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Director and State Public Health Officer

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Maggie Barsoum
Rady Children's Hospital Orange County
1201 W La Veta Ave
Orange, CA 92868

FACILITY: Rady Children's Hospital Orange County, LICENSE # 060000011

APPROVAL OF PROGRAM FLEXIBILITY FOR FLEX-14943

Dear Maggie Barsoum,

This letter is in response to the request submitted by **Rady Children's Hospital 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

As per hospital Policy MM329 Sterilization Shelf Life, event related sterility is defined as: An item is considered sterile until an action causes the item to become unsterile, i.e. excessive handling, excessive humidity in storage area, transportation methods, tears, or broken seals or puncture to the package. Policy:

A. Using event-related criteria (package is considered sterile unless the package is opened or damaged), there is no expiration date to indicate when the package is no longer sterile. The date indicating when the package was sterilized, in conjunction with the sterilization identification and load number, and a statement that indicates



the product is sterile unless opened or damaged, shall confirm sterility, unless item has been exposed to event-related criteria.

B. It is the responsibility of all users to ensure the packages have not been compromised due to event-related conditions. Generally, visual evidence of compromised packaging includes the presence of tears, holes, rupture of seals, closures, wetness, and crushed packages. Additionally, packages that are dropped on the floor are no longer considered sterile.

C. In order to ensure that packages are used in a timely manner, a rotating inventory system will be maintained and audited at least once per month for all sterilized packages. No sterilized packages will be used after one year from the date of sterilization.

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

1. Hospital is approved to use event-related shelf-life practices as an alternative means for dating and outdating of hospital items sterilized. The shelf-life may be event-related unless otherwise specified by the manufacturer or distributor when providing expiration dating in the form of labeling, instructions of use, or other statements. Medications will not be sterilized by the hospital.
2. Hospital will ensure that an indefinite shelf-life label is placed on each hospital sterilized item and designating it as being “event-related”. The sticker will indicate the sterilization date, sterilizer number, and load number. And, expiration date, if applicable.
3. Hospital will ensure that items are decontaminated/cleaned, wrapped, sterilized, stored, transported, and handled to maintain package integrity without compromise.
4. Hospital process will rotate supplies to ensure previously processed items are used before the most recently processed items.
5. Hospital will have a process for packages to be inspected by the user before being opened. If the package is dropped on the floor, opened/torn, wet, or

damaged in any way, it is not to be used. Packages will be stored in a clean, dry environment.

6. Hospital will have a process for the user to verify that the external indicator has been exposed to sterilization prior to opening the package and all parameters for sterile processed items met. And process to ensure the internal indicator signifies sterility prior to use.
7. Hospital will ensure monitoring that involves checking sterilizer gauges, computer displays, or printouts, and documenting in hospital sterilization records that pressure, temperature, and exposure time have reached the levels recommended by the sterilizer manufacturer and documentation will be provided to the California Department of Public Health (CDPH) upon request.
8. Hospital will ensure that staff will be assigned tasks within their scope, experience, training, and competence.
9. Hospital personnel will receive orientation and training related to event-related shelf-life practices, including Occupational Safety and Health Administration (OSHA), patient safety, and job specific tasks/needs and documentation will be provided to CDPH upon request.
10. Hospital shall will maintain a current written policy and procedure that follows infection control standards, disinfection and sterilization guidelines, including, but not limited to, those from the Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), The Joint Commission (TJC), American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI), and U.S. Food and Drug Administration (FDA) enforcement documents.
11. Hospital will have continued compliance with adverse event and unusual occurrence reporting requirements specified in HSC Section 1279.1.

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

This approval shall remain in effect from Aug 10, 2026 until Aug 09, 2029.

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,

Danielle Boles

Danielle Boles, Program Manager
Centralized Program Flex Unit