

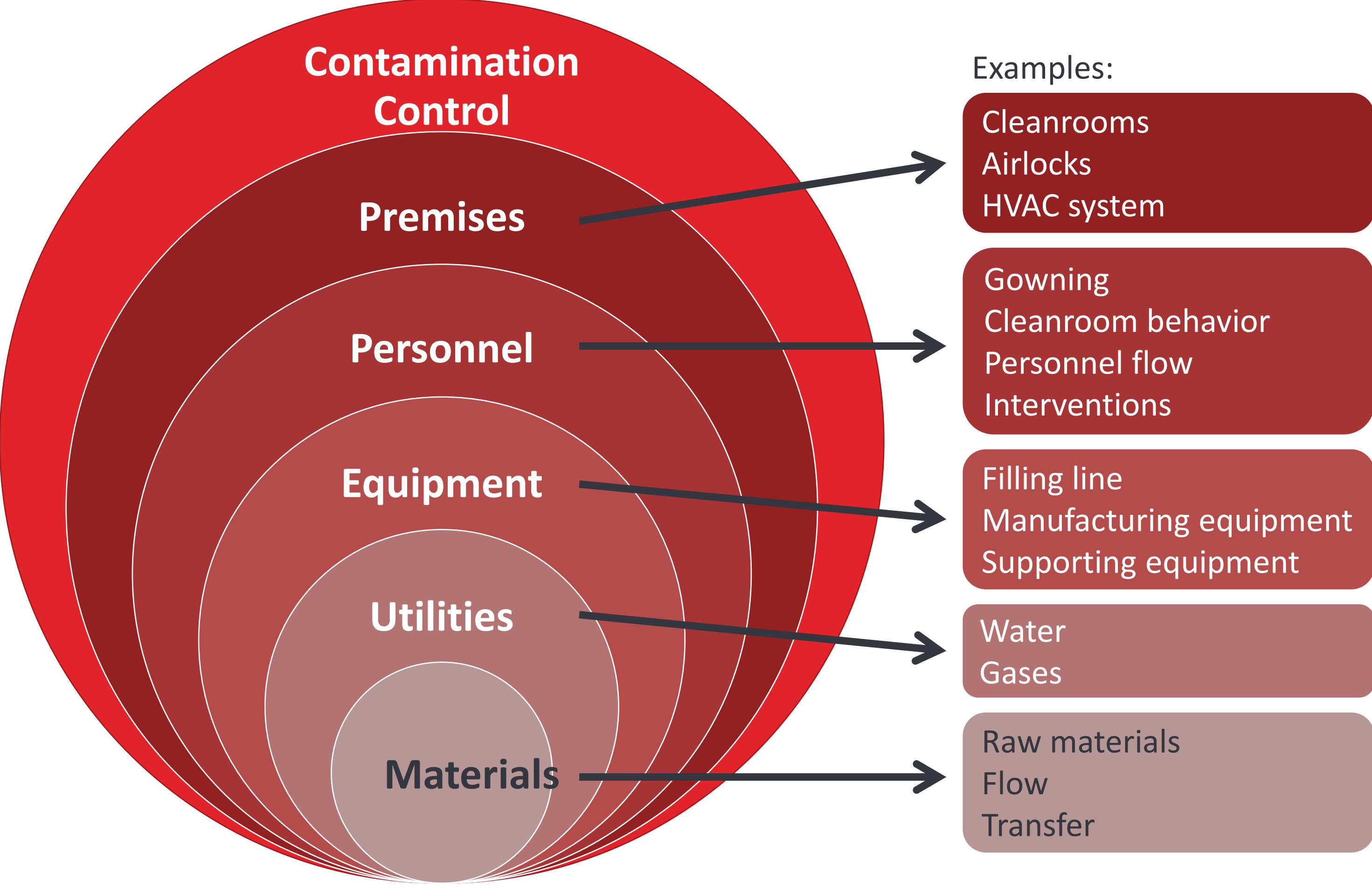
Developing a Site-Wide Contamination Control Strategy: From Risk Mapping to Implementation

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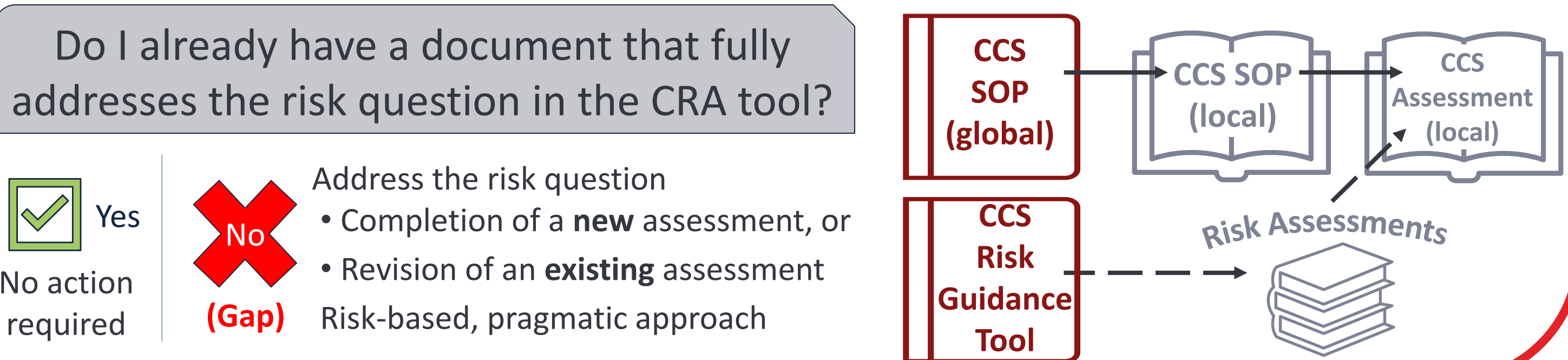
Introduction

Recent revisions to EU Annex 1 heavily emphasize the importance of a contamination control strategy (CCS) for manufacturers, and the requirements and guidance are numerous and cover many topics. This poster will provide an overview of one company’s approach for interpreting and implementing the Annex 1 CCS requirements, including updating existing CCS global guidance and implementing tools such as a template for sites to create local CCS and global contamination risk assessment with recommended risk questions, appropriate risk assessment tools/methods for each risk question, and guidance on how to group risk assessments for efficient management.

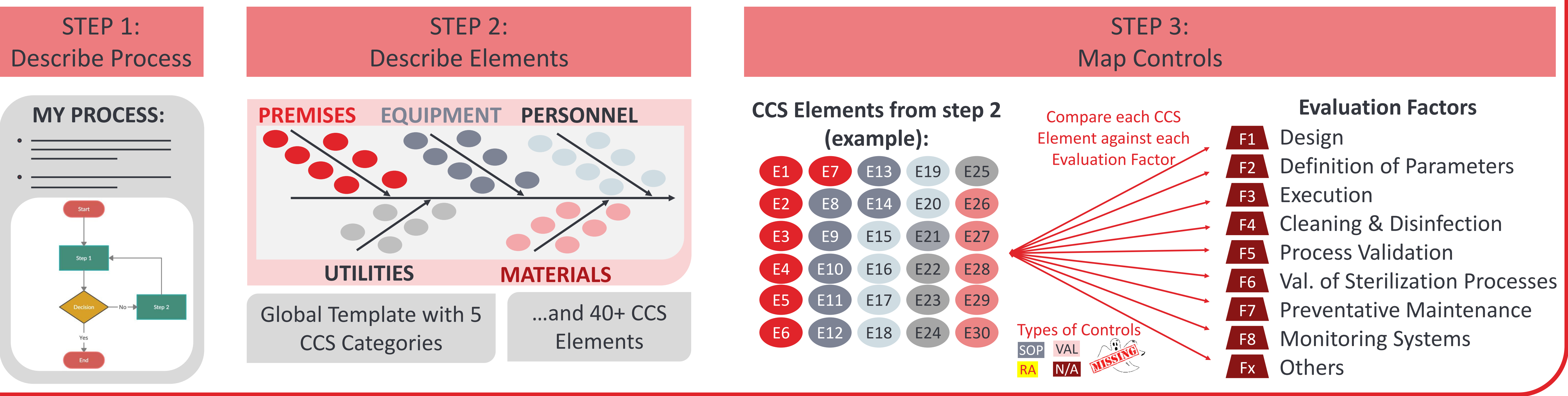


Annex 1 / Quality Risk Management Challenge

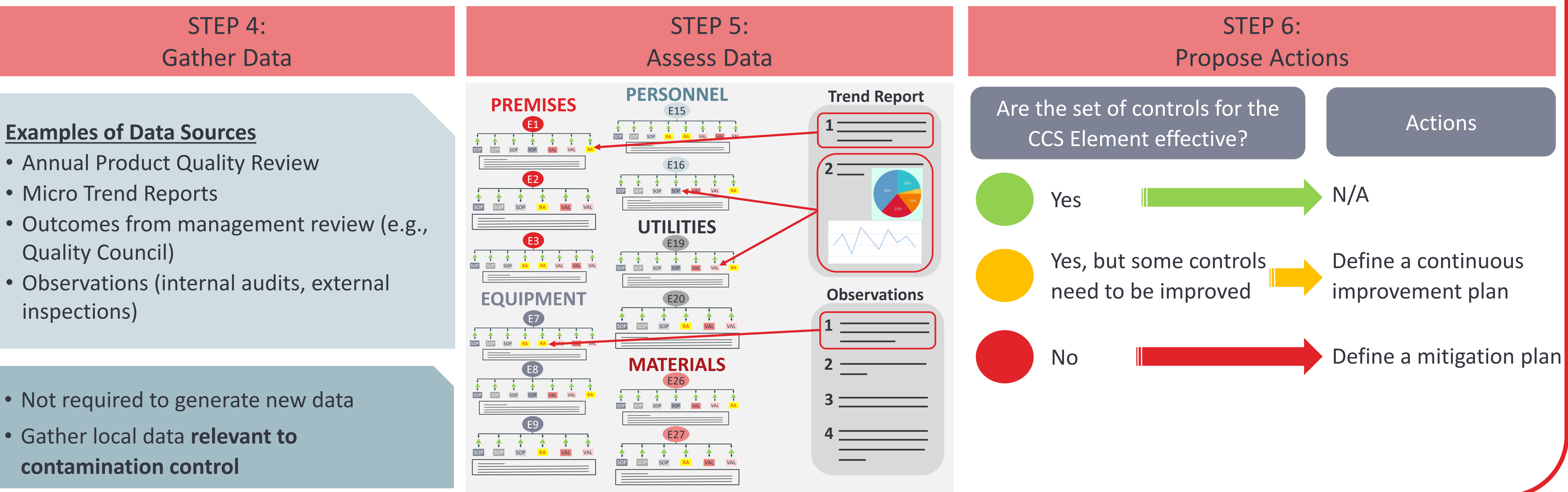
Risk Question	Recommend Level(s) of RA Formality	RA Methodology to Consider	Best Practice Considerations
<ul style="list-style-type: none">Clear statement of the question to be answeredCritical to ensure the stated requirement is metE.g., “What contamination risk is posed by...?”	<ul style="list-style-type: none">Based on ICH Q9 guidance for RA formality and rigorCommensurate with complexity, criticality, and uncertainty present	<ul style="list-style-type: none">Recommended for each risk questionE.g., FMEA, HACCP, Risk Ranking and Filtering	<ul style="list-style-type: none">Risk factors specific to the risk question (where applicable)Guidance documents relevant to the risk question (where applicable)RA methodology best practice considerations



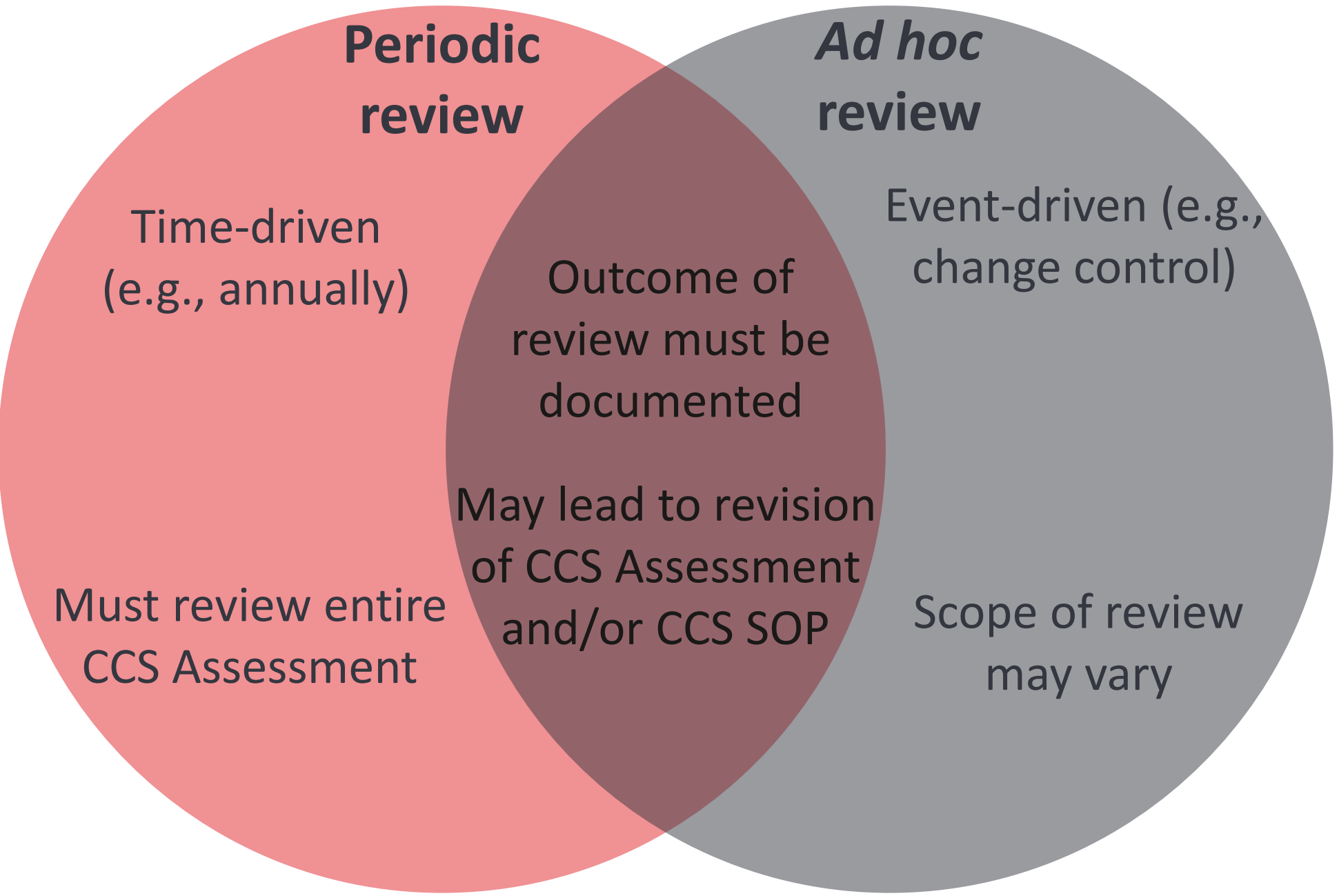
CCS Definition



CCS Effectiveness



CCS Lifecycle



Conclusion

