



DEPARTMENT: **POLICY NUMBER:**

Ancillary Division DPOTMH-MPP-HEMO-P007 (01)

TITLE/DESCRIPTION:

CORRECTIVE MEASURES FOR EXCEEDING AAMI WATER QUALITY STANDARDS IN HDC OPERATIONS

EFFECTIVE DATE: **REVISION DUE:** REPLACES NUMBER: NO. OF PAGES: 1 of 7

May 30, 2025 May 29, 2028 N/A

APPLIES TO: Hemodialysis Unit, Engineering

Department, IPCU

POLICY TYPE: Multi Disciplinary

PURPOSE:

1. To establish a standard procedure for taking immediate corrective action when water quality results exceed the Association for the Advancement of Medical Instrumentation (AAMI) standards in Hemodialysis Centers (HDC).

DEFINITIONS:

Association for the Advancement of Medical Instrumentation - is an alliance of individuals and organizations sharing interests in medical devices and instrumentation. Its 5,000 individual members include clinical and biomedical engineers and technicians, physicians, nurses, hospital administrators, educators, researchers, manufacturers, government representatives, and other health professionals. AAMI has 250 institutional members and 125 corporate members.

AAMI Standard - The standard set forth by the AAMI for water quality in medical device processing and dialysis.

RESPONSIBILITY:

Safety Officer, Hemodialysis Personnel, Infection Prevention and Control Unit Head

POLICY:

- 1. Corrective actions shall be performed to guarantee patient safety and regulatory compliance in the event that water quality test results surpass AAMI minimum limits.
- 2. Testing shall be conducted by Hemodialysis Supervisor and Safety officer and shall be documented.
- 3. The hemodialysis supervisor/safety officer shall maintain complete records of:
 - 3.1 Initial water test results.
 - 3.2 Investigation findings.
 - 3.3 All corrective and preventive measures taken.
 - 3.4 Repeat testing results.
 - 3.5 Records shall be retained in accordance with regulatory and organizational requirements.
- 4. System Downtime
 - 4.1 HDC operations shall remain suspended until:
 - a) All corrective actions have been completed.
 - b) The safety officer/hemodialysis supervisor repeats the water test and verifies that all effected parameters satisfy AAMI water standards.

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PROCEDURE (SOP):

1. Identification and Immediate Response

- 1.1. The Hemodialysis Supervisor/Safety Officer obtains water analysis findings that are higher than AAMI guidelines, they shall promptly stop operations in the affected area.
- 1.2. The Hemodialysis Supervisor/Safety Officer notifies the appropriate HD unit Head or HD unit Manager.
- 1.3. Hemodialysis Clinic's Head will notify the DOH and management once operations are suspended.

2. Root Cause Investigation

- 2.1. Hemodialysis patient in affected area will be transferred/rescheduled to other unit.
- 2.2. The Safety Officer conducts a thorough investigation to identify the suspected source of contamination or deviation.
- 2.3. Safety officer documents the suspected cause(s).

3. Corrective Actions

- 3.1. Hemodialysis Technician undertakes necessary disinfection, maintenance or repair in the identified area(s).
- 3.2. All corrective measures taken by Hemodialysis Technicians/Safety Officer are meticulously recorded, including the replacement of parts, the services rendered, and the accountable parties.

4. Repeat Testing

4.1. The Safety Officer/Hemodialysis Supervisor performs repeat testing of all parameters that initially exceeded the standard.

5. Resume Operations

5.1. The Hemodialysis Unit Head, Safety Officer, and Infection Prevention and Control Head notifies and recommend the management and DOH to resume the operation once the repeat testing result is compliance with the AAMI water quality standard.

6. Documentation and Record Keeping

6.1. The DOH will be informed of the findings of repeat testing result by the Hemodialysis Unit Head.





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ORK INSTRUCTION:			
KEY TASKS	PERSON RESPONSIBLE		
 Upon receiving water analysis results the exceed AAMI standards, operations in th affected area shall be immediately halted. 	Hemodialysis Supervisor/Safety Office		
2. Hemodialysis patient in affected areas will b transferred/rescheduled to other unit.			
3. Notifies the appropriate Head of the HD un Head or Unit Manager.			
4. Notifies the DOH once operation is suspended.	Hemodialysis Unit Head		
5. Conducts a thorough investigation to identify th suspected source of contamination or deviation.			
6. Documents the suspected cause(s).			
 Documents all corrective actions, including parts replaced, services performed, and responsible personnel. 			
8. Performs repeat testing of all parameters that initially exceeded the standard.	t Hemodialysis Supervisor/Safety Officer		
 Maintains detailed records of initial water test results, investigation findings, corrective measures, and repeat testing results, retained in accordance with regulatory and organizational requirements. 			
10. Undertakes necessary disinfection, maintenanc or repair in the identified area(s).	Hemodialysis Supervisor		
11. Operations will be resumed once the corrective	HD Unit Head/IPC Unit Head/ Safety Offic		





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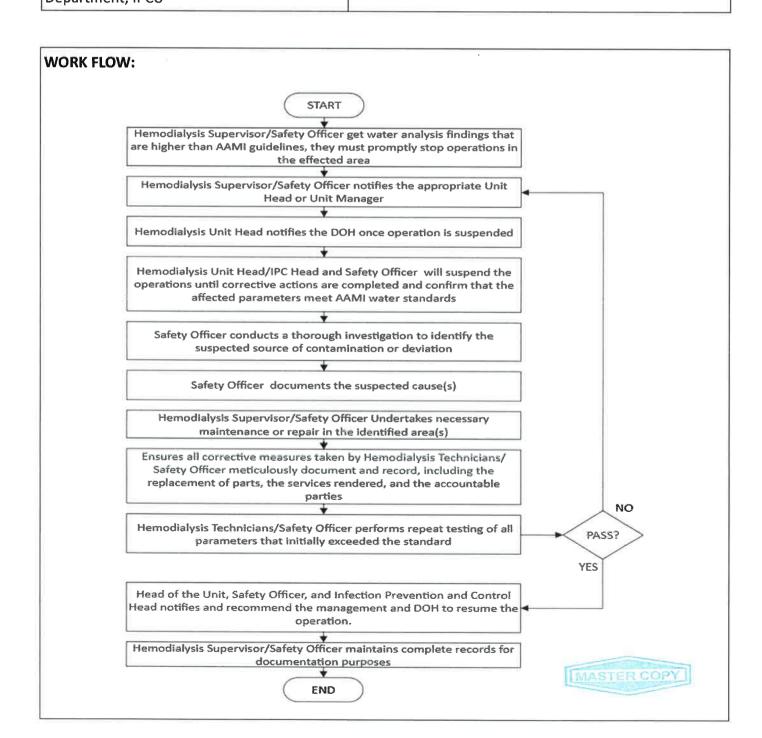
actions are completed and confirm that the	
affected parameters meet AAMI water	
standards.	





METRO PACIFIC HEALTH

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FORMS: N/A

EQUIPMENT: N/A

REFERENCES:

AAMI Water Quality Standards for Hemodialysis (ANSI/AAMI 26722)







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Approvals:				
	Name/Title	Signature	Date	TQM Stamp
Prepared by:	JACKLYN ROSE B. PALMARES Hemodialysis Supervisor	Helme	\$ 26/25	
	CARL JAMES BOLLON OIC-Hemodialysis Technician Supervisor	- American	t-24.NI	
Reviewed by:	WENDY MAE D. GOMEZ Accreditation and Documentation Manager	gran	J. 24. W.S	
Approved By:	JOHAIRAH M. DIRAMPA Kidney Care Center Manager	Stry	05-27-2025	
	DOLORES ROMMELA T. RUIZ, MD Infection Prevention and Control Unit Head	Ank	OJ- 29-2T	TOD
	LEO MANUEL D. TUMANENG, MD Kidney Care Center Director		05-30-25	
	MARIA REMEDIOS R. TOMAS, MD Hemodialysis Unit Head	Mus	5-30-25	
	ROSARIO D. ABARING Ancillary Division Head	Placing & 4.	05 - 26 - 2025	
	JOSE PEPITO B. MALAPITAN, MD Medical Director	7	5-30-25	
	MA. ANTONIA S. GENSOLI, MD VP/Chief Medical Officer	man	05-30-15	
Final Approved By:	GENESIS GOLDI D. GOLINGAN President and Chief Executive Officer	#18	05-30-25	

