

ISO 7199:2017 VERSUS ISO7199:2024

Based on the clause-by-clause comparison between ISO 7199:2024 and ISO 7199:2017, the 2024 edition introduces several substantive changes affecting biological safety, physical integrity testing, connector standards, performance validation, and documentation practices. The major gaps requiring action are summarized below, with the applicable parameters highlighted for implementation.

1. Biological Safety

- Sterility and non-pyrogenicity requirements remain aligned.
- Biocompatibility clause drops explicit reference to ISO 10993-7, retaining ISO 10993-1 only. Action: Update DHF and risk files to reflect reduced explicit cytogenetic testing; maintain ISO 10993-1 compliance.

