



2022 Critical Elements Standards

Critical Elements are criteria identified to have greater potential for adverse effects on patient health and safety.

I. Access/Safety Reviewer Standards

I.C.4) (CE) Exit doors and aisles are unobstructed and egress (escape) accessible.

Access Aisle:

- Accessible pedestrian paths of travel (ramps, corridors, walkways, lobbies, elevators, etc.) between elements (seats, tables, displays, equipment, parking spaces, etc.) provide a clear circulation path.
- The minimum clear passage needed for a single wheelchair is 36 inches along an accessible route but may be reduced to a minimum of 32 inches at a doorway.
- Means of egress (escape routes) are maintained free of obstructions or impediments to full instant use of the path of travel in case of fire or other type of emergency.
- Building escape routes provide an accessible, unobstructed path of travel for pedestrians and/or wheelchair users at all times when the site is occupied.
- Cords (including taped cords) or other items are not placed on or across walkway areas.

I.D. 4) (CE) Airway management: oxygen delivery system, nasal cannula or mask, bulb syringe and Ambu bag

Without the ability to adequately maintain the patient's airway, all other interventions are futile. Minimum airway control equipment with various sizes of airway devices appropriate to patient population within the practice and examples of oxygen delivery systems include:

- Wall oxygen delivery system.
- Portable oxygen tank.
- Portable oxygen concentrator (POC).

All oxygen delivery systems must be able to be regulated up to 6 liters of oxygen per minute, maintained for a minimum of 15 minutes. This flow rate establishes a minimum total oxygen delivery capacity of 90 liters for these devices:¹

- Nasal cannula or mask.
- Bulb syringe.
- Ambu bag as appropriate to patient population served. Masks should be replaced when they no longer make a solid seal.
- Portable oxygen tanks are maintained at least $\frac{3}{4}$ full. There is a method/system in place for

¹ See the Food and Drug Administration (FDA) guidelines for oxygen generators and oxygen equipment for emergency use, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/review-guidelines-oxygen-generators-and-oxygen-equipment-emergency-use>.



oxygen tank replacement. If oxygen tanks are less than $\frac{3}{4}$ full at time of site visit, site has a back-up method for supplying oxygen if needed *and* a scheduled plan for tank replacement.

- Oxygen tubing does not need be connected to oxygen tank but must be kept in close proximity to tank.

Oropharyngeal airways are no longer required.

I.D.5) (CE) Emergency medicine such as asthma, chest pain, hypoglycemia and anaphylactic reaction management

Emergency Medication/Anaphylactic Reaction Management:

Severe allergic reaction can cause urticaria (hives), hypotension, bronchospasm, wheezing and pulmonary edema. Per the American Academy of Family Practice (AAFP), the minimum equipment to manage emergency anaphylactic reaction, asthma exacerbation, chest pain, opioid overdose and hypoglycemia, based on the patient population served, shall include:

- Epinephrine 1mg/mL (injectable).
- Diphenhydramine 25 mg (oral) or 50 mg/ml (injectable).
- Naloxone.²
- Chewable Aspirin 81 mg.³
- Nitroglycerin spray/tablet.⁴
- Bronchodilator medication (solution for nebulizer or metered dose inhaler).
- Glucose (any type of glucose containing at least 15 grams).
- Appropriate sizes of ESIP needles/syringes⁵ and alcohol wipes.

The typical adult strength to address cardiac emergencies is 325 mg (four doses of 81 mg chewable Aspirin or one dose of 325 non-enteric coated Aspirin).

If the site is seeing adults, the reviewer shall assess whether the appropriate number of chewable Aspirin tablets of 81 mg is available (at least four tablets).

² In 2018, the U.S. Surgeon General issued an advisory emphasizing the importance of health care professionals having naloxone (an opioid antagonist) on hand and being trained in how to use it. The U.S. Surgeon General's advisory is available at <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html>. Also see the FDA's approval of Narcan to reverse opioid overdose: <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/narcan-naloxone-nasal-spray-approved-reverse-opioid-overdose>, and articles regarding overdose preparedness for ambulatory clinics, available at <https://www.aafp.org/fpm/2021/0100/p17.html> and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/>.

³ See the American Heart Association's article on Aspirin and Heart Disease, available at <https://www.heart.org/en/health-topics/heart-attack/treatment-of-a-heart-attack/aspirin-and-heart-disease>.

⁴ Pediatric offices only serving patients under 18 years old are not required to keep Nitroglycerin in their emergency kit. According to the FDA, "The safety and effectiveness of nitroglycerin in pediatric patients (under 18 years old) have not been established." Also see page 8 of an article on Nitrostat, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021134s007lbl.pdf.

⁵ If the emergency kit or "crash cart" has only non-safety needles/syringes, score that deficiency in Section VI., Infection Control, criteria B.2. See Infection Control Standards.



II. Personnel Criteria

II.C.2) (CE) Only qualified/trained personnel retrieve, prepare or administer medications.

Medication administration by an MA means the direct application of pre-measured medication orally, sublingually, topically, vaginally or rectally; or by providing a single dose to a patient for immediate self-administration by inhalation or by simple injection.

- All medications including vaccines must be verified with (shown to) a licensed person prior to administration.
- Unlicensed staff (e.g. MAs) have evidence of appropriate training and supervision in all medication administration methods performed within their scope of work.
- To administer medications by subcutaneous or intramuscular injection, or to perform intradermal skin tests or venipunctures for withdrawing blood, an MA must have completed at least the minimum number of training hours established in CCR, Title 16, Section 1366.1.

Note:

- MAs cannot administer anesthetics, including local anesthetic agents (such as Rocephin hydrated with Xylocaine).⁶
- MAs may not place an intravenous needle, start or disconnect the intravenous infusion tube, administer medications or injections into an intravenous line, or administer anesthesia.
- The supervising physician must specifically authorize all medications administered by an MA. "Authorization" means a specific written or standing order prepared by the supervising physician.

III. Office Management Criteria

III.E.2 (CE) Physician Review and follow-up of referral/consultation reports and diagnostic test results.

- There is a documented process of the practitioner review of diagnostic tests/consultations and subsequent outreach to follow up with the patient to communicate results and provide next steps.
- Practitioner review is evidenced by date and signature/initials on the report of the reviewing practitioner.

IV. Clinical Services

IV.C.4) (CE) Only lawfully authorized persons dispense drugs to patients.

Drug Dispensing:

- Drug dispensing complies with all applicable State and federal laws and regulations.

⁶ 16 CCR 1366.3(a)(1), also see information from the Medical Board of California on Medical Assistants, available at <https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/Medical-Assistants.aspx>, <https://www.mbc.ca.gov/FAQs/?cat=Licensees&topic=Medical%20Assistants>



Facility Site Review - Standards



- Drugs are dispensed only by a physician, pharmacist or other persons (e.g., NP, CNM, RN, PA) lawfully authorized to dispense medications upon the order of a licensed physician or surgeon.
- Personnel such as MAs, office managers and receptionists do not dispense drugs.
- Drugs are not offered for sale, charged or billed to Medi-Cal members.⁷
- A record of all drugs and formulas dispensed shall be entered in the patient's medical record.

Drug Administration:

- Basic safe practices for medication/vaccine administration, assess and document:
 1. Patient's identity.
 2. Correct medication.
 3. Correct dose.
 4. Correct route.
 5. Appropriate time CMS Manual System.⁸
- Proper preparation is critical for maintaining the integrity of the vaccine during transfer from the vial to the syringe.
- Personnel can demonstrate or verbally explain procedure(s) used on site to confirm correct patient, medication/vaccine, dosage, route and vaccine are prepared and drawn only prior to administration.
- Proper vaccine administration is critical to ensure that vaccination is safe and effective.
- CDC recommends that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures before administering vaccines.
- Comprehensive, skills-based training should be integrated into existing staff education programs such as new staff orientation and annual education requirements.

IV.C.5) (CE) Drugs and Vaccines are prepared and drawn only prior to administration.

ACIP discourages the routine practice of providers prefilling syringes.

- Vaccines have a similar appearance after being drawn into a syringe. Prefilling may result in administration errors.
- Unused, provider prefilled syringes must be discarded if not used within the same day that they are filled.
- Unused syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed, or needle attached) should be discarded at the end of the clinic day.

In certain circumstances in which a single vaccine type is being used (e.g., in preparation for a community influenza vaccination campaign), filling a small number (10 or fewer) of syringes may be considered. The doses should be administered as soon as possible after filling by the same person who filled the syringes.

The Center for Biologics Evaluation and Research (CBER) at the FDA offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary

⁷ BPC 4193

⁸ 42 CFR 482.23(c)



electrical power failure or flood conditions.⁹

VI. Infection Control Criteria

VI.B.1)(CE) Personal Protective Equipment for Standard Precautions is readily available for staff use.

Personal Protective Equipment (PPE): PPE must be readily available.¹⁰

PPE for protection against bloodborne pathogen hazards is available on site and must include:

1. Gloves.
2. Water repellent clothing barrier/gown.
3. Face/eye protection (e.g., goggles/face shield).
4. Respiratory infection protection (e.g., mask).

PPE does not include general work clothes (e.g., uniforms, cloth lab coats) that will permit liquid to soak through. The storage of PPE should be adequate to protect the PPE from contamination, loss, damage, water or sunlight. Proper storage often requires a dry and clean place that is not subject to temperature extremes.

VI.B.2)(CE) Blood, other potentially infectious materials and Regulated Wastes are placed in appropriate leak proof, labeled containers for collection, handling, processing, storage, transport or shipping.

Blood and Other Potentially Infectious Materials (OPIM):

- OPIM are all human body fluids, any unfixed tissue or organ (other than intact skin) from a human (living or dead), and HIV or HBV-containing blood, cells, tissue, organs, cultures, medium or solutions.
- Containers for blood and OPIM are closable, leak proof, and labeled and/or color-coded.
- Double bagging is required only if leakage is possible.

Labels:

- A warning label is affixed to red-bagged regulated wastes, sharps containers, refrigerators/freezers containing blood or OPIM, containers used to store or transport blood or OPIM, and contaminated laundry or equipment for storage or transporting.
- The international biohazard symbol with word "BIOHAZARD" or the words "Biohazardous Waste" label (fluorescent orange or red orange with contrasting lettering/symbols) is part of, or affixed to, the container.
- Sharps containers are labeled with the words "Sharps Waste" or with the international biohazard symbol and the word "BIOHAZARD".
- Individual containers of blood or OPIM are exempted from warning labels if placed inside a labeled secondary container for storage, transport or disposal.
- Alternative marking or color coding may be used to label contaminated laundry or specimen

⁹ See the CDC's Vaccine Recommendations and Guidelines of the ACIP, available at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>.

¹⁰ 29 CFR 1910.1030



containers if the alternative marking permits employees on site to recognize that container requires compliance with Universal Precautions.

VI.B.3)(CE) Needlestick safety precautions are practiced on site.

Needlestick Safety:¹¹

- Contaminated sharps are discarded immediately.
- Sharps containers are located close to the immediate area where sharps are used and are inaccessible to unauthorized persons.
- Sharps are not bent, removed from a syringe, or recapped. Recapping, bending, or removing contaminated needles is permissible only if there is no feasible alternative or if such actions are required for a specific medical procedure. If recapping, bending, or removal is necessary, employers must ensure that workers use either a mechanical device or a one-handed technique. Needleless systems, needles with Engineered Sharps Injury Protection (ESIP) devices, and non-needle sharps are used (incl. in emergency kits), unless exemptions have been approved by Cal/OSHA.¹²
- Security of portable containers in patient care areas is always maintained.
- Any device capable of cutting or piercing (e.g. syringes, hypodermic needles, needleless devices, blades, broken glass, slides, vials) are placed in a closable, puncture-resistant, labeled, leak-proof container. If these requirements are met, containers made of various materials (e.g., cardboard, plastic) are acceptable.
- Containers are not overfilled past the manufacturer's designated fill line, or more than $\frac{3}{4}$ full.
- Supply of containers on hand is adequate to ensure routine change-out when filled.

VI.D.3a) (CE) Staff demonstrate /verbalize necessary steps/process to ensure sterility and/or high-level disinfection of equipment.

- Personnel can demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, and to locate written directions on site.
- Product efficacy tests (i.e. test strips) shall be performed according to manufacturer's guidelines.

Cold Chemical Sterilization/High Level disinfection:

- Product manufacturer's directions are strictly followed for instrument pre-soaking treatment, solution preparation, solution exposure procedures, safety precautions (e.g., room temperature, area ventilation), and post-sterilization processes.
- Sterilization and/or high-level disinfection exposure times and solution expiration date and time are available to staff.
- Written procedures for cold sterilization and/or high-level disinfection are available on site to staff.

¹¹ See the OSHA Needlestick Safety Frequently Asked Questions, available at <https://www.osha.gov/needlesticks/needlefaq.html>, and the OSHA Standards for Bloodborne Pathogens, available at <https://www.hercenter.org/rmw/osh-bps.php>.

¹² 8 CCR 5193



VI.D.3c) (CE) Appropriate PPE is available, exposure control plan, Material Safety Data Sheets (MSDS) and clean up instructions in the event of a cold chemical sterilant spill.

Cold Chemical Sterilants Spillage: The OSHA Hazard Communication Standard requires manufacturers and importers of hazardous chemicals to develop MSDS for each chemical or mixture of chemicals.^{13, 14}

- Employers must have the data sheets for cold chemical sterilants readily available to employees who work with the products to which they could be exposed.
- Staff should attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site.
- Personnel are familiar with and can recognize signs and symptoms of exposure to cold chemical sterilants used on site.
- Staff must be aware of the procedures for clean up in the event of spillage.
- Staff can demonstrate or verbally explain procedure(s) used on site for chemical spill cleanup.
- If personnel are unable to demonstrate or explain site-specific chemical spill cleanup procedures *and* cannot locate written chemical spill cleanup procedure instructions, site is considered deficient.
- Cleanup procedures may vary from site to site depending on the cold chemical sterilants used.
- The appropriate PPE for cold chemical sterilants clean up must be readily available.

(National Institute for Occupational Safety and Health (NIOSH) with the Centers for Disease Control and Prevention. Environmental Health and Safety guidelines for disinfectants and sterilization methods. MSDS for cold chemical sterilants. The American National Standard (ANSI)/Advancing Safety in Medical Technology (AAMI) ST58:2013.)

Control Methods and Work Practices are in place to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous.

- Cold chemical sterilants must be used strictly in accordance with the manufacturer's directions. Always consult the manufacturer for safety precautions and MSDS information.
- The appropriate PPE must be used to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process.

Examples of cold chemical sterilants include:

- Glutaraldehyde (Cidex).
- Peracetic acid.
- Hydrogen peroxide-based solutions.

Glutaraldehyde is a common cold chemical sterilant. Exposure to glutaraldehyde can cause the following health effects: throat and lung irritation, breathing difficulty, nose irritation, nosebleed, burning eyes and

¹³ 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59 and 1928.21.

¹⁴ See CDC guidelines on sterilizing heat sensitive dental instruments, available at <https://oshareview.com/2013/10/cdc-guidelines-sterilizing-heat-sensitive-dental-instruments-dental-infection-control/>. 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134. See the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html>.



conjunctivitis, rash, hives, headaches and nausea.

Exposure to glutaraldehyde may be prevented or reduced by using the following control methods and work practices:

- Use local exhaust ventilation.
- Keep glutaraldehyde baths under a fume hood where possible.¹⁵
- Avoid skin contact (use appropriate PPE: gloves and aprons made of nitrile or butyl rubber wear goggles and face shields).
- Use only enough sterilants to perform the required sterilization procedure.
- Seal or cover all containers holding the sterilants.
- Attend training classes.

VI.D.4c) (CE) Spore testing of autoclave/steam sterilizer with documented results (at least monthly).

Spore Testing:

- Autoclave spore testing is performed *at least monthly* unless otherwise stated in manufacturer's guidelines.
- Documentation of biological spore testing includes:
 - Date.
 - Results.
 - Types of spore test used.
 - Person performing/documenting test results.
- Written procedures for performing routine spore testing and for handling positive spore test results are available on site to staff.
- For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. Procedures include:
 - Report problem.
 - Repair autoclave.
 - Retrieve all instruments sterilized since last negative spore test.
 - Re-test autoclave.
 - Re-sterilize retrieved instruments.
- Biologic spore test products vary and are designed for use based on specific autoclave type. Biologic control testing challenges the autoclave sterilization cycle with live, highly resistant, nonpathogenic spores. If spores are killed during processing, it is assumed that all other microorganisms are also killed and that the autoclave load is sterile.

Note: Documentation of monthly spore testing must be maintained onsite even for sterilization that is performed offsite.

VI.D.4.d) (CE) Management of positive mechanical, chemical and biological indicators of the sterilization process.

¹⁵ For more information on glutaraldehyde exposure and safety tips, refer to the CDC guidance, available at <https://www.cdc.gov/niosh/docs/2001-115/default.html>.



Facility Site Review - Standards



Autoclave/Steam Sterilization Mechanical, Chemical and Biological Indicators:¹⁶

- Sterilization failure can occur for reasons such as slight variation in the resistance of the spores, improper use of the sterilizer and laboratory contamination during the culture.
- Per CDC, the autoclave/steam sterilization procedure should be monitored routinely by using a combination of:
 - **Mechanical Indicator:** monitor sterilization process with a daily assessment of cycle time and temperature by examining the temperature record chart and an assessment of pressure via the pressure gauge (e.g., graphs, gauges, printouts).
 - **Chemical Indicator:** are usually either heat-or chemical-sensitive inks that change color when one or more sterilization parameters (e.g., steam-time, temperature and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are present.
 - **Biological:** spore test – an indicator to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items.

Staff should adhere to site-specific protocol and/or manufacturer/product label for management of positive indicator(s).

¹⁶ See the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>.