Validation certificate template

The staff member with designated responsibility for sterilisation is required to:

1. Review the documented procedures encompassing all parts of the reprocessing procedure to ensure reproducibility:
   * workflow issues: dirty through to clean and environmental cleaning
   * precleaning and cleaning of instruments, including drying and visual inspection
   * packing of contents in a sterile barrier system, including sealing and labelling
   * loading of the steriliser
   * mechanical/physical monitoring (chemical indicators and recording of exposure time and temperature) of the sterilisation cycle parameters
   * unloading of the steriliser and checking the packs are dry and intact and checking monitoring results and correct chemical indicator change
   * storage of sterile items
   * maintenance of steriliser as required by the manufacturer (including water changes and cleaning).
2. Perform or supervise the documented procedures.
3. Check that the procedures were performed correctly.
4. Record correct completion of each procedure.

The [validation certificate template](#template) below can be used to record the correct completion of each required procedure.

This template is drawn from the Royal Australian College of General Practitioners *Infection prevention and control guidelines for general practices and other office-based and community-based practices*. Refer to [Section 10 – Reprocessing reusable medical devices](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/overview) of the guidelines for more information.

**Disclaimer**

The information set out in this publication is current at the date of first publication and is intended for use as a guide of a general nature only and may or may not be relevant to particular patients or circumstances. Nor is this publication exhaustive of the subject matter. It is no substitute for individual inquiry. Compliance with any recommendations does not guarantee discharge of the duty of care owed to patients.

The RACGP and its employees and agents have no liability (including for negligence) to any users of the information contained in this publication.

© The Royal Australian College of General Practitioners 2022

This resource is provided under licence by the RACGP. Full terms are available at www.racgp.org.au/usage/licence

We acknowledge the Traditional Custodians of the lands and seas on which we work and live, and pay our respects to Elders, past, present and future.

Insert practice name here.

Validation certificate template

Steriliser identification: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Process | Process documented in policy and procedure manual | Process performance, effectiveness and reliability checked (ie validated) | Check by (name) | Signature | Date |
| Cleaning of the environment and workflow issues (dirty to clean) |  |  |  |  |  |
| Precleaning and cleaning of instruments |  |  |  |  |  |
| Content, packing and sterile barrier system of challenge pack |  |  |  |  |  |
| Loading of challenge load |  |  |  |  |  |
| Monitoring of cycle parameters |  |  |  |  |  |
| Unloading of the steriliser (steriliser log) |  |  |  |  |  |
| Storage of sterile items |  |  |  |  |  |
| Cleaning and maintenance of steriliser (maintenance log) |  |  |  |  |  |
| Cleaning and maintenance of ultrasonic cleaner |  |  |  |  |  |
| Cleaning and maintenance of washer-disinfector |  |  |  |  |  |
| Cleaning and maintenance of drying cabinet |  |  |  |  |  |
| Cleaning and maintenance of incubator |  |  |  |  |  |
| Name of service company: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Steriliser technician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Date: Click or tap to enter a date. | | | | | |
| Name of staff member with responsibility for practice sterilisation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Date: Click or tap to enter a date. | | | | | |