Objectives

*After completing this module, the learner will be able to:*

1. Discuss the history of dialyzer reprocessing.
2. List two reasons why dialysis centers reprocess dialyzers.
3. Explain the steps involved in dialyzer reprocessing.
4. Discuss the hazards to patients and staff that can occur with dialyzer reprocessing.
5. List the required documentation for dialyzer reprocessing.
Introduction

The dialyzer is a feat of engineering: complex enough to do some of the work of a human kidney, yet simple enough to be mass-produced, and reliable enough to be used many times. For medical and non-medical reasons, many dialyzers are reprocessed: cleaned and disinfectected to be used again by the same patient instead of being thrown out after a single use. This is called reuse.

Dialyzer reprocessing is regulated by the federal and some state governments. Regulations include the standards and conditions centers must follow so reuse is as safe and effective as possible for both patients and staff.

A reprocessing technician has the immense job of maximizing patient benefits of reuse and reducing the risks. This is done by carefully following all of the guidelines, regulations, and center procedures.

This module covers the history of the reasons for reprocessing, the role of regulations and guidelines, and the steps used to reprocess dialyzers.

History of Dialyzer Reprocessing

Dialyzer reprocessing has been around since the late 1960s. At first done by hand, reprocessing is now most often done with a machine. Many factors aided the development and types of reuse equipment; one was the evolution of dialyzers themselves.

By the mid-1960s, most patients were treated with Kiil dialyzers (see Figure 1). A Kiil was a “sandwich” made of layers of membrane sheets held apart by grooved boards of polypropylene plastic. Rubber gaskets and metal clamps held the sandwich together. The Kiil had to be assembled and pressure tested before each use—a slow and complex technique. Often—10%–20% of the time—it would fail the pressure test, and the whole process would have to start over with fresh sheets of membrane.

In 1967, Dr. Belding Scribner (who helped devise the vascular access) reported that the blood compartment of a Kiil could be filled with a germicide (germ-killing solution), rinsed, and used for the next treatment. The Kiil did not have to be taken apart and rebuilt. This was one of the first examples of dialyzer reprocessing. For Dr. Scribner, the main reason for reusing Kiiils was to save home patients the time and trouble of “tearing down” and rebuilding them. At that time, most of Dr. Scribner’s patients were doing home hemodialysis in his Seattle program.
By the late 1960s, new coil dialyzers were preferred for reuse. Coils were easier to set up and prime (fill and rinse with normal saline) than Kiils, but too costly for many hospitals to use as disposable or single-use products, as manufacturers suggested. Prior to reuse, they were filled with a disinfecting solution to kill germs and kept in a refrigerator with sterile water in the blood compartment.2

By the late 1970s, “disposable” parallel plate dialyzers were being reused. The dialyzer could be sealed off with germicide in both the blood and dialysate sides. This reduced the chances of contamination by bacteria.

When hollow fiber dialyzers came on the market in 1970, they proved to be well-suited for reuse. With strong structural integrity, they were easy to rinse. Water pressure could be used to wash fibrin and blood out of the dialyzer fibers. Reused hollow fiber dialyzers performed better than other types. Cell volume (fiber bundle volume) was easy to measure. Since the fiber bundle volume could be measured and used to decide when the dialyzers should be discarded, the hollow fiber dialyzer became the preferred choice for reuse.

From 1964 to 1976, dialyzer reuse evolved; it was studied, changed, refined, tested, and practiced. Researchers looked at how reprocessed coil, parallel plate, and hollow fiber dialyzers differed from new dialyzers in clearance and removal of small molecules. They tried a number of germicides, dwell times, concentrations, and temperatures. In time, they found ways to reliably kill and prevent the growth of bacteria.

Companies built single-station and multi-station automated systems for reprocessing.

Single-station systems were used for dialysis centers and home hemodialysis. These included the ECHO™ by Mesa Medical, Inc., and the Renatron® by Renal Systems. A few companies made multi-station systems of varying sizes for center use. The ADR-22 by Texas Medical Devices, Seratronics DRS-4, and the Lixivitrion 2 by Harco Medical Electronic Devices were four-station systems. The Belro Company built a six-station systems. Computer Dialysis Systems made larger systems; the Compudial KP-1 was 12 stations.

In 1976, about 18% of U.S. dialysis patients were treated with reused dialyzers. In the 1980s, many studies found that reuse with proper quality control was safe. Machines that made reprocessing easier and more efficient aided growth of the practice. In 1983, dialysis payment from Medicare was changed: centers were paid a fixed sum—the composite rate—for each treatment. The change to a composite rate may have been the single largest reason for the rapid growth of reuse, which reached a peak in 1997, with 82% of centers using it. In 2002, this dropped to 63%. In 2001, the largest dialysis company in the United States announced a change to single-use dialyzers. Their market share ensures that dialyzer reuse will continue to drop in the United States.

Why Dialyzers Are Reused

The reasons for dialyzer reuse, both medical and non-medical, have changed over time.
MEDICAL REASONS FOR DIALYZER REUSE

The main medical reason to reuse dialyzers is to reduce hypersensitivity reactions. A patient may have such a reaction in the first 15–30 minutes of treatment with a new dialyzer. Symptoms include anxiety, itching, and trouble breathing, which can lead to respiratory failure. This is also called “first-use syndrome.” In rare cases, patients may have an anaphylactic reaction to a new dialyzer; this is a severe, sometimes fatal allergy, which may include hives and respiratory failure.

The most severe hypersensitivity reactions are due to ethylene oxide (ETO). ETO is used to sterilize most new dialyzers in the United States. The chance of a reaction is less with a reused dialyzer because the repeated rinsings can lower the levels of ETO. Rinsing new dialyzers can also reduce reactions. The rinsing done for preprocessing and reprocessing can also remove other noxious substances from the dialyzers.

Some centers reuse dialyzers because they want to remove more middle molecules, such as beta-2-microglobulin (β2m). Reuse makes it possible for these centers to afford the costly high-flux dialyzers that do a better job of removing middle molecules.

SAFETY OF REUSE

In 1997, the National Kidney Foundation's Council on Dialysis had an expert panel review clinical experience with dialyzer reuse since 1988. The group looked at patient symptoms, death, chemical toxicity, and dialyzer clearance. While the Council did not take a stand for or against reuse, they found no effect of reuse on patient illness or death. It has recently been suggested that there was a patient survival advantage when dialyzer use was switched from reuse to single-use. On the other hand, studies suggesting that patients who reuse dialyzers do not have a higher mortality rate than patients on single-use dialyzers continue to emerge. Many authors believe reuse is safe and can deliver quality care if it is done using recognized reprocessing protocols such as those recommended by the Association for the Advancement of Medical Instrumentation (AAMI) guidelines (as well as dialyzer manufacturers’ instructions).

NON-MEDICAL REASONS FOR DIALYZER REUSE

The most common non-medical reason for dialyzer reuse is cost. Reusing a dialyzer can reduce the cost per dialysis treatment, even including the staff time that is used.

Another argument for reuse is the environmental impact. Throwing out dialyzers can be a major problem and expense. Reusing them reduces the amount of biohazardous waste.

Dialyzer Reprocessing Procedure

Dialyzers should be reprocessed using the AAMI standards and recommendations. The Centers for Medicare and Medicaid Services (CMS) adopted the AAMI guidelines as a Condition for Coverage for dialysis centers, and as federal regulations. The AAMI guidelines cover equipment, cleaning and disinfecting,
labeling, record keeping, supplies, environmental safety, staff qualifications, training, and quality assurance (see Figure 2). All water used for reprocessing must meet AAMI standards.

**TYPES OF DIALYZERS**

In 1996, the Food and Drug Administration (FDA) required that a dialyzer’s label must reflect its commercial marketing and clinical use. Therefore, each dialyzer must be labeled for “single” or “multiple” use. Companies who sell dialyzers to centers that reuse them must give instructions for safe and effective reuse. The label must have at least one recommended way to reprocess the dialyzer and scientific documentation that it is safe and effective. Not all dialyzers are approved for use with all germicides used in reprocessing. Only dialyzers that can be reused can be labeled for “multiple use.” Before you start to prepare a dialyzer for reprocessing, check the label for “multiple use.”

**AUTOMATED VERSUS MANUAL SYSTEM**

Dialyzer reprocessing can be done with a machine (see Figure 3) or manually (by hand). All the tasks done by the machine can also be done by hand, but the automated system offers better quality control. Use of an automated reprocessing machine is more efficient, more consistent, provides better records, and is safer for patients.

**Preparing for the First Use of a Dialyzer**

**DIALYZER LABELING**

Put the patient’s name on a dialyzer before you use it for the first time. If you have patients with the same or similar last names, the dialyzer label must have a warning or alert. The label should also have extra information such as the first name and middle initial, color code, or medical record number, to prevent mix-ups (see Figure 4). The label will need space for the number of uses, date and time of the last reuse, an identifier for the reprocessing staff member, and results of tests done on the dialyzer.
Labels need to stay readable through reprocessing and dialysis. The label should not cover up the model number, lot number, arrows for direction of blood and/or dialysate flow, or other key data. Labels on dialyzers with clear casings should be small enough that you can see the blood path.

**TOTAL CELL VOLUME**

Before using a new dialyzer for the first time, you will need to test it for baseline total cell volume (TCV)—also called fiber bundle volume (FBV)—or a baseline clearance value (e.g., urea, sodium, or ionic clearance). The TCV measures the ability of the dialyzer to transport solutes and ultrafilter at its next use. Compare the baseline TCV or a baseline clearance with the TCV or clearance result after each reprocessing. Check each dialyzer against its own TCV or its own clearance value. There are differences between dialyzers in TCV or clearance value that you will miss if they are only measured in a batch.

![Figure 3: Automated reprocessing systems](image1)

*Drawings adapted with permission from Seratronics and Renal Systems, respectively.*

![Figure 4: Example of a reprocessing label](image2)

*Drawing adapted with permission from Seratronics.*

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PREPROCESS

Many centers preprocess new dialyzers. Preprocessing removes more residual germicides, such as ETO, or other products of manufacturing, such as spallated particles, bore fluid, cleaning chemicals, phthalates, bisphenols, and other noxious substances that could cause harmful reactions the first time a dialyzer is used. Preprocessing allows for an accurate measure of a dialyzer's total cell volume.

After Dialysis

At the end of a treatment, blood in the dialyzer is “rinsed back” — returned to the patient. It is important to rinse as much of the blood as possible back to the patient. A rinseback that is fair or poor leaves blood in the dialyzer (see Figure 5). Fair or poor rinseback leads to patient blood loss and is a reason to discard a dialyzer. After rinseback, a dialyzer that passes inspection is taken off of the extracorporeal circuit and brought to the reprocessing room.

Figure 5:
Good, fair, and poor rinsebacks

PRE-CLEANING

The first step in reprocessing is to pre-clean the dialyzer. Pre-cleaning removes some of the blood from the blood compartment. Pre-cleaning may use reverse ultrafiltration; you do this by placing a cap on one of the dialysate ports and sending a controlled supply of water into the other port. For some dialyzers, you may need to remove the header (see Figure 6). If the header of the dialyzer is removed to allow for cleaning, take special care to rinse and disinfect the area, including the O-rings, before putting the headers back on the dialyzer. Germicides may be used during pre-cleaning.

PERFORMANCE TESTS

After you rinse and clean the dialyzer, you will need to test its functional and structural integrity. Federal and state regulations require measuring the TCV after each reuse. You will also need to do a leak test; this measures how well the dialyzer can withstand a pressure load, and protects the patient from a dialyzer blood leak. Finally, inspect the dialyzer for cracks, chips, or defects in the plastic housing.

DIALYZER REJECTION

If a dialyzer fails the performance tests or visual inspection, throw it away. KDOQI guidelines recommend that dialyzers with less than 90% of the original clearance value (whether urea, sodium, or ionic clearance measures are used), or with less than 80% of the original TCV value, should be thrown out. Note: Loss of a dialyzer's transport capacity does not directly relate to fiber clotting because the (now) greater blood flow velocity in the remaining unclotted fibers will cause a higher diffusion rate inside.
each such fiber. So, when the residual TCV value of a hollow fiber dialyzer is 80% of the original TCV, the relative fall in urea, sodium, or ionic clearance will only be about 10%.15

You will also discard dialyzers that have reached their maximum number of uses (per your center’s policy); fail the leak test; have cracks, chips, or defects in the plastic housing; have been exposed to more than one germicide; or have many discolored fibers.18

**DISINFECTION**

The next step is to disinfect the dialyzer. The automated system fills dialyzers with a germicide or disinfectant (agent that kills pathogenic microorganisms). Dialyzers must be exposed to only one germicide during reprocessing. Use of more than one germicide may damage a dialyzer.20 The four main types of germicides used in the U.S. are peracetic acid, formaldehyde, glutaraldehyde, and heat disinfection with citric acid. Peracetic acid is the most-commonly-used germicide.3 Each germicide has pros and cons (see Table 1).17

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Pro</th>
<th>Con</th>
<th>Contact Time</th>
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</thead>
<tbody>
<tr>
<td>Peracetic acid</td>
<td>• When diluted, breaks down to biodegradable acetic acid, oxygen, and water</td>
<td>• Cost</td>
<td>11 hours</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>• Cost</td>
<td>• Technician must use a respirator • Quick drench shower needed in the center • May cause cancer • Disposal costs</td>
<td>24 hours</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>• Cost</td>
<td>• Linked with respiratory and skin problems • Disposal costs</td>
<td>10 hours</td>
</tr>
<tr>
<td>Heat disinfection with citric acid</td>
<td>• No staff safety concerns • No environmental concerns</td>
<td>• Not all dialyzers can be heat disinfected</td>
<td>20 hours</td>
</tr>
</tbody>
</table>

To ensure proper disinfection, the germicide must stay in the dialyzer for a certain amount of time. The contact time (amount of time the germicide remains in the dialyzer) differs for each germicide (see Table 1).17

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**Figure 6:**

*Parts of hollow fiber dialyzer*

Translucent polyurethane or polycarbonate (plastic) potting material. If endotoxin leaks into the potting material, it is difficult to remove it.
**HANDLING HAZARDOUS MATERIALS**

Germicides for reuse kill microorganisms—and they can also harm you and your patients. Occupational Safety and Health Administration (OSHA) Standards require centers to tell staff about all hazardous chemicals in the workplace. The center must provide a list of all chemicals and keep it current. One copy of the material safety data sheet (MSDS) for each substance must be kept in a file that you can read. Another must be posted near where a chemical is used, so you can find the information quickly in an emergency. All containers should be labeled clearly to avoid mix-ups.

Your center must train you in its procedures for handling hazardous materials. The center must also encourage you to read its written policies. You should know where policies, emergency procedures, and training materials are kept in your center. A center with more than 10 staff must also keep records of occupational illnesses and injuries. It is the employer’s duty to ensure compliance with safety practices and policies.

Procedures alone cannot prevent worker injury from toxic substances. Each staff member must learn the steps and follow them. Taking shortcuts with hazardous materials is not a time-saver if it causes an accident. You must protect yourself and others around you by learning how to handle hazardous materials safely.

**STORAGE OF REPROCESSED DIALYZERS**

Before being stored, the outside of the dialyzer must be wiped or soaked clean with a disinfectant. Don’t store reprocessed dialyzers with new ones. Storage conditions should keep deterioration, contamination, and breakage to a minimum. Reprocessed dialyzers can be stored on wall racks or in carts until they are needed. The storage system should be designed to be easy to clean. Always follow your center’s policies and procedures.

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**Preparing for Next Use**

**DIALYZER INSPECTION**

The first step in getting a dialyzer ready for its next use is looking at it (see Figure 7) to be sure that:

- It is labeled properly.
- No structural damage or tampering has occurred.

![Figure 7: Reprocessed dialyzer](image-url)
■ Ports are capped, and there is no leakage from the ports or other parts of the dialyzer.
■ It was stored long enough for the germicide to work, but not so long as to exceed acceptable shelf life.
■ The cosmetic appearance is acceptable—it looks clean.

After you look at the dialyzer, use a positive indicator test strip or ampule to confirm that germicide is present and strong enough to work. Looking at the dialyzer cannot tell you how strong or concentrated the disinfectant is. You must test the fluid itself to confirm the presence and strength of germicide.15

REMOVAL OF GERMICIDE
The next step is to thoroughly rinse the germicide out of the dialyzer before it is used, using the center's procedure. Then, test the dialyzer to make sure the residual germicide is at or below the manufacturer's and center's specifications, using a residual germicide test. It is important to keep fluids flowing in the extracorporeal circuit after you test for removal of the germicide. If not, you will need to retest for germicide before starting the treatment. If you don't rinse the dialyzer well enough, the patient could be exposed to the toxic germicide.

PRIOR TO TREATMENT
Just before the start of treatment, two people (staff and/or patient) must check the patient information on the dialyzer to make sure it matches the patient. Record this step on the reprocessing record or dialysis flowsheet, and sign it to show who did the check. Staff members should ensure that the dialyzer has been prepared for use. The dialyzer must be properly labeled, structurally sound (no cracks or leaks, all caps in place, etc.), free of germicide, and clean.15

Potential Hazards
Dialyzer reprocessing is safe and effective if it is done correctly. If it is done wrong, dialyzer reprocessing poses hazards to patients.

BACTERIA AND ENDOTOXIN
The greatest risk of reuse comes from contamination of a dialyzer with bacteria or endotoxin (toxins on the membranes of certain bacteria). Bacteria and endotoxin may enter the dialyzer from the water used to make dialysate. After a treatment, some bacteria in the dialysate compartment may stay in the dialyzer. If bacteria and endotoxin multiply in the dialyzer and enter the patient's body, pyrogenic reactions (fever, chills, nausea, vomiting, hypotension, muscle pain) or septicemia (blood infection) could occur. For patients, this can be life-threatening.18

Problems with bacterial or endotoxin contamination may occur due to:
■ Improperly prepared germicide
■ Use of outdated germicide
■ Not enough contact time between the dialyzer and germicide
■ Improper storage conditions
■ Inadequate filling of the dialyzer

Dialyzer housings, support structures, and membranes can adsorb (attract and hold) endotoxin. This makes endotoxin hard to rinse out. So, levels of bacteria and endotoxin in the water used for reprocessing must be kept as low as possible. Bacteria in water used to reprocess dialyzers must not exceed the AAMI standard of 200 colony forming units (CFU).15 The AAMI action level is 50 CFU for bacteria in water used for dialysate.
The endotoxin level should be <2 endotoxin units/mL (EU/mL) with an action level of 1 EU/mL.\(^{22}\) If it is found that a patient had a pyrogenic reaction or septicemia due to dialyzer reprocessing, the center must stop reusing dialyzers. Reuse may not restart until the whole reprocessing system has been checked.\(^{20}\)

**CHEMICALS**

Reprocessing germicides are toxic if they enter the patient’s blood, even in small amounts (see Figure 8). If all of the germicide is not rinsed out before the next treatment, the patient may have burning in the access limb, blurred vision, or numbness in the lips. Death can occur from poisoning. Acute (sudden) toxicity may also occur if dialysis does not start right after an acceptable residual germicide test; waiting may cause a rebound of the germicide in the blood compartment. Small amounts of some germicides that don’t cause acute symptoms may still cause long-term problems, such as trouble sleeping and changes in the body’s immune system. You must follow center policies and procedures for chemical use exactly to avoid the risks and hazards of chemical use in reprocessing. More importantly, you must test every dialyzer before use to be sure all of the chemicals have been removed.\(^{18}\)

**ALTERED DIALYZER PERFORMANCE**

In time, reprocessing and reusing dialyzers reduces and alters their membrane surface area. This can cause poor solute transport and ultrafiltration, so the dialysis prescription is not delivered. Reprocessing dialyzers can change their performance from the manufacturer’s specifications in a number of ways. Contact with cleaning agents and germicide can harm the membrane, causing leaks and reducing clearance. During reuse, hollow fibers can clog with blood, or membrane surfaces may be coated with blood products or other material. This can reduce flow and/or the surface area of the dialyzer. A slower flow rate or smaller surface area can reduce clearance as well as the ultrafiltration rate (UFR).\(^{6}\)

**Documentation**

Dialyzer reuse is a vital part of hemodialysis in many centers today. While reuse is a medical procedure, the reprocessing is much like a manufacturing process. Centers should follow the “good manufacturing practice” standards used by dialyzer makers. This means that a lot of documentation is needed (see Table 2).\(^{23}\) The staff person who documents reprocessing and reuse must be diligent and precise.
Quality Assurance and Quality Control

A center must prove it can safely and effectively reprocess dialyzers. Federal regulations require a center that reuses dialyzers to have a program to monitor the system. Quality assurance and quality control are the two parts of the program.

The center needs to develop, implement, and evaluate policies and procedures on reuse. All standards, as well as state and federal regulations, must be included in the policies and procedures. Quality assurance provides the proof that policies and procedures have been written and are being implemented. AAMI standards on reprocessing have details on all aspects of a quality assurance program (see Table 3 on page 220).15

Quality control shows that the materials, processes, and final product meet set standards. Examples of quality control for dialyzer reprocessing are TCV measurement, bacterial and endotoxin tests, and tests for the presence or absence of germicide.

Conclusion

Dialyzer reprocessing, done correctly, is safe and effective for patients. If done incorrectly, it can pose a hazard to patients and staff. As a dialysis technician, your role is to follow the center’s policies and procedures on dialyzer reprocessing to ensure patient and staff safety.

Table 2: Dialyzer Reprocessing Documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Dialyzer Reprocessing Manual</td>
<td>A summary of all reuse specifications, policies, procedures, training materials, manuals and methods, and samples of forms and labels</td>
</tr>
<tr>
<td>Reprocessing Log</td>
<td>Record of every step in the use of a dialyzer – from entry in the center to all performance testing, to disposal</td>
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<tr>
<td>Water Quality</td>
<td>Record of water treatment system maintenance and operation to meet AAMI standards and the center’s policies and procedures</td>
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<tr>
<td>Complaint Investigation File and Special Incident Report</td>
<td>Record of all complaints by patients and staff about dialyzer failures or possible harmful reactions, which includes results of any investigation of the complaints and any actions taken to correct the problem</td>
</tr>
<tr>
<td>Environmental Testing</td>
<td>Record of testing required by regulatory agencies on any germicides or cleaning agents used in dialyzer reuse</td>
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<tr>
<td>Equipment Maintenance</td>
<td>Log of the dates of preventive maintenance, repairs, and results of scheduled testing on all reprocessing equipment</td>
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<tr>
<td>Incoming Materials Log/Material Quality Records</td>
<td>Log of incoming materials such as dialyzers, port caps, disinfectants, other reprocessing supplies, and results of any quality control tests</td>
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<tr>
<td>Personnel Health Monitoring Records</td>
<td>Record of the results of medical exams of workers to monitor exposure to substances that may be toxic, as required by regulatory agencies</td>
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<tr>
<td>Training Records</td>
<td>Record of staff’s completion of a training course in dialyzer reprocessing and proven ability to do reuse correctly</td>
</tr>
<tr>
<td>Quality Assurance and Quality Control</td>
<td>Record of the dates and results of all quality assurance and quality control evaluations</td>
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</tbody>
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# Dialyzer Reprocessing

**Table 3: Quality Assurance Schedule – Dialyzer Reprocessing**

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<tr>
<th>Q.A. Monitoring Activity</th>
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<td>Germicide concentration verification (before dialysis)</td>
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<td>Patient monitoring procedures audit</td>
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<td>QA &amp; QC procedures audit</td>
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<td>Validation of clearance vs. TCV or FBV</td>
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<td>Reprocessing supplies parameters audit</td>
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<td>Master record review &amp; audit</td>
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<td>Audit of compliance with informed consent policy</td>
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<td>Audit of written policies &amp; procedures</td>
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<td>Audit &amp; trend analysis of maintenance &amp; repair records</td>
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*Table adapted with permission from the Association for the Advancement of Medical Instrumentation*
References


For more information on reuse and its history, two recent references are available:
