Example 1 - Fatigue testing of a dental implant system

This summary has **not** been previously reviewed by Health Canada.

The application had multiple tests presented in tabular form; an excerpt is shown below:

Report Number	Description	Acceptance Criteria	Results (pass/fail)
TR-XXXX (Fatigue)	Verify fatigue strength of the XYZ dental implant in the worst-case loading configuration. This test applies to the proposed implants, abutments and abutment screw.	The worst-case implant/abutment assembly must be able to withstand 5,000,000 cycles at a load ≥185N per ISO 14801. Three implant assemblies must survive, and none fail in 5 million cycles.	Pass, 3 samples survived 5MC at 250N with no failures. Acceptance criteria of 185N was met.

Missing

- Discussion and justification of the worst-case scenario
- Justification of the acceptance criteria as ISO 14801 doesn't have numeric values

Example 2 – Shelf Life of Packaging

This summary has **not** been previously reviewed by Health Canada.

"The modified packaging shall enable a shelf life of 5 years which is the same as the currently licenced shelf life period. Stability testing and performance testing was performed to confirm the shelf life of 5 years.
Stability testing and performance testing are separate entities. Performance testing evaluates the interaction between the packaging system and the products in response to the stresses imposed by the manufacturing and sterilization processes and the handling, storage and shipping environment. Stability testing shall demonstrate that the sterile barrier system maintains integrity over time.
The stability testing and performance testing reports are included in this section."

Missing

- Separate summary for shelf life and packaging validation
- Identification and justification of acceptance criteria
- # samples tested for each
- Identification of real-time or accelerated aging
- Tests conducted on the packaging (seal strength, dye penetration)
- Quantitative results

Example 3 – Pre-clinical testing for cosmetic laser system

This summary has been previously reviewed by Health Canada.

“The test reports for the types of tests performed are listed below:

a) Engineering Test Reports
The engineering tests report on the software control of the laser power settings, device thermal tests and skin temperature tests. These tests verify the software control of the hardware and verify there are no conditions generated that would adversely affect the patient. The optical power versus tablet control is a test of different laser control methods. The frequency control method was chosen as it provided a linear response over the entire power range.

Appendix T: Thermal Tests
Appendix U: Skin Temperature Tests
Appendix V : Verification of Probe Settings
Appendix W: Optical Power vs Tablet Control

b) Laboratory test Reports
These sets of tests verify the device conforms to the applicable standards. The tests are performed by an independent regulatory testing agency. The reports for the various electrical safety tests, laser safety tests and biocompatibility tests verify the devices are safe.

Electrical and Laser Safety Tests:
Appendix G: IEC60601-1 3rd Ed.
Appendix H: IEC60601-1-2
Appendix I : IEC60601-2-22
Appendix J : IEC60825-1
Appendix K : IEC60601-1 3rd Ed AT1

Bio-compatibility Tests:
Appendix M : ISO10993-5
Appendix N & O: ISO10993-10”

Missing

- No mention or justification of acceptance criteria
- No methods
- No quantitative results

Example 4 – Software verification and validation

This summary has been previously reviewed by Health Canada.

The application had multiple tests presented in tabular form; an excerpt is shown below:

Device Questions	Document Name	Description
What are results of the verification and validation activities performed? What are the defects that were logged as a result of this testing? What Verification and Validation tests were performed for the device? What were the observed results from the Verification and Validation tests?	XYZ System documents: Verification and Validation Summary Report Test reports: • Verfication testing - Hardware - Control console software - Service software - Interruption matrix • Validation testing	These documents summarize the results of the verification and validation activities performed and defects logged as a result of the verification and validation efforts performed on the XYZ System software.
What are the existing unresolved anomalies in the release version of the device software? What are the justifications for the inclusions of these items?	Unresolved anomalies	This document lists the Discrepancy Reports that have not been fixed in the device during the project. The standard procedure has been followed which requires that these are reviewed by the Review Board. Review criteria are included.

Missing

- Summaries of any of the reports identified
- Acceptance criteria
- List of unresolved anomalies and impact