

July 22, 2009

**DATA COLLECTION ON MISLABELED SPECIMENS FOR PATHOLOGY AND  
LABORATORY MEDICINE SERVICE (P&LMS)**

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive provides policy for data collection regarding incidents of mislabeled specimens throughout all VHA facilities.

**2. BACKGROUND:** Standardized data collection allows accurate comparisons and sharing of best practices between facilities, Veterans Integrated Service Networks (VISNs), and national data pre- and post-Bar Code Expansion (BCE) project implementation. The scope of the BCE project covers labeling activities related to the pre-analytical phase of testing only.

a. The National Center for Patient Safety (NCPS) has a growing database of patient misidentification adverse events exposing vulnerability in VHA facilities for clinical specimens and anatomic pathology specimens. Bar code scanning technology can improve the accuracy of patient identification at the point of care and reduce the incidence of adverse events due to misidentification.

b. National laboratory standards require laboratories to collect data on specimen mislabeling events. *NOTE: VHA Handbook 1106.01 further reinforces these standards of practice.*

c. Pathology and Laboratory Medicine's National Enforcement and Program Office Strategic Plan (Objective 2.2: leverage technology to improve laboratory quality and patient safety) clearly supports improving quality and patient safety on a national level. Standardizing specimen mislabeling data collection in all VHA laboratories and comparing baseline, post implementation, and periodic checks provides evidence that strategic goals are met or identifies opportunities for improvement.

d. Evaluation of the clinical bar coded systems at the point-of-care for specimen collection ensures the delivery of safe, effective, timely, and high quality patient care.

e. Standardized data collection on specimen mislabeling provides valuable baseline, post implementation, and sustained process improvement data to measure the effectiveness of introducing bar code scanning technology to the laboratory setting as a part of the BCE project.

f. The Joint Commission National Patient Safety Goal (NPSG) to "Improve the accuracy of patient identification" requires the use of at least two patient identifiers when providing care, treatment, or services.

**3. POLICY:** It is VHA policy that each facility must implement a procedure for Data Collection on Mislabeled Specimens for Pathology and Laboratory Medicine Service (P&LMS) no later than November 2, 2009.

**THIS VHA DIRECTIVE EXPIRES JULY 31, 2014**

July 22, 2009

#### 4. ACTION

a. **P&LMS Program Office.** The P&LMS Program Office is responsible for:

- (1) Distributing a standardized data collection tool and related data definitions to the field;
- (2) Serving as the focal point for promoting a coordinated, “One Standardized National Program” approach to data collection, and managing the resulting database containing inputs from the field;
- (3) Identifying opportunities for improvement based on findings reported by the Bar Code Resource Office (BCRO);
- (4) Evaluating reports of adverse events and close calls (also known as “near misses”) related to mislabeled specimens and related topics and providing feedback to the field; and
- (5) Providing and communicating guidance on patient safety best practices and lessons learned related to labeling specimens.

b. **National Center for Patient Safety (NCPS).** NCPS is responsible for:

- (1) Receiving reports of adverse events and close calls related to mislabeled specimens and related topics from VHA facilities, and
- (2) Providing redacted or summary information to the P&LMS Program Office based on those reports.

c. **VHA Bar Code Resource Office (BCRO).** The BCRO is responsible for:

- (1) Creating and publishing the data reporting tools, processes, and schedules;
- (2) Reporting data to P&LMS Program Office;
- (3) Monitoring data submissions and reporting the findings to the Bar Code Oversight Board;
- (4) Compiling submitted data, analyzing the data, and posting the findings; and
- (5) Reporting data findings in the annual performance and accountability report.

d. **Medical Center Director.** The Medical Center Director, or designee, is responsible for:

- (1) Ensuring successful implementation of a local procedure for the Data Collection on Mislabeled Specimens for P&LMS.

(2) Appointing a Clinical Bar Code Multidisciplinary Committee (CBCMC) to be responsible for:

(a) Reviewing facility and national data to identify opportunities for improvement; and

(b) Facilitating corrective actions, monitoring the progress of actions to completion and providing periodic progress reports to the Clinical Executive Board (CEB) or its equivalent.

(3) Designating a Bar Code Expansion (BCE) Coordinator who is responsible for:

(a) Implementing and ensuring compliance with the standardized procedure and related data collection tool for the collection of specimen mislabeling data in the laboratory;

(b) Reviewing aggregate facility data and reporting findings to the CBCMC; and

(c) Submitting data as required by the data reporting schedule to the BCRO.

e. **Chief P&LMS.** The Chief P&LMS is responsible for ensuring that all Laboratory staff document specimen mislabeling events as defined by the data definitions on the data collection tool found at:

<http://vaww.national.cmop.va.gov/bcma/BCEC/Mislabeled%20Specimens%20Data%20Collection%20Supporting%20Do/Forms/AllItems.aspx> . **NOTE:** *This is an internal Web site and not available to the public.* Laboratory staff includes: Pathologists, Medical Technologists, Medical Technicians, Phlebotomists, and Histologists.

## 5. REFERENCES

a. VHA Handbook 1106.01.

b. VA Secretary's Strategic Plan, found at: [http://vaww1.va.gov/op3/docs/VA\\_2006\\_2011\\_Strategic\\_Plan.pdf](http://vaww1.va.gov/op3/docs/VA_2006_2011_Strategic_Plan.pdf). **NOTE:** *This is an internal website and not available to the public.*

c. Food And Drug Administration (FDA) Regulations, Title 21 Code of Federal Regulations (CFR) 606.

d. Laboratory Accreditation Standards, Accreditation Checklist, College of American Pathologists (CAP), 325 Waukegan Road, Northfield, IL 60093.

e. Standards for Blood Banks and Transfusion Services, 25<sup>th</sup> edition or latest edition, AABB, 8101 Glennbrook Road, Bethesda, MD 20814.

f. Accreditation Standards, Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, FL 60181.

g. Clinical Laboratory Improvement Amendments (CLIA), 42 CFR 493.

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h. Specimen Labeling Errors: A Q-Probes Analysis of 147 Clinical Laboratories, Wager et al, Archives of Pathology Laboratory Medicine (Arch Pathol Lab Med). Vol. 132, October 2008.

i. National Enforcement and Program Office Strategic Plan (Objective 2.2).

**6. RESPONSIBILITY:** P&LMS (115A) is responsible for the content of this Directive. Questions may be directed to P&LMS Program Office at (202) 461-7359.

**7. RECESSIONS:** None. This VHA Directive Expires July 31, 2014.

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Acting Under Secretary for Health

**DISTRIBUTION:** E-mailed to the VHA Publications Distribution List 7/24/2009

ATTACHMENT A

DATA COLLECTION PROCESS, REPORTING SCHEDULE AND TOOLS

1. Field Reporting Tool

a. A Field Reporting Tool has been developed to support the data collection process. Use of this tool is recommended. This tool is posted within the Shared Document library of the Bar Code Expansion Coordinator SharePoint site at:

<http://vaww.national.cmop.va.gov/bcma/BCEC/Mislabeled%20Specimens%20Data%20Collection%20Supporting%20Do/Forms/AllItems.aspx>. *NOTE: This is an internal Web site and not available to the public.*

Deleted: <http://vaww.national.cmop.va.gov/bcma/BCEC/Mislabeled%20Specimens%20Data%20Collection%20Supporting%20Do/Forms/AllItems.aspx>

b. Regardless of the choice to use this tool or another, all sites must utilize the same data definitions which are identified within the supplied Field Reporting Tool.

2. **SharePoint Reporting Tool.** The BCE Coordinator or designee must compile mislabeled data using the data definitions found within the Field Reporting Tool at:

<http://vaww.national.cmop.va.gov/bcma/BCEC/Mislabeled%20Specimens%20Data%20Collection%20Supporting%20Do/Forms/AllItems.aspx> and enter summary data into the SharePoint Reporting Tool. *NOTE: This is an internal Web site and not available to the public.* The SharePoint Reporting Tool is located within the Bar Code Expansion Coordinator SharePoint at: <http://vaww.national.cmop.va.gov/bcma/BCEC/Lists/Monthly%20Facility%20Specimen%20Mislabeled%20Data/overview.aspx>. *NOTE: This is an internal Web site and not available to the public.*

Deleted: (<http://vaww.national.cmop.va.gov/bcma/BCEC/Mislabeled%20Specimens%20Data%20Collection%20Supporting%20Do/Forms/AllItems.aspx>)

3. Reporting How To Manual

a. A manual on "How to Report" has been developed to support the data collection process, which provides a substantial number of screen shots to support a step by step description of the process.

b. This manual is posted within the Shared Document library of the Bar Code Expansion Coordinator SharePoint site at:

<http://vaww.national.cmop.va.gov/bcma/BCEC/Mislabeled%20Specimens%20Data%20Collection%20Supporting%20Do/Forms/AllItems.aspx>. *NOTE: This is an internal Web site and not available to the public.*

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