

Tips for Evaluating a Third-Party Reprocessor

The Association for Medical Device Reprocessors (AMDR) is an excellent resource for keeping up-to-date on research and activity around device reprocessing (www.amdr.org). AMDR is a trade association for third-party reprocessors whose members account for about 95 percent of the third-party reprocessing done in the United States. AMDR suggests that hospitals ask the following questions to vendors before choosing a SUD reprocessor:

General FDA Requirements:

1. Is the company registered with FDA and can the company provide evidence of such FDA-registration?
2. Does the company have a reputable FDA inspection record?
3. Has the company listed its products with FDA and can the company share a listing of its product offerings?
4. Does the company comply with FDA's Quality System Regulation (QSR) requirements for medical device manufacturers?
5. Does the company comply with FDA's Medical Device Reporting requirements for medical device manufacturers?

Sterilization Requirements:

1. Is sterilization performed by a commissioned and certified sterilization system, in accordance with ANSI/AAMI/ISO ST 11135 ST 1994?
2. Is the sterilization cycle requalified annually?
3. Are biological indicators used to monitor routine sterilization?
4. Are the sterilization systems routinely calibrated?
5. Is the residual sterilant level routinely tested?

Reprocessing Procedures:

1. Does the company have reprocessing procedures tailored to the specific types of medical devices you wish to have reprocessed?
2. Does the reprocessor have in place validated cleaning procedures?
3. Is product functionality routinely tested?
4. Does the company track the number of uses per device?
5. Does the company recycle the raw materials from a device when it is no longer capable or eligible to be reprocessed?

Business Considerations:

1. Does the company have adequate liability insurance coverage?
2. Will the company permit you to visit its plant and review its quality manual?
3. How will the company partner with you and your staff to integrate a reprocessing program into your established supply, storage and usage patterns?
4. Is the collection program designed to ensure optimal compliance? Does the reprocessing partner support your efforts with regular business reviews, tracking programs and educational services that maximize staff participation?