- If a specific method is being validated, then specificity studies need to be performed for the analyte of interest. The potential for interference from the following should be considered:
    - Swab extractables
    - Cleaning agents
    - Sample containers and lids
    - Excipients and other compounds potential present

- If a specific method is being validated for a cleaning agent, the only specificity experiment typically executed is specificity from swab extractables.

Range
The equipment cleaning analytical method should be validated around the calculated RAL for the material. The method is considered valid for any RAL within the validated recovery range. If the RAL falls outside the validated recovery range, the method should be revalidated with respect to the affected elements (e.g. range, linearity).

Linearity
Linearity should at a minimum cover the expected analyte RAL and encompass the levels included in repeatability and recovery studies. The lower end of the linearity study shall take into consideration the correction factor for sampling recovery, if applicable (e.g. if the RALs have a range of 4-6 ug/cm2 and the recovery is 50 percent, the linearity study should include levels of 2-6 ug/cm2).

Intermediate Precision
Intermediate precision is the study of the effects of random events (e.g. days, analysts, equipment etc.) on the precision of the analytical procedure. A method intermediate precision experiment should be conducted unless there is a documented rationale otherwise (e.g. a reliable and robust swabbing verification program is implemented). Method intermediate precision should include use of a second Lab Analyst, on a different day, using different solutions and different analytical equipment, if possible.

System Suitability
System suitability should be conducted for systems such as HPLC and TOC. Although non-specific methods like UV, pH etc. may be used; the ability of the selected method to detect the residue shall be demonstrated (for example UV absorbance at the residue maximum wavelength and non-interference of the rinse solution).

Recovery Studies
Analyte residue recovery shall be challenged as part of the analytical method validation. The recoveries of each material (product or cleaning agent) from the different process-contact surfaces that constitute the major portions of equipment's surface area are typically demonstrated. Alternatively, the recovery value of a worst case material could be substituted for all the materials sampled with the same rinse solvent. Typical surfaces may include hastelloy, stainless steel, glass/glass lined carbon steel and PTFE (polytetrafluoroethylene).

The solvent used in the recovery study should be the same as is used for routine sampling.

The range (in µ g/swab) over which the method is validated; Different criteria may be applied to generate this according to site procedures. Examples of this could be:

a) proving linearity of results from swabbing spiked coupons at a range of concentrations and compared to linearity of the test method, or
b) by performing the recovery at 50%, 100% and 150% of the RAL, and thus proving the recovery is applicable to this range of concentrations.

If a recovery is performed at 50%, 100% and 150% of the RAL and all three recovery values are within the criteria set at the originating site; the originating site should report the mean of the three values expressed as a percentage. As the individual recovery values are within set criteria, this mean should be "similar" to all 3 values obtained.

If the values for the recoveries performed individually at 50%, 100% and 150% are within acceptance criteria but are significantly different from the mean, then the method would probably not be transferable and the STP should document this fact. Because the range over which the recovery applies could not be reported with certainty; the changing recovery values with concentration could not be assumed to be the same at the receiving site, even if equivalence was shown at one concentration. In this case, another method may need to be developed and validated at the receiving site.

Equivalence of Methods Transferred Between Sites
Adherence to the principles described above by the developing site will allow another site interested in receiving a test method to focus on what is required in order to establish equivalence (i.e. to confirm the method is suitable for use at the receiving site). The following should be considered when transferring a method to another site with different swabbing practices; equivalence should be demonstrated as follows:

- Ensure the validated range is adequate for the receiving site. If the validated range needs to be extended, then a separate swab linearity study should be performed by the receiving site over the required range.

- Perform a recovery on 6 coupons using the receiving site's procedure. This should be performed at the lowest RAL for that product at the receiving site.

- Calculate the mean of the 6 recovery results. If the absolute % difference between the mean recovery and that stated in the originating site's STP is not greater than 15%, then the recovery value stated in the STP will remain unchanged (e.g., if the STP states a recovery of 85%, then the receiving site would target to obtain a recovery of 70% to 100%).

- Calculate the RSD of the 6 recovery results. If the RSD is not greater than 15%, then the new technique is considered acceptable (providing the mean result meets the criteria above).

- An STP, stating the new conditions/technique/extraction should be written, referencing the equivalence proven to the originating STP

- If the mean and RSD criteria are not met, then equivalence in not proven, and the following could be performed:

