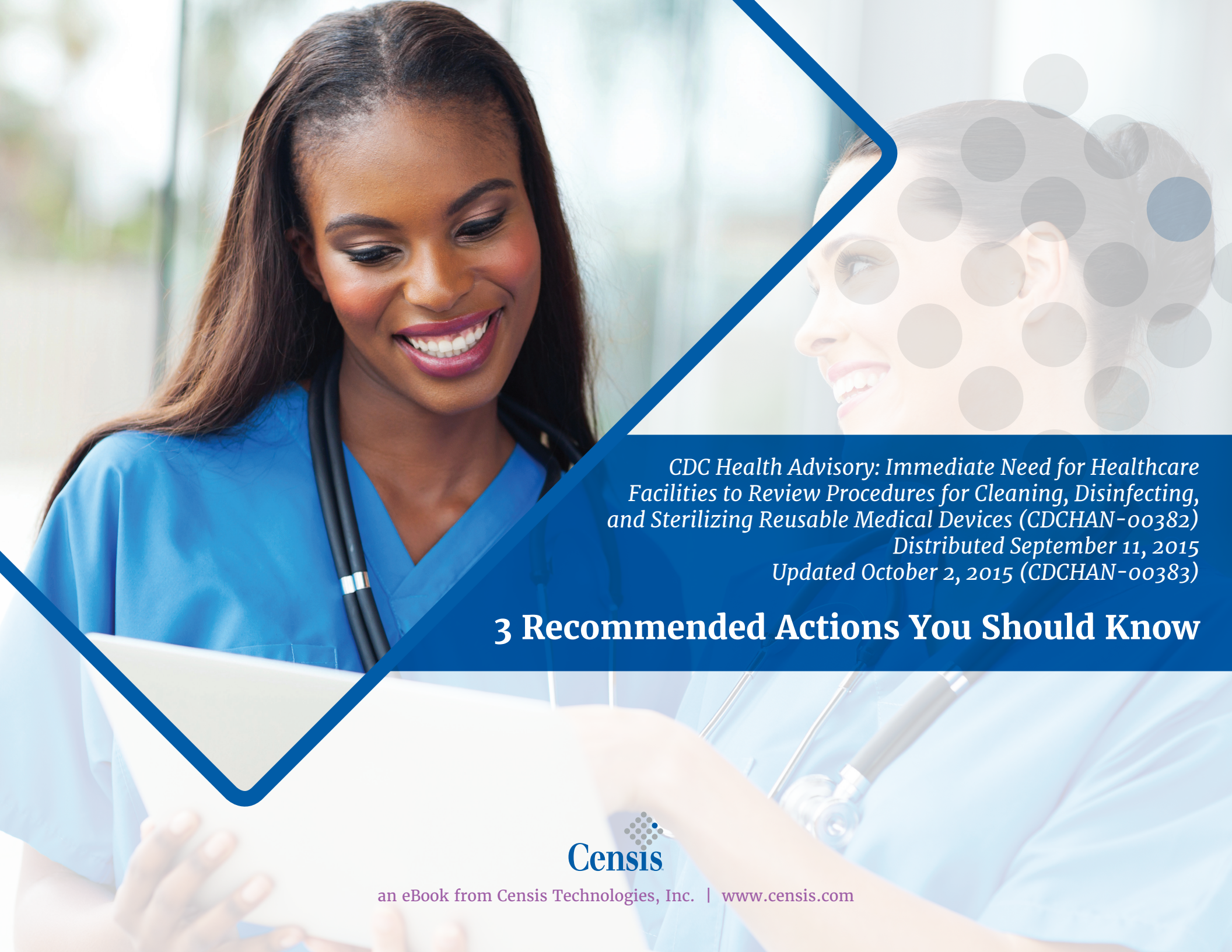

CDC Health Advisory: Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices (CDCHAN-00382)
Distributed September 11, 2015
Updated October 2, 2015 (CDCHAN-00383)

3 Recommended Actions You Should Know

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Introduction

On September 11, 2015, CDC issued HAN 00382, alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. The Health Advisory urged healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices to immediately review current reprocessing practices at their facility to ensure the following:

- Their facility is complying with all steps as directed by the device manufacturers
- Their facility has in place appropriate policies and procedures that are consistent with current standards and guidelines.

On October 2, 2015, after considering feedback, the CDC issued an update to HAN 00382, HAN 00383, that removed a statement related to facilities that contract maintenance and repair of these devices to third-party vendors.

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical and semi-critical items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Critical item = (e.g., surgical instruments) objects used to enter sterile tissue or the vascular system and must be cleaned and sterilized prior to reuse.

Semi-critical item = (e.g., endoscopes for upper endoscopy and colonoscopy, laryngoscope blades) objects that contact mucous membranes or non-intact skin and require, at a minimum, cleaning and high-level disinfection prior to reuse.[1]

Recommendation 1

- Healthcare facilities should provide training to all personnel who reprocess medical devices.
  - Upon hire or prior to provision of services at the facility
  - At least once a year
  - When new devices or protocols are introduced, including changes in the manufacturer's instructions for use during the device's life cycle
- Personnel should be required to demonstrate competency with device reprocessing (i.e., trainer observes correct technique) prior to being allowed to perform reprocessing independently.
- Healthcare facilities should maintain current documentation of trainings and competencies.
- If the healthcare facility hires a contractor for device reprocessing, the facility should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices the healthcare facility uses.
- Copies of manufacturers' instructions for operating and reprocessing each type of reusable device should be readily available to staff and inspectors. This file should include instructions for use of chemical disinfectants.[1]

Recommendation 2

- Healthcare facilities should regularly audit (monitor and document) adherence to cleaning, disinfection, sterilization, and device storage procedures. Audits should assess all reprocessing steps, including:
  - Performing prompt cleaning after use, prior to disinfection or sterilization procedures
  - Using disinfectants in accordance with manufacturers' instructions (e.g., dilution, contact time, storage, shelf-life)
  - Monitoring sterilizer performance (e.g., use of chemical and biological indicators, read-outs of sterilizer cycle parameters, appropriate record keeping)
  - Monitoring automated endoscope reprocessor performance (e.g., print out of flow rate, time, and temperature, use of chemical indicators for monitoring high-level disinfectant concentration)
- Audits should be conducted in all areas of the facility where reprocessing occurs.
- Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures.[1]

Recommendation 3

- Healthcare facilities should allow adequate time for reprocessing to ensure adherence to all steps recommended by the device manufacturer, including drying, proper storage, and transport. Additionally, consideration should be made regarding scheduling of procedures and supply of devices to ensure adequate time is allotted for reprocessing.
- Healthcare facilities should have protocols in place to ensure that healthcare personnel can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in a designated area).
- Healthcare facilities should have policies and procedures outlining facility response to a recognized reprocessing error or failure. Healthcare personnel should assess the cause of the error or failure and the exposure event to determine the potential risk of infection. The procedure should include how to identify, notify, and follow patients who might have been exposed to the event.
- Individuals responsible for infection prevention and reprocessing at the healthcare facility should be consulted in new device purchases to ensure that infection control considerations are included in the purchasing decision, appropriate implementation of reprocessing policies and procedures is completed, and that the recommended reprocessing equipment is available at the healthcare facility.
- Healthcare facilities should maintain documentation of reprocessing activities, including maintenance records for reprocessing equipment (e.g., autoclaves, automated endoscope reprocessors, medical washers, washer-disinfectors, and water treatment systems), sterilization records (physical, chemical, and biological indicator results), and records verifying high-level disinfectants were tested and replaced appropriately.
- Healthcare facilities should follow manufacturer recommendations for maintenance and repair of medical devices that are processed or used to perform reprocessing functions.[1]

October 2, 2015 Update

After considering feedback from vendors that perform servicing and repair of reusable medical devices, the CDC amended HAN Advisory 00382 to remove the following sentence:

> *"If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services."*[1]

The stated reason behind this change was due to the fact that there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors.

The CDC Advisory Update goes on to recommend that healthcare facilities which hire contractors to perform device reprocessing verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.

Where to Go from Here

Having an automated instrument management system in place not only makes your department more efficient, but it also helps you implement and maintain the three recommendations from the CDC Health Advisory.

1. ELECTRONIC COMPETENCY TOOLS

These tools help manage training, certification, or competency requirements for employees. Competency tools should also manage functional access within the application based on those requirements.

- Competency Record – The complete competency training record for each technician.
- Competency Warning Log – A list of warnings issued to technicians who lacked a competency required to access a desired function.

2. ONLINE INSTRUCTIONS AT EACH WORKSTATION

Ability to display manufacturers' and customer-generated instructions for every instrument and endoscope in your inventory automatically when specific instrument ID is entered or scanned.

3. DATA CAPTURED FOR EVERY STEP IN THE REPROCESSING CYCLE WITH COMPREHENSIVE RECORDKEEPING.

Examples of reports:

- Out-of-Sequence Warnings – Out of sequence warnings issued by date
- Productivity – Processing activity by technician and activity type
- Sterilizer reports including but not limited to:
  - Indicator Results Summary – Summary of load indicator results by sterilizer and date
  - Instrument Level – Instruments sterilized by sterilizer, date, and time, including instruments in containers and peel packs
  - Instrument Level by Load – Instruments sterilized by load number, sterilizer, date, and time, including instruments in containers and peel packs
  - Sterilizer Load Summary – Tally of loads and contents by sterilizer and time period
  - Sterilizer Loads – List of sterilizer loads by sterilizer and date

REFERENCES:

[1]Centers for Disease Control. CDC Health Advisory: Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices, September 11, 2015. Accessible at: http://emergency.cdc.gov/han/han00382.asp

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With more than 600 organizations utilizing solutions in the Censis portfolio, Censis is committed to partnering with healthcare facilities year after year to enhance patient safety through innovative technology.

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