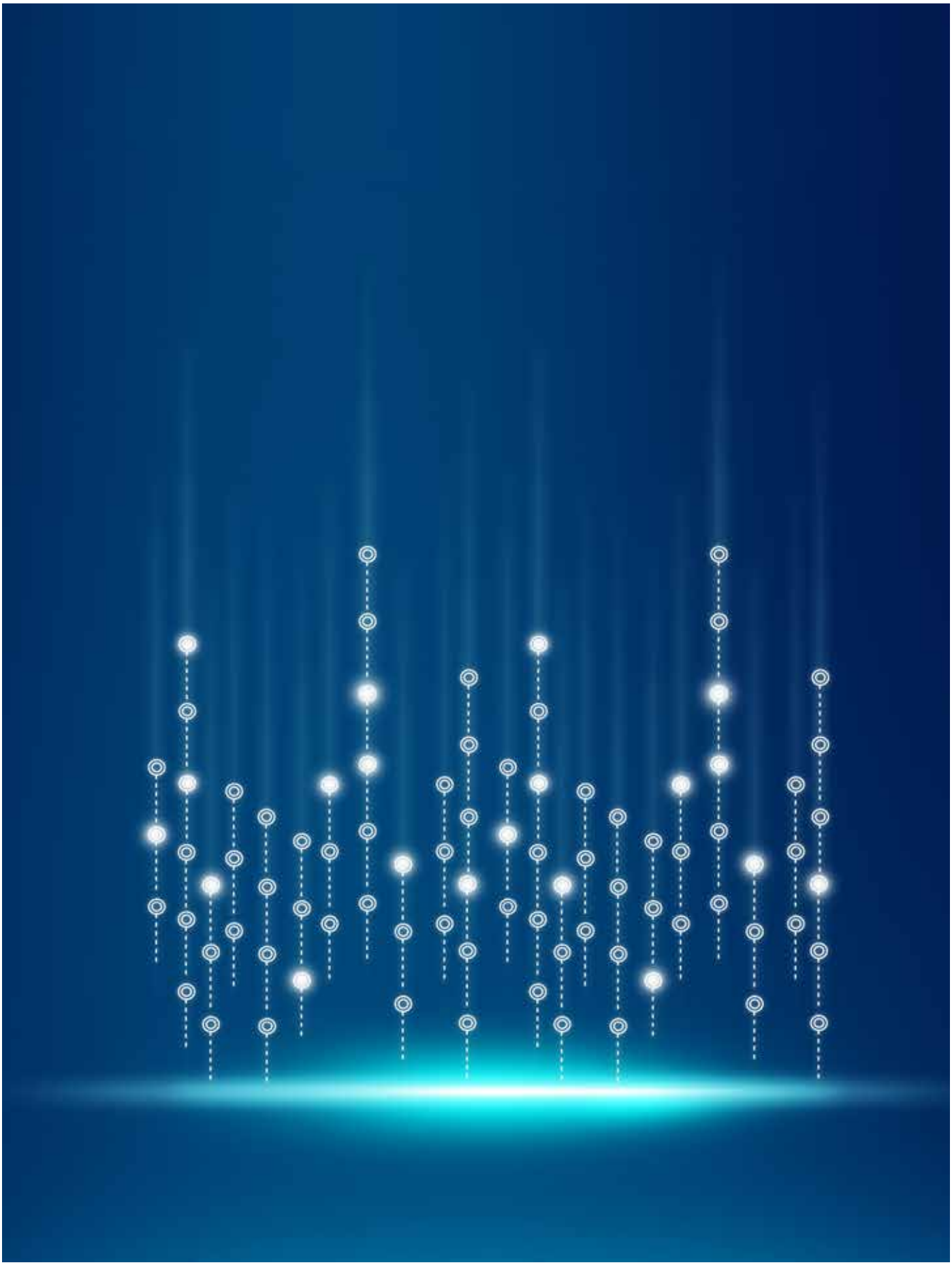

Statistics in Action: Quality Assurance and Patient Safety Begins with Sterility Assurance Programs

BY WILLIAM LEIVA, MBA, MPH, SENIOR PROGRAM MANAGER, STERILE REPROCESSING—MEDTRONIC

This series of self-study lesson plans was developed by HSPA. Certified Registered Central Service Technician (CRCST) lessons provide members and certification holders with ongoing education on core Sterile Processing-related topics and processes. Purdue University's Extended Campus and HSPA both offer grading opportunities.

Earn Continuing Education Credits

Online: Visit www.myhspa.org for online grading.

By mail: For written grading of individual lessons, send completed quiz and $15 to:
Purdue Online – Central Service
Young Hall, Room 448
155 S. Grant St.
West Lafayette, IN 47907

Scoring: Each quiz with a passing score is worth two continuing education (CE) credits toward your CRCST recertification (12 credits).

Subscription series: Purdue Extended Campus offers an annual mail-in or online self-study lesson subscription for $75 (six specific lessons worth two credits each toward CRCST recertification of 12 credits). Call 765.494.0959 for details.

More information: HSPA provides online grading service for any of the Lesson Plan varieties. **Note: Purdue University provides grading services ONLY for CRCST and CIS lessons. Please do not send the CHL or CER lessons to Purdue for grading.** Direct any questions about online grading to HSPA at 312.440.0078. Questions about written grading are answered by Purdue University at 765.494.0959.

For paper/pencil scoring requests, please allow up to two weeks for grading.

LEARNING OBJECTIVES

1. Describe the principles of quality assurance
2. Understand the gaps in quality assurance programs in Sterile Processing departments
3. Apply statistical analysis tools to assess current quality assurance strategies

Those responsible for medical device processing understand the complexity of the processes and the challenges in achieving clean, sterile and safe devices. The sterility assurance programs Sterile Processing (SP) professionals rely on play a vital role in quality assurance and patient safety. This lesson aims to help readers understand the statistical aspects of pack control and load release using statistical tools.

Objective 1: Describe the principles of quality assurance

Quality assurance is a systematic and holistic process to ensure a specific product, service or process meets specified requirements, which must remain consistent over time. A good example of quality assurance within the Sterile Processing department (SPD) is the sterile condition a critical device must have for use in a surgical procedure. Another example is eliminating bioburden before the final device inspection and packaging.

Quality assurance is the overarching goal of medical device processing. It is achieved through quality control activities, which involve testing and inspection to meet the desired specifications. Examples of testing and inspection within the SPD include the visual inspection of decontaminated devices, the use of external tools, such as ultrasonic cleaner monitors (either by standard soil removal or cavitation), a washer-disinfector cycle report, or the results of biological and chemical indicators (BIs and CIs) on sterilization cycles.

Using these tools and others helps SP professionals determine whether the quality control has demonstrated that the process meets the specified requirements. The information generated can feed the quality assurance program. The SPD is continuously creating new data

Sterilization Technology	Process Indicator	Chemical Integrator	Air Removal Indicators
Saturated steam	Available	Available	Available
Ethylene Oxide	Available	Available	Not available
Hydrogen Peroxide*	Available	Available	Not available
Hydrogen Peroxide**	Available	Available	Not available

* Including vaporized and plasma hydrogen peroxide systems
** Hydrogen peroxide and adjutant gases such as ozone

Table 1: U.S. Food and Drug Administration categories of chemical indicators
Source: Author

related to the results of monitoring and measurement activities. On the monitoring side, there is qualitative and quantitative data. Qualitative data generally comes in the form of approved (pass) or rejected (fail), such as in the case of cleaning and sterilization monitoring, in which the cycle did or did not achieve the expected outcome. On the measurement side, the devices provide quantitative data, often digitally exported or printed on reports from washer-disinfectors, automated endoscope reprocessors, and sterilizers. These provide essential information about temperature, time, pressure, and whether the expected parameters were achieved. This information has a number (e.g., 194° F for a washer cycle); therefore, it is presented in a quantitative format.

Among the biggest challenges of quality assurance is the effective use of data to assess the consistent quality of the process over time. While every processing step generates a large amount of data, only its effective use and transformation into valuable information can help sustain quality assurance goals. Unlike other areas of healthcare, the data generated from SPD processes can be easily quantified and, therefore, used to inform, improve and report deviations. The question is how this can best be achieved.

Objective 2: Understand the gaps in quality assurance programs in Sterile Processing departments

Two potential gaps in quality assurance programs exist during the processing of reusable medical devices: device decontamination and sterilization monitoring. While the decontamination process is often done in automated washer-disinfectors, several devices require manual decontamination (e.g., some ophthalmologic devices, robotic surgical devices, and some hinged and lumened devices). This poses a challenge to SP professionals, and there are ongoing calls from industry stakeholders to improve manufacturers' instructions for use (IFU) and make them applicable to all settings.

Whenever IFU call for manual decontamination, the ability to effectively control all the steps of the process can be difficult, particularly the steps involving specific water temperature, concentration and the need for specific brushes. In some cases, IFU call for a time range in which a particular step must be completed (e.g., brush between 20 and 60 seconds), which often leads to an arbitrary process and confusion in the SPD. From a quality perspective, this contributes to potential breaches in the assurance and control level when comparing manually processed devices versus those processed in automated systems.

The quality assurance program also faces challenges on the sterilization side, as quality control differs in many facilities. The sterilization process can be monitored using CIs (See **Table 1**) and BIs. In the CI segment, there are currently process indicators, chemical integrators, and air removal indicators. Although some facilities use the same CI category for all sterilized materials despite their sterile barrier, others use less-specific and lower-cost CIs for materials deemed "less critical" such as single instruments wrapped in peel-pouch sterile barriers. This creates variations in the quality assurance strategy because some devices are monitored using more specific devices (e.g., integrators or type 5 CIs), and others are monitored with less-sensitive devices (e.g., mono-parameter, type 3 or multi-parameter CIs, type 4).

Regarding the use of BIs, some variation is observed between facilities and different sterilization technologies. This is because loads sterilized using saturated steam are often monitored with BIs at a different frequency than those sterilized using ethylene oxide (ETO). Although this is caused by current recommended guidelines (i.e., ANSI/AAMI ST79, ANSI/AAMI ST41, ANSI/AAMI ST58; See **Table 2**), these guidelines state the minimum

Sterilization Technology	Standard	Recommendation
Saturated steam	ANSI/AAMI ST79:2017/(R)2022 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*	15.5.3.2. "Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI."
Ethylene Oxide	ANSI/AAMI ST41:2008/(R)2018 *Ethylene oxide sterilization in health care facilities: safety and effectiveness*	10.6.1 "A BI PCD should be used in every load."
Hydrogen peroxide	ANSI/AAMI ST58:2013/(R)2018 *Chemical sterilization and high-level disinfection in health care facilities*	9.5.4.3 "A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle."

* Including vaporized and plasma hydrogen peroxide systems

Table 2: Current recommendations for load release based on sterilization modality
Source: Author

$$Rate = \lfloor \frac{\#Packs\ released\ from\ cycles\ using\ PCD}{total\ \#\ cycles\ of\ packs\ sterilized} \rfloor X100$$

Equation 1: Rate of packs monitored with PCD versus total number of packs
Source: Author

recommended practices and, therefore, can be taken as a baseline and not as the ultimate requirements.

Objective 3: Apply statistical analysis tools to assess current quality assurance strategies

Imagine 20 cycles evaluated based on the number of CIs that show cycle problems (see **Table 3**). To simplify this, each cycle had 200 single-instrument peel pouches. Based on when the packs were identified as having issues, they are recorded in the column "Packs with Problem." With this simple dataset, there are three possible scenarios regarding the detection of packs with sterilization cycle problems: the detection shows a random trend (**Figures 1** and **2**), the detection shows an upward trend (**Figures 2** or **3**), or the detection shows a downward trend (**Figure 3**).

Each of the three trends provides different information about the event occurrence. If the trend shows a random pattern, the cause analysis might be more complex; however, it may indicate human factors or specific problems with the steam supply. If there is an upward trend, one can quickly identify that something is wrong as the cycles continue. If there is a downward trend, it may have detected cycles or process issues that were adequately addressed because process improvements were made.

The red trend lines in **Figures 1 to 3** were obtained using linear regression; however, the general principle is that even a simple visual guide can provide tremendous value when assessing what is occurring with a specific metric. For other assessments, such as the analysis of cycle monitoring with process challenge devices (PCDs), calculating the rate of instruments with evidence of lethality may be more adequate because it provides insight into two quality assurance strategies. To assess this, the rate of packs effectively monitored

Cycle	Packs	Packs with problem
1	200	0
2	200	1
3	200	0
4	200	0
5	200	0
6	200	0
7	200	0
8	200	13
9	200	7
10	200	2
11	200	2
12	200	9
13	200	35
14	200	0
15	200	0
16	200	0
17	200	9
18	200	0
19	200	2
20	200	0

Table 3: Reference for trend analysis
Source: Author

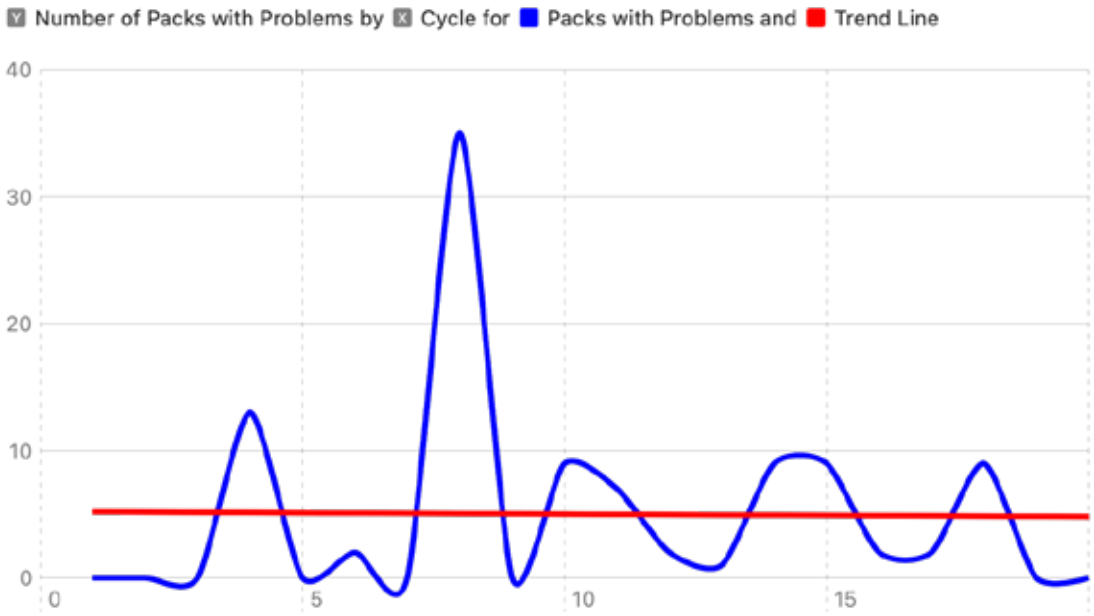

Figure 1: Random trend in chemical indicators, evidencing cycle failure
Source: Author

Use of BI for load release	Rate of packs with evidence of lethality
Every load	100%
Once a day	20%
Once a week	5%

Table 4: Simulated rates of load release with evidence of lethality
Source: Author

for lethality versus the total number of sterilized packs may be useful (See **Equation 1**). For the context of this exercise, the definition of "pack" is broad and will encompass pouches, trays and containers.

To illustrate this, let's assume that a single sterilizer is used four times a day, with each cycle containing 25 packs. When using this formula, the rate of packs with evidence of lethality, as provided by the use of PCDs with BIs, is shown in **Table 4**.

Although this example does not account for loads with implantable material, it nonetheless helps with understanding the critical factors of a quality assurance program. Whenever standardized quality should be delivered, a standardized monitoring strategy must be in place. This example may be even more relevant when considering the variation of load release strategies across the different sterilization technologies and the complexity of the devices requiring sterilization.

Conclusion

SP-related activities should be subjected to multiple assessments. There are high expectations of quality, which require quality assurance and quality control activities. Once implemented within the organization, the data flows into different systems to deliver actionable information, which often relates to the performance of processing technologies and human resources.

Choosing the appropriate tools will ensure an adequate quality assurance program. In turn, this will contribute to healthcare facilities' overall goals, specifically as they relate to patient safety and the reduction of adverse events.

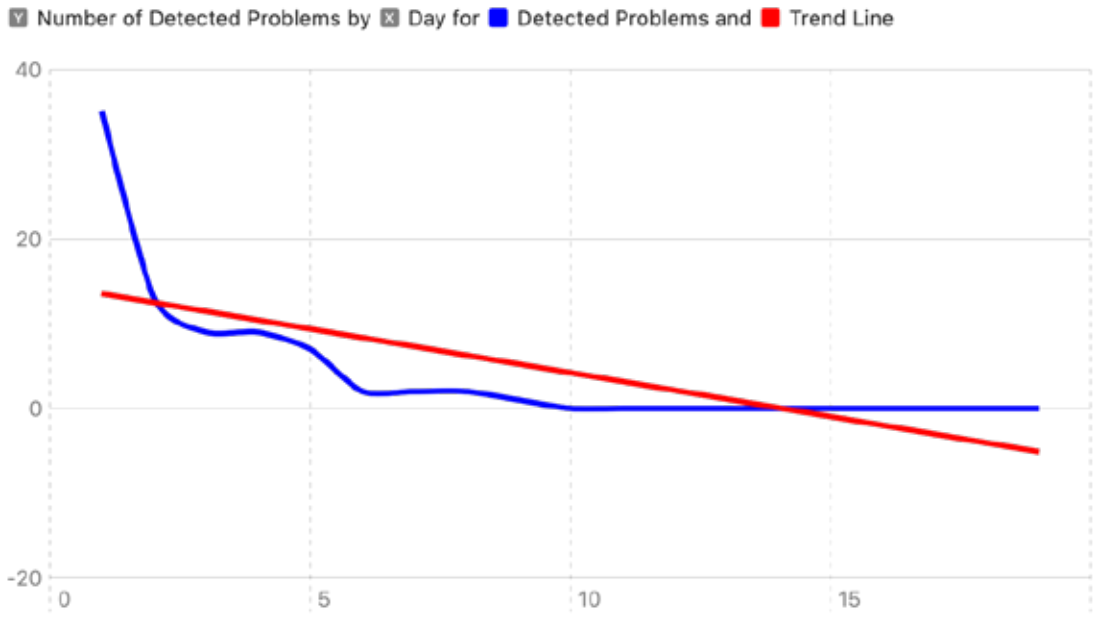

Figure 2: Downward trend in chemical indicators demonstrating a cycle failure
Source: Author

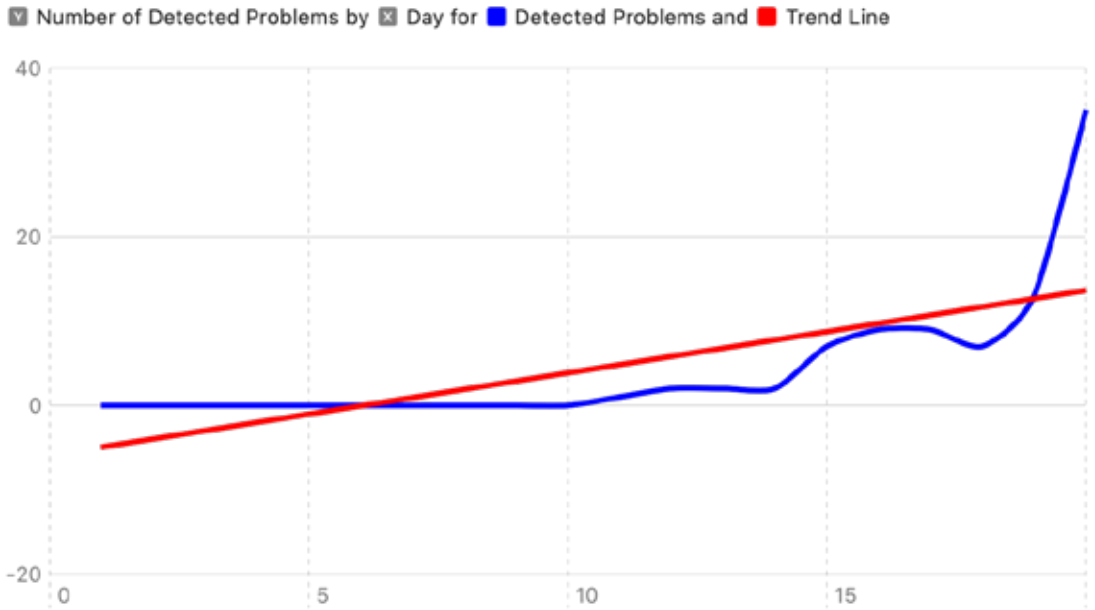

Figure 3: Upward trend upward in chemical indicators, evidencing cycle failure

CRCST Self-Study Lesson Plan Quiz: Statistics in Action: Quality Assurance and Patient Safety Begins with Sterility Assurance Programs

Lesson No. CRCST 199 (Technical Continuing Education – TCE) • Lesson expires December 2027

1. Quality assurance means:
   a. A product complies with standards
   b. A service complies with a standard
   c. A product or service meets specified requirements
   d. A complete absence of errors in a process

2. Quality control involves which of the following?
   a. Testing only
   b. Testing and inspection according to specification
   c. Inspection only
   d. Physical parameters to prevent errors

3. Which is not an example of testing and inspection for Sterile Processing (SP)?
   a. Sterilizer acquisition
   b. Water quality
   c. Soil removal monitors
   d. Cavitation monitors

4. Which is an example of quantitative data?
   a. Sterilizer printout
   b. Type of washer cycle
   c. Type of sterilization cycle
   d. None of the above

5. An example of qualitative data is:
   a. An employee attendance report
   b. Cleaning and sterilization monitoring
   c. The technicians responsible for a process
   d. Quarterly employee evaluations

6. Which can be potential gaps in SP quality assurance?
   a. Quality management and quality control
   b. Employee turnover
   c. Device decontamination and sterilization monitoring
   d. Sterilization standards

7. Manual cleaning is:
   a. Required for most devices
   b. More effective than automated cleaning
   c. Less effective than automated cleaning
   d. A process that is more difficult to control

8. Sterilization can be monitored using:
   a. Biological indicators (BIs)
   b. Chemical indicators (CIs)
   c. Process indicators
   d. All the above

9. Variations in the use of BIs are caused by:
   a. Different facility policies
   b. Current guidelines
   c. A lack of BIs for hydrogen peroxide
   d. A lack of Bowie-Dick tests for hydrogen peroxide

10. Which of the following trends in process outcomes can be identified?
   a. Inferential statistics
   b. A rate analysis
   c. Graphical representation of results
   d. Bar charts created by facility executives

11. Rates are useful for:
   a. Comparing the results of two different quality assurance strategies
   b. Comparing BIs and CIs
   c. Comparing errors across different technicians
   d. Determining which technicians require additional training or termination

12. Qualitative data generally comes in the form of:
   a. Before and After
   b. Required or Optional
   c. Approved (Pass) or Rejected (Fail)
   d. Rejected and Documented

13. Which entity provides standards for the use of biological testing in healthcare sterilization?
   a. Centers for Disease Control and Prevention
   b. National Institute of Occupational Safety and Health
   c. U.S. Food and Drug Administration
   d. Association for the Advancement of Medical Instrumentation

14. Which is an example of an external quality assurance tool used in Sterile Processing departments?
   a. Ultrasonic cleaner monitors
   b. Air pressure/flow tests
   c. Visual inspection
   d. Staff training

15. One of the biggest challenges of quality assurance is:
   a. Costs associated with implementing and maintaining the system
   b. Technological limits of the testing devices
   c. Effective use of data to assess consistency of the quality of a process over time
   d. Availability of testing devices for consistent use

Request for paper/pencil scoring

(Please print or type information)

❍ I have enclosed the scoring fee of $15. (Please make checks payable to Purdue University. We regret that no refunds can be given.)

❍ Check here if you have a change of address.

❍ Check here if you wish to have your results emailed to you.

Detach quiz, fold, and return to:
Purdue Online – Central Service
Young Hall Room 448
155 S. Grant St.
West Lafayette, IN 47907

Name

Mailing Address (Be sure to include apartment number or post office box.)

City | State/Province | Zip Code/Postal Code

Daytime Telephone | HSPA Membership Number

Email Address

If your name has changed in the last 12 months, please provide your former name. Purdue University is an equal access/equal opportunity institution.