# Validation for Control Value Setting



- 1. Choose the sample point according to risk assessment
- Swab after rinsing water (after detergent step) and collect the result 5 times for each point
- 3. Choose the 2nd highest RLU value to be the "Tentative standard"
- 4. Use the Tentative standard for 1 month
- 5. Take latest 5 RLU values of the month, and choose the 2nd highest RLU value to be the standard
- 6. Round up to the nearest hundred unit
- 7. Example:  $523 \rightarrow 600$  $1,245 \rightarrow 1,300$

<sup>\*\*</sup>This procedure can be repeated periodically and the Standard can be revised. \*\*

## Validation for Control Value Setting



#### Step 1

## Step 2

### Step 3

### Step 4

Choose sample point

Ex)
cutting knife,
cutting board,
sink, conveyor
belt, tank, joint
part, filling
nozzle, rinse
water, etc.

Swab after rinsing (after detergent step) and collect 5 results for each sample point. Choose 2<sup>nd</sup> highest RLU value as a tentative standard

Ex)
If the results are 234, 456,

1,234, 789, 1,567

→ Choose 1,234

tentative standard: 1,300\*

\*Round up tens place

Use tentative standard for 1 month

Take latest 5
RLU values of
the month, and
choose the 2nd
highest RLU
value to be the
standard in the
same way as
step 2

This procedure can be repeated periodically and the Standard can be revised.

A3 test is the tool for improvement!