



EL CENTRO REGIONAL MEDICAL CENTER  
BOARD OF TRUSTEES – REGULAR MEETING

MONDAY, FEBRUARY 26, 2024  
5:30 PM

MOB CONFERENCE ROOM 1&2  
1271 ROSS AVENUE, EL CENTRO, CA

**PRESIDENT:** Tomas Oliva

**MEMBERS:** Sylvia Marroquin; Martha Cardenas-Singh; Edgard Garcia; Sonia Carter; Patty Maysent-CEO, UCSD Health; Christian Tomaszewski-M.D.-CMO, UCSD; Pablo Velez-CEO ECRMC

**CLERK:** Belen Gonzalez

**ATTORNEY:** Douglas Habig, ECRMC Attorney  
Elizabeth Martyn, City Attorney

*This is a public meeting. If you are attending in person, and there is an item on the agenda on which you wish to be heard, please come forward to the microphone. Address yourself to the president. You may be asked to complete a speaker slip; while persons wishing to address the Board are not required to identify themselves (Gov't. Code § 54953.3), this information assists the Board by ensuring that all persons wishing to address the Board are recognized and it assists the Board Executive Secretary in preparing the Board meeting minutes. The president reserves the right to place a time limit on each person asking to be heard. If you wish to address the board concerning any other matter within the board's jurisdiction, you may do so during the public comment portion of the agenda.*

BOARD MEMBERS, STAFF AND THE PUBLIC MAY ATTEND VIA ZOOM.

To participate and make a public comment in person, via Zoom or telephone, please raise your hand, speak up and introduce yourself.

**Join Zoom Meeting:** <https://ecrmc.zoom.us/j/86744553952?pwd=uGu3URrhTmWacMUPR9kZoeCLOJYmG.1>

**Optional dial-in number:** (669) 444-9171

**Meeting ID:** 867 4455 3952 **Passcode:** 585780

Public comments via zoom are subject to the same time limits as those in person.

### OPEN SESSION AGENDA

#### ROLL CALL:

#### PLEDGE OF ALLEGIANCE:

**PUBLIC COMMENTS:** Any member of the public wishing to address the Board concerning matters within its jurisdiction may do so at this time. Three minutes is allowed per speaker with a cumulative total of 15 minutes per group, which time may be extended by the President. Additional information regarding the format for public comments may be provided at the meeting.

#### BOARD MEMBER COMMENTS:

#### CONSENT AGENDA: (Item 1-4)

All items appearing here will be acted upon for approval by one motion, without discussion. Should any Board member or other person request that any item be considered separately, that item will be taken up at a time as determined by the President.

1. Review and Approval of Board of Trustees Minutes of Regular Meeting of January 22, 2024.
2. Review and Approval of Annual Policy: Emergency Preparedness Management Plan (*Board Quality*)

3. Monthly Human Resources Statistical Update for January 2024—**Informational** (*Finance*)
4. Review and Approval of the Medical Equipment Management Plan (*Finance*)

**PUBLIC HEARING**

5. Approval of Temporarily Relocation of Med Surg unit from Building 5 to Buildings 2 and 8.

**FINANCE and OPERATIONAL UPDATE**

6. Review and Approval of the Financial Statements for Month and Year-to-Date as of January 2024 (*Finance*)
7. Presentation of Current Weekly Cash Budget—**Informational** (*Finance*)

**CHIEF EXECUTIVE OFFICER UPDATE**

8. Verbal Report from the CEO to the Board of Trustees—**Informational**
9. Manager Update—Patty Maysent—**Informational**

**RECESS TO CLOSED SESSION:**

**A. HEARING/DELIBERATIONS RE MEDICAL QUALITY COMMITTEE REPORTS/STAFF**

**PRIVILEGES.** The Hospital Board will recess to closed session pursuant to Government Code Section 37624.3 for a hearing and/or deliberations concerning reports of the \_\_\_ hospital medical audit committee, or X quality assurance committees, or X staff privileges.

**B. TRADE SECRETS.** The Hospital Board will recess to closed session pursuant to Govt. Code Section 37606(b) for the purpose of discussion and/or deliberation of reports involving hospital trade secret(s) as defined in subdivision (d) of Section 3426.1 of the Civil Code and which is necessary, and would, if prematurely disclosed create a substantial probability of depriving the hospital of a substantial economic benefit:

<u>Discussion of:</u>	<u>Number of Items:</u>
<u>X</u> hospital service;	<u>2</u>
<u>X</u> program;	<u>0</u>
<u>X</u> hospital facility	<u>3</u>

**C. LABOR NEGOTIATIONS.** The Hospital Board will recess to closed session pursuant to Government Code 54957.6 **Agency Negotiator:** Chief Executive Officer. **Employee organization:** Teamsters Union Local 542

**RECONVENE TO OPEN SESSION – BOARD PRESIDENT**

**ANNOUNCEMENT OF CLOSED SESSION ACTIONS, IF ANY – GENERAL COUNSEL**

11. Approval of Report of Medical Executive Committee’s Credentials Recommendations Report for Appointments, Reappointments, Resignations and Other Credentialing/Privileging Actions of Medical Staff and/or AHP Staff (*Approved in Closed Session*)

**ADJOURNMENT:** Adjourn. (Time: ) Subject to additions, deletions, or changes.



**El Centro Regional Medical Center**  
**BOARD OF TRUSTEES – REGULAR MINUTES**  
**OPEN SESSION MINUTES**  
 MOB CONFERENCE ROOMS 1 & 2  
 1271 Ross Avenue, El Centro, CA 92243

Zoom Meeting link: <https://ecrmc.zoom.us/j/82535827931?pwd=Z0qkyNL55jB8sIraSKRyaGIWUQUmJd.1>

**Monday, January 22, 2024**

TOPIC	DISCUSSION/CONCLUSION	RECOMMENDATION/ACTION
<b>ROLL CALL</b>	<p><b>PRESENT:</b> Oliva; Marroquin; Cardenas-Singh (<i>present at 6:15pm</i>) ; Carter (<i>present at 6:15pm</i>); Maysent; Tomaszewski; Chief Executive Officer Pablo Velez; and Executive Board Secretary Belen Gonzalez</p> <p><b>ALSO PRESENT:</b> Chief of Staff, Sunny Richley; City of El Centro Manager Cedric Ceseña; City of El Centro Attorney Elizabeth Martyn; David Momberg-CFO; Matthew Jenusaitis, UCSD; Wes Thew- CPA, Wipfli, LLP;</p>	
<b>CALL TO ORDER</b>		The Board of Trustees convened in open session at 5:35 p.m. Board President Oliva called the meeting to order.
<b>OPENING CEREMONY</b>	The Pledge of Allegiance was recited in unison.	None
<b>NOTICE OF MEETING</b>	Notice of meeting was posted and mailed consistent with legal requirements.	None
<b>Request to add: Item 6A. The Wipfli Audit Presentation to the Board of Trustees—Informational</b>	A request to add Item 6A. The Wipfli Audit Presentation to the Board of Trustees was introduced to the Board of Trustees and a copy of the presentation was given to all Board Trustees and public present.	<b>MOTION:</b> by Maysent second by Garcia and carried to approve adding Item 6A. The Wipfli Audit Presentation to the Board of Trustees—Informational

Regular Meeting  
January 22, 2024, 5:30 p.m.

TOPIC	DISCUSSION/CONCLUSION	RECOMMENDATION/ACTION
		All present in favor; none opposed.
<b>PUBLIC COMMENTS</b>	None	None
<b>BOARD MEMBER COMMENTS</b>	None	None
<p><b>CONSENT AGENDA</b> <i>(Items 1-5)</i></p> <p><b>Item 1. Review and Approval of Board of Trustees Minutes of Regular Meeting of December 18, 2023</b></p> <p><b>Item 2. Review and Approval of Board of Trustees Minutes of Special Meeting of December 29, 2023.</b></p> <p><b>Item 3. Triennial Review and Approval of Dress and Grooming Policy</b> <i>(Board Quality)</i></p> <p><b>Item 4. Triennial Review and Approval of Timekeeping Edits Policy</b> <i>(Finance)</i></p> <p><b>Item 5. Monthly Human Resources Statistical Update for December 2023—Informational</b> <i>(Finance)</i></p>	<p>All items appearing here were acted upon for approval by one motion (or as to information reports, acknowledged receipt by the Board and directed to be appropriately filed) without discussion.</p>	<p><b>MOTION:</b> by Garcia second by Marroquin and carried to approve the Consent Agenda.</p> <p>All present in favor; none opposed.</p>
<p><b>FINANCE and OPERATIONAL UPDATE</b></p> <p><b>Item 6A. The Wipfli Audit Presentation to the Board of Trustees—Informational</b></p>	<p>David Momberg introduced Wes Thew, Wipfli LLP representative.</p> <p>Wes Thew presented the Wipfli Audit to the Board of Trustees and answered questions.</p>	<p><b>MOTION:</b> by Maysent second by Garcia and carried to accept Item 6A. The Wipfli Audit Presentation to the Board of Trustees—Informational.</p>

TOPIC	DISCUSSION/CONCLUSION	RECOMMENDATION/ACTION
		All present in favor; none opposed.
<b>Item 6B. Presentation of the Financial Statements for Month and Year-to-Date as of December 2023</b> <i>(Finance)</i>	David Momberg presented the Financial Statements for Month and Year-to-Date as of December 2023 and answered questions.  Presentation included: <ul style="list-style-type: none"> <li>• Comparative volumes vs. Prior Month/Year</li> <li>• Balance Sheet vs. Prior Month comparison</li> <li>• Operating Statement vs. Prior Month comparison</li> <li>• Monthly Cash Flow (Fiscal Year to Date)</li> </ul>	MOTION: by Maysent second by Marroquin and carried to approve the Financial Statements for Month and Year-to-Date as of December 2023.  All present in favor; none opposed.
<b>Item 7. Presentation of Current Weekly Cash Budget—Informational</b> <i>(Finance).</i>	David Momberg presented the 2024 Fiscal Year Cash Flow Projection.	Informational.
<b>CHIEF EXECUTIVE OFFICER UPDATE</b> <b>Item 8. Verbal Report from the CEO to the Board of Trustees—Informational</b>	Item to be discussed in Closed Session.	Informational
<b>Item 9. Manager Update—Patty Maysent—Informational</b>	Item to be discussed in Closed Session.	Informational
<b>RECESS TO CLOSED SESSION</b>		MOTION: by Cardenas-Singh, second by Garcia and carried to recess to Closed Session at 6:34 p.m. for HEARING/DELIBERATIONS RE MEDICAL QUALITY COMMITTEE REPORTS/STAFF PRIVILEGES, TRADE SECRETS, and LABOR NEGOTIATIONS.

TOPIC	DISCUSSION/CONCLUSION	RECOMMENDATION/ACTION
		All present in favor to recess to Closed Session. None opposed.
<b>RECONVENE TO OPEN SESSION</b>		The Board of Trustees reconvened to Open Session at 7:38 p.m.
<b>ANNOUNCEMENT OF CLOSED SESSION ACTIONS, IF ANY— GENERAL COUNSEL</b>		<p><b>[A. HEARING/DELIBERATIONS RE MEDICAL QUALITY COMMITTEE REPORTS/STAFF PRIVILEGES— GOVERNMENT CODE SECTION 37624.3]</b></p> <p>MOTION: by Garcia, second by Carter and carried to approve the Report of Medical Executive Committee’s Credentials Recommendations Report for Appointments, Reappointments, Resignations and Other Credentialing/Privileging Actions of Medical Staff and/or AHP Staff.</p> <p>All present in favor; none opposed</p>
<b>ADJOURNMENT</b>		There being no further business, meeting was adjourned at approximately 7:39 p.m.

\_\_\_\_\_  
BELEN GONZALEZ, BOARD EXECUTIVE SECRETARY

APPROVED BY

\_\_\_\_\_  
TOMAS OLIVA, PRESIDENT  
Regular Meeting  
January 22, 2024, 5:30 p.m.



**TO:** HOSPITAL BOARD MEMBERS  
**FROM:** Luis Castro, Chief Human Resources Officer  
**DATE:** February 26, 2024  
**COMMITTEE:** Board of Quality Committee

**SUBJECT:** Emergency Preparedness Management Plan

**BUDGET IMPACT:**  Does not Apply  
A. Does the action impact/affect financial resources?  Yes  No  
B. If yes, what is the impact amount: \_\_\_\_\_

**BACKGROUND/DISCUSSION:** The Emergency Preparedness Management Plan encompasses all areas and functions of the hospital, delineating procedures to follow before, during and after disasters and large emergencies. This Plan has been reviewed by Senior Management and is being brought to the ECRMC's Board of Trustees for approval. Only minor changes related to formatting and job titles were made to the previous Plan.

Annually, the Board of Trustees shall receive an evaluation of this plan and recommendations for improvements for the year.


**RECOMMENDATION:** Move to approve the annual review of El Centro Regional Medical Center's (ECRMC) Emergency Preparedness Management Plan.

**ATTACHMENT:**

- Annually Reviewed Policy: Emergency Preparedness Management Plan

Approved for agenda, Chief Executive Officer

Date and Signature: Pablo V. [Signature]

		<b>Department:</b> Emergency Management Department	
		<b>Document Owner/Author:</b> Emergency Preparedness Director	
		<b>Category:</b> Hospital Wide	<b>Approval Type:</b> Annually
<b>Date Created:</b> 04/08/2004	<b>Date Board Approved:</b> 09/27/2021	<b>Date Last Review:</b> 01/25/2024	<b>Date of Next Review:</b> 01/25/2025
<b>Policy Name:</b> Emergency Preparedness Management Plan			

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**Purpose**

As a healthcare provider and community leader, El Centro Regional Medical Center (ECRMC) must assume the responsibility of providing care to the community during times of crises. To this end, ECRMC has adopted the Hospital Incident Command System (HICS) as our mitigation strategy, which applies to the main hospital as well as all other hospital properties. HICS serves our mission through a well-defined structure, clearly defined goals/objectives and defined expectations for communication and reporting, and is compliant with California Standardized Emergency Management System (SEMS) and National Incident Management System (NIMS). Timely coordinated response to emergency situations saves lives and minimizes pain and suffering. Emergency management planning shall identify actions to take to protect the health and safety of patients, staff and visitors and to limit property losses within our control. ECRMC, in conjunction with Imperial County Public Health Department and other community agencies and other area healthcare organizations will continue to provide care and resources during emergency and disaster events consistent with our mission and values.

**Scope**

This plan encompasses all areas and functions of the hospital, delineating procedures to follow before, during, and after disasters and large emergencies.

**Policy Statement**

It is the policy of ECRMC to prepare for, and respond to, disasters and emergencies in the most efficient manner possible, while maintaining quality of care and safety of staff, visitors, and patients.

**Responsibilities**

The Board of Trustees of ECRMC, through the Chief Executive Officer, has designated the Emergency Preparedness Director to manage day-to-day implementation of this Plan. This individual shall establish, maintain and support the hospital’s Emergency Preparedness Management Plan and related Emergency Preparedness activities. The position of Emergency Preparedness Director reports to the appropriate Chief Officer, and is tasked with providing

Deleted: Nursing



33 coordination, support, and interface with community, governmental, and other stakeholder  
 34 agencies to assure a continuous, functional state of readiness for ECRMC.  
 35

Person/Title	Responsibilities
<b><u>BOARD OF TRUSTEES:</u></b>	The Board of Trustees is responsible to receive and consider on a biannual basis a summary of significant issues, trends and actions of the EM-MDT Emergency Management-Multidisciplinary Team. Annually, the Board of Trustees shall receive an evaluation of this plan and recommendations for improvements in the coming year. The Board of Trustees is ultimately responsible for the emergency management of the hospital as a whole.
<b><u>CHIEF EXECUTIVE OFFICER:</u></b>	The Chief Executive Officer (CEO) is responsible for assuring the existence and effectiveness of an Emergency Preparedness Management Plan for ECRMC. The CEO shall support implementation of the Plan through creation of a reporting structure and designation of responsible individuals to manage Emergency Management strategies.
<b><u>EMERGENCY PREPAREDNESS DIRECTOR:</u></b>	<p>An Emergency Preparedness Director will be designated by the CEO and will be delegated the responsibility to oversee, implement and monitor the Emergency Management Plan. The Emergency Preparedness Director shall assure the following:</p> <ul style="list-style-type: none"> <li>•Develop performance standards designed to monitor key components of the Emergency Preparedness Management Plan.</li> <li>•Provide liaison with law enforcement, <u>Fire &amp; EMS</u>, public service agencies, and other area hospitals.</li> <li>•Report to the Emergency Management-Multidisciplinary Team summaries of statistical data that through analysis and trending allows for corrective actions and recommendations.</li> <li>•Evaluate and participate in all planned and unplanned activities.</li> <li>•Coordinate Emergency Management Team activities to evaluate and respond to identified opportunities and recommendations for improvement.</li> <li>•Maintain awareness of Disaster Management issues and oversee education and implementation of the HICS model.</li> <li>•Evaluate and participate in all planned and unplanned activities.</li> </ul>

	<ul style="list-style-type: none"> <li>•Ensure facility-wide and department-specific policies and procedures are integrated to support the plan and reviewed on a consistent basis.</li> <li>•Participate in the ongoing hospital-wide Performance Improvement Process that collects information regarding performance of the Emergency Preparedness Management Plan to be reviewed by the Emergency Management - Multidisciplinary Team.</li> </ul>
<b><u>EMERGENCY MANAGEMENT MULTIDISCIPLINARY TEAM:</u></b>	The Emergency Management - Multidisciplinary Team (EM-MDT) of ECRMC is established to govern issues as they relate to Emergency Management. The EM- MDT Team is authorized by the Administrative Body and composed of individuals from Administration, Nursing Services and General Services as well as others deemed appropriate by the chair. The EM-MDT meets at least quarterly to monitor, review and analyse components of Emergency Preparedness. The EM-MDT monitors all functions of Emergency Preparedness and considers information/recommendations supplied by other functions within that environment such as Infection Control, Radiation Safety, Education, etc. Policies and procedures related to emergency preparedness shall be reviewed and approved by the EM-MDT annually and as needed.
<b><u>DIRECTORS, DEPARTMENT MANAGERS AND CLINICAL COORDINATORS:</u></b>	The Emergency Preparedness Director is responsible for emergency preparedness policies and procedures, which shall be consistent with objectives of the HICS model. Department Managers are responsible to orient staff to these policies and procedures, and to provide appropriate education and training to assure the competence of staff within their Department.
<b><u>INDIVIDUAL EMPLOYEES:</u></b>	<p>Employees are required to adhere to the provisions of the Emergency Preparedness Management Plan, as well as any departmental plans. Employees shall maintain knowledge of Plan expectations and will be responsible to:</p> <ul style="list-style-type: none"> <li>• Know their specific roles and responsibilities during an emergency and/or disaster.</li> <li>• Know how to assemble and supply resources to assure maximum utilization of their individual skills.</li> <li>• Be knowledgeable regarding emergency systems, contingencies and the HICS Plan (command, communication, supply, etc...) used during emergency and disaster events.</li> </ul>

36 **Procedure/Plan**

- 37 ○ The Emergency Preparedness Management Plan provides for continued hospital  
38 operations during unusual events. ECRMC has developed this Plan to outline  
39 collective and individual responsibilities, expected levels of performance, space and  
40 resource utilization, and contingency plans utilized in response to emergency/disaster  
41 events. Processes exist to exercise our readiness and to evaluate performance of the  
42 Plan and individuals. Knowledge of and adherence to the following plans/procedures  
43 should provide for the continued operation of Hospital systems during emergencies  
44 and for the continued provision of care.  
45
- 46 ○ **Disaster Planning**
- 47 ■ Coordinate with local/county/state/federal civil authorities as well as Pioneers  
48 Memorial Hospital and other medical service agencies to make appropriate  
49 jurisdictional provisions. The Emergency Preparedness Director will  
50 participate in area community forums and planning meetings to develop  
51 strategies for notification and communications procedures, document public  
52 agency and healthcare organization capabilities, and develop plans and  
53 agreements with community organizations to facilitate continued treatment  
54 of patients in the event evacuation and/or closure of ECRMC is deemed  
55 appropriate.
  - 56 ■ Develop procedures and assign responsibilities for response to internal  
57 disasters (fire, utility failure, structural damage, etc.).
  - 58 ■ Develop procedures and assign responsibilities for response to external  
59 disasters (storm, earthquake, flood, etc.).
  - 60 ■ Establish Emergency Operations Plan activation criteria, and identify a  
61 management strategy for the management of emergency events.
  - 62 ■ Determine appropriate use and allocation of space, supplies, and resources,  
63 and establish treatment facilities, logistical support, and site management, for  
64 a significant influx of casualties (internal or external).
  - 65 ■ Coordinate care, treatment, and placement of in-house and emergency  
66 victims, and plan for the expansion of the facility and independent operations  
67 as dictated by the event.
  - 68 ■ Designate routes, procedures and responsibilities for the orderly evacuation  
69 of buildings if dictated by the nature of the event.

70  
71 **MITIGATION**

72 Imperial County, California is vulnerable to many hazards, all of which have  
73 potential for disrupting communities, causing damage, and creating casualties.  
74 Possible natural hazards include earthquakes, hurricanes, droughts, and  
75 extremely high temperatures. Other disaster situations could develop from a  
76 hazardous materials incident, water or air pollution, major transportation  
77 accident, water, gas or energy shortage, power plant accident, terrorism or civil

78 disorder. California is also vulnerable to acts of bioterrorism because of its  
79 international border, airports, tourism industry, and military bases.

80 Rural hospitals may have less risk for patients contracting diseases because of  
81 bioterrorism, but could face an influx of people from an urban terrorist event, and  
82 therefore may need greater autonomy in an emergency since it may take longer  
83 for government resources to reach them.

84  
85 ○ **Contingency Planning/Mitigation**

- 86 ■ Continuous provision of medical care requires the assured functioning of  
87 essential operating systems (utilities, communications, medical gases,  
88 etc.). Any interruption of these systems may jeopardize the continued  
89 provision of care. To minimize the occurrence and/or the severity of such  
90 failures and interruptions, ECRMC has developed contingency plans to  
91 promote the reliable operation of the facility. These contingencies overlap  
92 with other functional areas of Emergency Preparedness and will be jointly  
93 coordinated as appropriate with other Management Plans. Some of the  
94 contingencies that will maintain predetermined response plans include:

95  
96 ○ **Recovery**

- 97 ■ Recovery begins during the emergency response process and continues  
98 until normal business operations are restored. This may be a short or  
99 long-term process. Recovery should not conflict with response activities.
- 100 ■ Accurate damage assessment is important to the recovery process.
  - 101 • Determine extent of damage and communicate it to the  
102 appropriate agencies.
  - 103 • Work with outside resources to support the recovery process.
    - 104 ○ Reestablishment of the individual sense of wellbeing is an  
105 essential part of the community's recovery process.

106  
107 ○ **Hazard and Vulnerability Analysis**

- 108 ■ ECRMC performs ongoing a biennial hazard vulnerability analyses to  
109 identify potential emergencies and the direct and indirect effects these  
110 emergencies may have on the organization's operations and the demand  
111 for its services. The analysis is developed with input from local emergency  
112 responders (El Centro Fire Department, El Centro Police Department,  
113 ambulance providers, Imperial County Public Health Department) and  
114 various hospital departments.
- 115 ■ Disaster exercises are conducted as required by TJC and other regulatory  
116 entities, in order to utilize and exercise the HOSPITAL INCIDENT  
117 COMMAND SYSTEM (HICS).

118  
119 ○ *The Hazardous Materials and Waste Management Plan* requires the development of  
120 procedures for one or more of the following:

- 121                   ▪ Hazardous Materials Spill or Release (internal and external) – Code Orange  
122                   ▪ Disposal of Medical Waste and Limiting Exposure to Infectious Agents  
123                   ▪ Radioactive Materials Release  
124
- 125           ○ The *Utility Management Plan* requires the development of emergency procedures to  
126 follow in the event of failure of any one of the following systems:  
127                   ▪ Electrical Distribution/Emergency Power  
128                   ▪ Failure of Nurse Call System  
129                   ▪ Vertical and Horizontal Transportation  
130                   ▪ Heating, Ventilation and Air Conditioning  
131                   ▪ Plumbing (Water/Sewer)  
132                   ▪ Boiler and Steam  
133                   ▪ Medical Gas/Vacuum  
134                   ▪ Communications Systems/Data Exchange  
135                   ▪ Water Distribution System  
136
- 137           ○ The *Medical Equipment Management Plan* requires the development of procedures  
138 for immediate response to medical equipment/supplies failure.  
139
- 140           ○ The *Security Management Plan* defines response to:  
141                   ▪ Civil Disturbance  
142                   ▪ Code Grey – Combative Individual  
143                   ▪ Code Silver – Hostage/Weapon Situation  
144                   ▪ Code Black - Bomb Threat (Explosion)  
145                   ▪ Code White - Hospital Evacuation  
146
- 147           ○ Additional contingency plans are developed as essential services/functions are  
148 identified.  
149
- 150                   ▪ Staffing Issues (mass illness/walkout/strike)  
151                   ▪ Code Pink - Infant abduction  
152                   ▪ Code Triage - Acuity Overload – Activation of Expanded Services  
153                   ▪ Code Orange - Management of contaminated patient presenting to the ED,  
154 or accidental spill/release of hazardous material inside the hospital or on  
155 hospital grounds  
156

## 157 **PREPAREDNESS**

158 The preparedness phase of emergency management refers to activities to build capacity and  
159 identify resources that may be used should a disaster or emergency occur. This includes  
160 organizational planning, cooperative planning with the city, county, and other healthcare  
161 organizations, staff training on basic response actions, and conducting drills.  
162  
163

164 **Continuity of Operations**

165 It is the policy of ECRMC to maintain service delivery, and restore services, as rapidly as possible  
166 following an emergency that disrupts those services. As soon as the safety of patients, visitors,  
167 and staff has been assured, the hospital will give priority to providing and ensuring patient access  
168 to health care.

169  
170 ECRMC will take the following actions to increase its ability to maintain or rapidly restore  
171 essential services following a disaster:

- 172 • Ensure patient, visitor and staff safety.
- 173 • Ensure continuous performance of, and rapid restoration of, the hospital's  
174 essential services during an emergency.
- 175 • Protect medical records, to the extent possible, from fire, damage, theft  
176 and public exposure. If the hospital is evacuated, provide security to  
177 ensure privacy and safety of medical records.
- 178 • Protect other vital records, data and sensitive information, such as  
179 personnel files, and insurance information.
- 180 • Ensure offsite back-up of financial and other data.
- 181 • Maintain a contact list of vendors who can supply replacement equipment.
- 182 • Relocate services as feasible and appropriate, to prepare for an event that  
183 makes the facility unusable.
- 184 • Identify a back-up site for continuation of hospital business functions and  
185 emergency management activities.
- 186 • Maintain contact list of utility emergency numbers.
- 187 • Ensure continuity of telephone service.
- 188 • Request priority status for maintenance and restoration of telephone  
189 service from local telephone service provider.

190  
191 **Delegation of Authority**

192 To ensure rapid response to any emergency and minimize any disruption, ECRMC has pre-  
193 delegated authority for making policy decisions or for taking necessary actions in emergencies.  
194 The identification of delegations of authority for the continued performance of the essential  
195 functions is critical, and therefore is established prior to disaster events to avoid lapses in  
196 leadership and ensure continuity.

197  
198 Each department within ECRMC shall complete a delegation of authority list and shall provide  
199 that document to all departments, and maintain the currency of the document to accommodate  
200 personnel changes.

201  
202 Generally, the pre-determined delegation of authority for ECRMC will take effect when normal  
203 channels of authority are disrupted and will terminate when these channels have been  
204 reestablished.

205

206 These delegations of authority for ECRMC:

207

208 • Authorize the legal authority for designated official to make key policy decisions  
209 during an emergency situation

210 • Identify the programs and administrative authorities needed for effective  
211 operations at all facility levels.

212 • Ensure that officials who might be expected to assume authorities in emergencies  
213 are trained to carry out their duties. Training should be at least annual.

214

215 The Delegation of Authority documentation is considered a vital record is contained in the  
216 hospital's Continuity of Operations Plan (COOP).

217

#### 218 **Order of Succession**

219 An Order of Succession to key ECRMC leadership positions ensures an orderly and pre-defined  
220 transition within the facility in the event that individuals occupying key leadership positions  
221 become incapacitated or otherwise unavailable.

222

223 The Order of Succession is delineated in the hospital Continuity of Operations Plan.

224

#### 225 **Internal Command Structure**

226 ECRMC has incorporated the principles of Standardized Emergency Management System (SEMS)  
227 and the National Incident Management System (NIMS) into the Emergency Operations Plan to  
228 ensure the maximum compatibility with other responders such as neighboring hospital clinics,  
229 hospitals, and local government agencies. ECRMC leadership is organized to clearly define roles  
230 and responsibilities and mobilize all resources to respond quickly. The hospital's command  
231 structure will follow the Hospital Incident Command System (HICS).

232

#### 233 **HOSPITAL INCIDENT COMMAND SYSTEM (HICS)**

234 ○ The Hospital uses the Hospital Incident Command System (HICS), a nationally  
235 used, standardized, emergency management process specifically designed to  
236 allow its users to adopt an integrated organizational structure equal to the  
237 complexity and demands of single or multiple incidents.

238

239 ○ The HICS plan is flexible. Only those positions or functions that are needed are  
240 activated. The HICS plan allows for the addition of needed positions, as well as  
241 the deactivating of positions at any time.

242

#### 243 **Communications**

244 Internal Notification

245 • ECRMC will compile and maintain an internal contact list that will include the  
246 following information for all staff: name, position title, home phone, cell phone,  
247 and preferred method of contact during off duty hours.

- 248           • The Call Back List contains sensitive contact information and is confidential. The  
249           list of staff phone numbers is kept by key employees and at key locations.

250  
251 External Notification

252 The Emergency Operations Plan contains contact information for external stakeholders utilized  
253 in a disaster or emergencies.

254 Primary Communication Methods.

- 255  
256           • Dependable, reliable, and redundant communication systems are essential during  
257           emergency situations. ECRMC recognizes that the success of facility operations  
258           during an emergency is dependent upon the identification, availability, and  
259           redundancy of critical communication systems to support connectivity among  
260           internal organizations, other agencies, and the public.
- 261           • The primary means of emergency communication is the local telephone system.  
262           If telephones fail, ECRMC staff will notify the telephone provider by any means  
263           available including telephones in another area of the hospital, cell phones,  
264           messenger, e-mail, or other methods.
- 265           • In addition to its telephone system, the hospital maintains the following radio  
266           communications equipment:
- 267                 1. County specific radio 800MHz
  - 268                 2. Reddinet
  - 269                 3. Fax and Analog phones
  - 270                 4. Cell phones, internet/email, and voice messaging
  - 271                 5. Handheld radios – ECRMC uses handheld radios for internal  
272                 communications in both routine and emergency situations.
- 273           • If telephone and radio communications are unavailable, runners will be used to  
274           take messages to and from the appropriate agencies rendering assistance
- 275           • The Emergency Preparedness Director will maintain and test communications  
276           equipment. All communications equipment will be tested twice per year.  
277           Defective equipment will be repaired or replaced. Batteries will be replaced per  
278           manufacturer's recommendation or as required. Spare batteries will be stored  
279           with equipment.
- 280           • California Area Health Alert Network (CAHAN). The Emergency Preparedness  
281           Director or designee will be registered with CAHAN. The web-based CAHAN  
282           system is designed to broadcast warnings of impending or current disasters  
283           affecting the ability of health officials to provide disaster response services to the  
284           public, and to provide a collaborative work environment where sensitive disaster  
285           planning and response information may be securely shared between California  
286           local and state health agencies.
- 287
- 288           ○ In the event of a disaster, the highest-ranking Chief Officer on duty shall assume  
289           the role of Incident Commander and shall have the authority to activate the



290 Emergency Operations Plan. The Incident Commander is then responsible for  
291 determining when the recovery phase of the activation begins as well as when to  
292 deactivate the Code Triage.

293  
294 ○ Alternative Care Sites:

- 295 ■ When the Emergency Operations Plan has been activated, alternative care  
296 sites within the hospital may be established as follows:
  - 297 • Triage/Treatment areas (additional care sites) will be set up in the  
298 southwest parking lot, south of the Operating Room suites. This  
299 provides for controlled access by EMS and controlled entry into the  
300 facility. Alternate or additional locations may be designated  
301 depending on the nature of the specific emergency or disaster.
- 302 ■ In the event that portions of the hospital are destroyed or rendered  
303 unusable, the Incident Commander, HICS section chiefs, in conjunction  
304 with the Imperial County Emergency Operations Center, MHOAC, and  
305 Department of Health and Human Services will designate alternative sites  
306 off campus. Evacuation of visitors, patients, and staff will proceed as per  
307 ECRMC Evacuation Policy..
- 308 ■ ECRMC will also assist the Imperial County Emergency Operations Center  
309 in conjunction with the Department of Health and Human Services, in  
310 determining the appropriate locations of alternative care sites when it is  
311 clear that the number of casualties have or will surpass the resources  
312 available.
  - 313 • Transportation of staff, supplies, equipment and patients to  
314 alternative care sites will be organized by Imperial County  
315 Emergency Operations Center in accordance with priority and  
316 transportation availability.
  - 317 • It is essential that written agreements such as Memorandum of  
318 Agreement (MOA) and Patient Transfer Agreements be in place  
319 prior to emergency events requiring cooperation from other  
320 entities.

321  
322 Acquiring Resources

- 323 • Supplies, equipment and personnel can be augmented through the  
324 following channels:
  - 325 1. Prior agreement with vendors for emergency re-supplies
  - 326 2. Stockpiles of medical supplies and pharmaceuticals (Imperial  
327 County Health Dept.)
  - 328 3. Medical Health Operational Area Coordinator (MHOAC) assistance  
329 to hospital.

330  
331 **EDUCATION AND TRAINING (Implementation Expectations)**

- 332           ○ Leadership will take the following measures to ensure that ECRMC will be able to  
333           respond during an emergency.
- 334           1. Assign emergency response duties to personnel.
  - 335           2. Provide for ongoing training for hospital staff and new personnel.
  - 336           3. Ensure staff is trained to perform emergency roles.
  - 337           4. Ensure the locations of key supplies, hazardous materials, and other  
338           supplies or hazards are maintained and updated as necessary.
  - 339           5. Ensure that drills and exercises are conducted as required by law,  
340           regulation, and/or adopted standards and records are maintained.
  - 341           6. Review and update this plan at least biennially.
  - 342           7. Ensure the hospital's emergency preparedness program meets all  
343           regulatory standards.
- 344

#### 345 **INFORMATION COLLECTION AND EVALUATION SYSTEM (Measure & Monitor)**

346

- 347           ○ **Performance Standards** - Quality measures (indicators) will be developed to  
348           monitor the performance of key components in the Emergency Management  
349           Plan. Each indicator will establish levels of performance, which will be  
350           continuously monitored to evaluate achievement and to identify opportunities for  
351           improvement.
- 352
- 353           ○ **Variance Reports/Improvement Opportunities** - Organizational performance that  
354           is not in accordance with existing standards/benchmarks shall require reporting  
355           to the EM-MDT and a plan of action for improving the process shall be developed.  
356           Improvement plans will make use of existing indicators for monitoring or new  
357           indicators will be established.
- 358
- 359           ○ **Annual Performance Improvement Evaluation** - The Emergency Preparedness  
360           Director will review the performance of the Emergency Preparedness  
361           Management Plan and compile an evaluation, which will be provided to the EM-  
362           MDT for review. This evaluation will provide an opportunity to illuminate  
363           successes achieved, and the identification of improvement opportunities. The  
364           review will be based on the Plan's achievement, as judged by the quality indicators  
365           (Performance Standards).
- 366
- 367           ○ **Reporting Requirements** - All events that are or may develop into  
368           emergency/disaster events will be reported immediately to the CEO or the  
369           Administrator on Call (after hours), and the Emergency Preparedness Director.
- 370

#### 371 **COMMUNITY INTERFACE**

- 372           ○ ECRMC, in conjunction with local/county/state/federal agencies and other  
373           medical services agencies including Pioneers Memorial Hospital, will establish its

374 role in the provision of care during disasters. The Emergency Preparedness  
 375 Director will coordinate or participate in:

- 376       ▪ Coordinating with local/county/state/federal civil authorities and medical  
 377 services agencies to make appropriate jurisdictional provisions.
- 378
- 379
- 380       ▪ Providing staff to participate in area community forums and planning  
 381 meetings to develop strategies to support the efforts of  
 382 local/county/state/federal emergency services.
- 383
- 384       ▪ Establishing notification and communications procedures to be used in the  
 385 event of disaster, which link civil authorities with hospital Emergency  
 386 Services. Maintain equipment and relationships with volunteer  
 387 organizations to assure countywide communications (i.e. ARES –RACES).
- 388
- 389       ▪ Documenting public agency and health care organization capabilities and  
 390 resource availability in preparation for emergency events.
- 391
- 392       ▪ Developing plans and agreements with community organizations to  
 393 facilitate continued treatment of patients in the event evacuation and/or  
 394 closure is appropriate.

395               1. After-Action Report

396               ECRMC will conduct after-action debriefing with staff and  
 397 participate in consortium and Operational Area after-action  
 398 debriefings. The hospital will also produce an after-action report  
 399 describing its activities and corrective action plans including any  
 400 recommendations for modifying procedures, additional training  
 401 and improved coordination.  
 402

403

404 **Definitions**

Term	Definition
Disaster	An unusual event which surpasses the hospital’s capacity to respond without disrupting normal operations

405

406 **Associated Policies/Plans/Protocols/Procedures/Forms**

Title	Number	Location (Hyperlink)
ECRMC Emergency Operations Plan and Annexes	21534	<a href="http://navexone.com">Emergency Operations Plan v.1 (navexone.com)</a>

ECRMC Continuity of Operations Plan	21549	<a href="https://ecrmc.navexone.com/content/dotNet/documents/?docid=21549">https://ecrmc.navexone.com/content/dotNet/documents/?docid=21549</a>
Medical Equipment Management Plan	11399	<a href="https://ecrmc.navexone.com/content/dotNet/documents/?docid=11399">https://ecrmc.navexone.com/content/dotNet/documents/?docid=11399</a>
Security Management Plan	16535	<a href="https://ecrmc.navexone.com/content/dotnet/documents/?docid=16535">https://ecrmc.navexone.com/content/dotnet/documents/?docid=16535</a>

407  
408 **References**  
409 None

approval



**TO:** HOSPITAL BOARD MEMBERS  
**FROM:** Luis Castro, Chief Human Resources Officer  
**DATE:** February 26, 2024  
**COMMITTEE:** Finance Committee

**SUBJECT:** Statistical data for the Human Resources Department for the month of January 2024.

**BUDGET IMPACT:**  Does not Apply  
A. Does the action impact/affect financial resources?  Yes  No  
B. If yes, what is the impact amount: \_\_\_\_\_

**BACKGROUND/DISCUSSION:**

Report includes statistical data such as total number of new hires, total number of separations, workers compensation data, and turnover percentages. Data is compared to the previous months.

**RECOMMENDATION:** Informational only.

**ATTACHMENT(S):**

- 2024 2 – February Finance Committee Report

Approved for agenda, Chief Executive Officer

Date and Signature: \_\_\_\_\_ *Pablo Velazquez*



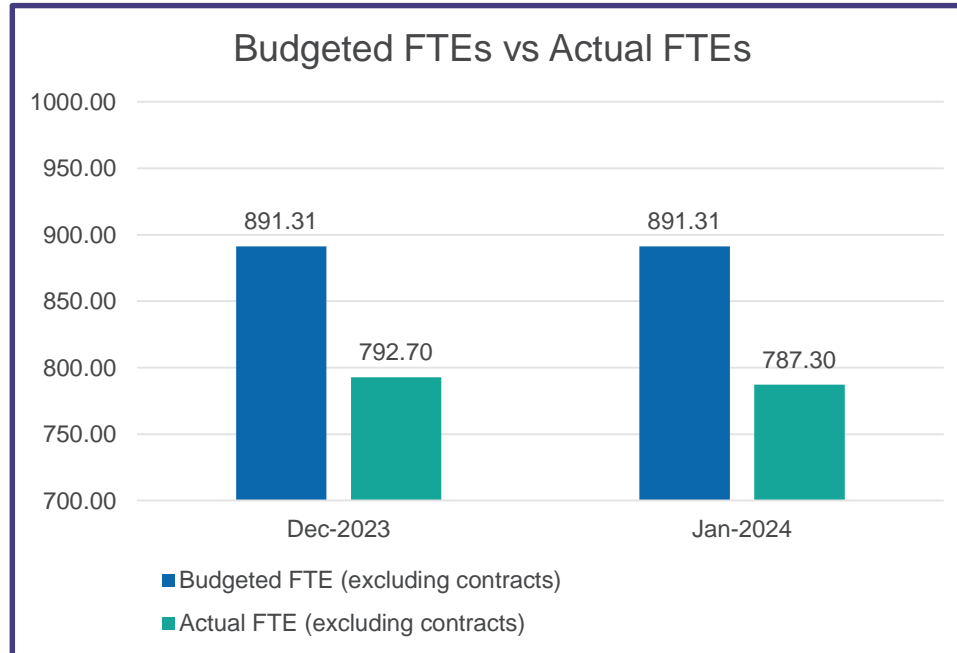
# Human Resources Report

## February 2024

# Manpower

Manpower	October 2023	November 2023	December 2023	January 2024
Full Time Employee Head Count	769	768	762	759
Part Time Employee Head Count	49	51	55	55
Per Diem Employee Head Count	127	119	117	113
Budgeted FTE	891.31	891.31	891.31	891.31
Actual FTE	798.2	788.8	792.7	787.3

*This data represents a comparison of current ECRMC full-time, part-time, and per-diem employees to the prior month and the prior year.*



# Statistics

Statistics	October 2023	November 2023	December 2023	January 2024
Total New Hires	24	10	13	9
New Hires (RN only)	4	1	2	1
New Hires (LVN only)	0	0	0	0
New Hires (Nurse Intern / Resident)	0	0	0	4
Total Separations	14	15	14	16
Separations (RN only)	2	4	1	2
Voluntary Separations (RN only)	2	4	1	2
Total Open Positions	23	29	31	38
Litigation	0	0	0	0
Total No. of Employees on Leave	44	32	29	30
*Employees on Maternity Leave	9	11	11	9

*This data represents the number of new employees hired during the reporting period, employees separated during the period and the number of open jobs at the Medical Center. Additionally, we also capture the number of HR related law suits in process in this chart. Note: These numbers are drawn from different points in the month, so they are independent from the data depicted in other charts.*

*\* This number is included in "Employees on Leave" calculation section*



# EMPLOYEE RETENTION DASHBOARD

2024

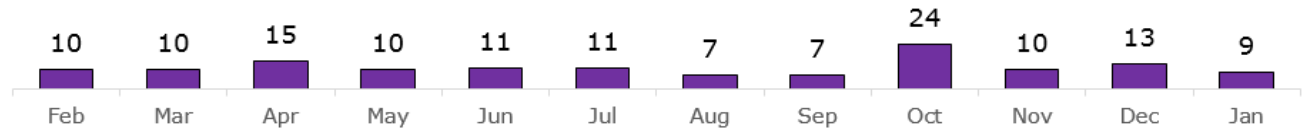
## ACTIVE EMPLOYEES

924



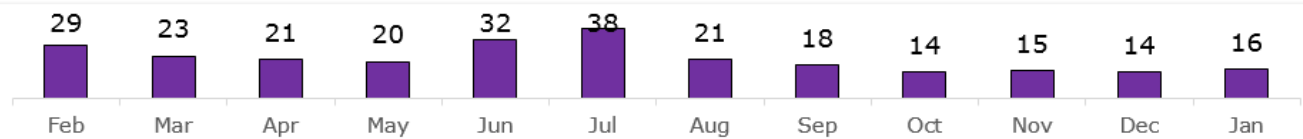
## HIRES

137



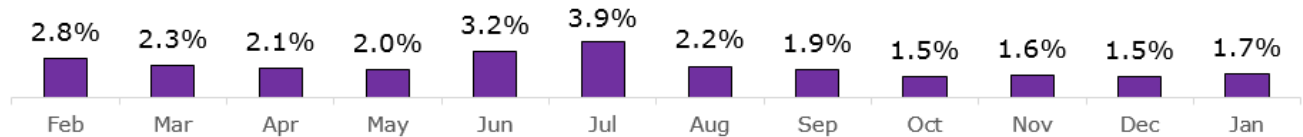
## EXITS

261



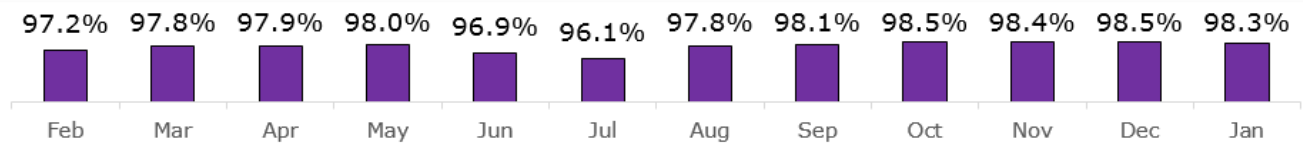
## TURNOVER RATE

26.5%



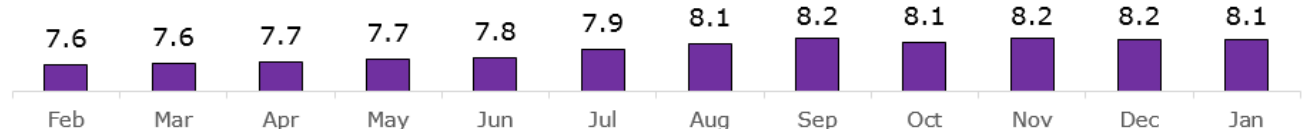
## RETENTION RATE

77.2%



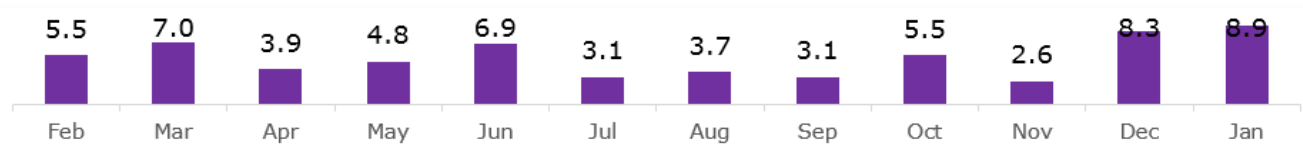
## AVG. TENURE (YRS)

8.1



## AVG. TENURE (YRS) OF EXITS

5.1

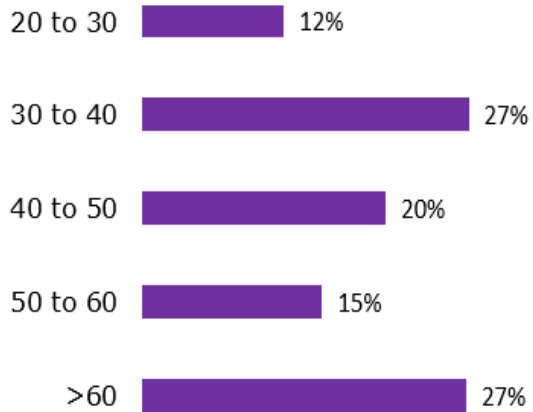


# EL CENTRO REGIONAL MEDICAL CENTER SNAPSHOT DASHBOARD

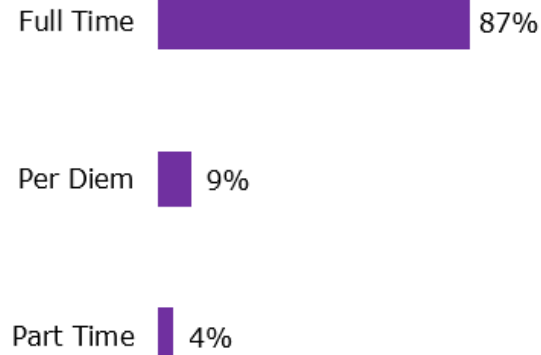
## Employees

924

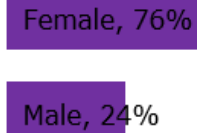
### AGE



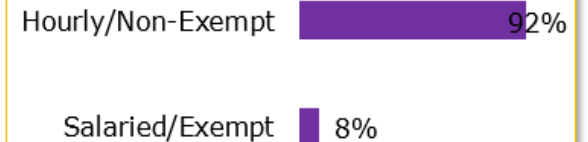
### JOB TYPE



### GENDER



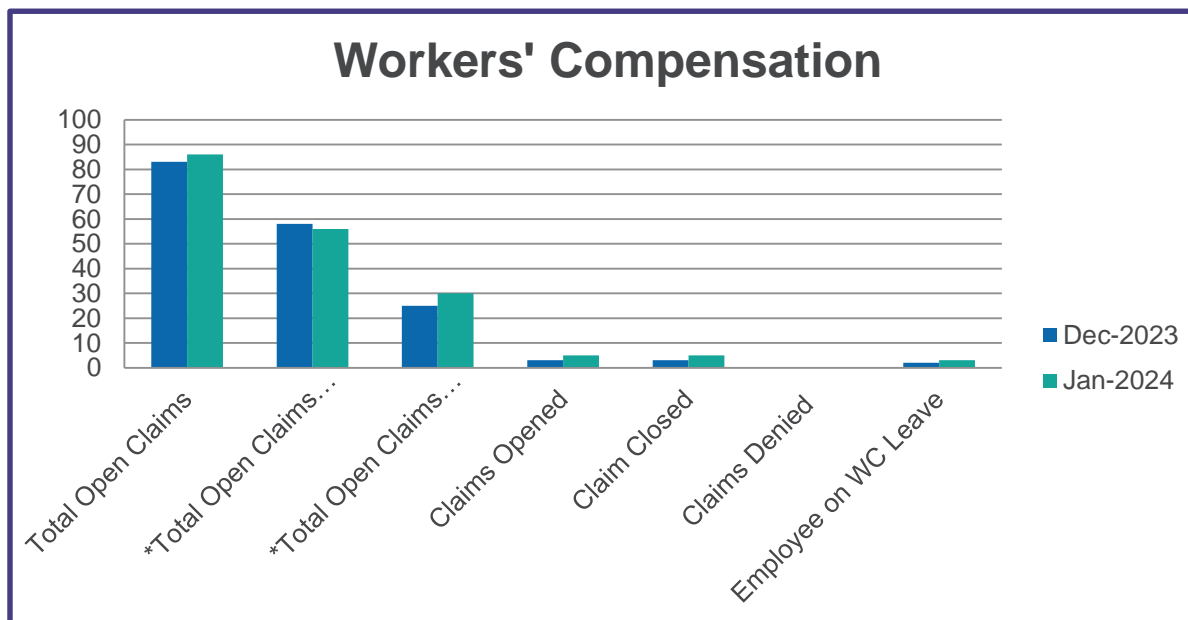
### JOB CATEGORY



# Workers' Compensation

Workers' Compensation	December 2023	January 2024
Total Open Claims	83	86
*Total Open Claims (Active Employees)	58	56
*Total Open Claims (Separated Employees)	25	30
Claims Opened	3	5
Claims Closed	3	5
Claims Denied	0	0
Employees on WC Leave	2	3

- This number is included in "Total Open Claims" row



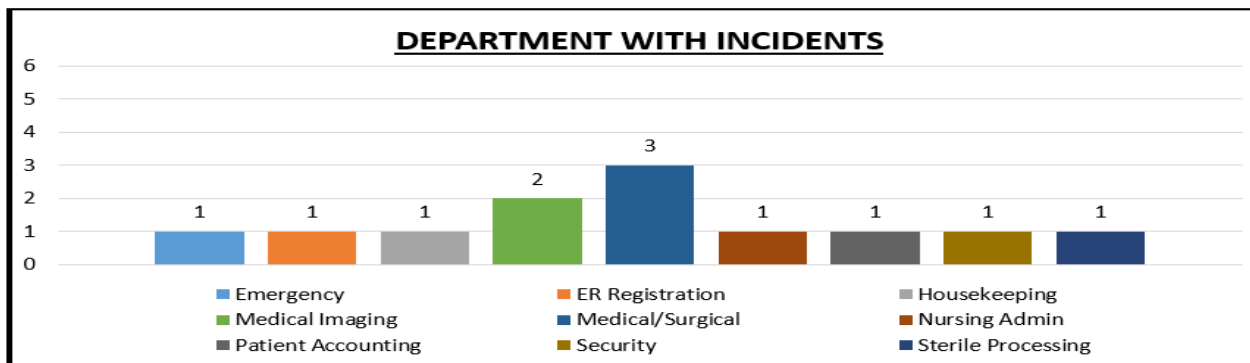
# Workers' Compensation

	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	JANUARY 2024
TOTAL INCIDENTS	15	14	11	10	7	12
TOTAL REPORTABLE	7	9	8	5	3	5
NOT REPORTED TO Athens	8	5	3	5	4	7
DEPT W/HIGHEST INJURIES	EVS	ER	ER / EVS	Laboratory	N/A	Medical/Surgical

## REPORTED INCIDENTS

1	Right shoulder, returning gurney	1	Hit to left eye by patient
1	Left ankle, mopping floor	1	Left wrist strain, restraining patient
1	Left hand/knee, rib cage, slip and fall	1	Crushed 3 <sup>rd</sup> /4 <sup>th</sup> left fingers on door
1	Needle stick to right ring finger	1	Scratch to right hand
1	Right arm/bicep, moving equipment	1	Left leg contusion, bottle thrown
2	Back strain assisting patients		

## DEPARTMENT WITH INCIDENTS



THANK YOU



**TO:** HOSPITAL BOARD MEMBERS  
**FROM:** David Momberg, Chief Financial Officer  
**DATE:** February 26, 2024  
**COMMITTEE:** Finance Committee  
**SUBJECT:** Medical Equipment Management Plan

**BUDGET IMPACT:**  Does not Apply  
A. Does the action impact/affect financial resources?  Yes  No  
B. If yes, what is the impact amount: \_\_\_\_\_

**BACKGROUND/DISCUSSION:** The Medical Equipment Management Plan (MEMP) has been approved by Senior Management, Quality and Risk Management, and is being brought to the El Centro Regional Medical Center (ECRMC) Board of Trustees for approval.

The Medical Equipment Management Program manual provides a written plan to ensure compliance of ECRMC's medical equipment. The MEMP includes a description of each of the elements that comprise the scope of the plan as well as an organizational basis for a systematic, documented process of continuous performance improvement. This manual contains both the written plan and the compliance documents for ECRMC's Medical Equipment Management Program. These documents are consistent with the requirements of applicable State and Federal Regulatory and Accreditation Agencies.

**RECOMMENDED ACTION/MOTION:** Move to approve the Annual review of ECRMC's Medical Equipment Management Plan.

**ATTACHMENT:**

- 2024 Medical Equipment Management Plan Manual

Approved for agenda, Chief Executive Officer

Date and Signature: Pablo U. Lopez

El Centro Regional Medical Center  
2024 Medical Equipment Management Plan



**MEDICAL EQUIPMENT  
MANAGEMENT PLAN  
MANUAL**

**The Joint Commission**

**El Centro Regional Medical Center**  
2024 Medical Equipment Management Plan



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# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

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### Approval of Medical Equipment Management Plan (MEMP)

ECRMC Biomedical Engineering and Quality Resource Management Department shall be responsible for the development and establishing policies and procedures as required by The Joint Commission and CMS for implementation of the same, required to achieve ongoing compliance with the Regulatory, Accreditation Agencies and ISO 9001:2015.

	<b>Name</b>	<b>Title</b>	<b>Date</b>
<b>Revised by</b>	Joseph Thompson	Biomedical Engineering Manager	12/27/2023
<b>Reviewed by</b>	Mersedes Martinez	Director of QRM	1/12/2024
<b>Reviewed by</b>	Kinberly Probus	Chief Nursing Officer	1/12/2024
<b>Approved by</b>	Pablo Velez	Chief Executive Officer	1/15/2024

The electronic version of this document posted on ECRMC Policy Tech is the latest revision. It is the responsibility of the individual to ensure that any paper material is the current revision. The printed version of this manual is uncontrolled and must be replaced with the current version identifiable with a revision date. The print version is termed expired when an updated electronic document is available and is communicated across the Organization.

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

### Revision History

This manual is reviewed to ensure its continuing relevance to the regulatory requirements that it describes. A record of changes is given below:

Revision Date	Policy Revised	Description/Notes
11/27/2023	MEMP 1.0.1-24	Elements of Performance related to AEM program removed, and now listed in TJC's Survey Activity Guide
11/27/2023	MEMP 4.0.H.1-24	Maintenance interval clarified, and allowance made for longer intervals if recommended by the OEM
11/27/2023	MEMP 4.0.G.1-24	Visual inspections changed from being captured on SM's to on a service event
11/27/2023	MEMP 4.0.H.1-24	Test equipment certificates to be uploaded to the corresponding SM service event
12/30/2022	MEMP 8.0.1-23	Policy statement updated to include "likelihood" of injury
12/15/2021	MEMP 3.0.E.1-22	Included precautions for transport of contaminated devices
12/15/2021	MEMP 8.0.1-22	Removed the statement to avoid confusion about multiple reports to risk management
12/15/2021	MEMP 4.0.G.1-22	Included environmental rounds as per hospital's policy
12/22/2020	MEMP 8.0.1-20	Policy merged with MEMP 7.0.A.1-22
12/22/2020	MEMP 8.0.1-22	Added reporting recommendations for SMDA policy
12/22/2020	MEMP 5.0.C.1-22	Added service continuity plan flowchart for emergencies
1/2/2020	MEMP 7.0.B.1-20	Included Annual Assessment template
1/2/2020	MEMP 5.0.1-20	Updated Technician responsibilities after repairs and document retention period
1/2/2020	MEMP 4.0.1-20 MEMP 4.0.H.1-20	Updated the document retention period
1/2/2020	MEMP 4.0.I.1-20	Updated OOT re-verification documentation process
1/2/2020	MEMP 4.0.C.1-20	Updated the policy to reflect the updated EST limits
1/2/2020	MEMP 3.0.E.1-20	Established a policy for disposal of medical equipment
1/2/2020	MEMP 1.0.1-20	Updated to reflect the TJC standards followed by a brief explanation
1/2/2019	MEMP 1.0.1-19	New standards included as per the revised 2019 TJC manual.
5/1/2018	MEMP 4.0.L.1-18	CMS requirements for power strips in non-patient care areas; flowchart
5/1/2018	MEMP 2.0.1-18	Hospital should maintain a library of information
1/26/2018	MEMP 4.0.F.1-18	Vendor test equipment calibration certificates should be made available by the vendor upon request
1/26/2018	MEMP 4.0.H.1-18	Deleted the requirement to maintain vendor test equipment calibration certificates on-site
1/26/2018	MEMP 4.0.J.1-18	Vendor test equipment calibration certificates should be made available by the vendor upon request

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

### Abbreviations:

AABB	American Association of Blood Banks
AEM	Alternate Equipment Maintenance
AOA	American Osteopathic Association
CAP	College of American Pathologists
CCR	California Code of Regulations
CDC	Centers for Disease Control and Prevention
CET	Chief Executive Team
CE#	Clinical Equipment ID
CFR	Code of Federal Regulations
CIU	Continuously in Use
CLIA	Clinical Laboratory Improvement Amendments
CMMS	Computerized Maintenance Management System
CMS	Centers for Medicare & Medicaid Services
CPOE	Computerized Provider Order Entry
CT	Computed Tomography
ECRMC	El Centro Regional Medical Center / Hospital
EEPROM	Electrically Erasable Programmable Read– Only Memory
EMI	Electromagnetic Interference
EMS	Emergency Medical Services
EOC	Environment of Care
ePHI	Electronic Protected Health Information
ETO	Ethylene Oxide
FDA	Food & Drug Administration
FEMA	Federal Emergency Management Agency
HBV	Hepatitis B Virus
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HTM	Healthcare Technology Management
ISM	Integrated Systems Management
IT	Information Technology
IS	Information Systems
MDS2	Manufacturer Disclosure Statement for Medical Device Security
MEMP	Medical Equipment Management Plan
MRI	Magnetic Resonance Imaging
NFPA	National Fire Protection Association
NHO	Non– Hospital Owned
NIST	National Institute of Standards and Technology

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NM	Nuclear Medicine
NPSG	National Patient Safety Goals
NVLAP	National Voluntary Laboratory Accreditation Program
OPIM	Other Potentially Infectious Materials
OSHA	Occupational Safety and Health Administration
PCD	Personal Communications Devices
PET	Positron Emission Tomography
PG	Performance Goal
PI	Performance Improvement/Performance Indicator
PPE	Personal Protective Equipment
RC	Risk Criteria
RL	RenovoLive – CMMS used by El Centro Regional Medical Center
RFP	Request for Proposal
SM	Scheduled Maintenance
SMDA	Safe Medical Devices Act
SSD	Solid– State Drive
TJC	The Joint Commission
UFM	Unavailable for Maintenance
USB	Universal Serial Bus
UTL	Unable to Locate

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### **ORGANIZATIONAL RESPONSIBILITY**

Organizational responsibility for implementation of the MEMP for ECRMC lies with the hospital's Board of Directors through the ECRMC's Administration.

- ECRMC's Biomedical Engineering department is tasked to maintain its medical equipment and manage the MEMP as specified. All or part of the program is implemented by ECRMC staff and the Biomedical Manager.
- Overall responsibility for the implementation and performance of the ECRMC MEMP programs, resident or field based, is assigned to the Biomedical Manager with oversight by ECRMC QRM, EOC Committee and CET.
- The Facility's "Board of Directors" accepts responsibility through Administration for the overall performance of the MEMP. Day-to-day management responsibility for the program has been assigned to the Chief Financial Officer with additional oversight by the Safety Officer and/or EOC Chairman and the members of the Safety or Environment of Care Committee.
- Communications with outside regulatory and accreditation agencies, such as the State Department of Health Services, CMS, FDA, and The Joint Commission, would normally be handled by the Director of QRM.
- In accordance with applicable regulatory standards, ECRMC retains professional and administrative responsibility for all contracted services rendered.

**El Centro Regional Medical Center**  
2024 Medical Equipment Management Plan

**Medical Equipment Management Program Manual**

**ECRMC'S ACCEPTANCE OF THE DOCUMENTS CONTAINED HEREIN**

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This manual contains both the written plan and the compliance documents for ECRMC's Medical Equipment Management Program. These documents are consistent with the requirements of applicable State and Federal Regulatory and Accreditation Agencies and are accepted by the Facility as part of the Facility's general operating policies.

The methods, practices and information contained in this manual are proprietary and are for the sole use of El Centro Regional Medical Center. Reproduction and distribution of this manual or any documents herein to any other party without written authorization from ECRMC is strictly prohibited.

**ACCEPTED and APPROVED by:**

Pablo Velez	Chief Executive Officer	Date
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Kimberly Probus	Chief Nursing Officer	Date
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# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 1</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 1.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Medical Equipment Management Program Plan</b>		

### **I. Objectives of the Program:**

ECRMC has created an organized Medical Equipment Management Program with the following objectives:

Provide the facility medical and clinical staff with assurance that:

- It has equipment available which is appropriate for the clinical services that it provides.
- All medical equipment, specifically equipment that could create hazards for the patients or staff, are safe and functioning properly and are always maintained in this condition that they are in use.
- The staff and services supporting the use of medical equipment remain in full compliance with the regulatory requirements of the relevant Local, State and Federal agencies having jurisdiction, including CMS, FDA, NFPA and accrediting agencies including DNV, The Joint Commission, AABB, and CAP.
- This vital medical equipment support services are provided to the facility as efficiently and cost effectively as possible.

### **II. Scope of the Plan:**

The Facility has a comprehensive written plan for the Medical Equipment Management Program which includes a description of each of the elements that comprise the scope of the plan. The plan also provides an organizational basis for a systematic, documented process of continuous performance improvement. The plan is reviewed and revised as necessary at least once per year for compliance with applicable regulatory and accrediting agencies and is approved and endorsed by ECRMC's Board, Senior Management, QRM and, EOC Committee.

The scope of service for this program is as follows:

*EC.01.01.01 (8): The facility has a written plan for managing the following: Medical equipment.*

MEMP manual provides a written plan to ensure compliance of ECRMC's medical equipment to The Joint Commission standards.

# El Centro Regional Medical Center

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*EC.01.01.01 (3): The hospital has a library of information regarding inspection, testing, and maintenance of its equipment and systems.*

*NOTE: The library includes manuals, procedures provided by manufacturers, technical bulletins, and other information.*

ECRMC requires that complete service manuals, operator's manuals, and other technical documentation, as applicable, is included with all new equipment purchases. ECRMC maintains a library of information (includes manuals, procedures provided by manufacturers, technical bulletins etc.) regarding inspection, testing and maintenance of its equipment either in digital version through their CMMS or onsite hard copy manuals.

*EC.02.04.01 (2): The hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life-support equipment) and equipment incident history. The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory.*

ECRMC's Biomed/Clinical Engineering department maintains a database documenting all equipment identified in the medical equipment management plan. This includes hospital owned equipment as well as loaner, demo, physician-owned, patient owned etc. Biomed/Clinical Engineering department also assesses the medical equipment or system for inclusion in the equipment management program using risk-based criteria to classify the equipment as high risk or non-high risk.

*EC.02.04.01 (3): ECRMC identifies High-Risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail.*

*Note: High-Risk medical equipment includes life-support equipment.*

All equipment is evaluated at the time of entry into the medical equipment database using a risk-based scoring system. The scoring to determine the risk is comprised of a score for equipment function, clinical application, manufacturer scheduled maintenance requirement, likelihood of failure and equipment environment. If the total score is greater than or equal to 18, then equipment is identified in the database as high risk. All equipment with scores less than 18 is considered as non-high risk.

*EC.02.04.01 (4): ECRMC identified the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory.*

*Note: Activities and associated frequencies for maintaining, inspecting, and testing of medical equipment must have a 100% completion rate.*



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All equipment included in the medical equipment management program will receive scheduled maintenance and testing based on the manufacturer's recommendations unless otherwise identified for inclusion into the alternative equipment maintenance (AEM) program. The record of this schedule will be included in the medical equipment database. Items included in the AEM will be recommended by Biomed/Clinical Engineering department. Items recommended for inclusion to the AEM will be approved by the Safety/EOC Committee.

EC.02.04.01 (5): *The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:*

- *Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements*
- *Medical laser devices*
- *Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)*
- *New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies.*

Note: *Maintenance history includes any of the following documented evidence:*

- *Records provided by the hospital's contractors*
- *Information made public by nationally recognized sources*
- *Records of the hospital's experience over time.*

The hospital will follow the manufacturer's recommendation for maintenance of items identified in the above standard and for all equipment not included in the AEM program.

EC.02.04.01 (6): *A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following:*

- *How equipment is used, including the seriousness and prevalence of harm during normal use*
- *Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm*
- *Availability of alternative or back-up equipment in the event the equipment fails or malfunctions.*
- *Incident history of identical or similar equipment*
- *Maintenance requirements of the equipment.*

The Biomed/Clinical Engineering department developed a methodology, based on the above criteria, for the identification of equipment to be included in the alternative equipment maintenance (AEM) program. Biomed/Clinical Engineering will be able to demonstrate the qualifications of the individuals making recommendations based on formal education, certification, and relevant work experience.

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EC.02.04.01 (7): *ECRMC identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.*

Biomedical Engineering will identify in its medical equipment database all items that have been recommended and approved by the Safety/EOC Committee for inclusion into the AEM program.

EC.02.04.01 (9): *ECRMC has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.*

ECRMC's clinical staff is responsible for determining the appropriate clinical interventions to be implemented for specific medical equipment failures. Should a piece of medical equipment malfunction or fail, hospital staff should first ensure the safety of the patient, remove the piece of equipment from service, label it, and notify Biomed. Backup equipment is available for many types of equipment within the user department and through loaners or spares maintained by Biomedical Engineering.

EC.02.04.01 (10): *ECRMC identifies quality control and maintenance activities to maintain the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced. The hospital identifies how often these activities should be conducted.*

Medical Physicists are responsible for these activities, and they may be assisted with the testing and evaluation of equipment performance by qualified individuals as determined by the Physicist. The departments will work with the physicists, Biomedical Engineering and the vendors to correct any deficiencies identified.

EC.02.04.01 (11): *ECRMC monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990*

The ECRMC's QRM department is primarily responsible for managing incidents involving medical devices. Biomed/Clinical Engineering plays an integral role in these events and should be notified immediately following a patient incident to assist with the sequestering of equipment and supplies as directed by the hospital's QRM department.

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## 2024 Medical Equipment Management Plan

EC.02.04.03 (1): *Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the hospital performs safety, operational and functional checks.*

Biomedical Engineering performs an initial inspection and an electrical safety inspection (where applicable) in accordance with all applicable policies and procedures before initial use. These inspections are electronically documented and entered into the ECRMC database. Biomedical Engineering also performs safety, operational, and functional checks after major repairs or upgrades and these records are also maintained in the equipment management database.

EC.02.04.03 (2): *The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented.*

NOTE 1: *High-risk equipment includes medical equipment for which there is a risk of serious injury or even death to a patient or staff member should it fail, which includes life-support equipment.*

NOTE 2: *Required activities and associated frequencies for maintaining, inspecting, and testing of medical equipment completed in accordance with manufacturers' recommendations must have a 100% completion rate.*

Biomedical Engineering performs inspections and maintenance on high-risk equipment as per manufacturer recommendations and documents all work performed on high-risk equipment included in the medical equipment inventory plan in accordance with all applicable policies and procedures. Scheduled maintenance for high-risk medical equipment will have a 100% completion rate of available equipment within the month due.

EC.02.04.03 (3): *The hospital inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented.*

NOTE: *Scheduled maintenance activities for non-high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.*

Biomedical Engineering performs inspections and maintenance on non-high-risk equipment as per manufacturer recommendations and documents all work performed on non-high-risk equipment included in the medical equipment inventory plan in accordance with all applicable policies and procedures. Scheduled maintenance for non-high-risk medical equipment will have a 100% completion rate of available equipment within the month due.

EC.02.04.03 (4): *The hospital conducts performance testing of and maintains all sterilizers. These activities are documented.*

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The hospital's clinical staff is responsible for performance testing or biological cultures on all sterilizers used. Biomed/Clinical Engineering provides maintenance support on sterilizers via an in-house program or through other maintenance vendors and maintenance records are documented in the medical equipment database.

EC.02.04.03 (5): *The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.*

The hospital inventories all renal dialysis equipment and documents equipment maintenance, chemical and biological testing of water used in renal dialysis, and other applicable tests based upon regulations, manufacturers' recommendations, and facility experience. Biomedical Engineering has limited or no responsibility, as identified in Policy Tech, for either the service or service documentation of renal dialysis equipment, peripheral devices, and/or systems.

EC.02.04.03 (8): *Equipment listed for use in oxygen-enriched atmospheres is clearly and permanently labeled (withstands cleaning/disinfecting) as follows:*

- *Oxygen-metering equipment, pressure-reducing regulators, humidifiers, and nebulizers are labeled with name of manufacturer or supplier.*
- *Oxygen-metering equipment and pressure-reducing regulators are labeled "OXYGEN-USE NO OIL."*
- *Labels on flowmeters, pressure-reducing regulators and oxygen-dispensing apparatuses designate the gases for which they are intended.*
- *Cylinders and containers are labeled in accordance with Compressed Gas Association (CGA) C-7.*

The hospital's Cardio-Pulmonary department along with Purchasing will ensure that all flowmeters, pressure-reducing regulators, humidifiers, nebulizers, and oxygen metering equipment contain all the information as outlined in this standard prior to purchase.

EC.02.04.03 (16): *Qualified hospital staff inspect, test, and calibrate nuclear medicine equipment annually. The results and completion dates are documented.*

The Biomedical Engineering is responsible for maintenance and repair of specific nuclear medicine equipment, to the manufacturer specifications either via an in-house program or other maintenance vendors. A diagnostic medical physicist is responsible to conduct an annual performance evaluation of Nuclear Medicine imaging equipment and he/she may be assisted with the testing and evaluation of equipment performance by qualified individuals as determined by the Physicist.

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EC.02.04.03 (18-25): *The hospital maintains the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI) and nuclear medicine (NM) images produced.*

Medical Physicists are responsible for these activities, and they may be assisted with the testing and evaluation of equipment performance by qualified individuals as determined by the Physicist.

EC.02.04.03 (26): *The hospital performs equipment maintenance on anesthesia apparatus. The apparatus is tested at the final path to patient after any adjustment, modification, or repair. Before the apparatus is returned to service, each connection is checked to verify proper gas flow and an oxygen analyzer is used to verify oxygen concentration. Areas designated for servicing of oxygen equipment are clean and free of oil, grease, or other flammables.*

Biomedical Engineering Department maintains the oversight of all repairs to the anesthesia equipment. Biomedical Engineering will work with departments to identify and designate a space for servicing oxygen equipment and that the area designated is free of oil, grease, or other flammables.

EC.02.04.03 (27): *ECRMC meets NFPA 99-2012: Health Care Facilities Code requirement related to electrical equipment in the patient care vicinity. (For full text, refer to NFPA 99-2012: Chapter 10)*

NOTE: *ECRMC meets the applicable provisions of the Health Care Facilities Code Tentative Interim Amendment (TIA) 12-5*

The hospital's policies and procedures regarding electrical equipment are in accordance with NFPA 99-2012: Chapter 10, including the policies and procedures described in this management plan.

EC.02.04.03 (34): *At least annually, a diagnostic medical physicist conducts a performance evaluation of fluoroscopic imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented.*

Medical Physicists are responsible for these activities, and they may be assisted with the testing and evaluation of equipment performance by qualified individuals as determined by the Physicist.

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*EC.02.01.01 (11): ECRMC responds to product notices and recalls.*

Manufacturers recall notifications are directed through the hospitals Purchasing Department or Risk/Safety Officer and forwarded to the appropriate user or maintainer departments for follow up. All notifications directed to the Biomed/Clinical Engineering Department are reviewed by the Biomedical Manager and resolved in the appropriate manner and completed in accordance with the manufacturer's instructions as detailed in the equipment alert/recall.

*EC.02.05.01 (23): Power strips in the patient care vicinity are only used for components of movable electrical equipment used for patient care that have been assembled by qualified personnel. These power strips meet UL 1363A or UL 60601-1. Power Strips used outside of a patient care vicinity, but within the patient care room, meet UL 1363. In non-patient care rooms, power strips meet other UL standards.*

The Hospital regulates the use of power strips. No power strips may be used on medical equipment except under the circumstances described in this standard. The Facility supports the use of hospital-grade relocatable power taps listed to UL standards of 60601-1, or 1363A.

*EC.03.01.01 (1): Staff responsible for the maintenance, inspection, testing and use of medical equipment are competent, receive continuing education and training.*

Training content will vary based on perceived need through evaluation of technical staff, staff feedback, technology changes and equipment purchase. All employees will complete facility required orientation and safety training such as Universal Precautions, Fire and Life Safety, HIPAA, Infection Control and Sexual Harassment, as applicable.

*EC.04.01.03 (2): The hospital uses the results of data analysis to identify opportunities to resolve environmental safety issues.*

The hospital reviews program performance indicators through data collection and establishes goals to improve the effectiveness of the program along with patient care.

*EC.04.01.01 (10): Based on its process(es), the hospital reports and investigates the following: Medical/laboratory equipment management problems, failures, and use errors.*

The Biomedical Engineering monitors, investigates and reports medical and laboratory equipment problems, failures, and use errors to the EOC or Safety Committee on a quarterly basis.

*EC.04.01.01 (15): Every 12 months, the hospital evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness.*

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A comprehensive annual assessment of all components of the program including the management plan, program objectives, scope, performance, and effectiveness of the program is evaluated and presented to the EOC and Safety Committee.

*EM.02.01.01 (1): The hospital has a written all-hazards emergency operations plan (EOP) with supporting policies and procedures that provide guidance to staff, volunteers, physicians, and other licensed practitioners on actions to take during emergency or disaster incidents.*

The MEMP has established strategies and actions for identifying, tracking, and controlling the transfer, replacement, recovery, and restoration of medical equipment and services necessary to restore the organization's services after an emergency.

*HR.01.04.01 (1): The hospital orients its staff to the key safety content it identifies before staff provides care, treatment, and services. Completion of this orientation is documented.*

*Note: Key Safety content may include specific processes and procedures related to the provision of care, treatment, or services; the environment of care; and infection control.*

The hospital provides orientation to all its staff (including contractors) of the hospital's key safety content before providing care, treatment, and services. ECRMC provides mandatory safety training to all its staff through HealthStream.

*HR.01.05.03 (1): Staff participate in ongoing education and training to maintain or increase their competency and as needed, when staff responsibilities change. Staff participation is documented.*

The Biomedical Engineering staff receive Continuing education and training to increase their competency through OEM/Vendor service training and ECRMC On-the-Job training & certification programs. Training content will vary based on perceived need through evaluation of technical staff, staff feedback, technology changes and hospital equipment purchases. All the staff training certificates are documented by ECRMC Human Resources.

*HR.01.06.01 (1): The hospital defines the competencies it requires of its staff who provide patient care, treatment, or services.*

The competencies of the staff maintaining the medical equipment are identified based on the requirement, assessed, and documented.

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- IC.01.04.01 (1): The hospital's written infection prevention and control goals include the following:*
- *Addressing its prioritized risks*
  - *Limiting unprotected exposure to pathogens*
  - *Limiting the transmission of infections associated with procedures*
  - *Limiting the transmission of infections associated with the use of medical equipment, devices, and supplies*
  - *Improving compliance with hand hygiene guidelines*

The MEMP has procedures for limiting the transmission of infections associated with the use of Medical and Laboratory equipment. In accordance with standard hospital infection control policies and procedures, ECRMC Biomed personnel shall ensure that all medical equipment received for service or destined to patient care areas is properly disinfected prior to service and upon return to the patient care areas.

- IM.01.01.01 (2): The hospital identifies how data and information enter, flow within, and leave the organization.*

Biomedical Engineering in collaboration with ECRMC IS department will ensure that prior to transfer or disposal of equipment, ePHI will be securely overwritten or physically destroyed and that such steps will be documented. Biomedical Engineering will ensure that all labels have been removed from such devices before disposal.

- ISO 9001/NIST: Test equipment calibration at specified intervals against measurement standards traceable to international or national measurement standards.*

ECRMC calibrates its test equipment annually to ensure the medical equipment is within the established tolerances. Calibrations are performed through external resources with the use of standards that are traceable to NIST, and calibration certificates are maintained for records.

- NPSG.06.01.01 (1): Leaders establish alarm system safety as a hospital priority.*

ECRMC's Senior Management establishes Clinical Alarm Management as a hospital priority with a multi-disciplinary committee determining the criteria.

- NPSG.06.01.01 (2): Identify the most important alarm signals to manage based on the following:*
- *Input from the medical staff and clinical departments*
  - *Risk to patients if the alarm signal is not attended to or if it malfunctions*
  - *Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue*
  - *Potential for patient harm based on internal incident history*
  - *Published best practices and guidelines*



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Clinical Alarm Management committee identifies the most important alarms to manage based on ECRMC's own internal situations such as input from medical/clinical staff, risk to patients due to lack of response and published best practices/guidelines.

*NPSG.06.01.01 (3): Establish policies and procedures for managing the alarms identified above and at a minimum address the following:*

- *Clinically appropriate settings for alarm signals*
- *When alarm signals can be disabled*
- *When alarm parameters can be changed*
- *Who in the organization has the authority to set alarm parameters*
- *Who in the organization has the authority to change alarm parameters*
- *Who in the organization has the authority to set alarm parameters to "off"*
- *Monitoring and responding to alarm signals*
- *Checking individual alarm signals for accurate settings, proper operation, and detectability.*

Clinical Alarm Management committee develops and implements specific components of policies and procedures that address the responsibilities of staff managing the clinical alarm settings.

*NPSG.06.01.01 (4): Educate staff about the purpose and proper operation of alarm systems for which they are responsible.*

ECRMC's Clinical Alarm Management committee should educate the staff about the purpose and proper operation of alarm systems, response protocols to clinical alarms, and proper application of clinical interventions.

### **III. Program Plan:**

The following is a summary of the individual program elements. Detailed policies and procedures specific to day-to-day operations are outlined in sections 2 through 12 of the ECRMC MEMP manual.

#### **A. Equipment Selection/Acquisition**

The facility may have a policy that describes the selection/acquisition process for medical equipment. On an ad hoc basis, Biomedical Engineering plays a critical role in the acquisition process. Details of involvement are outlined in **Section 2** of the MEMP manual.

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### **B. Inclusion Criteria (Risk), Inventory, Incoming Inspection, SM Intervals and Scheduling**

Once it is determined that a new piece of equipment is to be acquired, the facility utilizes a routine selection procedure which involves a formal or informal analysis of responses from alternate vendors to a written Request for Proposal (RFP) before the purchase decision is made. This process requires assurance from the vendors that the equipment meets appropriate minimum safety and performance standards. Consideration is also given to the equipment's ease of operation and to the availability of assistance with on-going user training.

- i. All patient care equipment, regardless of ownership, is evaluated for inclusion into the MEMP by the application of the established Risk Based Inclusion Criteria detailed in **Section 3A** of the MEMP manual.

Medical Equipment is categorized as:

1. **High Risk**

2. Moderate Risk

3. Low Risk

4. Hazard Surveillance Only

5. Tracking Only

} **Non-High Risk**

- ii. After establishing the risk level, all pertinent equipment information is entered in the RenovoLive database, and the equipment is added to the equipment inventory. A maintenance interval is established in accordance with the manufacturer's recommendations unless otherwise identified for inclusion into the AEM program. Please refer to **MEMP 4.0.B** for inclusion into the AEM program. All continuing maintenance and repair services are entered into and tracked by the RenovoLive database. Equipment acquisitions and deletions are reported to the EOC Committee via the ECRMC Medical Equipment Management Report.
- iii. Prior to initial use, all patient care equipment, whether owned, leased or rented are required to receive a safety, operational and functional check. These checks are documented in RenovoLive. Similarly, equipment that has been withdrawn from use and placed in storage is also tested before being returned to service. Equipment incoming inspections and deletions are reported to the EOC Committee via the ECRMC Medical Equipment Management Report.

### **C. Rented, Leased, and other Non-Hospital-Owned Equipment**

Rented, Leased, and other non-hospital-owned equipment that enters the hospital receives a minimum of an incoming inspection and is managed according to the detailed policy in **MEMP 3.0.D** of the manual. Long-term non-hospital-owned equipment (defined as remaining in the hospital for a period longer than its recommended maintenance interval) is added to the equipment inventory and tracked by the RenovoLive database.

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### **D. Inspection, Testing & Maintenance Scheduling, and Incomplete maintenance**

- i. The scheduled maintenance service schedule will be established congruent with all equipment located within or assigned to a specific department. Maintenance completion is tracked by the RenovoLive database, and the data is reported to the EOC Committee. Incomplete maintenance due to any justifiable reason such as “unable to locate” or “Unavailable for maintenance” is subject to a 30-day follow-up and completion period in accordance with policy **MEMP 4.0** in the MEMP manual.
- ii. Scheduled maintenance is performed in accordance with an established maintenance procedure. Maintenance procedure includes the manufacturer’s recommendations, intervals, specifications, and tolerances, or established AEM strategies as per regulatory or accreditation agency requirements and recognized safety standards. All scheduled maintenance is documented (by exception) including maintenance completed by assigned vendors and is entered into and tracked by the RenovoLive database.
- iii. Radiographic Equipment shall be maintained in accordance with the manufacturer’s recommendations, specifications and tolerances and CMS CFR 482.41 c (2).
- iv. Nuclear Medicine Equipment shall be maintained in accordance with the manufacturer’s recommendations, specifications and tolerances and CMS CFR 482.53 c.
- v. Sterilization Equipment and surgical endoscopes shall be maintained in accordance with manufacturer recommendations and the FDA requirements for endoscope reprocessing and prevention of cross-contamination.
- vi. Laboratory equipment and blood warmers shall be maintained in accordance with manufacturer and applicable regulatory agency requirements such as AABB, and CAP.
- vii. **Clinical Alarm Management:** The Medical Equipment Management Program will test and maintain all clinical alarm systems associated with applicable medical and clinical equipment included in the program during scheduled maintenance as recommended by the manufacturer. The MEMP will also assist the management of medical and clinical equipment alarm systems via coordinated interaction and education with the clinical staff to increase the effectiveness and safety of clinical alarm systems, reduce alarm fatigue by prioritizing alarms, optimize alarm settings, and thereby eliminating “no action” (false) alarms.

### **E. Test Equipment Calibration**

Test equipment (“master device”) utilized to ensure the accuracy and safety of clinical/medical equipment is calibrated in accordance with the manufacturer’s specifications and NIST standards (as applicable) **every year before the calibration due date**. Current certificates of compliance are kept on-site at the hospital (and in digital

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format) where the test equipment is used. Test equipment calibration certificates are maintained for a minimum of 3 years unless otherwise specified by the manufacturer or regulatory agencies.

ECRMC assigned vendors are required to maintain current test equipment calibration certificates for all test equipment used in the performance of both scheduled maintenance and repair services of medical equipment. Copies of the certificates will be made available to the hospital(s) where the test equipment is used upon request.

Test equipment found to be “out of compliance” will be removed from service and re-calibrated by an authorized calibration vendor as detailed in policy **MEMP 4.0.H** of the MEMP manual. If a piece of test equipment (master device) is found out of tolerance during its calibration, an evaluation of the medical equipment it was used to test shall be confirmed to be working within the specified tolerances of the manufacturer. All records of this process will be documented through the RenovoLive CMMS.

### F. **Equipment Repair**

- i. Equipment repairs will be conducted in accordance with the manufacturer’s specifications and tolerances. A minimum of a functional test and safety inspection will be conducted upon completion of the repair. Additional functions such as calibration and overhaul will be conducted as needed. All other invasive procedures such as manufacturer required upgrades and modifications and/or any other invasive actions that may affect the safety or functionality of the equipment will include a minimum of a functional test and safety inspection upon completion of said action(s). All equipment repairs will be documented and tracked in the RenovoLive database. The FDA regulates the manufacture of medical devices in the United States. *ECRMC technical staff is specifically prohibited from altering or modifying any medical device in any way that might change its essential functional characteristics other than as directed by the device manufacturer.*
- ii. At no time, should equipment that is found to be malfunctioning be left in service unless a judgment is made by an appropriate physician or clinician that the risk to a patient’s well-being would be greater if the device were removed. In that case, when instructed to leave the equipment in service, the technician should (politely) request a written instruction to do so and obtain the clinician’s signature on the service report. A copy of the service report will be distributed to the Clinical Department Manager and the QRM department. Equipment that is considered to be hazardous shall be removed from service immediately. If the equipment is considered critical to the patient’s safety, Emergency Intervention Procedures will be implemented as defined below.
- iii. **Emergency Intervention Procedures:** Should the failed equipment be considered essential to the continuation of care (anesthesia machine, ventilator, defibrillator, Infant Incubator, etc.), then Biomedical Engineering staff will provide all available information

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to the clinical staff to aid in obtaining a suitable replacement via equipment rental, lease etc., or an emergency repair service, if the failed equipment cannot be repaired by the Biomedical Engineering Department.

- iv. If repair service is required during normal business hours, the hospital staff will attach an appropriate “defective” tag to the item and contact the Biomedical Engineering to acquire service. If the device requires service by someone other than the Biomedical Engineering the appropriate calls will be made to the qualified vendor(s) and the disposition of the call will be communicated immediately to the clinical staff so that appropriate plans can be made to ensure the continuity of patient care.
- v. Should service be required after normal hours of coverage, the clinical staff will contact the appropriate hospital staff for approval of after-hours call service. The appropriate “on-call” technician will be called.

### **G. Hazard, Alert and Recall Notices**

Hazard and recall notices from nationally recognized organizations, as well as manufacturer alerts, recalls and technical bulletins are reviewed on an ongoing basis, applicable equipment identified, and corrective actions taken as specified in the notice. All pertinent information is reported to the appropriate department and committees.

### **H. Reporting Systems / Data Collection and Evaluation**

Acquisition and aggregation of appropriate data is achieved through the RenovoLive database. Specific data collected for evaluation includes all services scheduled and performed such as Scheduled Maintenance, Repairs and “Special Conditions” service events such as accidental equipment damage, use errors and in-services, cannot duplicate problems, equipment incident, and repetitive repair data. The database also includes mechanisms for analysis, evaluation and reporting of maintenance and service information used for Service Management, Performance Improvement and Quality Management.

### **I. Performance Monitoring and Process Improvement**

Data collected through the RenovoLive database is utilized to evaluate the performance of the MEMP against specific measurable performance monitors such as maintenance completion, repair rates, and inventory accuracy. MEMP performance, weaknesses, corrective actions, improvement measures and recommendations, are reported on a quarterly basis to the ECRMC EOC Committee.

### **J. Annual Evaluation of the MEMP**

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A comprehensive Annual Assessment will be performed to determine the effectiveness of the MEMP and to establish a working baseline and effective program performance improvement goals going forward.

The following will be reviewed and reported:

- An annual summary of Planned Maintenance completion.
- An annual summary of repair rates and significant equipment-related trends from data evaluated on the quarterly reports.
- Trends in key component indicators related to equipment / user interface including cannot duplicate, accidental damage, operator error, hazard and recall, equipment incident, and incidental in-service data from the quarterly MEMP reports.
- Net changes to the inventory.
- Review and evaluation of that year's program goals and establish goals for the coming year. New goals will be established following a review of the quarterly MEMP reports. These goals will be created through a cooperative effort between the Biomedical Engineering staff and the appropriate hospital management staff to ensure that their shared values are seen and understood.
- Evaluation of the rental and leased policies.
- Review of the training and education program and specific staff goals.
- Customer satisfaction surveys.
- Review of the MEMP manual to ensure that all information is current.

### **K. Medical Equipment Related Incidents (Safe Medical Devices Act of 1990)**

If a possible negative patient outcome is linked to any item of patient care equipment, the Biomedical Engineering staff is to immediately contact the Biomedical Manager. The Biomedical Manager will contact the Director of QRM, or equivalent. All appropriate actions will be taken pursuant to the Safe Medical Device Act of 1990 and in accordance with ECRMC policy **MEMP 8.0**.

### **L. Education and Training/Skills and Competency (Staff Development)**

- i. Equipment User Training is limited to incidental in-service education when use-errors are identified, and technical and safety education as related to the safe operation and maintenance of the equipment as requested by the hospital (such as Safety Fairs). Medical and Clinical Application related education is the responsibility of the Medical/Clinical Staff. All incidental and technical education is documented and reported to the applicable department manager, the Education Department, and the ECRMC EOC Committee.

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- ii. Equipment Maintainer Education and training needs are identified on an ongoing basis. Staff education is based on evaluation of new equipment acquisitions, the service plan for each new system evaluated, training and certification requirements for specific equipment. The appropriate staff training is identified and planned for accordingly. The ECRMC Biomedical technical staff receives documented initial technical competency and orientation evaluations upon hire and performance and competency evaluations at a minimum of annually thereafter.

### **M. Infection Control**

ECRMC Biomed staff will conduct all medical equipment maintenance and repair activities in accordance with standard hospital infection control policies and procedures. Biomed personnel shall ensure that all medical equipment received for service or destined to patient care areas is properly cleaned (removal of dust, dirt, tape, and label residue) as recommended by the manufacturer and/or recognized safety agencies. Proper disinfection of medical equipment will be conducted by the hospital's Sterile Processing Department. Biomedical Engineering staff will be unable to receive, process or repair any equipment returned with evidence of biohazardous contamination. Equipment requiring service that is in an isolation room or any other area where the equipment could have been cross-contaminated will be removed from and returned to the room/area by **qualified hospital staff** if the protective equipment and/or the appropriate training is not available to the Biomedical Engineering staff. The Biomed staff will coordinate the required equipment service(s) with the Clinical Department Manager and the Infection Control Officer, as applicable.

### **N. Emergency Management**

- i. The Biomedical services staff will assist the organization in every way possible to return medical equipment and services to normal operation as quickly as possible after a disaster event.
- ii. The Biomedical services staff will, via the medical equipment inventory, assist the organization in identifying and tracking equipment that is **transferred out of** the organization by documenting a minimum of the equipment control number, the date of transfer and the intended destination of the equipment.
- iii. The Biomedical service staff will, via the equipment inventory, assist the organization in identifying and tracking equipment that is **transferred into** the organization from an outside source by documenting a minimum of the equipment control number and/or serial number, the description of the equipment, and any information obtained from identification tags identifying the outside source, and the date of transfer. The

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Biomedical staff will also assist in training the end users to identify the equipment to ensure it is not inadvertently placed into use without prior inspection.

- iv. The Biomedical service staff will identify and secure all non-functional medical equipment that has been removed from service and assist in training the end users to identify this equipment via “out of service” or “in-storage” tags to ensure the equipment is not inadvertently placed into use. Also, the Biomedical staff will inspect and repair this equipment for use, if needed.
- v. The Biomedical service staff will assist in the replacement of transferred and lost medical equipment and the restoration of medical equipment and services to pre-disaster conditions via equipment replacement, repair, and/or assisting the organization in obtaining spare equipment, as detailed in section F(iii), Emergency Intervention Procedures, above.



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### 2024 Medical Equipment Standards Reference Grid

MEMP Policy	Program Elements	TJC Standards	DNV Standards	HFAP Standards	ISO 9001:2015
MEMP 1.0.1-23	Medical Equipment Management Plan (MEMP)	EC.01.01.01(8)	PE.7		Section 4.3, Section 4.4
MEMP 2.0.1-23	Equipment Selection and Acquisition	EC.01.01.01(1)	PE.7 (SR.1, SR.3)	11.05.05	Section 6.1
MEMP 3.0.1-23	Equipment Inventory	EC.02.04.01(2)	PE.7 (SR.1) PE.7 (IG)	11.05.02	Section 8.5
MEMP 3.0.A.1-23	Inclusion Criteria – Risk Based	EC.02.04.01(2), EC.02.04.01(3)	PE.7 (SR.6)	11.05.02	Section 6.1
MEMP 3.0.B.1-23	Equipment Inventory Database	EC.02.04.01(2)	PE.7 (SR.1) PE.7 (IG)	11.05.02	Section 8.5
MEMP 3.0.C.1-23	Incoming Inspections	EC.02.04.03(1)	PE.7 (SR.2) PE.7 (IG)	11.05.02	Section 6.1
MEMP 3.0.D.1-23	Non-Hospital-Owned Equipment	EC.02.04.03(1)	PE.7 (SR.2)	11.05.02	Section 6.1
MEMP 3.0.E.1-23	Disposition of Hospital Owned Medical Equipment	EC.02.01.01(1) EC.02.01.01(3)	PE.7 (SR.6)		
MEMP 4.0.1-23	SM Activities	EC.02.04.01(4), EC.02.04.01(5), EC.02.04.03(2-5), EC.02.04.03(10), EC.02.04.03(16)	PE.7 (SR.6)	11.05.01	Section 8.1, Section 8.5, Section 9.1
MEMP 4.0.A.1-23	Scheduled Maintenance Service Procedures	EC.02.04.03(2), EC.02.04.03(3)	PE.7 (SR.6)	11.05.01	Section 8.1, Section 8.5, Section 9.1
MEMP 4.0.B.1-23	Alternate Equipment Maintenance (AEM)	EC.02.04.01(6), EC.02.04.01(7), Survey Activity Guide	PE.7 (SR.6) PE.7 (IG)	11.05.01 11.05.02	Section 8.1, Section 8.5, Section 9.1
MEMP 4.0.C.1-23	Electrical Safety Limits and Regulatory Documentation	EC.02.04.03(1)	PE.7 (SR.1, SR.2, SR.5)		Section 8.1
MEMP 4.0.D.1-23	Clinical Alarm Management	NPSG.06.01.01	PE.7 (SR.5)		Section 6.1
MEMP 4.0.E.1-23	Dialysis Equipment Maintenance and Documentation	EC.02.04.03(5)	PE.7 (SR.6)	11.05.01	Section 8.4
MEMP 4.0.F.1-23	Sterilization Equip. Maintenance	EC.02.04.03(4)	PE.7 (SR.6)	11.05.01	Section 8.4
MEMP 4.0.G.1-23	Visual/Environmental Inspections	EC.02.04.03(1), EC.04.01.01(1)	PE.7 (SR.5, SR.6)	11.05.01	Section 8.1, Section 9.1
MEMP 4.0.H.1-23	Test Equipment Calibration Documentation	ISO 9001, NIST	PE.7 (SR.6) PE.7 (IG)	11.05.01	Section 7.1

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MEMP 4.0.I.1-23	Test Equipment out of Tolerance	ISO 9001, NIST	PE.7 (SR.5, SR.6) PE.7 (IG)	11.05.01	Section 7.1, Section 8.7, Section 10
MEMP 4.0.J.1-23	Anesthesia Maintenance & Documentation	EC.02.04.03(26)	PE.7 (SR.6) AS.3	11.05.01	Section 8.4
MEMP 4.0.K.1-23	Radiation Service	EC.02.04.01(10), EC.02.04.03(16), EC.02.04.03(18), EC.02.04.03(20-25)	MI.3 (SR.1, SR.2)	11.05.01	Section 8.1
MEMP 4.0.L.1-23	Power Strips Management	EC.02.05.01(23) EC.02.05.01(24)	PE.7 (SR.5, SR.6)	11.05.01	Section 8.1
MEMP 5.0.1-23	Medical Equipment Repair Program	EC.02.04.03 EC.02.04.01(9)	PE.7 (SR.5, SR.6) QM.2 (SR.3d)	11.05.03	Section 8.7, Section 9.1
MEMP 5.0.A.1-23	After Hours Call Procedure	EC.02.04.03	PE.7 (SR.5, SR.6)		Section 8.1
MEMP 5.0.B.1-23	Equipment Failure Plan	EC.02.04.01(9)	PE.7 (SR.5, SR.6)	11.05.03	Section 8.1, Section 8.7, Section 9.1
MEMP 5.0.C.1-23	Emergency Management – Response & Procedures	EC.02.04.01(9), EM.12.01.01(1),	PE.6 (SR.1) PE.7 (SR.5) PE.7 (IG)		Section 6.1
MEMP 5.0.D.1-23	Disaster Management – Responsibilities	EM.10.01.01, EM.12.01.01 (1), EM.12.01.01(5)	PE.6 (SR.1) PE.7 (SR.5) PE.7 (IG) PE.8 (SR.5)		Section 6.1
MEMP 6.0.1-23	Description of System Database	IM.01.01.03, IM.03.01.01	PE.7 (SR.1) PE.7 (IG)	11.05.02	Section 7.1
MEMP 6.0-A.1-23	Database Reporting Functions	IM.01.01.03, IM.03.01.01	PE.7 (SR.1) PE.7 (IG)	11.05.02	Section 7.1
MEMP 6.0-B.1-23	Hazard and Recall Notification	EC.02.01.01(11)	PE.7 (SR.7)		Section 6.1
MEMP 6.0-C.1-23	HIPAA (ePHI) Policy	IM.01.01.01(2), IM.02.01.01, IM.02.01.03	MR.4 (IG)		Section 6.1
MEMP 6.0-D.1-23	Use of Personal Communication Devices	IM.02.01.01, IM.02.01.03	MR.4 (IG)		Section 6.1
MEMP 7.0.1-23	Medical Equipment Management PI and Annual Reporting	EC.04.01.01(1), EC.04.01.01(10)	PE.7 (SR.5) QM.5 (SR.1) QM.7		Section 8.2, Section 10

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MEMP 7.0.A.1-23	Performance Indicators & Improvement Goals	EC.04.01.01(1), EC.04.01.01(10) EC.04.01.01(15), EC.04.01.03(2)	PE.7 (SR.5) QM.5 (SR.1) QM.6 (SR.4, SR.5)		Section 8.2, Section 10
MEMP 7.0.B.1-23	Annual MEMP Program Assessment	EC.04.01.01(15), EC.04.01.03(2)	PE.7 (SR.5) QM.5 (SR.1) QM.7		Section 6.1, Section 6.2, Section 7.1, Section 8.1, Section 8.5, Section 9.1, Section 9.2, Section 10
MEMP 7.0.C.1-23	Quality Assurance	PI.02.01.01(8), PI.03.01.01(2), PI.03.01.01(3)	QM.2 (SR.3)		Section 6.1, Section 6.2, Section 8.1, Section 8.5, Section 8.7, Section 9.1, Section 9.2, Section 10
MEMP 8.0.1-23	Safe Medical Devices Act – Incident Reporting	EC.02.04.01(11)	PE.7 (SR.4) QM.8 (SR.1)	11.05.04	Section 8.1, Section 8.7
MEMP 9.0.1-23	Employment Requirements	HR.01.01.01(1)	PE.7 (IG) SM.5		Section 7.1, Section 7.2, Section 8.1, Section 8.5
MEMP 9.0.A.1-23	Continuing Education Program	EC.03.01.01(1) HR.01.04.01(1), HR.01.05.03(1)	PE.7 (IG) SM.5 (SR.2)		Section 7.2, Section 10
MEMP 9.0.B.1-23	Technical Competency Assessment	HR.01.06.01(5), HR.01.06.01(6) HR.01.07.01(1), HR.01.07.01(2)	PE.7 (IG) SM.5 (SR.1)		Section 7.2, Section 8.4
MEMP 10.0.1-23	Infection Control	IC.01.04.01(1), IC.02.01.01(2), IC.02.02.01(1), IC.02.02.01(2), IC.02.02.01(3), IC.02.02.01(4)	IC.1		Section 7.2, Section 8.1
MEMP 11.0.1-	Exposure Control Plan	EC.02.02.01(3),	IC.1		Section 7.2,

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23		EC.02.02.01(11)			Section 8.1
MEMP 12.0.1-23	User In-Service Training	EC.04.01.01(10)	SM.5		Section 7.2, Section 8.1

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<b>Section No:</b>	<b>Section 2</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 2.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Equipment Selection &amp; Acquisition</b>		

The facility may have policies, procedures and processes for the proper selection and acquisition of medical/clinical equipment. Involvement of equipment users and maintainers is left to the discretion of the hospital and may not always be a part of the selection committee.

The Biomedical Engineering department have the following responsibilities specific to Medical/Clinical Equipment Selection and Acquisition:

- Active participation in the Capital Equipment Committee.
- Review and final approval of purchase orders to ensure compatibility of new systems with existing systems, and anticipated installation schedules, and to ensure that the product is properly evaluated and inventoried for inclusion in the MEMP.
- Evaluation of the warranty, warranty period, and availability of technical training of Biomed/Clinical Engineering staff for post-warranty service.
- Evaluation of installation needs and requirements.
- Evaluation of the product, its performance, service history, and post-warranty maintenance expense and requirements.
- Evaluation of available service training, expense, and scheduling requirements.
- Evaluation of available operator and service documentation.

### **Note:**

- It is an ECRMC requirement that complete service manuals, operator's manuals, and other technical documentation, as applicable, is included with all new equipment purchases.
- As per the new TJC standards, ECRMC is required to maintain a library of information (including manuals, procedures provided by manufacturers, technical bulletins etc.) regarding inspection, testing and maintenance of its equipment.
- If available, enclose a copy of the ECRMC's medical equipment selection and acquisition policy and procedure for reference.

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<b>Section No:</b>	<b>Section 3</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 3.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Equipment Inventory</b>		

The Medical Equipment Management Program inventory and service database is inclusive of all medical equipment, regardless of ownership or origination except for short-term rental equipment (on-site for less than its recommended maintenance interval) which is in accordance with the Non-Hospital-Owned Equipment Policy, **MEMP 3.0.D** of this manual.

In accordance with applicable regulatory and accreditation agencies, all equipment intended for the direct care (treatment), diagnosis, monitoring and direct support of patients, that enters the facility must be evaluated for risk and inclusion in the medical equipment management program prior to use, in accordance with policy **MEMP 3.0.A** of this manual, to establish how it may impact the patient care environment, patient safety, user education and equipment maintenance requirements. This equipment includes, but is not limited to:

- Life Support and Non-Life Support Patient Equipment
- Clinical Laboratory Equipment
- Radiographic Equipment (both for treatment and diagnosis)
- Imaging Equipment
- Nuclear Medicine Equipment
- Sterilization Equipment
- Diagnostic equipment such as rigid and flexible endoscopes
- Medical Equipment related Computers and Computer Systems (ISM equipment).

Once the equipment is included in the program it is assigned a CE Tag number and the equipment is added to the inventory. Each equipment item (device) is a separate line item and includes a minimum of the following information:

- CE Tag number
- Cost Center (Department)
- Manufacturer and Model
- Device Description (device class)
- Serial number
- Location (if different than Cost Center)
- Equipment Status (active, in-storage, etc.)
- Scheduled Maintenance frequency and month

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<b>Section No:</b>	<b>Section 3</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 3.0.A.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Inclusion Criteria – Risk-Based</b>		

All medical/clinical equipment is evaluated for inclusion into the ECRMC Medical Equipment Management Program in accordance with strict risk-based inclusion criteria as described below:

### **Risk Criteria (RC) Categories**

The following five criteria are used to determine inclusion into the MEMP.

- Equipment Function (Category I)
- Clinical Application (Category II)
- Manufacturer Scheduled Maintenance requirement (Category III)
- Likelihood of Failure (Category IV)
- Equipment Environment (Category V)

### **Risk Category Definitions**

#### **Equipment Function (I) (E)**

The numerical value assigned to the equipment's Function (Category I) is determined by the following three risk factors that best describe the device's usual function.

- Medical equipment that is used in direct patient care (therapeutic, diagnostic, and monitoring equipment).
- Equipment whose function is to support items that are used in direct patient care in the clinical environment (e.g., battery chargers and printers).
- Equipment which is not used for direct patient care (e.g., televisions).

#### **Clinical Application (II) (A)**

The numerical value assigned to the equipment's Clinical Application (Category II) is determined by the following three risk factors that best describe the physical risks associated with the device's usual clinical application.

- Potential for serious injury or patient death.
- Potential for inappropriate therapy or misdiagnosis and consequent injury/illness.
- No significant risk of delay in therapy or diagnosis.

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### Scheduled Maintenance Requirements (III) (P)

The numerical value assigned to the equipment's Scheduled Maintenance requirements (Category III) is determined by the following three risk factors that best describe the device's manufacturer required or regulatory agency recommended level of maintenance.

- Equipment that requires frequent or extensive maintenance due to either the design characteristics or specific application.
- Equipment that requires relatively infrequent or light maintenance due to either its design characteristics or the specific application.
- Equipment that requires little or no maintenance due to either its design characteristics or the specific application.

### Likelihood of Failure (Category IV) (F)

The numerical value assigned to the equipment's likelihood of failure (Category IV) is determined by the following three risk factors that best describe the equipment's safety record as documented in the equipment service history, incidents and/or published hazard alerts or recalls.

- Equipment service history
- Equipment incident history
- Published hazard alerts or recalls

### Equipment Environment (Category V) (U)

The numerical value assigned to the equipment's use Environment (Category V) is determined by the following four risk factors that best describe the equipment's use environment.

- High risk environments such as ICU, Surgery and ER, where invasive clinical procedures subject the patient to the risk of micro-shock from the medical equipment or where an equipment malfunction may cause serious injury or death to the patient.
- Low risk environments such as general patient areas where the equipment and/or the equipment environment pose only minimal risk of patient injury or death.
- Hazard Surveillance only environments such as non-patient care areas where the equipment and/or the environment pose no significant risk to the patient.
- Tracking only environments such as non-clinical areas where the equipment and/or the environment pose no risk to the patient.

**Note:** The factors above also consider other parameters such as the rate of equipment use, damage and/or abuse, use errors and the condition of the environment such as cleanliness, temperature and air flow and filtration.



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Each risk category includes specific sub-categories that are assigned points, which when added together according to the formula listed below, yield a total score from three (3) to twenty (20). All equipment that scores six (6) or above is included in the medical equipment management program and is added to the equipment inventory.

### Risk Category Scoring Criteria

#### Risk Category I: Scoring Criteria

<u>Point Score</u>	<u>Function</u>	<u>Description</u>
10	Therapeutic	Life Support
9	Therapeutic	Surgical, Intensive Care, Labor and Delivery,
9	Therapeutic	NICU, Dialysis, GI Lab
8	Therapeutic	Items delivering direct or indirect treatment,
8	Therapeutic	*Sterilization Equipment.
7	Diagnostic	Surgical, Intensive Care Labor and Delivery,
7	Diagnostic	Monitoring Systems, Radiology Systems,
6	Diagnostic	Other Physiological Monitoring
5	Analytical	Laboratory Analytical
5	Volumetric	Laboratory Volumetric
4	Analytical	Laboratory Accessories
3	Analytical	Computer and Computer Related
2	Miscellaneous	Patient Related
1	Miscellaneous	Non-patient Related

*\*Categorized due to potential of treatment delay*

#### Risk Category II: Scoring Criteria

<u>Point Score</u>	<u>Description of Use Risk</u>
5	Potential patient death
4	Potential patient injury
3	Inappropriate therapy or miss-diagnosis
2	Equipment damage
1	No significant identified risk

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### Risk Category III: Scoring Criteria

<u>Point Score</u>	<u>PM Frequency</u>
5	Monthly
4	Quarterly
3	Semi-annually
2	Annually
1	Not required

### Risk Category IV: Scoring Criteria

<u>Point Score</u>	<u>Frequency of Failure</u>
5	Less than three months
4	Approximately six months
3	Approximately one year
2	Approximately three years
1	Greater than five years

### Risk Category V: Scoring Criteria

<u>Point Score</u>	<u>Primary Area of Equipment Use</u>
5	Anesthetizing Locations
4	General Surgery, Critical Care Areas, Labor and Delivery, Dialysis, NICU Emergency Department
3	Step Down, Electro-Diagnostic Areas, Wet Locations, Radiology, Physical Therapy
2	General Care Areas, Clinics, Laboratory
1	Non-patient Areas

### Risk Criteria (RC) Number and Risk Level Determination

The RC number ( $= E + A + [(P+F+U)/3]$ ) which corresponds to a Risk Level number that is assigned to the level and frequency of scheduled maintenance of Medical Equipment in the program.

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RC Number/Risk Level Criteria:

RC	Risk Level	Risk Definition
20 – 18	1	High Risk
17 – 15	2	Moderate Risk
14 – 11	3	Low Risk
10 – 6	4	Hazard Surveillance Only
< 6	5	Tracking Only

Non-High Risk

- Equipment with a RC number = **20 - 18** is classified as **Risk Level 1**. Level 1 equipment is considered High Risk-equipment.
- Equipment with an RC number = **17 - 15** is classified as **Risk Level 2**. This equipment is considered Moderate Risk equipment.
- Equipment with a RC number = **14 - 11** is classified as **Risk Level 3**. This equipment is considered Low risk equipment.
- Equipment with a RC number = **10 - 6** is classified as **Risk Level 4**. This equipment is considered Hazard Surveillance Only equipment that can be inspected via visual inspection or can be included in an environmental rounds program.
- Equipment with a RC number = **less than 6** is classified as **Risk Level 5** (Tracking Only) equipment that is maintained on the equipment inventory for tracking purposes only.

For the convenience of the ECRMC Technical Staff, **risk and priority level determinations have already been calculated and documented** on the Risk Classification Table. Equipment tracked through RenovoLive CMMS is classified accordingly.

**Risk Level / Maintenance Frequency Determination**

Using the criteria system described above, medical/clinical equipment is categorized according to the following level of risk.

**High Risk:** Equipment that scores from 18 to 20 points on the criteria evaluation system. This equipment is given the highest priority for testing, maintenance, calibration, and repairs and requires 100% on-time scheduled maintenance completion according to its schedule.

**Moderate Risk:** Equipment that scores from 15 to 17 points on the criteria evaluation system. Every effort should be made to test, calibrate, and repair this equipment promptly, but only after High-Risk equipment requirements have been completed.

**Low Risk:** Equipment that scores between and including 11 to 14 points on the criteria evaluation system. Every effort should be made to test, calibrate, and repair this equipment

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promptly, but only after High risk and Moderate risk equipment requirements have been completed.

**Hazard Surveillance:** Equipment that scores between and including 6 to 10 points on the criteria evaluation system and that poses little or no risk to patients. These devices are typically inspected on an annual basis and may be subject to a minimum of a visual /environmental inspection.

**Note:** Manufacturer or regulatory requirements may dictate a minimum service level for this equipment.

**Tracking Only:** Equipment that scores less than 6 on the criteria evaluation system is excluded from the management program but must remain on the clinical equipment inventory for tracking purposes.

**Note:** Manufacturer or regulatory requirements may dictate a minimum service level for this equipment.

**Note:** Equipment with a history of failure, manufacturer alerts/recalls or patient related incidents, may be moved to a higher risk category and/or may be subject to more frequent testing as per AEM program recommendations.

### **Risk Reclassification**

In situations where it is desired to place equipment in a higher or lower risk level than is indicated by the scoring formula, a recommendation must be made by the Biomedical Engineering Department and approved by the Safety/EOC Committee.

When it is desired to place equipment in a lower risk level than is indicated by the scoring formula, a recommendation must be made by the Biomedical Engineering Manager and approval must be obtained from the Director of QRM, and the Department Head of the affected equipment area(s). **High Risk equipment may not be re-categorized.**

**CLINICAL EQUIPMENT RISK ASSESSMENT EVALUATION FORM**

Equipment Type Description \_\_\_\_\_

Manufacturer \_\_\_\_\_

Environmental Area Used \_\_\_\_\_

Evaluation Information:

Risk Category I: Equipment Function (E) Score \_\_\_\_\_

Risk Category II: Clinical Application (A) Score \_\_\_\_\_

Risk Category III: PM Requirement (P) Score \_\_\_\_\_

Risk Category IV: Likelihood of Failure (F) Score \_\_\_\_\_

Risk Category V: Environmental Use Are (U) Score \_\_\_\_\_

Evaluation Scoring:

Total = E + A + ((P+F+U) / 3) Score \_\_\_\_\_

Inventory Classification Result:

\_\_\_\_\_ High Risk (Score is in the 18 – 20 range)

\_\_\_\_\_ Moderate Risk (Score is in the 15-17 range)

\_\_\_\_\_ Low Risk (Score is in the 11-14 range)

\_\_\_\_\_ Hazard surveillances check only (Score is in the 6-10 range)

\_\_\_\_\_ Tracking Only (Score is less than 6)

**Note:** This risk evaluation is embedded electronically in RenovoLive and automatically does the assessment for any new equipment added to the inventory.

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<b>Section No:</b>	<b>Section 3</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 3.0.B.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Equipment Inventory Database</b>		

Following acceptance into the program and risk classification, an inventory database is created for all equipment included in the Medical Equipment Management Program.

Each equipment item included in the Medical Equipment Management Program will have a unique Equipment Control Number assigned and affixed to it. This number will be used for tracking purposes.

Each database entry specific to a piece of equipment included in the Medical Equipment Management Program shall include the following information:

- Equipment Incoming Date
- Equipment Control Number
- Department Assigned
- Equipment Description
- Manufacturer
- Model Number
- Serial Number
- Assigned PM schedule
- Assigned PM procedure number
- Frequency of PM
- Status
- Warranty information
- Risk Classification
- Service History
- Incident History

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<b>Policy:</b>	<b>MEMP 3.0.C.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Incoming Inspections</b>		

Hospital-Owned Equipment: All incoming medical equipment, regardless of ownership, shall receive an incoming inspection that includes safety, operational, and functional checks. Incoming inspections shall be documented and entered in the RenovoLive database. Non-hospital-owned equipment shall receive an incoming inspection and shall be documented. In addition to initial inspection, the following steps are included in the incoming equipment evaluation process:

**Note:** *It is usually the responsibility of the ECRMC's Receiving personnel to receive and formally accept all incoming new equipment in accordance with facility's policy and procedure. If Biomedical staff is requested to assist in the unpacking and acceptance of the equipment the following guidelines should be observed.*

- Read all external warning labels and carefully follow the directions.
- Make a complete list of all equipment, accessories, and documents that were delivered.
- Do not discard any packing materials until the equipment is formally accepted and signed off by an appropriate facility representative.
- Perform and document any special acceptance procedures requested by the facility.
- For ePHI sensitive medical and ISM equipment, request a copy of the Manufacturer Disclosure Statement for Medical Device Security form (MDS2).

After the new equipment has been formally accepted by the facility and cleared to be added to the inventory:

- Attach a Biomedical Equipment Control (CE#) tag to the equipment in a position where it can be seen from the front of the device.
- Request a copy of the technical service manual for filing along with the other manuals. (Note: Operators manuals must also be requested if not delivered with the equipment).
- Review the manufacturer's service manual and assign the appropriate SM procedure and maintenance interval to the equipment.
- Create an equipment history record (equipment adds to inventory) in the RenovoLive database.
- As applicable, perform safety and functional tests and attach an incoming inspection or SM tag (as applicable) to the equipment.

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<b>Policy:</b>	<b>MEMP 3.0.D.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Non-Hospital Owned Equipment</b>		

In accordance with applicable regulatory and accreditation agencies, all medical equipment “regardless of ownership” must be evaluated for inclusion in the medical equipment management program. *It is the policy of ECRMC that an initial (incoming) inspection be performed on all new hospital owned and on all non-hospital owned medical equipment, both “short-term” and “long-term” upon receipt by the facility.* An incoming inspection should be performed on non-hospital owned medical equipment each time it enters the facility. The owner/vendor of the equipment will be responsible for ensuring that all medical equipment provided to the facility is maintained in accordance with manufacturer and regulatory agency recommendations and that current maintenance is evident by maintenance documentation and/or a maintenance tag.

**Responsibility:** Ultimate responsibility for policy conformance lies with the Clinical Department Manager requesting the equipment.

The following is required for each item of medical equipment provided by rental/lease/loaner equipment vendors:

- Fully compliant service documentation available when requested, including evidence that the equipment is periodically tested in accordance with applicable standards and state requirements.
- The equipment is currently compliant.
- The testing frequency and procedures are compliant with the manufacturer’s recommendations.
- The vendor will label each item placed in the facility with a tag indicating the ownership of the equipment, the next scheduled maintenance date, and the initials of the person last performing service.
- A monthly inventory report will be made available (or when requested) to the Biomedical Engineering department that includes:
  - The unique identifier used by the company to verify ownership.
  - Equipment description.
  - Equipment manufacturer.
  - Equipment model.
  - The date the equipment arrived.
  - The last date of service.
  - The next date of service.
  - Any items located on-site which are due for service.



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All rental/lease medical equipment is subject to incoming inspection by Biomedical Engineering and the periodic inspection by the rental vendor. All rental/lease/loaner vendor equipment testing documentation will be provided to the Biomedical Engineering department and filed.

Any medical equipment that will remain in the facility for **longer than its manufacturer recommended maintenance frequency** (long-term) will be added to the equipment inventory and assigned a SM schedule for tracking.

### **Physician/Patient Owned/Demonstration Equipment**

The following is required for medical equipment brought in for demonstration or evaluation:

A visual and electrical safety inspection will be performed and documented by Biomed and the appropriate sticker applied.

The following is required of patient/physician owned medical equipment brought into the hospital environment and deemed acceptable by hospital policy:

- A minimum of visual inspection by Biomed.
- The device is in good condition (clean, no frayed cords, case is intact and not damaged, does not smell hot when in use and appears to be in working condition).
- Infection control and daily maintenance will be the responsibility of the patient/physician.

### **Note:**

- Patient owned medical equipment that is three-wire, 110-120 volt, and UL approved may be subject to an electrical safety inspection.
- ECRMC Biomedical Engineering department is not responsible for repairs or maintenance to any Patient/Physician owned or Rental/Leased/Loaner medical devices.
- It is the responsibility of the hospital clinical staff to inform the arrival and departure of NHO medical equipment to Biomedical Engineering.
- NHO medical equipment (even though it is the same unit) is subject to incoming inspection every time it leaves the facility and brought back in, irrespective of time interval.
- The hospital should decide whether it is appropriate for the nursing staff to simply do a physical inspection on Patient/Physician owned equipment brought in after-hours or if it is necessary for the on-call Biomedical staff to perform the inspection.
- Rental/Leased/Loaner medical devices brought in after-hours must be accompanied by the most recent performance verification documentation and the hospital shall decide whether it is appropriate to use or is it necessary for the on-call Biomed staff to perform the inspection.

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<b>Policy:</b>	<b>MEMP 3.0.E.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Disposition of Hospital Owned Medical Equipment</b>		

***This policy must be aligned with the ECRMC's medical equipment retirement and/or disposal policy and is to be superseded where deemed appropriate.***

Purpose: To assist ECRMC in the retirement and disposition of medical equipment as a result of its natural obsolescence, failure to meet current standards, uneconomic or poor serviceability etc.

This procedure applies only to medical equipment purchased by the hospital, not to leased, rentals, loaners, demo, or patient-supplied equipment. This procedure applies to all those involved in equipment planning, utilization, retirement, and disposition decisions such as Clinical staff and management, Materials Management, Safety and Risk management, Clinical Engineering, Hospital IS department.

The final decision on capital spending rests with the ECRMC's CFO, Finance Department and/or Board of Directors

Equipment may be retired/disposed from service for any of the following reasons.

- i. It no longer permits an appropriate standard of care.
- ii. It does not meet currently accepted safety requirements and may present a unique risk to patients or personnel.
- iii. It breaks down frequently and is cost prohibitive to maintain.
- iv. Repair parts or service are no longer available.
- v. It is no longer cost effective to operate. The cost may relate to personnel time, availability, or costs of repair parts, or to the availability or costs of consumables.

A committee composed of representatives of interested user departments, hospital administration including but not limited to Materials Management, Safety and Risk Management, Biomed/Clinical Engineering staff shall be formed to analyze each piece of equipment proposed to be disposed from service including the proper disposal method.

After deliberation, the committee shall make a formal recommendation to the appropriate hospital leader (Administrator, Controller, or CEO) with the following information:

- Manufacturer, Model, CE# tag, Serial number.
- Reason for retirement.

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- Statement of what will replace it.
- Relative urgency of the request.
- Recommended disposition of the device.

Disposal Method: After receiving authorization from the appropriate hospital leader for disposing the equipment from service but before disposing the equipment the following alternatives for disposition shall be considered by the Biomedical Manager in consultation with the Finance department:

- i. Trade-in with the vendor who is interested in selling a replacement.
- ii. Re-sell the equipment to another trader.
- iii. Donate the equipment to a non-profit organization.
- iv. Sell the equipment to a scrap dealer.
- v. Put the equipment into trash or recycling program.

Before disposing of the equipment, the following checks shall be performed:

- i. The Biomedical Engineer Manager shall review the Incident Investigation file to review whether the device has been involved in any incident. If no reason has been found to prevent disposition, CE staff shall remove equipment from the active inventory in Renovolve and all equipment identification tags, budget and inspection stickers.
- ii. ECRMC IT department shall ensure that prior to transfer or disposal of equipment, ePHI will be securely overwritten or physically destroyed and that such steps will be documented.
- iii. The Material Management manager shall review appropriate laws, regulations, and codes on environment protection to ensure the disposal of the equipment does not violate any of those requirements.

Below are a few precautions to take for the transport of contaminated equipment:

- Contained during their transport from the point of use
- Type of container that should be used depends on the items being transported
- Puncture-resistant, leakproof, closable, impermeable
- Should be marked with a biohazard label or other means of identifying contaminated contents; a red bag or container may also be used to denote that the contents are hazardous

After disposing of the equipment, the following tasks shall be performed:

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- i. The Biomedical Engineering Manager shall take appropriate actions to ensure all equipment records are retained as per hospital record retention policy.
- ii. If equipment is deemed trackable by FDA, the Materials Management or Biomedical Engineering will inform the respective manufacturer and all other applicable agencies of final disposition.

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<b>Policy:</b>	<b>MEMP 4.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>SM Activities</b>		

### **Maintenance, intervals, and scheduling**

Activities and frequencies for inspecting, testing, and maintaining all medical equipment are in accordance with the manufacturer's recommendations or with strategies of an alternative equipment maintenance (AEM) program.

Activities and frequencies for inspecting, testing, and maintaining of following items must be in accordance with the manufacturer's recommendations:

- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)
  - Medical laser devices
  - Medical equipment that is subject to federal or state law or Medicare Conditions of Participation. It should be tested and maintained per the manufacturer's recommendations or by following an approach that establishes more stringent maintenance requirements
  - New medical equipment that usually does not have adequate maintenance history to support the use of AEM strategies. The maintenance history must include records provided by the hospital's contractors, information made public by nationally recognized sources, and records of the hospital's experience over time.
- 
- All the equipment within a given department is due and should be completed within the month scheduled. Hospital-wide total hours of maintenance are distributed as evenly as possible throughout the annual service cycle.
  - Following a documented incoming inspection new items brought into the program are scheduled at the time of initial data entry in accordance with the SM schedule of the owner department. Scheduled maintenance performed by service vendors other than ECRMC may be scheduled in accordance with the vendor's schedule if approved by the owning department.
  - All vendor owned/serviced equipment will be included in the equipment inventory including the designated maintenance frequency and schedule.
  - A computerized database listing items due are produced from the RenovoLive database at the beginning of each month. Completed service is documented. Data includes the disposition of the service for each scheduled item, and service details (as appropriate).
  - All maintenance activities for high-risk and non-high-risk equipment must have a 100% completion rate.

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### **Late/Incomplete SM (UTL/CIU/UFM) follow-up**

It is ECRMC Biomed's goal to complete all scheduled maintenance (SM) in the same month that it is due. If the SM work is not completed by the first day of the following month it is late. However, there are legitimate special conditions that, **with proper documentation, follow-up and SM completion or resolution**, justify a late or incomplete SM. These conditions include equipment that is not located during the month due (UTL), equipment that is in continuous use during the month due (CIU), and equipment requiring repair (UFM), overhaul, calibration, or other services during the month due, (such as resolving manufacturer recalls/alerts which according to risk are of higher priority), that delayed the SM from being completed on time.

**SM scheduling is based on the month**, not the date (day of the month) that the SM work is due. We do, however, allow an extension of **up to one additional month (30 days)** to follow-up and complete the SM for those items which have been identified as UTL, CIU, and UFM the previous month in which they were due.

### **Documenting attempted SM (UTL/CIU) and Customer interaction**

When an item for which SM is currently due (or overdue) is found to be continually in use (CIU), the date of all the attempted SM services should be noted on the SM service report and entered in RenovoLive as well as all attempts to interact with the Department staff (Director/Manager) to provide reasonable access to the equipment including replacement via spare equipment, or rental equipment. ***SM events for the equipment CIU during and after the follow-up period will be left open with CIU Special Condition and the event be closed only after completion of the SM.***

When an equipment item for which SM is currently due or overdue is not located (UTL) the date of all attempts should be noted on the SM service report, entered in RenovoLive, and the Department staff (Director/Manager) notified with a request to assist in the determination of the location or status of the equipment. **SM events for the equipment UTL after the follow-up period will be closed with UTL Special Condition and the status of the equipment should be changed to UTL.**

### **Reporting Incomplete Scheduled Maintenance**

Scheduled maintenance that is not completed (without any special conditions) by the end of the 30-day follow-up period is considered incomplete and will be reported to the Department Staff (Director/Manager) so appropriate actions can be taken and the maintenance completed. **The equipment not located will be moved to 'Unable to Locate' status until the scheduled maintenance can be completed.** Incomplete maintenance will be tracked via the

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ECRMC Biomed monthly SM Status report and reported to the EOC Committee via the Renovolve MEMR report.

*Refer to the Technical Policy & Procedures TPM 2.j for additional information on process for UTL items.*

### **Scheduled Maintenance documentation**

Scheduled maintenance (SM) inspections and services should be performed and **reported by exception** except for high-risk equipment and equipment for which documenting the output/measured values are critical in determining the performance of the equipment, list including but not limited to centrifuges, energy output devices etc., (list as deemed appropriate by the Biomedical Manager).

### **Service documentation**

When all the scheduled maintenance and performance verification components of the SM procedure have been completed successfully, verification that the device is functioning safely should be indicated on the service report with a **SM Complete** Resolution Code. If the device is found to be unsafe and requires repairs to bring it back into proper specifications, this should be indicated on the service report with a **SM Failed/Repair Needed** Resolution Code.

All equipment maintenance and repair services shall be documented including all measurements and manufacturer specifications and tolerances, as applicable, and text information including the problem, resolution, final disposition of the equipment and the status of the service call shall be documented and entered in the Renovolve maintenance management system utilizing the assigned service codes. Any hard copy service documentation, such as service vendor scheduled maintenance, repair service, and test equipment calibration documentation, is filed by equipment number in the Biomedical Engineering department. All equipment maintenance and repair service documentation and records including test equipment calibration documentation shall be retained for a minimum of three years.

**Note:** Stickers affixed on the equipment after successful completion of scheduled maintenance are only for the visual identification of the work completed by the Biomed staff. Missing stickers should not be accounted towards non-compliance or non-conformance if the documentation is available to justify the maintenance performed.

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<b>Policy:</b>	<b>MEMP 4.0.A.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Scheduled Maintenance Procedures</b>		

Scheduled maintenance service procedures are based on the manufacturers recommended service specifications and tolerances, and nationally recognized safety standards or based on the strategies of an alternative equipment maintenance (AEM) program. The SM service procedure number is linked to the individual equipment description and is available via the RenovoLive database. Procedure identification numbers are linked to the Master Classification Table (MCT) which references accepted nomenclature tables for recall tracking purposes. Planned maintenance will include the following, as appropriate:

- Electrical safety testing
- Performance verification testing and calibration as appropriate
- Ensure that all alarm parameters are tested
- Ensure free-flow protection on all general-use and PCA (patient-controlled analgesia) intravenous infusion pumps used in the organization.
- Minor corrective repairs, as required
- Cleaning of external and internal spaces and components, if applicable.

**Note:** If the equipment requires disinfecting prior to service, it is to be sent to the hospital's Sterile Processing Department (SPD) for proper disinfection. The Biomed staff must notify the appropriate Clinical Department Manager/Staff before removing or returning equipment to an isolated or potentially infectious patient area.

Equipment that fails to pass any of the above inspections, and that requires more than minor corrective repair to bring into manufacturer's compliance will be removed to the Biomedical Engineering Department to ensure that it is not placed back into service until repairs are completed. Equipment that passes inspection will be labeled indicating the date of inspection, the next date the equipment is due, and the initials of the individual performing the service.

Should equipment be removed from service for repair, the appropriate clinical staff must be notified so that plans can be made to ensure continuity of patientcare.



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<b>Policy:</b>	<b>MEMP 4.0.B.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Alternate Equipment Maintenance (AEM)</b>		

The Centers for Medicare & Medicaid Services (CMS) allows hospitals to implement an Alternate Equipment Management (AEM) program to adjust maintenance, inspection, and testing activities for medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel. The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice.

ECRMC EOC committee uses a **Reliability Centered Maintenance (RCM)** strategy to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner considering the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use.
- Likely consequences of equipment failure or malfunction
- Availability of alternative or backup equipment if equipment fails or malfunctions.
- Incident history of identical or similar equipment.
- Maintenance requirements of the equipment

The AEM committee developed a methodology, based on the above criteria, for the identification of equipment to be included in the AEM program. Medical equipment inclusion in the AEM program will be based on the RenovoLive national inventory records. Biomedical Manager will present the evaluations to the Environment of Care (EOC) committee for approval to include the equipment in the AEM program. The hospital identifies all the medical equipment on its inventory database that is approved by the EOC committee to be included in an AEM program.

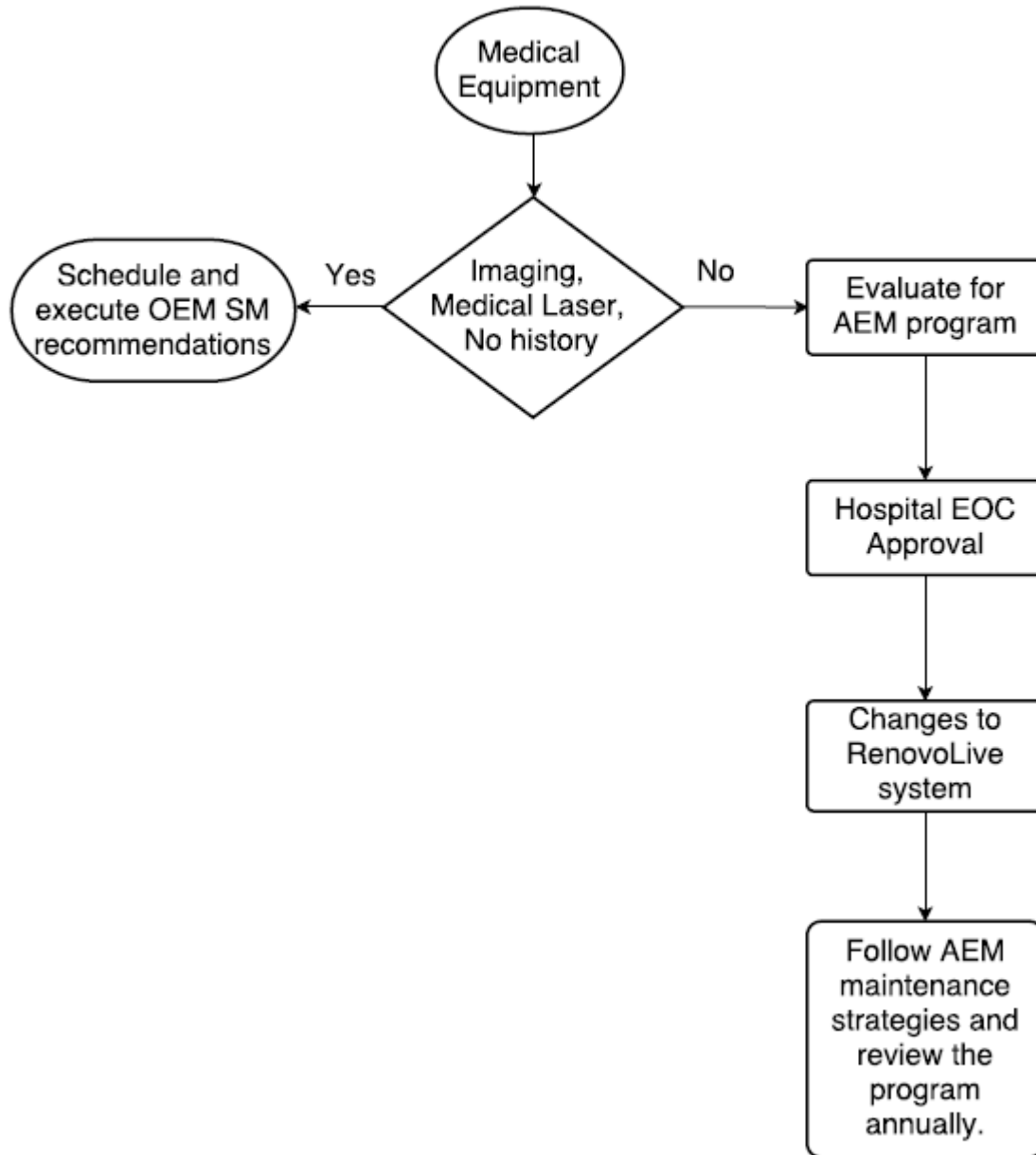
**NOTE:** The maintenance activities for all the medical equipment included in the AEM program must have a 100% completion rate.

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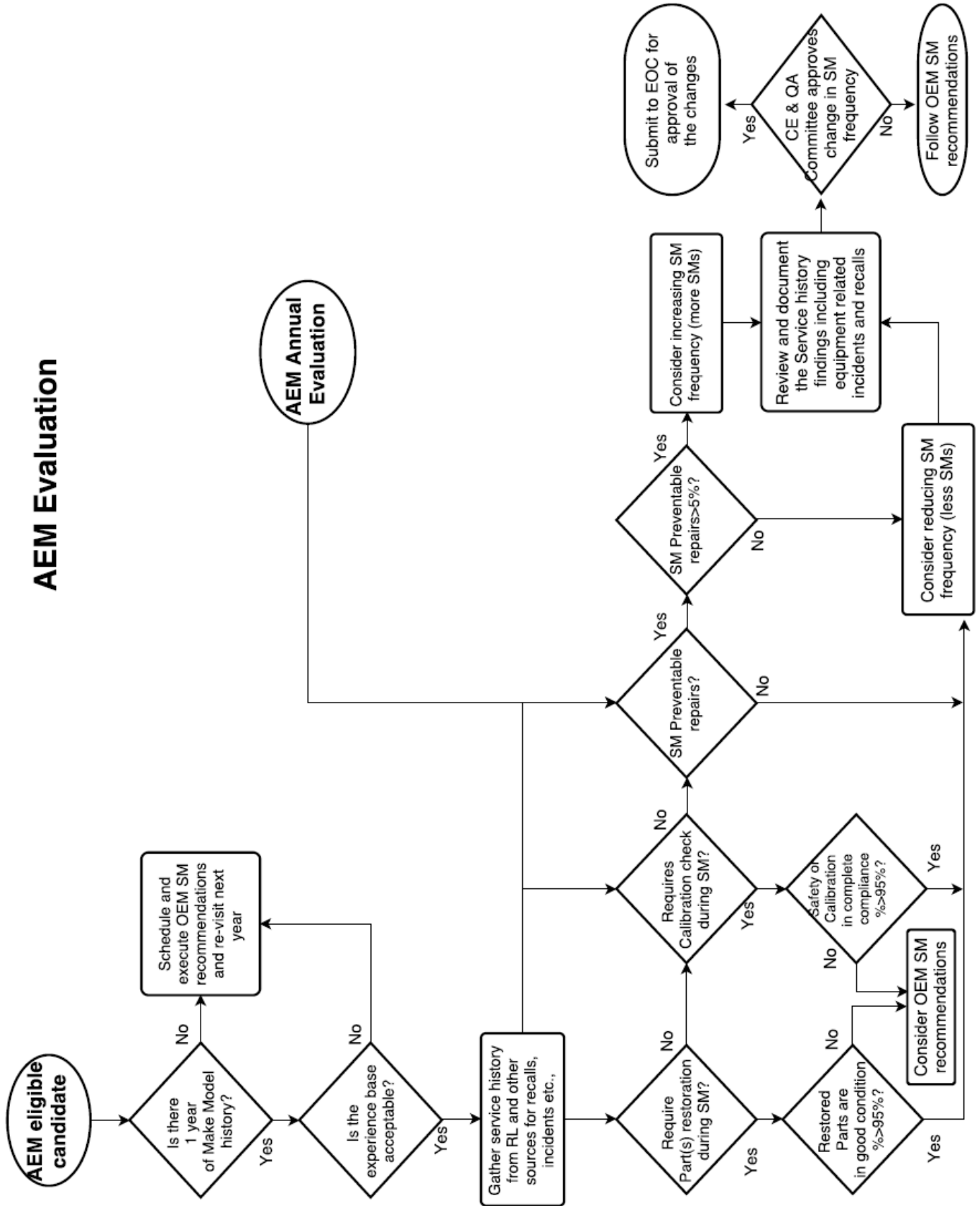
The below flowchart outlines the workflow of AEM program.

### AEM Workflow



**AEM Program Annual Evaluation:** The AEM Committee will evaluate the program annually for its scope, performance, and effectiveness. Any changes in scope will be addressed in the annual update of the plan, and any changes in the application will be incorporated into the plan. This information will be reported to the ECRMC EOC through the routine reporting channels.

# AEM Evaluation



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The RenovoLive AEM Committee demonstrates the qualifications required to make recommendations based on formal education, certification, and relevant work experience. The AEM Committee includes the following personnel:

- Director of Risk Rating
- Director, Healthcare Technology Management & QA
- Senior Clinical Engineer

### **AEM Exclusions:**

The hospital's activities and frequencies for inspecting, testing, and maintaining the following medical equipment **must be in accordance with the manufacturer's recommendations**:

- Equipment subject to Federal or State law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturer's recommendations, or otherwise established more stringent requirements.
- Medical Laser devices.
- Imaging and Radiologic equipment (whether used for diagnostic or therapeutic purposes).
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies.

### *Reference:*

- CMS S&C: 14-07-Hospital Memorandum
- [http://htmcommunitydb.org/wiki/index.php?title=Main\\_Page](http://htmcommunitydb.org/wiki/index.php?title=Main_Page)
- AAMI handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program
- [http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/HTM/Idea\\_Exchange/160523\\_Ridgway\\_RC\\_M\\_Tool.pdf](http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/HTM/Idea_Exchange/160523_Ridgway_RC_M_Tool.pdf)

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<b>Policy:</b>	<b>MEMP 4.0.C.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Electrical Safety Testing</b>		

Inspection and testing of all new medical equipment for safety and performance in all areas of the healthcare facility (patient and non-patient locations) should be done for compliance prior to initial use.

The following limits are observed and are consistent with recommended limits as set forth in the NFPA 99, AAMI and IEC 60601-1:

Reference	Electrical Safety Test	Limits	Conditions
NFPA 99 10.3.2.1	Ground Conductor resistance	0.5 ohms	
NFPA 99 10.3.5	Touch/Chassis Leakage Current	100 micro amps	Normal polarity, power on and off, ground closed
		500 micro amps	Normal polarity, power on and off, ground open
NFPA 99 10.3.6	Lead to Ground Leakage Current	100 micro amps	All leads to ground. Normal polarity, power on, ground closed.
		500 micro amps	All leads to ground. Normal polarity, power on, ground open.
IEC 60601-1	Lead to Lead Leakage Current	100 micro amps	Normal condition (Type B or BF)
		500 micro amps	Single fault condition (Type B or BF)
		10 micro amps	Normal condition (Type CF)
		50 micro amps	Single fault condition (Type CF)
IEC 60601-1	Isolation Leakage Current	5000 micro amps	Each lead and all leads. Normal Condition and Single Fault Condition (Type BF)
		50 micro amps	Each lead. Normal Condition and Single Fault Condition (Type CF)
		100 micro amps	All leads. Normal Condition and Single Fault Condition (Type CF)

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Each patient lead is classified as follow as per IEC 60601-1:

- Type B (body) equipment operates within the patient vicinity (a 6-foot radius from the patient), but without patient contact. Examples of type B equipment include x-ray machines, hospital beds, LED operating lighting, and MRI scanners.
- Type BF (body floating) equipment makes physical contact with the patient. Examples of type BF equipment include blood pressure monitors, ultrasound equipment, and thermometers.
- Type CF (cardiac floating) makes physical contact with the heart. Examples of type CF equipment include defibrillators and dialysis machines.

ECRMC Biomed tests all patient care-related medical equipment in accordance with NFPA 99-2012 before the equipment is put into service for the first time (during incoming inspections), during re-activation of the equipment (i.e., equipment brought back from storage etc.) and after any repair that might have affected or compromised electrical safety.

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<b>Policy:</b>	<b>MEMP 4.0.D.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Clinical Alarm Management</b>		

### **IMPROVE THE EFFECTIVENESS OF CLINICAL ALARM SYSTEMS AND REDUCE ALARM FATIGUE**

In accordance with The Joint Commission's National Patient Safety Goal 6, the hospitals are required to establish Clinical Alarms as an Organization priority and form a multi-disciplinary Committee for Alarm Safety Management.

Identify the most important alarm signals to manage based on the Facility's internal situations:

- Input from medical staff and clinical departments.
- Risk to patients due to lack of response, malfunction
- Are specific alarms needed or contributing to noise/fatigue?
- Potential for patient harm based on internal incident history
- Published best practices/guidelines

The Facility should develop and implement specific components of policies and procedures that address at a minimum:

- Clinically appropriate settings
- When they can be disabled
- When parameters can be changed
- Who can set, change parameters and who can set them to "off"?
- Monitoring and response expectations
- Checking individual alarm signals for accurate settings, proper operation, and detectability
- Educate those in the organization about alarm system management

The Medical Equipment Management Program will test and maintain all medical and clinical equipment alarm systems included in the program during scheduled maintenance as recommended by the manufacturer. The MEMP will also assist the management of alarm systems via coordinated interaction and education with the clinical staff to increase the effectiveness and safety of clinical alarm systems and reduce alarm fatigue by prioritizing alarms and optimizing alarm settings to minimize "no-action" and redundant alarms.

Clinical Alarm Systems have been defined as any alarm that is intended to protect the individual receiving care or alert the staff that the individual is at increased risk and needs immediate assistance. Although there are many types of clinical alarm systems, the intent and

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scope of this policy is to focus on Medical and Clinical Equipment critical alarms and alarm systems. *An example of an alarm system would be any Medical/Clinical equipment alarms that are transmitted to a central or remote monitoring system such as an ICU Central Station or MedSurg Patient Net Console.*

**Note:** In general, this does not include items such as nurse call systems, alerts from computerized provider order entry (CPOE), or other information technology (IT) systems.

The Medical Equipment Management Program inventory is inclusive of “all equipment (devices) used in the care, treatment, diagnosis, and monitoring of patients, including the alarms and systems that are triggered by physical or physiologic monitoring of the individual”. These devices and systems are included in the MEMP and are included in the ECRMC Scheduled Maintenance Program per Risk Level as determined by established Risk-Based Inclusion Criteria. Scheduled Maintenance Procedures require the testing of all alarms and systems in accordance with the manufacturer’s recommendations, specifications, and tolerances, as applicable.

**Note:** Most manufacturer-recommended alarm testing is based on the manufacturer’s default settings. Custom alarm settings and delays, as required by the clinical equipment operators or patient conditions, are the responsibility of the Clinicians and Medical Staff including Prioritizing alarms, selecting optimal alarm settings and delays, and reducing alarm fatigue by eliminating “no-action” and redundant alarm conditions via the methods by which they customize alarm parameters to specific patient data.

The Biomed department can assist the Clinical Staff as follows:

- Create an inventory of Medical Equipment with critical alarms and identify manufacturer default alarm settings.

**Note:** *In accordance with ECRMC’s Risk-Based Inclusion Criteria, equipment with critical alarms entered into the inventory will be prioritized by the level of risk or criticality of the alarm or alarm system beginning with High-Risk equipment and equipment with critical alarms, defined as; “Any audible or visual indication from a system or device, that when activated, may result in the injury or death of a patient unless immediate clinical intervention results”.*

- Conduct manufacturer recommended Medical/Clinical Equipment alarm testing and maintenance during Scheduled Maintenance. Ensure that alarms are activated with appropriate settings, prioritized, and are sufficiently audible with respect to distances and competing noise within the unit.
- Participate in Medical/Clinical Equipment alarm system management education for all medical/clinical equipment operators, Clinical Leadership, and the Education Department.



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**Note:** *Clinical Application training, clinical staff response protocols to clinical alarms, and proper application of clinical interventions are the responsibility of Clinical Leadership and are beyond the scope of this policy.*

- Monitor and report alarm failures, operator errors, in-service education, and other alarm data as applicable to the Safety/EOC Committee and Clinical Leadership.

Unless otherwise indicated, inventory and testing of the alarm systems listed below **are not included** in the scope of the MEMP:

- Nurse Call Panic Alarm and Code Blue alarm systems
- Centralized Gas Pressure Alarms
- Fire Alarms
- Security Alarms

*For additional information on Alarm Safety Management, refer to ECRMC [PolicyTech - Alarms](#)*

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<b>Section No:</b>	<b>Section 4</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 4.0.E.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Dialysis Equipment Documentation Policy</b>		

It is a requirement of the Medical Equipment Management Program that the facility inventory all renal dialysis equipment and document equipment maintenance, chemical and biological testing of water used in renal dialysis, and other applicable tests based upon regulations, manufacturers' recommendations, and facility experience.

Renal Dialysis equipment service and records are the responsibility of the Clinical Department/Manager. Equipment maintenance and water culture documentation including test equipment calibration documentation, as applicable, **must be current, located on-site, and available for inspection** by authorized hospital and/or regulatory agency personnel as requested.

If requested by the Facility, Biomed can assist the facility in obtaining and maintaining renal dialysis equipment, chemical and biological testing, and maintenance documentation in accordance with the service agreement and regulatory agency requirements.

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<b>Policy:</b>	<b>MEMP 4.0.F.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Sterilization Equipment Maintenance &amp; Documentation</b>		

It is a requirement of the Medical Equipment Management Program that the facility inventory and document equipment maintenance and performance testing of all sterilization equipment including endoscopic washers and related diagnostic equipment such as endoscope leak and electrical safety testers. The Biomedical Engineering department is responsible for maintenance and repair of ECRMC's sterilization systems, as identified in the MEMP, either via an in-house program or via other maintenance vendors as assigned.

All maintenance and repair service data for the equipment maintained will be entered into the RenovoLive database including current test equipment calibration information. Copies of the maintenance documentation and test equipment calibration certificates will be maintained in the RenovoLive database and on-site and are available upon request.

Vendor service documentation must **be current, and available for inspection** by authorized hospital and/or regulatory agency personnel as requested. In addition, copies of current calibration certificates for test equipment used by the vendors, as applicable, must be made available by the vendor upon request.

The ECRMC's clinical staff is responsible for conducting daily thermometer temperature tests and periodic bacteriological tests as specified by the manufacturer in accordance with applicable regulatory and accreditation agency requirements. In addition, the facility will maintain responsibility for the use, storage, and processes associated with cross-contamination prevention of diagnostic equipment such as rigid and flexible endoscopes.

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<b>Policy:</b>	<b>MEMP 4.0.G.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Visual/Environmental Inspections</b>		

Visual inspection (VI) is performed as part of medical equipment Scheduled Maintenance (SM) and incoming inspections or may be performed separately in the case of low-risk medical equipment or non-medical equipment as a visible means of ensuring the physical integrity of the equipment. Environmental inspections are visual inspections of equipment-intensive areas where environmental conditions may pose a hazard to the integrity of the medical equipment. Both types of inspections are detailed as follows:

Visual Inspection (VI) - is performed to detect visible discrepancies or situations, which are, or could lead to, an equipment-related hazard or safety problem. Examples of these types of hazards and safety problems include:

- Damaged power cords or broken cord caps which might expose conductors that could pose a risk of electric shock if touched by a patient, member of the staff, or a visitor.
- Damaged power cords or broken cord caps in which the conductors might form a short circuit that could pose a risk of fire.
- Indications that the equipment might have been dropped or otherwise damaged in such a way that could cause an internal short circuit and consequent risk of fire or create a physical risk of injury; Example: a broken knob or protruding metal work.
- Power cords lying across spaces where there is foot traffic, creating a risk of tripping and the risk of equipment carts or other wheeled traffic damaging the cord.
- Instances of equipment that is not mounted securely and at risk of falling.
- Other similar risks are also a good opportunity to catch and correct any items without a CE number, a past due SM sticker, or items with no SM sticker or Visual Inspection (VI) sticker.

Visual inspections can be performed for both equipment and the environment. For equipment-related visual inspections, follow the steps outlined in the SM procedure, if available. If not, follow inspection PROCEDURE # 310- 3073.

Environmental Inspections (EVI) - are generally conducted in assigned equipment-intensive areas such as ICU, ER, OR etc., and are usually scheduled to coincide with the SM schedule for that department or area. These area inspections are primarily focused on line-powered equipment items that have no non-durable parts and are not scheduled for regular SM and may include power receptacle testing including LIM testing in isolated areas. These

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inspections are normally conducted during Environment of Care environmental rounds either, as per The Joint Commission every 6 months or done regularly as per the hospital's policy. Examples of this type of equipment for inspection are View boxes, video monitors, and aneroid manometers. These are "low risk" items where their failure may constitute an inconvenience but not a safety risk to the patient. These items will need to be listed on the equipment inventory (by CE Tag number or other identification as assigned by ECRMC) and identified with a "Visual Inspection" sticker. Successful completion of the Visual Inspection is documented on a service event and entered in the RenovoLive database.

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### PROCEDURE # 310- 3073

#### VISUAL/ENVIRONMENTAL INSPECTION

If there is any **corrective action required** check the box on the left, next to the statement number, and make a record of what was done, or what was found, in the **Notes** section below.

- 1. Verify that all the devices in the area appear to be functional. If this is not the case, check the box on the left and open the necessary repair work order(s).
- 2. Appearance and general condition. Confirm that all the items in the area are clean, physically acceptable (displays and controls intact), and provided with the appropriate accessories. Adjust or replace any loose or damaged parts.
- 3. Labeling. Confirm that all the items in the area have CE tags and the proper labels (a PM sticker or a "visual inspection" sticker).
- 4. Physical condition of the power cords/cord caps of all the equipment items in the area:
  - The strain reliefs at the chassis end of the cords are all OK.
  - The insulation of each cord is intact, with no cuts, exposed conductors, or frayed ends.
  - None of the cords are rippled.
- 5. Physical condition of all the equipment items in the area:
  - There are no items showing evidence of having been dropped or otherwise damaged.
- 6. General safety:
  - There are no power cords lying across areas subject to foot traffic.
  - All the equipment is mounted securely and not at risk of falling.

Enter a brief note below (referencing the line number above) on the nature of any problems found; or any actions required.

Problems found?  NO or YES  Date: \_\_\_\_\_ Initials: \_\_\_\_\_

#### Notes:

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<b>Policy:</b>	<b>MEMP 4.0.H.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Test Equipment Calibration Documentation</b>		

All ECRMC Biomed owned test equipment is recalibrated annually unless otherwise recommended by the OEM and be labeled as due on the last day of the calibration month for the following year. This allows ECRMC to complete the calibrations within a reasonable time frame of the due date and allows for manpower and scheduling restraints.

Current certificates of compliance are kept on-site at the ECRMC Biomedical Engineering department where the test equipment is used. Certificates of calibration are to be uploaded to the corresponding SM service event within the RenovoLive database. Test equipment certificates of compliance are maintained for a minimum of 3 years.

Vendors assigned by ECRMC are required to maintain current test equipment certificates of compliance for all test equipment used in the performance of both scheduled maintenance and repair services of medical equipment. Copies of the certificates will be made available to ECRMC where the test equipment is used upon request.

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<b>Policy:</b>	<b>MEMP 4.0.I.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Test Equipment Out of Tolerance</b>		

If a piece of test equipment or “Master device” is found out of tolerance during its calibration, an evaluation of the medical equipment it was used to calibrate shall be confirmed to be working within the specified tolerances of the manufacturer.

If a piece of test equipment is found out of tolerance and is not being used for the service, Biomedical engineering department will inform the Quality Risk Management and remove it from the facility site.

ECRMC’s Environment of Care Committee will be informed about the master device found out of tolerance.

If the medical equipment calibrated by this master device can be **verified through documentation** in RenovoLive, **10%** of all the equipment it was used on in the last scheduled maintenance cycle (starting with the latest medical equipment tested) shall be checked **within 10 working days for High-Risk Equipment and 30 working days for Non-High-Risk Equipment** upon the receipt of the out of tolerance notification.

If the medical equipment calibrated by this master device **cannot be verified through documentation** in RenovoLive, **10%** of all the equipment it may have been used on in the last scheduled maintenance cycle (starting with the latest medical equipment tested) shall be checked **within 10 working days for High-Risk Equipment and 30 working days for Non-High-Risk Equipment** upon the receipt of the out of tolerance notification.

All records of this process will be documented through RenovoLive on the medical devices checked or on the test equipment using the special condition “Test equipment out of tolerance verification.”

If one of the medical equipment inspected is **found out of tolerance**, then **100%** of all the equipment it was used on will be inspected **within 60 working days** of the out of tolerance findings.

**Note:** If a piece of test equipment is known to be physically damaged and cannot be used for the intended testing until repaired then above-mentioned performance verification testing is not required.



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<b>Policy:</b>	<b>MEMP 4.0.J.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Anesthesia Equipment Maintenance &amp; Documentation</b>		

It is a requirement of the Medical Equipment Management Program that the facility inventory and document equipment maintenance and performance testing of the anesthesia machines. The Biomedical engineering department is responsible for the maintenance and repair of specific anesthesia systems, either via an in-house program or other maintenance vendors as contracted.

Anesthesia machines, anesthesia vaporizers, anesthesia ventilators, and all other applicable peripheral equipment shall be maintained in accordance with the manufacturer's recommended maintenance intervals, procedures, specifications, and tolerances, in accordance with CMS 42 CFR 482.41(c) (2).

All service vendors shall maintain current certification or equivalent qualifications for maintaining and repairing the assigned anesthesia machines, vaporizers, ventilators, and applicable peripheral equipment, as evidenced by documented proof of competency.

All maintenance and repair service data for the equipment maintained by ECRMC will be entered in the RenovoLive database including current test equipment calibration information. Copies of ECRMC maintenance documentation and test equipment calibration certificates will be maintained on-site and are available in the Biomedical Engineering Department. Vendor service documentation should be produced by the vendor when requested for inspection by authorized hospital and/or accreditation and regulatory agency personnel. In addition, copies of current calibration certificates for test equipment used by the vendors, as applicable, must be made available upon request.

ECRMC's clinical staff is responsible for conducting daily leak tests and operational checks as specified by the manufacturer in accordance with applicable regulatory and accreditation agency requirements.

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<b>Policy:</b>	<b>MEMP 4.0.K.1-24</b>	<b>Reviewed Date:</b>	<b>1-16-2024</b>
<b>Document:</b>	<b>Radiation Service</b>		

It is a requirement of the Medical Equipment Management Program that the facility inventory and document equipment maintenance and performance testing of all Radiology equipment including Nuclear Medical equipment. The Biomedical Engineering department is responsible for the maintenance and repair of specific Radiology systems to the manufacturer specifications either via an in-house program or via other maintenance vendors as assigned.

All maintenance and repair service data for the equipment maintained by ECRMC will be entered in RenovoLive database including current test equipment calibration information. Copies of ECRMC maintenance documentation and test equipment calibration certificates will be maintained on-site and are available in the Biomedical Engineering department.

No ECRMC employee shall operate radiation generating equipment unless that individual is licensed or has received instruction and demonstrated an understanding of safe operating procedures. Only qualified individuals assigned by management to install, repair, or calibrate radiation generating equipment are authorized to service such equipment. Employees authorized to service radiographic equipment should familiarize themselves with the location of each of the customer's restricted areas.

A diagnostic medical physicist is responsible to conduct an annual performance evaluation of all CT, PET, MRI and NM imaging equipment and he/she may be assisted with the testing and evaluation of equipment performance by qualified individuals as determined by the Physicist.

Installations, or re-installations after a move, of radiation-generating equipment, or the replacement of components that carry a certification rating plate (such as x-ray generators, controls, or tables) shall be documented and reported, as required, to both the Food and Drug Administration (FDA) and the appropriate state authority having jurisdiction. Refer to TPM 3.g of Technical Procedure Manual for details.

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ECRMC Biomedical employees are not permitted to involve themselves with the shipment of radioactive materials. When this service is required, the customer facility shall be asked to dispose of them in an appropriate manner.

All individuals working in the restricted area(s) should not receive an annual total effective dose equivalent (TEDE) more than **500mrem**. (*Refer to Technical Manual TPM 3.h for details.*)

All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film whole body monitor (film badge) for the purposes of determining individual dose. These monitors will be provided by a contracted NVLAP dosimetry lab and will be evaluated quarterly unless it has been determined by the individual responsible for radiation protection that potential exposure is minimal, and individuals can be placed on a less frequent monitoring period. OSHA 1910.1096(d) (2). *Refer to TPM 3.h of Technical Procedure Manual for details on Radiation Exposure Monitoring Program.*

**Note:** Disciplinary action may be taken on the individuals failing to reset their dosimetry badges every month.

### **Record of Radiation Service Policy review**

Per rule 3701:1-38-11 (D) (3), OAC the signature(s) and date(s) below indicate the date on which the content and implementation of the radiation program was reviewed. Corrective action has been taken and documented, if necessary.

Name	Signature	Date
Joel Birdsong		1-12-2023
Jenifer Lopez, Medical Imaging Manager		1-16-2024

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<b>Policy:</b>	<b>MEMP 4.0.L.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Power Strips Management</b>		

The Centers for Medicare and Medicaid Services (CMS) allows the use of power strips in new and existing healthcare facilities if the facility follows all applicable power strip requirements and other electrical system and equipment provisions found in the 2012 edition of NFPA 99.

The election to use any **categorical waiver is no longer required** since the adoption of the 2012 Life Safety Code by CMS in 2016.

The purpose of this policy is to establish guidelines for the use of power strips (relocatable power taps) and adapters to encourage a safe electrical environment for patients, staff, visitors, and equipment. To achieve this compliance, the onsite Biomed department and facilities department should work in collaboration with the clinical departments.

The Facility regulates the use of power strips and adapters. No power strips or adapters may be used on medical equipment except under the circumstances described in this policy. The Facility supports the use of hospital-grade relocatable power taps listed to UL standards of 60601-1, or 1363A.

A power strip may be used with **medical equipment** under the following conditions:

- Power strips being used with medical equipment will be UL listed hospital grade and are required to be inspected, approved, inventoried, and controlled by Facility (a green dot on the plug or receptacle end of the power strip signifies hospital grade).
- Power strips that will be installed on mobile carts must be certified and compliant with UL 60601-1 or 1363A (e.g., crash carts, ventilators, IV poles)
  - UL 1363A power strips are for supplying power to equipment that is intended to form part of the medical system that it is mounted to.
  - Power strips certified and compliant to UL 1363A shall not be located or positioned on the floor.
  - Only power strips certified and compliant to UL 1363A may be used with life support equipment (e.g., ventilators, anesthesia machines)

A power strip may be used with **non-medical equipment** under the following conditions:

- Extension cords may only be used with non-medical equipment under emergency conditions when normal electrical power is interrupted. Facility will be required to

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inspect, approve, and endorse the use of extension cords and limit such use to the duration of the emergency conditions.

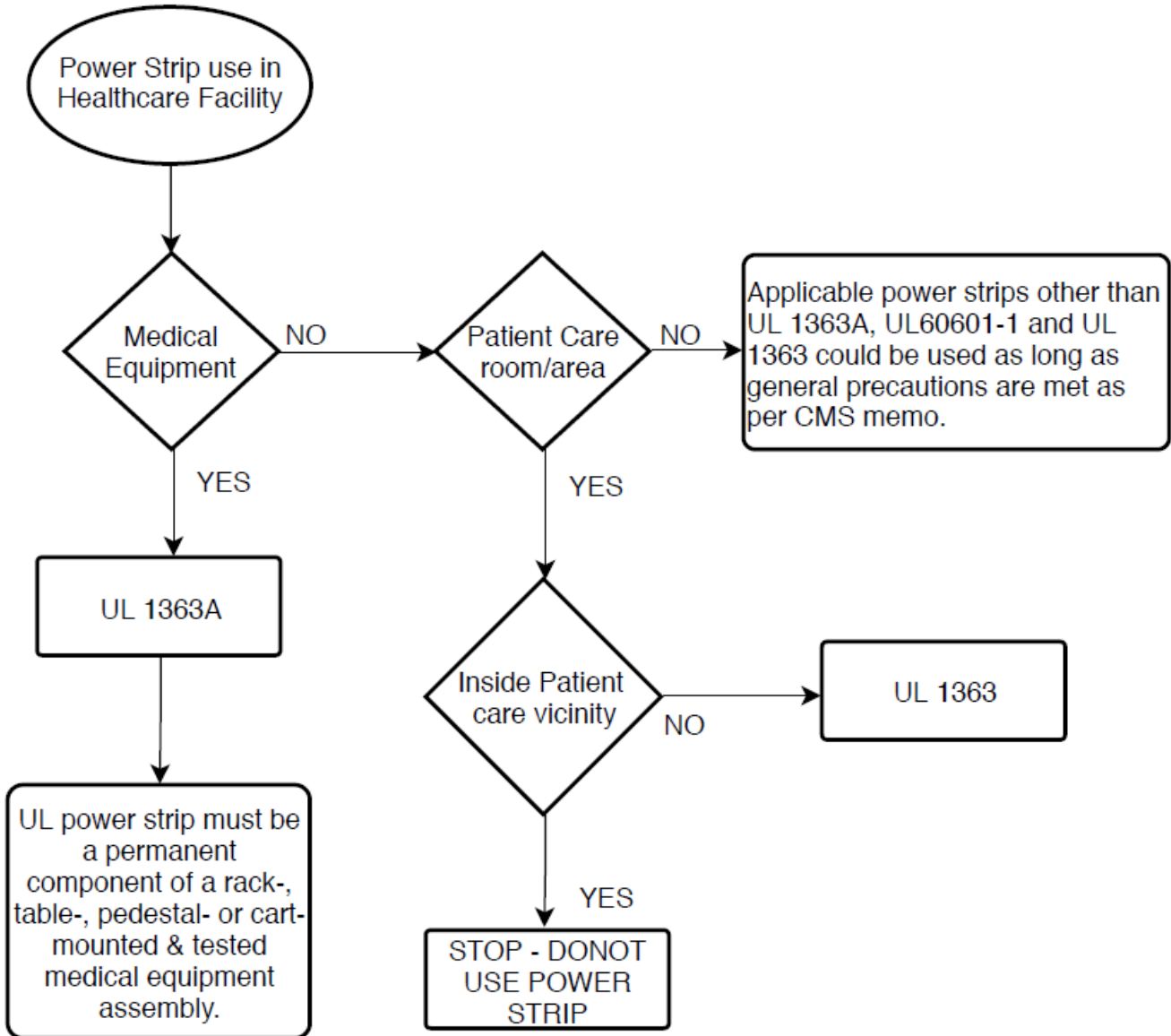
- Power strips being used with non-medical equipment in the patient care area will be certified and compliant to UL 1363 with surge suppression and are required to be inspected, approved, inventoried, and controlled by the Facility.
- In non-patient care areas (such as administrative offices), other UL power strips could be used adopting the general precautions listed by CMS.

### **Note:**

- The sum of the ampacity of all appliances connected to the receptacles shall not exceed 75 percent of the ampacity of the flexible cord supplying the receptacles.
- The electrical and mechanical integrity of the assembly is regularly verified and documented through an ongoing maintenance program.
- The power strip will not be used with appliances (e.g., microwaves, coffee machines, and refrigerators).
- The power strip will not be mounted to any permanent structure.
- Power strips with surge suppression may not be used with medical equipment.
- The power strip will be stored in a place that does not create a tripping hazard.
- The power strip will not be plugged into an extension cord or another power strip.
- The power strip is for indoor use only.
- Adapters (three-wire to two-wire) may not be used to connect two-wire electric cords to three-wire cords or electrical outlets.

*For more details on guidelines, surveyor's expectations, and responsibilities of the hospital departments' personnel, refer to the [ECRMC PolicyTech - "Power Strips Management – Guidelines."](#)*

### Power Strips usage in Healthcare Facilities



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<b>Policy:</b>	<b>MEMP 5.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Medical Equipment Repair</b>		

All repair service calls should be referred to the ECRMC Biomedical engineering department as applicable.

Should repair service be required the hospital staff will complete and attach an appropriate “defective” tag to the item and contact the Biomedical engineering department to acquire service. The item should be placed in a secure location to prevent it from being placed back in use. It is extremely important that clinical staff complete the “**defective**” tag and indicate the exact symptoms and nature of the failure, as well as the conditions under use.

Upon receipt of the call, Biomed will prioritize and dispatch the call to the appropriate service personnel.

After proper evaluation of the failure by the Biomedical engineering staff, should the item require service by someone other than the in-house staff, the appropriate calls will be made through Biomedical engineering. The disposition of the call will be communicated immediately to the clinical staff so that appropriate plans can be made to ensure continuity of patient care.

Should the failed item be considered essential to the continuation of care (ventilator, defibrillator, etc.) the Biomed staff will provide all available information to the clinical staff to aid in procurement of a suitable replacement or repair service. (See policy **MEMP 5.0.B** – Medical Equipment Failure Plan).

Repairs will be conducted in accordance with the manufacturer’s specifications and tolerances. **A minimum of a functional test and safety inspection will be conducted upon completion of the repair.** Additional functions such as calibration and overhaul will be conducted as needed. All other invasive procedures such as manufacturer required upgrades and modifications and/or any other invasive actions that may affect the safety or functionality of the equipment will include a minimum of a functional test and safety inspection upon completion of said action(s).

Equipment sent to manufacturers or external Vendors for maintenance or repairs should receive a functional test and safety inspection by Biomed staff before it is released to the clinical department for patient care. Technicians should ensure that all the open service work orders are closed immediately upon completion. Any open service work order should provide the most up to date information regarding the status of the repair.

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All equipment repair services shall be documented including any measurements, manufacturer specifications and tolerances as applicable, text information including problem, resolution, all parts replaced (new or rebuilt), final disposition of the equipment and the status of the service call are entered in the RenovoLive database utilizing the assigned service codes. Service documentation/records shall be retained for a minimum of three years.



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<b>Policy:</b>	<b>MEMP 5.0.A.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>After-Hours Contact Procedure</b>		

### After-Hours Contact Procedure

If repair services are required after normal working hours:

- Contact the House Supervisor or his/her designee and review the nature of the problem or failure and request approval for after hour's Biomedical Engineering support.
- Biomedical Engineering on-call technicians available:

**(254) 419-9521 Andres Resendes - Biomed**

**(928)920-8587 Miguel Hernandez - Biomed**

- Upon responding, the on-call technician will evaluate the call, and in conjunction with the Nurse Manager or his/her designee, decide on the best tactic for dealing with the problem or failure.
- If the necessary repair(s) require service by the manufacturer or vendor other than ECRMC Biomed, the service must be approved by the Biomedical Manager or House Supervisor prior to arranging manufacturer or vendor service.

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<b>Policy:</b>	<b>MEMP 5.0.B.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Medical Equipment Failure Plan</b>		

Incorporated into the facility's disaster plan are emergency service measures that serve to ensure the proper operation and safety of medical equipment including battery-operated/supported High-Risk equipment such as respiratory ventilators and back-up systems in the event of an equipment, system, and/or utility failure. These measures incorporate many coordinated clinical and technical service interventions to be performed by the appropriate staff as follows:

The hospital's clinical staff is responsible for determining the appropriate clinical interventions to be implemented for specific medical equipment failures. Should the equipment failure be considered by clinical staff to be essential to the continuation of care, Biomedical engineering may be contacted immediately.

- ECRMC Biomed will respond and upon verification of the failure, immediately assist in locating an equivalent replacement for the failed equipment by:
  - Use of intimate personal knowledge unique to the staff of the equipment inventory, and potential sources of equipment within the facility.
  - Use of the RenovoLive database to query for a list of equivalent equipment.
  - Refer to the inventory listing by equipment type and location found in the RenovoLive database to locate an equivalent replacement for the failed item.
- If an immediate replacement for the failed equipment is not available, the Biomedical engineering staff will take the appropriate actions to perform or obtain emergency repair service.
- If an emergency repair cannot be performed within reasonable time, the Biomedical engineering staff will assist the hospital in obtaining spare equipment by:
  - Use of knowledge of potential resources outside of the hospital such as equipment manufacturers and rental vendors.
  - Contacting the equipment manufacturer, service vendor or a suitable rental vendor directly.
- Should the equipment failure occur outside of the Biomedical engineering normal working hours, the clinical staff will:
  - Immediately follow the after-hours call procedure for contacting the Biomed on-call staff.
  - Upon contact and notification of the equipment emergency, Biomed staff will follow the above procedure.

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<b>Policy:</b>	<b>MEMP 5.0.C.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Emergency Management</b>		

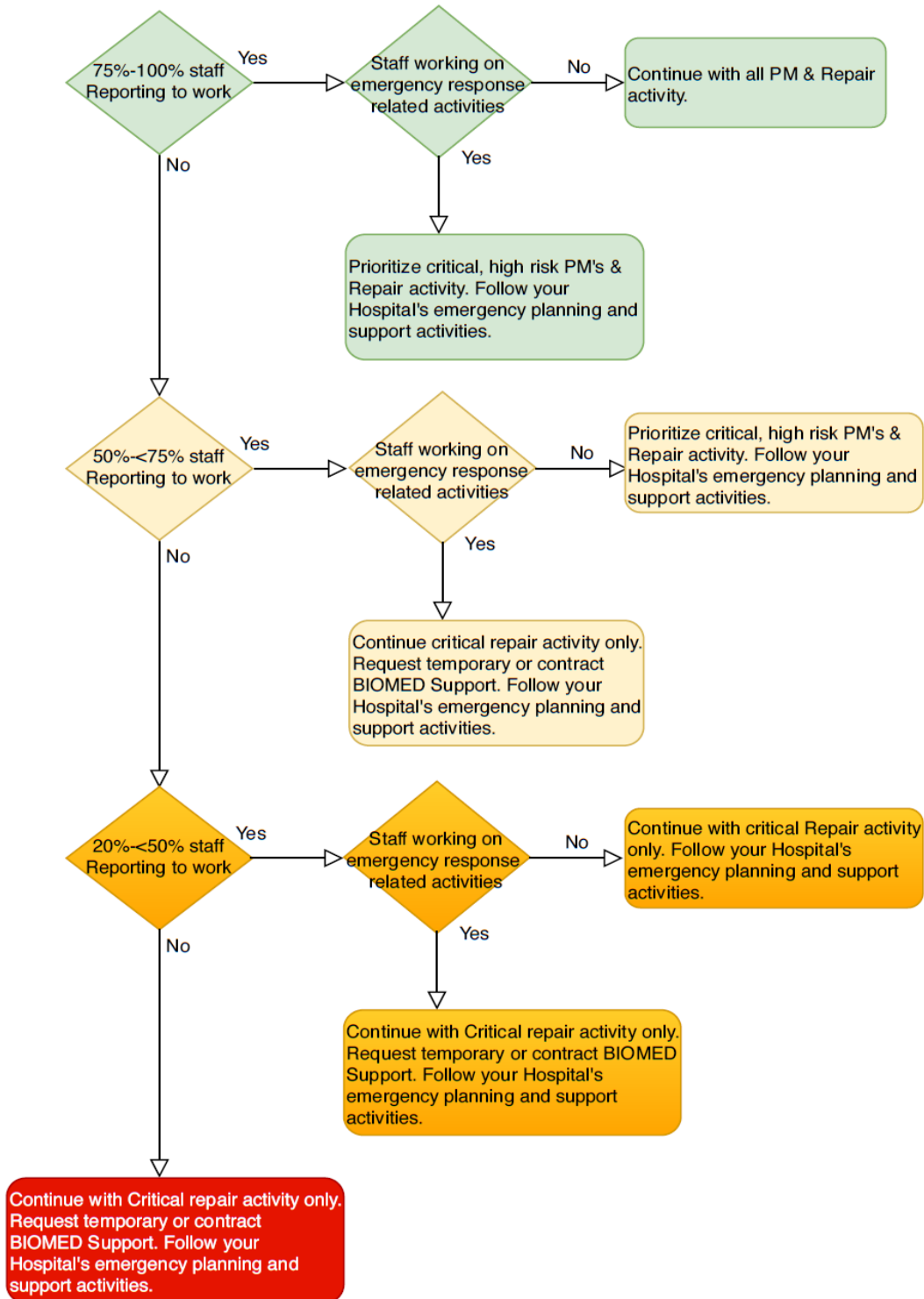
### EMERGENCY MANAGEMENT – Response & Procedures

- The Biomedical services staff will assist the organization in every way possible to return medical equipment and services to normal operation as quickly as possible after a disaster event.
- The Biomedical staff will, via the medical equipment inventory, assist the organization in identifying and tracking equipment that is **transferred out of** the organization by documenting a minimum of the equipment control number, the date of transfer and the intended destination of the equipment.
- The Biomedical staff will, via the equipment inventory, assist the organization in identifying and tracking equipment that is **transferred into** the organization from an outside source by documenting a minimum of the equipment control number and/or serial number, the description of the equipment, and any information obtained from identification tags identifying the outside source, and the date of transfer.
- The Biomedical staff will also assist in training the end users to identify this equipment to ensure the equipment is not inadvertently placed into use without prior inspection.
- The Biomedical staff will identify and secure all non-functional medical equipment that has been removed from service and assist in training the end users to identify this equipment via “out of service” or “in-storage” tags to ensure the equipment is not inadvertently placed into use. The Biomedical staff will inspect and repair (if possible) this equipment for use, if needed.
- The Biomedical staff will assist in the replacement of transferred and lost medical equipment and the restoration of medical equipment and services to pre-disaster conditions via equipment replacement, repair, and/or assisting the organization in obtaining spare equipment, as detailed in Emergency Intervention Procedures.
- The Biomedical staff will assist to ensure that life support equipment like ventilators and defibrillators are always plugged directly into emergency RED outlets.

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### HTM Department Service Continuity Plan During Emergency



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<b>Policy:</b>	<b>MEMP 5.0.D.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Disaster Management</b>		

### **Disaster Management – Natural disasters (Earthquakes, Tornadoes, Hurricanes, Typhoons)**

With no Disaster management plan, or a poorly conceived plan, one can expect chaos. If the plan has been carefully thought out, contributions to mitigate the disaster will be apparent.

Notifying emergency contacts, acquiring an up-to-the-minute inventory and location list, and ensuring function of critical High-Risk equipment will fall into place naturally. Troubleshooting and problem solving are likely to be the watchwords, with flexibility to respond to the situation paramount.

Being prepared, to the extent practicable, to anticipate need, the potential problems that may result, and alternative methods to address both, can help to make the process of disaster mitigation more successful. Anticipating the need for evacuation and challenges to equipment and medical support can help avert situations in which no reasonable alternative is available or in which the impact of the need is underestimated.

The Biomedical staff will, via the medical equipment inventory, assist the organization in identifying and tracking of the equipment by documenting a minimum of the equipment control number, the date of transfer and the intended destination of the equipment.

### Pre-disaster Responsibilities

- Inventory including photographs of all fixed and possibly expensive equipment should be taken.
- Note the age of the equipment and the expected life cycle.
- A master log and tracking system for all equipment that leaves the building during a disaster with patients and staff should be maintained. Locating displaced equipment can be almost impossible without a tracking system.
- Educate the clinical staff to use the equipment only on the needy and to use the rest as backup.
- Make sure to unplug the equipment from power outlets to avoid damage to equipment due to power fluctuations.
- Alert staff to use equipment on battery if possible.

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### Post-disaster Responsibilities

- Recovery assessment should be performed as soon as possible after the event.
- Clinical engineering should complete an inventory of all medical equipment for damage assessments.
- Take pictures of all equipment prior to cleanup. Decisions will need to be made regarding the repair of equipment.
- Identify the condition of existing equipment and develop a strategy for replacement/repair of equipment, what can be repaired cost effectively, and who should be performing the repair.
- Evaluate the cost and requirements of in-house versus contracted repair services.
- Track the repairs, cost, and time expended.
- Evaluate the effects of sudden power loss when bringing equipment back online.
- All settings and alarms must be tested before patient use.
- Document decisions to repair or discard equipment.
- Accurately record all expenses. This information will be necessary to secure insurance, FEMA, and state reimbursement

The Biomedical services staff will assist in the replacement of transferred and lost medical equipment and the restoration of medical equipment and services to pre-disaster conditions via equipment replacement, repair, and/or assisting the organization in obtaining spare equipment.

Thoroughly and thoughtfully addressing planning, mitigation, and recovery issues on a comprehensive, detailed basis can save lives.

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## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 6</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 6.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Description of Equipment Database</b>		

The RenovoLive database is a web-based application system that has been specifically designed to support the various requirements and operations of a Medical Equipment Management Program with integrated systems management (ISM) capabilities to include and support medical equipment-related computer systems and networks and integration with the hospital's information management system.

Features specific to its Biomed/Clinical Engineering support functions are integrated equipment tracking and reporting systems including Equipment inventory, maintenance scheduling, and completion, unique repair service history including Use errors and in-services, equipment damage, repeat service events, "cannot duplicate", incidents and hazard alert/recall events, that are necessary for hospital Safety/EOC Committee reporting and regulatory agency compliance.

Each Device is evaluated for inclusion in the equipment inventory and is entered into the RenovoLive database. The system database contains and tracks a minimum of the following parameters for each device:

- Identification of High Risk or Non-High-Risk equipment, including associated risk criteria
- Required maintenance activities (maintenance, inspection, and/or testing)
- The frequency of each required activity, including whether the frequency is based on manufacturer recommendations or risk based AEM maintenance schedule.
- Equipment incoming date (i.e., date new or repaired equipment inspected and put into service)
- Dates of most recent maintenance activities; and
- Equipment incident history.

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<b>Policy:</b>	<b>MEMP 6.0.A.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Database Reporting Functions</b>		

The RenovoLive database has been designed to support all required elements of a Medical Equipment Management Program. Reports specific to the safety program are designed to support the collection and analysis of aggregated data needed to effectively manage the risks associated with medical equipment. These reports have been designed to aid in identifying training needs, establish program goals, measure program effectiveness, and monitor potential clinical equipment failure trends.

- Reports for tracking of all scheduled planned maintenance separated according to risk, including service scheduled, completed, “unable to locate” and incomplete.
- Reports for tracking of all repair service events which may impact patient safety or indicate training needs:
  - Use error (confirmed use-error)
  - Can-not-duplicate (unconfirmed use-error or possible intermittent failure)
  - Repeat failure (possible intermittent failure)
  - Incidental In-service
  - Device Alert/Recall
  - Patient-related equipment incidents (in accordance with SMDA of 1990)
- Reports that track additions and deletions of equipment to the Medical Equipment Management Program.



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<b>Policy:</b>	<b>MEMP 6.0.B.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Hazard and Recall Notification</b>		

***This policy must be aligned with the ECRMC's medical equipment recall/alerts tracking policy and is to be superseded where deemed appropriate.***

Manufacturers' recall notices/letters are monitored by the Hospital's Biomedical, Materials Management, and Quality Risk Management Departments.

Hazard alerts and manufacturer recall notification is handled through the following procedures:

- Manufacturers' recall notifications are directed through the Hospital's Materials Management or Quality Risk Management Departments and forwarded to the appropriate user or maintainer departments for follow-up.
- All notifications directed to the Biomedical engineering department are reviewed by the Biomedical Engineering Manager and resolved in the appropriate manner and completed in accordance with the manufacturer's instructions as detailed in the equipment alert/ recall.
- The Biomedical engineering department reviews hazard and alert notifications, reports and information that includes updates on all pertinent medical equipment related topics.
- Following review, the information that is pertinent to the facility is to be summarized and acted upon, as necessary.
- All applicable notifications and subsequent follow up actions are documented, the information is entered in the equipment database, aggregated, and reported to the Environment of Care Committee.

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<b>Policy:</b>	<b>MEMP 6.0.C.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>HIPAA (ePHI) Policy</b>		

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the U.S. Department of Health and Human Services (HHS) to develop regulations protecting the privacy and security of certain health information. The Security Standards establish a national set of security standards for protecting certain health information that is held or transferred in electronic form. PHI is any information that can be used to identify the past, present, or future healthcare of an individual or the payment for that care.

### Scope:

This policy applies to ECRMC in its entirety, including all its workforce members. Further this policy applies to all devices in the Medical Equipment Management Program inventory (**MEMP 3.0**) which create, maintain, or transmit ePHI. **This policy should serve as a guidance for Hospitals where existing policies are in place and is to be superseded where deemed appropriate.**

### Policy:

For medical devices that maintain and/or transmit ePHI, ECRMC's Purchasing Department will be responsible to obtain a copy of the Manufacturer Disclosure Statement for Medical Device Security form (MDS2) (See Appendix A). As per the hospital request, Biomedical engineering department will provide a list of devices that can create, maintain, or transmit ePHI.

It is the responsibility of Biomedical engineering to collaborate with ECRMC IS department and ensure the security of the ePHI on the medical device that needs to be sent out for calibration and repairs. Medical Equipment containing ePHI that was not located or missing will be reported to the QRM and IS departments of the hospital immediately. Clinical Staff will also be notified to assist in locating the missing unit. **Hospital standard breach protocols should be followed in case of a breach which potentially could result in the unauthorized disclosure of a patient's healthcare information.**

In collaboration with ECRMC IS department, Biomed will ensure that prior to transfer or disposal of equipment, ePHI will be securely overwritten or physically destroyed and that such steps will be documented. Biomed will ensure that all labels have been removed from such devices before disposal.

Biomedical engineering department will ensure the Configuration Management Database portion of the Computerized Maintenance Management System (RenovoLive) is appropriately updated upon the transfer or disposal of components containing ePHI.

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Disposal is a required implementation specification defined within the Device and Media Controls standard within the Physical Safeguards category of the HIPAA Security Rule (164.310 (d) (1)).

### **Compliance:**

Failure to comply with this or any other security policy will result in disciplinary actions.

### **Procedures:**

Determining media control and access to ePHI on any medical device being transferred or disposed must be established before the device leaves an organization. Media control may be transferred when a device is returned from a leasing agreement, is being donated or resold to be reused outside the organization. The following are examples of media control:

#### Under Hospital/Organization Control:

- Medical devices being turned over for maintenance are still considered under organization control if contractual agreements are in place with the organization and the maintenance provider specifically provides for the confidentiality of the information.
- Maintenance being performed on an organization's site, under the organization's supervision, by a maintenance provider is also considered under the control of the organization.

#### Not Under Organization Control (External Control):

- Medical devices that are being donated, sold, exchanged for warranty, cost rebate, or other purposes and where the specific media will not be returned to the organization are out of organizational control.

If the device will not be under organization control, the following procedures must be followed.

#### Removable Media types:

- Removable flash-based storage devices
- CD/DVD or other optical disks
- Magnetic tapes and optical disks
- Internal and External Hard drives

The storage media will be physically destroyed by the Hospital IS Department or an approved IT Asset Disposition company and the certificate of media disposition forms are collected and retained. RenovoLive will be updated to reflect that the storage media has been securely destroyed.

Fixed/Permanent Media Types: Embedded storage media such as EEPROM, permanent SSD or other fixed flash-based media. Fixed media will be sanitized using the device vendor's approved method of sanitization. If a vendor method does not exist, ECRMC staff will consult

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with the leadership to determine the best course of action. Methods may include Clearing (overwriting media), Purging (cryptographic erase), and Destruction.

After sanitization, verification must be performed per NIST SP800-88. RenovoLive database will be updated to reflect that the storage media has been effectively sanitized.

### References:

Services, U. D. (2015, 1 1). *HHS.gov*. Retrieved from <http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/securityrulepdf.pdf>  
Technology, N. I. (n.d.). *NIST SPECIAL PUBLICATIONS*. Retrieved from Computer Security Division : <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf>

### **Appendix A**

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Manufacturer Disclosure Statement for Medical Device Security – MDS <sup>2</sup>			
Device Category <sup>1</sup> <b>Class II</b>	Manufacturer <sup>1</sup> <b>Vital Images, Inc.</b>	Document ID <b>VPMC-11799</b>	Document Release Date
Device Model <b>Vitreia Enterprise Suite</b>	Software Revision <b>1.2</b>	Software Release Date <b>December 2009</b>	
Manufacturer or Representative Contact Information:	Name <b>Brian Diaz</b> Company Name <b>Vital Images, Inc.</b>	Title <b>Marketing Product Manager</b> Telephone # <b>952-487-9500</b>	Department <b>Marketing</b> e-mail <b>Support@vitalimages.com</b>
<b>MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI)</b> <small>As defined by HIPAA Security Rule, 45 CFR Part 164</small>			
1. Can this device transmit or maintain electronic Protected Health Information (ePHI)?			Yes No N/A Note #
2. Types of ePHI data elements that can be maintained by the device:			
a. Demographic (e.g., name, address, location, unique identification number)?			Yes
b. Medical record (e.g., medical record #, account #, test or treatment date, device identification number)?			Yes
c. Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?			Yes
d. Open, unstructured text entered by device user/operator?			Yes
3. Maintaining ePHI: Can the device			
a. Maintain ePHI temporarily in volatile memory (i.e., until cleared on by power-off or reset)?			Yes
b. Store ePHI persistently on local media?			Yes
c. Import/export ePHI with other systems?			Yes
4. Mechanisms used for the transmitting, importing/exporting of ePHI: Can the device			
a. Display ePHI (e.g., video display)?			Yes
b. Generate hardcopy reports or images containing ePHI?			Yes
c. Retrieve ePHI from or record ePHI to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick)?			Yes
d. Transmit/receive or Import/export ePHI via dedicated cable connection (e.g., IEEE 1394, serial port, USB, FireWire)?			Yes
e. Transmit/receive ePHI via a network connection (e.g., LAN, WAN, VPN, Intranet, Internet)?			Yes
f. Transmit/receive ePHI via an integrated wireless connection (e.g., WiFi, Bluetooth, infrared)?			Yes
g. Other _____?			NA
<b>ADMINISTRATIVE SAFEGUARDS</b>			
5. Does manufacturer offer operator and technical support training or documentation on device security features?			Yes No N/A Note #
6. What underlying operating system(s) (including version number) are used by the device? <b>Microsoft Windows XP Professional x32/x64 Edition, Microsoft Windows Vista - x64/x32 Business Edition, Microsoft Windows 2003 Server Editions</b>			Yes No N/A Note #
<b>PHYSICAL SAFEGUARDS</b>			
7. Are all device components maintaining ePHI (other than removable media) physically secure (i.e., cannot remove without tools)?			Yes No N/A Note #
8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)?			Yes No N/A Note #
9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?			Yes No N/A Note #
<b>TECHNICAL SAFEGUARDS</b>			
10. Can software or hardware not authorized by the device manufacturer be installed on the device?			Yes No N/A Note #
11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)?			Yes No N/A Note #
a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)?			Yes No N/A Note #
b. Can the device log provide an audit trail of remote-service activity?			Yes No N/A Note #
c. Can security patches or other software be installed remotely?			Yes No N/A Note #
12. Level of owner/operator service access to device operating system: <i>Can the device owner/operator</i>			
a. Apply device manufacturer-validated security patches?			Yes No N/A Note #
b. Install or update antivirus software?			Yes No N/A Note #
c. Update virus definitions on manufacturer-installed antivirus software?			Yes No N/A Note #
d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)?			Yes No N/A Note #
13. Does the device support user/operator specific ID and password?			Yes No N/A Note #
14. Are access sessions terminated after a predetermined length of inactivity (e.g., auto logoff)?			Yes No N/A Note #
15. Events recorded in device audit log (e.g., user, date/time, action taken): <i>Can the audit log record</i>			
a. Login and logout by users/operators?			Yes No N/A Note #
b. Viewing of ePHI?			Yes No N/A Note #
c. Creation, modification or deletion of ePHI?			Yes No N/A Note #
d. Import/export or transmittal/receipt of ePHI?			Yes No N/A Note #
16. Does the device incorporate an emergency access ("break-glass") feature that logs each instance of use?			Yes No N/A Note #
17. Can the device maintain ePHI (e.g., by internal battery) during power service interruptions?			Yes No N/A Note #
18. Controls when exchanging ePHI with other devices:			
a. Transmitted only via a physically secure connection (e.g., dedicated cable)?			Yes No N/A Note #
b. Encrypted prior to transmission via a network or removable media?			Yes No N/A Note #
c. Restricted to a fixed list of network addresses (i.e., host-based access control list)?			Yes No N/A Note #
19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology?			Yes No N/A Note #

<sup>1</sup>Recommend use of ECRI's Universal Medical Device Nomenclature System (UMDNS).

**Note:** A copy of MDS2 should be sent to ECRMC QRM

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<b>Policy:</b>	<b>MEMP 6.0-D.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Use of Personal Communication Devices</b>		

**PURPOSE:** To promote the responsible use of Personal Communications Devices (PCD's) while minimizing the risk of potential performance degradation of electronic medical devices resulting from electromagnetic interference (EMI) and to protect patient confidentiality during mobile communications.

**RATIONALE:** Risk of patient harm is believed to be extremely low, but not zero. The risks associated with EMI from cell phones is a diminishing concern since newer cell phone technology produces lower EMI and newer medical devices have improved electromagnetic compatibility.

Personal Communication Devices (PCDs) may be used safely in most areas of the hospital and near life-support and diagnostic laboratory medical equipment where wireless antenna systems are available, and users observe some basic rules.

The Hospital retains the right to ask an employee, patient, visitor, or member of the Medical Staff to turn off their PCD while in the patient care area if there is a concern regarding possible disruption to patient care.

ECRMC staff are restricted from any unauthorized use of cell phone cameras to protect the confidentiality of individually identifiable patient health information in accordance with federal and state laws and ethical duties.

The use of wireless devices shall be regulated as follows:

- **Cell Phone** use is permitted in almost all areas of the Hospital without restrictions.

Cell phone use is restricted in the following areas:

- **OR Services** (i.e., all anesthetizing and procedural areas): The use of cell phones in operating rooms facilitates communication which can significantly improve the quality of healthcare. Therefore, staff are permitted to use cell phones in these locations under the following conditions: They are educated about the potential for cell phones to interfere with energized medical devices, and to report all incidents involving the malfunction of medical devices to Clinical Engineering promptly for evaluation.

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- Cell Phones may be left in “standby mode”, i.e., they do not need to be turned completely off, when closer than three feet. However, the user must move the device to the **three-foot limit to use it**.
- User should not allow a Cell Phone to come into direct contact with a medical device or implanted device.

**NOTE:** Air waves are unprotected, and conversations may be intercepted by other telephones. Refrain from the disclosure of protected health information during cellular phone conversations to prevent the breach of a patient’s right to confidentiality.

- **USB Ports:** Plugging unauthorized devices or accessories into USB ports on medical devices can cause the medical devices to malfunction.

Direct effects on medical device operation include device rebooting, shutting down, change of device settings, alarm failures etc. Uncontrolled access to medical device USB ports could also lead to a security breach, putting the patient’s data and the healthcare facility’s systems at risk.

Patients, Visitors, and all hospital personnel are prohibited from using the USB ports on the medical devices for personal use. It is the responsibility of the hospital IT department and Biomed to restrict access to USB ports on medical devices for unauthorized personnel.

- **Two-way Radios** may be used in the receive mode only in all patient care areas.

Whenever maintenance staff, security officers, EMS personnel, Life Flight employees, or other personnel with two-way radios are in a patient care unit and an emergency occurs which requires the use of their radio, they should make their best effort to adhere to the following guidelines, which are listed in order of preferred compliance:

- Leave the patient care unit to use the two-way radio.
- Keep the two-way radio at least 10 feet away from any energized medical device.
- If output levels are adjustable, use the lowest setting possible that still facilitates acceptable communications.
- If any equipment near the radio user should malfunction while the radio is in use, terminate the use of the radio immediately. Any further use should be conducted from the visitor waiting area or a non-patient care unit.

### Special Cases:

- **Implanted Devices:** Patients and staff with implanted devices such as pacemakers, defibrillators, etc. must exercise caution when carrying and using wireless devices. Recommended procedures, as delineated by the medical device manufacturer, must be followed.
- **Emergency Vehicles:** Operators of Hospital emergency vehicles, which transport patients with sensitive medical devices, and their supervisors, must be cognizant

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of the fact that two-way radios / beepers and cell phones can cause electromagnetic interference at close range. Medical devices used in these applications must be carefully selected for this demanding application.

- Any suspected incidents of medical device electromagnetic interference must be reported to Biomedical Engineering. Biomed will investigate each incident, develop recommendations, and report findings to ECRMC QRM, Clinical Safety Committee and/or the EOC Committee as appropriate.

### References:

- 8.6.2. *AAMI TIR18: 1997, Guidance on electromagnetic compatibility of medical devices for clinical/biomedical engineers — Part 1: Radiated radio-frequency electromagnetic energy.*
- 8.6.3. *ANSI C63.18-1997: American National Standard, Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters.*
- 8.6.4. *ECRI, Wireless Communication Devices and Electromagnetic Interference: ECRI's Updated Recommendations, Health Devices 30 (11), November 2001*
- 8.6.5. *IEC 60601-1-2, Second edition, 2001-09: Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*



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<b>Section No:</b>	<b>Section 7</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 7.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>MEMP PI Measures &amp; Reporting</b>		

### Performance Improvement Measures & Reporting

The intent of the quarterly MEMP performance improvement reports is to provide the facility-specific data (collected monthly) regarding the function of the Medical Equipment Management Program. The data provided is intended to identify potential problems related to the function and clinical use of equipment in the program to improve medical equipment safety for the patient and clinical staff.

Performance Improvement reports are produced for the Medical Equipment Management Program during the second week following the end of each calendar quarter. The reports review the following “typical” performance indicators as compared to established performance measures (thresholds):

- Scheduled maintenance due and completed for the quarter
- Total repairs closed for the quarter.
- Total repairs open for the quarter.
- Repeat repairs for a single device.
- Special Case Reporting including:
  - Accidental Damage reports
  - Can-Not-Duplicate reports
  - Equipment Incidents
  - Incidental In-service
  - Operator Errors
  - Equipment Recalls
- Inventory changes for the quarter.
- Program Improvement goal updates and plans for improvement.

The actual performance of each threshold is measured and compiled into a quarterly Performance Improvement report and reported to ECRMC EOC Committee where overall performance of the program is evaluated, problems identified, and a plan of correction and/or goals assigned. Participation in the EOC Committee is assigned to the Biomedical Manager or an authorized committee designee.

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<b>Policy:</b>	<b>MEMP 7.0.A.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Performance Indicators &amp; Improvement Goals</b>		

As a part of the Quality Management System for addressing performance improvement and patient safety, the Medical Equipment Management Program establishes annual Quality and Performance Improvement Goals that focus attention on various processes, functions, and areas of the MEMP.

In conjunction with the Annual Assessment Report, Quality and Performance Improvement goals will be established during the first quarter of each year. Progress will be reported on a quarterly basis in the quarterly Performance Improvement reports. As goals are completed during the year, new goals may be established.

These goals will be documented to include the rationale for selection and measurable progress achieved based on the areas identified for improvement in the previous year’s Annual Evaluation of the MEMP.

All the performance indicators and goals listed below will be monitored monthly and reported quarterly via the ECRMC Medical Equipment Management Report. From the results of performance monitoring, additional or revised performance indicators and goals may be established. In addition, specific performance indicators and goals may be established by the facility.

- PI 1            Maintain the level of UTL equipment at or below **5%** of the total number of equipment scheduled for maintenance per quarter.
  
- PI 2            Maintain the SM on-time completion rate for all High-Risk equipment at 100%.
  
- PI 3            Maintain the SM completion rate for all Non-High-Risk equipment at 100%.
  
- PI 4            Maintain the average level of service events due to equipment damage or abuse to at **3%** or less of the total service events per quarter.
  
- PI 5            Maintain the average percentage of service events due to use errors at **2%** or less per quarter by increasing the number of incidental in-services
  
- PI 6            Maintain the average level of service events that were found to be “cannot duplicate” problem calls to below **3%** of the total number of service events per quarter by investigating the number of repeat calls reported for the same device for possible user-related and/or intermittent problems.

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- PI 7 Complete and report 100% of all medical equipment related recalls and incidents received in accordance with manufacturer requirements and ECRMC's policy and procedure.
- PI 8 Maintain the equipment repairs completion rate at greater than **95% per quarter**.
- PG 1** **Alarm Safety Management:** Hospital should develop and implement specific policies and procedures that address clinically appropriate settings, monitoring, and response expectations.
- PG 2** **Power Strips Use in Patient Care Areas:** In Collaboration with onsite facilities department, establish guidelines for the use of power strips (relocatable power taps) and adapters to encourage a safe electrical environment for patients, staff, visitors, and equipment.
- Note:** Establish any other goals as elected by the Biomedical Manager and ECRMC's EOC Committee.
- Note:** Schedule Maintenance events coded as UTL, CIU or UFM will be **accounted as 'SM complete'** with due diligence done to perform the SM. (i.e., If you have 100 SMs and 3 of them were UTL at the end of the month, then your completion rate is 100% provided you have done due diligence trying to locate the equipment, communicated with user department and documented the same).

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<b>Policy:</b>	<b>MEMP 7.0.B.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Annual Assessment</b>		

The purpose of the annual assessment is to perform a functional review of all components of the Medical Equipment Management Program. From information gathered during the year in the quarterly PI reports, a complete analysis of the effectiveness of the program will be performed, strengths and weaknesses identified, and performance improvement goals established.

The Annual Assessment Review includes the following:

- A complete review of the previous program improvement goals, including an evaluation of the success in meeting those goals.
- A review of the previous twelve (12) months of aggregated data for trend indicators to be included in the Annual Assessment. This includes examination of issues involving equipment incidents and Hazard Alert/Recall issues.
- A review of the clinical equipment inventory and the risk criteria used to establish service intervals, including a review of changes to the inventory such as new acquisitions which may indicate training needs, or deletions of equipment, and adherence to the Rental and Leased Equipment Policy.
- A review of the planned maintenance database for completeness of service history, consistency in data collection, and appropriateness of all service procedures.
- A review of Education, Training, skills, and competency component of the program. This will include assessment of employee evaluations, training needs, and job descriptions.

Information collected following review of the preceding will be evaluated, and reported to EOC which is designed to evaluate the previous year's performance and effectiveness. As well set new Performance and Quality Improvement Goals to define and drive the process improvement for the next 12 months.

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### 2024 Performance Goals

**Program Objective:** The essential objective of the Medical Equipment Management Program is to establish policies and procedures that ensure all equipment used in the care and treatment of patients within the hospital environment is safe and properly maintained pursuant to federal, state, and local regulations.

**Scope:** The scope of the program includes all medical equipment included in the medical equipment inventory of ECRMC. Medical equipment is tested at a frequency determined by the manufacturer or as per the AEM program, to ensure reliable and safe operation of medical equipment used throughout the facility.

### **2023 Performance:**

Performance Indicators	Measured Performance	Effectiveness Goal Met Y/N	Performance Improvement Goals
<b>UTL =&lt; 5% of total SM</b>	2.82%	Yes	Maintain/Reduce the number of UTL's to 5% or less of the total SM's scheduled per quarter and continue to monitor.
<b>SM Completion High Risk = 100%</b>	100%	Yes	Maintain/Improve the High-Risk maintenance completion at 100%.
<b>SM Completion Non-High Risk = 100%</b>	100%	Yes	Maintain/Improve the Non-High-Risk SM completion at a minimum of 100% per quarter.
<b>Accidental Damage =&lt; 3% of Total Repairs</b>	0.6%	Yes	Maintain/Reduce the number of damaged equipment to 3% or less of the total repair calls per quarter by improving customer contact and in-service education about resolving equipment damage issues.
<b>User Errors =&lt; 3% of Total Repairs</b>	0.8%	Yes	Maintain/Reduce the number of user-errors at 3% or less of the total number of repair calls per quarter.
<b>Cannot Duplicate =&lt; 3% of Total Repairs</b>	0.2%	Yes	Maintain/Reduce the number of cannot duplicate events to 3% or less of the total repair calls per quarter.
<b>Equipment Repair Completion &gt;95%</b>	99.2%	Yes	Maintain/improve the equipment repair completion rate to greater than 95% per quarter.

- Number of individual Recalls addressed – 11
- Number of medical equipment related incidents reported - 1
- Net Inventory Change % – -0.21%

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### Effectiveness:

The Clinical Engineering department continues to place emphasis on timely completion of SMs and medical equipment repairs. Several performance improvement objectives have also been initiated to improve the overall effectiveness of the program. The program was found to be effective; continued enhancements to the repair and SM process have been implemented. The Biomedical department and members of the EOC will continue to work in a collaborative manner to ensure that changes are improving the overall Program effectiveness.

### 2024 Performance Goals:

Performance Indicators
UTL =< 5% of total SMs
SM Completion High-Risk = 100%
SM Completion Non-High Risk = 100%
Accidental Damage =< 3% of Total Repairs
User Errors =< 3% of Total Repairs
Cannot Duplicate =< 3% of Total Repairs
Equipment Repair Completion >95%
Equipment Repair Turnaround time <2.8days

(!)- Cells Highlighted were elected as 2024 PI Goals

Name: Joseph Thompson, CBET

Organizational Role: Biomedical Engineering Manager

Date: 12-29-2023

Reviewed by: El Centro Regional Medical Center EOC Committee

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Signature of the Hospital EOC Representative

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## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 8</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 8.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>SMDA Incident Reporting</b>		

Policy: Any event at ECRMC in which someone is injured, or where there was the likelihood of injury without immediate clinical intervention, and patient care equipment is in any way suspect, is immediately reported to the QRM department / QRM Director. All appropriate actions will be taken according to the Safe Medical Devices Act and hospital incident investigation/reporting policy.

The Medical Equipment Management Plan must be integrated with the facility-wide policy and procedure. Under the Safe Medical Devices Act of 1990, it is required that reports be submitted by the facility to the FDA and/or the device manufacturer, dependent on the outcome of the incident as defined by the specific SMDA requirements and definitions. Individual State Regulatory and Advisory Agency requirements may be subject to reporting as well.

Procedure:

Upon any notification of a potential incident, **IMMEDIATELY** contact the hospital's QRM department and notify the QRM Director.

ECRMC Biomedical staff should take whatever measures they are directed to take by the Risk Management and the Clinical Staff to minimize existing risk to the staff or the patient. Take pictures of the scene, equipment setup and settings (if possible). Only under the supervision of the Risk Management and in collaboration with clinical staff, sequester the equipment and all accessories in question, if not already done, with minimal disturbance to the settings and other evidence that might aid the investigation.

Equipment sequestered should be tagged appropriately (DO NOT USE) and stored. The storage location should be within the hospital as identified by the Risk Manager to permit equipment to be impounded while an investigation is ongoing.

**NOTE:** *Equipment with on-board memory that retains settings and performance history needs to be connected to power to maintain the internal battery.*

**NO FURTHER ACTION SHOULD BE TAKEN WITHOUT DIRECTION FROM THE RISK MANAGER.**

# El Centro Regional Medical Center

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Under no circumstances should the device be tested or put back in patient care until a written authorization has been received by ECRMC QRM. Equipment can be tested only in the presence of the Biomedical Manager and a hospital QRM representative.

**Note:** *The Facility's Incident report should be received by ECRMC QRM* A signed and dated Biomedical Service Report is MANDATORY if the Risk Manager or designee authorizes you to test, repair, or take any other actions with the equipment other than those detailed herein. (See 14. below)

If the Incident resulted in an **INJURY or DEATH**, the equipment in question **MUST NOT BE TESTED** or put back in service until approved by the ECRMC QRM Director.

The responding technician is required to fill out the Medical Device Related Incident Fact Sheet and generate a Service Event in RenovoLive indicating the following:

1. Technician
2. Facility representative in charge at the scene
3. Date
4. Time
5. Location
6. Name of person who reported the potential incident
7. Department responsible for the device
8. Device description including:
  - a. Description
  - b. Manufacturer
  - c. Serial number
  - d. Model number
  - e. Control number
9. Date of last inspection
10. Due date of the next inspection
11. Original instrument settings and display readings
12. A brief description of the incident.

**Note:** ***DOCUMENT FACTS ONLY.** Never assume responsibility or make any assumptions as to the cause of the incident.*



# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

13. Scan and attach the Incident Fact Sheet to the service event.
14. Print a copy of the service event (only) and have ECRMC QRM Sign the printed copy as an acknowledgment of receipt and/or authorization to perform any tasks not detailed herein. Provide the QRM department a copy. Retain the original signed service report for the Biomed/Clinical Engineering files.

### Processing the ECRMC Medical Device-Related Incident Fact Sheet:

**The Incident Fact Sheet is a legal document and should never be copied.** Scanning the Incident Fact Sheet into the service event and attaching it to an ECRMC Corporate email (only) is permitted.

- Email the completed Incident Fact Sheet to the ECRMC QRM department at [quality-resource-management@ecrmc.org](mailto:quality-resource-management@ecrmc.org) and cc; the ECRMC QRM Director.
- Upon receipt, the QRM Department will review the Incident Fact Sheet and will contact the Biomedical Manager within 48 hours to discuss the details of the incident.
- The details of the discussion will be reviewed with ECRMC Senior Management Team. Legal Counsel will be contacted if necessary.

### Reporting Recommendation:

As applicable, The Facility's Risk Manager should submit reports of individual adverse events no later than **10 workdays** after the day that he/she becomes aware of a reportable event:

- Submit reports of device-related deaths to FDA and to the manufacturer
- Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to FDA

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan



ECRMC Clinical Engineering  
**MEDICAL DEVICE RELATED INCIDENT - INTERNAL FACT SHEET**  
**CONFIDENTIAL**

From: (ECRMC Staff Person): \_\_\_\_\_

Employee ID#: \_\_\_\_\_

**Incident date/time/facility:**

At (Time): \_\_\_\_\_ On (Date): \_\_\_\_\_

Facility Name: \_\_\_\_\_

At (Full address of facility): \_\_\_\_\_

Reported by: \_\_\_\_\_ Person in charge at the scene: \_\_\_\_\_

Name of User Department or Location: \_\_\_\_\_

Received Hospital Incident report:  YES  NO If yes, Report# \_\_\_\_\_

**Patient/Staff Status:** On the date and time of the incident as documented above, did this incident result in serious injury or death to the patient/staff?  YES  NO  Unknown

**Equipment Involved:** Date and time ECRMC representative first saw the equipment after incident:

At (Time): \_\_\_\_\_ On (Date): \_\_\_\_\_ RL SE# (generated): \_\_\_\_\_

Device Description: \_\_\_\_\_

Manufacturer: \_\_\_\_\_ Model: \_\_\_\_\_

(CE#) No.: \_\_\_\_\_ Serial No.: \_\_\_\_\_

(If Applicable) Lot No.: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Equipment last inspected on: \_\_\_\_\_ Next inspection due: \_\_\_\_\_

Observed equipment condition, switch settings, display readings, accessories, error codes; etc.:

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Brief description of the incident:

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**El Centro Regional Medical Center**  
2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 8</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 9.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Employment Requirements</b>		

Each employee will have their job description, duties, and expectations reviewed with them at the time of hire. Basic competency and skills necessary for the job duties will be assessed and training goals identified in accordance with **policy 9.0.B** in the MEMP manual.

In accordance with applicable State, regulatory, and accreditation agency requirements, contracted employees will be required to meet the same employment requirements and expectations as hospital staff including criminal background checks and health screening as applicable.

ECRMC meets these requirements via an audit of appropriate information for each employee including an attestation - Employment/Competency Verification Letter as to the accuracy of the information which is signed by an Officer of the Company. Copies of pertinent employee information is available to the Human Resources Department of the ECRMC upon request.

**All pertinent employee information shall be in the Human Resources Department and is considered *strictly confidential*.** The ECRMC Human Resources Department must obtain authorization prior to releasing any employee information for any reason.

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

### ECRMC Employment/Competency Verification

**Employee:** (First Name, Last Name) \_\_\_\_\_ has been employed by El Centro Regional Medical Center since Date \_\_\_\_\_ as **Title/Position:** \_\_\_\_\_ and deemed competent per the requirements of his/her Job Description to perform the duties as assigned for **El Centro Regional Medical Center:** \_\_\_\_\_. (See attached Job Description).

Employees are required to complete and pass a Facility Orientation and Safety Training Session, drug screening, TB screening, DMV review, criminal background review, and all requirements of an ECRMC new employee orientation session. TB Screening should be current and updated annually (if necessary).

If an employee refuses to undergo the testing / review process, they are not considered to be eligible for employment. If, because of the pre-employment / employment screening process it is established that an employee is not qualified for the job in question, the conditional job offer is withdrawn.

<b>New Hire Mandatory Testing Audit Findings</b>		
<b>Criteria</b>	<b>Audit Date</b>	<b>Compliance Finding (Pass/Pending)</b>
Facility Orientation / Safety Training		
TB Test		
Drug screening		
MMR/Hep. B/ Varicella Titer		
Criminal Background Review		
Competency Review		

If you have any other questions or requirements, please contact the ECRMC Human Resources

# El Centro Regional Medical Center

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<b>Section No:</b>	<b>Section 9</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 9.0.A.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Continuing Education Program</b>		

The key component of the continuing education program is outside service training and ECRMC on the Job Training. The need for service training is dependent upon several factors:

- Specific requirements of the job description and related duties
- Specific service requirements of the medical equipment inventory being serviced
- New equipment acquisitions and Hospital training requirements
- Changes and advancements in medical equipment technology
- Certification and Licensing requirements (as applicable)

Scheduling and attendance will be determined by the Biomedical Engineering Department Manager. Training content will vary based on perceived need through evaluation of technical staff, staff feedback, technology changes and equipment purchase.

All employees will complete facility required orientation training such as Universal Precautions, Fire and Life Safety, HIPAA, Infection Control and Sexual Harassment, as applicable. In addition, **ECRMC provides on-going safety training to all its staff through an external resource, HealthStream.**

All training that is completed outside of the facility via manufacturer's service schools or third-party training programs will be documented. This documentation is maintained and available in the Biomedical Engineering Department and ECRMC HR. Competency assessment related to the training are conducted a minimum of annually as needed.

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 9</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 9.0.B.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Technical Competency Assessment</b>		

All ECRMC technical staff are evaluated during the initial orientation and competency assessment process to assess their technical competency with the requirements of the job description for the specific position which includes the experience, educational and physical requirements, and supervision and performance expectations of the duties assigned.

From this process, educational needs are identified, and a training plan is established. The progress and completion of the plan is documented in the initial evaluation and competency assessment and re-evaluated against measurable indicators in their annual Performance Evaluation. Documented competency assessments are conducted a minimum of annually thereafter as needed.

Education/training needs are met through the Continuing Education Program, manufacturer training, or third-party training. On-the-job Training is offered to an engineer through OEM certified ECRMC personnel. In addition, ECRMC's technical staff is strongly encouraged to attend continuing education programs outside of work as well (AAMI, MDEspo, TechNation etc.).

**Note:** In case where medical equipment is contracted with manufacturer or third-party vendors, it is required by the vendor to provide the technical competency records of their Field Service Engineer (when requested).

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 10</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 10.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Infection Control</b>		

**Purpose:** To ensure proper infection control of medical equipment handling, use, service, and disposal of equipment and its components and accessories by Biomedical staff at ECRMC.

**Policy:** In accordance with standard hospital infection control policies and procedures, ECRMC personnel shall ensure that all medical equipment received for service from patient care areas is properly disinfected prior to service. Biomedical Engineering staff will be unable to receive, process or repair any equipment returned with evidence of biohazardous contamination. To avoid delays in receiving, please clean equipment with sterilizing solvent prior to returning product.

- As appropriate, medical equipment received from patient care areas, specifically, equipment removed from infectious or isolated patient areas, shall be properly disinfected by ECRMC's Sterile Processing Department. The equipment will be cleaned by Biomed personnel as recommended by the manufacturer during scheduled maintenance and repair service, as needed, prior to delivery to the user-department.

**NOTE:** *If applicable, Biomed personnel shall contact the hospital infection control officer or other appropriate hospital personnel to receive instructions prior to removing medical equipment from an infectious or isolated patient area.*

- Biomedical personnel shall perform frequent and proper hand washing per standard hospital procedure while handling and servicing hospital equipment.
- Biomedical personnel shall comply with all standard hospital policies and procedures while working in sterile and infectious environments.
- Biomedical personnel shall not handle or consume any food or drinks while servicing medical equipment in any area utilized for servicing medical equipment.
- Biomedical personnel will comply with all standard precautions including prohibiting handling and consumption of food or liquids in areas designated for servicing medical equipment.
- Biomedical personnel will comply with all standard hospital policies and procedures regarding protective clothing and gear (i.e., lab coats, gowns, face shields, masks, gloves, etc.) when exposed to blood borne pathogens, body fluids, and infectious areas.
- Biomedical personnel will comply with all standard hospital policies and procedures regarding proper attire for sterile areas (i.e., scrubs, cover gowns, hats, masks, and shoe covers).

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 11</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 11.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>Exposure Control Plan</b>		

It is the policy of ECRMC to follow OSHA, CDC, and other applicable regulatory agency requirements to identify employees at risk for occupational exposure to blood or other potentially infectious chemicals and hazardous materials to eliminate or minimize their risk of exposure.

### KEY DEFINITIONS

**Occupational Exposure:** Reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

**Exposure Incident:** A specific eye, mouth or other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from performance of an employee's duties.

**Blood:** Human blood, human blood components and products made from human blood.

**Blood borne Pathogens:** Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV) and Ebola virus.

**Hazardous Material:** Any material that, because of its quantity, concentration, or physical or chemical characteristics, may pose a real hazard to human health.

**Contaminated:** The presence or the reasonably anticipated presence of blood or of OPIM on a surface or on an item in a location where it could lead to an exposure.

**Contaminated Sharp:** A contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, and broken glass.

**Decontamination:** The use of physical or chemical means to remove, inactivate or destroy blood borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal.

**Engineering Controls:** Mechanisms (e.g., sharps disposal containers, plexi-glass shields) that isolate or remove the blood borne pathogen hazard from potential contact with the employee workplace.



# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

### **Other Potentially Infectious Materials (OPIM):**

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
- Any unfixed tissue/organ (other than intact skin) from a human living or dead.
- HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions including blood, organs, or other tissues from humans, living or dead, infected with HIV, HBV, or Ebola.
- Parenteral: Piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

**Personal Protective Equipment (PPE):** Specialized clothing or equipment worn by an employee for protection against hazards. General work clothes (e.g., uniforms) not intended to function as protection against a hazard are not considered to be personal protective equipment.

**Work Practice Controls:** Controls that reduce the likelihood of exposure by altering the way a task is performed.

### BLOODBORNE PATHOGENS OCCUPATIONAL EXPOSURE CATEGORIES

**Category I:** Employees who routinely contact potentially contaminated items.

**Category II:** Employees who occasionally (one to three times per month on average) contact potentially contaminated items.

**Category III:** Employees who never contact potentially contaminated items.

### OTHER TASKS AND PROCEDURES IN WHICH OCCASIONAL EXPOSURES MAY OCCUR

- Handling, working on, or disposing of, hospital equipment, which may be contaminated with human blood or OPIM.
- Handling or disposing of potentially contaminated sharps.
- Handling of and exposure to chemical and hazardous materials such as formalin, ethylene oxide (ETO) and mercury.
- Handling and disposal of chemicals and hazardous materials.

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

### COMPLIANCE METHODS

- Universal Precautions: Employees will utilize universal precautions to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious material will be considered infectious.
  
- Work Practice Controls: These controls will be utilized to eliminate or minimize exposure to employees. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be utilized.
  - Biomedical personnel may decline to handle or work on equipment or enter areas, which could conceivably be contaminated until it has been decontaminated.
  - Pursuant to OSHA requirements, **hand-washing facilities** and **emergency decontamination stations** are usually available within the hospital to employees who incur exposure to blood or other potentially infectious materials. OSHA requires that these facilities be readily accessible after incurring exposure. **For specific information, discuss this issue with the hospital's Infection Control Officer prior to commencing work.**

After removal of personal protective gloves, employees shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water. If Biomedical personnel incur exposure to their skin or mucous membrane, then those areas shall be washed with water as soon as feasible following contact. Discuss locations of emergency shower and eyewash facilities with hospital department contact prior to commencing work.
  - Biomedical personnel are prohibited from storing and/or disposing of any hazardous chemicals or materials. Storage and disposal of these chemicals and materials must be conducted by authorized hospital employees in accordance with the hospital's Hazardous Materials control program.
  - Any chemicals and/or other hazardous materials such as isopropyl alcohol and batteries, necessary for the proper maintenance of medical equipment, stored on-site in the Clinical Engineering Department must be identified and listed in accordance with the hospital's MSDS and Infection Control programs.
  
- Work Area Restrictions: Employees are not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses in work areas in which potentially contaminated items are usually located.

Work will be conducted in a way to minimize splashing, spraying, splattering and generation of droplets of blood or other potentially infectious material.  
Equipment, which has become contaminated with blood or OPIM, shall be examined prior to servicing or shipping and shall be decontaminated, as necessary.

# El Centro Regional Medical Center

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- Personal Protective Equipment (PPE): PPE that are required to be used by employees (such as gloves) will be provided upon request by ECRMC at no cost to the employee. Maintaining stock of these items is the responsibility of the ECRMC warehouse. PPE includes, but is not limited to, the following:
  - Latex Gloves
  - Disposable Face Shields
  - Goggles
  - Rubber Gloves (sterilizer maintenance group)

Biomedical personnel are responsible for carrying an adequate supply of PPE (gloves) and notifying the Biomed Manager when supplies need replenishing. In addition, employees are responsible for notifying the Biomed Manager that repairs are needed to PPE where applicable.

ECRMC personnel must wear protective gloves whenever there is the possibility of contact with human blood or other potentially infectious materials

Disposable gloves are not to be washed or decontaminated or re-used and are to be replaced as soon as feasible if they are torn, punctured or when their ability to function as a barrier is compromised. Utility gloves may be decontaminated for re-use if the integrity of the gloves is not compromised. Utility gloves will be discarded if they are cracked, peeling, torn, punctured or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

Biomedical personnel must wear masks in combination with eye protective devices, such as goggles or glasses with solid side shields or chin length face shields, whenever splashes, spray, splatter or droplets of blood or other potentially infectious materials may be generated, and eye, nose and mouth contamination can reasonably be anticipated.

If an ECRMC employee determines that a work surface or piece of equipment is potentially contaminated, he/she should immediately contact the facility's department director or designee for information on appropriate decontamination procedures. If the status of the equipment cannot be ascertained, the employee should immediately notify their direct supervisor.

### ENFORCEMENT OF BLOODBORNE PATHOGENS PROGRAM

Compliance to include, but is not limited to:

Employees who willfully fail to comply with the mandatory safeguard established by this policy are subject to disciplinary action, job reassignment or termination.

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

**Hepatitis B Vaccine:** The Hepatitis B vaccine is offered to all ECRMC personnel. Those employees who choose not to be vaccinated must sign a Hepatitis B Vaccination Declination Form.

**POST EXPOSURE FOLLOW-UP:** When an ECRMC employee incurs an exposure incident he/she shall immediately report it to his/her supervisor, fill out an Employee Accident Report, and seek medical treatment.

### INFORMATION AND TRAINING

- Employees with occupational exposure risk in Category I shall be trained.
- Employees in Category I shall be retrained at least annually.
- Employees whose responsibilities change so that their occupational exposure risk changes to Category I shall be given appropriate training immediately.
- Training for employees will include the explanation of the following:
  - The OSHA standard for bloodborne pathogens.
  - Epidemiology and symptomatology of bloodborne diseases.
  - Modes of transmission of bloodborne pathogens.
  - This Exposure Control Plan (i.e., points of the plan, lines of responsibility, how the plan will be implemented, etc.).
  - Procedures, which might cause exposure to blood or OPIM.
  - Control methods, which will be used to control exposure to blood or other potentially infectious materials.
  - PPE available and who should be contacted concerning it.
  - Post-exposure evaluation and follow-up.
  - Hepatitis B vaccination program.
- The MEMP addressing the Exposure Control Plan is readily available on the ECRMC Policy Tech site to provide all the employees with instant access.
- Employee training records shall be maintained for a duration of 3 years from the date of training.

### RECORD KEEPING

- All records will be kept including, but not limited to, exposure record and follow-up records for each employee, consistent with OSHA standards available through the ECRMC Human Resources Department.
- ECRMC personnel medical record confidentiality shall be maintained.
- ECRMC personnel exposure medical records shall be maintained for the duration of the individual employment plus 30 years as per OSHA standards.

# El Centro Regional Medical Center

## 2024 Medical Equipment Management Plan

<b>Section No:</b>	<b>Section 12</b>	<b>Revision:</b>	<b>1-24</b>
<b>Policy:</b>	<b>MEMP 12.0.1-24</b>	<b>Reviewed Date:</b>	<b>12/1/2023</b>
<b>Document:</b>	<b>User Training</b>		

### Equipment Users:

Clinical-level user training which addresses the capabilities, limitations, and special application of the equipment is the primary responsibility of the ECRMC's Clinical Education Department. The Biomed/Clinical Engineering staff is available to assist upon request through specific presentations such as electrical safety and Safety Fair education, as well as in-service training.

During the daily performance of their job duties, Biomedical engineering staff is frequently requested to inspect and evaluate equipment in the clinical setting. When use errors are identified, or as appropriate, the Biomed staff will coordinate an incidental in-service with the department manager and in-service the clinical staff on the basic operation and performance characteristics of the equipment. When this service is provided, the Biomedical engineering staff will document the in-service for review by the department manager and the Clinical Education Department, with an entry into the RenovoLive database as a service event. The in-service data will be reviewed for inclusion in the quarterly Performance Improvement reports.

**Note:** *Clinical/Medical applications of medical equipment training is the responsibility of the ECRMC Clinical Education Department, Clinical and/or Medical Staff.*



**TO:** HOSPITAL BOARD MEMBERS  
**FROM:** David Momberg, Chief Financial Officer  
**DATE:** February 26, 2024  
**MEETING:** Board of Trustees

**SUBJECT:** Notice of Temporary Service Relocation – Public Hearing

**BUDGET IMPACT:**  Does not Apply  
 Yes  No  
 A. Does the action impact/affect financial resources?  
 B. If yes, what is the impact amount: \_\_\_\_\_

**BACKGROUND:**

HSC 1276.05 requires public comment period for temporary relocation of services.

We are requesting public comments in relation to temporarily relocating In Patient services beds from Building 5 (North Wing) to Buildings 2 and 8 (OB and Labor Delivery to complete seismic retro fit IAW AB 2190.

**DISCUSSION:** N/A

**RECOMMENDATION:** N/A

**ATTACHMENT(S):**

- Order Confirmation of Public Comment in local paper.

Approved for agenda, Chief Executive Officer

Date and Signature: Pablo Velazquez

AFFIDAVIT OF PUBLICATION  
(2015.5 C.C.P.)

This space is for the County Clerk's  
Filing Stamp:

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County of Imperial

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over the age of eighteen years, and not a party to  
or interested in the above entitled matter. I am  
the principal clerk\* of the printer of the

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of Imperial and which newspaper has been  
adjudged a newspaper of general circulation by  
the Superior Court of the County of Imperial,  
State of California, under the date of October 9,  
1951, Case Number 26775; that the notice, of  
which the annexed is a printed copy, has been  
published in each regular and entire issue of said  
newspaper and not in any supplement thereof or  
the following dates, to-wit:

**EL CENTRO REGIONAL MEDICAL CENTER  
NOTICE OF TEMPORARY HEALTH FACILITY LICENSING**

El Centro Regional Medical Center (ECRMC) is requesting approval from the California Department of Health Care Access and Information (HCAI) and the California Department of Public Health (CDPH) to temporarily relocate the MedSurge unit from Building 5 to Buildings 2 and 8.

This program flexibility is needed in order to allow ECRMC time to complete necessary seismic upgrades to Building 5 in order to be reopened. ECRMC is requesting this approval for temporary Med Surge operation until 12/31/24.

Pursuant to HSC 1276.05, ECRMC is accepting public comments on the proposed interim use. Please submit your comments to the following email address: [belen.gonzalez@ecrmc.org](mailto:belen.gonzalez@ecrmc.org). We also welcome your comments in person, Monday 2/26/2024 at ECRMCs open board meeting at 5:30 PM held at 1271 Ross Ave, El Centro CA, 92243.  
#309458

F23

02/23/2024

All in the year 2024

I certify (or declare) under penalty of  
perjury that the foregoing is true and  
correct.

Alexis Ponce

SIGNATURE

Name of Account:  
ECRMC -EL CENTRO REGIONAL MEDICAL CENTER\*  
Ad Number: 309458

\* Printer, Foreman of the Printer,  
or Principal Clerk of the Printer  
Date: 23rd day of February, 2024  
at El Centro, California.



**TO:** HOSPITAL BOARD MEMBERS  
**FROM:** David Momberg, Chief Financial Officer  
**DATE:** February 26, 2024  
**MEETING:** Board of Trustees

**SUBJECT:** January 2024 Month and Year-to-Date Financial Statements

**BUDGET IMPACT:**  Does not Apply  
A. Does the action impact/affect financial resources?  Yes  No  
B. If yes, what is the impact amount: \_\_\_\_\_

**BACKGROUND:** The month of January resulted in net operating gain of \$4.4M, a positive margin of 25.2% and positive EBIDA of \$6.1M. FYTD EBIDA is positive at \$8.3M and positive margin increase from 3% to 10%.

**DISCUSSION:** For a more detailed description of financial performance, please see the attached Financial Report.

**RECOMMENDATION:** (1) Approve

**ATTACHMENT(S):**

- Financial Packet for January 2024

Approved for agenda, Pablo Velez

Date and Signature: \_\_\_\_\_

*Pablo Velez*





# January 2024 Financial Report

February 26, 2024

**To: Finance Committee**

**From: David Momberg, Chief Financial Officer**

The following package contains:

- Comparative volumes vs. Prior Month/Year
- Balance Sheet vs. Prior Month comparison
- Operating Statement vs. Prior Month comparison
- Monthly Cash Flow (Fiscal Year to Date)

## **Balance Sheet:**

- a) Cash balance increased (\$0.9M) mainly due to CMS 340B settlement (\$5.9M) partially offset by vendor payments.
- b) Net patient receivables increased (\$1.6M) mainly due to higher Outpatient Visits (7,501 vs 6,318 last month) higher RHC visits (7,623 vs. 5,975 last month) and higher ER visits (3,126 vs. 2,834 last month).
- c) Other receivables decreased (\$77k) due to 340b pharmacy payments.
- d) Due from third-party payers increased (\$1.6M), no supplemental payments received.
- e) Prepaid expenses decreased (\$472k) due to Cardinal Health prepaid payments applied to orders.
- f) Restricted building capital fund increased (\$18k) due to UBS generated interest.
- g) Other Assets decreased (\$262k) due to Cardinal Health credit memo applied to invoices.
- h) Days in A/R decreased to 39.75 from 40.46 days. The goal is 50 days.

- i) Accounts payable days decreased, 85.72 vs. 89.19 days from previous month.
- j) Current Ratio increased to 0.84 vs. 0.77 previous month.

**Income Statement – Current Month Actual vs. Prior Month:**

- a) Our Inpatient Revenue is 13.3% higher than prior month due to higher patient days (1,506 vs. 1,383 prior).
- b) Outpatient Revenue is 7.8% higher than last month due to Outpatient, RHC and Emergency Room visits.
- c) Other Operating Revenues were increased \$6.0M due to CMS 340B settlement received (\$5.9M)
- d) Contractuals for the month are 17.0% of gross revenues (18.4% last mo.).
- e) Charity and Bad debt increased \$53k related to higher gross revenues.
- f) Salary expense is lower 9.3% due to lower worked hours (809 FTEs vs. 900 prior).
- g) Registry expense is lower 98.1% related to lower number of travel nurses required for operations.
- h) Employee benefits expense is higher 50.8% due to higher Health Insurance employee claims coupled with reclassification from “Other Fees”.
- i) Medical Prof Fee expense is 8.8% higher due to higher volumes.
- j) Non-Medical Prof Fee expense is 26.4% lower mainly due to lower attorney related expenses.
- k) Supplies medical are 4.7% higher due to higher volumes.
- l) Non-medical supplies are 12.1% higher mainly due to Oncology binders purchase (\$7k).
- m) Other Fees are lower 14.3% due to expense reclassification to insurance expense reclassification to “Employee Benefits”.
- n) Rent expense is higher \$14k related to Shared Imaging lease true-up in December 2023.
- o) Utilities expense is 7.2% higher due to electricity expenses.
- p) Insurance expense is 34.4% higher due to timing on Marsh Malpractice and Workers comp. installments.
- q) January 2024 shows a Net Gain of \$4.5M (*\$6.2M positive EBIDA*), showing steady improvement over the last couple of months.

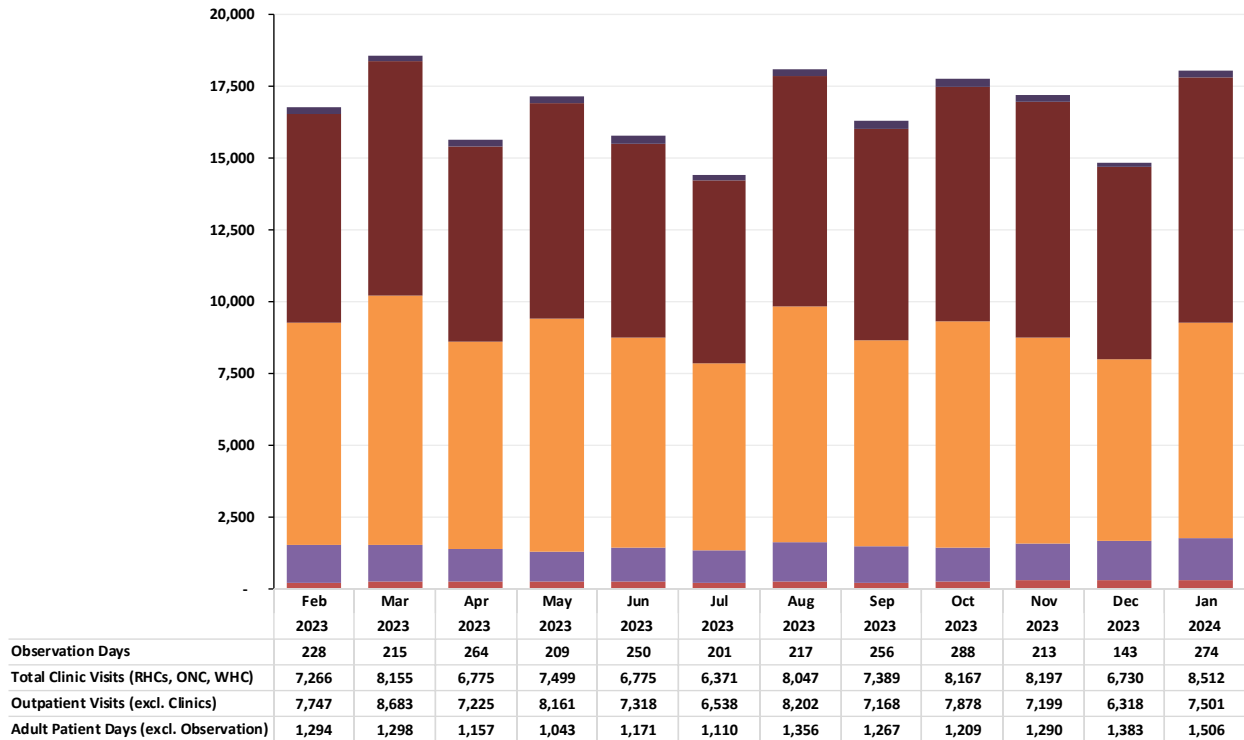
## **Definitions:**

- **EBIDA** - Earnings Before Interest, Depreciation, and Amortization.
- **Contribution Margin** – Total Revenue minus Expenses (excluding functional areas of IT, Finance, HR, and management assessments/restructuring costs).
- **EBIDA Margin** –  $EBIDA / \text{Total Revenue}$ .
- **Operating Expenses Per Day** – Total Expenses less Depreciation divided by Days.
- **Operating Revenue Per Day** –  $\text{Operating Income} / \text{Days}$ .
- **Days Cash on Hand** –  $\text{Cash} / \text{Operating Expenses per Day}$ .
- **Days Revenue in A/R** –  $\text{Accounts Receivable} / \text{Operating Revenue per Day}$ .
- **Current Ratio** –  $\text{Current Assets} / \text{Current Liabilities}$ .
- **Equity Financing Ratio** –  $\text{Total Capital} / \text{Total Debt}$ .

## EI Centro Regional Medical Center Comparative Volumes as of January 31, 2024

	Oct 2023	Nov 2023	Dec 2023	Jan 2024	YTD Actual	YTD Budget	YTD Variance
Adult Admissions (excl. Observation)	229	282	274	276	1,748	2,150	(402)
Patient Days (excl. Observation)	1,209	1,290	1,383	1,506	9,121	11,200	(2,079)
Average Length of Stay (excl. Observation)	5.3	4.6	5.0	5.5	5.2	5.2	0.0
Average Daily Census (excl. Observation)	39.0	43.0	44.6	48.6	42.4	42.4	-
Average Daily Census (ADC) Observation	9.3	7.1	4.6	8.8	7.4	6.9	0.5
Total ADC (including Observation)	48.3	50.1	49.2	57.4	49.8	49.3	0.5
Observation Days (excluding Obstetrics)	288	213	143	274	1,592	1,484	108
Outpatient Visits (excluding Clinics)	7,878	7,199	6,318	7,501	50,804	58,007	(7,203)
Emergency Room Visits	2,858	2,898	2,834	3,126	19,932	23,032	(3,100)
EI Centro Rural Health Clinic Visits	4,061	4,007	3,373	4,362	26,273	30,092	(3,819)
Calexico Rural Health Clinic Visits	3,224	3,221	2,602	3,261	21,064	21,467	(403)
Rural Health Clinic Visits - Total	7,285	7,228	5,975	7,623	47,337	51,559	(4,222)
Wound Healing Center Visits	222	210	158	206	1,312	1,236	76
Oncology Center Visits	660	759	597	683	4,764	4,806	(42)
Oncology Center Infusion Procedures	1,426	1,504	1,320	1,300	9,385	9,469	(84)
Surgeries without C-Sections	540	465	436	428	3,353	3,665	(312)
DaVinci Cases	56	59	60	35	378	254	124

### Rolling-12 Volume Trend



## ECRMC BALANCE SHEET COMPARED TO PRIOR MONTH

	January 31, 2024	December 31, 2023	Variance (\$)	Variance (%)
<b>Assets</b>				
<b>Current Assets:</b>				
Cash and Cash Equivalents	\$ 21,778,432	\$ 20,866,300	\$ 912,131	4%
Net Patient Accounts Receivable	16,024,861	14,427,839	1,597,022	11%
Other Receivables	69,952	147,222	(77,270)	-52%
Due from Third-Party Payors	18,698,372	17,054,501	1,643,871	10%
Inventories	2,815,708	2,830,580	(14,872)	-1%
Prepaid Expenses & Other	2,666,881	3,139,481	(472,600)	-15%
<b>Total Current Assets</b>	<b>62,054,207</b>	<b>58,465,924</b>	<b>3,588,283</b>	<b>6%</b>
<b>Assets Limited as to Use</b>				
Restricted Building Capital Fund	42,735	23,833	18,902	79%
Funds Held by Trustee for Debt Service	13,137,064	12,347,737	789,327	6%
Restricted Programs	11,497	11,497	-	0%
<b>Total Assets Limited as to Use</b>	<b>13,191,296</b>	<b>12,383,068</b>	<b>808,229</b>	<b>7%</b>
Property, Plant, and Equipment: Net	147,478,803	148,652,651	(1,173,848)	-1%
Other Assets	647,238	909,833	(262,595)	-29%
<b>Total Assets</b>	<b>223,371,543</b>	<b>220,411,475</b>	<b>2,960,068</b>	<b>1%</b>
<b>Deferred Outflows of Resources</b>				
Deferred Outflows of Resources - Pension	8,618,550	9,004,817	(386,267)	-4%
<b>Total Deferred Outflows of Resources</b>	<b>8,618,550</b>	<b>9,004,817</b>	<b>(386,267)</b>	<b>-4%</b>
<b>Total Assets and Deferred Outflows of Resources</b>	<b>\$ 231,990,093</b>	<b>\$ 229,416,292</b>	<b>\$ 2,573,801</b>	<b>1%</b>
<b>Liabilities</b>				
<b>Current Liabilities:</b>				
Current Portion of Bonds	1,320,000	1,310,000	10,000	1%
Current Portion of Capital Lease Obligations	1,288,683	1,331,408	(42,725)	-3%
Accounts Payable and Accrued Expenses	24,654,757	26,779,164	(2,124,406)	-8%
Accrued Compensation and Benefits	9,037,863	8,501,707	536,155	6%
Due to Third-Party Payors	38,097,181	38,097,181	-	0%
<b>Total Current Liabilities</b>	<b>74,398,484</b>	<b>76,019,460</b>	<b>(1,620,976)</b>	<b>-2%</b>
Long-Term Bond Payable, Less Current Portion	113,200,075	113,296,343	(96,267)	0%
Capital Lease Obligations, Less Current Portion	6,201,833	6,402,504	(200,671)	-3%
Net Pension Liability	54,174,600	54,174,600	-	0%
<b>Total Liabilities</b>	<b>247,974,992</b>	<b>249,892,907</b>	<b>(1,917,915)</b>	<b>-1%</b>
<b>Deferred Inflows of Resources</b>				
Deferred Inflows of Resources - Pension	113,800	113,800	-	0%
<b>Total Deferred Inflows of Resources</b>	<b>113,800</b>	<b>113,800</b>	<b>-</b>	<b>0%</b>
<b>Net Position</b>				
Restricted Fund Balance	17,238	17,238	-	0%
Fund Balance	(16,115,937)	(20,607,653)	4,491,716	-22%
<b>Total Net Position</b>	<b>(16,098,699)</b>	<b>(20,590,415)</b>	<b>4,491,716</b>	<b>-22%</b>
<b>Total Liabilities, Deferred Inflows of Resources and Net Position</b>	<b>\$ 231,990,093</b>	<b>\$ 229,416,292</b>	<b>\$ 2,573,801</b>	<b>1%</b>
Days Cash on Hand	52.51	48.04		
Days Revenue in A/R	39.75	40.46		
Days in A/P	85.57	89.19		
Current Ratio	0.83	0.77		
Debt Service Coverage Ratio	(0.19)	(0.82)		

## STATEMENTS OF OPERATIONS COMPARISON TO BUDGET

	MTD October 31, 2023	MTD November 30, 2023	MTD December 31, 2023	MTD January 31, 2024	YTD January 31, 2023	YTD January 31, 2024	YTD BUDGET January 31, 2024
Adult Admissions	229	282	274	276	2,451	1,748	2,150
Adult Patient Days (excl. Observation)	1,209	1,290	1,383	1,506	11,681	9,121	11,200
Outpatient Visits (excl. Clinics)	7,878	7,199	6,318	7,501	55,723	50,804	58,007
Total Clinic Visits (RHCs, ONC, WHC)	8,167	8,197	6,730	8,512	58,460	53,413	57,601
Observation Days	288	213	143	274	1,363	1,592	1,484
<b>OPERATING REVENUE</b>							
I/P Revenue	\$ 14,356,601	\$ 16,086,283	\$ 15,570,835	\$ 17,637,846	\$ 127,184,891	\$ 105,063,515	\$ 115,589,822
O/P Revenue - Laboratory	6,662,846	6,516,066	5,939,106	6,837,507	47,682,464	45,509,703	44,763,567
O/P Revenue - CT Scanner	6,284,614	6,053,020	6,058,167	6,494,259	44,815,602	44,577,487	42,614,797
O/P Revenue - Emergency Room	6,015,509	6,132,301	5,955,077	6,459,621	42,916,609	42,275,546	47,753,813
O/P Revenue - Oncology	5,742,087	6,490,018	5,197,115	6,275,825	35,646,793	40,277,812	40,665,682
O/P Revenue - Others	20,606,460	17,770,753	17,607,160	17,873,063	132,326,104	129,784,725	126,139,451
Gross Patient Revenues	59,668,118	59,048,441	56,327,461	61,578,121	430,572,463	407,488,788	417,527,132
Other Operating Revenue	316,468	257,669	286,607	6,280,334	2,729,366	8,240,945	3,312,763
Total Operating Revenue	59,984,585	59,306,110	56,614,068	67,858,456	433,301,829	415,729,733	420,839,895
Contractuals							
IP Contractuals	11,939,998	10,752,946	11,847,646	13,697,191	99,351,100	82,382,449	91,337,356
OP Contractuals	37,008,939	37,190,467	34,095,880	37,406,889	245,735,351	251,713,910	239,363,067
Charity	320,558	281,285	270,574	491,024	5,324,909	2,220,345	5,197,367
Provision for Bad Debts	425,000	443,470	446,303	278,400	2,934,136	2,871,264	2,304,582
Other Third Party Programs	(1,591,268)	(1,949,241)	(1,591,268)	(1,591,268)	(8,207,832)	(11,731,296)	(11,138,873)
M/Cal Disproportionate Share	(226,793)	(226,793)	(226,793)	(226,793)	(1,346,889)	(2,603,280)	(1,587,550)
Total Deductions	47,876,434	46,492,135	44,842,343	50,055,443	343,790,775	324,853,392	325,475,948
Total Net Revenues	12,108,151	12,813,975	11,771,725	17,803,012	89,511,054	90,876,342	95,363,947
<b>EXPENSES</b>							
Salaries & Wages	4,955,883	4,771,365	5,315,930	4,823,226	38,279,549	34,724,891	33,056,698
Registry	87,098	99,986	54,108	1,023	7,156,370	551,185	722,481
Employee Benefits	1,277,736	1,165,193	900,752	1,358,295	8,730,216	8,366,965	9,320,787
Employee Benefits - Pension GASB 68	376,430	386,267	375,986	386,267	1,996,763	2,683,751	2,237,200
Professional Fees - Medical	1,492,069	1,436,498	1,127,234	1,226,886	10,343,535	9,189,039	10,628,564
Professional Fees - Non-Med	239,220	352,065	340,075	250,417	2,606,186	1,954,421	1,670,281
Supplies - Medical	2,389,927	2,182,866	2,157,393	2,259,530	16,142,161	15,971,936	15,879,007
Supplies - Non-Medical	160,376	164,907	144,038	149,101	1,433,863	991,051	1,499,815
Food	74,460	83,904	78,801	70,026	609,152	545,635	567,797
Repairs and Maintenance	608,083	645,726	519,683	580,145	4,972,450	4,143,112	5,160,220
Other Fees	637,405	676,853	640,547	546,804	4,848,416	4,149,191	4,670,843
Lease and Rental	8,707	38,115	(3,819)	10,554	654,580	133,867	326,600
Utilities	183,103	212,258	198,873	213,151	1,381,576	1,483,375	1,380,362
Depreciation and Amortization	679,455	656,343	709,727	702,920	4,626,362	4,780,573	5,055,830
Insurance	173,067	300,249	163,738	220,143	1,397,392	1,574,583	1,414,295
Other Expenses	123,164	118,663	134,683	165,924	1,093,118	879,127	1,038,043
Total Operating Expenses	13,466,181	13,291,256	12,857,748	12,964,411	106,271,690	92,122,700	94,628,822
Operating Income	(1,358,030)	(477,281)	(1,086,023)	4,838,601	(16,760,636)	(1,246,358)	735,125
Operating Margin %	-11.2%	-3.7%	-9.2%	27.2%	-18.7%	-1.4%	0.8%
Non-Operating Revenue and Expenses							
Investment Income	16,138	100,590	2,561	244,192	287,297	542,161	127,166
Grants and Contributions Revenue	18,565	12,500	1,360	0	426,000	199,282	394,798
Non Operating Revenue/(Expense)	8,283	704,754	9,143	8,611	177,209	1,390,681	1,163,183
Interest Expense	(601,808)	(610,132)	(600,468)	(599,688)	(4,303,704)	(4,219,124)	(4,239,080)
Total Non-Operating Rev. and Expenses	(558,822)	207,711	(587,404)	(346,885)	(3,413,199)	(2,087,000)	(2,553,933)
(Deficit)/Excess Rev. Over Exp.	\$ (1,916,852)	\$ (269,570)	\$ (1,673,427)	\$ 4,491,716	\$ (20,173,835)	\$ (3,333,358)	\$ (1,818,808)
(Deficit)/Excess Rev. Over Exp. %	-15.8%	-2.1%	-14.2%	25.2%	-22.5%	-3.7%	-1.9%
EBIDA	(259,160)	1,383,171	12,754	6,180,590	(9,247,005)	8,350,089	9,713,302
EBIDA %	-2.1%	10.8%	0.1%	34.7%	-10.3%	9.2%	10.2%

**El Centro Regional Medical Center**  
**Monthly Cash Flow**

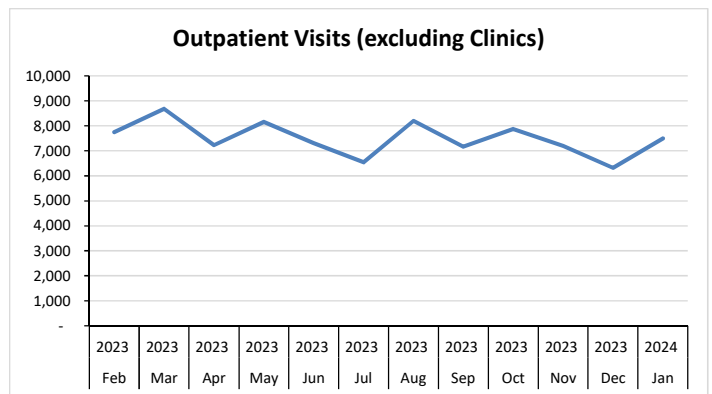
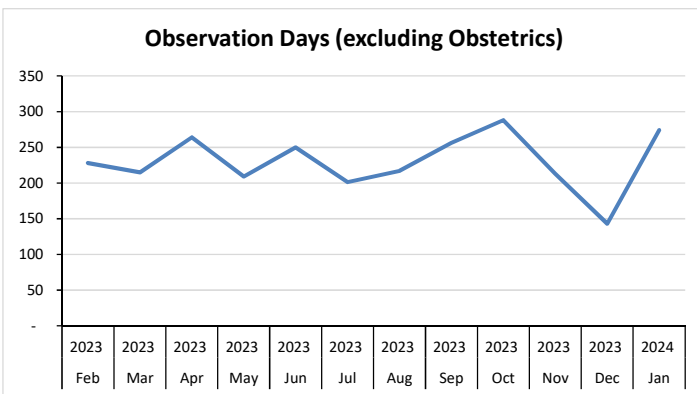
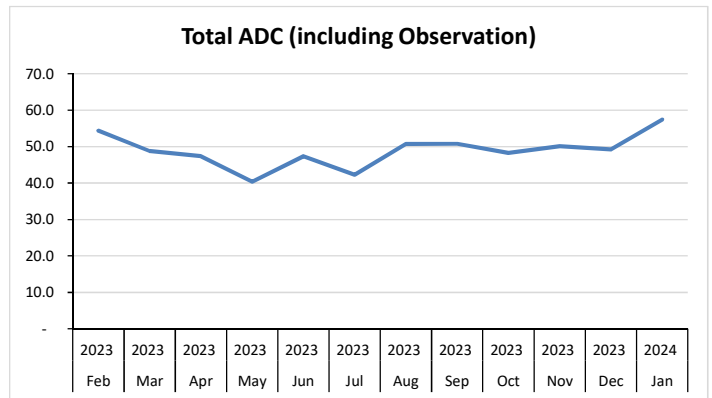
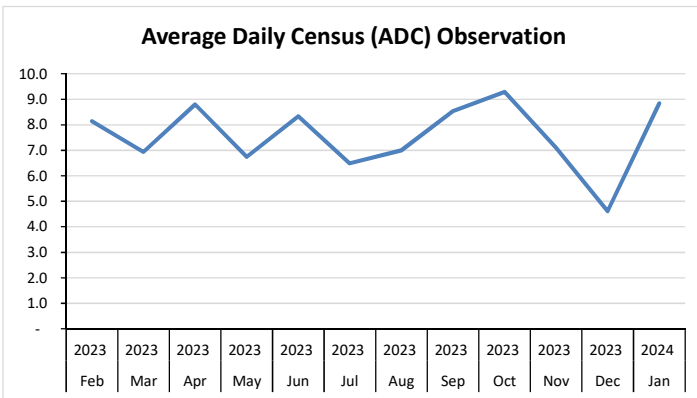
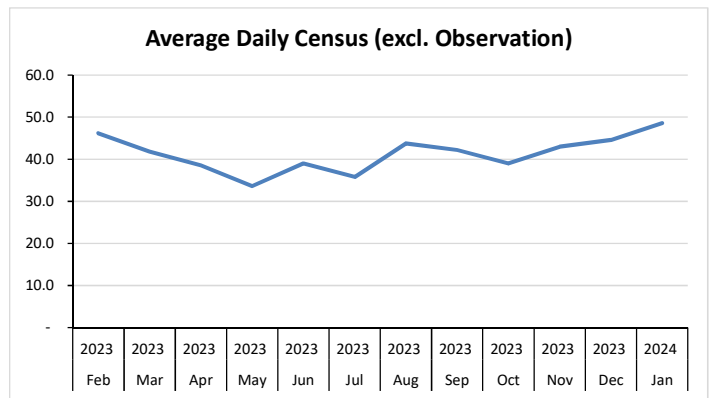
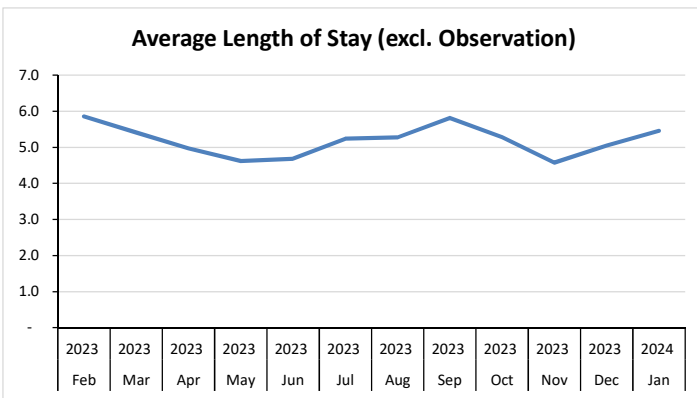
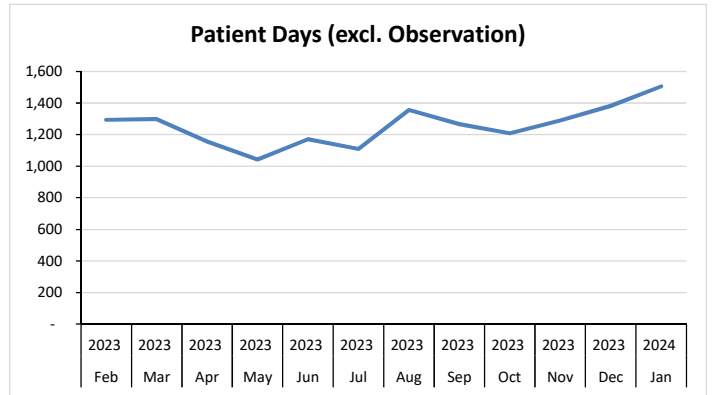
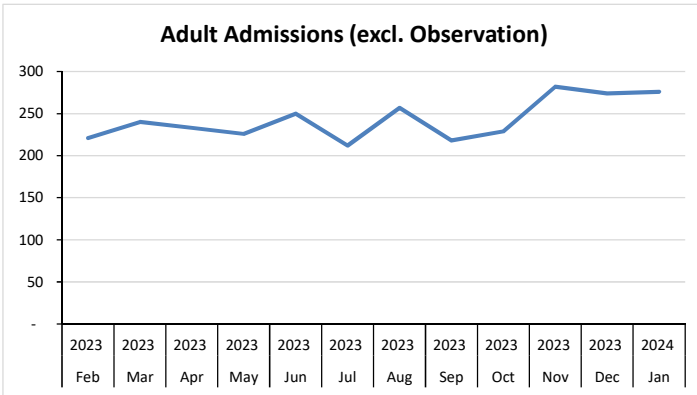
Unaudited

	July 2023	August 2023	September 2023	October 2023	November 2023	December 2023	January 2024	Year-to-Date 2024
<i>Cash Flow From Operating Activities</i>								
Net Income/(Loss)	\$ (1,693,276)	\$ 83,018	\$ (2,341,907)	\$ (1,916,852)	\$ (282,630)	\$ (1,673,427)	\$ 4,491,716	\$ (3,333,358)
<i>Adjustments to reconcile net income to net cash:</i>								
Add: Depreciation	687,349	685,421	659,358	679,455	656,343	709,727	702,920	\$ 4,780,573
Capital Lease Interest	10,925	10,082	9,561	8,804	12,188	10,271	9,266	\$ 71,096
Bond Interest	588,073	588,073	588,073	588,073	588,073	588,073	588,073	\$ 4,116,512
Accounts Receivable	525,767	(874,155)	425,746	(840,534)	(1,508,166)	1,226,187	(1,597,022)	\$ (2,642,178)
Other Receivables	53,835	(135,607)	3,196	90,258	(63,653)	54,942	77,270	\$ 80,241
Inventory	(90,320)	62,497	3,184	(17,349)	3,621	(37,635)	14,872	\$ (61,130)
Prepaid Expenses/Other Assets	(135,337)	341,100	241,311	(101,557)	(158,490)	(77,557)	735,195	\$ 844,664
Accounts Payable and Accrued Expenses	378,705	96,138	2,040,657	1,838,873	261,768	(2,035,283)	(2,872,479)	\$ (291,620)
Accrued Compensation and Benefits	339,108	(1,581,815)	281,567	612,150	342,711	579,715	609,887	\$ 1,183,322
Third-Party Liabilities	(1,818,060)	(1,842,679)	(1,781,141)	(1,174,454)	26,778,577	(1,203,959)	(1,643,871)	\$ 17,314,412
Net Pension Obligation	386,267	386,267	386,267	376,430	386,267	375,986	386,267	\$ 2,683,751
<i>Net Cash From Operating Activities</i>	\$ (766,964)	\$ (2,181,659)	\$ 515,872	\$ 143,296	\$ 27,016,608	\$ (1,482,961)	\$ 1,502,093	\$ 24,746,286
<i>Cash Flow From Investing Activities</i>								
Fixed Assets - Gross	\$ (21,365)	\$ (100,025)	\$ (625,596)	\$ (292,897)	\$ (4,187,130)	\$ (72,988)	\$ 470,928	\$ (4,829,073)
Intangible Assets - Gross	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Restricted Assets	4,509,875	(300,196)	(1,330,489)	468,290	(674,930)	(662,640)	(808,229)	\$ 1,201,680
<i>Net Cash From Investing Activities</i>	\$ 4,488,509	\$ (400,221)	\$ (1,956,085)	\$ 175,393	\$ (4,862,061)	\$ (735,627)	\$ (337,300)	\$ (3,627,392)
<i>Cash Flow From Financing Activities</i>								
Bond Payable	\$ (4,661,219)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ (4,661,219)
Capital Leases	(320,043)	(303,673)	(272,050)	30,075	(403,389)	(301,363)	(252,661)	\$ (1,823,104)
Notes Payable	-	-	-	-	-	-	-	\$ -
<i>Net Cash From Financing Activities</i>	\$ (4,981,262)	\$ (303,673)	\$ (272,050)	\$ 30,075	\$ (403,389)	\$ (301,363)	\$ (252,661)	\$ (6,484,323)
<i>Total Change In FY 2024 Cash</i>	\$ (1,259,717)	\$ (2,885,553)	\$ (1,712,263)	\$ 348,765	\$ 21,751,158	\$ (2,519,951)	\$ 912,131	\$ 14,634,570
<i>Cash &amp; Cash Equivalents, Beginning Balance</i>	7,143,861	5,884,145	2,998,592	1,286,329	1,635,094	23,386,252	20,866,300	7,143,861
<i>Cash &amp; Cash Equivalents, Ending Balance</i>	\$ 5,884,145	\$ 2,998,592	\$ 1,286,329	\$ 1,635,094	\$ 23,386,252	\$ 20,866,300	\$ 21,778,432	21,778,432

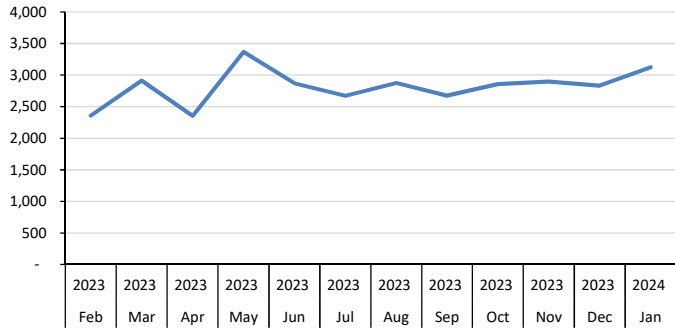
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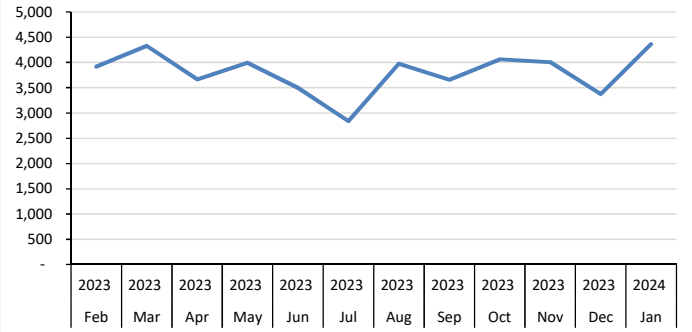
# El Centro Regional Medical Center Rolling-12 Volume trend



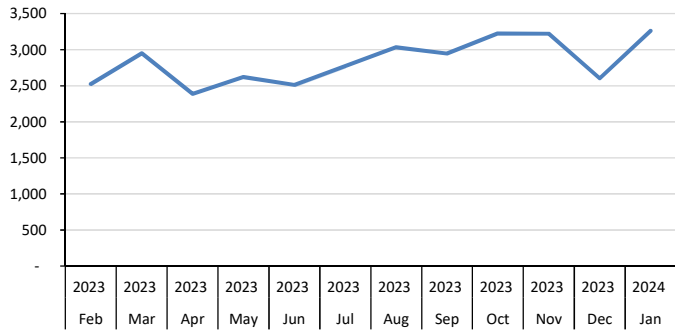
### Emergency Room Visits



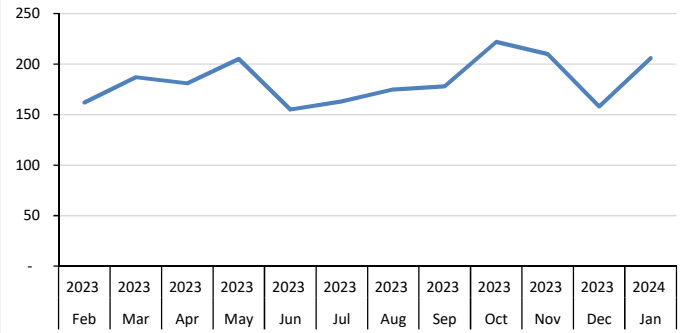
### El Centro Rural Health Clinic Visits



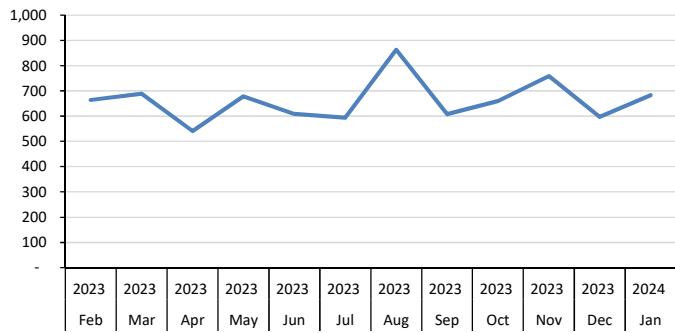
### Calexico Rural Health Clinic Visits



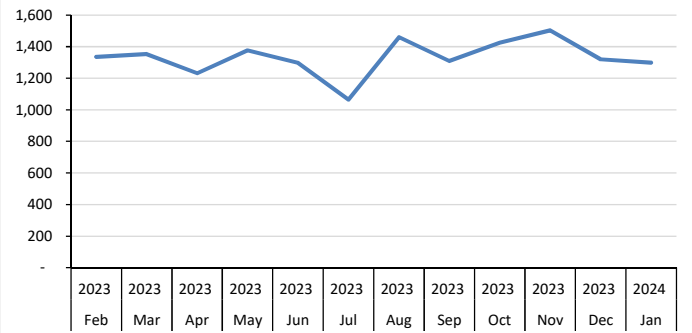
### Wound Healing Center Visits



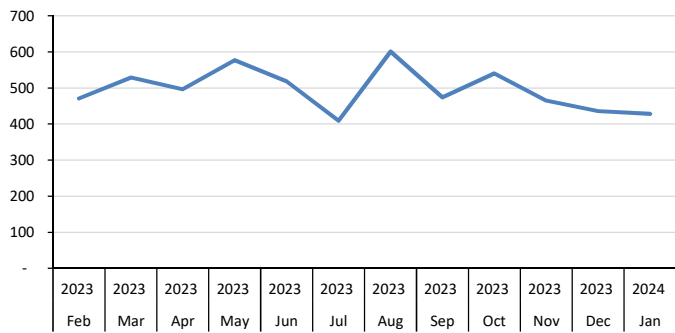
### Oncology Center Visits



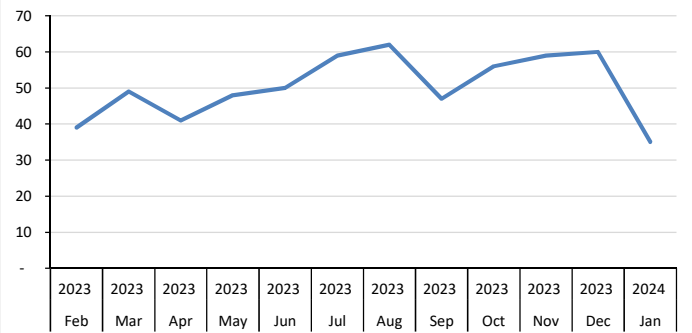
### Oncology Center Infusion Procedures



### Surgeries without C-Sections



### DaVinci Cases





**TO:** HOSPITAL BOARD MEMBERS  
**FROM:** David Momberg, Chief Financial Officer  
**DATE:** February 26, 2024  
**MEETING:** Board of Trustees

**SUBJECT:** 2024 Fiscal Year Cash Flow Projection (Informational)

**BUDGET IMPACT:**  Does not Apply  
A. Does the action impact/affect financial resources?  Yes  No  
B. If yes, what is the impact amount: \_\_\_\_\_

**BACKGROUND:**

Cash flow projection is an organizational overview to help leadership understand operational impacts of both cash receipts and disbursements. It is also a tool to ensure those cash outlays with significant impacts.

**DISCUSSION:** N/A

**RECOMMENDATION:** N/A

**ATTACHMENT(S):**

- Cash Flow Forecast –CY2024

Approved for agenda, Chief Executive Officer

Date and Signature: \_\_\_\_\_ *Pablo Velazquez*

El Centro Regional Medical Center

Cash Flow Forecast dated: January 27, 2024

Actual/Projection	Projection	Projection	Projection	Projection	Projection	Projection	Projection	Projection	Projection	Projection	Projection	Projection
Month	Jan 2024	Feb 2024	Mar 2024	Apr 2024	May 2024	Jun 2024	Jul 2024	Aug 2024	Sep 2024	Oct 2024	Nov 2024	Dec 2024
<b>Beginning Wells Fargo cash balance</b>	<b>20,927</b>	<b>21,642</b>	<b>18,610</b>	<b>10,835</b>	<b>27,682</b>	<b>28,987</b>	<b>29,551</b>	<b>28,922</b>	<b>26,434</b>	<b>22,833</b>	<b>21,149</b>	<b>20,230</b>
<b>Cash receipts</b>												
Patient receipts	7,698	10,842	13,553	10,842	10,842	13,553	10,842	13,553	10,842	10,842	13,553	10,842
Cerner Implementation - AR Slowdown	-	-	-	-	-	-	-	(750)	(1,200)	(1,425)	(1,125)	818
Pharmacy receipts	6,029	411	513	411	411	513	411	513	411	411	513	411
Collector deposits	-	98	123	98	98	123	98	123	98	98	123	98
Rent collection	-	3	4	3	3	4	3	4	3	3	4	3
Cafeteria receipts	5	5	6	5	5	6	5	6	5	5	6	5
Other receipts	323	66	83	66	66	83	66	83	66	66	83	66
<b>Total operating receipts</b>	<b>14,055</b>	<b>11,425</b>	<b>14,282</b>	<b>11,425</b>	<b>11,425</b>	<b>14,282</b>	<b>11,425</b>	<b>13,532</b>	<b>10,225</b>	<b>10,000</b>	<b>13,157</b>	<b>12,244</b>
<b>Total operating disbursements</b>	<b>(11,978)</b>	<b>(11,022)</b>	<b>(14,701)</b>	<b>(11,022)</b>	<b>(11,022)</b>	<b>(12,855)</b>	<b>(11,022)</b>	<b>(14,759)</b>	<b>(10,965)</b>	<b>(11,022)</b>	<b>(12,855)</b>	<b>(11,080)</b>
<b>Cash flow from operations</b>	<b>2,077</b>	<b>403</b>	<b>(419)</b>	<b>403</b>	<b>403</b>	<b>1,427</b>	<b>403</b>	<b>(1,227)</b>	<b>(739)</b>	<b>(1,022)</b>	<b>302</b>	<b>1,163</b>
Supplemental receipts	-	(2,580)	(4,547)	20,410	2,274	(104)	340	-	(1,650)	550	-	1,737
Capital expenditures	(1,290)	(160)	(2,105)	(3,271)	(677)	(717)	(677)	(557)	(517)	(517)	(517)	(517)
Bond payments	-	(662)	(662)	(662)	(662)	-	(662)	(662)	(662)	(662)	(662)	(662)
Other loan payments	(71)	-	-	-	-	-	-	-	-	-	-	-
Transfers (to)/from bond funds	-	-	-	-	-	-	-	-	-	-	-	-
Transfers (to)/from UBS	-	-	-	-	-	-	-	-	-	-	-	-
Restructuring Cost	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net non-operating cash flows</b>	<b>(1,361)</b>	<b>(3,435)</b>	<b>(7,356)</b>	<b>16,443</b>	<b>902</b>	<b>(863)</b>	<b>(1,032)</b>	<b>(1,260)</b>	<b>(2,862)</b>	<b>(662)</b>	<b>(1,220)</b>	<b>525</b>
<b>Net cash flow excl. sweep transfers</b>	<b>716</b>	<b>(3,032)</b>	<b>(7,775)</b>	<b>16,846</b>	<b>1,305</b>	<b>564</b>	<b>(629)</b>	<b>(2,487)</b>	<b>(3,601)</b>	<b>(1,684)</b>	<b>(919)</b>	<b>1,688</b>
<b>Beginning unrestricted cash</b>	<b>20,333</b>	<b>21,049</b>	<b>18,017</b>	<b>10,242</b>	<b>27,088</b>	<b>28,393</b>	<b>28,957</b>	<b>28,328</b>	<b>25,841</b>	<b>22,240</b>	<b>20,556</b>	<b>19,637</b>
Total net cash flow	716	(3,032)	(7,775)	16,846	1,305	564	(629)	(2,487)	(3,601)	(1,684)	(919)	1,688
<b>Ending unrestricted cash</b>	<b>21,049</b>	<b>18,017</b>	<b>10,242</b>	<b>27,088</b>	<b>28,393</b>	<b>28,957</b>	<b>28,328</b>	<b>25,841</b>	<b>22,240</b>	<b>20,556</b>	<b>19,637</b>	<b>21,325</b>