BIOMETRICAL ENGINEERING PERFORMANCE MONITORING AND IMPROVEMENT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive defines VHA policy for the Biomedical Engineering Performance Monitoring and Improvement program.

2. SUMMARY MAJOR CHANGES: This directive:

   a. Changes from a focus on resources survey to a framework of metrics to drive benchmarking, the spread of strong practices, and continuous program improvement.

   b. Develops a balanced scorecard approach to serve as a measure of business processes and quality outcomes for VHA’s Healthcare Technology Management and Biomedical Engineering functions.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: Office of Healthcare Technology Management (10NA9), is responsible for the contents of this directive. Questions may be directed to 612-467-5778.


6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

CERTIFIED BY: /s/ Renee Oshinski
Acting Deputy Under Secretary for Health for Operations and Management

BY DIRECTION OF THE UNDER SECRETARY FOR HEALTH: /s/ Renee Oshinski
Acting Deputy Under Secretary for Health for Operations and Management

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on [DATE].
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BIOMEDICAL ENGINEERING PERFORMANCE MONITORING AND IMPROVEMENT

1. PURPOSE

This Veterans Health Administration (VHA) directive defines VHA policy for the Biomedical Engineering (BME) Performance Monitoring and Improvement program.

AUTHORITY: Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. The Office of Healthcare Technology Management (HTM) provides oversight of BME and the management of medical technology across VHA consistent with relevant laws, regulations (e.g. Public Law 101-629, Safe Medical Devices Act of 1990; 21CFR 803, Medical Device Reporting), industry standards (e.g. American National Standards Institute Association for the Advancement of Medical Instrumentation (AAMI) EQ56, Recommended Practice for a Medical Equipment Management Program), and accreditation requirements (e.g. The Joint Commission Standard Environment of Care EC.02.04.01, EC.03.01.01, EC.04.01.01). The Office of HTM strives to manage variation, reduce risk, and spread strong practices to improve the performance of BME programs and to ensure medical equipment safety, reliability, and availability for patient care.

b. The Office of HTM provides oversight to BME programs in all Veterans Integrated Service Networks (VISN) and VA medical facilities. Collectively, BME programs directly manage 800,000 medical devices worth over $8 billion, with a field workforce of approximately 1,300 individuals. The Office of HTM develops and implements standards, services, and initiatives to support BME field operations. One such service is the BME Performance Monitoring and Improvement Program.

c. The VA BME Resources Survey was initially developed in the 1970s to quantify resource consumption and analyze cost data. HTM developed the BME Performance Monitoring and Improvement framework in 2014 for organizational performance monitoring, benchmarking, and continuous program improvement. The framework incorporates dimensions of patient safety, process and quality, employee learning, customer satisfaction, and financial performance. The framework tracks and trends numerous metrics related to BME functions. By quantifying and analyzing metrics on a regular and recurring basis, HTM develops national averages for metrics, recognizes operational performance variations across VISNs and VA medical facilities, and establishes performance goals for BME. The BME Performance Improvement framework is regularly reviewed with the field BME community of practice.

d. Consistent data and outcomes monitoring is crucial in assuring sound BME practices. Key Performance Indicators (KPI) and Monitors are established through a balanced scorecard to serve as a measure of business processes and provide the VHA BME professional community with actionable data to strengthen practices to achieve program excellence. HTM has developed standard data definitions, standard business
processes, and universal metrics, and automated data extraction capabilities to reduce reliance upon self-reported data.

3. DEFINITIONS

a. **Biomedical Engineering Performance Monitoring and Improvement Framework.** Organizational improvement model comprised of KPIs and Measures.

b. **Key Performance Indicator.** A measure of business processes and outcomes that provide actionable data to strengthen practices and achieve program excellence. KPI results are intended to:

   (1) Monitor health of the program at the VISN and VA medical facility levels to identify high performers and those needing improvement;

   (2) Promote the value of BME at the VA medical facility, VISN, and organizational levels and inform leaders of the contribution of BME programs at all levels of VHA to support clinical operations; and

   (3) Facilitate continuous program improvement within VA medical facilities, VISNs, and the VHA enterprise to foster and maintain a high standard of Biomedical Engineering performance within VHA.

c. **Scorecard.** A measure of business processes and the primary reporting tool for the BME Performance Monitoring and Improvement framework. The scorecard is comprised of the following domains and sub-categories:

   (1) **Patient Safety and Risk Management:** Includes equipment safety alerts and recalls, incident response investigations, purchasing for safety, medical device cybersecurity, regular inspections, planned equipment maintenance, and related measures.

   (2) **Process and Quality:** Includes professional technology assessment, deployment, and sustainment services, service production and outcomes, conformance to business process standards, and other measures related to operational excellence.

   (3) **Employee Demographics and Learning:** Includes staffing levels and mix, continuous learning and growth, experience, certifications, and other workforce related measures.

   (4) **Financial Performance:** Includes portfolio value and complexity, internal operating costs, outsourced operating costs, cost savings and avoidance, and related financial measures.

   (5) **Customer Satisfaction:** Includes responsiveness, staff knowledge, courtesy, communication, scope of services, and other measures related to customer experience.
4. POLICY

It is VHA policy that each VISN and VA medical facility record BME services in accordance with standards defined by the HTM Program Office; adhere to the standardized business processes that drive consistent data reporting to inform performance monitoring, improvement, and analytics; and report information that is not automatically extracted from various databases per direction from the Office of HTM and Office of the Deputy Under Secretary for Health for Operations and Management.

**NOTE:** The documentation of services standards, the standard data definitions, and the standardized business processes are located at the following link: https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/CommResource/SitePages/homepage.aspx. This is an internal VA Web site that is not available to the public.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

   1. Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).
   2. Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all of the VA medical facilities within that VISN.
   3. Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **Director, Office of Healthcare Technology Management.** The Director of the Office of HTM is responsible for:

   1. Determining and promulgating BME performance monitoring benchmarks that are used in the Biomedical Engineering Performance Improvement and Monitoring framework for the purpose of supporting VA’s mission of providing quality medical care.
   2. With VISN and VA medical facility input, evaluating the efficacy of BME performance benchmarks on an ongoing basis to ensure the benchmarks are accomplishing their intended purpose (e.g. ensuring that performance metrics accurately capture and represent current services, current data standards, and up-to-date business process standards).
   3. Maintaining and developing data automation enhancements and communicating reporting timelines to the VISNs and the VHA BME professional community.
   4. Compiling and distributing scorecards and reports to VISNs to facilitate local recognition of program strengths and opportunities to improve quality and outcomes.
(5) Analyzing quality, outcomes, and data across the VA enterprise for trends to identify low performing or at-risk VA medical facilities.

(6) Recommending actions to the Deputy Under Secretary for Health for Operations and Management or VISN Directors, especially related to low performing or risk areas and providing consultation to VISN or VA medical facility Directors upon request, or as indicated by high risks to quality outcomes.

(7) Identifying high performing leaders to assess internal business processes and standardized work practices that can be shared amongst the VHA BME professional community as a best practice. Identifying low performing or at-risk VA medical facilities for further review based on HTM targets, field based-group data reviews, and field input.

(8) Annually reviewing the BME Performance Monitoring and Improvement framework, and implementing improvements recommended by VA medical facilities.

(9) Submitting any field based-group data review final reports to the corresponding VA medical facility Director.

d. **Director, Veterans Integrated Service Network.** The VISN Director is responsible for:

   (1) Communicating the contents of this directive to each of the VA medical facility Directors.

   (2) Ensuring that each VA medical facility Director has the sufficient resources to fulfill the terms of this directive and to achieve successful outcomes of BME functions in all the VA medical facilities within that VISN.

   (3) Relaying communications from the Director, HTM Program Office to VA medical facility Directors.

   (4) Reviewing and approving strategies, recommendations, processes, and programmatic strengths based on performance reports from the Chief Biomedical Engineer, Veterans Integrated Service Network.

e. **Chief Biomedical Engineer, Veterans Integrated Service Network.** The VISN Biomedical Engineer is responsible for:

   (1) Reviewing reports and scorecards provided by the Office of HTM and developing action plans to address opportunities for improvement. **NOTE:** Action plans do not require approval by the Director, Office of HTM; however, the HTM Office is available for consultation.

   (2) Reviewing data, processes, and programmatic strengths with the VISN Director; developing strategies and recommendations from the data, processes, and programmatic outcomes to improve program operations and effectiveness. When strategies and recommendations have been developed, presenting to the VISN Director
for approval. Upon approval by the VISN director, implementing strategies and recommendations to the Chief Biomedical Engineers at each VA medical facility.

(3) Ensuring VA medical facility Chief Biomedical Engineers adhere to documentation of services, data, and business process standards defined by the Office of HTM for their respective BME departments. **NOTE:** The standard business processes are located at the following link: https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/CommResource/SitePages/homempage.aspx. This is an internal VA Web site that is not available to the public.

f. **VA Medical Facility Directors.** VA medical facility Directors are responsible for:

(1) Assigning the responsibility for adhering to national business processes to the Chief Biomedical Engineer.

(2) Ensuring the Chief Biomedical Engineer has sufficient resources to fulfill the terms of this directive and to achieve successful outcomes of BME functions within the VA medical facility.

(3) Supporting the Chief Biomedical Engineer in implementing strategies and recommendations to improve program operations and effectiveness.

g. **Chief Biomedical Engineer, VA Medical Facility.** The VA medical facility Chief Biomedical Engineer (or other comparable leader as designated by the VA medical facility Director if a Chief Biomedical Engineer, VA Medical Facility is not established) is responsible for:

(1) Reviewing reports and scorecards provided by the VISN Biomedical Engineer and developing action plans to address opportunities for improvement. Timelines to address improvements are established on a case-by-case basis.

(2) Reviewing data (either manually entered or automated), processes, and program performance with the VA medical facility Director or other leaders identified by the VA medical facility Director and developing strategies and recommendations to improve program operations and effectiveness.

(3) Ensuring Biomedical Engineering Staff captures and adheres to documentation of services, data standards, and business process standards defined by the Office of HTM. **NOTE:** The standard business processes are located at the following link: https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/CommResource/SitePages/homempage.aspx. This is an internal VA Web site that is not available to the public.

h. **Biomedical Engineering Staff.** BME staff, also called Healthcare Technology Management in VA medical facilities, is responsible for:

(1) Adhering to the documentation of services, data standards, and business process standards defined by the Office of HTM. **NOTE:** The standard business processes are located at the following link:
(2) Verifying the accuracy of data presented in tools, dashboards, and reports (either manually entered or automated) developed by the Office of HTM compared to source inputs for national initiatives.

(3) Identifying and addressing potential risks identified by VA medical facility leadership (e.g. Chief Biomedical Engineer and VA medical facility Director), VISN leadership (e.g. VISN Director and VISN Biomedical Engineer), or the Office of HTM.

6. TRAINING

The Office of HTM provides regular and recurring training to Biomedical Engineering personnel to support the Continuous Performance Improvement program. Training is not mandatory. **NOTE:** Presentations are available through the following SharePoint: https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/EBERS/default.aspx. This is an internal VA Web site and is not available to the public.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be directed to the facility Records Manager or Records Liaison.

8. REFERENCES

a. 38 U.S.C. 7301(b).

b. American National Standards Institute AAMI EQ56, Recommended Practice for a Medical Equipment Management Program.

c. The Joint Commission Standard Environment of Care EC.02.04.01, EC.03.01.01, EC.04.01.01: https://www.jointcommission.org/

d. HTM Program Office standard business practices SharePoint: https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/CommResource/SitePages/hompage.aspx. **NOTE:** This is an internal VA Web site that is not available to the public.