

**OPTIONAL WORKSHEET**  
**INTERVIEW/OBSERVATION: REPROCESSING TECHNICIAN**  
**REVIEW OF LOGS & QA (TASK 7)**

**Facility:** \_\_\_\_\_ **CCN:** \_\_\_\_\_

**Surveyor:** \_\_\_\_\_ **ID#:** \_\_\_\_\_

Note: This worksheet is intended for use while conducting Tasks 7a, 7b, and 7c. The observations of the set up/priming of reprocessed dialyzers in preparation for dialysis, and corresponding germicide tests and safety checks are conducted during Task 3b Observations of Hemodialysis Patient Care.

If you identify concerns while conducting the Reuse review, refer to the facility policy/procedure, training program and/or personnel files of involved staff for further investigation of the concern(s).

**Task 7a: Observations and Interview with Reprocessing Personnel**

Reuse Tech: \_\_\_\_\_ Date/time: \_\_\_\_\_

Reprocessing Equipment: \_\_\_\_\_ Germicide: \_\_\_\_\_

Observation of reprocessing area, equipment, & stored dialyzers	Deficient Practice?	
Does the reprocessing area and equipment appear clean, sanitary, organized and maintained; Are "clean" and "dirty" areas separated, new and reprocessed dialyzers stored separately, and clear separation between used/dirty, failed, and reprocessed dialyzers?	<input type="checkbox"/> V318 <input type="checkbox"/> V321	<input type="checkbox"/> No
Are there noticeable odors of germicide? If so, ask: When/how are air levels of germicide tested? ( <b>Note:</b> You may wish to review the germicide vapor testing results now rather than during Task 7b)	<input type="checkbox"/> V318	<input type="checkbox"/> No
Is the room temperature appropriate for storage of the germicide in use and the storage of reprocessed dialyzers?	<input type="checkbox"/> V319 <input type="checkbox"/> V321 <input type="checkbox"/> V345	<input type="checkbox"/> No
Are used/dirty dialyzers on the counters at room temperature? Are they reprocessed within 2 hours or refrigerated? Is the refrigerator maintained at blood storage temperature & temperature monitored?	<input type="checkbox"/> V331	<input type="checkbox"/> No
Are reprocessed dialyzers labels intact with at least the patient's name, number of previous uses, date of last reprocessing, and initials of person who did the reprocessing?	<input type="checkbox"/> V327	<input type="checkbox"/> No
Are dialyzers of patients with same or similar names clearly marked to alert staff?	<input type="checkbox"/> V330	<input type="checkbox"/> No
Are reprocessed dialyzers protected from unauthorized access, damage and contamination?	<input type="checkbox"/> V321	<input type="checkbox"/> No

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Observe the Reuse Technician reprocess 2-3 dialyzers. Ask the Reuse Technician to describe the reprocessing procedures. Ask the interview questions before or during the observations.

Observation of reprocessing procedures	Deficient Practice?	
<b>PPE use:</b> Observe: Are staff using PPE appropriate to the tasks performed and the germicide (durable gloves, face shield/mask/goggles, gown) ?(if formaldehyde, a respirator program including fit testing must be in place)	<input type="checkbox"/> V320	<input type="checkbox"/> No
<b>Germicide safety:</b> Ask/observe: What are the procedures for germicide/chemical spills; Are there readily available equipment & supplies in the case of splashes (i.e. eyewash station, spill kit) or spills of chemicals and/or germicide?	<input type="checkbox"/> V319 <input type="checkbox"/> V320	<input type="checkbox"/> No
<b>Dialyzer Labeling and Preprocessing:</b> Ask/Observe: When is a patient's dialyzer labeled? How is the original volume of each dialyzer determined? What system is used for labeling the dialyzers of patients with same or similar names?	<input type="checkbox"/> V328  <input type="checkbox"/> V336 <input type="checkbox"/> V330	<input type="checkbox"/> No
<b>Transport to Reprocessing Area:</b> Observe: Are used/dirty dialyzers transported in a clean/sanitary manner (all ports capped, not cross-contaminating other dialyzers)? If dialyzers are refrigerated, Ask: How long after dialysis must a dialyzer be reprocessed or refrigerated; What is the maximum time a dialyzer may be refrigerated prior to reprocessing?	<input type="checkbox"/> V331	<input type="checkbox"/> No
<b>Pre-Rinsing/Cleaning Dialyzers:</b> Observe/Ask: Are water pressures at the pre-rinse sink monitored and maintained within dialyzer parameters? Is cross-contamination avoided by disinfecting equipment connections between dialyzers or the use of barrier adaptors? If header caps are removed, are the dialyzer headers, caps and o-rings cleaned and disinfected appropriately?	<input type="checkbox"/> V332  <input type="checkbox"/> V331  <input type="checkbox"/> V334	<input type="checkbox"/> No
<b>Volume and Pressure/Leak Testing:</b> Ask/Observe: How is the dialyzer total cell volume after each treatment tested; What is the cut off for volume failing a dialyzer? How is the pressure/leak (blood path integrity) test done? Where are dialyzer failures recorded?	<input type="checkbox"/> V336  <input type="checkbox"/> V337 <input type="checkbox"/> V356 <input type="checkbox"/> V357	<input type="checkbox"/> No

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<b>Observation of reprocessing procedures (continued)</b>	<b>Deficient Practice?</b>	
<b>Filling with Germicide:</b> Observe/Ask: Is germicide used in accordance with manufacturer's directions for dilution and shelf-life (not used beyond expiration date)? Is the exterior of the dialyzer cleaned with a low-level disinfectant? Are the port caps disinfected before use and reuse? Are dialyzers filled with sufficient amount of germicide before being capped? How are dialyzers tested to verify the correct concentration of germicide is present after reprocessing? How long must dialyzers be filled with germicide before they can be used for dialysis? How long may a reprocessed dialyzer stay on the shelf (when a patient is absent) before it must be refilled with fresh germicide?	<input type="checkbox"/> V339  <input type="checkbox"/> V342 <input type="checkbox"/> V340  <input type="checkbox"/> V341  <input type="checkbox"/> V349  <input type="checkbox"/> V345	<input type="checkbox"/> No
<b>Inspection and Labeling After Reprocessing:</b> Observe/Ask: Is the dialyzer examined after reprocessing; What criteria are you looking for? What and where is dialyzer reprocessing information recorded?	<input type="checkbox"/> V343  <input type="checkbox"/> V326	<input type="checkbox"/> No

**Task 7b: Review of Reuse Logs and QA**

<b>Review of reuse logs</b>	<b>Deficient Practice?</b>	
<b>Reprocessing logs: Review the logs for several patients:</b> Are complete, accurate dialyzer reprocessing records kept for each patient separate? Is there a log for dialyzer failures? For adverse events possibly related to reuse?	<input type="checkbox"/> V305 <input type="checkbox"/> V326 <input type="checkbox"/> V357 <input type="checkbox"/> V356	<input type="checkbox"/> No
<b>Air Vapor Testing: Review the results of air vapor tests for the last 3 tests:</b> Were the tests conducted per facility policy, and results recorded? Did the air vapor levels exceed acceptable levels? If so, what action was taken to protect patients and staff?	<input type="checkbox"/> V318 <input type="checkbox"/> V364	<input type="checkbox"/> No
<b>Reuse Water Quality/Cultures: Review the past 12 months of water cultures done in the reuse room:</b> Were at least monthly cultures taken as close as possible to where the dialyzers are connected to the reprocessing system? Is only AAMI quality water used for reprocessing (the inside compartments of the dialyzers)?	<input type="checkbox"/> V314	<input type="checkbox"/> No
<b>Preventive Maintenance (PM) and Repair: Review 12 months of reprocessing equipment PM and repair logs:</b> Are PM procedures and repairs performed by qualified personnel, in accordance with manufacturer's directions and recorded? Is equipment tested after repairs and before being placed back in service?	<input type="checkbox"/> V316  <input type="checkbox"/> V317	<input type="checkbox"/> No

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Review of reuse logs (continued)	Deficient Practice?	
<p><b>Quality Assurance:</b> If you do not identify problems with the dialyzer reprocessing program, briefly review 12 months of QA Audit results, to verify they are routinely done. For problems identified in reprocessing, focus the QA review on the facility's oversight of those problem areas:</p> <p><b>The required Reuse QA Audits are:</b></p> <p><b>Monthly:</b>  Water cultures</p> <p><b>Quarterly:</b>  Dialyzer labeling</p> <p>Preparation for Dialysis</p> <p>Storage; PPE use</p> <p><b>Semi-annual:</b>  Reprocessing procedures</p> <p>Supplies/stock rotation; Germicide quality testing</p> <p><b>Annual:</b>  Written procedures; Maintenance/repair policies</p> <p>Reprocessing area/ventilation</p> <p>Patient informed consent</p>	<input type="checkbox"/> V314  <input type="checkbox"/> V366  <input type="checkbox"/> V368  <input type="checkbox"/> V364  <input type="checkbox"/> V367  <input type="checkbox"/> V365  <input type="checkbox"/> V363  <input type="checkbox"/> V364  <input type="checkbox"/> V362	<input type="checkbox"/> No

**Task 3c Centralized Reprocessing**

When dialyzers are reprocessed at another (off-site) location, you must conduct Task 7a and applicable parts of Task 7b at that location, using the guidelines/questions above. Additional questions for centralized reprocessing are focused on the safe transportation of dialyzers between the dialysis facility and the reprocessing location and the coordination between the two.

Centralized Reprocessing	Deficient Practice?	
<p><b>Transportation: Ask/Observe:</b> How are dialyzers transported to and from the reprocessing location; Are temperature parameters monitored and maintained during transport (within blood product parameters for dirty dialyzers; within germicide manufacturer instructions for reprocessed dialyzers)?</p>	<input type="checkbox"/> V331	<input type="checkbox"/> No
<p><b>Communication with facility/QA:</b> Ask: How do you communicate with the dialysis facility about daily activities and problems? How do you coordinate QA activities with the facility?</p>	<input type="checkbox"/> V360	<input type="checkbox"/> No