



TOMÁS J. ARAGÓN, M.D., Dr.P.H.
State Public Health Officer & Director

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

Aug 03, 2023

Daniel Price
Children's Hospital of Orange County
1201 W La Veta Ave
Orange, CA 92868

APPROVAL OF PROGRAM FLEXIBILITY

Dear Daniel Price,

This letter is in response to the request submitted by **Children's Hospital of Orange County** for program flexibility for California Code of Regulations T22 DIV5 CH1 ART8-70833(c).

The alternative means of compliance with T22 DIV5 CH1 ART8-70833(c) include

Children's Hospital of Orange Co. (CHOC) is requesting program flexibility for regulation T22 DIV5 CH1 ART8-70833(c). Event related sterilization is permitted per industry standards (ANSI/AAMI ST 79) for sterile processing. CHOC requests to follow our policy Sterilization Shelf Life for Event Related Sterilization processes in order to facilitate sterilization processing in accordance with operational internal procedures.

Your request for program flexibility of **T22 DIV5 CH1 ART8-70833(c)** is approved under the following conditions:

- Hospital will ensure compliance to the most current version of the American National Standard Institute/Association for the Advancement of Medical Instrumentation: **ANSI/AAMI ST79** standards.

Center for Health Care Quality
Centralized Program Flex Unit (CPFU)
P.O. Box 997377 MS 3405 Sacramento, CA 95899-7377
e-mail: CentralizedProgramFlex@cdph.ca.gov



- Inclusion: Shelf life may be event-related unless otherwise specified by the packaging system manufacturer's labeled expiration date.
- Exclusion: Expiration dates on commercially processed sterile packages will remain on time shelf life, Medications are specifically excluded.
- Supplies processed by the facility's Central Service Department will be packaged using materials appropriate to the item and process of sterilization pursuant to 22 CCR Section 70833.
- Supplies will be:
 - Labeled and identified with a lot number/quality control label with specific date of sterilization for recall of supplies.
 - Considered sterile unless opened or damaged or equivalent language.
 - Stored in a clean, dry environment.
 - Used on a first-in first-out manner.
 - Inspected prior to opening for signs of damage.
 - Checked on a daily, weekly and monthly basis.
 - Sent for reprocessing if any signs of questionable sterility.
 - Supplies dropped on the floor will be considered contaminated.
 - Initial and annual training will be provided to personal responsible for packaging/processing, handling, storage and inspection and use of sterile supplies.
 - Records of event related sterilization in-service training with attendance sheets will be maintained.
 - Hospital will adhere to their Event Related Sterilization policy(s) and procedures.
 - Hospital will adhere to infection control policy(s) and procedures.
 - Hospital will notify the California Department of Public Health for changes to their Event Related Sterility Policy.

Either this letter or a true copy thereof shall be posted immediately adjacent to the facility's license.

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This approval shall remain in effect from Aug 11, 2023 until Aug 10, 2026.

NOTE: The Department may revoke the program flexibility if the licensee does not comply with the conditions set forth in the approval or if the department determines the proposed alternative does not adequately meet the intent of the regulations.

If you have any questions, please contact Centralized Program Flex Unit at (916) 323-5053 or by email at CentralizedProgramFlex@cdph.ca.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Banks', written over a horizontal line.

Sevrine A. Banks, Program Manager
Centralized Program Flex Unit