Guidance Document on root cause investigations of Sterilization Dose Audit (SDA) positives and failures

IRPN25-2026

Introduction

This document provides guidance on the investigation of Sterilization Dose Audit (SDA) positive results and failures. It contains best practices shared from industry panel members and example tools that can aid the targeted investigation and evaluation of root cause. It also provides guidance on eradication methods. The guidance is intended to promote a proactive approach to SDA positive results, enabling manufacturers to identify emerging trends, address underlying causes, and reduce the risk of future SDA failures. This guidance supplements, but does not replace, the requirements of ISO 11137, ISO 11737 and applicable company quality management system requirements.

Scope

This guidance is intended for product manufacturers who experience SDA positive results or failures in routine testing and require guidance on a structured approach to finding the root cause of the surviving microorganism and methods of how to eradicate it.

The document assumes any lab error has already been ruled out and that these are genuine positives or failures. (The first step in any investigation should be to confirm the result is true and that there was not a laboratory error / laboratory contamination. It is vital this information is included in the investigation pack. This could be from an in-house laboratory or contract laboratory and sterilization contractor for the SDA dosing.) This document does not cover Dose Establishment studies.

The occurrence of 1 or 2 positives in SDA tests is accepted and statistically accounted for. Because ISO 11137-2 Table 4 bases the verification dose on a conservative standard distribution of resistances (SDR) the model allows for approximately 55% probability of 1 or 2 positives on any SDA test. (37% probability of 1 positive, 18.5% probability of 2 positives). While actual positive rates are typically much lower due to natural bioburden being less resistant than the SDR, this represents the maximum expected probability under the standards model.

With the differing options of Dose Establishment methods the number of positives allowed in the acceptance criteria differs. A method 1 or 2 dose audit passes with no more than two positives, whereas a VDmax dose audit passes with no more than one positive. (with a second stage confirmatory step allowed after 2 positives).

When evaluating SDA positive results, the key consideration is not solely the occurrence of a positive, but whether there is evidence of an adverse trend. Examples include repeated positives within the same family, an increasing number of positives over time, or changes in the type or resistance profile of recovered microorganisms. In such cases, investigating SDA positives can be a proactive step to prevent future SDA failures.

References

ISO 11737-1:2018, Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on products

TIR 106 :2024 Microbiological methods – Understanding and use of product bioburden data.

ISO 14644 series, Cleanrooms and associated controlled environments.

EN 17141:2020, Cleanrooms and associated controlled environments. Biocontamination control

ISO 11137-1:2025, Sterilization of health care products – Radiation – Requirements for the development, validation and routine control of a sterilization process for medical devices.

ISO 11137-2: 2013 Sterilization of health care products – Radiation – Establishing the sterilization dose.

The Irradiation Panel publications :

> Guidance on the Sterilization Dose Audit Failure Risk Assessment as per the requirements of ISO11137 standard. 2020. IRPN16-2020
>
> Guidance Document on ISO 11737, ISO 11137 and ISO 13004 Microbiological Methods. 2026 IRPN26-2016

Reasons for investigating positives and failures

Several industry standards emphasise the importance of understanding the microorganisms present on medical devices and within the manufacturing environment.

ISO 11737-1 states in section 6.2.1 'Microbial characterisation is necessary to detect a change to the product bioburden that can affect some aspects of the use of bioburden data (e.g. establishing a sterilization process). Furthermore, knowledge of the types of microorganisms can be helpful for identifying sources of contamination. '

TIR 106 states 'Certain microorganisms can be more resistant to a particular sterilization modality than other microorganisms…The presence of these microorganisms in the bioburden could potentially be indicative of greater resistance to the sterilization process. Knowledge of the microorganisms' resistance can be used to establish and support the type and frequency of monitoring, level of characterisation, and trending of bioburden'.

In addition to supporting sterilization process control, understanding the microorganisms that survive SDA testing is important for mitigating potential product impacts and reducing the risk of future SDA failures. A proactive approach to the evaluation of SDA positives, before they progress to an SDA failure, allows the manufacturers to identify emerging contamination issues and implement corrective actions at an early stage. Understanding what type of microorganism survived an SDA dose and their origins can help prevent them reoccurring and causing a failure in future.

Characterisation of microorganisms recovered from pre-sterilised or pre-irradiated product also provides manufacturers valuable insight into the contamination sources and environmental conditions that support their presence.

Adopting a comprehensive approach to contamination control, which includes understanding and regulating microbial proliferation in the manufacturing environment as per ISO 14644/EN17141 standards, is crucial to prevent contamination and therefore potential sterility issues and SDA failures.

It is best practise to fully identify all positives to species level for both SDA failures and positives that have not yet led to failures. It is also beneficial to review the bioburden results from the same batch tested for SDA to determine if bioburden was at an elevated level or contained microflora that may be resistant to sterilization. Identification to species level of unusual or elevated microflora in bioburden tests will be beneficial to then gain more information on the contamination levels in the product and how they may be changing.

References to contaminant identification in the relevant standard :

ISO Standard / TIR	Title	Section
ISO 11737-1	Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products	6.2 Microbial characterisation of bioburden Table A.3 Attributes of common bioburden characterisation methods Section A.6.2 Microbial Characterisation of bioburden
TIR 106	Microbiological methods – Understanding and use of product bioburden data	6 Bioburden resistance to sterilization

The investigation process should not only be applied following an SDA failure, but also when recurring or unusual SDA positives are observed. Early investigation of adverse trends can provide an opportunity to identify and address underlying contamination issues before they progress to a failed dose audit or create a broader sterility assurance concern.

By following the structured investigation process flow in Figure 1 below, manufacturers can investigate and track the root cause of a positive / failure and take steps to eradicate those isolates ;

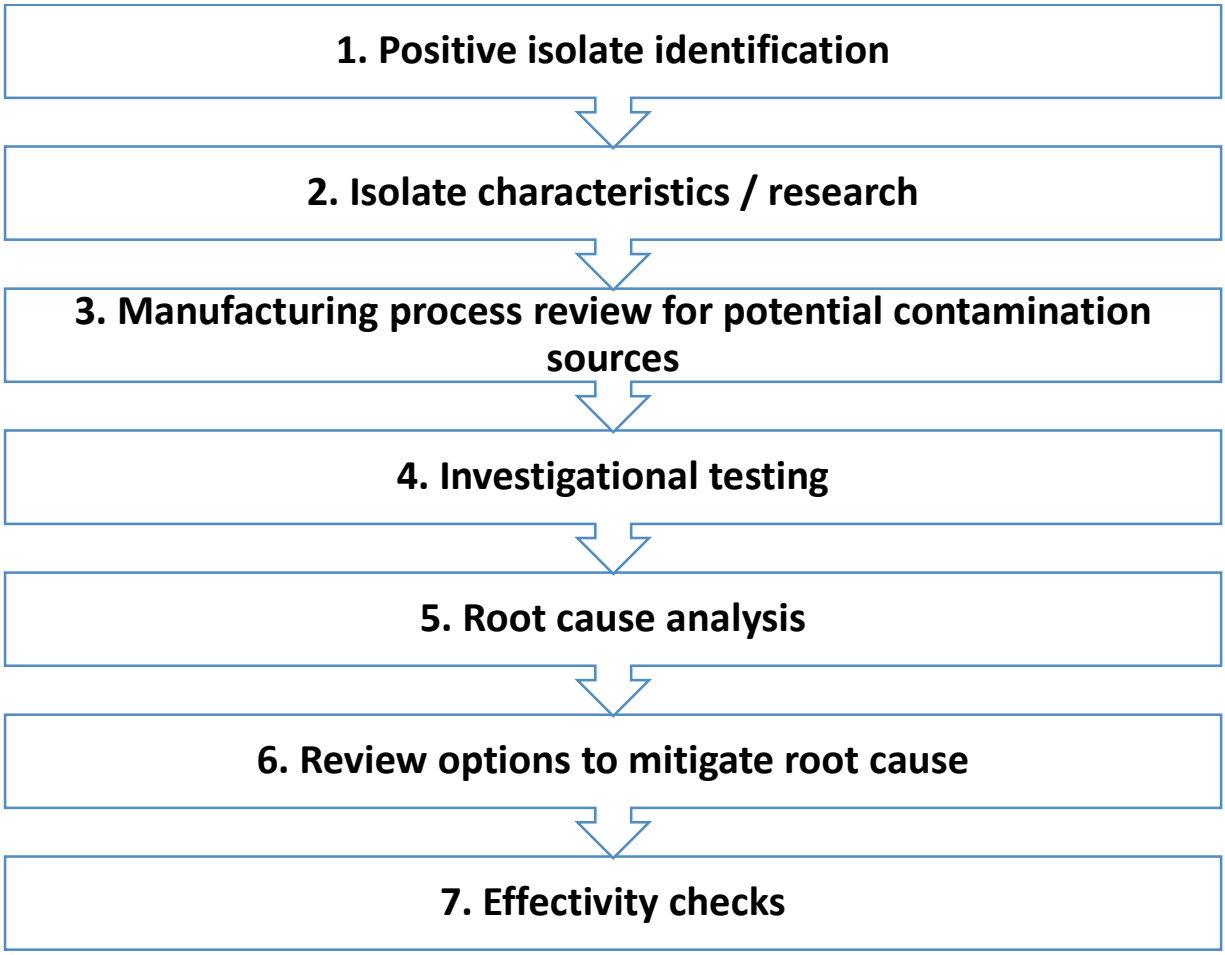


Figure 1 Investigation Process Flow

1. Identification of positive isolate(s)

The first step in root cause investigations is to understand what isolate(s) there are. ISO 11737-1 States that 'appropriate techniques for microbial characterisation of bioburden shall be selected.' And that 'Microbial characterisation is necessary to detect a change to the product bioburden that can affect some aspects of the use of bioburden data (e.g. establishing a sterilization process). Furthermore, knowledge of the types of microorganisms can be helpful for identifying sources of contamination. '

TIR106 states 'Characterisation of microorganisms can be a valuable part of a bioburden monitoring program. Characterisation provides information to help evaluate sources of bioburden and can help with the early identification of potentially sterilization-resistant microorganisms or other microorganisms of concern.'

In the event of positive(s) from an SDA, identification of those isolates is key to understanding what isolate survived the verification dose level and why. The information obtained can provide insight into whether the microorganism is likely to be naturally resistant to irradiation, associated with a specific raw material, linked to the manufacturing environment, or indicative of a change in process controls. Without identification of the recovered microorganisms, investigation efforts are often limited to speculation rather than evidence-based decision-making.

Identification can take many forms and depending on which method is selected will gain more information that can be useful going forward in investigating the root cause / source of the microorganism. The choice of method should be based on the objectives of the investigation, the level of detail required, and the resources available.

The variety of identification methods is also covered in ISO 11737-1 Table A.3 showing their specificity:

Table A.3 — Attributes of common bioburden characterization methods

Method	Example	Specificity
Colony morphology	Form, elevation, margin, size, colour	Low
Cell morphology	Shape (rod, cocci, yeast) Size, aggregation (clusters, chains) Anatomy (fungal structures)	Low to moderate
Staining properties	Differential stains (Gram reaction, spore staining, acid fastness) Mycological stains	Low to moderate
Selective culturing and differential media	Heat shock, incubation parameters, selective culture media	Moderate to high
Genus/species identification	Genetic and biochemical ID techniques and systems	High

Microbial characterisation of bioburden and SDA positives

ISO 11737-1 section 6.2.2 states; Bioburden shall be characterized using one or more of the following techniques:

a) colony morphology;

b) cell morphology;

c) differential staining;

d) culture using selective and/or differential conditions;

e) biochemical properties;

f) genotypic analysis, e.g. pattern or fingerprint-based techniques or sequence-based techniques;

g) proteomic methods, e.g. mass spectrometry.

The differing methods of identification are discussed further in ISO 11737-1 section A.6.2.1 ; 'The degree of characterisation necessary is dependent on the nature of the product, diversity of the detected population, and the use of the data (e.g. sterilization qualification).' Typical microbial characterisation methods for bioburden include colony morphology, cellular morphology, staining properties, selective culturing and microbial identification.

Summarising some of these methods ;

a) Colony morphology includes colour, shape, size, texture, margin, elevation and other physically observable characteristics of the colony. It can usually be used to distinguish between bacterial and mould isolates and to initially determine if the colonies on a plate are likely to be the same microorganism.



***Methylobacterium* on Tryptic Soy Agar (TSA)**



***Bacillus simplex* on TSA.**

b&c) Cellular morphology and staining techniques, such as a wet mount and Gram stain can distinguish between Gram negative / Gram positive, rods and cocci etc.

d&e) Selective culturing and differential media can be used to select for certain microorganisms, which can be useful to isolate microorganisms of interest. This should be followed up with further techniques to confirm the specific microorganism.

f&g) Phenotypic or genotypic methods are more complex biochemical and serological tests, to identify a bacterium to genus, species or strain level. A similar approach can be taken with yeast and mould. This gives the most specific identification option although is limited to the specific library of strains in the test laboratory/equipment.

It is recommended to select the method that provides the most specific and detailed identification of the microorganisms recovered as this will aid in the investigation of their origin and make it more likely to be able to track and trace them.

Selecting colonies to identify to give the most beneficial information can be done based on morphology of those most likely to be radiation resistant. For example orange / pink colonies on TSA plates can often indicate a *Methylobacterium spp* or *Deinococcus spp.*

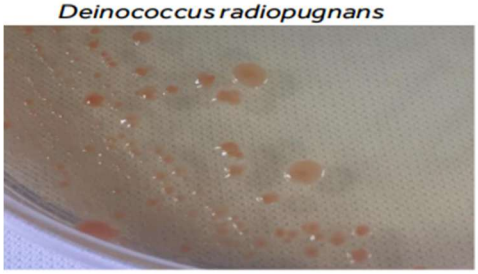


Deinococcus proteolyticus

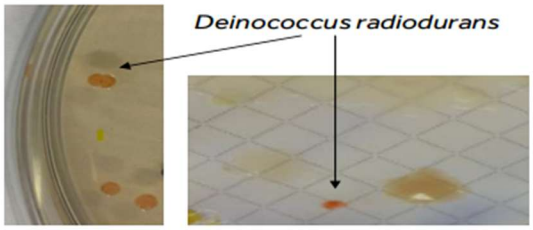


Deinococcus wulumuqiensis

Deinococcus radiopugnans



Deinococcus radiodurans



2. Isolate characteristics / Research

Once the isolate from the positive test has been identified the manufacturer can review their trends to see if this isolate has been seen before at their manufacturing site.

Example of Investigative checklist of questions to answer:

Question to be posed	Yes	No
Has it been isolated previously from the same product or product family ? - In SDA tests ? - In bioburden tests ?		
If isolated in bioburden test did this exceed alert or action limits for this product family ?		
Has the microorganism been recovered from other product families manufactured within the facility?		
Has it been isolated from the same manufacturing environment ?		
Has it been isolated in any environmental sampling tests ? - viable air monitoring ? - surface monitoring ? - Personnel monitoring ?		
Has it been isolated in any raw material or subcomponent/component testing relevant for this product ?		
Has it been isolated in the water system, compressed air system or any other product contact utility supply ?		
If this isolate has been recovered before – how frequently and were there any trends in occurrence (such as seasonal) ?		
Are currently implemented disinfectants / sanitisers in the manufacturing area documented to be effective against this isolate ?		
Have there been historical excursion root causes that can give clues to the cause in this case?		
Have steps been taken previously to eradicate this microorganism ?		
Have they failed ?		
Were the controls not fully embedded into routine procedures, allowing recurrence?		
Has the population changed for this product family in terms of numbers or resistant types of microorganism?		
Could the presence of this microorganism have an impact on the effectiveness or robustness of the sterilization process?		

The responses to these questions can help focus subsequent investigation activities and guide decisions regarding additional testing, environmental assessments, and corrective actions.

In addition to reviewing internal data, it is highly beneficial to conduct a literature review and gather publicly available information on the recovered microorganism. Understanding the microorganism's natural habitat, growth requirements, environmental tolerances, resistance characteristics, and typical routes of transmission can provide valuable clues regarding its likely source and persistence mechanisms.

Potential sources of information include :

- Literature search – Pub Med https://pmc.ncbi.nlm.nih.gov/articles
- Irradiation Panel D10 resistance tables – https://www.irradiationpanel.org/publications
- Own Company databases
- Contract laboratory used for testing (they may be willing to share)
- Published standards, technical reports, and industry guidance documents

Combining historical facility data with published information about the microorganism can significantly improve understanding of the likely contamination source and support the development of an effective investigation strategy.

3. Manufacturing process review for potential contamination sources

Following microorganism identification and background research, the manufacturing process should be reviewed systematically to identify potential sources of contamination and determine how the microorganism may have been introduced to the product.

The investigation should consider the complete product lifecycle from incoming materials through to sterilization, rather than focusing solely on the point at which the microorganism was detected. Contamination may originate from multiple sources and be introduced at any stage of manufacture, assembly, packaging, storage, or transportation.

The objective of the process review is to identify all potential contamination pathways and to assess where conditions may exist that allow the recovered microorganism to enter, survive, or proliferate within the manufacturing process.

Manufacturing process review

Following the manufacturing process can help guide an investigation and a testing plan to start to narrow down the likely source of contamination.

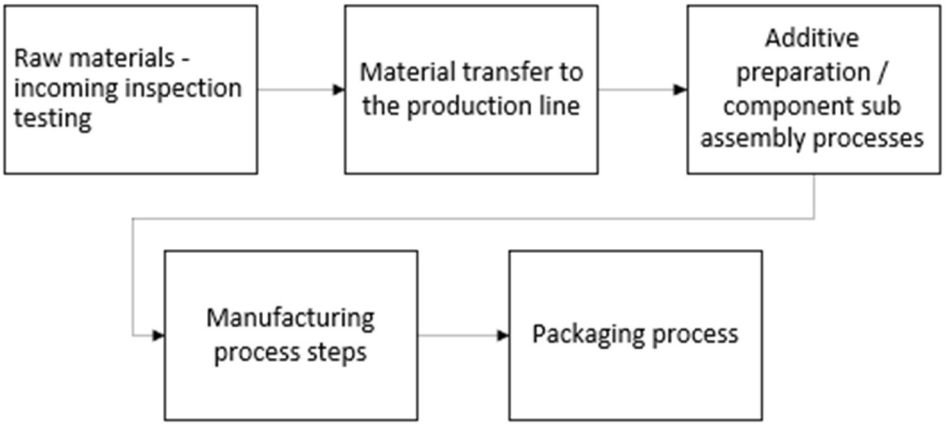


Figure 2 : Production process end to end review

Ancillary / support systems :

Also important to consider are the ancillary support systems that may have impacts on the contamination of finished products :

- Process utility monitoring; purified water/ compressed air etc
- Room controls; HEPA filters, air ducts, cleaning schedules
- Maintenance activities
- Personnel; Occupancy, PPE, GMP, behaviours

At each step of the process review or support systems it will be key to ask questions such as ;

	Detail	None
What changes have there been in the manufacturing process ? (e.g. New line / equipment / layout)		
What changes have there been in the manufacturing environment ? (e.g. new air handling, airlocks, occupancy)		
What deviations to the standard manufacturing process are in place ?		
Has there been any unusual activity in or around the manufacturing environment ? (e.g., construction or other disruptive activity)		
Has there been any relocation of equipment or processing lines ?		
What changes have there been in materials / process steps / room access / new equipment ? (These may point to some inadvertent outcomes that led to the contaminating isolate.)		
Have any steps been missed / delayed / incorrectly performed - such as maintenance activities / filter changes / cleaning & sanitizing steps ? (This may point to potential risk areas to investigate.)		
Have there been excursions in the room monitoring, break in integrity occurrences to manufacturing? (e.g., fire evacuations, airlock breakdowns etc)		
Have there been any manufacturing start up or shutdown periods, or interruptions ? (Consider - were components left on the line for extended periods?)		
Are there new or relocated personnel in the area ? (Have they all been trained accordingly, do they fully understand their link to product contamination and how to prevent it?)		

If the answer is yes to any of the above – this may indicate a focal area for further investigate testing.

Each of these process steps can also be reviewed for routine bioburden testing specific to each step that may already be conducted. If there isn't any routine testing or recent data then a testing plan for the investigation can be built.

4. Investigational testing

Testing plan :

Conduct Bioburden testing along the production process and follow this with Identification of any isolates that look similar to the SDA positive / fail isolates;

Item	Isolate recovered – similar to positive from SDA under investigation	
Raw material / component part(s) -bioburden testing	Yes / no	Any isolates recovered that appear morphologically similar to the SDA isolate should undergo further identification to determine whether they are consistent with the microorganism under investigation.
Water / air supply point(s) to the production process – bioburden testing	Yes / no	
Viable monitoring in manufacturing area: Active air sampling, Settle plates air sampling, Surface swabbing or surface contact plates, Operator hand swabs or finger dabs, (gloved or ungloved hands) Cleanroom gown contact plates in target locations, Disinfectant solutions or containers in use	Yes / no	
In process reusable materials in production area e.g. bags / covers	Yes / no	
Finished product bioburden testing throughout manufacture	Yes / no	

Once the testing regime has been carried out, review the data to narrow down the possible root causes / sources of the positive isolate from the SDA and to focus any further testing to the most likely process step to have caused the contamination.

Limitations of Investigational Testing:

It is important to recognise that failure to recover the exact microorganism identified during the SDA does not necessarily invalidate the investigation findings or prove that the microorganism was not responsible for the SDA positive or failure.

Dose audit testing often utilises extended incubation periods and may expose the entire product to culture media for longer durations than conventional bioburden testing. Depending on the method used, the product may remain immersed in culture media throughout incubation, allowing recovery of microorganisms that might not be detected using routine bioburden methods.

Consequently, the microorganism recovered during SDA testing may not always be recovered during subsequent investigation testing.

Other factors may also impact microorganism recovery, including:

- Limitations of the recovery method.
- Low population levels of the target microorganism.
- Overgrowth of faster-growing microorganisms.
- Selectivity of the culture media used.
- Competition between microorganisms during incubation.

Where possible, investigation samples and culture plates should be retained under appropriate laboratory storage conditions for the duration of the investigation. This allows investigators to revisit cultures for comparison of colony morphology or additional testing if required. If retention is not feasible, photographs of colonies and culture plates should be taken and retained as part of the investigation record.

There could also be approaches in the investigative testing to improve the discovery of the specific microorganism :

- The use of selective media or agars that are more successful for the specific microorganism
- Product components could be split down and tested separately to try to reduce overgrowth or competition on the resulting test plates
    - (The testing of components separately may already have a validated test method with correction factors or may be performed without application of a correction factor in investigation testing conducted to review types of microorganisms present rather than numbers.)

Even when the specific SDA isolate is not recovered, investigative testing may still provide valuable information regarding likely contamination sources. Contamination sources often harbour multiple microorganisms, particularly where biofilms, moist environments, or persistent environmental contamination are present. Consequently, corrective actions that eliminate other microorganisms recovered during the investigation may also reduce or eliminate the microorganism responsible for the SDA positive.

Narrowing it down :

Utilising all the investigative test results as above - potential root causes can be eliminated or shortlisted / confirmed as data is gained.

5. Root cause analysis

Once the investigation data has been collected and reviewed an analysis can be done to determine what was the most likely root cause or source of the microorganism in question.

At this point there are also tools that can be utilised to collate the testing data and knowledge gathered in order to pin point the cause and some will be discussed here.

6M / fishbone

The 6M root cause analysis uses a Fishbone diagram or Ishikawa diagram to identify potential causes of a problem by focusing on six key categories: Manpower, Machine, Material, Method, Measurement, and Mother Nature. This structured approach helps to systematically explore different factors that might be contributing to a problem.

6M Categories Explained:

Manpower: Human factors like training, skills, motivation, and communication.

Machine: Equipment, tools, and machinery used in the process.

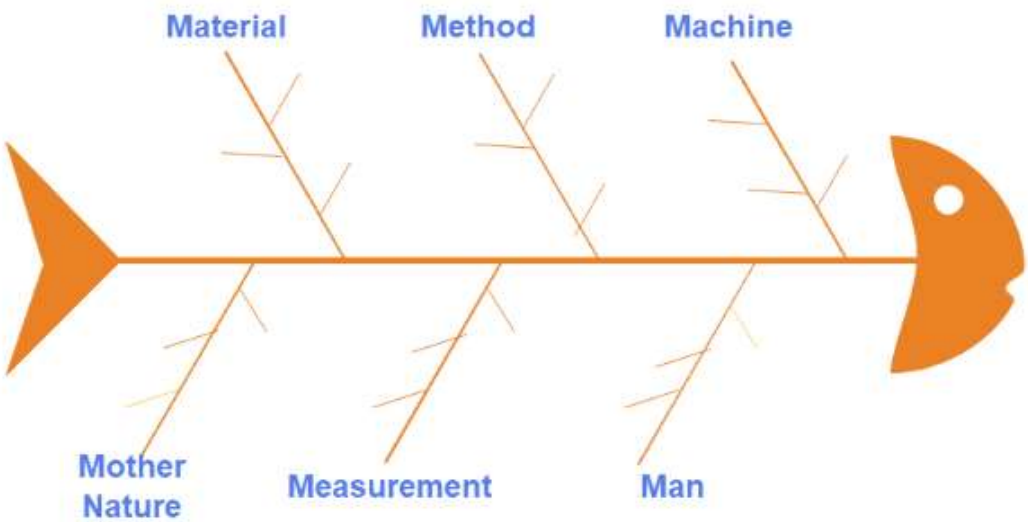
Material: Raw materials, components, and consumables.

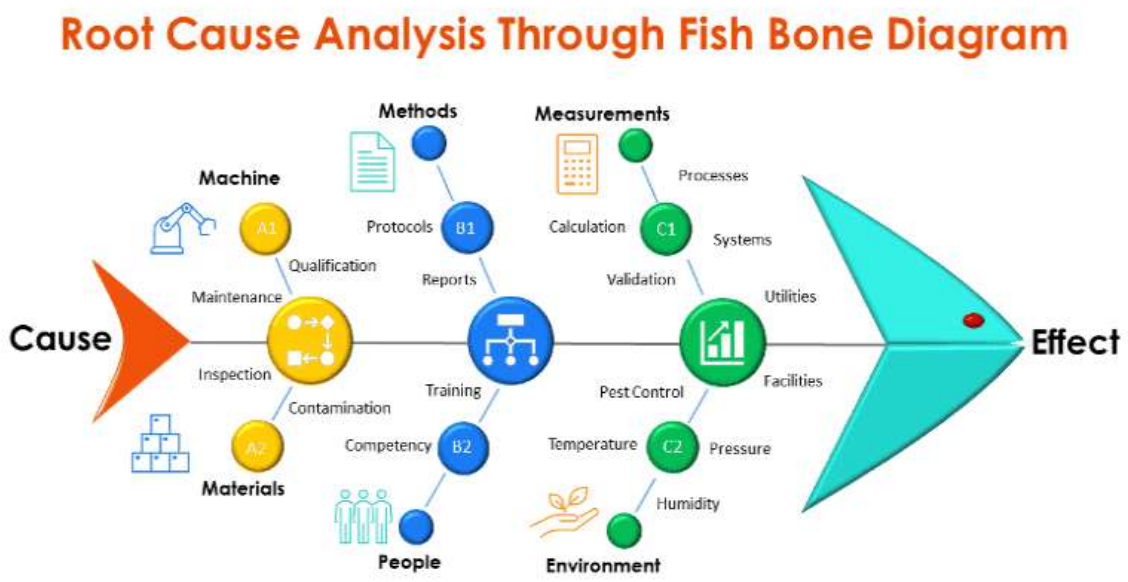
Method: Procedures, techniques, and processes.

Measurement: Metrics, inspection data, and instrumentation.

Mother Nature: External environmental factors (temperature, humidity, etc.).

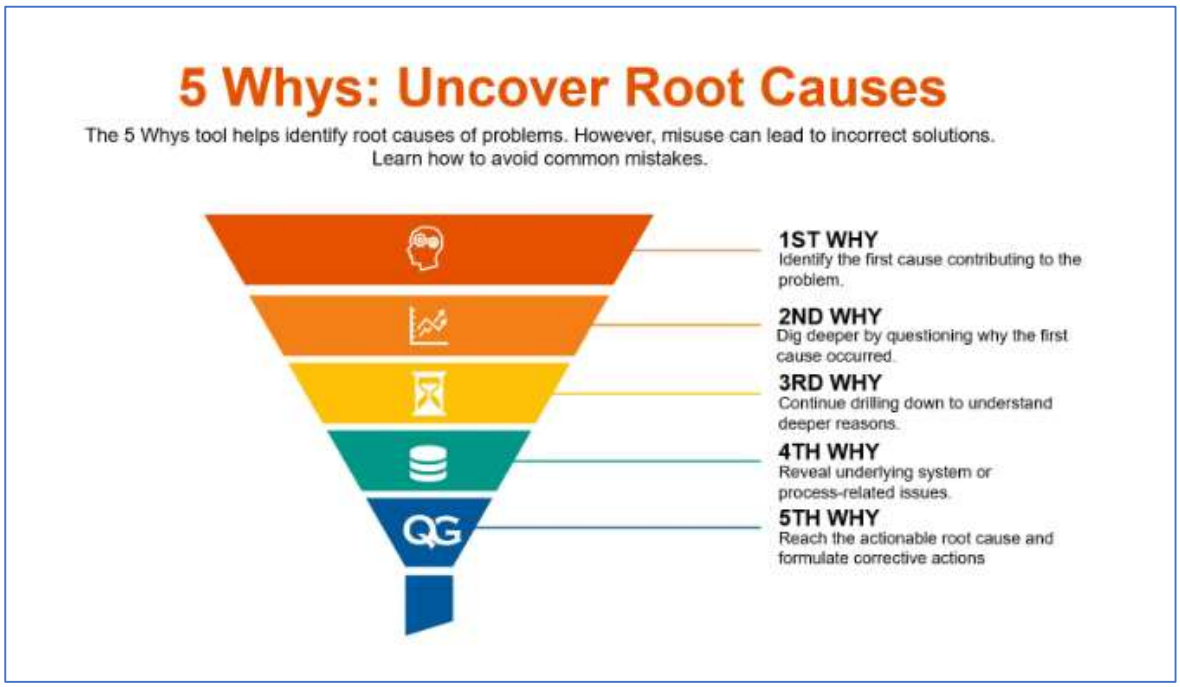
Under each of these headings all the inputs and potential contamination causes are listed and then can be reviewed to determine the next steps of the investigation. Test data collected for each step can then be used to eliminate or shortlist the likely root cause of the contamination.





Note : in this example People is used for Manpower and Environment for Mother nature.

5why

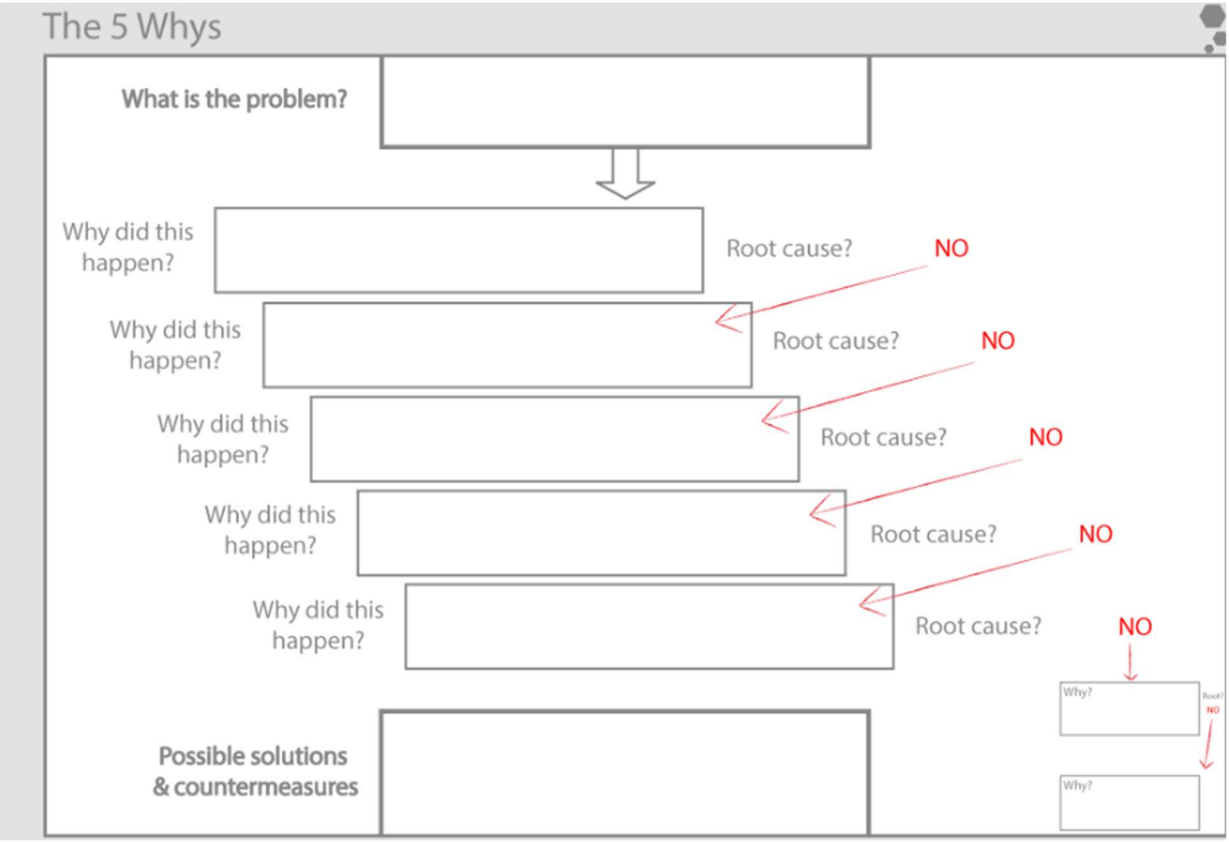


The Five Whys method is a straightforward yet powerful tool for identifying root causes and addressing problems at their source. By repeatedly asking “why,” organizations can uncover the true cause of an issue and implement long-term solutions.

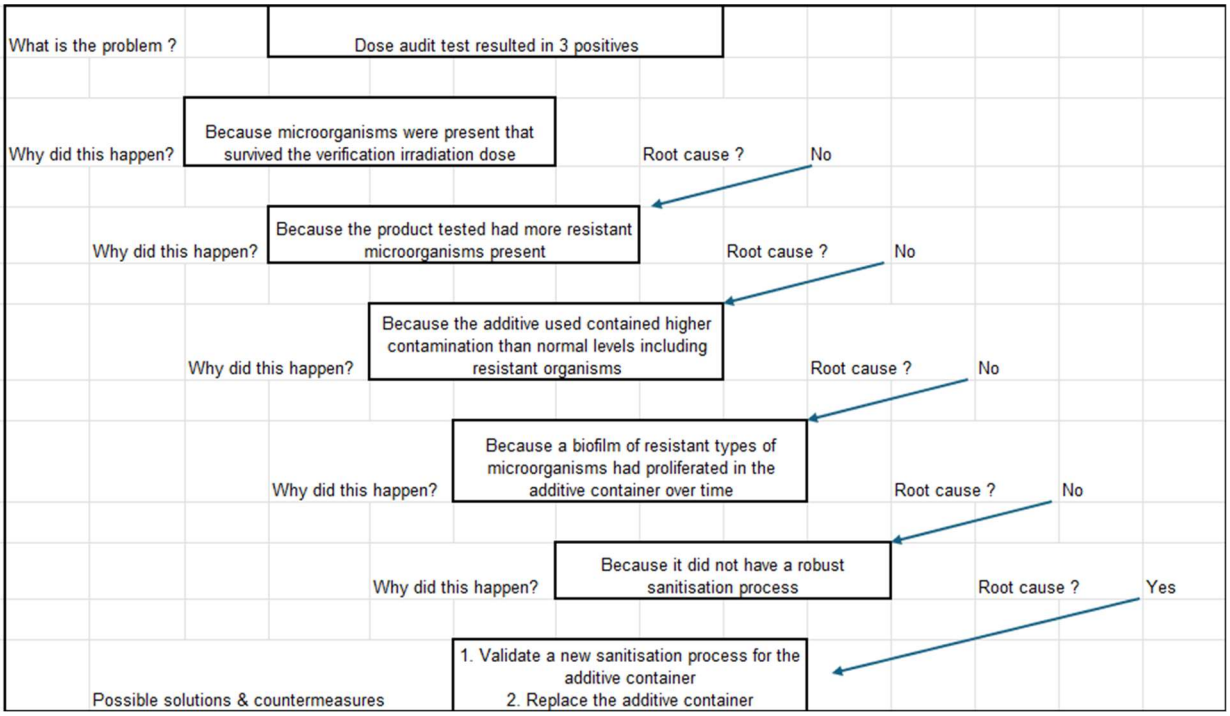
The Five Whys is not just about finding a solution; it’s about understanding why problems exist in the first place. Many issues arise from deeper, often hidden causes, such as communication breakdowns or flawed processes. This method helps teams move beyond surface-level symptoms to uncover and address the root causes effectively.

Example 5 why case study for contamination :

Example Template :



Example investigation : (this example is a Method 1 dose audit - 3 positive failure)



IS/ IS NOT

An "Is/Is Not" analysis is a problem-solving technique that helps clarify the scope of a problem by contrasting what is present (the "Is" factors) with what is absent (the "Is Not" factors). This structured approach helps to isolate the core elements of a problem, guiding the investigation and focusing on potential causes. Example template :

Problem description		
	IS	**IS NOT**
Who	Who is affected by the problem?	Who is not affected by the problem and could?
What	What is the problem?	What could be the problem and is not?
Where	Where problem occurs?	Where could the problem occur but didn't occur?
When	When the problem was observed first time?	When was the first time problem could be observed but was not detected?
How Many	How many parts are affected by the problem?	How many parts aren't affected by the problem?
How Often	What is the trend cycle for this problem?	What may the trend be but is not?

Example bioburden / contamination IS / IS NOT : (this example is Method 2 dose audit – 2 positives identified)

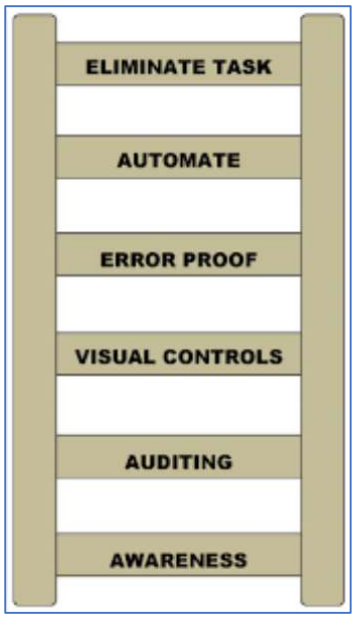
IS /IS NOT ANALYSIS			
Problem statement : *Methylobacterium radiotolerans* was isolated from product A routine SDA test, made on production line B in manufacturing cleanroom area A. Isolate not seen previously in product bioburden or SDA tests. 2 positives both identified as this same microorganism. Last SDA showed zero positives. Bioburden test passed to limits with low level *Pseudomonas spp.*			
	IS	**IS NOT**	**Comment / conclusion**
Who	Manufacturing leader, team and operators for product A	Manufacturing leader, team and operators for other products	N/a
What	SDA test for product A Samples taken from Line B Water used for additive also contaminated with this microorganism	Bioburden test – did not isolate the same microorganism Other product families – no other instances of *Methylobacterium spp* Powder / component raw materials used in manufacturing – no similar contamination seen Air viable samples in cleanroom A – no similar contamination seen	Further investigation needed in water user points in additive mixing for product A Contamination control measures required in water supply
Where	Line B Cleanroom A	Line A C D Cleanroom B C D	N/a
When	Product made on xx date	Product made prior to xx date	N/a
How much / how many	2 positives First occurrence of this microorganism First occurrence of positives on this product family SDA	0 positives	N/a
How often	First occurrence of this microorganism First occurrence of positives on SDA	n/a	N/a

The IS / IS NOT tool can then focus any further testing required or conclude the most likely source of the contamination for focus of the control measures to prevent recurrence.

6. Review options to mitigate root cause

When determining how to fix the root cause of a contamination issue there are many types of corrective action or 'countermeasure' that could be put into place with varying levels of success. Each type of solution requires varying levels of time and investment to implement so businesses have to weigh up the benefits with the costs of any solutions.

The countermeasure ladder tool shows these different levels and explains ;



Level 1 – Tell and Train

The lowest level of countermeasure is to tell people how to do something new or differently and train them accordingly. This may have some positive impact but also relies upon the human element to continue to perform the task correctly and at the right frequency. It can be prone to failure when personnel change or priorities compete.

> Example : Training persons in the cleanroom to change a water supply microbial filter on a weekly basis.

Level 2 – Auditing

Auditing a process or task can be conducted as a regular check to make sure things are working and being conducted as they should be. This again has drawbacks as it relies on the human element to conduct the audits and remind associates of their training and importance of the task.

> Example : A quality person visiting the area to check weekly that the filter change has occurred.

Level 3 – Visual control

Can the improvement be linked to a visual control, a beacon that signals when the task is due or when things are abnormal? This then provides a system control to flag and relies less on the human elements.

Example : Linking the weekly filter change out to a beacon that lights up to tell / remind the person to change it out.

Level 4 – Mistake Proofing

Can the root cause be prevented altogether – the task completely mistake proofed? This then prevents the error from ever occurring again.

Example : Without acknowledging / sensors detecting that the filter has been changed, the production process is not allowed to continue.

Level 5 – Automate

If a task is required at a certain frequency can it be automated in some way so it always occurs and doesn't need any human intervention.

- Example : The new filter can be automatically fitted to the correct area when required by way of machinery / equipment.

Level 6 – Eliminate

The utopia solution is to entirely eliminate the root cause of the contamination so that no further mitigations are needed.

Example : Change to the water supply to a higher grade so that it no longer requires filtration at point of use.

7. Effectivity checks following implementation of corrective actions

Effectivity checks are precise points in time where testing or data reviews take place to ensure the improvement or corrective action is still in place and that the contamination risk is still eradicated or being effectively controlled.

Prior to implementing any changes it is often required to document when an effectivity check is to take place. The time period chosen should be sufficient to ensure that any changes made have had enough time to have made an impact on the root cause/process. A short time period may not be sufficient to gain evidence that the change has had an impact. In the case of a long time period selected, there may have been other changes/circumstances made that affect the process. These could be negative or positive changes, but either way could still mask the effectivity of the change that was implemented as part of the corrective action.

> For example in the case of an SDA failure and subsequent corrective action – the effectivity check may include at least 2 future SDA test results to ensure the root cause microorganism has been eradicated and has not caused further SDA positives or failures.

Following a failure and corrective action implementation, it can be prudent to implement more frequent test regimes in the area of concern for a period to gain confidence that the corrective action is working. This extra testing comes with a cost of course (in either contract laboratory fees, or in house consumables and labour time), therefore the business must weigh up the costs vs benefits of this extra data.

It can occur that future testing can show the same positives / failures and indicate the potential of the root cause having returned. At this point the investigation should check;

- is it a new failure mode ?
- or is it the same failure mode again ?
- is it the same microorganism ?
- is it from the same source ?
- or is this now a new microorganism / new source of contamination ?

Further root cause analysis process and tools discussed above should be used, to ensure a structured approach to the new failure and avoid a pre-conceived idea of the source.

‘Sustaining the gains’ from a corrective action implemented will be dependent on the countermeasure employed and how robust it is. As with the countermeasure ladder above different approaches are more sustained than others and some rely on human factors which do have risk of failure rather than system based or automated solutions. Again the cost vs benefit must be weighed up in a business to protect product quality.