1 What is Reprocessing?

What is Reprocessing?

- Reprocessing is a multi-step process including the cleaning, disinfection, sterilization and repackaging of a used medical device so that it can be put back in service again.
- Focus of this presentation is on reusable medical devices that health care providers can reuse to diagnose and/or treat multiple patients.
- Examples: surgical instruments (clamps, forceps) and scopes (bronchoscopes, duodenoscopes, colonoscopes), laparoscopic instruments.
- Goal of reprocessing is to remove contaminants such as microorganisms so that when the device is reused the risk of infection is eliminated.

Photo source www.montrealgazette.com

What is Reprocessing?

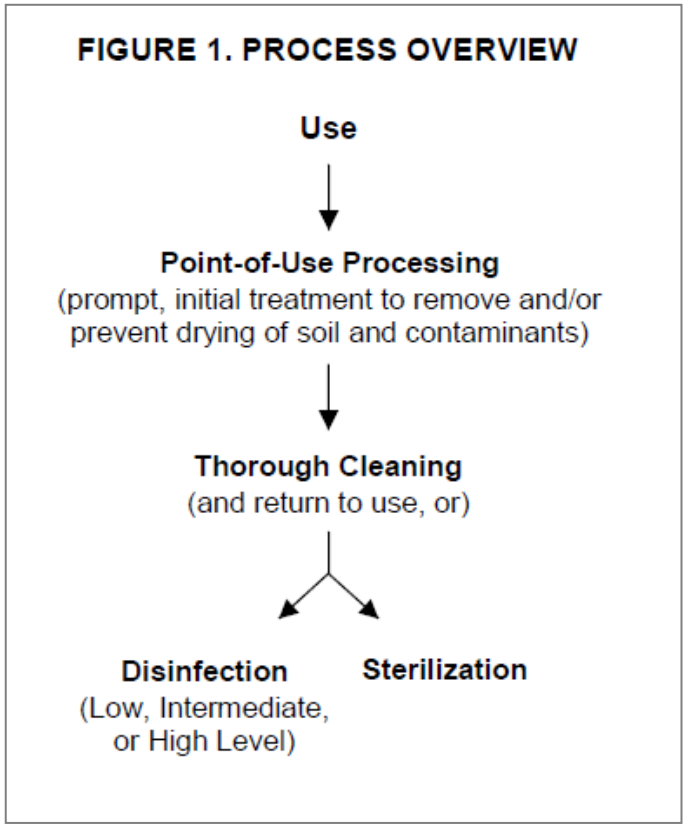


Photo source fda.gov

Photo source Biotest Laboratories

"Adequate reprocessing of reusable medical devices is vital to protecting patient safety." [fda.gov]

2 Where Does Reprocessing Happen?

Where Does Reprocessing Happen?

- Reprocessing of medical devices may happen in a variety of settings, including:
    - Large health care facilities like hospitals
    - Small inpatient and outpatient facilities
    - Small medical office suites
    - Stand along provider facilities such as ambulatory surgery centers
    - Stand alone reprocessing service facilities
- Reprocessing facilities go by different names, but we will refer to them as CSSDs (Central Sterile Supply Departments).

Photo source hpnonline.com

Where Does Reprocessing Happen?

The layout of CSSDs is fairly consistent:

- Materials come in the **dirty room** in the cleaning area, then are
- Passed into the **clean room** for drying, inspection, assembly, packaging and sterilization. Then materials are brought to the **storage and preparation** area

Dirty Room

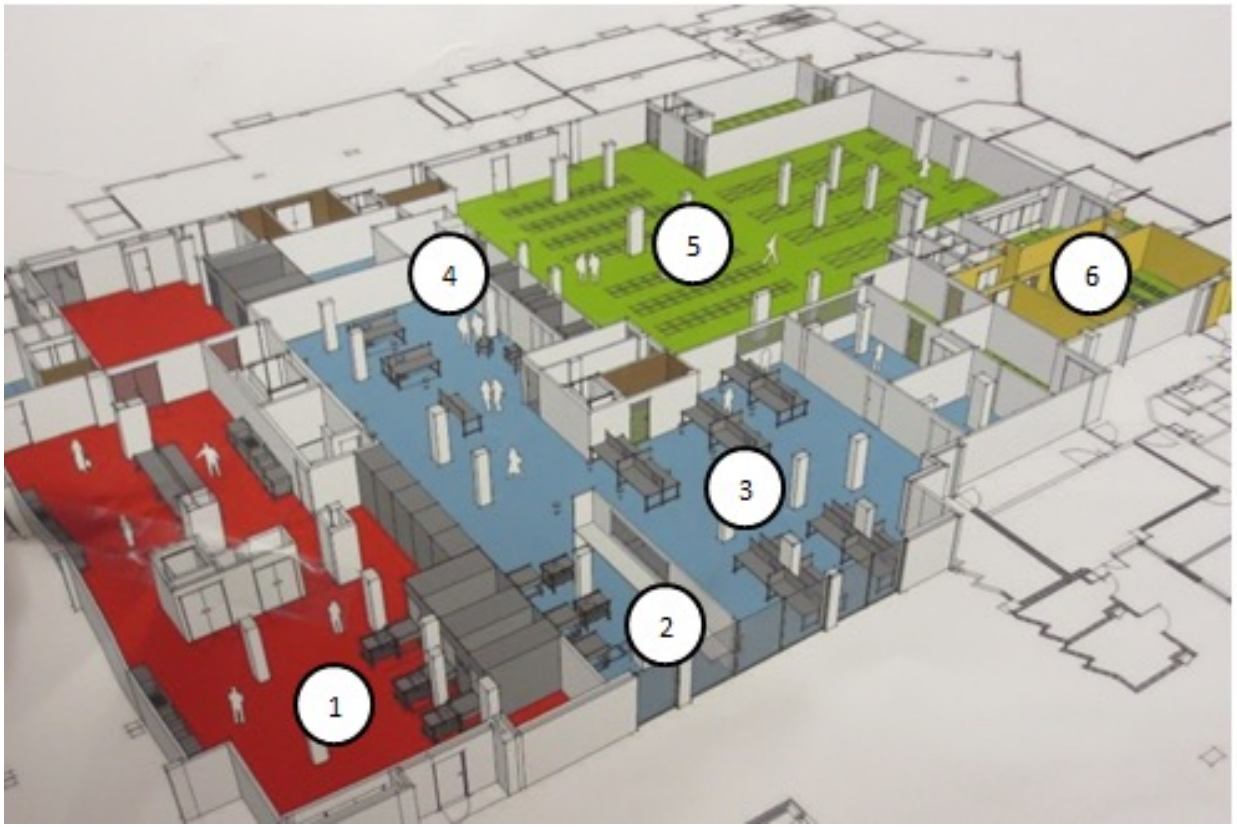
1. Cleaning Area

Clean Room

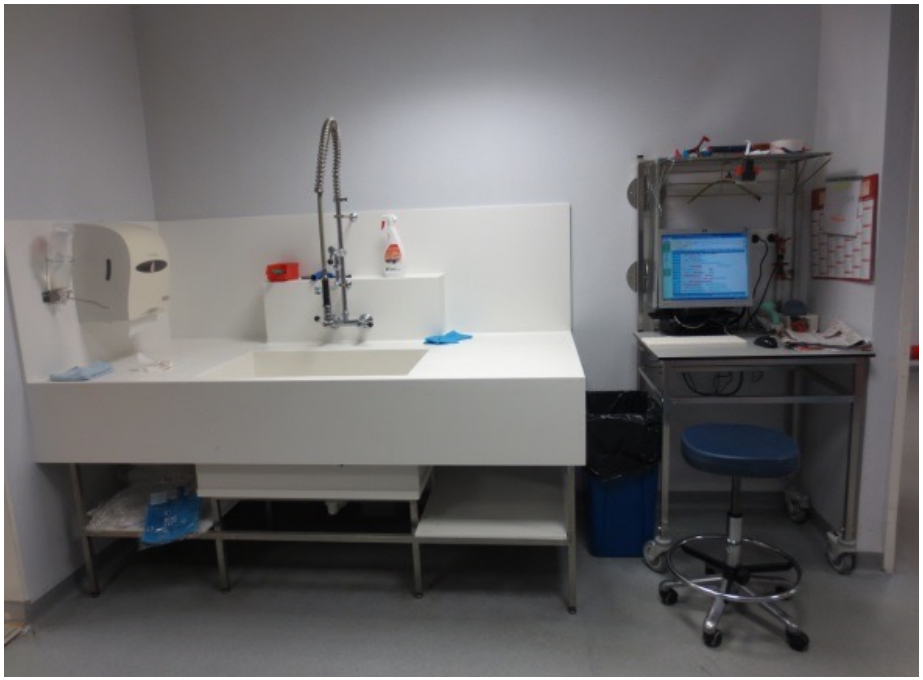
2. Drying Area
3. Inspection, Packaging, and Assembly Area
4. Sterilization Area
5. Storage and Preparation Area

Other

6. Administrative Area



Where Does Reprocessing Happen? Dirty Room



Cleaning Area

This Cleaning area is where the first steps (cleaning and/or disinfection) of reprocessing happen.

- Usually one person is responsible for the manual pre-cleaning process and then putting the instruments into the automatic washers/disinfectors (if the CSSD is using an automated cleaning process) or one person is responsible for the manual cleaning of the instruments and then putting the instruments into the ultrasonic bath.
- Other products may be disassembled here for cleaning and disinfection, to be reassembled on the clean side.

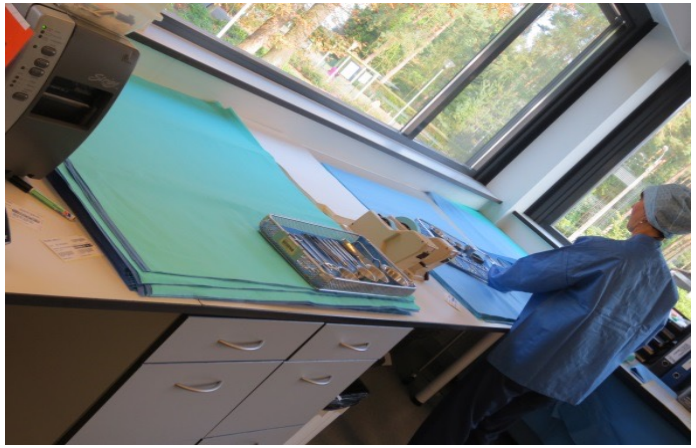
-Participant 1 (Pharmacist)

Where Does Reprocessing Happen? Clean Room

Instruments are brought to the clean side through either the automatic washer/disinfector or through a vaulted pass-through.

Drying Area

This is where instruments are either brought out of the automatic washer/disinfectors after the appropriate dry time (dependent on cycle) or instruments/scopes are dried before packaging.



Inspection, Assembly, and Packaging Area

This area is for packaging the instruments and endoscopes before they are sterilized. One person is typically responsible for inspecting that the instruments and scopes are clean (and, if necessary, disinfected). In this area, instruments are packed (either in paper or in cartons) to be sterilized

Where Does Reprocessing Happen? Clean Room

Sterilization Area

In the Sterilization area, packed instruments and endoscopes are put into the appropriate machine for sterilization. Sterilization machines include: autoclaves, Sterrad/Sterris, formaldehyde sterilization, among others.

Storage and Packaging Area

Once cleaned, disinfected, dried, assembled, validated, packaged, and sterilized, instruments and endoscopes are ready to be stored or to be prepped for distribution to the Operating Rooms.

4 Case Study

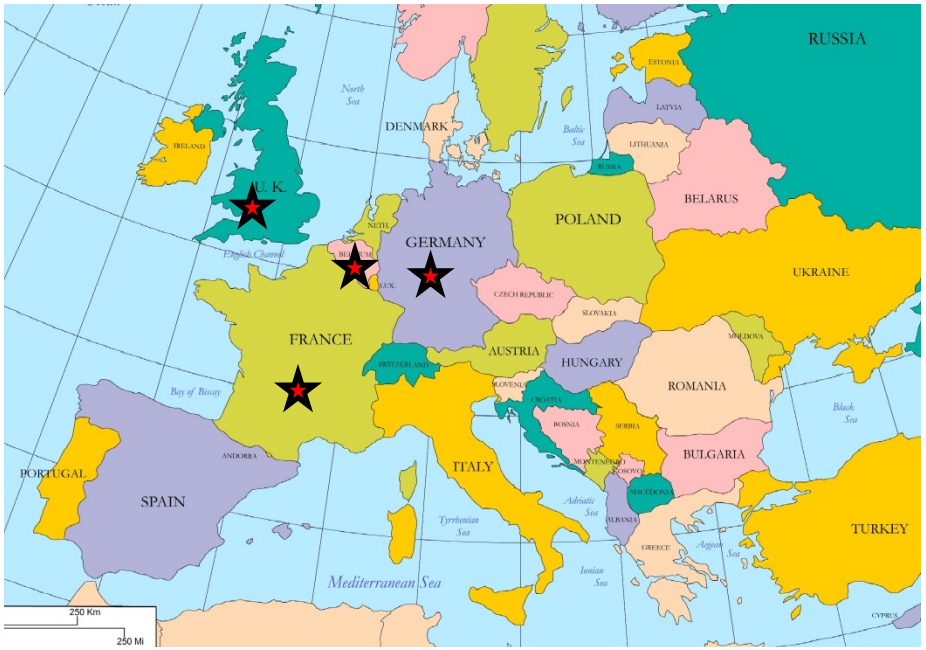
Study Overview

The purpose of the study was to:

- Gain an understanding of the way that surgical instruments make their way from the operating room through the CSSD at various hospitals.
- Document the CSSD use environment, noting any challenges, workarounds, use of reference documents and wall charts, etc.
- Take stock of the current reprocessing workflow, noting any issues, concerns, or major challenges.

The study was conducted:

- In September 2014.
- By a project team consisting of two Farm staff members and three client members.
- At 7 hospitals in four countries in Europe: Germany, France, Belgium, and the United Kingdom.



Study Overview

Methodology

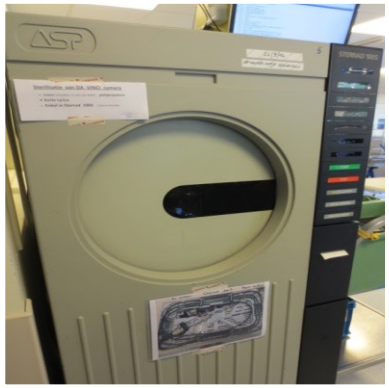
- The team conducted sit-down interviews with the CSSD managers and other pertinent staff members.
- Following the interviews, the research team was given a tour of the CSSD.
- When possible, the project team observed as CSSD participants demonstrated the process of cleaning and sterilizing certain instruments.
- Team members asked additional interview questions, took hand written notes, and documented the use environment by taking photos.

Study Results: Workflow

- Pre-treatment or point-of-use processing does not always take place in the OR.
- Instruments make their way from the OR down to the CSSD. This may happen in a variety of ways and can take varying lengths of time.
- CSSDs are organized by zones (clean, dirty, etc.) Within each zone certain tasks take place.
- Instruments move their way through the CSSD zone by zone. Personnel are usually assigned to a specific zone and are either rotated through other areas throughout the day or throughout the week.
- Different individuals at a given facility may be responsible for cleaning, sterilization, assembly, packaging, and validation of the same surgical instrument.
- Performing manual vs. automatic reprocessing had an influence on the path of a given instrument and how long it would take to complete the process.

Photo source matot.com

Study Results: Equipment



- CSSDs were caught by surprise at the sudden arrival of a new set of instruments. Although they may have been aware the hospital was purchasing a new system, CSSDs were widely not included in the planning stages.
- Because of their lack of involvement in planning for new devices, the CSSDs didn't have all of the desired equipment to reprocess the new instruments.
- Many of them were performing the manual process as opposed to the automatic process, and expressed concerns over the time consumption and domino effect it had on their workload.
- The CSSDs didn't always have access to the accessories (i.e., brushes) or supplies (i.e. high purity water) that were referenced in the IFU.

Study Results: Instrument Complexity

- Some CSSDs expressed concern over reprocessing new instruments that were deemed more complex than their predecessors.
- They worried that OR and CSSD staff would overlook new features and forget to perform certain steps. Others expressed concern over increased drying time for instruments with complex and hidden features.
- The ability to disassemble instruments is highly preferred, especially instruments with design features that are difficult to visually inspect (such as lumens).
- Increased length of certain instruments caused concerns over whether CSSD had the right sterilization and transportation trays that could accommodate them and whether they'd fit in the drying cabinet.

Photo source mdtmag.com

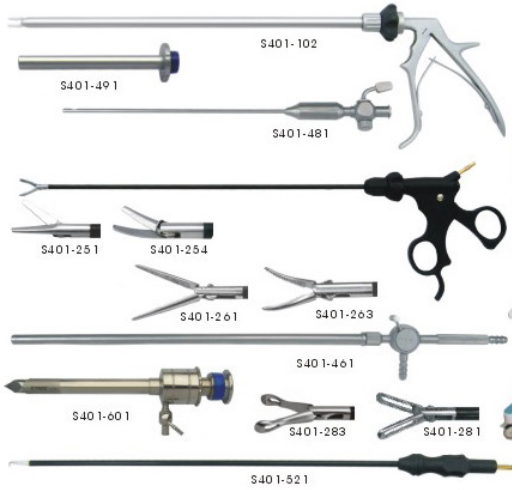


Photo source moore-inc.com

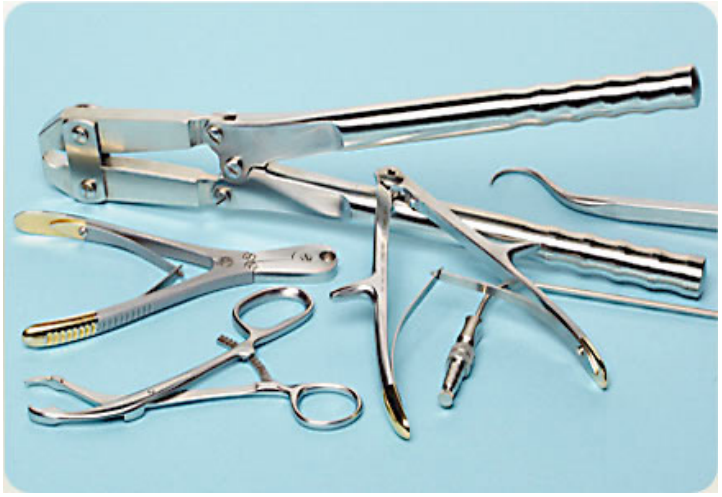


Photo source beeremedical.com

Study Results: Instrument Complexity

"I appreciate that this may be easier for the surgeon but I would like designs that are increasingly easier to reprocess, not harder."

"It would be difficult to do pre-treatment of [this instrument] due to its length."

"Why is this plastic? That doesn't dry very well even though it's good for cable management."

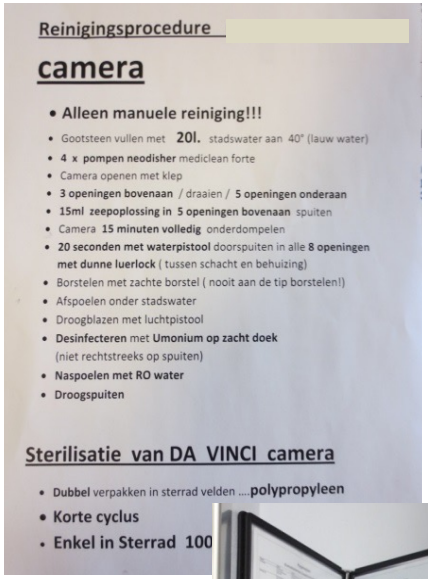
"There are too many ports. How easy is this going to be to flush with limited space and the angle at which you would have to place the syringe?"

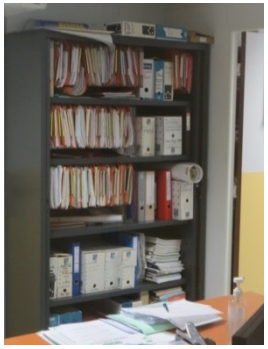
""This [instrument] will not fit in our sink so I have to use a bin right now and I'm spending £4,000 on a new sink!"

"What if water were to get in the connector end? It would cause damage, especially if it was an evening surgery and it was left overnight to be reprocessed the next day."

Study Results: Reference Materials

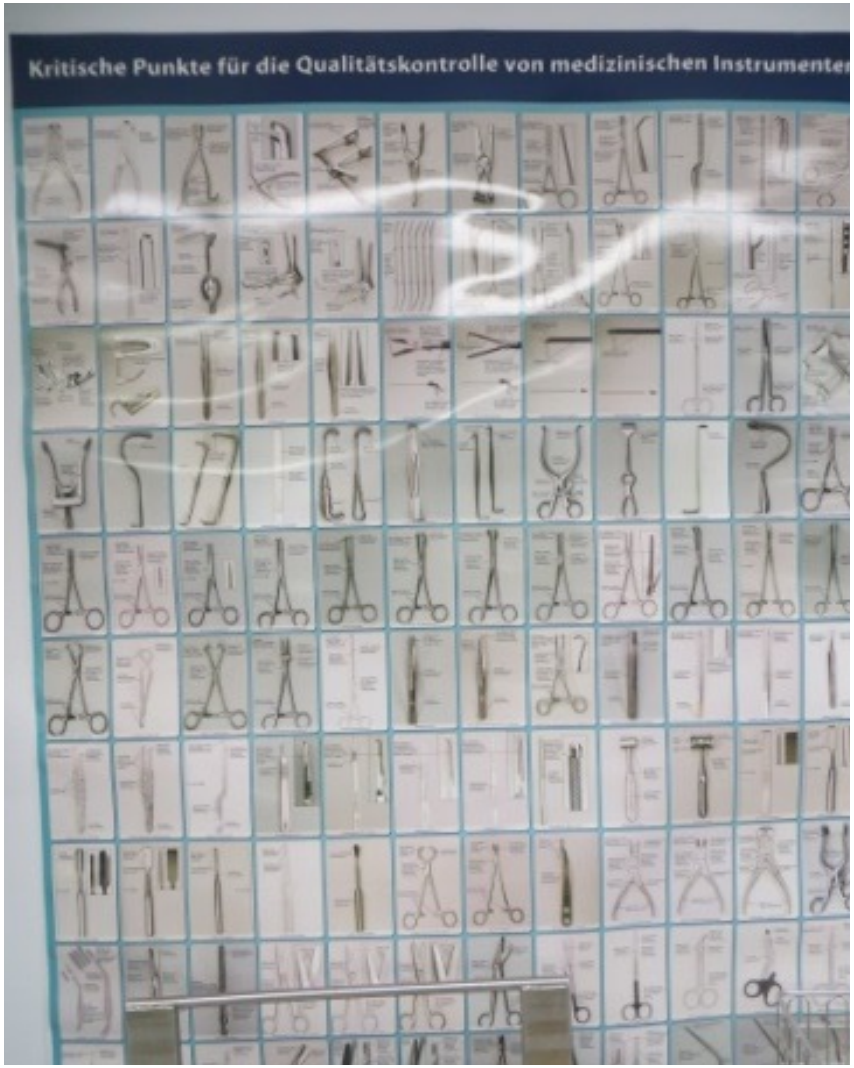
- Staff were generally only referring to manufacturers' manuals the first few times they reprocessed a particular instrument, if at all.
- All sites indicated that they review the manufacturers' reprocessing manuals and then create their own SOP which takes into consideration the manuals' recommendations, country-specific regulations, and hospital-specific policies. The SOPs were validated and then deemed as the governing set of instructions.
- Most sites had the manuals filed away and/or integrated into an SOP which was available electronically by PC lookup.
- Most sites expressed the desire to be able to access the manuals electronically for easier integration into their system.





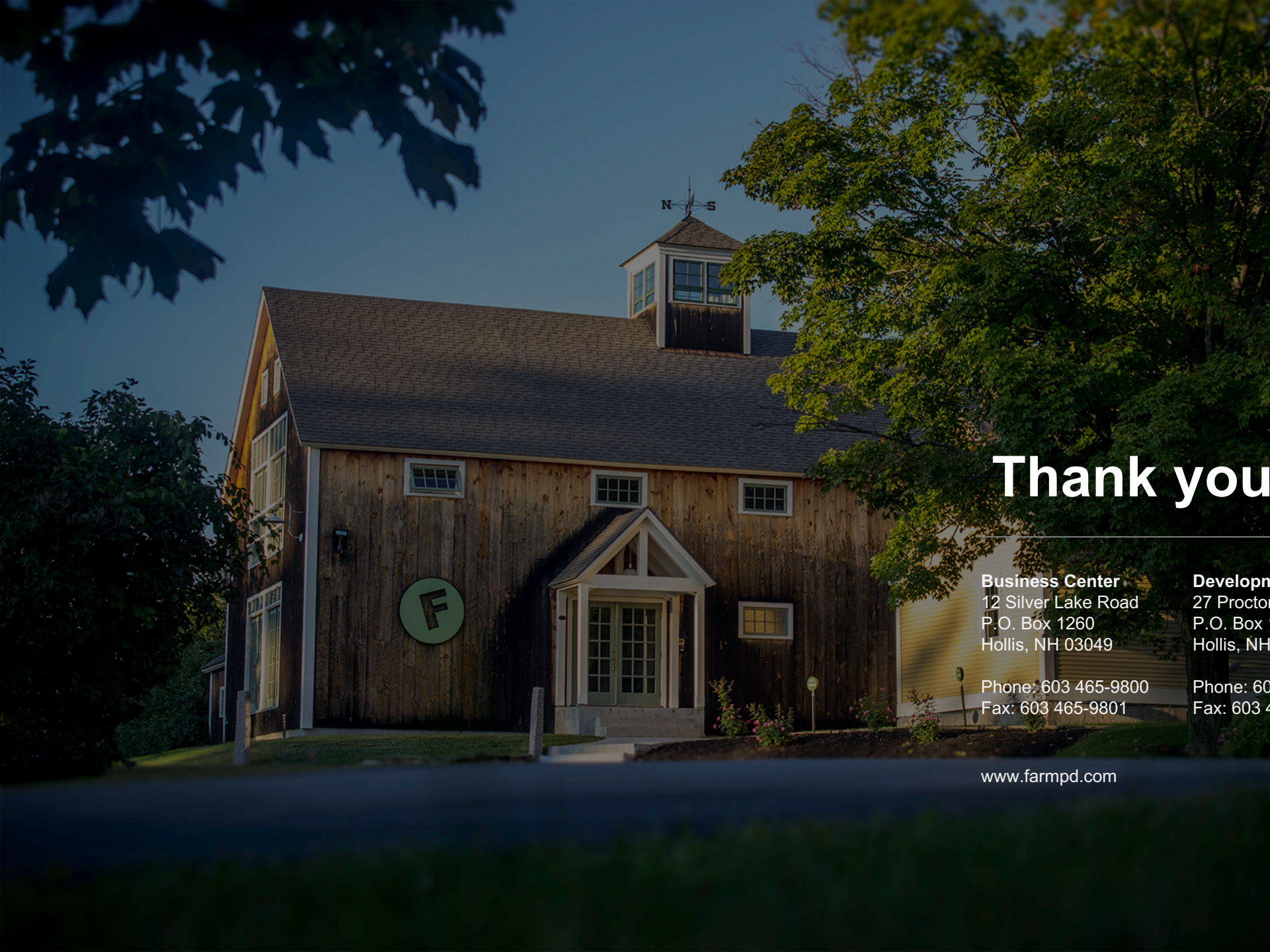
Study Results: Reference Materials

- Several sites commented that reprocessing manuals should include many descriptive images and visual pictorials so staff can easily scan and understand the step or task.
- The majority of sites indicated that they do not like to use wall charts.
    - Dust / concerns over environment
    - Revision validation by notified bodies
    - Excess number of wall charts
    - Not matching their specific SOPs
- Because of the zoned layout of the CSSDs, wall charts containing instructions that related to multiple zones were seen as unfavorable.
- Staff indicated they would be more likely to use wall charts that were laminated and contained helpful images.



6 Final Thoughts

7 Questions?



Thank you

Business Center
12 Silver Lake Road
P.O. Box 1260
Hollis, NH 03049

Phone: 603 465-9800
Fax: 603 465-9801

Developm
27 Procto
P.O. Box
Hollis, NH

Phone: 60
Fax: 603 4

www.farmpd.com