Technical Information Report

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Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection

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Advancing Safety in Health Technology

Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection

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AAMI

Abstract: This technical information report identifies the necessary steps to effectively manage medical devices not owned by the health care facility in which they are used.

Keywords: high-level disinfection, loaned medical device, medical equipment management, quality systems. sterilization

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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www.aami.org/standards/glossary.pdf

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Association for the Advancement of Medical Instrumentation

Reusable Sterilization Container Working Group

This standard was developed by the AAMI Reusable Sterilization Container Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the **AAMI Reusable Sterilization Container Working Group** had the following members:

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report (TIR) was developed by the AAMI Rigid Sterilization Container System Working Group under the auspices of the AAMI Sterilization Standards Committee.

Management of a loaned medical devices presents challenges to both the sending and receiving facilities. Currently, there is much variation in management of loaned medical devices across health care facilitates. This TIR was developed to provide a consistent approach to management of loaned medical devices by defining responsibilities and addressing critical requirements such as ensuring there is sufficient time to process a loaned device after delivery and before use.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the technical information report. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Ste. 301, Arlington, VA 22203-1633.

Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection

Introduction

Health care facilities frequently need to obtain medical devices they do not own in order to provide for an individual patient need. The facility may obtain these devices through a loan agreement with a vendor or another health care facility. The devices should be delivered to the receiving facility in a timely manner, cleaned and sterilized or high-level disinfected by the receiving health care facility or other designated facility prior to patient use, delivered to the point of care on schedule, cleaned and rendered safe to handle following use, and returned to the sender in good condition. Effective and safe management of loaned medical devices is a complex endeavor requiring systematic processes and clear communication among all involved parties.

This technical information report (TIR) is intended to provide guidance for the management of loaned medical devices. Only medical devices that are cleaned and sterilized or high-level disinfected according to the manufacturer's written IFU and functioning according to manufacturer's specifications should be used in a medical procedure. A formal program between the health care facility and the lending entity is necessary to ensure that loaned devices are properly handled, readied for patient use, and returned undamaged.

1 Scope

1.1 General

This TIR identifies the necessary steps to effectively manage medical devices not owned by the health care facility in which they are used.

1.2 Inclusions

This TIR addresses the management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection by the receiving facility prior to patient use. This document includes processes for the request, receipt, return, and documentation of loaned medical devices. Included are the roles and responsibilities of the health care facility ("receiver"), the lending entity ("sender"), and individuals.

1.3 Exclusions

This TIR does not address department design considerations, personnel considerations, cleaning and other decontamination processes, packaging, preparation, or sterilization (see ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*; ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*; and ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities*). Processes for management of non-critical loaned medical devices and single-use medical devices, as well as off-site reprocessing facilities, are outside the scope of this document.

2 Definitions and abbreviations

2.1 health care facility: hospital, free-standing surgical center, clinic, medical office, or dental office.

2.2 loaned: A medical device intended for use by a health care facility that is not owned by the facility.

2.3 medical device: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception