

# Department of Health Care Services (DHCS)

## Facility Site Review Preparation Packet

If you have any questions or need help, please contact our Delegation Oversight Coordinators:

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### Department of Health Care Services (DHCS) Facility Site Review and Medical Records Review

### **Clinic Policies for Primary Care Provider Settings**

#### Instructions:

All participating provider(s) sites are required to establish safety, member rights and general policies and procedures for their practice. Please review all sample policies and procedures in our educational packet and customize any or all of the policies and their respective attachments you wish to adopt based on your clinic's practice and processes. Please complete the *Approval date*, *Approved by*, *Effective Date*, and *Revision date* for each of the adopted policies. All providers and staff shall receive trainings/in-services on all clinic policies and procedures. Annual trainings/in-services are required for *Blood-Borne Pathogens Exposure Control*, *Biohazardous Waste Management* and *Infection Control/Standard/Universal Precautions*. All clinic policies and evidence of training shall be kept on site or made available upon request.

#### Facility Site Review Preparation Checklist

This communication applies to the Medicaid and Medicare-Medicaid Plan (MMP) programs.

Use this Facility Site Review (FSR) and Medical Record Review (MRR) preparation checklist to conduct an internal review of your practice to determine readiness for your upcoming FSR and/or MRR survey. You may reference the most current *California Department of Health Care Services (DHCS) Site Review and MRR Survey Standards*, the American Academy of Pediatrics (AAP), the U.S. Preventive Services Task Force (USPSTF), and other governing entity website links and health plan resources provided as embedded links (in blue) in the checklist below for more information. Reviewing the standards in the checklist (including directions/instructions, rules, regulation parameters, and/or indicators) prior to the FSR and MRR may improve and expedite the survey experience. Not all standards will be applicable to your location.

All new DHCS criteria are <u>underlined</u>. All critical element criteria are *bolded and italicized*. Critical elements are related to potential adverse effects on patient health or safety and have a weighted score of two points. Each critical element found deficient during a full scope site survey, focused survey or monitoring visit shall be corrected by the provider within 10 business days from the survey date. All other criteria have a weighted score of one point and shall be corrected by the provider within 30 calendar days from the survey report date.

Please mark each criteria as "Yes" if your site complies with the requirement, or as "No" if your site does not comply. For each criteria marked as "No," you are encouraged to begin corrective actions prior to your actual survey. Before or at the start of your site visit, it would be useful for you to contact/inform your reviewer to discuss any non-compliant criteria.

We appreciate your cooperation and partnership in completing a successful review.

|     | Facility Site   |     |    |           |  |
|-----|---|-----|----|-----------|--|
| Acc | cess/Safety   | Yes | No | Comments: |  |
| 1.  | Clearly marked (blue) curb or sign designating disabled-parking space near accessible primary entrance  |     |    |           |  |
| 2.  | Pedestrian ramps have a level landing at the top and bottom of the ramp   |     |    |           |  |
| 3.  | Exit and exam room doorway openings allow for clear passage of a person in a wheelchair   |     |    |           |  |
| 4.  | Accessible passenger elevator or reasonable alternative for multilevel floor accommodation  |     |    |           |  |
| 5.  | Clear floor space for wheelchair in waiting area and exam room  |     |    |           |  |
| 6.  | Wheelchair accessible restroom facilities   |     |    |           |  |
| 7.  | Wheelchair accessible handwashing facilities or reasonable alternative  |     |    |           |  |
| 8.  | All patient areas including floor/carpet, walls, and furniture are neat, clean, and well-maintained   |     |    |           |  |
| 9.  | Restrooms are clean and contain appropriate sanitary supplies   |     |    |           |  |
| 10. | There is evidence that site staff has received safety training and knows where to locate established Clinic Policies and Procedures on the following:  a. Fire safety and prevention  b. Emergency nonmedical procedures (e.g., earthquake/disaster, site evacuation, workplace violence) |     |    |           |  |
| 11. | Lighting is adequate in all areas to ensure safety  |     |    |           |  |

| Acc | ess/Safety  | Yes | No | Comments: |
|-----|---|-----|----|-----------|
| 12. | ·   |     |    |           |
| 13. | Exit doors are clearly marked with Exit signs   |     |    |           |
| 14. | Clearly diagramed Evacuation Routes for emergencies are posted in a visible location at all elevators, stairs, and exits  |     |    |           |
| 15. | Electrical cords and outlets are in good working condition  |     |    |           |
| 16. | Fire-fighting equipment in accessible location https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.157  |     |    |           |
| 17. | An employee alarm system utilized on site with back-up method to warn employees of a fire or other emergency shall be documented. For sites with 10 or fewer employees, direct verbal communication is acceptable and does not need does not need a back-up system  https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.37  |     |    |           |
| 18. | ,   |     |    |           |
| 19. | Emergency equipment is stored together in easily accessible location and is ready to be used  |     |    |           |
| 20. | Emergency phone number contact list is posted, dated, updated annually and as changes occur, and includes local emergency services (e.g., fire, police/sheriff, ambulance), emergency contacts (e.g., responsible managers/supervisors), and appropriate state, county, city, and local agencies (e.g., local poison control)   |     |    |           |
| 21. | Airway management equipment with sizes appropriate for patient population: oxygen delivery system, nasal cannula or mask, <u>bulb</u> <u>syringe</u> and Ambu bag   |     |    |           |
| 22. | Emergency medicine for anaphylactic reaction management, opioid overdose, asthma, chest pain, and hypoglycemia: Epinephrine 1:1000 (injectable), and Benadryl 25 mg (oral) or Benadryl 50 mg/ml (injectable), Naloxone, chewable Aspirin 81 mg (at least four tablets), nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), glucose containing at least 15 grams, appropriate sizes of ESIP needles/syringes and alcohol wipes https://www.aafp.org/afp/2007/0601/p1679.html |     |    |           |
| 23. | Medication dosage chart for all medications included with emergency equipment (or other method for determining dosage) is kept with emergency medications   |     |    |           |
| 24. | There is a process in place on site to document checking of emergency equipment/supplies for expiration and operating status at least monthly   |     |    |           |
| 25. | There is a process in place on site to replace/re-stock emergency medication, equipment and supplies <i>immediately</i> after use   |     |    |           |
| 26. | Medical equipment is clean  |     |    |           |
| 27. | Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer's guidelines  |     |    |           |

| Per | sonnel   | Yes | No | Comments: |
|-----|--|-----|----|-----------|
| 1.  | All required professional licenses and certifications issued from the  |     |    |           |
|     | appropriate licensing/certification agency are current   |     |    |           |
| 2.  | Notification is provided to each member that the Medical Doctor(s) (MD) is/are   |     |    |           |
|     | licensed and regulated by the Medical Board, and that the Physician  |     |    |           |
|     | Assistant(s) is/are licensed and regulated by the Physician Assistant Committee  |     |    |           |
| 3.  | Healthcare personnel wear identification badges/tags printed with name and   |     |    |           |
| 0.  | title  |     |    |           |
| 4.  | Documentation of education/training for non-licensed medical   |     |    |           |
| Ш   | personnel is maintained on site  |     |    |           |
| 5.  | Only qualified/trained personnel retrieve, prepare, or   |     |    |           |
|     | administer medications   |     |    |           |
| 6.  | Site has a procedure in place for confirming correct patient,  |     |    |           |
|     | medication/vaccine, dosage, and route prior to administration  |     |    |           |
| 7.  | Only qualified/trained personnel operate medical equipment   |     |    |           |
|     |  |     |    |           |
| 8.  | Scope of practice for non-physician medical practitioners (NPMPs) is   |     |    |           |
|     | clearly defined including the delegation of the supervision of Medical Assistants when supervising physician is off premises:                          |     |    |           |
|     | a. Standardized procedures provided for nurse practitioners (NPs)  |     |    |           |
|     | and/or certified nurse midwives (CNMs)   |     |    |           |
|     | https://www.rn.ca.gov/pdfs/regulations/npr-b-  |     |    |           |
|     | 03.pdf   |     |    |           |
|     | https://www.rn.ca.gov/pdfs/regulations/npr-b-  |     |    |           |
|     | 20.pdf   |     |    |           |
|     | <ul> <li>b. A <u>Practice Agreement</u> defines the scope of services provided<br/>by physician assistants (PAs) and supervisory guidelines</li> </ul> |     |    |           |
|     | define the method of supervision by the supervising physician  |     |    |           |
|     | http://www.pab.ca.gov  |     |    |           |
|     | https://www.pab.ca.gov/forms_pubs/sb697faqs.pdf  |     |    |           |
|     | c. Standardized procedures, <u>Practice Agreements</u> , and supervisory   |     |    |           |
|     | guidelines are revised, updated, and signed by the supervising   |     |    |           |
|     | physician and NPMP when changes in scope of services occur.  |     |    |           |
|     | Frequency of review to identify changes in scope of service shall  |     |    |           |
|     | be specified in writing.   |     |    |           |
| 9.  | NPMPs are supervised according to established standards:  a. The ratio of supervising physician to the number of NPMPs does not                        |     |    |           |
|     | a. The ratio of supervising physician to the number of NPMPs does not exceed established ratios in any combination at any given time/shift in          |     |    |           |
|     | any of the locations:  |     |    |           |
|     | • 1:4 NPs  |     |    |           |
|     | • 1:4 CNMs   |     |    |           |
|     | <ul> <li>1:4 PAs (per shift in any given location)</li> </ul>  |     |    |           |
|     | b. The designated supervising or back-up physician is available in person  |     |    |           |
|     | or by electronic communication at all times when a NPMP is caring for  |     |    |           |
|     | patients  There is evidence of NPMP supervision  |     |    |           |
| 10. | c. There is evidence of NPMP supervision.  There is evidence that site staff has received training and knows where to                                  |     |    |           |
| 10. | locate established Clinic Policies and Procedures on the following:  |     |    |           |
|     | a. Infection Control/Universal Precautions (annually)  |     |    |           |
|     | b. Bloodborne Pathogens Exposure Prevention (annually)   |     |    |           |
|     | c. Biohazardous Waste Handling (annually)  |     |    |           |
|     | d. Patient Confidentiality   |     |    |           |
|     | e. Informed Consent, including Human Sterilization   |     |    |           |
|     | f. Prior Authorization Requests  |     |    |           |

| Per | sonnel |  | Yes | No | Comments: |
|-----|--------|--|-----|----|-----------|
|     | g.     | Grievance/Complaint Procedure  |     |    |           |
|     | h.     | Child/Elder/Domestic Violence Abuse                                      |     |    |           |
|     | i.     | Sensitive Services/Minors' Rights  |     |    |           |
|     | j.     | Health Plan Referral Process/Procedures/Resources                        |     |    |           |
|     | k.     | Cultural and Linguistics   |     |    |           |
|     |        | https://www.health.pa.gov/topics/Documents/Health%20Equity/CLAS          |     |    |           |
|     |        | %20Standards%20FactSheet.pdf   |     |    |           |
|     | l.     | Disability Rights and Provider Obligations:                              |     |    |           |
|     |        | a. Post notice of consumers civil rights;                                |     |    |           |
|     |        | b. For sites with 15 or more employees, have civil rights                |     |    |           |
|     |        | procedure and an employee designated to coordinate                       |     |    |           |
|     |        | compliance; and  |     |    |           |
|     |        | c. Information on physical access and reasonable                         |     |    |           |
|     |        | <u>accommodations</u>  |     |    |           |
|     |        | https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsh |     |    |           |
|     |        | s/504.pdf  |     |    |           |
|     |        |  |     |    |           |

| Offi | ce Management   | Yes | No | Comments: |
|------|---|-----|----|-----------|
| 1.   | Clinic office hours are posted or readily available upon request  |     |    |           |
| 2.   | Provider office hour schedules are available to staff   |     |    |           |
| 3.   | Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff  |     |    |           |
| 4.   | Contact information for off-site physician(s) is available at all times during office hours   |     |    |           |
| 5.   | Routine, urgent, and after-hours emergency care instructions/telephone information is made available to patients  |     |    |           |
| 6.   | Appropriate personnel handle emergent, urgent, and medical advice telephone calls   |     |    |           |
| 7.   | Telephone answering machine, voice mail system or answering service is used whenever office staff does not directly answer phone calls  |     |    |           |
| 8.   | Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated  |     |    |           |
| 9.   | Appointments are scheduled according to patients' stated clinical needs within the timeliness standards established for plan members  |     |    |           |
| 10.  | Patients are notified of scheduled routine and/or preventive screening appointments   |     |    |           |
| 11.  | There is a process in place verifying follow-up on missed and canceled appointments   |     |    |           |
| 12.  | Interpreter services are made available 24 hours in identified threshold languages specified for location of site https://www.federalregister.gov/documents/2003/08/08/03-20179/guidance-to-federal-financial-assistance-recipients-regarding-title-vi-prohibition-against-national   |     |    |           |
| 13.  | Persons providing language interpreter services, including sign language on site, are trained in medical interpretation. Site personnel used as interpreters have been assessed for their medical interpretation performance skills/capabilities. A written policy shall be in place. |     |    |           |
| 14.  | Office practice procedures allow timely provision and tracking of:  a. Processing internal and external referrals, consultant reports, and diagnostic test results.   |     |    |           |

| Offi | ce Management   | Yes | No | Comments: |
|------|---|-----|----|-----------|
|      | <ul> <li>b. Physician review and follow-up of referral/consultation reports<br/>and diagnostic test results.</li> </ul>   |     |    |           |
| 15.  | Phone number(s) for filing grievances/complaints are located on site  |     |    |           |
| 16.  | Complaint forms and a copy of the grievance procedure are available onsite.   |     |    |           |
| 17.  | Medical records are readily retrievable for scheduled patient encounters.   |     |    |           |
| 18.  | Medical documents are filed in a timely manner to ensure availability for patient   |     |    |           |
| 19.  | Exam rooms and dressing areas safeguard patients' right to privacy.   |     |    |           |
| 20.  | Procedures are followed to maintain the confidentiality of personal patient information (sign-in sheets with only one patient identifier, signed confidentiality agreement from after-hours cleaning crew, etc.). |     |    |           |
| 21.  | Medical record release procedures are compliant with state and federal guidelines.  |     |    |           |
| 22.  | Storage and transmittal of medical records preserves confidentiality and security.  |     |    |           |
| 23.  | Medical records are retained for a minimum of 10 years  |     |    |           |

| Cli | nical Services  | Yes | No | Comments: |
|-----|---|-----|----|-----------|
| 1.  | Drugs are stored in specifically designated cupboards, cabinets, closets, or drawers  |     |    |           |
| 2.  | Prescription, drug samples, over-the-counter drugs, hypodermic needles/syringes, all medical sharp instruments, hazardous substances (disinfectant solutions/wipes), and prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic   |     |    |           |
| 3.  | Controlled drugs are stored in a locked cabinet accessible only to authorized personnel.  |     |    |           |
| 4.  | A dose-by-dose controlled substance distribution log is maintained.   |     |    |           |
| 5.  | Written site-specific policy/procedure for dispensing of sample drugs are available on site. (A list of dispensed and administered medications shall be present on site).   |     |    |           |
| 6.  | Drugs are prepared in a clean area or designated clean area if prepared in a multipurpose room.   |     |    |           |
| 7.  | Drugs for external use are stored separately from drugs for internal use.   |     |    |           |
| 8.  | Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.  |     |    |           |
| 9.  | Refrigerator thermometer temperature is 36° to 46° Fahrenheit or 2° to 8° Centigrade (at time of site visit).   |     |    |           |
| 10. | Freezer thermometer temperature is 5° Fahrenheit, or -15° Centigrade or lower (at time of site visit).  |     |    |           |
| 11. | temperature. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf   |     |    |           |
| 12. | Daily temperature readings of drugs/vaccines refrigerator and freezer are documented. CDC recommends use of a continuous temperature monitoring device or digital data loggers (DDLs). Back-up DDL(s) for each transport storage unit shall be readily available for emergency vaccine transport or when primary DDL(s) is sent in for calibration. |     |    |           |

| Clir | nical Services  | Yes | No | Comments: |
|------|---|-----|----|-----------|
| 13.  | Has a written plan for vaccine protection in case of power outage or  |     |    |           |
|      | malfunction of the refrigerator or freezer  |     |    |           |
| 14.  | Drugs and vaccines are stored separately from test reagents, germicides, disinfectants, and other household substances.   |     |    |           |
| 15.  | Hazardous substances are appropriately labeled  |     |    |           |
| 16.  | Site has method(s) in place for drug and hazardous substance disposal   |     |    |           |
| 17.  | There are no expired drugs on site.   |     |    |           |
| 18.  | Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas  |     |    |           |
| 19.  | All stored and dispensed prescription drugs are appropriately labeled   |     |    |           |
| 20.  | Only lawfully authorized persons dispense drugs to patients   |     |    |           |
| 21.  | Drugs and ∨accines are prepared and drawn only prior to administration  |     |    |           |
| 22.  | Current Vaccine Information Sheets (VIS) for distribution to patients are present on site.  |     |    |           |
| 23.  | If there is a pharmacy on site, it is licensed by the California State Board of Pharmacy  |     |    |           |
| 24.  | Site utilizes California Immunization Registry (CAIR)   |     |    |           |
| 25.  | Laboratory test procedures are performed according to current site-specific CLIA certificate  |     |    |           |
| 26.  | Testing personnel performing clinical lab procedures have been trained  |     |    |           |
| 27.  | Lab supplies (vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.   |     |    |           |
| 28.  | Lab test supplies are not expired.  |     |    |           |
| 29.  | Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.   |     |    |           |
| 30.  | Site has current California Radiologic Health Branch Inspection Report (in the last 5 years) and proof of registration if there is radiological equipment on site <a href="https://www.cdph.ca.gov/rhb">https://www.cdph.ca.gov/rhb</a>   |     |    |           |
| 31.  | <ul> <li>The following documents are posted on site:</li> <li>a. Current copy of <i>Title 17</i> with a posted notice about availability of <i>Title 17</i> and its location</li> <li>b. Radiation Safety Operating Procedures posted in highly visible location</li> <li>c. Notice to Employees Poster posted in highly visible location</li> <li>d. Caution, X-ray sign posted on or next to door of each room that has X-ray equipment</li> <li>e. Physician supervisor/operator certificate posted and within current expiration date</li> <li>f. Technologist certificate posted and within current expiration date</li> </ul> |     |    |           |
| 32.  | The following radiological protective equipment is present on site:  a. Operator protection devices: radiological equipment operator must use lead apron or lead shield   |     |    |           |

| Clinical | Services  | Yes | No | Comments: |
|----------|---|-----|----|-----------|
|          | <ul> <li>Gonadal shield (0.5 mm or greater lead equivalent): for patient<br/>procedures in which gonads are in direct beam</li> </ul> |     |    |           |

| Pre | ventive Services   | Yes | No | Comments: |
|-----|--|-----|----|-----------|
| 1.  | Examination equipment appropriate for primary care services is available on site.  |     |    |           |
| 2.  | Exam tables and lights are in good repair.   |     |    |           |
| 3.  | Stethoscope and sphygmomanometer with various size cuffs appropriate for patient population (e.g., small, regular, large/obese/thigh)  |     |    |           |
| 4.  | Thermometer with a numeric reading   |     |    |           |
| 5.  | Basic exam equipment: percussion hammer, tongue blades, patient gowns  |     |    |           |
| 6.  | Scales: standing balance beam and infant scales  |     |    |           |
| 7.  | Measuring devices for stature (height/length) measurement and head circumference measurement   |     |    |           |
| 8.  | Eye charts (literate and illiterate) and occluder for vision testing (proper use of heel line) are available on site. Wall mounted eye charts should be height adjustable and positioned at the eye-level of the patient. Examiners shall stand their patients with their heels to the line unless the eye chart that is being used to screen specifically instructs the patient to be positioned elsewhere. Heel lines are aligned with center of eye chart at 10 or 20-feet depending on whether the chart is for the 10-foot or 20-foot distance. Eye charts are in an area with adequate lighting and at height(s) appropriate to use. Effective occlusion, such as with tape or an occlusive patch of the eye not being tested, is important to eliminate the possibility of peeking. The AAP recommended eye  • LEA symbols (children 3 to 5 years old)  • HOTV chart (children 3 to 5 years old)  • Sloan letters (preferred) or Snellen letters (children over 5 years old and adults) |     |    |           |
| 9.  | Ophthalmoscope   |     |    |           |
| 10. | Otoscope with adult and pediatric ear speculums  |     |    |           |
| 11. | A pure tone, air conduction audiometer is in a quiet location for testing.   |     |    |           |
| 12. | Health education materials and plan-specific resource information are:  a. Readily accessible on site or are made available upon request b. Applicable to the practice and population served on site c. Available in threshold languages identified for county and/or area of site location  |     |    |           |

| Infe | ection Control   | Yes | No | Comments: |
|------|--|-----|----|-----------|
| 1.   | Soap or antiseptic hand cleaner and running water are available in exam and/or treatment areas for hand washing.                         |     |    |           |
| 2.   | A waste disposal container is available in exam rooms, procedure/treatment rooms, and restrooms.   |     |    |           |
| 3.   | Site has procedure for effectively isolating infectious patients with potential communicable conditions.                                 |     |    |           |
| 4.   | Personal protective equipment for standard precautions is readily available for staff use (e.g., gloves, water-repelling gowns, face/eye |     |    |           |

| Infe | ection Control  | Yes | No | Comments: |
|------|---|-----|----|-----------|
| 5.   | Blood, other potentially infectious materials, and regulated wastes are placed in appropriate leak-proof, labeled containers for collection, handling, processing, storage, transport, or shipping.   |     |    |           |
| 6.   | Needle-stick safety precautions are practiced on site. (Only safety needles and wall-mounted/secured sharps containers are used on site; Sharps containers are not overfilled; etc.)  |     |    |           |
| 7.   | All sharp injury incidents are documented.  |     |    |           |
| 8.   | Contaminated laundry is laundered at the workplace or by a commercial laundry service.  |     |    |           |
| 9.   | Biohazardous (non-sharp) wastes are contained separate from other trash/waste.  |     |    |           |
| 10.  | Storage areas for regulated medical wastes are maintained secure and inaccessible to unauthorized persons.  |     |    |           |
| 11.  | Transportation of regulated medical wastes is only by a registered hazardous waste hauler or to a central location of accumulation in limited quantities (up to 35.2 pounds).   |     |    |           |
| 12.  | after contact with blood or other potentially infectious material.  |     |    |           |
| 13.  | Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule.   |     |    |           |
| 14.  | Disinfectant solutions used on site: a. Are approved by the Environmental Protection Agency (EPA). b. Are effective in killing HIV/HBV/TB. c. Follow manufacturer instructions.   |     |    |           |
| 15.  | Written site-specific policy/procedures or manufacturer's instructions for instrument/equipment sterilization are available to staff.   |     |    |           |
| 16.  | Staff adheres to site-specific policy and/or manufacturer/product label directions for the following procedures:  a. Cleaning reusable instruments/equipment prior to sterilization   |     |    |           |
| 17.  | Cold chemical sterilization/high level disinfection:  a. Confirmation from manufacturer item(s) is/are heat-sensitive b. Staff demonstration /verbalize necessary steps/process to     sterility and/or high-level disinfection ensure sterility of c. Appropriate PPE is available, exposure control plan and clean up     instructions in the event of a cold chemical sterilant spill —     so I u ti o n 's M SDS shall be available on site  https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.ht |     |    |           |
| 18.  | MI Auto clave/steam sterilization:  |     |    |           |
|      | <ul> <li>a. Staff demonstration/verbalize necessary steps/process to ensure sterility Documentation of sterilization loads include date, time, and duration of run cycle, temperature, steam pressure, and operator of each run. </li> <li>b. Autoclave maintenance per manufacturer's guidelines</li> <li>c. Spore testing of autoclave/steam sterilizer with documented results (at least monthly)</li> <li>d. Management of positive mechanical, chemical, and/or biological indicators of the sterilization process</li> </ul>    |     |    |           |

| Infection Control |   | Yes | No | Comments: |
|-------------------|---|-----|----|-----------|
| 19.               | Sterilized packages are labeled with sterilization date and load identification information   |     |    |           |
| 20.               | Storage areas for sterilized packages are clean, dry, and separated from non-sterile items by a functional barrier. Site has a process for routine evaluation of sterilized packages. |     |    |           |