem.
(d) Reprocessing. If appropriate, you may reprocess a batch of a PET drug product that does not conform to specifications. If material that does not meet acceptance criteria is reprocessed, you must follow procedures stated in the product’s approved application and the finished product must conform to specifications, except for sterility, before final release.

Subpart J—Distribution

§ 212.90 What actions must I take to control the distribution of PET drug products?

(a) Written distribution procedures. You must establish, maintain, and follow written procedures for the control of distribution of PET drug products shipped from the PET drug production facility to ensure that the method of