# Do What You Document and Document What You Do – Impact on Liability

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## Objectives

- Define documentation
- Identify essential activities and processes to document
- Discuss length of retention of documentation

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# Why Document?

- Someone once said, “Do what you document and document what you do”.
- There are many processes we document in our daily lives.
- In healthcare, documentation becomes essential.
- We live in a litigious society – must be on guard.

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# Why Bother?

- To avoid litigation, health care providers must comply with established standards of care.
- Standards of care arise from regulations based on state and federal legislation or statutes.
- Regardless of the term used, they are the law.
- Practice standards and guidelines, such as the AAMI, CDC, AORN are also important.

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# Documentation

- **Practice guidelines and facility policies/procedures** are **not** laws.
- Often introduced as standards of care by a prosecuting attorney trying to prove that negligence has occurred.
- Also, a defense attorney will use the same guidelines and policies/procedures as evidence that standards of care **were** met.
- Are your policies referenced to current AAMI standards?
- These are national standards; considered as evidence in litigation.

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# Expert Witnesses

- **Expert witnesses** - used by both prosecuting and defense attorneys to establish standards of care.
- Could be a nurse, a doctor, a facility administrator, etc.
- Usually individuals who are well known and respected in their field.
- Expert's role - to explain to the jury the standard of care based upon their particular area of expertise.
- Allowed to use articles, practice guidelines, policies, etc. to prove their point.
- Jury will interpret the opinions of the expert witnesses and determine for themselves if negligence has occurred.

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# Risks

- Failure to document or faulty documentation on your part is risky behavior - should be avoided.
- Obtain copies of the policies requiring documentation where you are employed.
- Become very familiar with them.
- Review documentation each day to ensure it is accurate and complete.

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# Documentation

Refers to the process of providing evidence ("to document something") or to the communicable material used to provide such documentation.

Webster's Dictionary

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# Documentation

- Importance
  - Written record of incident
  - May be the only source of information for persons subsequently interested in the event
  - Provides a source for identifying pertinent reportable data

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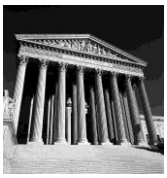
# Documentation

- Legal record of incident - records can be subpoenaed in a court of law
  - E.g. sterilization records
- May be used in court proceedings
- May be the sole source of reference to a case



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# Uses of Documentation

- Audits – to verify compliance with documentation policies
- Conferences - to present data
- Educational forums – to share information

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# Uses of Documentation

- Quality improvement
- May be used to tally the individual's performance of procedures.
- May be used to identify systems issues regarding quality improvement .
- Review individual performance
- Data collection
- Research purposes

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# Consequences

- Consequences of inappropriate documentation:
- An incomplete, inaccurate, or illegible report may cause subsequent personnel to provide inappropriate services.
  - E.g; signed off on sterilization printout without checking it – next person assumes sterilizer OK to use

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# THINK…….

- **MISTAKE** = an act or condition of ignorant or imprudent deviation from a code of behavior.

- **ACCIDENT** = a blunder in an unforeseen and unplanned event or circumstance the choice of; a series of events followed with an element of surprise.
- Which would be less favorable?????????

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# THINK…..

- Legal implications
  - **A lawyer considering the merits of an impending lawsuit can be dissuaded from a case when the documentation is done correctly.**
- The converse is true if documentation is anything less.
- Timeliness of documentation is essential – trying to document after the fact is risky - events will not be fresh in your mind.

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# Types of Documentation

- There are many types of documentation in sterile processing.
- Some do not relate to the process itself, e.g.
  - time we report to work
  - when we leave
    - Required for payment of wages.
- Documentation can be required for other reasons such as return from a medial leave (clearance to return), etc.

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# Types of Documentation

- In the processing areas, there are many types of documentation needed.
- **Orientation** – One of the most important pieces of documentation.
  - Documents the training the employee has received.
  - Proof that the employee received the training needed to be successful in the job.
  - Can be used in wrongful termination if employee feels they were not trained properly.

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# Orientation Documentation

- Who did the training? (Usually more than one person)
- What was demonstrated and when? (Specific)
- Return demonstration – When given and results (pass or fail).
- Retraining if indicated – Who, when and second return demonstration with results.
- Comments about employee's ability to retain information, work under stress, attention to detail, etc.

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# Orientation Documentation

- Can provide important information about the nature and quality of training.
- How much time is needed for each area?
  - Decontamination (1 week? 1 month? 6 months?)
  - Prep/Packaging?
  - Is training based on each employee's ability or all must fit into the same mold?

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# Orientation Documentation

- Instrument Preparation?
- Sterilization?
- Distribution?
- Effective and detailed documentation can provide important information about the training received.

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# Types of Documentation

- **Annual Competency** – required by the Joint Commission (JC) to verify employee performance.
- Requires that the facility verify specific competencies for each employee on an annual basis.
- What should be tested?
- Must include critical components of the employee's job.

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# Annual Competency Documentation

- Focus on high-risk, high-volume tasks or high-risk low volume tasks.
- Should select about 20-40 knowledge and tasks areas.
- Focus on employee and patient safety issues
  - PPE, mixing chemicals, loading washers, manual cleaning, selection of packaging, high-materials, high-level disinfection, etc.
  - Donning and Doffing PPE

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# Annual Competency Documentation

- Use of rigid containers
- Loading and unloading sterilizers
- Use of manufacturer's instructions for cleaning, preparation and sterilization
- Interpretation of sterilizer printouts
- Use of BIs and control vials, etc.
- Routine and Qualification testing

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# Types of Documentation

- **Continuing Education** – All continuing education should be documented.
- Do not leave a Seminar without your certificate
- Make sure the education has been approved by the certifying board.
- The certificate should state the number of points approved for the program.
  - These certificates usually cannot be replaced especially after a year so keep them in a safe place, so you have them for re-certification when needed.
  - May be requested in litigation.

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# Types of Documentation

- **Environmental Documentation** –
  - Daily documentation of temperature and humidity levels in the Decontamination, HLD, Prep/Packaging/Sterilization and Sterile Storage areas.
  - All environmental cleaning should be documented as well as sterilizer cleaning.

AAMI ST-79 Amendment #1, 2020

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# Types of Documentation

- **Maintenance records** – All installation documentation should be documented.
- All qualification testing performed.
- All preventive maintenance on sterilization and processing equipment should be documented and records retained for the life of the equipment or per legal advisor.
- All repairs should also be documented.

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# Types of Documentation

**Decontamination**

- Current IFUs for each device being processed – readily available
- IFUs for detergents and other chemicals, PPE, cleaning implements
- Documentation of who cleaned each device
- Documentation detergent levels verified in washers
- Temperature and humidity levels daily
- SPD environmental cleaning activities in area (equipment, counters)
- Cleaning effectiveness testing all cleaning equipment/results
- Quality checks of mechanical washers
- Verification of wash cycles/printouts (if applicable)
- Action taken if anything out of range.
- Water Quality checks (if your responsibility)

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# Types of Documentation

- **Prep and Packaging** – All sets assembled should be documented by person performing the work.
- IFUs readily available for items assembled for special protocols
- The initials of the preparer or an ID# should be prominently displayed on each package processed, even paper-plastic pouches.
- Daily temperature and humidity levels. Action taken if out of range.
- Tray audits performed; results and action taken.
- Complaints received; investigation and action taken.

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# Types of Documentation

- Special testing performed (e.g. verification of the integrity of insulation on laparoscopic instruments).
- Document EACH instrument tested, result and action taken.
- Lubrication/testing of drills.
- If sharps are routinely sharpened, have the repair service document the date and keep a record.

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# Types of Documentation

- **Sterilization** – the majority of the documentation is in the sterilization area. This area requires extensive and accurate documentation.
- All items processed should be recorded on a log
  - **Writing must be legible!!!**
- Some facilities use a preprinted envelope.

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# What Should I Document?

- All cycles run, including leak tests, daily air-removal tests and aborted cycles.
- The contents of each load should be recorded.
  - Including the number of items, **a description of the items**, and the using department. Information should be specific rather than generic – six OR Mayo scissors, not six OR peel packs.
- All Process Challenge Devices -PCDs (biological test packs) included in the load.
- All routine and qualification testing.
- All information should be written neatly and legibly. The use of whiteout to correct errors is prohibited, because it could suggest that the records were altered.
  - Instead, the operator should draw a line through the incorrect information and initial it.

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# What Should I Document?

- **Implants** - All implants should be documented on the Sterilization Log.
  - Helpful to keep a separate Implant Log form to help identify implants in the event of a follow-up with Infection Prevention.
- Documentation that implants were not released until the result of the biological test is known.
- In a documented emergency and an implant must be released before the BI test result is known, this should be documented on an Early Release form.
- Copy in AAMI ST-79 Annex "K".

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# What Should I Document?

- **CJD** - Due to the difficulty inactivating prions, when known or suspect patients have eye, brain or spinal cord surgery, their instruments should receive special prion processing.
- Consider documenting items processed for CJD precautions on a separate form (in addition to the sterilization log and similar to the implant log) to be able to quickly identify instruments and how they were processed (e.g., Prion Processing Log Form).
- Audits should be performed to ensure all staff compliance with this policy.

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# What Should I Document?

- **Rigid Container Testing** - Rigid containers require pre-purchase biological testing as well as ongoing (annual) BI testing.
- The pre-purchase and annual testing should be documented and records kept where they can be retrieved.
- Some facilities copy the results from the BI record book and save them in a file folder labeled Rigid Container testing so facilitate location of the records.

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# What Should I Document?

- All **Product Testing** as described in AAMI ST-79
  - Trays/items tested
  - Location of BIs and CIs inside samples
  - Test Results; BI and CI results by location in set
  - Evidence of moisture present
  - Action taken if test(s) failed

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# What Should I Document?

- **Recalls** – Action taken if positive or suspect positive BI.
- Need a recall report with actions taken.
- Need a method to identify those items retrieved (and reprocessed) versus those that could not be retrieved.
- If the device cannot be located or was already used; listing of items for Infection Prevention.
- Any similar process is acceptable as long as the records show who retrieved the items, what items were retrieved and when they were retrieved
- Infection Prevention notification.

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# What Should I Document?

- **Outside Manufacturer Recalls** – Sometimes manufacturers have recalls of their products.
- If the product is used or dispensed from your department, it is your department's responsibility to retrieve the product from the various locations and return to the manufacturer per their instructions or per policy.
- Document all steps taken in the recall from receipt of notice to return of materials.
- Ever had the FDA visit our facility after a recall???

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# What Should I Document?

- **Incidents** – anything that can or did result in a patient or employee safety issue.
  - Date, time, location of incident, specific details about what occurred, witnesses, etc.
  - **Problems –** Complaints about trays (e.g. wet, torn wrapper, missing instruments, etc. Need to perform investigation of complaint with response back to department.
  - Document the results of the investigation and what was done to prevent recurrences.
- Tally complaints – track error rates.

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# What Should I Document?

- Listing of borrowed items received from other facilities with a signature when they were picked up and returned.
- Repairs to all patient care equipment
- Damage to equipment or instruments
- Repairs to instruments

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# What Should I Save?

- ✓ All test sheets from Bowie-Dick testing (Pass or fail tests).
- ✓ All cards from Process Challenge Devices (PCDs).
- ✓ All BI records
- ✓ All Sterilization Logs for all sterilization methodologies
- ✓ All chemical integrators from all cycles (if in PCD)
- ✓ All sterilizer printouts.
- ✓ Store in a safe area for period of time as recommended by facility's legal advisor (usually 7 years).

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# What Should I Save?

- If your washer has a printout you must save the printouts (JC) for a period of time recommended by your facility's legal advisor
- High Level Disinfection Log forms for all items HLD
  - MEC (minimum effective concentration) testing log
    - Verifies the efficacy of the high-level disinfectant
  - QA testing of strips log
  - Name(s) of devices / department processed
  - Documentation of temperature of the solution (if recommended)
  - Rinsing performed, number of rinses and water quality

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# What Should I Save?

- Whenever updating policies, save the old policies.
- Keep old copies of AAMI standards – the ones in effect at the time of the incident is what the standard was at the time.
- Litigation could take years – the procedures that would be judged at the time of the incident would be admissible in court.
- Procedures could be very different that what you are currently doing!

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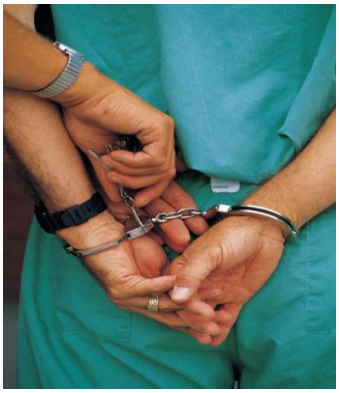
# FALSIFICATION

- Documents that are falsified can lead to immediate termination of employment.
- Falsified documents can lead to criminal prosecution.
- Falsification of documentation of CEUs can lead to revocation of your certification!



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# Summary

- Document all required information
- Make it legible and accurate
- Document immediately to ensure accuracy of the data
- Don’t falsify or mask data
- Sometimes the falsification of data carries more weight against you than the offense!

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# SUMMARY

- You be the judge.
- How good is your documentation?
- Can you prove all processes you performed?
- Can you defend your work?


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# THE END

**REMEMBER….**

**WHEN YOU DO NOT COMPLY WITH A STATED POLICY YOU CAN BE FOUND NEGLIGENT!!**

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# QUESTIONS?????


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