

# Prepublication Requirements

• Issued April 25, 2017 •

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## Standards and Elements of Performance Deletions Related to EP Review Phase III

### APPLICABLE TO LABORATORIES

**Effective July 1, 2017**

## Environment of Care Chapter

### EC.01.01.01

The laboratory plans activities that minimize risks in the environment of care.

Note: One or more persons can be assigned to manage risks associated with the management plans described in this standard.

#### Elements of Performance for EC.01.01.01

2. Laboratory leaders identify an individual(s) to intervene whenever environmental conditions immediately threaten life or health or threaten to damage equipment or buildings.

**Rationale: Implicit in EP 1 of this standard**

### EC.02.04.01

The laboratory manages laboratory equipment risks.

#### Elements of Performance for EC.02.04.01

1. The laboratory solicits input from individuals who operate and service equipment when it selects and acquires laboratory equipment.

**Rationale: Issue that should be left to the discretion of the organization**

**EC.02.05.01**

The laboratory manages risks associated with its utility systems.

**Elements of Performance for EC.02.05.01**

12. The laboratory's procedures address how to obtain emergency repair services.

**Rationale: Issue should be left to organization discretion**

**EC.02.05.07**

The laboratory inspects, tests, and maintains emergency power systems.

Note: This standard does not require laboratories to have the types of emergency power equipment described in the elements of performance of this standard. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.

**Elements of Performance for EC.02.05.07**

9. If a required emergency power system test fails, the laboratory implements measures to protect patients, visitors, and staff until necessary repairs or corrections are completed.

**Rationale: Part of regular operations/processes**

10. If a required emergency power system test fails, the laboratory performs a retest after making the necessary repairs or corrections.

**Rationale: Part of regular operations/processes**

**EC.03.01.01**

Staff and licensed independent practitioners are familiar with their roles and responsibilities relative to the environment of care.

**Elements of Performance for EC.03.01.01**

1. Staff and licensed independent practitioners can describe or demonstrate methods for eliminating and minimizing physical risks in the environment of care. (See also HR.01.04.01, EP 1)

**Rationale: Should be left to organization discretion**

3. Staff and licensed independent practitioners can describe or demonstrate how to report environment of care risks. (See also HR.01.04.01, EP 1)

**Rationale: Should be left to organization discretion**

### EC.04.01.01

The laboratory collects information to monitor conditions in the environment.

#### Elements of Performance for EC.04.01.01

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|-----|--|---|
| 13. | The laboratory conducts environmental tours at least annually. | <input type="checkbox"/> <input type="checkbox"/> |
|-----|--|---|

**Rationale: Should be left to organization discretion**

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|-----|--|---|
| 14. | The laboratory uses its tours to identify environmental deficiencies, hazards, and unsafe practices. | <input type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Should be left to organization discretion**

### EC.04.01.03

The laboratory analyzes identified environment of care issues.

#### Elements of Performance for EC.04.01.03

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|----|--|---|
| 1. | Representatives from the laboratory participate in the analysis of environment of care data. | <input type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Should be left to organization discretion**

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|----|---|---|
| 3. | Annually, representatives from the laboratory recommend one or more priorities for improving the environment of care. | <input type="checkbox"/> <input type="checkbox"/> |
|----|---|---|

**Rationale: Implicit in other EPs in this standard**

### EC.04.01.05

The laboratory improves its environment of care.

#### Elements of Performance for EC.04.01.05

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|----|---|---|
| 2. | The laboratory evaluates changes to determine if they resolved environmental safety issues. | <input type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Implicit in EC.04.01.05, EP 1**

## Human Resources Chapter

### HR.01.05.03

Staff participate in education and training.

#### Elements of Performance for HR.01.05.03

6. Staff participate in education and training that incorporates the skills of team communication, collaboration, and coordination of services. Staff participation is documented.



**Rationale: Content should be left to the discretion of the organization**

7. Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented.



**Rationale: Implicit in EPs 1 and 4 of this standard and in safety program reporting requirements in the Leadership chapter**

## Infection Prevention and Control Chapter

### IC.01.05.01

The organization plans for preventing and controlling infections associated with laboratory services.

#### Elements of Performance for IC.01.05.01

3. The laboratory describes in writing its method for evaluating the infection prevention and control activities associated with its laboratory services.



**Rationale: Process should be left to the discretion of the organization**

7. The laboratory has a method for communicating responsibilities about preventing and controlling infection to staff, visitors, and patients. (See also IC.02.01.01, EP 7)  
Note: The opportunity to prevent or control infections may encompass a range of activities (for example, while transporting specimens, wearing laboratory coats, or collecting specimens outside of the organization).



**Rationale: Duplicative of IC.02.01.01, EP 7**

8. The laboratory identifies methods for reporting or supporting the reporting of infection surveillance, prevention, and control information to local, state, and federal public health authorities in accordance with law and regulation. (See also IC.02.01.01, EP 9)



**Rationale: Duplicative of IC.02.01.01, EP 9**

### IC.01.06.01

The organization prepares to respond to an increased number of potentially infectious patients or patient specimens.

#### Elements of Performance for IC.01.06.01

5. If the organization decides to accept an increased number of potentially infectious patients or patient specimens, then the laboratory describes in writing its methods for managing laboratory services for these patients or specimens over an extended period of time.



**Rationale: Duplicative of EP 4 in this standard**

6. When the organization determines it is necessary, the laboratory activates its response to an increased number of potentially infectious patients or patient specimens.



**Rationale: Process should be left to the discretion of the organization**

## Information Management Chapter

### IM.01.01.01

The laboratory plans for managing information.

#### Elements of Performance for IM.01.01.01

1. The laboratory identifies the internal and external information needed to provide safe, quality laboratory services.



**Rationale: Duplicative of LD.03.02.01, EP 1**

3. The laboratory uses the identified information to guide development of processes to manage information.



**Rationale: Duplicative of LD.03.02.01, EP 1**

4. The laboratory selects staff and licensed independent practitioners to participate in the assessment, selection, integration, and use of information management systems for the delivery of laboratory services.





**Rationale: Duplicative of LD.03.02.01, EP 1**



**IM.01.01.03**

The laboratory plans for continuity of its information management processes.

**Elements of Performance for IM.01.01.03**

5. The laboratory's plan for managing interruptions to electronic information systems is tested for effectiveness according to time frames defined by the laboratory.  

**Rationale: Duplicative of EC utilities management requirements and EM emergency management requirements**



6. The laboratory implements its plan for managing interruptions to information processes to provide laboratory results needed for patient care. (See also IM.03.01.01, EP 1)  

**Rationale: Duplicative of EC utilities management requirements and EM emergency management requirements**

**IM.02.01.01**

The laboratory protects the privacy of health information.

**Elements of Performance for IM.02.01.01**



5. The laboratory monitors compliance with its policy on the privacy of health information.  

**Rationale: Implicit in EP 3 of this standard**

**IM.02.01.03**

The laboratory maintains the security and integrity of health information.

**Elements of Performance for IM.02.01.03**



8. The laboratory monitors compliance with its policies on the security and integrity of health information.  

**Rationale: Part of regular operations; process should be left to the discretion of the organization**

**IM.02.02.01**

The laboratory effectively manages the collection of health information.

**Elements of Performance for IM.02.02.01**

1. The laboratory uses uniform data sets to standardize data collection throughout the laboratory.  

**Rationale: Process should be left to the discretion of the organization**

## Leadership Chapter

### LD.01.07.01

Individual leaders have the knowledge needed for their roles in the laboratory or they seek guidance to fulfill their roles.

**Rationale: Issue should be left to the discretion of the organization. Applies to all EPs within this standard.**

#### Elements of Performance for LD.01.07.01

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|--|---|
| <p>2. Leaders are oriented to all of the following:</p> <ul style="list-style-type: none"> <li>- The laboratory's mission and vision</li> <li>- The laboratory's safety and quality goals</li> <li>- The laboratory's structure and the decision-making process</li> <li>- The development of the budget as well as the interpretation of the laboratory's financial statements</li> <li>- The population(s) served by the laboratory and any issues related to that population(s)</li> <li>- The individual and interdependent responsibilities and accountabilities of leaders as they relate to supporting the mission of the laboratory and to providing safe and quality care</li> <li>- Applicable law and regulation</li> </ul> | <input type="checkbox"/> <input type="checkbox"/> |
| <p>3. The laboratory director has access to information and training in areas where he or she needs additional skills or expertise.</p>  | <input type="checkbox"/> <input type="checkbox"/> |

### LD.02.03.01

Leaders regularly communicate with each other on issues of safety and quality.

#### Elements of Performance for LD.02.03.01

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| <p>1. Leaders discuss issues that affect the laboratory and the population(s) it serves, including the following:</p> <ul style="list-style-type: none"> <li>- Performance improvement activities</li> <li>- Reported safety and quality issues</li> <li>- Proposed solutions and their impact on the laboratory's resources</li> <li>- Reports on key quality measures and safety indicators</li> <li>- Safety and quality issues specific to the population served</li> <li>- Input from the population(s) served</li> </ul> | <input type="checkbox"/> <input type="checkbox"/> |
| <p><b>Rationale: Leave to organization discretion. Also implicit in other requirements such as LD.04.04.05</b></p>   |   |
| <p>2. The laboratory establishes time frames for the discussion of issues that affect the laboratory and the population(s) it serves.</p>  | <input type="checkbox"/> <input type="checkbox"/> |

**Rationale: Leave to organization discretion**

### LD.03.01.01

Leaders create and maintain a culture of safety and quality throughout the laboratory.

#### Elements of Performance for LD.03.01.01

3. Leaders provide opportunities for all individuals who work in the laboratory to participate in safety and quality initiatives.

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**Rationale: Process should be left to the discretion of the organization**

6. Leaders provide education that focuses on safety and quality for all individuals.

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**Rationale: Process should be left to the discretion of the organization**

7. Leaders establish a team approach among all staff at all levels.

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**Rationale: Process should be left to the discretion of the organization**

8. All individuals who work in the laboratory, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality. (See also LD.04.04.05, EP 6)

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**Rationale: Process should be left to the discretion of the organization**

9. Literature and advisories relevant to patient safety are available to all individuals who work in the laboratory.

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**Rationale: Process should be left to the discretion of the organization**

10. Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the laboratory.

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**Rationale: Process should be left to the discretion of the organization**

### LD.04.02.03

Ethical principles guide the laboratory's business practices.

#### Elements of Performance for LD.04.02.03

3. The laboratory follows ethical practices for marketing and billing.

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**Rationale: Part of operations**



4. Marketing materials accurately represent the laboratory and address the services that the laboratory provides either directly or by contractual arrangement.

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**Rationale: Part of regular operations/processes**

### LD.04.03.07

Patients with comparable needs receive the same standard of laboratory services throughout the laboratory.

#### Elements of Performance for LD.04.03.07

2. Laboratory services are consistent with the laboratory's mission, vision, and goals.

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**Rationale: Issue should be left to the discretion of the organization**

### LD.04.04.03

New or modified services or processes are well designed.

#### Elements of Performance for LD.04.04.03

7. Leaders involve staff and patients in the design of new or modified services or processes.

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**Rationale: Process should be left to the discretion of the organization**

## Performance Improvement Chapter

### PI.01.01.01

The laboratory collects data to monitor its performance.

#### Elements of Performance for PI.01.01.01

30. The laboratory considers collecting data on staff opinions and needs.  
Note: If the laboratory has not collected data on this topic, consideration can be demonstrated through methods such as interviews or meeting minutes.

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**Rationale: Issue should be left to organization discretion**

### PI.02.01.01

The laboratory compiles and analyzes data.

#### Elements of Performance for PI.02.01.01

1. The laboratory compiles data into formats that enable them to be analyzed.

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**Rationale: Issue should be left to organization discretion**

2. The laboratory identifies the frequency for data analysis.

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**Rationale: Issue should be left to organization discretion**

### PI.03.01.01

The laboratory improves performance.

#### Elements of Performance for PI.03.01.01

1. Laboratory leaders prioritize the identified improvement opportunities. (See also PI.02.01.01, EP 8)

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**Rationale: Issue should be left to organization discretion**

3. The laboratory evaluates actions to confirm that they resulted in improvements.

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**Rationale: Duplicative of PI.03.01.01, EPs 2 and 4**

## Transplant Safety Chapter

### TS.03.01.01

The organization uses standardized procedures for managing tissues.

#### Elements of Performance for TS.03.01.01

4. The organization coordinates its acquisition, receipt, storage, and issuance of tissues throughout the organization.

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**Rationale: Part of regular operations that should be left to the discretion of the organization**

## Waived Testing Chapter

### WT.01.01.01

Policies and procedures for waived tests are established, current, approved, and readily available.

#### Elements of Performance for WT.01.01.01

7. The criteria for confirmatory testing are followed as specified in the waived testing written procedures.

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**Rationale: Part of regular operations that should be left to the discretion of the organization**

8. Clinical use of results is consistent with the organization's policies and the manufacturers' recommendations for waived tests.

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**Rationale: Part of regular operations that should be left to the discretion of the organization; covered by law and regulation or other external requirements**

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