

Subject: Sample stratification**10.3 Sample stratification****Decision if sample stratification is needed**

- 10.3.1 The CAB shall review the group's proposed scope and sites to make a decision on whether sample stratification is required.
- 10.3.1.1 Stratification shall take place where the group's sites can be classified into distinct sub-groups according to activities shown in Table 4.
 - 10.3.1.2 Stratification shall take place where manufacturing and/or processing activities occur within a group but where not all sites perform these activities.
 - 10.3.1.3 Stratification shall take place where a group operation is not within 1 geographic region.

Guidance 10.3.1.3

This is especially useful for certificates covering sites in multiple countries or continents, where operation culture, language, or location may be different from the central office.

Geographic region refers to a group of countries in close proximity or with similar characteristics, or a region within a country with a similar characteristic, for example sharing a language.

- 10.3.2 If stratification is required, the CAB shall follow the sampling procedure for each sub-group independently.
- 10.3.3 The CAB shall keep a record of the sample stratification process and rationale in the CoC audit checklist.