PCC			X
PCNC			X***

(*) Including contract laboratories, warehouses, labeling, calibration centers, etc.

(**) These materials should be audited initially, if possible; then SQR is normally acceptable, if no quality issues and no major changes occurred. Some NCRMs (e.g. solvents going into final stage) need to be audited to the same frequency as CRMs. SQR should not be substituted for full audits of suppliers of critical materials or services.

(***) SQR is acceptable. The frequencies detailed in the above table are guidelines, valid for "Approved" status suppliers. The frequencies for "Provisional Approval" or "Disapproved" status suppliers should be increased.

If a supplier supplies more than one type of material, the audit frequency shall be determined by the material with the minimum (shortest) audit frequency.

All routine scheduled audits should be performed within a ± 3 month interval of the routine scheduled audit date. Extensions in supplier audit frequencies should be exceptional. A supplier's routine audit frequency may increase for cause (e.g. from 2 years to annually). Any changes to the routine scheduled audit frequency shall be agreed with the Receiving Sites management, fully justified and documented by the LAT and recorded.

Quality & Technical Review meetings are not considered audits. Notes/minutes of such meetings may be recorded.

5.5.1 R&D QA Audit Frequency (principles)

The audit frequency and types of audits completed by R&D sites may vary from the detail specified in the table above (providing the supplier is supplying solely to R&D).The frequencies listed in the table should be used as guidance and following principles should be applied:

- Suppliers of raw materials, excipients or packaging components that are intended for use in clinical studies should be audited. If intended to be used for Phase I studies only, the material may be subjected to intensive testing and a SQR instead of a full supplier audit. This should be considered and documented on a case-by-case basis.

Suppliers of finished product (sterile and non-sterile) intended for use in clinical studies should be audited applying the frequencies listed above. In the event the product is a biopharmaceutical, consideration should be given as to whether the supplier should be audited on a more frequent basis.

- Supplier evaluation via risk assessment in lieu of a full audit may be acceptable, however this should be based on the Supplier history and the nature and criticality of the service being provided.
- Clinical Pharmacology Units (CPUs) and comparator suppliers (wholesalers and pharmacies) should be considered for inclusion in audit plans.
- Stability testing providers critical to R&D should be audited at a

