Component Level Impact Assessment

Introduction

In this workshop, we are establishing what items within our clean in place system need validating. A Component Level Impact Assessment happens at the start of the validation project and what you decide here will determine the validation activities.

You are looking to establish the critical and non-critical items within our clean in place system. For items you determine to be critical, you must then decide if they are product-contact critical or operationally critical. You also have to be able to give a rationale for your decision.

As outlined previously, if non-critical items are validated, the cost of manufacturing increases (leading to unaffordable medicines for patients). So it's crucial that you can see the decision making process and understand how we reach the point where we are validating the things that are essential in ensuring a safe and effective product, without over-validating.

Preparation

1. Download the following 2 documents
    a. Component Level Impact Assessment Workshop Doc
    b. Generation of Piping and Instrumentation Diagrams (P&ID) (you should already have a copy of this from previous workshops)

2. Re-watch the following two videos
    a. System Impact Assessment (originally in Session 2, Topic 2)
    b. Component Level Impact Assessment: Part 1 - Product Contact Components (originally in Session 2, Topic 3)

3. Find a place where you can spread out all these documents and won't be disturbed

NOTES

This assignment can be completed electronically and electronic signatures are acceptable. It is also acceptable to hand-write your work but please do make sure that your writing is legible.

Workshop Instructions

(These instructions are very similar to the wording of one question in the assignment. Don't worry if it's not immediately clear what they mean, we're going to walk through the process stepby-step)

1. Locate the 5 pieces of **equipment** not greyed out in the Equipment Component form below, and find them on the P&ID. Conduct a Component Level Impact Assessment (CLIA). Decide whether each item is product-contact critical, operationally critical, or both.
2. Complete the same process for 5 **instruments** and 5 **pipes** (filling out the Instrument Components form, and the Piping Components form, respectively).
3. For any identified operationally critical components, complete the summary table for operational critical components and include rationale.

Component Level Impact Assessment (to be completed)

Equipment Components

Item #	Tag	Description	Critical		Non-Critical
			Operational Critical	Product Contact Critical	
1-1	T-211	Hot Detergent Tank	No	Yes	No
1-2	T-411	Hot PUW2 Tank	Yes	Yes	No
1-3	P-207	Detergent Centrifugal Transfer Pump	Yes	No	No
1-4	P-209	Detergent Centrifugal Transfer Pump	Yes	No	No
1-5	P-415	PUW2 Centrifugal Transfer Pump	Yes	No	No
1-6	P-417	PUW2 Centrifugal Transfer Pump	Yes	No	No

1-7	P-223	Detergent Metering Pump			
1-8	HX-211	Detergent Plate Heat Exchanger			
1-9	HX-411	PUW2 Plate Heat Exchanger			
1-10	FL-399	Detergent Cartridge Filter			
1-11	FL-401	PUW2 Cartridge Filter			
1-12	PSV-001	PUW2 Sanitary Pressure Relief Valve			
1-13	PSV-002	Detergent Sanitary Pressure Relief Valve			

Instrument Components

Item #	Tag	Description	Critical		Non-Critical
			Operational Critical	Product Contact Critical	
2-1	TCV-005	Steam Temperature control valve	Yes	No	No
2-2	TCV-006	Steam Temperature control valve	Yes	No	No
2-3	TT-001	3 wire RTD Temperature transmitters	Yes	No	No
2-4	TT-002	3 wire RTD Temperature transmitters			
2-5	TT-003	3 wire RTD Temperature transmitters			
2-6	TT-004	3 wire RTD Temperature transmitters	Yes	No	No
2-7	PT-001	Sanitary Diaphragm type Pressure Indicating transmitters			

2-8	PT-002	Sanitary Diaphragm type Pressure Indicating transmitters	Yes	No	No
2-9	PI-007	Local pressure indicators c/w bourdon type gauges			
2-10	FT-001	Magnetic flow Transmitter	Yes	Yes	No
2-11	FT-002	Magnetic flow Transmitter			
2-12	FT-003	Magnetic flow Transmitter			
2-13	FT-004	Magnetic flow Transmitter			
2-14	FS-005	Low Flow switch			
2-15	CT-001	Conductivity transmitter			
2-16	PI-003	Diaphragm type pressure indicator			
2-17	PI-004	Diaphragm type pressure indicator			
2-18	PI-005	Diaphragm type pressure indicator			
2-19	PI-006	Diaphragm type pressure indicator			
2-20	PI-008	Diaphragm type pressure indicator			
2-21	TI-007	Bimetalic Temperature indicator			
2-22	TI-008	Bimetalic Temperature indicator			
2-23	TI-009	Bimetalic Temperature indicator			
2-24	TI-010	Bimetalic Temperature indicator			

Piping Components

Item #	Tag	Description	Critical		Non-Critical
			Operational Critical	Product Contact Critical	
3-1	50-PUW1-S6-147-IH	From LN-486 To T-211			
3-2	50-PUW1-S6-148-IH	From LN-486 To T-411	Yes	No	No
3-3	80-DETERGENT-S6-149-IH	From T-211 To FL-399	Yes	Yes	No
3-4	80-DETERGENT-S6-150-IH	From FL-399 To P-207	Yes	Yes	No
3-5	80-DETERGENT-S6-151-IH	From LN-150 To P-209	Yes	Yes	No

3-6	65-DETERGENT-S6-152-IH	From P-209 To LN-153			
3-7	65-DETERGENT-S6-153-IH	From P-207 To HX-211	Yes	Yes	No
3-8	65-DETERGENT-SS1-154-IH	From HX-211 To XV-021 @ DETERGENT change-over valves			
3-9	80-PUW2-S6-156-IH	From FL-401 To P-415			
3-10	80-PUW2-S6-157-IH	From LN-156 To P-417			
3-11	65-PUW2-S6-158-IH-	From P-417 To LN-159			
3-12	65-PUW2-S6-159-IH-	From P-415 To HX-411			
3-13	65-PUW2-SS1-160-IH-	From HX-411 To XV-016 @ PUW2 change-over valves			
3-14	25-PROCESS-S6-161-NI	From Conc. Detergent Dosing System To P-223			
3-15	25-PROCESS-S6-162-NI	From P-223 To LN-149			
3-16	65-DETERGENT-SS1/S6-163-IH	From XV-018 @ DETERGENT change-over valves To T-211			
3-17	65-PUW2-SS1/S6-164-IH	From XV-013 @ PUW2 change-over valves To T411			
3-18	100-VENT-S6-166-NI	From T-211 To Safe Area			

Summary Table - Operational Critical Components

#	*Operational Critical Component	**Additional components in the loop (if applicable)	Rationale
1	T-411 (Hot PUW2 Tank)	**N/A**	Handles PUW2 used in processes that directly affect product safety
2	P-207 (Detergent Centrifugal Transfer Pump)	Linked to FL-399, HX-211	Essential for transfers of detergent, which affects the effectiveness of the system's cleaning

3	P-209 (Detergent Centrifugal Transfer Pump)	Linked to FL-399, HX-211	Essential for transfers of detergent, which affects the effectiveness of the system's cleaning
4	P-415 (PUW2 Centrifugal Transfer Pump)	Linked to FL-401, HX-411	Essential for transferring PUW2, impacting system's cleaning and processing performance.
5	P-417 (PUW2 Centrifugal Transfer Pump)	Linked to FL-401, HX-411	Essential for transferring PUW2, impacting system's cleaning and processing performance.
6	TCV-006 (Steam Temperature control valve)	N/A	Monitors and transmits data about the temperature of steam, which also plays a role in operational control
7	TT-001 (3 wire RTD Temperature transmitters)	Linked to TCV-006	Monitors and transmits temperature data, vital for operational control.
8	TT-004 (3 wire RTD Temperature transmitters)	Linked to TCV-006	Monitors and transmits temperature data, vital for operational control.
9	PT-002 (Sanitary Diaphragm type Pressure Indicating transmitters)	Linked to system pressure controls	Monitors pressure in the system, which is essential for safety .
10	FT-001 (Magnetic flow Transmitter)	Monitors flow in piping systems	Handles detergent, which again critical for operational control and frequently relevant for product operation
			.
11	50-PUW1-S6-148-IH (From LN-486 To T411)	Linked to T-411	Transports PUW1 to T-411, which directly affects operations
12	80-DETERGENT-S6-149-IH (From T-211 To FL-399)	Linked to T-211, FL-399	Carries detergent, which is also linked to both operational control and the products in that it is effectively applied

13	80-DETERGENT-S6-150-IH (From FL-399 To P-207)	Linked to FL-399, P-207	Carries detergent, critical for the detergent supply to pumps, impacting system cleanliness.
14	80-DETERGENT-S6-151-IH (From LN-150 To P-209)	Linked to LN-150, P-209	Handles detergent, which is relevant for the availability of detergent supply to the pumps
15	65-DETERGENT-S6-153-IH (From P-207 To HX-211)	Linked to P-207, HX-211	Transports detergent to P-209, which is also linked to the overall operations. Carries detergent to heat exchangers
16			
17			

Instruction Walkthrough

(You'll also find a video walking through these steps. We'd recommend reading through the instructions below and then watching the video to fully follow the process).

Part 1 - Locate the 5 pieces of equipment not greyed out in the Equipment Component form below, and find them on the P&ID. Conduct a Component Level Impact Assessment (CLIA). Decide whether each item is product-contact critical, operationally critical, or both.

We begin by considering the equipment within the system. You'll find these already listed out in the Equipment Component form.

For this exercise, we've greyed out everything except 5 pieces of equipment.

You have to decide, for these 5 items, whether they are critical (differentiating between productcritical or operationally critical) or non-critical.

In a real world scenario, you would use Risk Management tools to make these decisions.

But we're not going to assume you all have that level of knowledge right now, so here's a rough guide to help you decide about items within this system...

Product-contact critical items come into direct contact with the product OR are part of the chain of surfaces through which there is a risk of contamination being carried to the product.

The first part of that is quite self-explanatory but the second part can take a bit of thinking about. So let's consider an everyday example…

You're in the kitchen and you cut raw chicken. Once you've finished, you don't wash your hands. Instead you go to the fridge and take out salad items. You cut them, and serve the salad to your friend. Your friend gets ill from salmonella after eating the salad.

Now your friend was never near the raw chicken but there was a chain of surfaces (i.e. the skin on your hands and the outer surface of the salad items) that brought the salmonella directly from the raw chicken to your friend.

Our clean in place system has that type of product-contact critical items. The final medicine or its ingredients never come near the clean in place system but the system is part of a chain of surfaces that can pass contamination to the product.

Think of the detergent tank of our system. The inner surface of the tank touches the detergent liquid. That detergent liquid passes along a system of pipes and into the reactors during a drawdown. That same liquid then touches the inner surface of the reactor. After a cleaning cycle is finished and manufacturing restarts, the inside of that reactor will come into direct contact with product ingredients.

So although no final products (or even ingredients) are ever in direct contact with the inside of the detergent tank, there is a chain of surfaces that leads from the tank to a surface that will come into contact with the product. If there was contamination in the detergent tank, there is a possibility it could ultimately reach the product via this chain of surfaces. Therefore, our detergent tank is product-contact critical.

Operationally critical items don't come into direct contact with the product and they're not part of that chain of surfaces that can introduce contamination. But they contribute to maintaining a state of balance (dynamic equilibrium) for the key factors (i.e. temperature, flow, level, concentration) in our CIP system.

If any of these 4 key factors are out of specification in our CIP system (e.g. liquid is not hot enough or detergent concentration isn't strong enough), we cannot guarantee that the system is working as intended. Operationally critical items are involved in controlling, monitoring or reporting these 4 factors so it's essential that we validate them.

(Note that these key factors may be different depending on the system you're validating, the 4 listed are the specific ones necessary to control our CIP system.)

Non-critical items do not come into contact with the product, nor can they influence the factors that are essential for the correct functioning of the system.

Fill in the form using Yes / No - as shown in the examples Dr Brady talked through in the videos.

If you haven't already, you should first complete the multiple choice questions provided within the module, to familiarise yourself with how to make these decisions.

16.8.Appendix H: Component Impact Assessment

Equipment Components

Item #	Tag	Description	Critical		Non-Critical
			Operational Critical	Product Contact Critical	
1-1	T-211	Hot Detergent Tank			
1-2	T-411	Hot PUW2 Tank			
1-3	P-207	Detergent Centrifugal Transfer Pump			
1-4	P-209	Detergent Centrifugal Transfer Pump			
1-5	P-415	PUW2 Centrifugal Transfer Pump			
1-6	P-417	PUW2 Centrifugal Transfer Pump			
1-7	P-223	Detergent Mentering Pump			
1-8	HX-211	Detergent Plate Heat Exchanger			
1-9	HX-411	PUW2 Plate Heat Exchanger			
1-10	FL-399	Detergent Cartridge Filter			
1-11	FL-401	PUW2 Cartridge Filter			
1-12	PSV-001	PUW2 Sanitary Pressure Relief Valve			
1-13	PSV-002	Detergent Sanitary Pressure Relief Valve			

Part 2 - Complete the same process for 5 instruments and 5 pipes (filling out the Instrument Components form, and the Piping Components form, respectively).

You'll find 5 items not greyed out on the Instrument Component form and 5 items not greyed out on the Piping Component form.

Follow exactly the same rationale as Part 1 to decide if these items are product-critical, operationally critical, both, or non-critical.

N.B. you might be confused by seeing valves listed on the Instrument Component form - these values are actuated, so are classed as instruments.

Part 3 - For any identified operationally critical components, complete the summary table for operational critical components and include rationale.

On the "Summary Table - Operational Critical Components", list all the items you have identified as operationally critical from Part 1 and Part 2 in this workshop.

For now, we're greying out the "additional components" column. You would require additional information to be able to successfully complete that, so for the purpose of the workshop you can ignore it.

For each operationally critical item, fill in the "rationale" box. You should refer back to your own decision making (and the advice given in Part 1) to help with this.

Now save your work document and send it on to your course coordinator via email.