



**ESRD Update:
Transitioning to New ESRD Conditions for Coverage
Student Manual**

Lesson #5: Reuse

Learning Objectives

At the conclusion of this lesson, you will be able to:

- List requirements for the Condition of Reuse
- List survey tasks to be used in evaluating compliance with the Condition of Reuse
- Describe changes from previous requirements of the Condition of Reuse

Reuse

Or... Everything You Never *Really*
Understood About Reuse
Requirements

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Objectives

- List requirements for the Condition of Reuse
- List survey tasks to be used in evaluating compliance with the Condition of Reuse
- Describe changes from previous requirements of the Condition of Reuse

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Reuse Overview

- Approx 40% of facilities currently reprocess and reuse dialyzers
- ESRD Survey Task 7- Reuse includes:
 - 7a: Observations of reprocessing procedures/interview with reuse personnel
 - 7b: Review of reuse logs
 - 7c: Centralized reprocessing review

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Reuse Overview

Clarification of terms:

- “Reprocessing:” *the processes of cleaning and germicide instillation into the dialyzer*
- “Reuse:” *the clinical use of the reprocessed dialyzer*
- “Manufacturer’s Directions for Use” (DFU): common theme throughout the technical areas of these regs
- “Manual” vs. “Automated” reprocessing

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Centralized Reprocessing

- Dialyzers are transported to an off-site location for reprocessing
- No separate tags: discussed in the IGs of pertinent tags (i.e. V331 for transportation and handling)
- Surveyors must observe dialyzer reprocessing at the centralized location
- Any deficient practices in centralized reprocessing locations affect all user ESRD facilities; Condition-level findings must be cited for all user facilities.
- Each ESRD user facility must have P&Ps for tasks performed at that facility (e.g., set up for use, rinse back post tx.)

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Reuse of Hemodialyzers § 494.50

- The Condition most like the current CfCs, due to updates in the '90s
- Adopts an updated version of RD47 from 2002/2003
- Much of the technical, “chatty” language has been eliminated
- Reordered for better “flow”

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Reuse Regs Overview

- Organized into 3 general areas:
 - “**Process**” - general requirements, program set up, design, and environmental safety (V301-V325)
 - “**Practices**” - actual dialyzer reprocessing and reuse procedures (V326-V353)
 - “**Oversight**” - patient monitoring, adverse events and QA (V354-V383)

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Reuse Regs: “Process”

- No reuse dialyzers for HBV+ patients (V301)
- Dialyzers for reuse must be labeled for multiple use (V302)
- Program set up and design = 5 sections:
 - **Records**: meet MR standards, centralized in reprocessing manual (V305,V306)
 - **Personnel**: qualifications, training, health monitoring (V307-310)
 - **Patients**: must be informed, individual medical conditions considered, have an order for reuse (V311, V312)

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Reuse Regs: “Process”

- Program set up and design:
 - **Equipment/physical environment**: AAMI quality water used for ALL processes, ventilation adequate, germicide air testing, reprocessing equipment set up and maintenance, PPE (V313-321)
 - **Reprocessing supplies/testing**: efficacy and testing established, proper storage (V322-V325)

How do we survey for these requirements???

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Surveying for Reuse “Process”

- **Task 7b: Review of Reuse logs:**
 - o Look at the **reprocessing logs** for several patients: track the dialyzer hx, check dialyzer storage times for absent patients
 - o Review the results of **cultures and EU testing** done in the reuse room: monthly from the water source and each reprocessing system
 - o Review the reprocessing **equipment maintenance** and repair logs-per manufacturer DFU or at least semiannually ¹⁰

Surveying for Reuse “Process”

- **Task 7a: Observations of reprocessing procedures/interview with reuse personnel:** if concerns are identified, refer to the corresponding P&P, manufacturer’s DFU, reuse training program &/or the personnel files
- **Task 10: Patient interviews:** patients informed regarding reuse
- **Task 11: Medical record reviews:** evidence of patients informed, order for dialyzer reuse

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Clicker Question!!!

- **The regulations at the beginning, “process” part of the Reuse CfC refer to:**
 - A. The sediment filter in the water system
 - B. Life Safety Code 2000 requirements
 - C. The set up, design and environmental safety of the reuse program
 - D. P&Ps for involuntary discharge

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Reuse Regs: "Practices"

Here's the BEEF!!!!

- Organized into 3 sections:
 - o **Records and dialyzer labeling** (V326-330)
 - o **Transporting, rinsing, testing, germicide instillation; a.k.a. reprocessing** (V331-345)
 - o **Set up for clinical use; a.k.a. reuse** (V346-353)

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Reuse Regs: "Practices"

Records and dialyzer labeling

- **Reprocessing record:** track hx of dialyzer, "when, who", part of patient medical record (V326)
- **Dialyzer labeling:** prior to first use, sufficient information,
similar names warning (V327-330)

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Reuse Regs: "Practices"

Transporting, rinsing, testing, germicide instillation; a.k.a. **reprocessing**

Transportation and handling: of the dialyzers (V331)

- o Clean and sanitary, prevent cross-contamination
- o Reprocessed or refrigerated within 2 hours max

Especially important with centralized reprocessing

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Reuse Regs: "Practices"

Transporting, rinsing, testing, germicide instillation; a.k.a. **reprocessing**

▪ Rinsing/cleaning

- o **Pre-rinse/precleaning:** if done, pressures monitored (V332), AAMI quality water (V333)
- o **Header space cleaning:** a stream of AAMI quality water only, end caps and O-rings kept together, disinfected and reassembled wet w/germicide (V334)

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Reuse Regs: "Practices"

Transporting, rinsing, testing, germicide instillation; a.k.a. **reprocessing**

▪ Testing the dialyzer:

- o **Total Cell Volume (TCV):** original volume must be known prior to first use: "preprocessed" **required** if the dialyzer will be reprocessed and reused. Dialyzer must maintain at least 80% TCV to continue to be used (V336)
- o **Blood path integrity/leak test:** done with every reprocessing (V337)
- * **Manual reprocessing: observe these tests**

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Reuse Regs: "Practices"

Transporting, rinsing, testing, germicide instillation; a.k.a. **reprocessing**

▪ Germicide instillation:

- **Process must provide "high level disinfection"** for blood and dialysate compartments, "low level disinfection" for outer casing & port caps(V338-342)
- **After reprocessing:** germicide concentration verified-at least once/mo from each automated system (V341)
- **Inspection/storage:** passes "aesthetics" inspection prior to storage, storage time(V343-345)

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Reuse Regs: "Practices"

- Set up for clinical use; a.k.a. **reuse**
- **Visual inspection:** aesthetics prior to rinsing: *Yes, there is a second one!* (V347)
 - **Patient ID:** 2 people verify **after** patient is present at the patient station (V348)

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Reuse Regs: "Practices"

- Set up for clinical use; a.k.a. **reuse**
- **Germicide tests:** germicide contact time (V349), germicide presence prior to rinsing(V350-351), germicide residual after rinsing (V353)
 - **Priming/rinsing:** by a process proven to rinse out the germicide, re-test if delay in dialysis start: "rebound" (V353)

How do we survey for reuse practices???

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Surveying for Reuse "Practices"

Observe, Observe, Observe!!

Task 3a: Environmental tour:

- **Observe** the dialyzers and dialysis treatment records for patients on dialysis: pre-dialysis checks documented, dialyzers appearance and labeling as required
- **Observe** the stored reprocessed dialyzers for aesthetics and labeling

Task 3b: Observation of hemodialysis patient care: Watch carefully for the pre-dialysis safety/germicide checks and priming procedures.

- Note the reagents being used: high level vs. low level sensitivity
- Patient ID done by 2 people

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Surveying for Reuse “Practices”

Task 7a-Observations of reprocessing procedures/interview with reuse personnel:

- **Observe** reprocessing for 2-3 dialyzers, from transportation to storage. Interview reuse tech to determine knowledge level.

Task 7c-Centralized reprocessing:

- **Observe** the set up and take down of the reprocessed dialyzer at the facility, and go to the centralized site for reprocessing observations.

Task 11-Medical record review:

- Review the **dialysis treatment records** for documentation of the safety/germicide tests

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Clicker Question!!!

- **Safety checks that must be completed and documented before a patient’s dialysis is started include:**

- A. Verification of germicide contact time
- B. Visual inspection
- C. Germicide presence and residual test
- D. Verification of patient ID
- E. All of the above

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Reuse Regs: Oversight Divided into 3 Sections:

1. **“Routine” patient monitoring:** each patient’s clinical course (V354), fluid removal/weight (V359), Kt/V/adequacy (V358)
2. **Adverse events:**
 - **Patient symptoms:** fever/chills, symptoms which may be related to the reprocessed dialyzer (V355, V381)
 - **Cluster of adverse patient reactions:** STOP reuse! (V382)
 - **Dialyzer leaks and failures:** recorded on “complaint log” (V357)
 - **FDA reporting:** facility responsibility if AE occurs, not manufacturer (V383)

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Reuse Regs: “Oversight”

3. Quality Assurance requirements for reuse:

These are not new, but always look for them!

- **Reuse QA program established**, Medical Director responsible (V360-361)
- **Scheduled audits** of specific aspects of reprocessing/reuse program
 - **Quarterly**: dialyzer labeling (V366), preparation for dialysis i.e. priming, germicide tests, pt ID (V368) **must observe practice!**
 - **Semiannual**: reprocessing procedures (V367) **observe the reuse techs**; reprocessing supplies (V365)
 - **Annually**: patients informed (V362), manuals & P&Ps (V363)

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Surveying for Reuse “Oversight”

Task 7b-Review of reuse logs:

- Briefly review completion of the audits: especially if you identify concerns in any of the reprocessing and reuse practices

Task 13-QAPI:

- Audits should be summarized in the QAPI minutes;
- Look for action/performance improvement plans if problems were identified by the QAPI committee

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Clicker Question!!!

- **The Reuse QA audit of “reprocessing procedures” can be completed by giving the reuse technicians a written test twice a year.**

- A. True
- B. False

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Reuse

The Last Slide!!!

Questions?

Thanks!

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