Standards BoosterPak™ for Sample Collection

The Joint Commission

Updated April 2014
Standards BoosterPak™ for Sample Collection

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Preface

In 2007 an article was published in *Clinical Chemistry* that compared the error rate of a stat laboratory in 1996 to the error rate in 2006. Although there was a significant reduction of errors, the distribution between preanalytical, analytical, and postanalytical phases of testing remained relatively consistent. Carraro and Plebani found that 87% of the errors occurred in the preanalytical phase, which includes proper patient and specimen identification, appropriate and correct test requests, accuracy in blood drawing, specimen handling, and specimen transportation. Furthermore, 73% of all the errors in all phases were classified as being preventable.¹

This BoosterPak™ is a unique offering, as it covers standards from multiple accreditation programs that cover two activities that all share in common: collecting a blood sample and transporting it to the lab.* The issues are similar in each of these settings and good practices translate across all of them.

This resource is designed to assist you with the following:

1. Identifying regulatory requirements impacting clinical areas involved in sample collection
2. Understanding practices that will meet the regulatory requirements and provide a reliable level of practice
3. Listing other resources that can assist you with process improvement efforts in high-impact areas, such as sample contamination, sample hemolysis and patient identification leading practices

In many instances, the standard and EP language is exactly the same for all accreditation programs. An exception to this is the noun describing the care setting. For example, in some instances, the word “laboratory” is used rather than “hospital” or “organization.” Instead of repeating the same standard or EP and substituting the single word “hospital,” “organization,” and so on, the standard and relevant EPs are only stated once.

There are some standards in this BoosterPak™ that only relate to the laboratory, but are still important for other healthcare settings to understand. Ultimately, the laboratory will be held responsible for the quality of the sample during survey even when it is collected remotely or by nonlaboratory staff. As a result, activities that other care settings perform which are related to their laboratory’s sample collection practices can benefit from following these guidelines. An organization should contact the testing laboratory with any questions or concerns regarding sample collection.

Important note: The language in this BoosterPak™ is deliberately designed to help the reader differentiate those suggestions and tips that are required versus those that are suggestions only. If the term *must* is used, applicable standards require that point. In the absence of this or other imperative language, the point should be considered purely suggestive.

**Joint Commission Vision:** All people always experience the safest, highest-quality, best-value health care across all settings.

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*Note: If your organization does not collect or transport samples, this BoosterPak™ does not apply.*

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A. Description of Standard and Implementation Expectations

Section A1: Standard Rationale, Elements of Performance (EPs), Scoring Categories, Implementation Suggestions

Staff

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Chapter: Human Resources

Standard number: HR.01.04.01

Standard text: The laboratory provides orientation to staff.

Elements of Performance for The Joint Commission:

The laboratory orients staff on the following:

4. 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)

9. (LAB only) 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.

10. (LAB only) 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.

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

Scoring Categories:

Criticality level: Indirect

Documentation required: EPs 4, 10, 12 = Yes; EP 9 = No

Scoring category (A or C): C

Measure of Success: EPs 4, 9 = Yes; EPs 10, 12 = No

Identified Risk Area: Lab = Yes (EP 4, EP 9); Hospital/Critical Access Hospital = Yes (EP 4), Ambulatory/OBS = Yes (EP 4); Nursing Care Center = Yes (EP 4); Home Care = Yes (EP 4); Behavioral Health = No
Implementation Suggestions:
- A policy should be in place that describes the orientation process and competency assessment process.
- A policy should be in place to address the situation when an employee does not meet the minimum requirements of the competency assessment. The action taken and the final results should be documented in the employee’s personnel file.
- There should be written job descriptions. These job descriptions should be signed by the employees and retained in their personnel file.
- For LAB only, newly hired employees are oriented and assessed for competency by a qualified individual. The qualified individual is the laboratory director, supervisor, or designee. This is documented prior to any unsupervised patient contact.
- For LAB only, the orientation paperwork should include a statement that the newly hired employee is able to perform the duties listed in the paperwork. This statement must be signed by the employee after successfully completing orientation.
- For LAB only, all staff are oriented to any new sample collection method introduced and are assessed for competency. This competency is documented prior to using the new sample collection method on patients.

Tips:
- Data show that dedicated phlebotomy staff can have lower sample error rates and improved turnaround times.² ³
- Competency assessment is a focus on the individual’s ability to perform assigned tasks according to defined processes and procedures to ensure accurate and reliable laboratory results. It is not an evaluation of initiative, interpersonal relationships, and/or work ethic.
- If continuing education is required as part of the job description, it must be maintained in the employee’s personnel file.
- The management team may increase the frequency of competency assessments if performance improvement data (for example, customer complaints, labeling errors, rejected specimens) identify specific retraining needs.
- Additional benefits of a competency assessment program include the following:⁴:
  - It provides performance feedback to employees.
  - It identifies performance problems early before they develop into major problems.
  - It promotes performance consistency among the technologists.
  - It encourages employees to carefully and critically read manuals.
  - It pinpoints systems or processes needing improvement.
  - It reminds staff of important information that may have been forgotten or missed during orientation.
  - It demonstrates to employers, employees, inspectors, and clients that all personnel are qualified to perform assigned tasks.
  - It ensures high-quality patient care.

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Chapter: National Patient Safety Goals
Standard Number: NPSG.07.01.01
Standard Text: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

Rationale: According to the Centers for Disease Control and Prevention, each year, millions of people acquire an infection while receiving care, treatment, or services in a health care organization. Consequently, health care–associated infections (HAIs) are a patient safety issue affecting all types of health care organizations. One of the most important ways to address HAIs is by improving the hand hygiene of health care staff. Compliance with the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines will reduce the transmission of infectious agents by staff to patients, thereby decreasing the incidence of HAIs. To ensure compliance with this National Patient Safety Goal, an organization should assess its compliance with the CDC and/or WHO guidelines through a comprehensive program that provides a hand hygiene policy, fosters a culture of hand hygiene, and monitors compliance and provides feedback.

Elements of Performance for The Joint Commission:
1. Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)
2. Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)
3. Improve compliance with hand hygiene based guidelines on established goals.

Scoring Categories:
Criticality level: EP 1 = Direct; EP 2 and EP 3 = Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: Yes

Implementation Suggestions:
- CDC hand hygiene basics, guidelines, training, and measurement suggestions can be found at http://www.cdc.gov/handhygiene/.
- WHO hand hygiene guidelines can be found at http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf.
- If a decision is made to write a hand hygiene policy, then items to include are the following:
  - All IA, 1B, and 1C recommendations from the chosen guideline
  - Examples of when hand hygiene would be required
  - When soap and water are required for hand hygiene
  - When hand sanitizers are acceptable for use
  - The goal for compliance with hand hygiene guidelines
  - How to measure and monitor guidelines
- Compliance with the guidelines must be documented per EP 2. This documentation must be used as a performance improvement project per EP 3. Only direct observation may be used for compliance with EPs 2 and 3.
Tips:
- According to the CDC, each year an estimated 1.7 million health care–associated infections occur in the United States, leading to 99,000 deaths. At least one third of such infections could be prevented, with provider hand hygiene being the single most effective prevention strategy due to its ability to reduce transmission of organisms that cause infections.
- For accurate direct-observation monitoring:
  - The observers must be unknown to the staff to eliminate influencing behavior of the staff. The observers must be trained to collect consistent and accurate data.
- To raise awareness of its employees, many organizations post their hand hygiene data for all employees to see.
- Some organizations reward employees for achieving and maintaining hand hygiene goals.

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Chapter: Infection Prevention and Control

Standard number: IC.02.01.01

Standard text: The laboratory implements its infection prevention and control activities.

Elements of Performance for The Joint Commission:

2. The organization uses standard precautions, including the use of personal protective equipment, to reduce the risk of infection. (See also EC.02.02.01, EP 4)

   Note: Standard precautions are infection prevention and control measures to protect against possible exposure to infectious agents. These precautions are general and applicable to all patients and patient specimens.

3. The laboratory implements transmission-based precautions in response to the pathogens that are suspected or identified within the organization’s service setting and community. (See also EC.02.02.01, EP 3)

   Note: Transmission-based precautions are infection prevention and control measures to protect against exposure to a suspected or identified pathogen. These precautions are specific and based on the way the pathogen is transmitted. Transmission-based precautions include contact, droplet, airborne, or a combination of these precautions.

6. The organization minimizes the risk of infection when storing and disposing of infectious waste. (See also EC.02.02.01, EPs 1 and 12)

7. The laboratory implements its methods to communicate responsibilities for preventing and controlling infection to staff, visitors, and patients. (See also HR.01.04.01, EP 4; IC.01.05.01, EP 7)

References:
8. For further information regarding standard precautions, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hai/ (Infection Control in Healthcare Settings).
9. For further information regarding transmission-based precautions, refer to the website of the Centers for Disease Control and Prevention at http://www.cdc.gov/HAI/ (Infection Control in Healthcare Settings).
Scoring Categories:

Criticality level: EPs 2, 3, 6 = Direct; EP 7 = Indirect

Documentation required: No

Scoring category (A or C): C

Measure of Success: Yes (EPs 2, 3, 7); No (EP 6)

Identified Risk Area: Lab = No; Hospital/Critical Access Hospital = Yes (EP 3), No (EPs 2, 6, 7);
Ambulatory/OBS = Yes (EPs 2, 3, 6), No (EP 7); Nursing Care Center = No;
Home Care = Yes (EP 2), No (EPs 3, 6, 7); Behavioral Health = No

Implementation Suggestions:

• The organization must comply with Occupational Safety & Health Administration (OSHA) requirements
  for handling hazardous chemicals and blood-borne pathogens per [“Leadership” standard] LD.04.01.01,

• The organization must comply with state and local requirements for the disposal of hazardous waste.

• Policies should be in place that address standard precautions and transmission-based precautions. It should
  include what disease states require transmission-based precautions and how staff are notified of the
  additional requirements.

• A policy should be in place that addresses handling, storage, and disposal of toxic and biohazardous
  materials.

• The personal protective equipment (PPE) selected should be appropriate for the task and the risk of
  exposure.

• Gloves are required for all phlebotomies outside of volunteer blood donation centers¹⁰ and may be the only
  PPE needed for someone drawing blood. Studies show that when a contaminated needle pierces a glove,
  the material of the glove wipes off up to 86% of the blood from the needle before it passes into your
  tissue.¹¹

• The organization’s hand hygiene policy must be followed; this is true even if gloves were worn during pa-
  tient contact.

• Needles and other sharps must be disposed of in a “sharps container” that is clearly marked “biohazard.”

• Sharps containers must be closable, puncture resistant, and leakproof on the sides and bottom. They must
  be located as close as possible to the immediate area where sharps are used.

• Education materials are available to staff, patients, and visitors regarding what they can do to prevent the
  spread of infections.

Tips:

• Hand sanitizers can be placed in areas for patients and visitors to use.

• Have masks and educational materials available for patient and visitor use.

• To reduce the risk to staff, all needles should have a safety feature. According to the CDC, phlebotomy inj-
  uries were reduced by 76% with a self-blunting needle, 66% with a hinged needle shield, and 23% with a
  sliding-shield winged-steel butterfly-type needle.¹²

• Needles should not be removed from syringes or blood tube holders. They should not be recapped, bent, or
  sheared.

• PPE should be easily accessible. This include gloves, gowns, laboratory coats, face shields, masks, eye
  protection, and respirators.

¹⁰. Occupational Safety & Health Administration. OSHA Fact Sheet: Personal Protective Equipment (PPE) Reduces Exposure to Bloodborne
17;46(2):21–25.
A 2011 study performed by the Center for Phlebotomy Education found that 18% of all phlebotomists will rip off the tip of the gloved finger to better palpitate a vein, not realizing that this is an unsafe practice.\(^{13}\) Train the staff on techniques to identify and mark veins.

If blood is collected in exam rooms, a sharps container must be in each room. If younger patients may be seen by the practice, this container should be mounted high on the wall. For correct wall placement, please see [http://www.cdc.gov/niosh/docs/97-111/](http://www.cdc.gov/niosh/docs/97-111/). As an alternative, a portable phlebotomy tray that includes a sharps container may be used.

Never try to flatten the waste in a sharps container to get more in it.

Never put your hands or fingers in a sharps container.

Visually check sharps containers for overfilling, and replace them before they become overfilled.

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**Chapter:** Environment of Care  
**Standard number:** EC.02.02.01  
**Standard text:** The laboratory manages risks related to hazardous materials and waste.  
**Rationale:** Hazardous materials and waste cause harm if they are not managed properly. Examples of such materials include chemicals (such as cleaning products, solvents, and pesticides), compressed gases, and hazardous energy sources. Federal, state, or local regulations often guide the handling, use, and storage of hazardous materials and waste. The laboratory identifies materials it uses that need special handling to minimize the risks of unsafe use and improper disposal. This chapter previously addressed infectious and regulated medical waste, but this requirement has moved to the "Infection Prevention and Control" (IC) chapter. Nevertheless, it is important for laboratories to be aware that the presence of these substances in the environment could be harmful to staff. Note: This standard does not address oxygen because it is not a "hazardous material." Oxygen is covered under the safety standard, EC.02.01.01. However, other substances such as blood are covered by this standard.

**Elements of Performance for The Joint Commission:**
11. For managing hazardous materials and waste, the laboratory has the permits, licenses, manifests, and safety data sheets required by law and regulation. (Not applicable to Office-Based Surgery)
12. The laboratory labels hazardous materials and waste. Labels identify the contents and hazard warnings.* (Not applicable to Office-Based Surgery)

**Scoring Categories:**
- Criticality level: Indirect
- Documentation required: Yes for EP 11
- Scoring category (A or C): A
- Measure of Success: No
- Identified Risk Area: Lab = No; Hospital/Critical Access Hospital = No; Ambulatory = Yes; Nursing Care Center = No; Home Care = No

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\* The National Fire Protection Association (NFPA) and the Occupational Safety and Health Administration’s (OSHA) Bloodborne Pathogens and Hazard Communications Standards provide details on labeling requirements.

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Implementation Suggestions:
- The organization must comply with OSHA requirements for handling hazardous chemicals and blood-borne pathogens per LD.04.01.01, EP 2.
- The organization must refer to state and local requirements for the disposal of hazardous waste.
- Material safety data sheets (MSDS) must be readily available to all staff, particularly if samples are being transported on dry ice.
- The organization must have waste disposal manifests that indicates safe disposal of biohazards and dry ice.
- All sample transport containers (for example, coolers, bags) must have the hazardous materials warning visible on the exterior.
- Samples being transported outside the building must comply with International Air Transport Association/US Department of Transportation (IATA/DOT) requirements for absorbent materials within a leakproof container and packaged in a puncture-proof container.
- All waste disposal containers (for example, sharps containers, red waste bags) must have hazardous waste insignia warnings visible on the exterior.

Tips:
- Many organizations have MSDS available online and paper copies in one central location.
- Keep filled sharps containers for disposal in a secured area.
- Check your local and state regulations to see if an acid or a flammable cabinet is required. Be aware that 70% isopropyl alcohol is a flammable liquid.
- If you pour off chemicals into smaller bottles, make sure the smaller bottles are properly labeled and include the National Fire Protection Association (NFPA) Hazard Rating Diamond. Many organizations pour off the 70% isopropyl alcohol into smaller containers to be used at the individual draw stations or in phlebotomy trays.

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Chapter: Environment of Care
Standard number: EC.02.06.01
Standard text: The laboratory establishes and maintains a safe, functional environment.

Elements of Performance for The Joint Commission:
13. The organization maintains ventilation, temperature, and humidity levels suitable for the care, treatment, and services provided. (See also EC.02.05.01, EP 6)
30. All laboratory areas are safe for staff and visitors. (Applicable to Lab only)

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: No

Implementation Suggestions:
- A policy should be in place that explains how to manage and minimize any possibilities of patient injury. It should include combative patients, patients who lose consciousness, and patients who become ill.
- The laboratory should be located in a convenient, yet out-of-the-way place in the facility. It should not be a heavy traffic area and it should not be an area where patients must pass through on a routine basis.
• The laboratory must have access to the necessary utilities (power, environment, water, drainage and disposal systems). The utilities must be sufficient for the work and equipment used in the laboratory.
• If the laboratory handles biological or caustic chemicals, a proper ventilation system is essential for employee and patient safety. The type and quantity of materials handled will determine what type of ventilation system is required. For facility design and ventilation requirements, please see http://www.frigiguide.org/guidelines2010.php.
• Temperature regulation of the phlebotomy area is important. High temperatures may cause patients to experience profuse sweating and light-headedness, and low temperatures may cause vasoconstriction, making sample collection difficult.
• The phlebotomy area should be well lit.
• Many sample collection areas use special chairs with either an arm that can hold the patient in place or that have the ability to recline if the patient becomes light-headed.

Tips:
• Designate specific areas in the laboratory and collection areas for various tasks to minimize accidental spills, mix-ups, or contamination.
• A safe environment also requires that the area be free of blood or other sample splatters, which means they must be adequately cleaned. Flooring should either be bleachable or replaceable in segments if it should come into contact with body fluids.
• Never turn your back on a patient after completion of the draw. Many patients give no warning before passing out.
• If a patient becomes dizzy or loses consciousness during a collection, release the tourniquet and remove the needle at once.
• Avoid the use of ammonia inhalants. Patients who are asthmatic may develop respiratory distress as a result.
• Ergonomic risk factors for phlebotomy include repetition, awkward postures, static exertion, force, and contact stress. A worksite analysis may be performed to determine existing risks to employees. The following are questions to consider including\(^4\):
  o Does the working space allow for a full range of work movements?
  o Are the mechanical aids and equipment provided where feasible?
  o Is the work surface height proper and adjustable?
  o Can the work surface be tilted or angled if necessary?
  o Is the workstation designed to minimize or eliminate the following:
    – Twisting at the waist?
    – Reaching above the shoulder?
    – Extension of the arm?
    – Bending or twisting of the wrist?
    – Elevation of elbows?
  o Do staff members have the option to vary their posture?
  o Are staff members’ hands or arms subjected to pressure from sharp edges on work surfaces?
  o Is an armrest provided where needed?
  o Is a footrest provided where needed?
  o Is the floor surface irregular, slippery, or sloping?
  o Are cushioned floor mats provided for workers who are required to stand for long periods?
  o Where chairs or stools are provided, are they easily adjustable and suited to the task?
  o Is the workplace temperature too hot or too cold?
  o Are all task requirements visible from comfortable positions?
  o Is there a preventive maintenance program for mechanical aids, tools, and other equipment?

Laboratory Test Orders

Program:

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Chapter: Document and Process Control

Standard number: DC.01.02.01

Standard text: The laboratory performs testing based on written laboratory orders.

Elements of Performance for The Joint Commission:

1. The laboratory has written procedures for ordering tests.

Scoring Categories:
- Criticality level: Indirect
- Documentation required: Yes
- Scoring category (A or C): A
- Measure of Success: No
- Identified Risk Area: No

2. Individuals who order laboratory tests or receive laboratory test results are authorized to do so in accordance with law and regulation.

Scoring Categories:
- Criticality level: Indirect
- Documentation required: No
- Scoring category (A or C): A
- Measure of Success: No
- Identified Risk Area: No

3. Laboratory test orders are made in writing (paper or electronic).
   - Note: The test order may be located in the clinical record.

Scoring Categories:
- Criticality level: Indirect
- Documentation required: Yes
- Scoring category (A or C): A
- Measure of Success: No
- Identified Risk Area: No

4. Laboratory test orders for laboratory tests are legible.

Scoring Categories:
- Criticality level: Indirect
- Documentation required: No
- Scoring category (A or C): C
- Measure of Success: Yes
- Identified Risk Area: No
5. Laboratory test orders are complete and include the following:
   a. Patient's first and last name
   b. Patient's sex
   c. Patient's age or date of birth
   d. Contact information of the authorized person requesting the test, and if different, the individual responsible for using the test results, in order to report routine and critical test values
   e. Name of the test(s) ordered
   f. Any special handling required
   g. Date and, when pertinent to the test being ordered, time the specimen was collected
   h. Date and time the specimen arrived at the laboratory
   i. The specimen source, when pertinent to the test being ordered
   j. Additional information required by the laboratory to support accurate test interpretation and reporting of results, such as race, ethnicity, or family history

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): C
Measure of Success: Yes
Identified Risk Area: No

6. The laboratory has a policy defining the criteria for specimen and requisition acceptability which addresses the processes to follow to obtain missing test order information prior to processing specimens or reporting patient results.

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: No

7. If the laboratory permits verbal orders for laboratory testing, the laboratory requests written (paper or electronic) authorization within 30 days and retains the written authorization, or documentation of its attempts to obtain written authorization, in accordance with law and regulation.

Scoring Categories:
Criticality level: Indirect
Documentation required: Yes
Scoring category (A or C): C
Measure of Success: Yes
Identified Risk Area: No
Implementation Suggestions:

- A policy should be in place that lists what information must be included with every test order and the process to follow if there is missing information.
- Gender and age are important to correctly identify the patient normal range for interpretation of test results. Other relevant and necessary information to include will depend on the test requested. Examples of such information include the following:
  - For glucose or lipids, indicate whether the patient is fasting.
  - For drug levels, indicate the dosage of medication the patient is on and the time the last dose was taken.
  - For cultures, indicate the source of the specimen and whether the patient is already on antibiotics or may have just completed a course of antibiotics.
- Do not collect the sample until the order has been reviewed for complete and accurate information and all errors have been resolved.
- Each request for a blood specimen must be accessioned to identify all paperwork and supplies associated with each patient.
- Test requisitions, testing records, and test reports are all required documents for a complete Patient Test Management System. These documents may be paper based or electronic.
- A single document may serve multiple purposes. Often the charge sheet, super-bill, or routing slip is used as a requisition. Some facilities elect to combine all the requirements into the design of a single form. The patient's chart may also be used as both the requisition and report form, as long as the chart remains available for laboratory personnel during testing and can be made available at the time of survey.
- For in-house ordering, the requisition may be the written request on the chart if that is your normal method of requisitioning. Otherwise, a requisition must be obtained from the ordering physician.
- Standing orders are acceptable, as long as the facility has a Standing Order Policy and it is followed.

Tips:

- In a manual requisition system, there are many opportunities for error in order entry. In the College of American Pathologists Q-Probe study performed in 660 institutions, a total of 5,514 of 114,934 outpatients requisitions (4.8%) were associated with at least one type of order entry error. In 1,658 (1.4%) of the requisitions, one or more tests on the requisition were not ordered in the laboratory computer, whereas in 1,221 cases (1.1%) at least one test was ordered in the computer that had not appeared on the requisition. A total of 2,130 requisitions (1.9%) contained one or more physician name discrepancies between the requisition and the laboratory computer entry. Finally, in 943 requisitions (0.8%), an incorrect test priority was entered for at least one of the requested tests. In an Australian survey on transcription and analytic errors, the transcription error rate was up to 39%, the most frequent types of errors being associated with misidentification of the requested tests, the requesting physician, and/or the patient.
- An electronic order system can reduce the chance of errors but will not completely eliminate the problem. One study found that electronic order systems can have error rates as high as 19%.
- When space is an issue or due to information system limitations, the requesting party's name and address may be assigned a unique code number. In such cases, it is necessary to have a master list that defines the name and address assigned to each code number.

Standards BoosterPak™ for Sample Collection

Patient Identification and Specimen Handling

Program:

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Chapter: National Patient Safety Goals

Standard number: NPSG.01.01.01

Standard Text: Use at least two patient identifiers when providing laboratory services.

Rationale: Wrong-patient errors occur in virtually all stages of diagnosis and treatment. The intent for this goal is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Acceptable identifiers may be the individual’s name, an assigned identification number, telephone number, or other person-specific identifier.

Elements of Performance for The Joint Commission:

1. Use at least two patient identifiers when administering blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing other treatments or procedures. The patient’s room number or physical location is not used as an identifier. Note: An example of “other procedures” includes bone marrow aspirates.

2. Label containers used for blood and other specimens in the presence of the patient.

Scoring Categories:

Criticality level: Direct
Documentation required: No
Scoring category (A or C): EP 1 = C; EP 2 = A
Measure of Success: Yes (EP 1); No (EP 2)
Identified Risk Area: Yes

Implementation Suggestions:

• Do not rely on bed tags, charts, orders, or armbands to identify the patient. Major causes of laboratory error can be related to nonanalytical factors such as patient identification.

• Two unique patient identifiers (such as name, date of birth, medical record number, or social security number) must be used to verify that specimens are being collected from the correct patient. It has been estimated that 160,000 adverse patient events occur in the United States because of patient or specimen identification errors.¹⁸

• The preferred method of identifying a patient is to have the patient actively involved in the identification process by asking the patient to state his or her name and date of birth. If a patient is unable to actively participate, consider having a nurse, relative, or friend identify the patient.

• The information provided by the patient should be verified by doing the following:
  o For inpatients, compare it with the ID band and sample labels or requisitions.
  o For outpatients, compare it with the requisition or order.

• Do not proceed with collecting the sample until all errors and differences are resolved.

• Procedures should be written on how to identify patients under the following conditions:
  o Patients who are conscious
  o Patients who are unconscious, too young, cognitively impaired, or do not speak the language
  o Patients who are semiconscious, comatose, or sleeping
  o Patients who are unidentified emergencies

• Always label the sample in the presence of the patient. In the case of an inpatient, label the sample before exiting the patient room. In the case of an outpatient, label the sample before the patient is instructed that he or she is free to depart the drawing area. In one study, specimen labeling errors accounted for 55.5% of identification errors.18

• If using pre-printed labels:
  o Adhere the label to the tube so all information is visible.
  o Add other required information to the label per laboratory protocol (date, time, and initials of person collecting the sample).
  o Do not place a label only on the transport bag, as the bag gets thrown away.
  o Do not place a label only on the stopper or cap lid, as they can be removed.

• The laboratory should have a sample rejection policy that includes directions for handling both recollectable and nonrecollectable samples. Strict adherence to this policy for all recollectable samples has been shown to improve the rate of “wrong blood in tube.”19

Tips
• Be aware that bar-code scanners are not fail-safe,20 and visual identification should still be performed with active patient involvement of the information produced by a bar-code scanner.
• Bed and room numbers are not unique identifiers, as they stay the same while the patient changes.
• The procedure for patient identification must be followed even if the person collecting the sample has an established relationship due to prior visits with the patient. Facial recognition is not an acceptable patient identifier for collecting laboratory specimens. If utilizing preprinted labels, take only one patient’s label into the location (inpatient room or outpatient drawing station) at the time the sample is collected.
• Never label the sample at a desk location outside the patient’s room or draw station.
• Never label a sample collected by someone else.
• Most laboratories will not allow correction of a recollectable sample in non-urgent situations. In a study performed by Lamadue et al., samples that have any kind of missing or erroneous information were 40 times more likely to contain the wrong blood in the tube.21
• All incidences of patient and sample identification errors should be recorded and monitored. Additional training or appropriate corrective action may be necessary.

**Program:** Hospital/Critical Access Hospital

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**Chapter:** Document and Process Control

**Standard number:** DC.01.01.01

**Standard text:** The laboratory establishes procedures for collecting specimens.

**Rationale:** A specimen that is properly timed, collected, identified, preserved, stored, received, and processed is the first step toward achieving an accurate result.

**Elements of Performance for The Joint Commission:**

1. The laboratory has written procedures for collecting specimens that address the following:
   - Patient identification
   - Patient preparation
   - Specimen collection
   - Precautions for specimen collection
   - Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by laboratory policy
   - Specimen receipt, processing (including maintaining cell and organism viability), storage, preservation, and transport
   - Specimen rejection criteria
   - Collection of reference laboratory specimens

   **Note:** The laboratory may use a reference laboratory’s procedures—they need not be rewritten.

2. Current specimen collection procedures are made available to laboratory staff, nonlaboratory staff, and external providers who collect specimens for laboratory testing.

   **Note:** Electronic specimen collection procedure manuals may be used if they are accessible to staff.

**Scoring Categories:**

- Criticality level: Indirect
- Documentation required: EP 1 = Yes; EP 2 = No
- Scoring category (A or C): A
- Measure of Success: No
- Identified Risk Area: No

**Implementation Suggestions:**

- There must be written procedures for the following:
  - Patient identification
  - Patient preparation
  - Specimen collection
  - Precautions for specimen collection
  - Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by policy
  - Specimen receipt, processing (including maintaining cell and organism viability), storage, preservation, and transport
Specimen rejection criteria
Collection of reference laboratory specimens

- Prior to collecting the specimen, confirm that the patient has followed the physician’s test preparation orders (for example, fasting, timing of medications) and ensure that the necessary supplies are available for the selected test.
- The sample must be collected in the right tube for the assay being performed. Collection in the wrong tube will result in sample rejection. When a sample is collected in a wrong tube it cannot be removed and placed into the correct tube.
- Serum or plasma should be physically separated from contact with the cells as soon as possible. It has been determined that a two-hour delay in separation can cause clinically significant altered results for glucose (decreased), potassium (increased), and lactate dehydrogenase (increased). 22
- All tubes must be properly filled. Underfilled and overfilled tubes will change the blood-to-anticoagulant ratio, which may affect results. Carraro and Plebani found that tube-filling errors accounted for 13.1% of all preanalytical errors in their study. 1
- All tubes containing additives, except sodium citrate, should be gently inverted at least 5 to 10 times to mix the contents. Tubes containing sodium citrate should be mixed 3 to 4 times to mix the contents. 23
- To ensure specimen integrity, the phlebotomy team must be aware of specimen preparation requirements and the procedures for collecting specimens.
- If there is a policy to transport specimens internally, the policy must be followed. Organizations that have a pneumatic tube system may restrict the specimens that can be sent using the system. All specimens should be transported at room temperature unless chilling is required to maintain specimen integrity.
- If specimens are stored in lockboxes for pickup, perform risk assessments to ascertain whether specimen temperature requirements are maintained. It is recommended that this be performed at various times within a year to demonstrate compliance in temperature extremes.
- Verify that pickups occur as scheduled. It is common to require a quality monitor of the courier’s compliance with sample handling as part of supplier management for your reference laboratory.
- When specimens are transported by automobile, coolers must be placed on the floor of the vehicle behind the passenger’s seat as a first choice. If the floors are occupied with specimens, then the cooler must be held on the backseat with the seat belt. 24
- For external shipments, the sending organization is responsible for ensuring that the IATA/DOT requirements are met. IATA/DOT requirements call for an absorbent material within a leakproof container within puncture-proof packaging such as a cooler or certified container.
- It is recommended that paperwork accompanying specimens be kept in a baggie or packet separate from the specimens themselves; for example, a separate pouch attached to the specimen baggie, a separate moisture proof envelope placed in the cooler with the specimens, a separate envelope outside the cooler.
- Labels shall be affixed to containers of regulated waste; refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in OSHA paragraph 1910.1030 (g)(1)(i)(E), (F), and (G). 25

Tips:

- Many organizations elect to write general policies and procedures for specimen collection, handling, and transport and then refer to the specific test procedure for more detailed requirements.
- The correct order of draw is as follows:
  - Blood culture vials or bottles, sterile (yellow top) tubes
  - Coagulation tube (light blue top)
  - Serum tube with or without clot activator or silic gel (red or gold top)
  - Heparin tube (green top)
  - EDTA (lavender top)
  - Glycolytic inhibitor (gray top)
- There are special disinfection requirements for certain tests. Make sure all cleansers are available for use (70% isopropyl or ethyl alcohol; 1%–10% providone-iodine as swab sticks or chlorohexidine gluconate for blood cultures; non-alcohol-based cleanser for blood alcohol specimens [chlorohexadine]).
- Some patients may be sensitive to latex. Make sure there are nonlatex gloves, tourniquets, and bandages available for use. Many organizations have become latex-free.
- Vigorous hand pumping can cause changes in the concentration of certain analytes in the blood and should be avoided.
- It is important to know how long it took the specimen to arrive in the laboratory. Many specimens have limited transport or storage time at room temperature. If storage or transport conditions are not followed, this can affect the quality of results obtained. Studies have demonstrated that the evaluation of specimen adequacy is a critical preanalytical factor affecting test result accuracy and usefulness.
- For some practices the time of collection and receipt may be the same. However, there are almost always some situations in which patients may collect specimens at home or they may be collected at another site and sent to the laboratory. Be sure that, in these situations, staff are aware of the importance of capturing both time of collection and time of receipt.
- If your laboratory has not given you specific instructions for sample handling, insist on receiving those. All Joint Commission–accredited and COLA–accredited laboratories are required to provide current specimen collection procedures to nonlaboratory staff and external providers who collect specimens for testing.

Performance Improvement

Program: Standards BoosterPak™ for Sample Collection

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<th>Standard number</th>
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Chapter: Performance Improvement
Standard number: PI.01.01
Standard text: The laboratory collects data to monitor its performance.

Elements of Performance for The Joint Commission:

2. The laboratory identifies the frequency for data collection.

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: No

16. The laboratory collects data on the following: Patient perception of the safety and quality of laboratory services.

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: Lab = Yes; Hospital/Critical Access Hospital = No; Ambulatory/OBS = No; Nursing Care Center = Yes; Home Care = No; Behavioral Health Care = No

22. The laboratory collects data on the following: Processes or outcomes related to patient preparation, including the provision of patient instructions and preparatory steps for the procedures. (Applicable to Lab only)

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: Yes

23. The laboratory collects data on the following: Processes or outcomes related to handling specimens, including specimen collection, labeling, preservation, transportation, and rejection. (See also LD.04.04.01, EP 2) (Applicable to Lab only)

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified Risk Area: Yes
24. The laboratory collects data on the following: Processes or outcomes related to communication processes, including efficient transfer of information, completeness of test requisition, timeliness of reporting results, and accuracy of reports. (Applicable to Lab only)

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified risk area: Yes

Implementation Suggestions:
• The collection and handling of samples is an important part of the preanalytical process. A written Quality Assessment Program incorporates all the processes in the laboratory (general, preanalytical, analytical, and postanalytical). The intent of the program is to use a systematic approach to monitoring, assessing, and correcting problems identified in laboratory processes on an ongoing basis.
• A complete plan includes establishment of communication mechanisms for staff, documentation of all activities, and follow-up reviews to determine the effectiveness of corrective actions.
• A good PI program sets goals for error reduction and monitors the improvements over time.
• Sample collection errors that are important to document and target for improvement include the following:
  o Errors in sample collection, including anything causing a redraw such as unlabeled samples, illegible samples, and mislabeled samples
  o Unsatisfactory samples, particularly contaminated or hemolyzed
  o Any incomplete requisitions that prevented the results being reported promptly to the physician
  o Patient satisfaction with the process and the staff interactions
• The review should look at specimen collection, handling, labeling, transport, and acceptability. It should include a determination if the procedures are correct and appropriate for your laboratory and a verification that laboratory personnel are following them.
• In the preanalytical phase, this review should concentrate on the process for ordering tests, including assessment of the completeness and relevance of the content of test requisitions, as well as retention of requisitions.
• As the assessments reveal deviations between policy and performance, this alerts the laboratory that a problem exists. The laboratory must then review the process and data obtained by the assessment to develop corrective actions aimed at preventing recurrence.
• A follow-up review and analysis ensures that corrective actions have corrected the problem identified.
• Suggestions for data collection include the following:
  o Gather “near miss” data as well as events with actual patient impact.
  o Record events that are corrected internally.
  o Use it to show performance improvement.
  o It should be shared with all staff.

Tips:
• Analyze root causes associated with these events using tools such as fishbone charts.31
• Many laboratories use a chart audit or medical record review to easily assess the Patient Test Management System.
• Although staff collecting samples are not responsible for completing the requisitions, they will be the first to notice errors. This is helpful information to improve the ordering process and should be monitored.
• Assessments or reviews should be performed on an ongoing basis:
  o Consider what activities, that if not performed properly, have the most significant impact on the

quality of testing or the level of service provided by your laboratory.
- Select a minimum of one monitor for each phase noted above.
- Conduct assessments of each monitor throughout the year to assess performance, design process improvements, and monitor the effect of their implementation.

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Chapter: Leadership
Standard number: LD.03.06.01
Standard text: Those who work in the laboratory are focused on improving safety and quality.
Rationale: The safety and quality of laboratory services are highly dependent on the people who work in the laboratory. The mission, scope, and complexity of services define the design of work processes and the skills and number of individuals needed. In a successful laboratory, work processes and the environment make safety and quality paramount. This standard, therefore, applies to all those who work in or for the organization, including staff and licensed independent practitioners.

Elements of Performance for The Joint Commission:
3. Leaders provide for a sufficient number and mix of individuals to support safe, quality laboratory services.

Note 1 LAB only: 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 LAB only: 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.

Scoring Categories:
Criticality level: Direct
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified risk area: Lab = Yes; Hospital/Critical Access Hospital = Yes; Ambulatory/OBS = Yes; Nursing Care Center = Yes; Home Care = Yes; Behavioral Health = No
Implementation Suggestions:
- Policies and procedures must be reviewed by the medical director or designee on a regular annual basis. Be sure to consult your laboratory before making changes to critical elements of the process.
- Set turnaround time goals that meet the needs of the clinical staff and patients. Verify that the laboratory meets these goals.
- Monitor staff overtime and document the causes.
- Many facilities do time studies to review how many samples are drawn by time of day compared to the level of staff present.
- Many facilities monitor the turnaround time for stat testing in the emergency room.
- Many facilities monitor the quality of specimens received from outside locations.
- Failure of the laboratory to act on the data could result in noncompliance with these standards.

Tips:
- The safety of patients and the quality of laboratory results are highly dependent on the people who perform sample collection. Insufficient specimen quality and quantity may account for 60% of all preanalytic errors.32
- Patient satisfaction surveys can be used as a monitor of appropriate staffing levels as long as the date and time of sample collection is available.

Section A2: Assessing Compliance During the On-Site Survey for all Joint Commission Programs

Content adapted from the 2010 Laboratory & Point of Care Testing Survey Activity Guide—Tracer Activity

Objective: The objective is to evaluate the organization's compliance with standards as they relate to laboratory services.

- Surveyors will directly observe:
  - Patient identification process
  - Compliance with organization's infection control policies:
    - Personal protection equipment
    - Expiration dates of antimicrobial gels in use
    - Disposal of hazardous waste
  - Expiration dates of Vacutainers® and other devices in use
  - Potential environmental issues that might impact individual safety:
    - Location of gel dispensers in relation to electrical outlets
    - Location of fire extinguishers
    - Use of proper disposal containers, hazardous and nonhazardous waste
    - Patient and staff safety in relation to floor space, furnishings in use (age appropriate), location, availability to summon assistance
  - Confidentiality and privacy for patients
  - Compliance with laboratory's specimen labeling policies—also process improvement on sample issues
  - Compliance with laboratory's specimen processing policies and procedures

- The surveyors will interview:
  - Employees regarding knowledge of and access to procedures on specimen storage and transporting
  - Orientation, training, and competency testing
  - Job description

- Documents for review:
  - Policies and Procedures:
    - Patient identification
    - Specimen labeling
    - Laboratory testing procedure protocols
    - Infection control policies
    - Any reference laboratory agreements and instructions for sample collection and handling
  - Equipment maintenance records:
    - Temperature control records for refrigerators, freezers, transport coolers (if applicable), and room temperature
    - Centrifuge: RPMs and time
    - PM checks
    - Maintenance/service records
  - Waste manifest

- Human resources records:
  - High school diploma or educational degree
  - Evaluation of foreign credentials
  - License if required by state law
  - New employee orientation and initial competency (if new employee)
o Annual competency
o Annual performance evaluation
o If couriers are employees, review orientation and annual training for infection control, sample handling requirements, and expected turnaround times for delivery routes.
B. Frequently Asked Questions, Definitions, and Additional Information

Section B1: Frequently Asked Questions (FAQs)

Hand Hygiene: NPSG Goal 7—NPSG.07.01.01
Revised | June 8, 2010

Websites for CDC and WHO Guidelines

Q: Where can I find the current Center for Disease Control and Prevention (CDC) hand hygiene and World Health Organization (WHO) guidelines?

A. View the CDC report at http://www.cdc.gov/handhygiene/.

Choosing CDC or WHO Guidelines

Q. May we “pick and choose” some recommendations from CDC and some from WHO, or must we decide to follow one of the guidelines in its entirety?

A. Scientific guidelines are designed to function as a cohesive whole. Following parts of a guideline is not as efficacious as compliance with the entire document. Therefore, accredited organizations must choose to follow all IA, IB, and IC recommendations from either the CDC or WHO. Of course, The Joint Commission would encourage organizations to go “above and beyond” by complying with additional recommendations from either document as long as compliance has been achieved with all category I recommendations from either the CDC or WHO.

Categories of Recommendations

Q. Does Joint Commission require implementation of all the recommendations in the CDC or WHO hand hygiene guidelines?

A. Each of the CDC and WHO hand hygiene recommendations is categorized on the basis of the strength of evidence supporting the recommendation. All “category I” recommendations (including categories IA, IB, and IC) must be implemented. Category II recommendations should be considered for implementation but are not required for accreditation purposes. Category IA recommendations are strongly supported by well-designed experimental, clinical, or epidemiological studies; category IB recommendations are supported by certain experimental, clinical, or epidemiological studies and a strong theoretical rationale; category IC recommendations are required by regulation; category II recommendations are supported by suggestive clinical or epidemiological studies or a theoretical rationale. The CDC also includes among its recommendations several “unresolved issues” for which it makes “no recommendation.”
**Fingernails**

Q. The CDC guidelines say that health care personnel should not wear artificial nails and should keep natural nails less than one-quarter inch long if they care for patients at high risk of acquiring infections (such as patients in intensive care units or in transplant units). The WHO guidelines prohibit artificial nails and extenders for all health care workers. Will The Joint Commission actually be requiring this?

A. Each organization must follow the IA, IB, and IC recommendations from the guideline it chooses (CDC or WHO). Therefore, if WHO is chosen, no direct care providers should have artificial nails or extenders. If the CDC is chosen, providers in high-risk areas must not wear artificial nails. Please note that many organizations following the CDC guidelines have chosen to expand the ban on artificial nails to all care providers in the interest of safety. Regarding the length of natural nails, each organization may choose its own approach because the level of recommendation in both the CDC and WHO guidelines is “II,” thereby making compliance optional.

**Mandatory Use of Alcohol-Based Hand Products**

Q. Do we have to use alcohol-based hand products?

A. Accredited organizations are required to provide health care workers with a readily accessible alcohol-based hand product. However, use of such a product by any individual health care worker is not required. The guidelines describe when this type of cleaner may be used instead of soap and water. If a health care worker chooses not to use it, then soap and water should be used instead.

**Corridor Dispensers for Alcohol-Based Hand Products**

Q. What are the “conditions” that have to be met to be able to install alcohol-based hand rub (ABHR) dispensers in egress corridors?

A. Location conditions and permissible volume specifications for gel ABHR dispensers to be installed in egress corridors are as follows:

- The corridor width is 6 feet or greater and dispensers are at least 4 feet apart.
- The dispensers are not installed over or directly adjacent to an ignition source such as an electrical outlet or switch. *Adjacent* is defined as being at least 6 inches from the center of the dispenser to an ignition source.
- In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces are permitted only in smoke compartments with sprinklers.
- Each smoke compartment may contain a maximum aggregate of 10 gallons (37.9 liters) of ABHR gel in dispensers and a maximum of 5 gallons (18.9 liters) in storage.
- The maximum individual dispenser fluid capacity is 0.3 gallons (1.1 liters) for dispensers in rooms, corridors, and areas open to corridors.
- The maximum dispenser size for individual dispensers in areas designated as suites of rooms is 0.5 gallons (1.9 liters).
- The situation is a little different with respect to foam ABHR products because all of the testing upon which the NFPA and Centers for Medicare & Medicaid Services (CMS) decisions were based was done on the gel product, not on foam. However, industry experts and CMS have indicated that
small-quantity ABHR foam dispensers may be handled the same as for ABHR gel. Therefore, pending further review, both The Joint Commission and CMS will allow any ABHR foam installation that meets the location criteria stated above for ABHR gel. Volumes of ABHR foam are based on suppliers’ recommendations and in no case exceed the permissible volumes for ABHR gel as defined above. In the event that subsequent testing demonstrates a safety concern relating specifically to foam dispensers in egress corridors, The Joint Commission reserves the right to modify its position on the acceptability of such installations. In that event, previously installed dispensers would be subject to the newer restrictions; that is, they would not be “grandfathered,” and noncompliant installations would have to be removed.

Updated | November 24, 2008

Security of Syringes and Needles

Q: Do hypodermic needles and syringes need to be stored under lock and key?

A. The Joint Commission standards require that organizations conduct a comprehensive risk assessment to determine the potential adverse impact of equipment, supplies, and other factors on the safety and health of patients, staff, and others. The standards also require that organizations use the information from the risk assessment to implement procedures and controls to address the potential adverse impact, such as access control.

Revised | March 9, 2009

Mounting Sharps Boxes/Containers

Q. Is there a requirement that sharps/needle boxes or containers be mounted on the wall in patient rooms? If so, what is the required height?

A. The Joint Commission does not specify that sharps/needle boxes or containers need to be wall mounted; nor does it specify the height at which they are to be mounted. Rather, it is up to the organization to perform a risk assessment to determine whether the selected placement of the wall-mounted sharps container poses a risk to the occupants of the room. In addition to considering patient population, it is important to consider whether visitors (perhaps with small children) could access the containers. Include input from infection control, risk management, and the safety officer in the risk assessment process. The CDC and the National Institute for Occupational Safety and Health (NIOSH) provide further guidance for mounting heights based on application.
Q. Health care organizations are responsible for adhering to local, state, and federal regulations for proper handling and disposal of hazardous materials and wastes. How is it possible for Joint Commission surveyors to determine whether an organization is complying with all of these codes, standards, and regulations when they often differ from one location or state to another?

A. The process of conducting surveys at a wide range of geographic locations presents unique challenges to each surveyor. The federal Environmental Protection Agency (EPA) regulations apply to most organizations, and it is with these regulations that surveyors are most familiar. State and local regulations are generally even more restrictive. Thus, the surveyor must usually determine what additional requirements the state or local regulations have imposed.

The organization’s hazardous materials and waste management program is required to be designed and operated in accordance with all applicable laws and regulations. This written program contains the policies and procedures that are necessary for the organization to be in compliance with all applicable laws. Through a thorough review of the hazardous materials and waste program, surveyors are able to determine the extent to which the state and local regulations have been included within the scope of the program. Each organization is encouraged to maintain a reference library of all applicable federal, state, and local laws and regulations. Maintenance of this library helps demonstrate that all of the various regulatory requirements have been taken into consideration during program design. If the organization is unable to refer to the actual regulations, it is difficult to see what requirements the program is based on and how the organization keeps abreast of changes to these regulations.

Q. How long should medical waste manifests be retained by an organization?

A. The Joint Commission standards do not specify archival time recommendations, but would expect a minimum of three years. Other Authorities Having Jurisdiction (AHJs), such as the EPA, OSHA, and the DOT, may have longer archival requirements. Leadership standards require compliance with other AHJs, so confirmation with local, state, and federal AHJs would be needed.

Q. When does an item need to be included on the hazard inventory?

A. This is an OSHA requirement. The Joint Commission standards state that the organization “maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed...
standards BoosterPak™ for Sample Collection

by law and regulation” (for example, EPA and OSHA). An MSDS inventory is required by all employers in order to provide information to their employees about hazardous chemicals to which they are exposed in their workplaces, as stated in the OSHA Hazard Communication Standard, 29 CFR 1910.1200. A list of hazardous chemicals is available through OSHA—although this is not all inclusive; see 29 CFR 1910, Subpart Z, Toxic and Hazardous Substances. Consumer products (such as turpentine, gasoline, or cleaning solvents) that are used in a workplace in such a way that the duration and frequency of use are the same as that of a consumer are not required to be included in the hazard communication program. However, it is the responsibility of the employer to make the determination for their workplace by assessing the exposure potential of the consumer products that staff may encounter and ensuring that the frequency and duration of use are not greater than that of normal consumer use.

Current | January 13, 2009

Material Safety Data Sheets (MSDS) Alternatives

Q. We have access to a computer program that is maintained by the EPA, and it is more accurate than an MSDS. Is it acceptable to use this program to obtain the information we normally would get from an MSDS (this program is used by many fire departments and hazmat units)?

A. The Joint Commission neither recommends nor endorses specific brands or products. The concern is that the product conveys appropriate information to the users and if the product you are reviewing is deemed equivalent to the OSHA MSDS requirements. Consider the following questions: Do staff have adequate access to the necessary information? Do staff know how to read an MSDS? If the electronic format was unavailable, what alternative(s) is available? It is recommended that there be at least one hard copy of the MSDS documents within the organization in the event the electronic forms are not available.

Two Patient Identifiers: NPSG Goal 1–NPSG.01.01.01
Current | December 9, 2008

Intent of Using Two Patient Identifiers

Q. What is the intent of the requirement for using two identifiers?

A. The intent here is twofold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Therefore, the two patient/client/resident-specific identifiers must be directly associated with the individual, and the same two identifiers must be directly associated with the medications, blood products, specimen containers (such as on an attached label), or other treatments or procedures.
Armband for Patient Identification

Q. What do you mean by two patient identifiers?

A. For those patients with armbands, we're thinking patient name and ID number compared to the order/medication administration record would be the two identifiers. Yes, that is acceptable. The two identifiers may be in the same location, such as a wristband. It is the person-specific information that is the “identifier,” not the medium on which that information resides. Acceptable identifiers may be the individual’s name, an assigned identification number, telephone number, or other person-specific identifier. Electronic identification technology coding, such as bar coding or RFID, that includes two or more person-specific identifiers (not room number) will comply with this requirement. Please remember that active patient involvement is also required in EP 1.

Armband Not Attached to the Patient

Q. Is it acceptable practice to lay the patient armband on the bedside table or tape it to the bed if the patient is alert and is able to state his or her identifying information?

A. Although The Joint Commission does not require the use of armbands for patient/resident identification, if you do choose to use armbands as a means of conveying patient/resident identification information, the band must be attached to the patient/resident at all times. Simply placing it on the bedside table or taping it to the bed would not be acceptable if there is any reliance on the information contained on it.

Labs Accredited by Agencies Other than The Joint Commission

Q. EP 6 says, “Label containers used for blood and other specimens in the presence of the patient.” Our hospital is Joint Commission accredited but we have another accrediting agency for our lab. Does this requirement apply to us?

A. Yes. For any specimen collection that occurs in an accredited organization, NPSG.01.01.01 applies. Prelabeling of specimen containers, also known as batch processing, is a common approach that is assumed to improve efficiency but can increase the risk for patient/treatment/specimen misidentification. Prelabeling can be done on a patient-specific basis, but if not performed in the presence of the patient it will not be acceptable under this requirement.

Maintaining the Identity of Samples

Q. The laboratory version of this requirement refers to maintaining the identity of samples. Does this apply to specimens obtained in our hospital (which is Joint Commission accredited) by staff from our laboratory (which is not accredited by The Joint Commission)?

A. In the Laboratory manual, EP 7 says, “Processes are established to maintain samples’ identity throughout
the pre-analytical, analytical, and post-analytical processes.” This is a requirement for the laboratory itself and, therefore, applies only to Joint Commission–accredited laboratories.

**Outpatient Settings**

Q. A lot of our outpatients—those who come for a lab draw and other simple procedures, our home health patients and our ambulatory care patients—do not have an armband. Would asking them their name and comparing it to any paperwork we have constitute two identifiers?

A. No. In the requirement for using two identifiers, the term **identifier** refers to the specific items of information by which the care recipient can be identified rather than the source of the information. So, comparing the individual’s stated name with the name on the requisition would be one identifier. Examples of a second identifier for a care recipient without an armband might be date of birth, social security number, home address, or phone number.

**Same Identifiers Throughout the Organization**

Q. Do the same two identifiers have to be used throughout the organization?

A. No. Ideally a standardized or similar approach would be used throughout the organization; however, different identifiers may be used in different settings as long as their use is consistent with the intent of this requirement as stated above. However, the identifiers should be consistent within each setting, not just whatever the individual practitioner or staff person wishes to use.

**Temporary Names**

Q. How would you identify an injured emergency department (ED) patient who was unresponsive and could not communicate with others?

A. Such patients are usually assigned a temporary “name” (such as John Doe) and an ED number or medical record number. These identifiers could then be used to identify the patient and match against specimen labels, medications ordered for the patient, or blood product labels. In this process, formal identification of the patient should occur as soon as possible, and when confirmed, this identifying information should be used instead of the temporary identification.
Home Care Identification

Q. What about the home care situation? Do we need to keep checking two identifiers each time we give a medication?

A. The goal is to ensure accurate identification of care recipients. In the home care setting, this is much easier and less prone to error than in other settings. Certainly, at the first encounter, the requirement for two identifiers is appropriate in a literal sense. Thereafter, and in any situation of continuing one-on-one care where the nurse “knows” the individual, one of the identifiers can be direct facial recognition. In the home, the correct address (an acceptable identifier when used in conjunction with another person-specific identifier) is also confirmed.

Behavioral Health Care Identification

Q. We are a behavioral health care facility. The individuals in our care do not always wear wristbands. What other methods are acceptable for the “two identifiers”?

A. A common approach in these situations is to include the individual’s photograph in the clinical record for purposes of visual identification by staff. For residential care settings that may serve only a few individuals, such as a group home, in which the individual may stay for an extended period of time, where there is stability of the staff and client/resident populations, and the individuals receiving care are well-known to the staff providing that care, we would accept visual recognition as an identifier and focus the survey of this requirement on the use of two identifiers for high-risk interventions—perhaps for certain high-risk medications, like methadone—to ensure “matching” of the treatment to the individual. In other words, is the medication adequately identified (with two identifiers) for the specific individual who is to receive it? For high-risk interventions or in settings with less stable staffing and short length of stay, we would expect the full “two identifier” requirement to be followed.

Active Involvement of the Patient or Responsible Caregiver

Q: Are there any exceptions for active involvement of the patient or responsible caregiver? What if the patient is sleeping? Does this mean the patient’s nurse needs to help identify noncommunicative or confused patients whenever other health care workers, such as lab and respiratory therapy, use two patient identifiers?

A. The primary purpose of this requirement is to ensure the safety of patients during their care, including prevention of medication, diagnostic, and treatment errors. For those patients who are sleeping, are noncommunicative or are confused, each organization decides how its staff will assess these patients and when active involvement of the patient or responsible caregiver is necessary. Such decisions and expectations must be clearly communicated to staff and should be based on promotion of patient safety, not convenience or work flow.
Section B2: Definition of Key Terms

**Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88):** Federal legislation that created uniform federal standards for regulating laboratory testing. CLIA ’88 unified the disparate federal and state standards regulating clinical laboratories and extended government oversight to all testing facilities, including physician offices.

**Clinical and Laboratory Standards Institute (CLSI):** A global, nonprofit, standards-developing organization for clinical and laboratory services that promotes the development and use of voluntary consensus standards and guidelines within the health care community. Until 2005 CLSI was known under the name National Committee for Clinical Laboratory Standards (NCCLS).

**Competency:** The ability of an individual to perform a job properly. A competency is a set of defined behaviors that provide a structured guide enabling the identification, evaluation, and development of the behaviors in individual employees.

**Direct Impact requirements:** Requirements (standards, elements of performance, National Patient Safety Goals, and Accreditation Participation Requirements) that, if not met, are likely to create an immediate risk to patient safety or quality of care. The immediate risk usually results because there are no or few processes—or no or few protective defenses—intervening between the noncompliance and the impact on the safety or quality or an individual’s care.

**Element of Performance (EP):** Specific action(s), process(es), or structure(s) that must be implemented to achieve the goal of a standard. The scoring of EP compliance determines an organization’s overall compliance with a standard.

**Expiration date:** The date after which the product, when stored under recommended conditions, should no longer be used.

**Hazardous materials and waste:** Materials whose handling, use, and storage are guided or defined by local, state, or federal regulation, such as the Occupational Safety and Health Administration’s Regulations for Bloodborne Pathogens regarding the disposal of blood and blood-soaked items and the Nuclear Regulatory Commission’s regulations for the handling and disposal of radioactive waste. This also includes hazardous vapors (for example, gluteraldehyde, ethylene oxide, nitrous oxide) and hazardous energy sources (for example, ionizing or nonionizing radiation, lasers, microwave, ultrasound). Although The Joint Commission considers infectious waste as falling into this category of materials, federal regulations do not define infectious or medical waste as hazardous waste.

**Indirect Impact requirements:** Requirements that pose less immediate risk to the care and safety of the patient, resident, or individual served than Direct Impact requirements. However, noncompliance with these requirements increases risk to safety and quality of care over time, and this risk may ultimately exceed that of a Direct Impact requirement in scope or severity.

**Laboratory director:** A physician who is usually employed to serve in a medical and administrative capacity as head of the laboratory. He or she may also serve as liaison for the laboratory with the hospital’s administration and governing board.

**Laboratory test order:** A request for laboratory testing sent to the laboratory in writing, electronically, or verbally with follow-up written authorization.
**Order of draw:** Standardized sequence used during the blood collection process for the filing of the blood collection tubes to minimize carryover of tube additives from tube to tube.

**Orientation:** A process used to provide initial training and information while assessing the competency of clinical staff relative to job responsibilities and the organization’s mission and goals.

**OSHA:** Occupational Safety and Health Administration, an agency of the US government under the Department of Labor with the responsibility of ensuring safety at work and a healthful work environment.

**Performance improvement:** Data collection and analysis for the purpose of providing an indication of the organization’s performance on a specified process or outcome.

**Preanalytical errors:** Errors that occur from the time the test is ordered by the physician until the sample is ready for analysis.

**Ppm:** Parts per million.

**Q-Track:** A voluntary program offered by the College of American Pathologists that offers a continuous look at key anatomic and clinical pathology processes across all laboratories in your organization. Critical pre- and post-analytical processes include turnaround time, patient and physician satisfaction, and effectiveness of care.

**Root cause analysis (RCA):** A process for identifying basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event.

**Safety:** The degree to which the risk of an intervention (for example, use of a drug, or a procedure) and risk in the care environment are reduced for a patient and other persons, including health care practitioners. Safety risks may arise from the performance of tasks, from the structure of the physical environment, or from situations beyond the organization’s control (such as weather).

**Sample:** One or more parts taken from a system and intended to provide information on the system. In the context of this BoosterPak™, a sample may be serum or plasma, available for testing after centrifugation of the specimen or whole blood.

**Specimen (patient):** The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.

**Staff:** As appropriate to their roles and responsibilities, all people who provide care, treatment, or services in the organization, including those receiving pay (for example, permanent, temporary, part-time personnel, as well as contract employees), volunteers, and health profession students. The definition of staff does not include licensed independent practitioners who are not paid staff or who are not contract employees.

**Standard precautions:** Infection prevention and control measures for reducing the risk of transmission of bloodborne and other pathogens from both recognized and unrecognized sources of infection. They are applied to all patients regardless of their diagnosis or presumed infection status.

**Transmission-based precautions:** Infection prevention and control measures to protect against exposure to a suspected or identified pathogen. These precautions are specific and based on the way the pathogen is transmitted. Categories include contact, droplet, airborne, and a combination of these.

**Unique patient identifier:** A name or number that can uniquely identify a patient when at least two such identifiers are used. **Note:** The patient’s name is considered the primary unique patient identifier. In combination with the patient’s name, a unique number such as the medical record number (MRN), financial/account number, or episode number is also used.
Section B3: Additional Information

Preanalytical errors are the most difficult to detect and correct, so the focus needs to be placed on prevention. Standardizing the policies and procedures for collection, handling, and processing, along with having an understanding of the variables that effect laboratory results, is required for prevention (Table 1).33

Table 1. Preanalytical Variables

<table>
<thead>
<tr>
<th>Patient Variables</th>
<th>Specimen Collection Variables</th>
<th>Specimen Handling Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>Posture</td>
<td>Hemolysis</td>
</tr>
<tr>
<td>Body mass</td>
<td>Diurnal variation</td>
<td>Lipemia</td>
</tr>
<tr>
<td>Age</td>
<td>Time of collection</td>
<td>Centrifugation</td>
</tr>
<tr>
<td>Medications</td>
<td>Fasting status</td>
<td>Processing time</td>
</tr>
<tr>
<td>Gender</td>
<td>Tourniquet</td>
<td>Temperature</td>
</tr>
<tr>
<td>Smoking</td>
<td>Presence of IVs</td>
<td>Sunlight/light exposure</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Capillary vs venous</td>
<td>Evaporation</td>
</tr>
<tr>
<td>Exercise</td>
<td>Anticoagulants</td>
<td>Aliquoting</td>
</tr>
<tr>
<td>Race</td>
<td>Order of draw</td>
<td>Labeling</td>
</tr>
<tr>
<td>Dehydration</td>
<td></td>
<td>Transport conditions</td>
</tr>
</tbody>
</table>

Hemolysis is a common cause of sample rejection and may be due to improper specimen collection, processing, or transport. Here are some guidelines to keep your specimen rejection rate due to hemolysis to a minimum34:

- Use dedicated phlebotomy staff to collect samples.
- Avoid line draws if possible. One study found that specimens drawn by nurses through an IV catheter were three times more likely to be hemolyzed than those drawn by venipuncture (13.7% vs. 3.8%).35
- When using a syringe for sample collection, avoid excess pressure when pulling the plunger back and when transporting the sample from a syringe into a tube.
- Make sure the alcohol dries.
- Use the largest-bore needle that is appropriate.
- Place the needle properly in the vein.
- Remove the tourniquet as early as possible. The tourniquet should be left on for no longer than one minute.
- Pre-warm sites that will be used for capillary collections.
- Make sure all the tubes are filled to the correct volume.
- Avoid vigorous mixing or shaking of the tubes.
- Prolonged contact with serum or plasma with cells may cause hemolysis.36
- Exposure to excessive heat or cold can cause red cells to rupture and hemolysis.37
- When processing your samples, don’t rim clots.

Standards BoosterPak™ for Sample Collection

The Clinical and Laboratory Standards Institute promotes the development and use of voluntary laboratory consensus standards and guidelines within the health care community. Documents are available that address specimen collection and handling, including patient and specimen identification, labeling, processing, and transporting; quality management systems; needlestick prevention; and process improvement.

Documents Available from the Clinical and Laboratory Standards Institute
AUTO 07-A Laboratory Automation: Data Content for Specimen Identification; Approved Standard
AUTO12-A Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard
H01-A6 Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard, Sixth Edition
H03-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard, Sixth Edition
H04-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens by Venipuncture; Approved Standard, Sixth Edition
H18-A4 Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline, Fourth Edition
H21-A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline, Fifth Edition
GP32-A Management of Nonconforming Laboratory Events; Approved Guideline
GP33-A Accuracy in Patient and Sample Identification; Approved Guideline
GP34-A Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline
GP35-P Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline
X03-R Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report
C: Supporting Documentation, Evidence, Value, Historical Information, and Additional References
Section C1: Supporting Documentation and Evidence

Laboratory results influence 60%–70% of all critical decisions regarding patient care (admitting, discharging, and medication dosing).\(^\text{38}\) There have been advances in automation and instrument technology that have improved the analytical error rates, but preanalytical mistakes are still the main cause of laboratory errors. This is due to the fact that many of these preanalytical processes cannot be automated. The reliance on the human factor makes it difficult to standardize the processes and completely eliminate preanalytical laboratory errors. By applying the standards in this packet, along with the implementation suggestions and tips, the organization will have taken the preliminary steps to reducing preanalytical errors. With leadership support, sustained attention to specimen collection and handling, and implementation of interventions, it is possible to reduce the preanalytical error rates of the organization.

The Authority collaborative in the northeast region of Pennsylvania, a group of eight acute care hospitals and one rehabilitation hospital, set a goal of a 50% reduction in blood specimen labeling errors over 18 months. Their top three contributing factors to mislabeling errors were procedures not followed, distractions and interruptions, and unplanned workload increases. Over a 3-month period, the participants implemented more than 20 interventions in the following categories: technology, communication, education, staffing, work flow, and leadership. Overall, the collaborative experienced a 37% statistically significant decrease in blood specimen labeling errors.\(^\text{39}\)

A College of American Pathologists Q-Track performed between 1999 and 2000, demonstrated an initial preanalytical error rate of 7.40% that fell to 3.05% following continuous monitoring and educational initiatives of the organizations involved.\(^\text{40}\)

The 2007 study by Carraro and Plebani regarding the same stat laboratory comparison of data from 10 years apart found a significant decrease of the error rates from 4,667 to 3,092 ppm. This was achieved by using advances in technology such as transportation of specimens by pneumatic tube stations; order entry in the hospital information system, which immediately printed bar-code labels for the bedside identification of all patient samples; and automated check-in at the laboratory of all patient samples.\(^\text{1}\)

Section C2: Value to Field and Related Initiatives

Joint Commission standards are developed with input from health care professionals, providers, subject matter experts, consumers, government agencies (including the Centers for Medicare & Medicaid Services), and employers. They are informed by scientific literature and expert consensus. In addition, draft standards are distributed nationally for review and made available for comment on the Joint Commission website.

With the exception of NPSG.01.01.01, all of the standards listed in this BoosterPak™ were subjected to the field review process to collect feedback from internal and external stakeholders. Comments and suggestions were received from the field, and, when necessary, the standards and EPs were revised prior to approval by the Board of Commissioners. NPSG.01.01.01 did not follow the typical standards development process, as this requirement was initiated through the Sentinel Event Advisory Group (now called the Patient Safety Advisory Group).
Section C3: Historical Information and Changes

All of the standards listed above have been part of the Joint Commission accreditation standards for several years. Although some of the requirements have been revised over the past five years to include additional components or specificity, the overall issues have been included in Joint Commission standards in one form or another.

In August 2006 The Joint Commission launched the Standards Improvement Initiative (SII) as part of its continuous quality improvement efforts. The main goals of SII were to enhance the clarity of the Joint Commission standards and to better tailor them to the different types of accredited organizations. SII focused solely on revising standards and elements of performance (EPs); no new requirements were introduced during the project. However, as a result of the SII project, the standards were reorganized and renumbered. All of the standards in this BoosterPak™ were evaluated during SII, and much of the content was retained through that process.
Section C4: Additional References


Helpful Websites

Center for Phlebotomy Education
http://www.phlebotomy.com

American Society of Phlebotomy Technicians
http://www.aspt.org

National Phlebotomy Association
http://www.nationalphlebotomy.org

American Phlebotomy Association
http://www.apa2.com

Centers for Disease Control and Prevention, Current CLIA Regulations

The Safety Lady
http://www.safetylady.com/free_articles/dot/

FedEx Packaging Guidelines


International Air Transport Association, Guidance Document: Infectious Substances
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