

Welcome to
**Building a Defendable
Cleaning Process**
We will begin soon...



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PQCWebinar Building a Defendable Cleaning Process

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Ask your questions using
the **Q&A** button



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Product Quality Cleaning Workshops

- ▶ Workshops
- ▶ Webinars
- ▶ Resources for more effective cleaning processes
- ▶ More information
 - ▶ shsu.edu/pqcw
 - ▶ bfksolutions.com/manufacturing-minds-pqcw/

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Q: What was most valuable to you?
A: "The general overview of cleaning and the introduction to cleaning processes."
- a 2018 attendee

"The vendor demos were great."
- a 2018 attendee

"All the lab activities were interesting and made me think about things I need to consider in my own lab work."
- a 2018 attendee

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Overview: Building a Defendable Cleaning Process

- Overview of product cleaning
- The 4 D's of a successful process
- When to defend a process
- Who should defend a process
- How to defend a process

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Product Cleaning

- Soil
 - Matter out of place
 - E.g: burnt on lasagna on a casserole
- Cleaning
 - Removing matter out of place
 - Removing live dirt, dead dirt, any matter out of place
 - Not sterilization
 - Green cleaning – separate issue, cleaning ought to be green
- Most manufactured products have to be cleaned to work

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Soils – and soil residue

Particles (metal fines, chips, skin flakes, polishing grit, 3D powder)
Acids
Water
Solvent
Product Assortment
Residual product/breakdown (in processing equipment)
Deposited cleaning agent residue (including flux residue)
Oils, greases
Lapping, polishing compounds
Metal working fluids
Solder flux (rosin, organic acid, low residue)
Rust-preventative

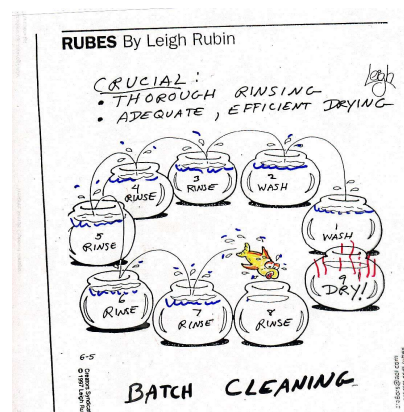
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Cleaning is a Process, usually involving

- Temperature (T)
- Force, Action (A)
- Cleaning chemistry (C)
- Time (T)
- Wash, rinse, dry
- Must consider worker safety, chemical emissions



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B F K
B F K Solutions LLC

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Precision Cleaning

- Precision cleaning
 - Cleaning items that already looks pretty clean
 - Cleaning with a well-defined process
 - Cleaning to a specified process or specified level of residue

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Critical cleaning

- Value-added, “tipping point” cleaning
- Cleaning with an EFFECTIVE, WELL-DEFINED process
- If you don’t do it, product quality suffers
- Any cleaning step is potentially critical cleaning
 - Could be at the beginning of fabrication



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The Four D's of a Successful Cleaning Process

- Design
- Develop
- Document
- Defend

Barbara Kanegsberg & Ed Kanegsberg, "4D Processes,"
Controlled Environments Magazine, Jan. 2014



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A defendable process: Begin with the end in mind

- Why are you cleaning?
- What soils are you removing?
- What are the next steps in the process?
- What risks are involved in removing the soil?
- What risks are associated with the residue?



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Achieve a defendable cleaning process *before*

- An inspection or audit (NADCAP, ISO, etc.)
- A customer audit or visit
- Starting a medical device validation
- You receive an FDA complaint
- You purchase new cleaning equipment
- You ask the boss for a budget for cleaning equipment
- Adding a new product line
- Attempting to sell to a new market
- Legal or insurance-related “finger pointing” begins
- Safety and environmental regulations change



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Who can best defend your cleaning process? *You*

- Build your confidence
 - Understand how cleaning works
 - Why are you cleaning the way you do?
 - Rely on more than sales hype
- Know your product
 - Why are you cleaning?
 - Do you need to clean?
 - Design cleaning with the end in mind
- Know your customer
 - Written and actual cleaning/performance requirements



Alex Lu of the Cleaning Research Group
<https://www.shsu.edu/academics/chemistry/cleanresearch/manufacturing-minds>



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Let's say your cleaning process has worked for 50 years
– that's defendable!

- Consistent, reliable cleaning
- Meet the standards, pass the inspections
- The product performs as expected
 - The coating sticks
 - The medical devices are successful
 - Bone grows around the device
 - Airplanes take off and land successfully

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Make that 50 year old cleaning process bullet-proof

- Maintain the process
- Write the process down - document
- Define how clean is clean
 - Pass/fail (even visual)
- Make sure the assemblers understand and follow the process
- Keep current about cleaning
 - Review, evaluate other cleaning methods
- Capture the wisdom of the tribal elders



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Knowledge Preservation

- Who designed your system?
- Video them:
 - Walking the line
 - Talking about each process
 - Talking about each product
 - Talking about inputs to your process (suppliers, sources, services)



Knowledge

Appreciation



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Quality Function Deployment (QFD)

- A structured methodology and mathematical tool used to identify and quantify customers' requirements and translate them into key critical parameters. In Six Sigma, QFD helps you to prioritize actions to improve your process or product to meet customers' expectations. (<https://www.isixsigma.com/dictionary/quality-function-deployment-qfd>)
- In “normal speak” → “Interview your customers”

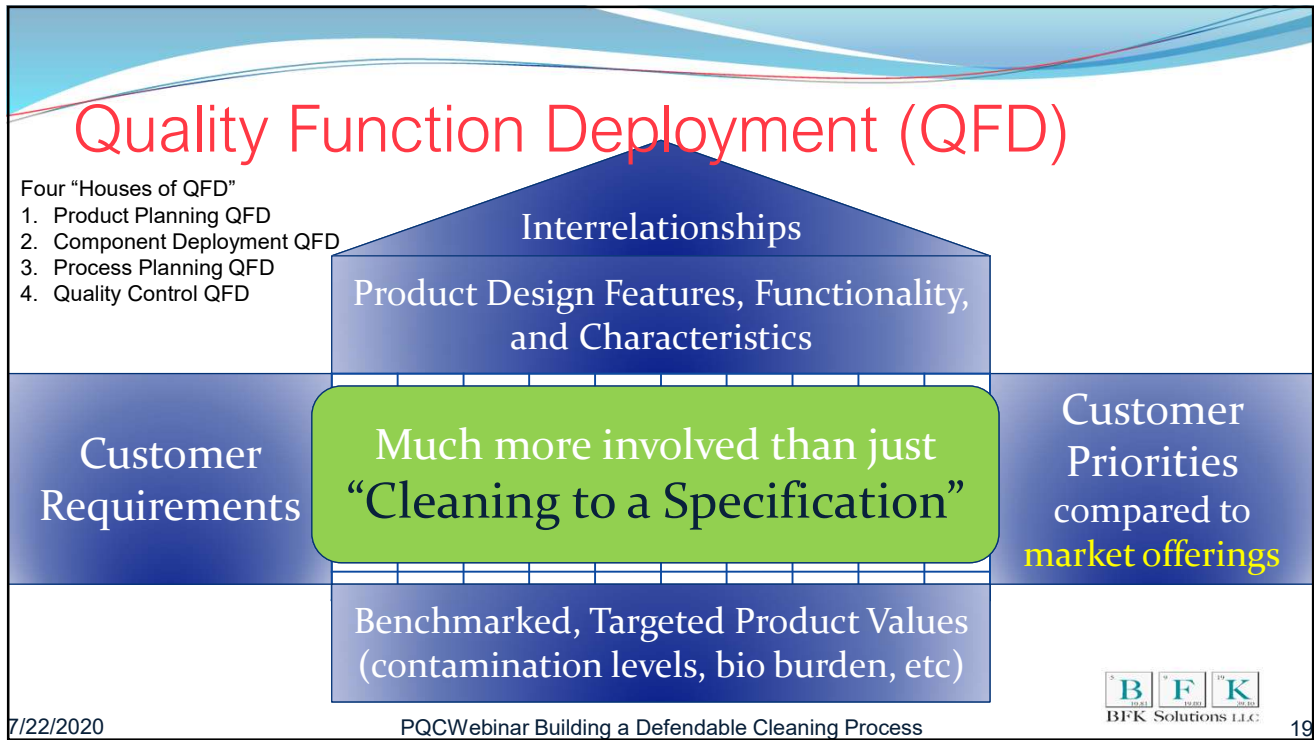
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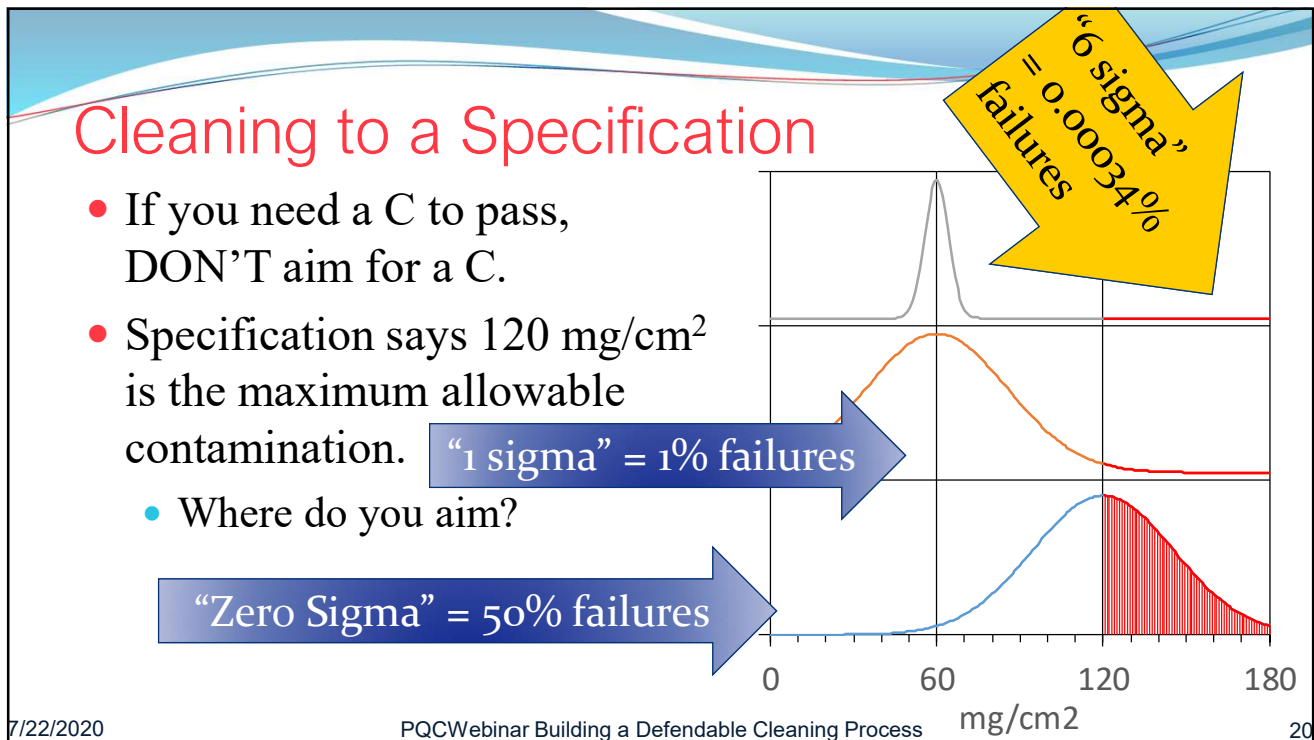


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PQCW Team

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We help manufacturers with effective,
value-added cleaning processes

Co-chairs of the Product Quality
Cleaning Workshops (PQCW)

Free “Clean Source” eNewsletter - Sign up!



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**Product Quality
Cleaning Workshops**
COME TO THE PQCW

- ▶ **When?** To Be Announced
- ▶ **Where?** Sam Houston St. Univ., Huntsville TX
- ▶ **More Info?** Visit <http://shsu.edu/pqcw>

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Have a great rest of your day

product quality
cleaning workshops

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4D Processes

Successful high-performance cleaning processes benefit from following a well-designed plan.

Barbara Kanegsberg
Edward Kanegsberg
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We all want manufacturing processes that are reliable, that don't cost an arm and a leg, that meet or exceed customer or regulatory requirements. To achieve high-performance cleaning processes, use the 4Ds—define, develop, document, defend.

Define

Know your target before you select a weapon, aim, or fire. What is the cleaning process supposed to accomplish? What specific factors are needed to get there? It is important to define the overall process as well as the sub-processes that are used to accomplish the goal. A process flow diagram can outline what comes before and what will ensue next in the process, but a flow diagram itself is not enough. It is also important to know what equipment and/or chemicals are needed, as well as how much time and labor will be required. You have to know where cleaning occurs, both in-house and by your suppliers. That can be easier said than done. Cleaning processes are not always recognized as being cleaning. Your suppliers may incorrectly assume that you have the responsibility for cleaning.

Process definition includes the methods and metrics that determine that the process step has been completed. For instance, if this is a cleaning process, how will the cleanliness be measured? Purely visual? Via an analytical method?

Develop

It takes a village, often a global village, to develop a world-class cleaning process. This includes working collaboratively and critically with vendors who supply cleaning equipment and chemicals. Define your plan to find and evaluate these vendors.¹ Develop your supply chain. Is it a good idea to use an inexpensive supplier who supplies partially cleaned or inconsistently cleaned parts? Does your supplier pass all the cleaning on to you? It may help to be reminded that the longer a soil resides on a part, the harder it is to remove.

Developing a process means planning for actual production conditions. Processes that are quite acceptable during R&D may be inadequate for production. How will you manage a surge in production?² Add shifts? Pull retired equip-

ment out of the warehouse? Outsource?

Consider the safety and environmental aspects of the cleaning process. Will you need to consider equipment for containment or personal protection? Consider the certifications you either need or would like to have. Even if a process is perfectly legal, will it meet resistance by the employees who perform it (for example, due to unpleasant odors)?

Document

Once a process has been defined and developed, it is necessary to have clear, executable instructions for implementing, duplicating, and performing the process. Employees need instructions they can follow. If another employee undertakes the task, will they be able to get the same result? A scientific research result will usually not be accepted until others can duplicate the findings. The same should be true for day-to-day production.

Documenting also includes training. How will the process be taught to employees? Step-by-step recipes have more value if rationales for process steps are provided. Technicians can become innovators to make processes better when they understand why a step is being done, rather than being simply ordered to follow directions.

Documentation also means adequate monitoring. This includes monitoring process conditions such as temperatures and the status of a cleaning bath. Periodically audit the cleaning process, whether it is in-house or outsourced. This includes auditing the cleaning processes of your supply chain.

Processes can and most likely will evolve. Sometimes this is because someone comes up with a better mousetrap, an improved or more cost effective way of performing the process. Maybe the process step really isn't needed and its functions can be accomplished somewhere else in the overall process. Or perhaps the process is not accomplishing its aims and needs to be made more robust. At times, change is dictated from outside, by a customer requirement or by a new regulatory restriction. When the inevitable change occurs, have a procedure for evaluating proposed changes and amending the process instructions. If questions should arise due to product performance, it can be invaluable to be able

to pinpoint what processes were in place in the manufacture of that product.

Defend

For a process to be useful in a manufacturing environment, it must be defensible. Does the process actually accomplish the goal? How does it reduce risks of product failure? These are questions that must be answered to validate a process. They may be needed to prove (unfortunately sometimes in court) that a process does what is expected and was performed properly. This is analogous to Performance Qualification (PQ) that is part of validation procedures utilized in medical device and pharmaceutical industries.³ If a change is suggested or required, will the change reduce the likelihood of product failure?


The 4Ds have to be defensible to company management. Justify the expense of developing, performing, and maintaining a particular process. Is the process needed? How does it increase value? Increasing value is a paramount principle of lean manufacturing. Sometimes the increased value of including a particular process is reflected in the costs associated with not including it. Would product failure increase? Will the product be less reliable and therefore less competitive?

A multi-dimensional world

Manufacturing has more than four dimensions. We cannot always anticipate the unexpected; we can be nearly certain that the unexpected will happen. Plan for the unexpected as part of each of the 4Ds.

References

1. B. Kanegsberg, "Evaluating, Choosing, and Implementing the Process: How to Get Vendors to Work with You," *Handbook for Critical Cleaning (Second Edition): Applications, Processes, and Controls*, CRC Press (2011).
2. B. Kanegsberg, "Process Flow," *Clean Source*, Dec. 2013 <http://bfksolutions.com/index.php/newsletter/77-clean-source-newsletter/227-process-flow#FeatureArticle>.
3. B. Kanegsberg and E. Kanegsberg, "Contamination Control in and out of the Cleanroom: Contamination Control and cGMP," *Controlled Environments Magazine*, Feb. 2008.

Barbara Kanegsberg and Ed Kanegsberg (*the Cleaning Lady and the Rocket Scientist*) are experienced consultants and educators in critical and precision cleaning, surface preparation, and contamination control. Their diverse projects include medical device manufacturing, microelectronics, optics, and aerospace. Contact: info@bfksolutions.com 



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