



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

Jan 22, 2024

Daniel Price
Children's Hospital at Mission
27700 Medical Center Rd
Mission Viejo, CA 92691

FACILITY: Children's Hospital at Mission, LICENSE # 060000348

APPROVAL OF PROGRAM FLEXIBILITY FOR FLEX-7818

Dear Daniel Price,

This letter is in response to the request submitted by **Children's Hospital at Mission** for program flexibility for California Code of Regulations T22 DIV5 CH1 ART8-70833(c)(3).

The alternative means of compliance with T22 DIV5 CH1 ART8-70833(c)(3) include

Use of event related sterilization equipment in the function of sterilizing instruments and equipment.

Your request for program flexibility of **T22 DIV5 CH1 ART8-70833(c)(3)** 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 minimally indicate the sterilization date,

Center for Health Care Quality
Centralized Program Flex Unit (CPFU)
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sterilizer number, and load number. Expiration date used, as 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/signs of moisture exposure, 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, 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. The hospital will have continued compliance with adverse event and unusual occurrence reporting requirements specified in Health and Safety Code (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 Jan 22, 2024 until Jan 21, 2027.

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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,



Sevrine A. Banks, Program Manager
Centralized Program Flex Unit