



Student Manual

Lesson 11: Laboratory and Radiologic Services

Learning Objectives

At the conclusion of this lesson, you will be able to:

- Understand the compliance requirements for the laboratory and radiologic CfC, including the required policies and procedures.
- Determine the appropriate measures to ensure safe use of radiologic services.
- Assess the proper staff required to provide radiologic services.

Laboratory and Radiologic Services

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Laboratory Services

§416.49(a)
If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter.

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Laboratory Services (cont.)

§416.49(a)
The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.





4

Laboratory Services (cont.)

ASC should have policies and procedures in place regarding laboratory services.
Should list:

- Laboratory services provided directly by the facility
- Laboratory services provided through a contractual agreement





5

Laboratory Services (cont.)

If provided through a contractual agreement, procedures must include:




- Well-defined arrangement with outside services
 - Need not be contractual
- Laboratory services provided by the ASC
- Routine procedures for requesting lab tests
- Process requiring incorporation of lab/radiological reports into patient records



6

Laboratory Services (cont.)



When laboratory tests are performed prior to the patient's admission to the facility, the results should be available to the attending ASC physician



7

Assessing Compliance – Laboratory Services

- Review the ASC's policies and procedures
 - Lists of lab services provided by ASC
 - Lists of lab services provided through a contractual agreement
 - Verify the ASC has a current CLIA certificate for all lab services performed by the ASC (ask to see the ASC's CLIA certificate)
- Review any contractual agreements
 - Determine if referral laboratory is a Clinical Laboratory Improvement Amendments (CLIA) lab (ask to see contract lab's CLIA Certificate)
 - Refer to 42 CFR 493 for CLIA specifications





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Radiologic Services

§416.49(b)



- (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.**
- (2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in §482.26 of this chapter.**



9

Radiologic Services (cont.)



If the ASC uses radiologic services as an integral part of its surgical procedures, then such services must be provided in compliance with the Hospital Conditions of Participation (42 CFR 482.26)



10

Radiological Services (cont.)



If the ASC does not perform any procedures where radiological services are integral to the procedure, then the ASC is not required to arrange to obtain radiological services



11

Integral to the Procedure

Defined as:
Imaging Services performed immediately before, during or after the procedure that are medically necessary to the completion of the procedure



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Radiologic Services (cont.)

ASC may provide services:

- Directly – utilizing its own staff

OR

- Via a contract or other formal arrangement from a Medicare-participating facility





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Governing Body

Scope and complexity of radiologic services

- Provided directly or indirectly
- As an integral part of surgical services must be:
 - Specified in writing and
 - Approved by governing body





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Compliance of Radiologic Services

ASC is equally responsible for compliance of radiologic services, whether:

- Provided directly by ASC or
- Under arrangement



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Radiologic Services (cont.)


- In compliance with the Hospital CoPs, the ASC must maintain or have available, diagnostic radiologic services
- If therapeutic services are also provided, must:
 - Be provided in accordance with acceptable standards of practice
 - Meet professionally approved standards for:
 - Safety
 - Personnel qualifications



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Radiologic Services (cont.)

- Acceptable standards of practice include maintaining compliance with:
 - Applicable Federal and State laws, regulations and guidelines
 - Facility licensure and/or
 - Certification requirements
 - Any standards and recommendations promoted by nationally recognized professional organizations
 - American Medical Association
 - American College of Radiology



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Radiologic Services (cont.)

Radiological services must be integrated into the QAPI program

- Including any contracted services





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Assessing Compliance – Radiologic Services

Elements to survey and investigate:



- Verify that the ASC offers radiologic services
- Verify that provided services meet professional safety standards and standards of practice
- Verify that personnel are appropriately qualified in accordance with Federal and State law
- Evaluate compliance with QAPI



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Needs of the Patients

In compliance with the Hospital CoPs, the ASC must maintain or have available, radiologic services according to the needs of the patients





20

Assessing Compliance – Needs of the Patient

Elements to survey and investigate:



- Verify that the scope and complexity of the radiology services are available to meet the needs of the patient population that is served
- Contractual services are also covered



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Safety for Patients and Personnel



§482.26(b)
The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel



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Assessing Compliance – Patient and Personnel Safety



- Observe facility to see that the location of the equipment and the radiology equipment are safe for use by personnel and patients
- Observe to see that ASC takes necessary preventive measures to ensure personnel and patients are safe at all times
 - Are there any hazards to patients or personnel present?
- Review incident reports, if any



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Safety Precautions

§482.26(b)(1)
Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials





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Safety Precautions (cont.)

Policy must contain safety standards for:

- Adequate shielding
- Labeling of materials, waste and hazardous areas
- Transportation of materials within facility
- Security of radioactive materials
- Testing of equipment
- Maintenance of personal radiation monitoring devices





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Safety Precautions (cont.)

Safety standards:

- Proper storage of badges when not in use
- Storage of radioactive materials and waste
- Disposal of radioactive materials and waste
- Methods of identifying pregnant patients





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Assessing Compliance – Safety Precautions

Elements to survey and investigate:



- Facility takes safety precautions for patients and staff
 - Shielding for patients, staff & facility
 - Appropriate storage, use & disposal of radioactive materials



27

Inspection of Equipment



- Equipment must be periodically inspected
- Identified hazards must be properly corrected



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**Assessing Compliance –
Inspection of Equipment**



- Review maintenance logs to verify compliance with the manufacturer’s guidelines for maintenance of the equipment and maintenance requirements of Federal and State law
- Check integrity of lead aprons/gloves/shields
- Determine whether identified hazards have been corrected in a timely manner



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Radiation Exposure




- Radiation workers
 - Checked periodically
 - By use of exposure meters or badge tests (required program – not at option of employee)
 - For amount of radiation exposure



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Assessing Compliance – Radiation Exposure



- Ensure all applicable personnel are appropriately equipped with exposure meters
- Review records to verify periodic checks of radiology personnel for level of exposure



31

Radiologic Services (cont.)



- Radiologic services must be provided
 - Only on the order of practitioners with clinical privileges
 - Other practitioners authorized by the medical staff and the governing body
 - Consistent with State law



32

Assessing Compliance – Radiologic Services

- Review medical records to determine that radiological services are provided to the patient only on the order of authorized practitioners or in accordance with State law





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Radiology Staff

A qualified full-time, part-time or consulting radiologist must:

- Supervise the ionizing radiology services
- Interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge



A radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology



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Assessing Compliance – Radiology Staff





- Verify that a radiologist (as defined by the regulation) supervises the radiology services according to policy and procedure
 - May be F/T, P/T or a consultant
- Verify that the medical staff has determined which radiologic tests require an interpretation by a radiologist



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Medical Staff



- Only qualified medical staff
 - Designated
 - May use radiologic equipment
 - Administer procedures



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Assessing Compliance – Medical Staff



- Review records to determine if there are written policies to designate which personnel may utilize equipment and administer procedures
- Review personnel files to ensure that the staff operating the radiologic equipment has the appropriate qualifications and training



37

Radiologic Services (cont.)



- Records of radiologic services must be maintained
- Radiologist or other practitioner performing radiology services must sign reports of interpretation
- Following records must be maintained for at 5 years:
 - Copies of reports and printouts
 - Films, scans and other image records, as appropriate



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Assessing Compliance – Radiologic Services



- Verify that the facility maintains a system of records for the radiology records
- Verify that the facility maintains adequate records for radiology services provided
 - Medical records and interpretations
 - Printouts and reports
 - Films, scans and other image records



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Assessing Compliance – Radiologic Services (cont.)



- Review medical records to verify that the radiologist (or other qualified/privileged practitioner) signs all reports of his interpretation
- The person who “interprets” the x-ray is the person who initially evaluates the radiologic image and provides information used to make treatment decisions
- A “second read” is a QAPI activity rather than an interpretation



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Assessing Compliance – Radiologic Services (cont.)

- Verify that the radiology medical records are at least 5 years old
- Ensure that policy and procedure for maintaining medical records coincide with the requirements of this regulation





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Summary

Laboratory Services



- Services must be integral to the procedure
- May perform services in-house
- If not, facility must use an appropriately certified laboratory
- Must be have procedures for obtaining services from certified laboratory
- Refer to 42 CFR 493



42

Summary (cont.)



- **Radiological Services**
 - Safety
 - Personnel
 - Records
 - QAPI program



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Summary (cont.)



- Surveyors may also want to coordinate with those surveying the following CfCs as the requirements may overlap:
 - Compliance with Federal, State, local laws
 - Governing body
 - Patient's rights
 - QAPI
 - Medical staff
 - Medical records
 - Pharmaceutical services
 - Infection control/physical environment



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Questions?

Thank you!



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Student Manual



Lesson 12: Environment

Learning Objectives

At the conclusion of this lesson, you will be able to:

- Locate and briefly describe the Environment CfC, including the four standards.
- Discuss the goals and objectives of requiring ASC to meet this CfC.
- Discuss the survey methods used to determine an ASC's compliance with this CfC.



42 CFR 416.44 Environment



Learning Objectives

At the conclusion of this lesson, you will be able to:



- Locate and briefly describe the Environment CfC, including the four standards
- Discuss the goals & objectives of requiring ASC to meet this CfC
- Discuss the survey methods used to determine an ASC's compliance with this CfC



2

§416.44 CfC: Environment



“The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.”



3

**42 CFR §416.44
Survey Process**



- When do we conduct a survey of Environment
 - with every full survey
 - or as a complaint?
 - LSC is only a component (1 of 4 standards) of evaluating compliance with this CfC
- Who conducts the survey of PE
 - health or life safety surveyor?
 - LSC surveyor evaluates LSC, & electrical systems, health surveyors evaluate compliance with the remaining standards
- Communication



4

§416.44: Environment

While the Standard (a)(1) discusses the design, construction, and equipment in the ORs, this CfC stem statement puts those type requirements on the entire ASC





5

§416.44: Environment (cont.)

The ASC must:

- Have a safe and sanitary environment
AND
- Be properly constructed, equipped and maintained
- To protect the health and safety of patients



6

§416.44: Environment (cont.)

- Have a safe and sanitary environment includes but not limited to:
 - Lack of hazards to safety
 - Ongoing processes to ensure patient safety
 - Proper cleaning that results in a clean environment
 - Proper sanitation including waste removal, pest control and food handling (when applicable)





7

§416.44: Environment (cont.)

The ASC must be maintained to protect the health and safety of patients



- “Maintained” includes preventive and ongoing maintenance of equipment and buildings
- “Maintained” includes ensuring that an acceptable stockage of supplies are kept on hand and in usable condition



8

§416.44: Environment (cont.)

- The ASC must have a system or systems in place to ensure compliance with the CfC – the stem statement in all four standards
- Evaluate situations:
 - That indicate the ASC does not have such systems, or their systems are inadequate or broken
 - Resulting in the ASC either failing to protect the health and safety of their patients, OR
 - Resulting in situations that are like to result in such failures to protect the health and safety of their patients



9

42 CFR §416.44 Standards

- (a) Physical Environment
- (b) Safety From Fire
- (c) Emergency Equipment
- (d) Emergency Personnel





10

§416.44 Standard (a): Functional and Sanitary Environment

“The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects and assures the physical safety of all individuals in the area.”



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Standard (a): Functional and Sanitary Environment

(1) OR design and equipment

ORs **must be designed and constructed** to provide a functional and sanitary environment that protects lives and assures the physical safety of all individuals

Design and Construction

- State rules for OR design and construction
- American Institute of Architects (AIA)
- Types of surgery may affect design
- Location of ORs within ASC
- Traffic flow (movement of people, equipment, and supplies)
- Temperature, humidity, and air flow per AIA
- Cleanable surfaces (flooring, walls)



12


Standard (a): Functional and Sanitary Environment (cont.)

(1) OR design and equipment

ORs **must be equipped** to provide a functional and sanitary environment that protects lives and assures the physical safety of all individuals

Equipment



- Includes both facility equipment and medical equipment
- Facility equipment includes: lighting, generators or other backup power, air handlers, medical gas systems, air compressors, temperature and humidity controls, etc
- Medical equipment includes: biomedical equipment, radiological equipment, OR tables, stretchers, anesthesia equipment, surgical devices, etc




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Standard (a)(1): OR Design & Equipment Survey Methods



- Do ORs meet State and AIA design and construction standards?
- Are ORs designed for the types of surgery conducted?
- Does each OR have the appropriate equipment for the types of surgery conducted?
- Does the ASC have and carry-out an appropriate preventive maintenance program for the facility and the equipment?
 - State rules
 - Manufacturer's instructions
 - Part of QAPI program

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Standard (a)(1): OR Design & Equipment Survey Methods (cont.)



- Who is responsible within ASC for equipment testing and maintenance?
- Is the facility maintained (cleanable surfaces, intact floors, walls and ceilings, rust, doors work properly, etc)
- If room(s) are used for radiologic procedures, is the room appropriately designed to protect from exposures (ex. Shielding, barriers)
- Are the rooms large enough and designed such that there is sufficient space to safely fit the equipment that is in each room, while maintaining physical safety
- Is there sufficient space for unobstructed movement of patients and staff?
- Are rooms monitored and results documented for temperature and humidity

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Standard (a): Functional and Sanitary Environment (cont.)



- (a)(2) separate recovery room (RR) and waiting area
- "The ASC must have a separate recovery room and waiting area."
 - ASC is required to have both & they must be separate from each other
 - Pre-op prep activities may be conducted in RR
 - Cannot be used for patients awaiting prep or for people who accompany patients to wait
 - Individuals may accompany patient in RR, but patient privacy, confidentiality, infection control, etc must be maintained for all patients in the RR
 - Survey Method: Verify Compliance with the items above



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Standard (a) Functional and Sanitary Environment (cont.)



- (a)(3) Infection Control Program
 - "(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities."
- This requirement was discussed with the presentation on infection control



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§416.44 Standard (b): Safety From Fire



(b)(1)
"Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Healthcare Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association regardless of the number of patients served."



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**§416.44 Standard (b):
Safety From Fire (cont.)**



- (b)(1) LSC
- Life Safety Code is the majority of Standard (b) Safety From Fire, but it is not all of that standard
- Additionally Standard (b) is only one of four standards of the entire Environment CfC
 - Survey Method: The LSC survey will typically be conducted by a specialist surveyor, however it is critical that all surveyors report any observations or concerns related to possible LSC issues the that surveyor



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**§416.44 Standard (b):
Safety From Fire (cont.)**



- (b)(1) LSC – Use of Alcohol-based Skin Preparations in Anesthetizing Locations
- To be evaluated by any surveyor
- See S&C-07-11
 - Contain alcohol, any type, any percentage
 - Surgical locations when electro scalpel, lasers or electro cautery will be used



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Alcohol-based Germicides



- Fires vs. infections
- Ignition sources
- Antiseptic value
- Safe method to address both issues



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Alcohol-based Germicides (cont.)



- Controlled delivery
- Unit dose (applicators, swabs)
- Clear & explicit manufacturer instructions
- Ensuring prep solutions do not spill, pool, or soak into patients hair or other absorbent materials on the table
- Ensure patient dry prior to draping by inspection
- Time out



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Alcohol-based Germicides (cont.)

- Documented in chart that time out occurred and site dry prior to draping
- Policies addressing all procedures
- Policies address spill prevention
- Policies address clean up of spill & removal of saturated materials
- Failure to take these measures when alcohol skin preps and ignition sources are used must be cited at the condition level at 416.44





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Standard (b): Safety From Fire

(b)(2) Waivers

"After consideration of State survey agency findings CMS may waive specific provisions of the Life Safety Code, which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients."

- State or AO evaluates and recommends, but only CMS may waive
- Waivers are for a specific situation that violates the LSC, but does not put anyone at risk





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**Standard (b):
Safety From Fire (cont.)**

(b)(3) State Code instead of LSC
"The provisions of the LSC do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals."

- None at this time
- Would be evaluated by CMS CO





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**Standard (b):
Safety From Fire (cont.)**

(b)(4) Emergency Lighting

"(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006."

- Essential Electrical Systems
- Should be evaluated by LSC surveyor
 - If use general anesthesia or life support equipment must have an "essential electrical system".
 - If constructed or renovated after 1/10/03 must have a Type 1 system that **may** include a generator for electrical back-up





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**Standard (b):
Safety From Fire (cont.)**

(b)(4) Emergency Lighting

- Essential Electrical Systems
 - ASC that existed prior to 1/10/03 may continue to have a Type 3 system with batteries for electrical back-up
 - Existing ASC that change their procedures to include the use of general anesthesia or life support, where not previously used must upgrade to a Type 1 system, including a generator for electrical back-up
- Back-up must be reliable
- Must protect patients and staff
- Must permit proceeding with procedure until such a point it is safe to either terminate or complete the procedure





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**Standard (b):
Safety From Fire (cont.)**

(b)(5) Alcohol-based hand rub dispensers

- To be evaluated by any surveyor
- Alcohol-based hand rub dispensers - OK
 - Must not conflict with State law
 - Must ensure no leaks and spills
 - Not accessible to vulnerable populations
 - Must be maintained in accordance with dispenser manufacturer guidelines





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**Standard (b):
Safety From Fire (cont.)**

(b)(5) Alcohol-based hand rub dispensers

- Installation
 - Corridors minimum width is 6 ft;
 - Maximum dispenser capacity is <0.3 gal in rooms, corridors; areas open to corridors; and <0.5 gal in suites of rooms;
 - Dispensers no closer than 4 ft apart;
 - No more than aggregate of 10 gal in single smoke compartment outside a [rated] storage cabinet
 - Storage of more than 5 gal in single smoke compartment must meet specific requirements in NFPA 30
 - Dispenser not installed adjacent to ignition source
 - If dispenser directly over carpeted area, smoke compartment must be sprinklered





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**§416.44 Standard (c):
Emergency Equipment**

“(c) Emergency equipment available to the operating rooms must include at least the following:



- (1) Emergency call system
- (2) Oxygen
- (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator
- (4) Cardiac defibrillator



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**§416.44 Standard (c):
Emergency Equipment (cont.)**



- (5) Cardiac monitoring equipment
- (6) Tracheostomy set
- (7) Laryngoscope and endotracheal tubes
- (8) Suction equipment
- (9) Emergency medical equipment and supplies specified by the medical staff"

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**Standard (c):
Emergency Equipment**



- Each OR is not required to have each of the listed items
- All listed equipment must be readily available to each OR
- If multiple OR, must have sufficient equipment to handle multiple simultaneous emergencies
 - Policy should state which of the required equipment/supply items must be present in each OR, and
 - For any equipment/supply item not present in each OR, how many items must be available, in which locations, in order to make the item "readily available" when needed in each OR

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**Standard (c):
Emergency Equipment (cont.)**



- The emergency equipment and supplies must be regularly inspected, tested, and maintained in accordance with State law and manufacturer's directions
- Failure to do so means the applicable items are not "available" and therefore the standard is not met for that particular required item
 - A broken, non-functioning, or malfunctioning piece of equipment is to be treated as "not available"
 - An expired supply item is to be treated as "not available"

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**Standard (c):
Emergency Equipment (cont.)**



- Emergency call system
 - Must have a system to call other staff into the OR in case of an patient emergency
 - May be specific specialties such as another surgeon, a CRNA, another surgical nurse or any available staff to address a situation
- What system do they use and does it work?



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**Standard (c):
Emergency Equipment (cont.)**



- Oxygen
 - Must comply with LSC and other standards referenced in NFPA 101
 - If tanks are used, storage, resupply, and connector changing policies and procedures must be evaluated
 - Evaluate monitoring of oxygen alarms
 - Do they have a functioning system to protect against supply interruption during a surgery?



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**Standard (c):
Emergency Equipment (cont.)**



- Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator
 - Are appropriate sized airways and masks for the population served?
- Cardiac defibrillator
 - Automated Electronic Defibrillator (AED) may be used
 - If the ASC's medical staff emergency equipment policy specifically states that an AED is sufficient, for the patient population and types of procedures



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**Standard (c):
Emergency Equipment (cont.)**



- Cardiac Monitoring Equipment
- Tracheostomy Set
 - Cricoidostomy set may be used
 - Ensure appropriate sizes available for population served
- Laryngoscope and endotracheal tubes
 - Evaluate for availability of appropriate sizes for the population served



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**Standard (c):
Emergency Equipment (cont.)**



- Suction equipment
 - If wall suction used, evaluate for available portable back-up suction
- Emergency medical equipment and supplies specified by the medical staff
 - The ASC may only ADD equipment and supplies (supplies include medications), they may not eliminate any of the listed by the standard
 - Evaluate



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**§416.44(d) Standard:
Emergency Personnel**



- “(d) Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC”



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**Standard (d):
Emergency Personnel (cont.)**



- Must have sufficient personnel who are trained to use every piece of emergency equipment/supply item
- Must have sufficient personnel who are trained to perform CPR
- Whenever there is a patient in the ASC
 - Have been registered, but have not yet departed the ASC
 - If perform multiple procedures simultaneously, or multiple patients remain in RR simultaneously, must be sufficient trained personnel to deal with multiple simultaneous emergencies
 - "In the ASC" includes in the waiting room, in pre-op area, in surgery, in RR, and anywhere else in the ASC



40

**Standard (d):
Emergency Personnel (cont.)**



- What is "sufficient personnel"?
 - Sufficient numbers of trained clinical personnel with the appropriate scope of practice to use the emergency equipment/supply item
 - Ex. Intubation not in scope of practice of RN, use of ambu-bag is within RN scope of practice, therefore must have someone who can intubate



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**Standard (d):
Emergency Personnel (cont.)**



- What is "sufficient personnel"?
 - If multiple patients present, must have sufficient numbers of trained clinical personnel, with the appropriate scope of practice, to address multiple simultaneous emergencies
 - Ex. If have 2 or more patients remaining in RR, 2 go into cardiac arrest. Must have sufficient trained staff present, who working within their scope of practice, can conduct 2 simultaneous codes, and, as needed, simultaneously intubate 2 patients, defibrillate 2 patients, suction 2 patients, administer oxygen to 2 patients, perform 2 tracheostomies (more likely 2 cricoidostomies), etc



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**Standard (d):
Emergency Personnel (cont.)**

- Personnel trained in CPR
 - Advanced Cardiac Life Support (ACLS) not required, **however**
 - An ASC would be well-advised to consider having staff trained in ACLS, depending on the types of surgery performed and the characteristics of the ASC's patient population





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**Standard (d):
Emergency Personnel (cont.)**

Survey Methods

- Evaluate issues discussed on previous slides
 - Request documentation that confirms sufficient staff with training, that includes demonstrated competency
 - Evaluate whether at the time of the survey, does the ASC have sufficient trained staff to handle, 1 emergency or 2 emergencies (if more than one patient in ASC) as discussed in these slides
 - Review ASC's evidence that sufficient staff are available whenever there is one or more patients in the ASC





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**Standard (d):
Emergency Personnel (cont.)**

Survey Methods

- Interview appropriate ASC staff regarding their role. Do they know their role? Can they state the location of all required emergency equipment/supplies?
- Ask staff with emergency responsibilities, what is the procedure when an emergency occurs, and the person designated to handle the emergency is participating in a procedure on another patient? What type of back-up system is available?



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§416.44 & the QAPI Program



- ASC quality assessment & performance improvement (QAPI) activities:
 - Routine physical plant inspections/environmental rounds
 - Routine & preventive maintenance & testing
 - Other
- Integration into the ASC QAPI program



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Questions?

Thank you!



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Student Manual

Lesson 13: Medical Records

Learning Objectives


At the conclusion of this lesson, you will be able to:

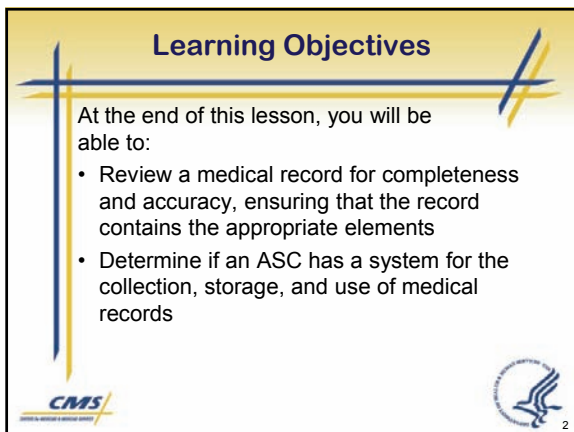
- Review a medical record for completeness and accuracy, ensuring that the record contains the appropriate elements.
- Determine if an ASC has a system for the collection, storage, and use of medical records.



Medical Records

CMS






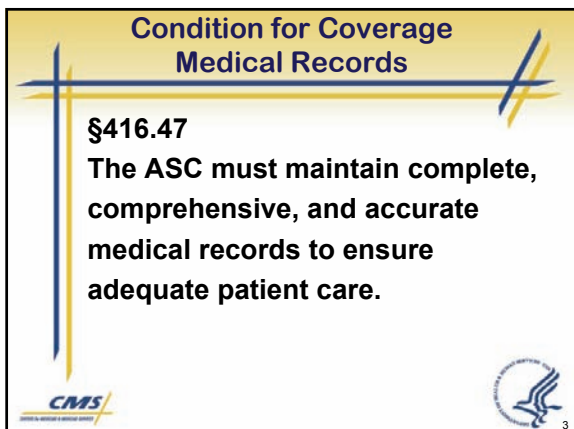
Learning Objectives

At the end of this lesson, you will be able to:

- Review a medical record for completeness and accuracy, ensuring that the record contains the appropriate elements
- Determine if an ASC has a system for the collection, storage, and use of medical records

CMS






**Condition for Coverage
Medical Records**



§416.47
The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

CMS



Medical Record

- A medical record is a systematic documentation of a patient's medical history and care
- Medical records include:
 - Written documents
 - Computerized/electronic information
 - Radiology films/scans/other imaging
 - Lab reports & pathology slides
 - Videos/audio recordings
 - Any other form of information about the patient




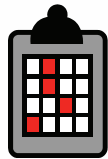


4

Medical Records

Each patient's medical record must be:



- Complete
- Comprehensive
- Accurate
- Confidential



5

Medical Records (cont.)



- Materials such as H&P or documentation of allergies to drugs and biologicals must be included in the medical record
 - in a timely fashion
 - But, prior to the administration of medications
- ASC should use information in medical records to assure delivery of adequate care



6

Assessing Compliance – Medical Records

- Review medical records – active and closed – looking for completeness and accuracy
 - In accordance with Federal and State laws and regulations
 - In accordance with ASC policy



7

Assessing Compliance – Medical Records (cont.)



- Review the medical record; look for:
 - Legible & complete entries
 - Dates and times
 - Authentication



8

Assessing Compliance – Medical Records (cont.)



- Surveyors, not facility staff, choose records
- Expand the sample size as needed to assess the facility's compliance with the CfC
- Use your professional judgment to select a sample that will enable you to make compliance determinations



9

Assessing Compliance – Medical Records (cont.)



- Review the ASC's policy regarding medical records
- Investigate medical record system
 - Look for a systematic manner of collection for easy access
 - If absent, annotate on survey report form



10

Medical Record System


§416.47(a)
The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.



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Organization



- Must have a documented system
 - Unique medical record
 - Timely access to support delivery of care
 - Storage of records



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Organization (cont.)



- Records may exist:
 - Hard copy
 - Electronic format
 - Combination
- There is no regulation prescribing the length of time a closed record must be maintained.
 - State law may exist governing retention of medical records



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Assessing Compliance – Medical Records (cont.)



- Review Medical Record policy to determine if the medical record system is **appropriately structured**:
 - Demonstrates information is collected in a systematic manner
 - Contains adequate information in order to deliver adequate care
 - Permits timely access to the medical record to support delivery of care



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Assessing Compliance – Medical Records (cont.)




- Interview medical record staff to ascertain that the system is structured appropriately
- Review medical records – active and closed – to assess **“structured appropriately”**



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Assessing Compliance – Medical Records (cont.)



- If ASC has a fully or partially electronic medical record system
 - Ask for demonstration of system
 - Staff are able to make entries
 - Staff are able to access needed information



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Assessing Compliance – Medical Records (cont.)



- Review a sample of active and closed medical records
 - Completeness and accuracy
 - In accordance with Federal and State laws and regulations
 - ASC policy
- Are closed records retained in accordance with applicable State law?



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Assessing Compliance – Medical Records (cont.)



If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.



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Form and Content of Record

§416.47(b)
The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed.





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Form and Content of Record (cont.)

§416.47(b)
Medical records must include at least the following:

- Patient identification
- Medical history
- Pre-operative diagnostic studies
- Findings/techniques of operation





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Form and Content of Record (cont.)

§416.47(b) (cont.)
Medical records must include at least the following:



- Allergies/abnormal drug reactions
- Anesthesia
- Patient consent
- Discharge diagnosis



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Form and Content of Record (cont.)

Each patient's medical record **must** contain all of the required elements listed in the regulation





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Form and Content of Record (cont.)

Patient Identification



- Identity must be clear through use of identifiers
 - Name
 - DOB
 - SSN



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Form and Content of Record (cont.)



- Medical History and Physical Assessment
 - Comprehensive
 - Must be completed and entered into medical record
 - See §416.52(a)(1)
- Results of pre-surgical assessments
 - Must be entered into medical record
 - See §416.52(a)(2)



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Form and Content of Record (cont.)



- Pre-Operative Diagnostic Studies
 - If performed, must be included
 - Prior to the start of surgery



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Form and Content of Record (cont.)



- Operative Report
 - Describes surgical techniques and findings
- Pathologist Report
 - All tissues removed; except if exempt by written policy adopted by governing body
 - No report required if no tissue removed
 - Exemption should provide clinical rationale supporting exemption decision



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Form and Content of Record (cont.)



- Allergies or Abnormal Drug Reactions
 - History prior to surgery
 - Occurring during surgery
 - Occurring after surgery



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Form and Content of Record (cont.)



- Anesthesia
 - Administration during procedure
 - Recovery after procedure



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Form and Content of Record (cont.)



- Patient Consent
 - Properly executed and documented
 - Well-designed informed consent process would include a discussion of:
 - Description of proposed surgery, including anesthesia
 - Indications for proposed surgery
 - Material risks and benefits related to surgery and anesthesia
 - Treatment alternatives
 - Who will perform important tasks?
 - Documentation of discharge diagnosis



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Assessing Compliance – Medical Records (cont.)



- Select a sample of open and closed records
 - Determine if they contain all required elements
 - For open records of patients whose surgery has not yet begun, focus on elements that must be present before surgery
 - H&P
 - Immediate pre-surgical assessment, including allergies
 - Informed consent



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Assessing Compliance – Medical Records (cont.)



- Expand the sample size as needed to assess the ASC's compliance with the CfCs
- Use your professional judgment to select a sample that will enable you to make compliance determinations



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Assessing Compliance – Medical Records (cont.)



- Absence of any required element = standard-level noncompliance
- Absence of a number of elements from a number of medical records = citation of condition-level noncompliance
- Absence of one element from a number of medical records = condition-level noncompliance



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Summary



- Medical Records
 - Located at 42 CFR 416.47, 2 standards
 - Medical records must be:
 - Complete
 - Comprehensive
 - Accurate
 - There must be a system for collection, storage, and use of medical records



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Summary (cont.)



- To survey medical records, look at:
 - The completeness and accuracy of the record
 - The medical record system
 - Form and content of the medical record



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Summary (cont.)



- Coordinate with surveyors working on the following CfCs:
 - Patient Rights
 - Pre-surgical Assessment
 - QAPI
 - Governing Body
 - Medical Staff
 - Emergency Services
 - Infection Control



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Questions?

Thank you!



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