1. **Testing Schemes Flow Charts**

6.1 Type EL Equipment & Components Evaluation Scheme

- **Start Project**
- **AEO** evaluation of design (drawing, documentation) and report
  - not good
  - manufacturer to re-design
- **AEO / Applicant** determination of worst case for testing, if necessary
- **Inspection of the equipment and report**
  - not good
  - deviations from criteria for essential technical or functional reasons, cleanability test required
  - meets the criteria
  - **Cleanability Testing** (two tests)
    - not good
    - **Cleanability Testing** (3 good tests out of the max. of 5 tests in total)
      - good
      - **Steam Sterilisability Testing** (three tests)
        - not good
        - **Bacteria Tightness Testing** (three tests)
          - good
          - **Test Reports**
            - **Cleanability Test Report and / or Hygienic Design Qualification Report**
              - **Class I**
              - **Class I AUX**
              - **Class II**
              - **Aseptic Class I**
              - **Aseptic Class II**
            - **Continuing Project**