

# History Tracking Report: 2009 to 2010 Requirements

## Accreditation Program: Laboratory

### 2009 Chapter: Management of Human Resources

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#### **Standard HR.1.10**

##### **2009 Standard Text:**

The {jc}organization{/2} provides an adequate number and skill mix of staff consistent with the {jc}organization{/2}'s staffing plan.

#### **Standard LD.03.06.01**

##### **2010 Standard Text:**

Those who work in the laboratory are focused on improving safety and quality.

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**2009 Standard:** HR.1.10**2009 EP:** 6**2009 EP Text:**

The organization has an adequate number of staff to provide relevant, timely data and avoid delays that could jeopardize the quality of specimens, cultures, differential testing methods, or results.

**Revision Type:** Consolidate**2010 Standard:** LD.03.06.01**2010 EP:** 3**2010 EP Text:**

Leaders provide for a sufficient number and mix of individuals to support safe, quality laboratory services.

Note 1: The following indicators demonstrate adequacy of technical and support staff to meet the service needs of the patients, including evenings, weekends, and holidays:

- Overtime is not significantly high.
- There are no lapses in quality control and proficiency testing.
- Performance testing and documentation of equipment maintenance have no lapses.
- Turnaround time is not prolonged.
- The quality of specimens, cultures, differential testing methods, or results is not jeopardized.

Note 2: The following indicators demonstrate adequacy of supervisory staff to meet the service needs of the patients, including evenings, weekends, and holidays:

- The background and experience of supervisory staff are consistent with work assignments and responsibilities.
- Quality control, proficiency testing, and maintenance are well performed and evaluated.
- Policies and procedures are current and well executed.
- Turnaround time is satisfactory.
- Record systems are well organized and current.
- Quality improvement mechanisms are implemented.
- Test analyses and specimen examinations are monitored to ensure that acceptable levels of analytic performance are maintained.

**2009 Standard:** HR.1.10**2009 EP:** 7**2009 EP Text:**

An individual qualified to provide technical consultation or supervision and general supervision is on duty or is available at all times (either on site, by telephone, or by electronic consultation) that testing is required. Note: Qualifications to provide technical consultation or supervision and general supervision are described in CLIA '88 under Subpart M – Personnel for Nonwaived Testing §493.1351 - §493.1495. A complete description of the requirement is located at <http://www.cms.hhs.gov/clia> or <http://www.phppo.cdc.gov/clia>.

**Revision Type:** Retain**2010 Standard:** HR.01.01.01**2010 EP:** 1**2010 EP Text:**

An individual qualified to provide technical consultation or supervision and general supervision is on duty or is available whenever testing requires consultation or supervision.

Note: This individual can be available on site, by telephone, or by electronic consultation.

Footnote: Qualifications to provide technical consultation or supervision and general supervision are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

**Standard HR.1.15**

**2009 Standard Text:**

One or more qualified professionals direct pathology and clinical laboratory services.

**2009 Standard:** HR.1.15

**2009 EP:** 1

**2009 EP Text:**

**Revision Type:** Split

A qualified individual directs clinical laboratory services.\* \*Note: Directors of embryology laboratories have a doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation. The director also has two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures. Directors of embryological laboratories who are not physicians or doctoral scientists, but were functioning as the director on or before July, 20, 1999, are considered qualified.

**2009 Standard:** HR.1.15

**2009 EP:** 1

**2009 EP Text:**

**Revision Type:** Split

A qualified individual directs clinical laboratory services.\* \*Note: Directors of embryology laboratories have a doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation. The director also has two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures. Directors of embryological laboratories who are not physicians or doctoral scientists, but were functioning as the director on or before July, 20, 1999, are considered qualified.

**Standard HR.01.02.03**

**2010 Standard Text:**

One or more qualified professionals direct pathology and clinical laboratory services.

**2010 Standard:** HR.01.02.03

**2010 EP:** 4

**2010 EP Text:**

A qualified individual directs clinical laboratory services.  
Footnote: Qualifications of the individual directing clinical laboratory services are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

**2010 Standard:** HR.01.02.03

**2010 EP:** 9

**2010 EP Text:**

A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:

- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation
- Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.

Note: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.

**2009 Standard:** HR.1.15**2009 EP:** 2**2009 EP Text:**

The qualifications of the laboratory director meet federal (42 CFR section 493) and state law and regulation.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 1**2010 EP Text:**

The qualifications of the laboratory director of record meet the requirements set forth in federal and state law and regulation. (See also QSA.03.01.01, EP 1)

Footnote: Qualifications of the laboratory director are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

**2009 Standard:** HR.1.15**2009 EP:** 3**2009 EP Text:**

Either a qualified physician or doctoral scientist directs a hospital laboratory.

**Revision Type:** Delete:NE**2010 Standard:** N/A**2010 EP Text:**

No EP

**2009 Standard:** HR.1.15**2009 EP:** 4**2009 EP Text:**

In a hospital where the director provides clinical consultation or medical opinion, he or she is a physician, preferably a pathologist.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 3**2010 EP Text:**

A qualified individual provides clinical consultation.

Note: In hospitals, it is preferable to have a pathologist providing clinical consultation.

Footnote: Qualifications of the individual providing clinical consultation are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

**2009 Standard:** HR.1.15**2009 EP:** 5**2009 EP Text:**

A pathologist directs anatomic pathology services.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 5**2010 EP Text:**

A pathologist directs anatomic pathology services.

**2009 Standard:** HR.1.15**2009 EP:** 6**2009 EP Text:**

A pathologist or another physician qualified in cytopathology directs cytopathology services.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 6**2010 EP Text:**

A pathologist or another physician qualified in cytology directs cytology services.

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**2009 Standard:** HR.1.15**2009 EP:** 7**2009 EP Text:**

A pathologist or another physician qualified in immunohematology, hemotherapy, and blood banking directs blood-transfusion services.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 7**2010 EP Text:**

A pathologist or another physician qualified in immunohematology, hemotherapy, and blood banking directs blood-transfusion services. (See also LD.04.05.01, EP 7)

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**2009 Standard:** HR.1.15**2009 EP:** 8**2009 EP Text:**

The director possesses effective management skills, which include delegating responsibility to others in the department or laboratory.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 2**2010 EP Text:**

The laboratory director possesses effective management skills.  
Note: An example of effective management is the ability of the laboratory director to delegate responsibility to others in the department or laboratory who have the qualifications to perform those responsibilities. (See also LD.04.05.01, EP 7)

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**2009 Standard:** HR.1.15**2009 EP:** 9**2009 EP Text:**

A pathologist, doctoral scientist, or other qualified physician with specialized training or experience in molecular pathology directs molecular pathology services.

**Revision Type:** Retain**2010 Standard:** HR.01.02.03**2010 EP:** 8**2010 EP Text:**

A pathologist, doctoral scientist, or other qualified physician with specialized training or experience in molecular pathology directs molecular pathology services.

**Standard HR.1.20**

**2009 Standard Text:**

Staff qualifications are consistent with his or her job responsibilities.

**2009 Standard:** HR.1.20

**2009 EP:** 2

**2009 EP Text:**

**Revision Type:** Retain

When the {jc}organization{/2} requires current licensure, certification, or registration, but these credentials are not required by law or regulation, the {jc}organization{/2} verifies these credentials at the time of hire and upon expiration of the credentials.

**2009 Standard:** HR.1.20

**2009 EP:** 3

**2009 EP Text:**

**Revision Type:** Retain

When current licensure, certification, or registration are required by law or regulation to practice a profession\*, the {jc}organization{/2} verifies these credentials with the primary source at the time of hire and upon expiration of the credentials. Note: It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented. For additional information, see "primary source" in the Glossary. Note: A primary source of information may designate another agency to communicate credentials information. The designated agency then can be used as a primary source. Note: An external organization [for example, a credentials verification organization (CVO)] may be used to collect credentials information. A CVO must meet the CVO guidelines listed in the Glossary. \*Profession is a specialized work function within society, generally performed by a professional. It often refers specifically to fields that require extensive study and mastery of specialized knowledge and skills.

**2009 Standard:** HR.1.20

**2009 EP:** 4

**2009 EP Text:**

**Revision Type:** Retain

The {jc}organization{/2} also verifies the education, experience, and competence appropriate for assigned responsibilities

**Standard HR.01.02.05**

**2010 Standard Text:**

The laboratory verifies staff qualifications.

**2010 Standard:** HR.01.02.05

**2010 EP:** 2

**2010 EP Text:**

When the laboratory requires licensure, registration, or certification not required by law and regulation, the laboratory both verifies these credentials and documents this verification at time of hire and when credentials are renewed. (See also HR.01.02.07, EP 2)

**2010 Standard:** HR.01.02.05

**2010 EP:** 1

**2010 EP Text:**

When law or regulation requires laboratory service providers to be currently licensed, certified, or registered to practice their professions, the laboratory both verifies these credentials with the primary source and documents this verification when a provider is hired and when his or her credentials are renewed. (See also HR.01.02.07, EP 2)  
 Note 1: It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented.  
 Note 2: A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source.  
 Note 3: An external organization (for example, a credentials verification organization (CVO)) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.

**2010 Standard:** HR.01.02.05

**2010 EP:** 3

**2010 EP Text:**

The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities.  
 Footnote: Education and experience requirements are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

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| <p><b>2009 Standard:</b> HR.1.20<br/> <b>2009 EP Text:</b><br/>                 The information obtained from EPs 2-4 is used in making decisions regarding staff job responsibilities.</p>  | <p><b>2009 EP:</b> 7<br/> <b>Revision Type:</b> Retain</p>  | <p><b>2010 Standard:</b> HR.01.02.05      <b>2010 EP:</b> 6<br/> <b>2010 EP Text:</b><br/>                 The laboratory uses the following information to make decisions about staff job responsibilities:<br/>                 - Verified licensure, certification, or registration required by law or regulation or the laboratory<br/>                 - Verified education and experience</p> |
| <p><b>2009 Standard:</b> HR.1.20<br/> <b>2009 EP Text:</b><br/>                 All staff that provide {j}patient{/1} care, treatment, and services possess a license, certification, or registration as required by law and regulation.</p> | <p><b>2009 EP:</b> 8<br/> <b>Revision Type:</b> Split</p>   | <p><b>2010 Standard:</b> HR.01.02.07      <b>2010 EP:</b> 1<br/> <b>2010 EP Text:</b><br/>                 All staff who provide laboratory services possess a current license, certification, or registration, in accordance with law and regulation.</p>  |
| <p><b>2009 Standard:</b> HR.1.20<br/> <b>2009 EP Text:</b><br/>                 All staff that provide {j}patient{/1} care, treatment, and services possess a license, certification, or registration as required by law and regulation.</p> | <p><b>2009 EP:</b> 8<br/> <b>Revision Type:</b> Split</p>   | <p><b>2010 Standard:</b> HR.01.02.07      <b>2010 EP:</b> 2<br/> <b>2010 EP Text:</b><br/>                 Staff who provide laboratory services practice within the scope of their license, certification, or registration and as required by law and regulation. (See also HR.01.02.05, EPs 1 and 2)</p>  |
| <p><b>2009 Standard:</b> HR.1.20<br/> <b>2009 EP Text:</b><br/>                 Supervisory staff has training and experience to supervise.</p>  | <p><b>2009 EP:</b> 18<br/> <b>Revision Type:</b> Retain</p> | <p><b>2010 Standard:</b> HR.01.03.01      <b>2010 EP:</b> 3<br/> <b>2010 EP Text:</b><br/>                 Supervisory staff have training and experience to supervise.</p>   |
| <p><b>2009 Standard:</b> HR.1.20<br/> <b>2009 EP Text:</b><br/>                 Staff supervises students when they are performing laboratory procedures.</p>  | <p><b>2009 EP:</b> 19<br/> <b>Revision Type:</b> Retain</p> | <p><b>2010 Standard:</b> HR.01.02.07      <b>2010 EP:</b> 5<br/> <b>2010 EP Text:</b><br/>                 Staff supervise and observe students when they are performing laboratory procedures.</p>   |

**Standard HR.1.25**

**2009 Standard Text:**

The {jc}organization{/2} may assign disaster responsibilities to volunteer practitioners.

**Standard EM.02.02.15**

**2010 Standard Text:**

During disasters, the laboratory may assign disaster responsibilities to volunteer practitioners who are not licensed independent practitioners, but who are required by law and regulation to have a license, certification, or registration.

Note: While this standard allows for a method to streamline the process for verifying identification and licensure, certification, or registration, the elements of performance are intended to safeguard against inadequate care during a disaster.

**2009 Standard:** HR.1.25

**2009 EP:** 1

**2009 EP Text:**

Disaster responsibilities are assigned only when the following two conditions are present: the emergency management plan has been activated, and the {jc}organization{/2} is unable to meet immediate {jc}patient{/1} needs.

**Revision Type:** Retain

**2010 Standard:** EM.02.02.15

**2010 EP:** 1

**2010 EP Text:**

The laboratory assigns disaster responsibilities to volunteer practitioners who are not licensed independent practitioners only when the Emergency Operations Plan has been activated in response to a disaster and the laboratory is unable to meet immediate patient needs.

**2009 Standard:** HR.1.25

**2009 EP:** 2

**2009 EP Text:**

The {jc}organization{/2} identifies in writing the individual(s) responsible for assigning disaster responsibilities.

**Revision Type:** Retain

**2010 Standard:** EM.02.02.15

**2010 EP:** 2

**2010 EP Text:**

The laboratory identifies, in writing, those individuals responsible for assigning disaster responsibilities to volunteer practitioners who are not licensed independent practitioners.

**2009 Standard:** HR.1.25

**2009 EP:** 3

**2009 EP Text:**

The {jc}organization{/2} describes in writing a mechanism (for example, direct observation, mentoring, and clinical record review) to oversee the professional performance of volunteer practitioners who are assigned disaster responsibilities.

**Revision Type:** Retain

**2010 Standard:** EM.02.02.15

**2010 EP:** 4

**2010 EP Text:**

The laboratory describes, in writing, how it will oversee the performance of volunteer practitioners who are not licensed independent practitioners who have been assigned disaster responsibilities. Examples of methods for overseeing their performance include direct observation, mentoring, and clinical record review.

**2009 Standard:** HR.1.25

**2009 EP:** 4

**2009 EP Text:**

The {jc}organization{/2} has a mechanism to identify volunteer practitioners that have been assigned disaster responsibilities.

**Revision Type:** Retain

**2010 Standard:** EM.02.02.15

**2010 EP:** 3

**2010 EP Text:**

The laboratory determines how it will distinguish volunteer practitioners who are not licensed independent practitioners from its staff.  
Note: This distinction could be made by using badges, vests, wristbands, or other articles.

**2009 Standard:** HR.1.25**2009 EP:** 5**2009 EP Text:**

For volunteer practitioners to be assigned disaster responsibilities, the organization obtains for each volunteer practitioner at a minimum, a valid government-issued photo identification issued by a state or federal agency (e.g., driver's license or passport) and at least one of the following: A current health care organization [such as a long term care, ambulatory care, laboratory, or hospital] picture identification card that clearly identifies professional designation A current license, certification, or registration Primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT\*), or MRC, ESAR-VHP, or other recognized state or federal organizations or groups Identification indicating that the individual has been granted authority to render patient care, treatment, and services in disaster circumstances (such authority having been granted by a federal, state, or municipal entity) Identification by current organization member(s) who possesses personal knowledge regarding the volunteer practitioner's qualifications\*

**DMAT** – A group of medical and support personnel designed to provide emergency medical care during a disaster or other unusual event. The DMAT is a component of the National Disaster Medical System (NDMS). The Department of Health and Human Services in partnership with other Federal Agencies such as Department of Defense, Department of Veterans Affairs, and the Federal Emergency Management Agency administer the program.

**Revision Type:** Retain**2010 Standard:** EM.02.02.15**2010 EP:** 5**2010 EP Text:**

Before a volunteer practitioner who is not a licensed independent practitioner is considered eligible to function as a practitioner, the laboratory obtains his or her valid government-issued photo identification (for example, a driver's license or passport) and one of the following:

- A current picture identification card from a health care organization that clearly identifies professional designation
- A current license, certification, or registration
- Primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice)
- Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT), the Medical Reserve Corps (MRC), the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), or other recognized state or federal response organization or group
- Identification indicating that the individual has been granted authority by a government entity to provide laboratory services in disaster circumstances
- Confirmation by laboratory staff with personal knowledge of the volunteer practitioner's ability to act as a qualified practitioner during a disaster

**2009 Standard:** HR.1.25**2009 EP:** 6**2009 EP Text:**

Primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) begins as soon as the immediate situation is under control, and is completed within 72 hours from the time the volunteer practitioner presents to the organization. Note: In the extraordinary circumstance that primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) cannot be completed in 72 hours (for example, no means of communication or a lack of resources), it is expected that it be done as soon as possible. In this extraordinary circumstance, there must be documentation of the following: why primary source verification could not be performed in the required time frame; evidence of a demonstrated ability to continue to provide adequate care, treatment, and services; and an attempt to rectify the situation as soon as possible. Primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) would not be required if the volunteer practitioner has not provided care, treatment, and services under the disaster responsibilities.

**Revision Type:** Split**2010 Standard:** EM.02.02.15**2010 EP:** 8**2010 EP Text:**

Primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice) of volunteer practitioners who are not licensed independent practitioners occurs as soon as the disaster is under control or within 72 hours from the time the volunteer practitioner presents him- or herself to the laboratory, whichever comes first. If primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice) for a volunteer practitioner who is not a licensed independent practitioner cannot be completed within 72 hours due to extraordinary circumstances, the laboratory documents all of the following:

- Reason(s) why it could not be performed within 72 hours of the practitioner's arrival
- Evidence of the volunteer practitioner's demonstrated ability to continue to provide adequate laboratory services
- Evidence of the laboratory's attempt to perform primary source verification as soon as possible

**2009 Standard:** HR.1.25**2009 EP:** 6**2009 EP Text:**

Primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) begins as soon as the immediate situation is under control, and is completed within 72 hours from the time the volunteer practitioner presents to the organization. Note: In the extraordinary circumstance that primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) cannot be completed in 72 hours (for example, no means of communication or a lack of resources), it is expected that it be done as soon as possible. In this extraordinary circumstance, there must be documentation of the following: why primary source verification could not be performed in the required time frame; evidence of a demonstrated ability to continue to provide adequate care, treatment, and services; and an attempt to rectify the situation as soon as possible. Primary source verification of licensure, certification, or registration (if required by law and regulation to practice a profession) would not be required if the volunteer practitioner has not provided care, treatment, and services under the disaster responsibilities.

**Revision Type:** Split**2010 Standard:** EM.02.02.15**2010 EP:** 9**2010 EP Text:**

If, due to extraordinary circumstances, primary source verification of licensure of the volunteer practitioner cannot be completed within 72 hours of the practitioner's arrival, it is performed as soon as possible. Note: Primary source verification of licensure, certification, or registration is not required if the volunteer practitioner has not provided laboratory services under his or her assigned disaster responsibilities.

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**2009 Standard:** HR.1.25**2009 EP:** 7**2010 Standard:** EM.02.02.15**2010 EP:** 6**2009 EP Text:****Revision Type:** Retain**2010 EP Text:**

The {jc}organization{/2} oversees the professional practice of volunteer practitioners.

During a disaster, the laboratory oversees the performance of each volunteer practitioner who is not a licensed independent practitioner.

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**2009 Standard:** HR.1.25**2009 EP:** 8**2010 Standard:** EM.02.02.15**2010 EP:** 7**2009 EP Text:****Revision Type:** Retain**2010 EP Text:**

The {jc}organization{/2} makes a decision (based on information obtained regarding the professional practice of the volunteer practitioner) within 72 hours related to the continuation of the disaster responsibilities initially assigned.

Based on its oversight of each volunteer practitioner who is not a licensed independent practitioner, the laboratory determines within 72 hours after the practitioner's arrival whether assigned disaster responsibilities should continue.

**Standard HR.2.10**

**2009 Standard Text:**

The {jc}organization{/2} provides initial orientation.

**2009 Standard:** HR.2.10

**2009 EP:** 1

**2009 EP Text:**

**Revision Type:** Retain

The {jc}organization{/2} determines what key elements of orientation should occur before staff provide care, treatment, and services.

**2009 Standard:** HR.2.10

**2009 EP:** 2

**2009 EP Text:**

**Revision Type:** Retain

The {jc}organization{/2} orients staff to the identified key elements prior to the provision of care, treatment, and services.

**2009 Standard:** HR.2.10

**2009 EP:** 3

**2009 EP Text:**

**Revision Type:** Delete:NE

As appropriate, staff orientation addresses the {jc}organization{/2}'s mission and goals.

**2009 Standard:** HR.2.10

**2009 EP:** 4

**2009 EP Text:**

**Revision Type:** Retain

As appropriate, staff orientation addresses organizationwide policies and procedures (including safety and infection control) and laboratory policies and procedures.

**2009 Standard:** HR.2.10

**2009 EP:** 5

**2009 EP Text:**

**Revision Type:** Retain

As appropriate, staff orientation addresses specific job duties and responsibilities and service, setting, or program-specific job duties and responsibilities related to safety and infection control.

**Standard HR.01.04.01**

**2010 Standard Text:**

The laboratory provides orientation to staff.

**2010 Standard:** HR.01.04.01

**2010 EP:** 1

**2010 EP Text:**

The laboratory determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3)  
Note: Key safety content may include specific processes and procedures related to the provision of laboratory services, the environment of care, and infection control.

**2010 Standard:** HR.01.04.01

**2010 EP:** 2

**2010 EP Text:**

The laboratory orients its staff to the key safety content before staff provides laboratory services. Completion of this orientation is documented. (See also IC.01.05.01, EP 6)

**2010 Standard:** N/A

**2010 EP Text:**

No EP

**2010 Standard:** HR.01.04.01

**2010 EP:** 3

**2010 EP Text:**

The laboratory orients staff on the following: Organization-wide and laboratory-specific policies and procedures related to job duties and responsibilities. Completion of this orientation is documented.

**2010 Standard:** HR.01.04.01

**2010 EP:** 4

**2010 EP Text:**

The laboratory orients staff on the following: Their specific job duties and responsibilities, including those related to infection prevention and control. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; IC.02.01.01, EP 7)

**2009 Standard:** HR.2.10

**2009 EP:** 6

**2009 EP Text:**

As appropriate, staff are oriented to each pre-analytic, analytic and post-analytic activity\* he or she will be expected to perform. \* For each test method or instrument, activities include, but are not limited to:Pre-analytic: Patient identification and preparation, specimen collection, labeling, handling, processing or preparation, preservation or fixation, transportation and storage; instrument preventive maintenance, troubleshooting and calibration procedures; quality control, documentation of all quality control activities including instrument and procedural calibrations and maintenance.Analytic: Test performance, knowledge of reagent stability and storagePost-analytic: Results reporting (including assessing and verifying the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results), identifying factors that may adversely affect test performance, correcting identified problems, or notifying the supervisor when problems arise.

**Revision Type:** Retain

**2010 Standard:** HR.01.04.01

**2010 EP:** 9

**2010 EP Text:**

Staff is oriented to each preanalytic, analytic, and postanalytic activity he or she will be expected to perform.  
 Note 1: Preanalytic activity includes patient identification and preparation; specimen collection, labeling, handling, processing or preparation, preservation, and fixation; transportation and storage; instrument preventive maintenance, troubleshooting and calibration procedures; and quality control and documentation of all quality control activities, including instrument and procedural calibrations and maintenance.  
 Note 2: Analytic activity includes test performance and knowledge of reagent stability and storage.  
 Note 3: Postanalytic activity includes results reporting (including assessing and verifying the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results), identifying factors that may adversely affect test performance, correcting identified problems, or notifying the supervisor when problems arise.

**2009 Standard:** HR.2.10

**2009 EP:** 7

**2009 EP Text:**

As appropriate, staff orientation addresses cultural diversity and sensitivity

**Revision Type:** Retain

**2010 Standard:** HR.01.04.01

**2010 EP:** 5

**2010 EP Text:**

The laboratory orients staff on the following: Sensitivity to cultural diversity based on their job duties and responsibilities. Completion of this orientation is documented.

**2009 Standard:** HR.2.10

**2009 EP:** 8

**2009 EP Text:**

Staff orientation includes education about the rights of patients and ethical aspects of care, treatment, and services and the process used to address ethical issues.

**Revision Type:** Retain

**2010 Standard:** HR.01.04.01

**2010 EP:** 6

**2010 EP Text:**

The laboratory orients staff on the following: Patient rights, including ethical aspects of laboratory services and the process used to address ethical issues based on their job duties and responsibilities. Completion of this orientation is documented.

**2009 Standard:** HR.2.10

**2009 EP:** 11

**2009 EP Text:**

The organization documents that staff have completed orientation and have been evaluated for competence in performing required laboratory tasks as well as other parameters defined in his or her job descriptions prior to analyzing patient specimens.

**Revision Type:** Retain

**2010 Standard:** HR.01.04.01

**2010 EP:** 10

**2010 EP Text:**

Prior to performing laboratory duties, the laboratory director or supervisor documents that staff have completed orientation and have demonstrated competence in performing their required duties.

**2009 Standard:** HR.2.10**2009 EP:** 12**2010 Standard:** HR.01.04.01**2010 EP:** 12**2009 EP Text:****Revision Type:** Retain**2010 EP Text:**

Documentation of orientation participation includes written approval by the laboratory director or appropriate supervisor noting that the staff member is capable of performing laboratory duties, and confirmation by the person that he or she feels qualified after orientation to perform the tasks required prior to analyzing patient specimens.

Prior to performing laboratory duties, the staff member affirms, in writing, that he or she can perform the duties for which orientation was provided.

**Standard HR.2.20**

**2009 Standard Text:**

Staff as appropriate, can describe or demonstrate their roles and responsibilities relative to safety.

**2009 Standard:** HR.2.20

**2009 EP:** 1

**2009 EP Text:**

Staff as appropriate, can describe or demonstrate risks within the organization's environment.

**Revision Type:** Consolidate

**2009 Standard:** HR.2.20

**2009 EP:** 2

**2009 EP Text:**

Staff as appropriate, can describe or demonstrate actions to eliminate, minimize, or report risks

**Revision Type:** Consolidate

**2009 Standard:** HR.2.20

**2009 EP:** 3

**2009 EP Text:**

Staff as appropriate, can describe or demonstrate procedures to follow in the event of an incident

**Revision Type:** Retain

**2009 Standard:** HR.2.20

**2009 EP:** 4

**2009 EP Text:**

Staff as appropriate, can describe or demonstrate reporting processes for common problems, failures, and user errors.

**Revision Type:** Retain

**Standard EC.03.01.01**

**2010 Standard Text:**

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

**2010 Standard:** EC.03.01.01

**2010 EP:** 1

**2010 EP Text:**

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)

**2010 Standard:** EC.03.01.01

**2010 EP:** 1

**2010 EP Text:**

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)

**2010 Standard:** EC.03.01.01

**2010 EP:** 2

**2010 EP Text:**

Staff and licensed independent practitioners can describe or demonstrate actions to take in the event of an environment of care incident. (See also HR.01.04.01, EP 1)

**2010 Standard:** EC.03.01.01

**2010 EP:** 3

**2010 EP Text:**

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

**Standard HR.2.30**

**2009 Standard Text:**

Ongoing education, including in-services, training, and other activities, maintains and improves staff competence.

**Standard HR.01.05.03**

**2010 Standard Text:**

Staff participate in education and training.

**2009 Standard:** HR.2.30

**2009 EP:** 1

**2009 EP Text:**

Staff training occurs when job responsibilities or duties change

**Revision Type:** Consolidate

**2010 Standard:** HR.01.05.03

**2010 EP:** 4

**2010 EP Text:**

Staff participate in education and training whenever staff responsibilities change, including when a test, methodology, or instrumentation changes. Staff participation is documented. (See also HR.01.06.01, EP 21)

**2009 Standard:** HR.2.30

**2009 EP:** 2

**2009 EP Text:**

Staff participate in ongoing in-services, training, or other activities to increase knowledge of work-related issues

**Revision Type:** Consolidate

**2010 Standard:** HR.01.05.03

**2010 EP:** 1

**2010 EP Text:**

Staff participate in education and training to maintain or increase their competency. Staff participation is documented.

**2009 Standard:** HR.2.30

**2009 EP:** 3

**2009 EP Text:**

Ongoing in-services and other education and training of staff are appropriate to the needs of the population(s) served and comply with law and regulation

**Revision Type:** Consolidate

**2010 Standard:** HR.01.05.03

**2010 EP:** 5

**2010 EP Text:**

Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented.

**2009 Standard:** HR.2.30

**2009 EP:** 4

**2009 EP Text:**

Ongoing in-services, training, or other staff activities emphasize specific job-related aspects of safety and infection prevention and control

**Revision Type:** Delete:NE

**2010 Standard:** N/A

**2010 EP Text:**

No EP

**2009 Standard:** HR.2.30

**2009 EP:** 5

**2009 EP Text:**

Ongoing in-services, training, or other staff education incorporate methods of team training, when appropriate

**Revision Type:** Consolidate

**2010 Standard:** HR.01.05.03

**2010 EP:** 6

**2010 EP Text:**

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

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|--|---|---|
| <p><b>2009 Standard:</b> HR.2.30<br/> <b>2009 EP Text:</b><br/>                 Ongoing in-services, training, or other staff education reinforce the need and ways to report unanticipated adverse events</p>   | <p><b>2009 EP:</b> 6<br/> <b>Revision Type:</b> Consolidate</p> | <p><b>2010 Standard:</b> HR.01.05.03      <b>2010 EP:</b> 7<br/> <b>2010 EP Text:</b><br/>                 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.</p>                       |
| <p><b>2009 Standard:</b> HR.2.30<br/> <b>2009 EP Text:</b><br/>                 Ongoing in-services or other staff education are offered in response to learning needs identified through performance improvement findings and other data analysis (that is, data from staff surveys, performance evaluations, or other needs assessments)</p> | <p><b>2009 EP:</b> 7<br/> <b>Revision Type:</b> Delete:NE</p>   | <p><b>2010 Standard:</b> N/A<br/> <b>2010 EP Text:</b><br/>                 No EP</p>   |
| <p><b>2009 Standard:</b> HR.2.30<br/> <b>2009 EP Text:</b><br/>                 Ongoing staff education is documented</p>  | <p><b>2009 EP:</b> 8<br/> <b>Revision Type:</b> Split</p>       | <p><b>2010 Standard:</b> HR.01.05.03      <b>2010 EP:</b> 1<br/> <b>2010 EP Text:</b><br/>                 Staff participate in education and training to maintain or increase their competency. Staff participation is documented.</p>   |
| <p><b>2009 Standard:</b> HR.2.30<br/> <b>2009 EP Text:</b><br/>                 Ongoing staff education is documented</p>  | <p><b>2009 EP:</b> 8<br/> <b>Revision Type:</b> Split</p>       | <p><b>2010 Standard:</b> HR.01.05.03      <b>2010 EP:</b> 4<br/> <b>2010 EP Text:</b><br/>                 Staff participate in education and training whenever staff responsibilities change, including when a test, methodology, or instrumentation changes. Staff participation is documented. (See also HR.01.06.01, EP 21)</p> |
| <p><b>2009 Standard:</b> HR.2.30<br/> <b>2009 EP Text:</b><br/>                 Ongoing staff education is documented</p>  | <p><b>2009 EP:</b> 8<br/> <b>Revision Type:</b> Split</p>       | <p><b>2010 Standard:</b> HR.01.05.03      <b>2010 EP:</b> 5<br/> <b>2010 EP Text:</b><br/>                 Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented.</p>   |
| <p><b>2009 Standard:</b> HR.2.30<br/> <b>2009 EP Text:</b><br/>                 Ongoing staff education is documented</p>  | <p><b>2009 EP:</b> 8<br/> <b>Revision Type:</b> Split</p>       | <p><b>2010 Standard:</b> HR.01.05.03      <b>2010 EP:</b> 6<br/> <b>2010 EP Text:</b><br/>                 Staff participate in education and training that incorporates the skills of team communication, collaboration, and coordination of services. Staff participation is documented.</p>                                      |

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**2009 Standard:** HR.2.30**2009 EP:** 8**2010 Standard:** HR.01.05.03**2010 EP:** 7**2009 EP Text:****Revision Type:** Split**2010 EP Text:**

Ongoing staff education is documented

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.

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**2009 Standard:** HR.2.30**2009 EP:** 9**2010 Standard:** N/A**2009 EP Text:****Revision Type:** Delete:NE**2010 EP Text:**

Supervisory staff, attendance at outside workshops, institutes, and local, regional, or national society meetings occurs as feasible

No EP

**Standard HR.3.10**

**2009 Standard Text:**

Staff competence to perform job responsibilities is assessed, demonstrated, and maintained.

**2009 Standard:** HR.3.10

**2009 EP:** 13

**2009 EP Text:**

The laboratory, technical consultant, or technical supervisor regularly assesses the continued competence of staff on all laboratory work shifts through performance evaluations.

**Revision Type:** Retain

**Standard HR.01.06.01**

**2010 Standard Text:**

Staff are competent to perform their responsibilities.

**2010 Standard:** HR.01.06.01

**2010 EP:** 3

**2010 EP Text:**

An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence.

Footnote: Qualifications for this individual are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

**2009 Standard:** HR.3.10

**2009 EP:** 14

**2009 EP Text:**

Staff members are evaluated for competence in performing required laboratory tasks as applicable, as well as for all other parameters defined in their job descriptions. Note: All staff who perform testing, including all physicians, dentists, and midlevel practitioners as defined in CLIA §493.2 performing PPMP (Provider-Performed Microscopy Procedures), must participate in competence demonstrations.

**Revision Type:** Delete:NE

**2010 Standard:** N/A

**2010 EP Text:**

No EP

**2009 Standard:** HR.3.10

**2009 EP:** 15

**2009 EP Text:**

Supervisory staff are evaluated for performance of their job responsibilities, as defined in their job descriptions.

**Revision Type:** Delete:NE

**2010 Standard:** N/A

**2010 EP Text:**

No EP

**2009 Standard:** HR.3.10

**2009 EP:** 16

**2009 EP Text:**

A job description and a completed competence assessment, an evaluation, or an appraisal tool are on file for each contracted or employed individual.

**Revision Type:** Delete:Redun

**2010 Standard:** N/A

**2010 EP Text:**

No EP

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|--|---|--|---------------------------|
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 During the first year, each staff member's testing performance is evaluated and documented at least semiannually.</p>  | <p><b>2009 EP:</b> 17<br/> <b>Revision Type:</b> Retain</p>       | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 During the first year of employment, each staff member's competence is assessed at least semiannually for all laboratory tests he or she performs. This assessment is documented.<br/>                 Note: For waived testing competency requirements, refer to the "Waived Testing" (WT) chapter.</p>   | <p><b>2010 EP:</b> 19</p> |
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 After the first year, each staff member's testing performance is evaluated and documented on an annual basis.</p>  | <p><b>2009 EP:</b> 18<br/> <b>Revision Type:</b> Retain</p>       | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 After the first year of employment, each staff member's competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented.<br/>                 Note: For waived testing competency requirements, refer to the "Waived Testing" (WT) chapter.</p>   | <p><b>2010 EP:</b> 20</p> |
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 An individual qualified to provide technical judgments about performance evaluates technical staff.</p>  | <p><b>2009 EP:</b> 19<br/> <b>Revision Type:</b> Delete:Redun</p> | <p><b>2010 Standard:</b> N/A<br/> <b>2010 EP Text:</b><br/>                 No EP</p>  | <p><b>2010 EP:</b> 19</p> |
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 The procedures to assess and document annually the competence of technical staff include but are not limited to the following: Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing Monitoring the recording and reporting of test results Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance Direct observation of performance of instrument maintenance function checks and calibration performance Test performance assessment as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency or testing samples) Assessment of problem-solving skills as appropriate to the job</p> | <p><b>2009 EP:</b> 20<br/> <b>Revision Type:</b> Retain</p>       | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 The staff member's competency assessment includes the following:<br/>                 - Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing<br/>                 - Monitoring, recording, and reporting of test results<br/>                 - Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance<br/>                 - Direct observation of performance of instrument maintenance function checks and calibration<br/>                 - Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)<br/>                 - Problem-solving skills as appropriate to the job<br/>                 (See also WT.03.01.01, EP 6)</p> | <p><b>2010 EP:</b> 18</p> |

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| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 If a test methodology or instrumentation changes or the individual's duties change, his or her performance is reevaluated to include skills in the areas of change.</p>   | <p><b>2009 EP:</b> 21<br/> <b>Revision Type:</b> Retain</p>      | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 If a test, methodology, or instrumentation changes, or the individual's duties change, his or her competence to perform these new skills or duties is assessed. This assessment is documented. (See also HR.01.05.03, EP 4)</p>  | <p><b>2010 EP:</b> 21</p> |
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 For histocompatibility testing, the laboratory uses a defined system to confirm testing competence and consistency.</p>   | <p><b>2009 EP:</b> 22<br/> <b>Revision Type:</b> Consolidate</p> | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 For histocompatibility testing, the competency assessment process includes the following:<br/>                 - A defined system to confirm testing competence<br/>                 - A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly<br/>                 - Established acceptable performance criteria<br/>                 - Documented performance levels<br/>                 - Documented corrective action</p> | <p><b>2010 EP:</b> 22</p> |
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 The competence assessment system for histocompatibility testing ensures the following: At least monthly, each individual in the laboratory performing histocompatibility testing is given a previously tested specimen as an unknown to verify his or her ability to reproduce test results</p> | <p><b>2009 EP:</b> 23<br/> <b>Revision Type:</b> Consolidate</p> | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 For histocompatibility testing, the competency assessment process includes the following:<br/>                 - A defined system to confirm testing competence<br/>                 - A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly<br/>                 - Established acceptable performance criteria<br/>                 - Documented performance levels<br/>                 - Documented corrective action</p> | <p><b>2010 EP:</b> 22</p> |
| <p><b>2009 Standard:</b> HR.3.10<br/> <b>2009 EP Text:</b><br/>                 The competence assessment system for histocompatibility testing ensures acceptable performance criteria are established</p>   | <p><b>2009 EP:</b> 24<br/> <b>Revision Type:</b> Consolidate</p> | <p><b>2010 Standard:</b> HR.01.06.01<br/> <b>2010 EP Text:</b><br/>                 For histocompatibility testing, the competency assessment process includes the following:<br/>                 - A defined system to confirm testing competence<br/>                 - A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly<br/>                 - Established acceptable performance criteria<br/>                 - Documented performance levels<br/>                 - Documented corrective action</p> | <p><b>2010 EP:</b> 22</p> |

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**2009 Standard:** HR.3.10**2009 EP:** 25**2009 EP Text:**

The competence assessment system for histocompatibility testing ensures performance levels are documented

**Revision Type:** Consolidate**2010 Standard:** HR.01.06.01**2010 EP:** 22**2010 EP Text:**

For histocompatibility testing, the competency assessment process includes the following:

- A defined system to confirm testing competence
- A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly
- Established acceptable performance criteria
- Documented performance levels
- Documented corrective action

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**2009 Standard:** HR.3.10**2009 EP:** 26**2009 EP Text:**

The competence assessment system for histocompatibility testing ensures when indicated, remedial action is taken and documented

**Revision Type:** Consolidate**2010 Standard:** HR.01.06.01**2010 EP:** 22**2010 EP Text:**

For histocompatibility testing, the competency assessment process includes the following:

- A defined system to confirm testing competence
- A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly
- Established acceptable performance criteria
- Documented performance levels
- Documented corrective action