AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Meeting Joint Commission Standards for SUD Reprocessing

The Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission) requires hospitals that reprocess single-use devices (SUDs) "implement infection prevention and control activities that are consistent with regulatory and professional standards."[1] U.S. hospitals that outsource their SUD reprocessing and re-manufacturing activities to vendors regulated by the Food and Drug Administration (FDA) are in compliance with the Joint Commission's requirements. Third-party SUD reprocessors are responsible for ensuring compliance with all U.S. FDA regulatory requirements, the same as an original medical device manufacturer.

AMDR is not aware of any instances in which hospitals have been found to be out of compliance when outsourcing SUD reprocessing to an FDA regulated vendor. Should accreditors in any way find fault with a hospital's contracting with an FDA regulated reprocessor, AMDR urges the hospital to get it in writing, have the accreditor provide the actual policy (if not the policy referenced above), and demonstrate how the hospital is out of compliance.

Hospitals that elect to reprocess SUDs in-house are required to meet FDA's medical device manufacturer requirements or risk facing FDA enforcement action, and likely the same from the Joint Commission. AMDR is not aware of any U.S. hospitals that have FDA clearance or other premarket authority to lawfully reprocess SUDs in-house.

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[1] **Joint Commission on Accreditation of Healthcare Organizations,** *Comprehensive Accreditation Manual for Hospitals*, Infection Prevention and Control, January 2015 at 11.

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