

Certificate of Materials Supplied to Receiving Site
Certification Reports and accompanying documentation should be filed within each Receiving Site Quality Assurance archive.

5.3 Review of Certification Status

A periodic review of the certification status of each material from a supplier site will be conducted and documented by each Receiving Site that has received deliveries during the time period based upon the following criteria:

- Regulatory Compliance
- Quality Agreement Compliance
- Service Performance
- Non-Conformities/Complaints
- Certificate of Analysis/Conformity
- Last Audit/Questionnaire
- Supplier Analytical Method Review
- Received Batches Analytical and Clearance Status Review
- Recommended Testing Protocol
- Change Control
- Trend Analysis (when applicable)
- Compliance confirmation of full testing (performed at appropriate intervals)
- Progress with audit observation closure
- Compliance Status of Supplier
- Periodic testing of the certified material. (This is only performed when required by the local GMPs of the receiving site).

If appropriate, the certification status of the material shall be downgraded to ‘decertified’ (see Section 5.5) or may stay ‘certified’ (see Section 5.4). This revised status shall be periodically reviewed. An updated version of the “Certification Report” should be issued to include the latest status.

Each Receiving Site should send a copy of their updated “Certification Report” to other sites receiving the same material from the same supplier site together with the Lead Audit Site so they may be aware of any new issues with the supplier.

5.4 Criteria for Maintenance of Certification Status

If no critical defects were observed during the latest audit, no serious problems or observations were noted with the monitoring program, and no serious observations were noted during the periodic quality review, the Receiving site may make the recommendation that the supplier shall maintain their status of “Certified Supplier” for use at site operations.

5.5 Criteria for De-certification

During the routine review period of certification status, the Receiving Site may determine that the material no longer meets the criteria for certification. Note: This may occur outside of the normal frequency of assessing the Supplier. The Receiving Site Supplier Certification team, using the following criteria, should determine the severity and scope of non-compliance by the supplier for assessing if de-certification is warranted. If areas were identified during the on site audit, monitoring program or in the historical quality review that poses a vulnerability