DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-43-ASC

DATE: **June 26, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)

Memorandum Summary

- ***ASC Infection Control Surveyor Worksheet Revisions*:** The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CfC).
- ***Change:*** Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in ASCs when assessing compliance with the infection control CfC.

Background

The ASC ICSW, Exhibit 351 of the SOM, provides detailed prompts or survey probes which help surveyors gain a better understand of infection prevention and control issues in the ASC setting. We have made minor revisions to the ASC ICSW in order to align with current nationally recognized standards of practice, as well as improve the clarity of some questions. Questions regarding the practice of immediate-use steam sterilization (IUSS) were also added to assist surveyors in assessing compliance with recently released guidance related to IUSS.

Citation instructions are provided for each section of the worksheet and surveyors will follow standard procedures when non-compliance is identified in ASCs, including documentation on the Form CMS 2567.

In addition, we continue to encourage ASCs to use this worksheet on a voluntary basis for self-assessment of their practices related to infection control.

An advance copy of the SOM update is attached. It may differ slightly from the final version that will be published at a later date.

Contact: Questions and comments may be submitted to: ascscg@cms.hhs.gov

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment: Advanced Copy SOM Chapter 9 Exhibits

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal **(Advance Copy)** **Date:**

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 9 Exhibits.

I. SUMMARY OF CHANGES: Revisions to Chapter 9, Exhibit 351. Revisions are due to updates and clarification to the Ambulatory Surgical Center Infection Control Surveyor Worksheet questions.

NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 9/Exhibit 351 Ambulatory Surgical Center Infection Control Surveyor Worksheet

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx operating budgets.
Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

Exhibit 351

ASC INFECTION CONTROL SURVEYOR WORKSHEET

(Rev.)

Name of State Agency or AO (please specify) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions). A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

2. Address, State and Zip Code _____
Address

_____
City State Zip

3. 10-digit CMS Certification Number | | | | | | | | | | |

4. What year did the ASC open for operation? | | | | |
y y y y

5. Please list date(s) of site visit: | | / | | / | | | | | | to | | / | | / | | | | |
m m d d y y y Y m m d d y y y y

6. What was the date of the most recent previous federal (CMS) survey: | | / | | / | | | | |
m m d d y y y y

7. Does the ASC participate in Medicare via accredited "deemed" status?
- ○ YES
- ○ NO

7a. If YES, by which CMS-recognized accreditation organization(s)?
- ○ Accreditation Association for Ambulatory Health Care (AAAHC)
- ○ American Associate for Accred. of Ambulatory Surgery Facilities (AAAASF)
- ○ American Osteopathic Association (AOA)
- ○ The Joint Commission (TJC)

7b. If YES, according to the ASC, what was the date of the most recent accreditation survey?

m	m	/	d	d	/	y	y	y	y

8. What is the ownership of the facility? **(SELECT only ONE bubble)**

- ○ Physician-owned
- ○ Hospital-owned
- ○ National corporation (including joint ventures with physicians)
- ○ Other (please print): _____

9. What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC)? **(Select only ONE bubble)**

- ○ Dental
- ○ Endoscopy
- ○ Ear/Nose/Throat
- ○ OB/Gyn
- ○ Ophthalmologic
- ○ Orthopedic
- ○ Pain
- ○ Plastic/reconstructive
- ○ Podiatry
- ○ Other (please specify): _____

10. What additional procedures are performed at the ASC? (**Select all that apply)**

Do not include the procedure type indicated in question 9.

- ○ Dental
- ○ Endoscopy
- ○ Ear/Nose/Throat
- ○ OB/Gyn
- ○ Ophthalmologic
- ○ Orthopedic
- ○ Pain
- ○ Plastic/reconstructive
- ○ Podiatry
- ○ Other (please specify): _____
- ○ N/A

11. Who does the ASC perform procedures on? **(Select only ONE bubble)**

- ○ Pediatric patients only
- ○ Adult patients only
- ○ Both pediatric and adult patients

12. What is the average number of procedures performed at the ASC **per month**? _____ per month

13. How many Operating Rooms (including procedure rooms) does the ASC have?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9+

Number actively maintained:

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9+

14. Please indicate how the following services are provided: **(fill in all that apply)**

	Contract	Employee	Other	If Other, Please print:
Anesthesia/Analgesia	○	○	○	
Environmental Cleaning	○	○	○	
Linen	○	○	○	
Nursing	○	○	○	
Pharmacy	○	○	○	
Sterilization/Reprocessing	○	○	○	
Waste Management	○	○	○	

INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program?

○ YES
○ NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.

16. Does the ASC's infection control program follow nationally recognized infection control guidelines?

○ YES
○ NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

16a. Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?

○ YES
○ NO

NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51.

16b. If YES to (a), *w*hich nationally-recognized infection control guidelines has the ASC selected for its program?
(Select all that apply)

- ○ CDC/HICPAC Guidelines:
  - ○ Guideline for Isolation Precautions (CDC/HICPAC)
  - ○ Hand hygiene (CDC/HICPAC)
  - ○ Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
  - ○ Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)
- ○ Perioperative Standards and Recommended Practices (AORN)
- ○ Guidelines issued by a specialty surgical society / organization (List)

  Please specify (please limit to the space provided):

- ○ Others

  Please specify (please limit to the space provided):

17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?
- ○ YES
- ○ NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an:
(Select only ONE bubble)
- ○ ASC employee
- ○ ASC contractor

17b. Is this person certified in infection control (i.e., CIC)
(Note: §416.50(b)(1) does **not** require that the individual be certified in infection control.)
- ○ YES
- ○ NO

17c. If this person is **NOT** certified in infection control, what type of infection control training has this person received?

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program? ____ hours per week

(Note: §416.51(b)(1) does **not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC?
NOTE! If the ASC does not have a documented identification system, a deficiency related to 42 CFR 416.51(b)(3) must be cited.

- ○ YES
- ○ NO

18a. If YES, how does the ASC obtain this information? **(Select ALL that apply)**

- ○ The ASC sends e-mails to patients after discharge
- ○ The ASC follows-up with their patients' primary care providers after discharge
- ○ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
- ○ Other (please specify):

18b. Is there supporting documentation confirming this tracking activity?

- ○ YES
- ○ NO

NOTE! If the ASC does not have supporting documentation, a deficiency related *to* 42 CFR 416.51(b)(3) **must** be cited.

18c. Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?

- ○ YES
- ○ NO

NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to *42 CFR 416.51(b)(3)*. CMS does not specify the means for reporting; generally this would be done by the State health agency.

19. Do staff members receive infection control training?
If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.

- ○ YES
- ○ NO

19a. If YES, how do they receive infection control training? (Select all that apply)

- ○ In-service
- ○ Computer-based training
- ○ Other (please specify):

19b. Which staff members receive infection control training? (Select all that apply)

- ○ Medical staff
- ○ Nursing staff
- ○ Other staff providing direct patient care
- ○ Staff responsible for on-site sterilization/high-level disinfection
- ○ Cleaning staff
- ○ Other (please specify):

19c. Is training:	○ the same for all categories of staff ○ different for different categories of staff
19d. Indicate frequency of staff infection control training (Select all that apply)	○ Upon hire ○ Annually ○ Periodically / as needed ○ Other (please specify):

19e. Is there documentation confirming that training is provided to all categories of staff listed above?

○ YES
○ NO

NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** by cited in relation to 42 CFR 416.51(b) and (b)(3).

20. How many procedures were observed during the site visit?	○ 1	○ 2	○ 3	○ 4	○ Other

If other, please specify the number: ____ procedures

PART 2 – INFECTION CONTROL & RELATED PRACTICES

INSTRUCTIONS:

- Please **select ONE bubble** for each "Was Practice Performed?" question, unless otherwise noted.
- If N/A *or unable to observe* is *selected as the* response, please explain why there is no associated observation, or why the question is not applicable, in the *surveyor notes* box. *Surveyors should attempt to assess the practice by interview or document review if unable to observe the actual practice during survey.*
- *During the survey, observations or concerns may prompt the surveyor to request and review specific policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.*

I. Hand Hygiene

Observations are to focus on staff directly involved in patient *c*are (e.g., physicians, nurses, CRNAs, etc.). Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey.

Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	**Was Practice Performed?**	***Surveyor Notes:***
A. All patient care areas have *readily accessible, in appropriate locations*:		
a. Soap and water	○ Yes ○ No	
b. Alcohol-based hand rubs	○ Yes ○ No	
I. If alcohol-based hand rub is available in patient care areas, it is installed as required. **(There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs)**	○ Yes ○ No	
B. Staff perform hand hygiene:		
a. After removing gloves	○ Yes ○ No	
b. Before direct patient contact	○ Yes ○ No	
c. After direct patient contact	○ Yes ○ No	
d. Before performing invasive procedures (e.g. placing an IV)	○ Yes ○ No ○ *Unable to observe*	

e. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)	○ Yes ○ No ○ *Unable to observe*
C. Regarding gloves, staff:	
a. Wear gloves for procedures that might involve contact with blood or body fluids	○ Yes ○ No ○ *Unable to observe*
b. Wear gloves when handling potentially contaminated patient equipment	○ Yes ○ No ○ *Unable to observe*
c. Remove gloves before moving to the next tasks and/or patient	○ Yes ○ No ○ *Unable to observe*
D. *Personnel providing direct patient care do not wear artificial fingernails and/ or extenders when having direct contact with patients.*	○ Yes ○ No

II. Injection Practices (injectable medications, saline, other infusates)

Observations are to be made of staff preparing and administering medications and performing injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

NOTE: Some types of infection control breaches, including some specific to medication administration practices, pose a risk of bloodborne pathogen transmission that warrant engagement of public health authorities. When management review confirms that a survey has identified evidence of one or more of the breaches described in S&C: 14-36-All, in addition to taking appropriate enforcement action to ensure the deficient Medicare practices are corrected, the SA should also make the responsible State public health authority aware of the identified breach.

Practices to be Assessed	**Was Practice Performed?**	***Surveyor Notes***
A. Needles are used for only one patient.	○ Yes ○ No ○ *Unable to observe*	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
B. Syringes are used for only one patient *(this includes manufactured prefilled syringes).*	○ Yes ○ No ○ *Unable to observe*	
C. The rubber septum on a medication, *whether unopened or previously accessed,* vial is disinfected with alcohol prior to piercing.	○ Yes ○ No ○ *Unable to observe*	
D. Medication vials are always entered with a new needle.	○ Yes ○ No ○ *Unable to observe*	
E. Medication vials are always entered with a new syringe	○ Yes ○ No ○ *Unable to observe*	
F. Medications that are pre-drawn are labeled with the date and time of draw, initials of the person drawing, medication name, strength and *beyond-use date* and time	○ Yes ○ No ○ *Unable to observe*	
Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
G. a. Single dose (single-use) medication vials are used for only one patient	○ Yes ○ No ○ *Unable to observe*	
b. Bags of IV solutions are used for only one patient *(and not as a source of flush solution for multiple patients).*	○ Yes ○ No ○ *Unable to observe*	
c. Medication administration tubing and connectors are used for only one patient	○ Yes ○ No ○ *Unable to observe*	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
H. *The ASC has voluntarily adopted a policy that medications labeled for multi-dose use for multiple patients are nevertheless only used for one patient.*	○ Yes ○ No ○ N/A	

(Fill in N/A if no multi-dose medications/infusates are used).

(Note: a "No" answer to question H. does not indicate a breach in infection control practices and does not result in a citation. ***However***, a "No" response to either or both of the related questions I and J should be cited).

If YES, please skip to "K"

If NO, you *must also* assess the practices *at questions* "I and J":

I. Multi-dose vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date for the vial. The multi-dose vial can be dated with either the date opened or the *beyond-use date* as per ASC policies and procedures, so long as it is clear what the date represents and the same policy is used consistently throughout the ASC.	○ Yes ○ No ○ *Unable to observe*	
J. *Multi-dose medication vials used for more than one patient are stored appropriately and do not enter the immediate patient care area (e.g., operating room, anesthesia carts).* *NOTE: If multi-dose vials enter the immediate patient care area, they must be dedicated for single patient use and discarded immediately after use.*	○ Yes ○ No ○ *Unable to observe*	
K. All sharps are disposed of in a puncture-resistant sharps container	○ Yes ○ No	
L. Sharps containers are replaced when the fill line is reached	○ Yes ○ No	

III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff *performing* equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed	**Was Practice Performed?**	***Surveyor Notes***
A. a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	○ Yes ○ No ○ N/A	
b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	○ Yes ○ No ○ N/A	

STERILIZATION

A. Critical equipment is sterilized	○ Yes ○ No	
B. Are sterilization procedures performed on-site? **(If NO, skip to "F")** (A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)	○ Yes ○ No	
a. **If YES to B**, please indicate method of sterilization:	○ Steam autoclave ○ Peracetic acid ○ Other (please specify):	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
C. Items are pre-cleaned according to manufacturer's instructions or*, if the manufacturer does not provide instructions,* evidence-based guidelines prior to sterilization	○ Yes ○ No ○ *Unable to observe*	
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	○ Yes ○ No ○ *Unable to observe*	
b. *A chemical indicator (process indicator) is placed correctly, as described in manufacturer's instructions for use, in the instrument packs in every load.*	○ Yes ○ No ○ *Unable to observe*	
c. *A biological indicator is used at least weekly for each sterilizer and with every load containing implantable items, as evidenced by ASC documentation (i.e., log).*	○ Yes ○ No ○ *Unable to observe*	
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	○ Yes ○ No ○ *Unable to observe*	
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	○ Yes ○ No	
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	○ Yes ○ No ○ *Unable to observe*	
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	○ Yes ○ No	
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	○ Yes ○ No	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
H. Is immediate-use steam sterilization (IUSS) performed on-site? ***If NO, skip to "High Level Disinfection Section"*** ***If YES, you must also assess the practices at questions "I - K":*** *(A "No" answer does not result in a citation)*	○ *Yes* ○ *No*	
I. If IUSS is performed, all of the following criteria are met: • *Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays or other containment devices before sterilization.* • *Once clean, the item is placed within a container intended for immediate use. The sterilizer cycle and parameters used are selected according to the manufacturers' instructions for use for the device, container, and sterilizer.* • *The sterilizer function is monitored with monitors (e.g., mechanical, chemical and biologic) that are approved for the cycle being used.* • *The processed item must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, the sterile field in an ongoing surgical procedure.* *Note: "Immediate use" is defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. IUSS is <u>not</u> equivalent to "short cycle" sterilization performed in accordance with manufacturers' IFUs. IUSS must not be a routine or frequent practice in the ASC.*	○ *Yes* ○ *No* ○ *Unable to observe* ○ *N/A*	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
J. Immediate-use steam sterilization is NOT performed on the following devices: • *Implants.* • *Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders.* • *Devices that have not been validated with the specific cycle employed.* • *Single-use devices that are sold sterile.*	*○ Yes* *○ No*	
K. Is IUSS performed on a routine basis? *(A "Yes" answer **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*	*○ Yes* *○ No*	

HIGH-LEVEL DISINFECTION

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
A. Semi-critical equipment is high-level disinfected or sterilized	○ Yes ○ No ○ N/A	
B. Is high-level disinfection performed on site? **(If NO, Skip to "F")**	○ Yes ○ No ○ N/A	

(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

a. **If answer to B was YES**, please indicate method of high-level disinfection:	○ Manual ○ Automated ○ Other (please specify):	
C. Items are pre-cleaned according to manufacturer's instructions or*, if the manufacturer does not provide instructions,* evidence-based guidelines prior to high-level disinfection	○ Yes ○ No ○ *Unable to observe*	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	○ Yes ○ No ○ *Unable to observe*	
b. High-level disinfection equipment is maintained according to manufacturer instructions	○ Yes ○ No ○ *Unable to observe*	
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	○ Yes ○ No ○ *Unable to observe*	
II. Tested for appropriate concentration according to manufacturer's instructions	○ Yes ○ No ○ *Unable to observe*	
III. Replaced according to manufacturer's instructions	○ Yes ○ No ○ *Unable to observe*	
IV. Documented to have been prepared and replaced according to manufacturer's instructions	○ Yes ○ No	
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or*, if the manufacturer does not provide instructions,* evidence-based guidelines	○ Yes ○ No ○ *Unable to observe*	
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions *or, if the manufacturer does not provide instructions,* evidence-based guidelines	○ Yes ○ No ○ *Unable to observe*	
E. Items that undergo high-level disinfection are allowed to dry before use	○ Yes ○ No ○ *Unable to observe*	
F. Following high-level disinfection, items are *placed* in a designated clean area in a manner to prevent contamination	○ Yes ○ No	

IV. Environmental Infection Control

Observations are to be made of staff performing **environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)**

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	○ Yes ○ No ○ *Unable to observe*	
B. Operating rooms are terminally cleaned daily	○ Yes ○ No ○ *Unable to observe*	
C. *Environmental surfaces in patient care areas are cleaned and disinfected, using an EPA-registered disinfectant on a regular basis (e.g., daily), when spills occur and when surfaces are visibly contaminated.*	○ Yes ○ No ○ *Unable to observe*	
D. The ASC has a procedure in place to decontaminate gross spills of blood.	○ Yes ○ No	

V. Point of Care Devices (e.g., blood glucose meter)

Observations are to be made of staff *performing* fingerstick testing (e.g., nurses)

If *unable to observe* or N/A is *selected*, please clarify in the *surveyor notes* box why it was not *observed or* applicable *and attempt to assess by means of interview or documentation review.*

*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
1. Does the ASC *use* a point-of-care *testing* device, such as a blood glucose meter? **If NO, STOP HERE.**	○ Yes ○ No	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
A. *Hand hygiene is performed before and after performing a finger stick procedure to obtain a sample of blood and using the point-of-care testing device.*	○ Yes ○ No	
B. *Gloves are worn by health care personnel when performing a finger stick procedure to obtain a sample of blood, and are removed after the procedure (followed by hand hygiene).*	○ Yes ○ No	
C. Finger stick devices are not used for more than one patient. *NOTE: This includes both the lancet and the lancet holding device.*	○ Yes ○ No ○ *Unable to observe*	
D. If used for more than one patient, the point-of-care testing device (e.g., blood glucose meter, INR monitor) is cleaned and disinfected after every use according to the manufacturer's instructions. *NOTE: if the manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for >1 patient.*	○ *Yes* ○ *No* ○ *N/A*	