



Moving Forward with Enhanced Standards: v41 for Medicare Deemed Status

August 2020

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Today's Presenters



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Standards Development



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Version 41

- Past editions identified by calendar year
- Switching to version numbers
- Separates release of new/revised Standards from a specific timeframe
- Provides flexibility



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What's new in v41?

Most significant change:

New process for rating the Standards

- Provides greater transparency, explains what surveyors will look for



- Facilitates your self-assessment of compliance

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Medicare Deemed Status

New and improved rating process

2017-18 Standard 7.II.P:

P. Products, including medications, reagents, solutions, and supplies that have a manufacturer's printed expiration date are monitored and disposed of in compliance with facility policy and manufacturer's guidelines.

Rating Options:

- Compliant
- Partially Compliant
- Not Compliant
- Not Applicable

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Medicare Deemed Status

New and improved rating process

F. All products, including medications, reagents, solutions, and supplies that have a manufacturer's printed expiration date are monitored and disposed of in compliance with facility policy and manufacturers' guidelines.

Elements of compliance

- | | CMS Tag | YES | NO |
|--|--------------------------|--------------------------|--------------------------|
| 1. A written policy for the monitoring and disposal of products with expiration dates is present. | - | - | - |
| 2. The policy describes the process for ensuring that products with a manufacturer's printed expiration date are monitored for currency. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. The policy for disposal or return of expired items complies with prevailing laws and regulations, and manufacturer guidelines. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Compliance Rating

<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
All elements are present	No rating option	2 of 3 elements are present	No rating option	1 or no elements are present



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Medicare Deemed Status

New and improved rating process

CMS Tag

E. The ASC must inform the patient or the patient's representative of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. [416.50] Q-0219

Compliance Rating

<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
Standard is met	No rating option		Standard is not met	

Same rating process for AAAHC (non-MDS) Standards when there are no Elements of Compliance

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Medicare Deemed Status

New and improved rating process

CMS Tag YES NO

K. The ASC must comply with the following requirements for advance directives. [416.50(e)] Q-0224

Elements of compliance

- The patient or, as appropriate, the patient's representative is provided written information concerning the ASC's policies on advance directives, including a description of applicable state health and safety laws and, if requested, official State advance directive forms. [416.50(c)(1)] Q-0224
- The patient or, as appropriate, the patient's representative is informed of the patient's right to make informed decisions regarding the patient's care. [416.50(c)(2)] Q-0224
- Documentation in a prominent part of the patient's current medical record indicates whether or not the individual has executed an advance directive. [416.50(c)(3)] Q-0224

Compliance Rating

<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
Standard is met	No rating option		Standard is not met	

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Medicare Deemed Status

New and improved rating process

CMS Tag YES NO

A. Patients are treated with respect, consideration, and dignity.

Elements of compliance

- The patient has the right to personal privacy. [416.50(f)(1)] Q-0231
- Patients are provided appropriate privacy:
 - At check-in.
 - In evaluation and treatment areas.
- Interpretation services are available.
- To the degree that it is known, patients are provided with information concerning their diagnosis, evaluation, treatment, and prognosis. When it is medically inadvisable to give such information to a patient, the information is provided to a person designated by the patient or to a legally authorized person.
- Patients are given the opportunity to participate in decisions involving their health care, except when such participation is contraindicated for medical reasons.

Compliance Rating

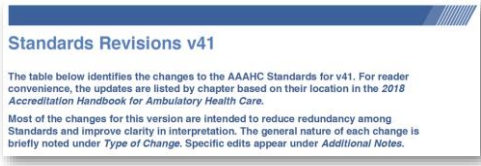
<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
All elements are present	4 of 5 elements are present	3 of 5 elements are present	2 of 5 elements are present	1 or no elements are present

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Guide to Version 41 Revisions

v41 Handbook Pages 281-282



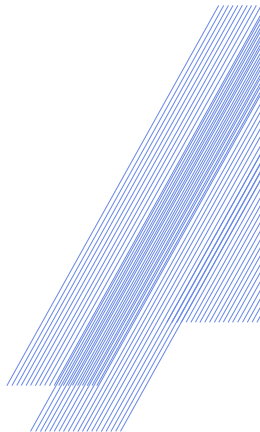
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Types of Revisions

- Reorganized / renumbered, without change in requirements
- Divided without change in requirements; max number of Elements of Compliance = 7
- Deleted for redundancy
- Edited for clarity and/or applicability
- Sub-elements of Compliance no longer rated individually; all must be present for Element to be rated "Yes"
- New and revised

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Version 41 Revisions



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2017-18 Standard 2.I.E

The names and address of all owners or controlling parties (whether individuals, partnerships, trusts, corporate bodies, or subdivisions of other bodies, such as public agencies or religious, fraternal, or other philanthropic organizations) are available upon request and furnished to AAAHC.

CMS maintains this requirement (v41 Standard 1.F.2):

- The ASC must disclose, in accordance with Title 42 CFR Part 420 and, where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing. [416.50(b)]



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CMS revised, but AAAHC maintains

2017-18 Standard 2:I.K deleted by CMS:

CMS requires Medicare-certified ASCs to EITHER: [416.41(b)(3)]

- Have a written transfer agreement with a hospital that meets the requirements of 416.41(b)(3)(i), OR
- Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of 416.41(b)(3)(ii).

v41 Standard 4.H:

One of the following is in place in the event of an emergency or unplanned outcome for which hospitalization is indicated to evaluate and stabilize the patient:

- A written transfer agreement for transferring patients to a nearby hospital.
- A written policy of only credentialing physicians who have admitting privileges at a nearby hospital.
- A written agreement with a physician or provider group with admitting privileges at a nearby hospital.



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CMS revisions effective late 2019

Addendum to Medicare Handbook, effective 4/13/20

CfC	CMS Revision	AAAHC v41 Revision
416.41(b)(3) [previous]	Deleted requirement for hospital transfer agreement or hospital admitting privileges	Deleted previous language and substituted corresponding Standard from non-deemed accreditation program, requiring transfer agreement, admitting privileges or agreement with physician group with admitting privileges (Standard 4.H)
416.41(b)(3) [revised]	Added requirement to periodically notify hospital of operations and population served	Added same requirement (Standard 4.K)



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CMS revisions effective late 2019

Addendum to Medicare Handbook, effective 4/13/20

CFC	CMS Revision	AAAHC v41 Revision
416.42(a)	Revised requirement for pre-surgical assessments: <ul style="list-style-type: none"> Anesthetist (vs. physician) may now conduct assessment for risk of anesthesia Physician must still conduct assessment for risk of the procedure 	Same revisions: Standard 9.G Standard 10.I.H
416.52(a)(1)	<ul style="list-style-type: none"> Deleted requirement for all patients to have H&P within 30 days Added requirement for a policy identifying patients requiring an H&P, and in what timeframe 	Added same policy requirement (Standard 10.I.D) and maintained requirement for all patients to have H&P within 30 days (Standards 10.I.D and E)

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CMS revisions effective late 2019

Addendum to Medicare Handbook, effective 4/13/20

CFC	CMS Revision	AAAHC v41 Revision
416.52(a)(2)	Revised language of the requirements for pre-surgical assessment upon admission, but did not change requirements	Same revision (Standard 10.I.F.1)
416.54	Revised timeframes from annual to every two years for: <ul style="list-style-type: none"> Reviewing and updating emergency preparedness plans, policies and procedures The frequency of emergency preparedness drills Added requirement for training when policies and procedures are significantly updated	Maintained annual requirements (Standards 8.II.G and 8.II.I) Added same requirement (Standard 8.II.F.5)

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What's new in v41?

Simplifying the Standards

Previous Standard 2.I.H contained 24 requirements within 18 elements

Now divided into five more focused Standards:

- 2.I.F
- 2.I.G
- 2.I.H
- 2.I.I
- 2.I.J

Previous Standard 2.II.B contained 30 requirements within 7 elements

Now divided into five more focused Standards:

- 2.II.B
- 2.II.C
- 2.II.D
- 2.II.E
- 2.II.F

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Standard 2.I.J

Ch. 2.I, Governance: General Requirements

New Statement of Requirement:

The governing body is responsible for ensuring appropriate communication within and on behalf of the organization.

- Elements of Compliance are not new; formerly present at 2017-18 Standards:
 - 2.I.H.8
 - 2.I.H.9
 - 2.I.H.15
 - 3.B.6
 - 3.B.12

No new or different actions are required

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New Standard 2.II.G

Ch. 2.II, Governance: Credentialing and Privileging

	CMS Tag	YES	NO	NA
G. The governing body makes appointment and reappointment decisions following review of the applications, or based on recommendations from a delegated entity.				
<i>Elements of compliance</i>				
1. Applications are reviewed by the governing body or its delegate.		<input type="checkbox"/>	<input type="checkbox"/>	
2. If the governing body delegates responsibility for reviewing the applications, documentation of the delegation is present.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Peer references and/or peer review activities and results, completed in accordance with AAAHC Standards for peer review, are incorporated into the decision process.		<input type="checkbox"/>	<input type="checkbox"/>	
4. Appointment and reappointment decisions made by the governing body are documented.		<input type="checkbox"/>	<input type="checkbox"/>	

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Standard 2.II.G (cont.)

References / Notes:

- In this context, “delegated entity” refers to an internal reviewer or reviewers, e.g., the Medical Director or a Committee that provides recommendations for appointment and reappointment to the governing body. The governing body remains responsible for making appointment and reappointment decisions. Such delegation is not an option for solo providers because Standard 2.II.K.4 requires review by an outside provider.

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What's new in v41?

Ch. 3: Administration

Formerly:

- Subchapter 1, Administration, and
- Subchapter II, Nursing Services

- CfCs for Nursing Services remain in Chapter 3, but no longer a separate subchapter

- Subchapter II also previously contained requirements related to employee health (bloodborne pathogens, etc.)
- These Standards have been relocated to Chapter 7.II, Safety; see 7.II.N, O, P and Q



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What's new in v41?

Ch. 3: Administration

New Standard 3.D:

- Combines requirements for various types of training (e.g., infection control, risk management) previously located in different chapters into one Standard – easier to track what is required

Deleted 2017-18 Standards 3.II.F and G:

- Some requirements for nursing staff were redundant with requirements for all staff



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Standard 5.I.G (formerly 5.I.C)

Ch.5.I: Quality Improvement Program

The organization demonstrates that continuous improvement is occurring by conducting quality improvement studies when the data collection processes described in Standard 5.I.C indicate that improvement is or may be warranted.

1. As evidenced by documentation of quality improvement studies conducted, the studies include the applicable components of the quality improvement process.
2. At least one current quality improvement study demonstrates that improvement occurred and has been sustained.
3. As documented in committee and/or staff meeting minutes, and/or in records of educational activities, the findings of quality improvement activities are communicated:
 - a. To the governing body.
 - b. Throughout the organization, as appropriate.



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Standard 5.II.A

Ch. 5.II: Risk Management

2017-18:

The organization's governing body approves a written risk management program and/or policies.

V41:

The risk management program includes written policies.

Former Element 6 deleted as redundant with Chapter 2.II: Persons authorized to perform or assist in the procedure area.

New Element 5 (may be NA):

The policies require documentation of clinical advice provided after normal working hours.

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Standard 6.N

Ch. 6: Clinical Records

If a patient's primary or specialty care provider(s) or health care organization is elsewhere, timely summaries or pertinent records necessary for continuity of patient care are available.

1. Summaries or records are obtained from the external provider(s) or organization. (Yes, No)
2. Summaries or records are incorporated into the clinical record. (Yes, No, NA)
3. Summaries or records are provided to the external health care professional as appropriate and in accordance with Standard 6.F. (Yes, No)

References / Notes

Surgical organizations may choose to maintain such records in a file other than the clinical record. Therefore, Element 2 has an NA rating option.

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Standard 7.I.C (formerly 7.I.B.4)

Chapter 7.I: Infection Prevention and Control

C. The infection control program is under the direction of a designated and qualified professional who has training in infection control. [416.51(b)(1)]

CMS Tag YES NO
Q-0243

Elements of compliance

1. The governing body or its designee has assigned a qualified health care professional to direct the program. YES NO
2. There is documented evidence that the assigned person: YES NO
 - a. Has obtained training in infection prevention and control.
 - b. Demonstrates current competence in infection prevention and control.

Compliance Rating

<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
Standard is met	No rating option		Standard is not met	

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Standards 7.I.F and G (former 7.I.G)

Ch. 7.I: Infection Prevention and Control

New F: Safeguards are in place to protect patients and others from cross-infection.

New Element 4:

Written policies identify people authorized to be in patient care areas.

Part of former 7.I.G remains 7.I.G but elements have been added: Resources are sufficient to protect patients and others from cross-infection.

1. Space is sufficient.
2. Equipment is sufficient.
3. Supplies are sufficient.
4. Personnel are sufficient.



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2018 Standard (formerly 8.I.P)

When an organization undergoes demolition, construction, or renovation projects, the organization performs a proactive and ongoing risk assessment for existing or potential environmental hazards.



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Standard 7.II.B (former 8.I.P; revised)

Ch. 7.II: Safety

The **safety program** requires performance of a proactive, documented risk assessment before commencing demolition, construction or renovation while the facility is occupied.

1. The risk assessment identifies potential risks to occupant health and/or safety.
2. The risk assessment identifies actions necessary to eliminate or adequately mitigate such risks.
3. The risk assessment identifies provisions for monitoring and mitigating risks during the process, and for updating or expanding the risk assessment if necessary to ensure continued protection of all occupants.



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Standard 7.II.C (former 8.I.P; revised)

Ch. 7.II: Safety

Documentation demonstrates that the risk assessment was conducted or is underway in accordance with the requirements of the organization's safety program.

References / Notes

- For initial surveys, apply the NA rating. May also be rated NA on reaccreditation surveys if none of the types of projects described in Standard 7.II.B have occurred in the last three years, or no such project is anticipated.

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Standard 7.II.H (formerly 8.I.Q)

Chapter 7.II: Safety

	CMS Tag	YES	NO
H. The temperature of items that are frozen, refrigerated, and/or heated is continuously monitored to ensure that the product manufacturer's recommended temperature range is maintained.	—		
<i>Elements of compliance</i>			
1. A mechanism is present for continuously measuring the temperature of frozen, refrigerated, and/or heated items.		<input type="checkbox"/>	<input type="checkbox"/>
2. Logs or other documentation demonstrate that temperature monitoring occurs.		<input type="checkbox"/>	<input type="checkbox"/>
3. Recommended temperature ranges are readily available to staff performing the monitoring function.		<input type="checkbox"/>	<input type="checkbox"/>
4. Documentation and/or interviews confirm that staff performing the monitoring function have been trained what to do if the temperature falls outside of the recommended range.		<input type="checkbox"/>	<input type="checkbox"/>

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Standard 8.I.A (Revised)

Ch. 8: Facilities and Environment

The organization provides evidence of compliance with the following: Documentation demonstrates that the facility complies with applicable building codes and regulations.

1. Applicable state and local building codes and regulations.
2. Applicable state and local fire prevention regulations.
3. Periodic inspection by the local or state fire control agency, if this service is available in the community.

References / Notes

- Examples of such documentation include an occupancy permit, a report or letter from a relevant fire authority, and/or a report or letter from the relevant building approval authority.

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Chapter 9: Anesthesia Services

Standard 9.B (formerly 9.H):

- The governing body has appointed one or more qualified physicians or dentists to supervise the anesthesia service.

2017-18 Standard 9.I deleted; redundant with Core Standard in Ch.7.II:

~~All clinical support staff with direct patient contact maintain at a minimum skills in basic life support.~~

Same requirement at Standard 10.I.L.1 also deleted



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Standard 9.F (formerly 9.H)

Chapter 9: Anesthesia Care Services

F. Resuscitation equipment is available.		CMS Tag	YES	NO
Elements of compliance		-		
1.	Oxygen is available.		<input type="checkbox"/>	<input type="checkbox"/>
2.	A device such as a self-inflating hand resuscitator bag capable of administering at least 90% oxygen is available.		<input type="checkbox"/>	<input type="checkbox"/>
3.	Appropriate emergency drugs, supplies, and equipment are available.		<input type="checkbox"/>	<input type="checkbox"/>
4.	A manual defibrillator, or an automated external defibrillator (AED), is available.		<input type="checkbox"/>	<input type="checkbox"/>
Compliance Rating				
<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
All elements are present	No rating option	2 or 3 of 4 elements are present	No rating option	1 or no elements are present



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Standard 10.I.C (formerly 10.I.B)

Chapter 10.I, Surgical Services: General Requirements

Previously:

Adequate supervision of surgery conducted by the organization is a responsibility of the governing body. It is recommended that supervision of surgical services be provided by a physician or dentist.

v41:

The governing body has appointed one or more qualified physicians, dentists, or other qualified practitioners to supervise surgical services.



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Standard 10.I.I (formerly 10.I.L)

Chapter 10.I, Surgical Services: General Requirements

- I. A written policy requires that, whenever patients are present in the facility, at least one physician, dentist, or other practitioner qualified to address medical emergencies and authorized by the governing body is present or immediately available by telephone.

CMS Tag

—

Compliance Rating

<input type="checkbox"/> Fully Compliant	<input type="checkbox"/> Substantially Compliant	<input type="checkbox"/> Partially Compliant	<input type="checkbox"/> Minimally Compliant	<input type="checkbox"/> Non-Compliant
Standard is met	No rating option		Standard is not met	



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Checklist of required documentation

Pages 169-174 in the v41 Deemed Status Handbook

AAAHC Documentation Requirements

This tool is designed to help you ensure that you have the written documentation required to comply with v41 AAAHC Standards. Note that Chapters 1–8 apply to all organizations, while the remaining chapters apply only if your organization provides that service. This tool is not meant to be inclusive of all written documentation that your organization may choose or need to maintain, nor does it address additional documentation that CMS may require of Medicare-certified ambulatory surgery centers.



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Standards 10.I.R and 10.I.S (former 10.I.R)

Ch. 10.I: Surgical Services – General Requirements

- Previous Standard 10.I.R combined requirements for procedure verification and site marking
- Revised Standards address topics separately

10.I.R

Prior to the surgery or procedure, the intended procedure is verified.

1. A written verification policy is present.
2. The patient or their authorized representative is involved in the verification process.
3. Clinical records contain documentation of procedure verification.



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Standards 10.I.R and 10.I.S (former 10.I.R)

Ch. 10.I: Surgical Services – General Requirements

10.I.S

Prior to a surgery or procedure involving level or laterality, the site is marked.

1. A written site marking policy is present.
2. The policy includes the organization's definition of "surgical team."
3. The patient or their authorized representative is involved in the site marking process prior to the administration of anesthesia.
4. The site is marked by the person performing the procedure, or by their designated member of the surgical team who will be present during the time-out.
5. Clinical records contain documentation of site marking.

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Laser, Light-based Technologies and Other Energy-Emitting Equipment

Subchapter 10.II

- Formerly three Standards, now reorganized into five
- Major change, Standard 10.II.B.2:
 - The (laser safety) program is supervised by an individual delegated the responsibility and authority to serve as Medical Laser Safety Officer (MLSO).
 - The MLSO has the requisite education and training applicable to each type of laser used in the facility, including knowledge of laser-specific information (e.g., wave lengths, pulse shapes, modes, power/energy classification, controlled areas).

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Definition of Laser Safety Officer

ANSI Z136.3-2011, Standard 1.3.1*

The LSO is the one person in each facility or organization responsible for the laser safety program. This individual has the training and experience to administer a laser safety program. The LSO is authorized by the HCF administration and is responsible for monitoring and overseeing the control of laser hazards. The LSO shall effect the knowledgeable evaluation and control of laser hazards by utilizing, when necessary, the most appropriate clinical and technical support staff and other resources....The LSO can be the laser user, laser operator, or other trained person responsible for the laser safety program (see ANSI Z136.1 2007, Appendix A).

* As of February 2018; may have been revised

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Chapter 11: Pharmaceutical Services

- New Standard 11.H requires monitoring the medication inventory to track the presence or absence of high-alert medications and medications with confused drug names.
 - If high-alert medications are present, Standard 11.I applies
 - If medications with confused drug names* are present, Standard 11.J applies
- Standards 11.I and J require maintaining lists of the drugs present and having procedures to prevent errors with their administration
- New Standard 11.P for vaccine management applies to all organizations that store and handle vaccines, even if the vaccines are intended for staff only.

* Look-alike/sound-alike



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Standards 11.K and M (formerly D and I)

Ch. 11: Pharmaceutical Services

Former 11.D:

- Records and security are maintained to ensure the control and safe dispensing of drugs, including samples, in compliance with federal and state laws.

Former 11.I:

- All injectable medications drawn into syringes and oral medications removed from the packaging identified by the original manufacturer must be appropriately labeled if not administered immediately.

Both have been revised to include new Elements of Compliance; review carefully



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Standards 12.D - 12.H

Ch. 12: Pathology and Medical Laboratory Services

Expanded to address additional types of laboratory certificates, both CLIA and state

- Standards 12.D and 12.F address requirements for CLIA and/or state certificates based on lab services provided
 - State laboratory programs in New York and Washington are currently exempt from CLIA requirements
 - Other states require both CLIA and state certificates
- Standards 12.E, 12.G and 12.H address the qualifications of persons directing lab services, based on required certificates
- Some may not apply, depending on state and services provided



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Standard 12.L (former 12.B.3)

Ch. 12: Pathology and Medical Laboratory Services

Laboratory quality control procedures are performed.

1. Quality controls are performed in accordance with manufacturer instructions.
2. The results of quality control procedures are documented.
3. Equipment is calibrated in accordance with manufacturer instructions.
4. Validation tests for new equipment are performed in accordance with manufacturer instructions.

References / Notes

- Elements 3 and 4 apply only if moderate complexity and/or high complexity testing are conducted.



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New Standard 12.M

Ch. 12: Pathology and Medical Laboratory Services

Proficiency testing is performed if required by CLIA, the CLIA accrediting body, the state, and/or the organization's policies.

- May be NA
- Check requirements for your CLIA and/or state certificate type
- To learn more about proficiency testing, see:
<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf>



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Standard 12.P (former 12.G)

Ch. 12: Pathology and Medical Laboratory Services

Laboratory work is performed with optimal accuracy, precision, efficiency, and safety.

1. All test kits, laboratory devices and supporting supplies are FDA approved for use under the type of CLIA or state certificate obtained.
2. Observation and interviews confirm that the following are sufficient:
 - a. Space.
 - b. Equipment.
 - c. Supplies.

References / Notes

- Not all "supporting supplies" must be FDA approved, e.g., cotton balls.



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Chapter 13: Diagnostic and Other Imaging Services

- No significant revisions in terms of new requirements
- But has been reorganized, and new rating process applies
- Note the following statement in the Handbook:
All Standards apply to organizations that provide imaging services for screening, diagnosing, monitoring, or assisting with procedures. Standards 13.K, L, M and N do not apply if the organization only provides peri-operative imaging services.

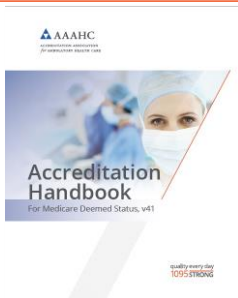
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Additional chapters now located in v41 MDS

18. Teaching and Publication Activities
19. Research Activities
20. Overnight Care and Services
24. Radiation Oncology Treatment Services

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How to Obtain the v41 Handbook



- In support of our *1095 Strong, quality every day* philosophy, AAAHC offers a complimentary PDF of the *Accreditation Handbook* to all accredited organizations.
- On September 1, your primary survey contact person will receive an email containing instructions for obtaining the PDF.

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When does v41 take effect?



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