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Quality and Accreditation Institute

Centre for Accreditation of Health & Social Care

ADDITIONAL REQUIREMENTS

CENTRAL STERILE SUPPORT DEPARTMENT

FIRST EDITION

MAY 2026

These Additional Requirements are developed to support applicant/ accredited Health Care Facilities (HCFs). These Additional Requirements constitute addendum to the requirements under various QAI accreditation standards and are applicable to applicant/ accredited HCFs. All applicant/ accredited HCFs may like to adopt and comply with these Additional Requirements.

QAI assessors of various accreditation programmes under the Centre for Accreditation of Health & Social Care (CAHSC) should check the adherence to these Additional Requirements during assessments.

CSSD/sterilization unit should have suitable location and the design must support a one-way workflow (unidirectional flow) and separation from the decontamination area to the clean area and finally to the sterile area. There shall be adequate space to ensure that the activities can be performed properly with proper zoning including separate areas for receiving used items, washing, cleaning, packing, sterilizing, sterile storage and dispensing of sterilized items.

CSSD to be divided in following three key zones i.e. Red, Yellow and Green:

1. Red Zone (Dirty/Decontamination):

Where soiled instruments are received and checked for torn/puncture/cracked/brokage etc then entered in register/system and sorted into different packs for different methods of cleaning and washing.

2. Yellow Zone (Clean/Processing):

After cleaning and washing, instruments move to inspection, where instruments are inspected and assembled into sets and packaged for sterilisation. Provision of gauze cutting/preparation or sub store is given in this zone. Additionally, an ethylene oxide sterilizer (ETO) / Plasma can be included in a separate compartment of this area. After proper packaging and labelling of items i.e. batch no, expiry date, set description etc items moves to sterilizers (autoclaves, ETO or plasma) for sterilisation. Sterilization is achieved by sterilizers working at specified cycles of temperature and duration to attain adequate sterility assurance level (SAL). It is better to have 2 steam sterilizers in case of breakdowns

3. Green Zone (Sterile/Storage):

After sterilisation of items, sterilized items are stored in sterile storage room/area and issued from the sterilised area/Green Zone, never re-entering the dirty areas.

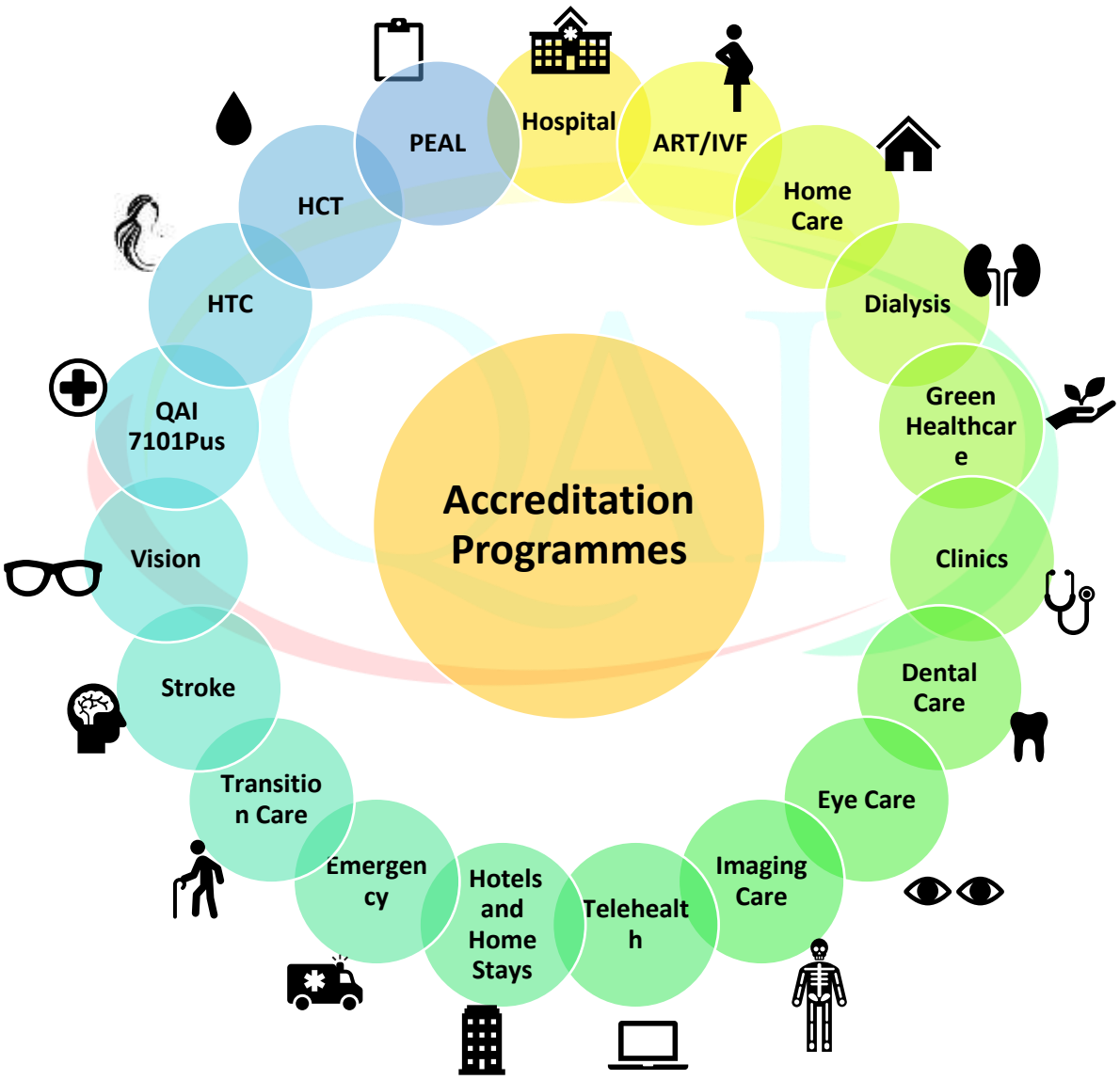
I. Appropriate validation tests are carried out at regular intervals for sterilization activities in CSSD/sterilization unit.

II. Physical and chemical validation tests have to be carried out on a daily basis. Biological tests for validation should be carried out on a weekly basis and also with every implant tray. The Health Care Facility (HCF) must ensure negative biological indicator report prior to using the implant.

III. Bowie dick test should be done on an empty cycle on a daily basis. Pressure, temperature and hold timings have to be documented and each load to have a load and batch number, content description, temperature, pressure and time-record chart. The expiry date should be mentioned on sterilized items

IV. The HCF should identify those devices which are meant for re- use. The number of reuses and the process of re-use of these items are defined and monitored based on best practices and available literature.

V. Recall procedure should be in place in case of breakdown/failure in sterilization process.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