1. Testing Schemes Flow Charts

Class I

Class I AUX

6.1 Type EL Equipment & Components Evaluation Scheme Start Project submit improved design AEO Hygienic Design Criteria, evaluation of design (drawing, documentation) and report not good Doc. 8, etc AEO / Applicant determination of worst case for manufacturer to testing, if necessary re-design Practical examination: AE0 surface roughness, radii, inspection of the equipment and not good surface structure, joints, ... report. not done meets the criteria deviations from criteria for essential technical or functional reasons, cleanability test required no Certificate Cleanability Testing ➤ not good -Doc. 2, (two tests) Test Method in-place cleanability good Cleanability Testing (3 good tests out of the max. of 5 not good tests in total) not good Doc. 5, Test Method in-line Steam Steralisability Testing sterilizability (three tests) good good not good Test Method Bacteria Tightness Testing Bacteria Tightness (three tests) Cleanability Test Report and / or Hygienic Design Qualification Report

Class II

Continuing Project

Test Reports

Aseptic Class II

Aseptic Class I