Episode 12: Validation

What is validation?

Validation is a method used to assess compliance of the cleaning process.

What do you use validation for?

Validation is conducted to monitor the effectiveness of cleaning. It can and is used in several different areas such as the food industry, hospitality, and healthcare. Studies within healthcare have demonstrated that after a validation program was put into place, healthcare associated infections decreased. A validation system is used as coaching/education tool. It is not to be punitive.

What types of validation programs are available?

There are four basic forms of validation:

a) **Observation or Visual Assessment** — this method is very subjective depending on the individual performing the observation. It is not measurable. It is easy to perform, but has no correlation to microorganisms on the surface. It indicates the area 'looks' clean.

b) **Fluorescent Marker** — a non-visible gel that fluoresces under black light is placed on High Touch Surfaces (HTS) within the area being audited. After the area has been cleaned, a black light is used to look for traces of the gel. This can be labor intensive as a person needs to place the marks on the surfaces being monitored, and go back after cleaning is performed to assess how well cleaning was performed. Cost of the tools are inexpensive and results are measurable, usually as a percentage of marks removed. The results does not determine what removed the mark (disinfectant wipe, wet wipe, other object), nor if a contact time was met for the disinfectant.

c) **Start Adenosine triphosphate (ATP)** — detects organic matter on a surface, as all organic matter has ATP present in their cells. After cleaning, the surface is swabbed with a special swab that is inserted into a handheld machine that will generate a value expressed as relative light units (RLU). The higher the RLU, the more organic matter on a surface. The values do not correlate to microorganisms on the surface: you can have low RLU but have many bacteria, and on a dirty surface you may have high RLU, but few bacteria. The handheld machine may be provided by the manufacturer, however the swabs used are expensive. Results are also measurable, but 'pass' values for clean must be established for each manufacturer's machine within each setting.
d) **Microbiological culture** is not for routine, daily use. Culture takes time, generally 24-48 hours, requires a laboratory that is familiar with environmental testing, so it does not provide a quick result. Testing is expensive and generally used for research or outbreaks. When cultures are performed, special media will be required to detect a specific outbreak organism.

**Who generally does validation?**

Validation can be performed by EVS or housekeeping supervisors and, in healthcare by Infection Prevention and Control (IP & C). In healthcare, validation within a surgical department may be done by IP & C. Other departments may also contribute to validation monitoring.

Validation should be done regardless who performs cleaning and disinfection: all cleaning processes need to be validated. Facilities such as Ambulatory Surgery Centers or office buildings, that may have a clean done in the evening by a contractor, should validate that the cleaning is being performed properly by utilizing one of the above methods.

Validation has been used in the food and beverage manufacturing industry for many years to determine that surfaces are hygienically clean.

**How is validation recorded and reported?**

It is important to have consistent, measurable data, as this will be part of a Quality program. Seeing trends will help to identify issues and then corrective measures and education can be performed. If compliance with cleaning is down, validation can help determine what needs to be addressed. Is there an issue with training? Is there an issue with the time allotted to perform the daily clean or room turnover? Is there clutter that is impeding the cleaning process? In healthcare, are staff being interrupted by medical staff, and can’t complete the clean? Is the need for a bed due to a surge in patients provoking an incomplete terminal clean? Cleaning issues can contribute to an increase of infections in healthcare. Cleaning issues within hospitality can lead to poor ratings from customers.

Data can be recorded in an electronic format using a tablet or phone, or manually and then entered onto a spreadsheet. Graphs can be generated by floor, department, or by surface which can help with improvement in all aspects of the cleaning process. Data can be presented to other management teams, or end user such as the IP & C Committee within a hospital, long term care center, or for the Ambulatory surgery center. It also be discussed at operational meetings in the food and beverage industry to discuss opportunity for improvement.