How to perform cleaning validations of **non-critical devices** according to ANSI/AAMI ST98

Under AAMI TIR30 non-critical devices were validated in the same way as semi-critical or critical devices. With AAMI TIR30 now replaced by ANSI/AAMI ST98, a less rigorous approach is allowed for validating non-critical devices.

SIMULATED USE TESTING

- Non-critical devices that only require a visual inspection are considered **exempt** from simulated use testing

SAMPLE SIZE

- Number of test replicates is **justification** based depending on:
  - Medical device complexity
  - Criticality can also be considered
- Sample size should be **at least 3**

ENDPOINTS

- At least a **visual inspection**
- If a **higher risk** of the presence of residuals below visually detectable levels is anticipated, qualitative or quantitative detection of analytes can be appropriate

VALIDATION OF THE CLEANING PROCESS

- Visual inspection for cleaning can be combined with low-level disinfection testing which allows for a **one-step** cleaning and disinfection procedure and validation (also mentioned in ISO17664-2)

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