

Cleaning Memo for November 2015

Only Read This If Applicable

Well, you are reading this, so you must have thought it was applicable. My question to you is “How did you know it was applicable?” Unless I give you more information as to the content, you cannot decide whether it is applicable or not. That information might be something like “Only read this if you write cleaning procedures for manual operators.” Then, you could decide whether the information I am presenting might be applicable to you.

So, what’s the point of this Cleaning Memo? The point is that cleaning process instructions may be written in a manner that requires operators to make decisions without having appropriate directions. Examples of those types of written instructions include:

If applicable, remove the gasket before cleaning.

If necessary, repeat the entire cleaning process beginning with step 4.

If required, physically remove the bulk of any residue before the washing step.

If needed, hot water up to 45°C may be used.

So, how do I (the operator) know whether it is *applicable* to remove the gasket? How do I know if it is *necessary* to repeat the entire cleaning process (starting with step 5)? How do I know when it is *required* to physically remove the bulk of any residue before the washing step? How do I know if hot water is *needed*?

I think you get the point. “If clauses” do not belong in a written SOP *unless* there is more definition as to when or how to apply that “if clause”. Here are examples as to how I might rewrite those instructions to make them more defined and specific.

If the equipment is to be used for a different product, remove and discard the gasket prior to cleaning the equipment; otherwise clean the equipment with the gasket in place. (Note that I will also have to have some way for the operator to determine what the next product manufactured will be.)

Visually inspect the equipment following rinsing, but before drying. If the equipment is visibly soiled after completion of the rinsing process, repeat the entire cleaning process beginning with step 4.

For any ointment product (but not for liquid products), physically remove the bulk of any residue remaining on equipment surfaces using a plastic scraper before performing the washing step.

In all cases for coated tablets, use hot water at $45^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for the soaking, washing and rinsing steps. (Note that I changed the temperature from “up to” to a specified range. “Up to”, which allows for any temperature up to the maximum, should also be avoided. It’s like stores that advertise a sale with “all merchandise up to 80% off”. You look inside the store and find that there is only one item (and who would wear that color?) at 80% off; most items are marked only 10% off.)

I hope I have made this issue clear. If there are variations possible in a cleaning process, make sure that the operators know *when* those variations should be used. While you can provide definition and clarification outside the written SOP, it is best to capture it in the written SOP itself. Now if necessary, go back and read this Cleaning Memo again. Whoops! I meant to say “If you are unclear what point I am making, go back and read this Cleaning Memo again.”