

*National
Audit
Systems
Network*

ROOT CAUSE ANALYSIS

The network of national audit experts have produced this non-binding reference document based on agreed good practices to provide guidance on how auditors may approach Root Cause Analysis.

November 2016
Version 1

The National Audit Systems (NAS) Network

The NAS network¹ is a network of officials (auditors) from national competent authorities, responsible for the performance of audits of official control systems as provided for by article 4(6) of Regulation (EC) No 882/2004². The network meets regularly, under the chairmanship of, and facilitated by, Directorate F of the European Commission Directorate general for Health and Food Safety to exchange experiences in implementing national audit systems on official control activities. During the course of these exchanges; discussions, workshops etc. good principles and practices are identified and agreed by the network.

To enable dissemination of information the network, working in plenary session and through sub-groups, facilitated by Directorate F, consolidate agreed principles and good practices on specific topics into reference documents. These reference documents may be used as guidance documents, however, they do not constitute an audit standard and are not legally binding.

Root Cause Analysis

INTRODUCTION

Root Cause Analysis is a collective term for a number of structured methods that competent authorities, management and control staff as auditees and audit bodies as auditors can use to assist in identifying the underlying factors which lead to the occurrence of an issue.

Frequently the issue identified by the auditor is either a symptom or the end point of a causal chain and not the real systemic issue. Taking a purely compliance approach will result in the issue being corrected but if the root cause is not addressed the issue will recur.

To avoid the recurrence of the same non-compliances internal audits should be focused on a more diagnostic system approach. This approach is more likely to provide long term solutions for the improvement of the system.

Use of Root Cause Analysis is voluntary and this document has been developed to raise awareness of its benefits in the context of internal audits.

The document addresses the subject from an auditor's perspective but is also useful for auditees to assist their understanding of the topic and its application to audits.

¹ Cross reference to introduction and overall picture of the NAS network [link to be added]

² OJ L 191, 28.5.2004

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OBJECTIVES

The objective of this document is to:

- guide and support competent authorities' in the use of Root Cause Analysis;
- provide principles and definitions regarding Root Cause Analysis;
- promote a Root Cause Analysis approach by highlighting the benefits for competent authorities;
- support the development of good practice in Root Cause Analysis in (a) auditing and (b) following up audits, of official control activities.

SCOPE

This document applies to audits carried out for the purposes of Article 4(6) of Regulation (EC) No 882/2004 and is limited to the *identification* of the root cause of an issue. It does not explain how to draft conclusions, recommendations or assess action plans.

DEFINITIONS

This document should be read in conjunction with the definitions contained in Regulation (EC) No 882/2004 and Commission Decision 2006/677/EC bearing in mind that the definitions of those documents still apply.

I. WHAT IS ROOT CAUSE ANALYSIS?

Root cause: the trigger for a chain of events which leads to an issue and when addressed prevents recurrence or mitigates the impact of the issue.

A "root cause" can be explained as a "cause"(a condition or a causal chain that results in the issue of interest), that is the "root" the origin or source of the issue. A "root cause" is usually used to describe the point in the causal chain where action could reasonably be taken to prevent or mitigate an undesirable outcome or to improve performance.

In the context of internal auditing the Institute of Internal Auditors (IIA) defines Root Cause Analysis in the following terms:

Root cause analysis is defined as the identification of the underlying cause of why an issue occurred (versus only identifying or reporting on the issue itself).³

In this context, an **issue** is defined as a problem, error, instance of non-compliance, or missed opportunity.³

³ IIA Practice Advisory 2320-2: Root Cause Analysis.

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In general terms Root Cause Analysis:

- Helps auditors to reach a better understanding of issues detected during the audit.
- Is one of the core building blocks in a competent authority's continuous improvement efforts.
- Is an important part of a problem-solving process.

II. WHY USE ROOT CAUSE ANALYSIS

Root cause analysis is a method that can be used

- A. by auditors, for both desk based and on-site activities, to assist in reaching appropriate conclusions and recommendations by helping to
 - a) decide whether an issue is likely to be systemic rather than individual or localised;
 - b) distinguish between the immediately apparent cause of the issue and the underlying root cause(s) of the issue;
 - c) link various issues detected during an audit that have a common Root Cause (see Annex I);
 - d) identify in general terms the areas to be addressed by the auditee to correct or mitigate the issue;
 - e) where applicable, to assist auditors in evaluating the suitability of auditees corrective actions.
- B. by auditees to
 - a) investigate and identify the underlying causes of the issue, and
 - b) determine the appropriate action to be taken to correct or mitigate the issue in a manner that improves the system and reduces the likelihood of recurrence of the issue.

An auditor uses Root Cause Analysis to maximise the added value from the audit and to address systemic root causes. On a purely compliance audit this does not happen. It is not very effective to repeatedly conclude that the auditee is behaving in a non-compliant way and only recommend that the auditee fixes the issue and not its underlying cause.

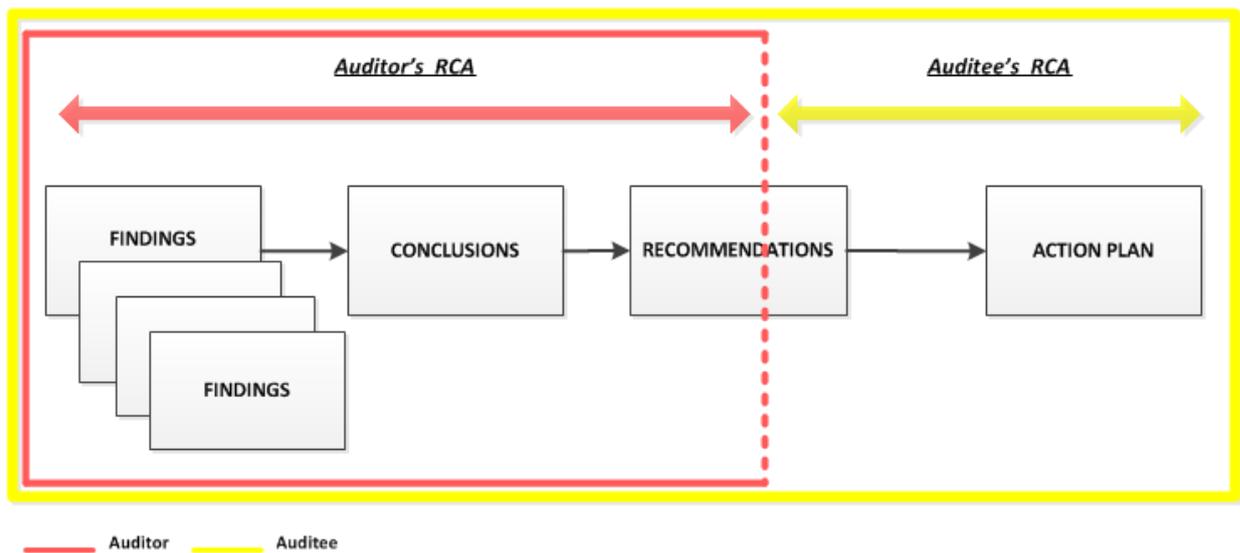
A more diagnostic system approach to internal audits should encourage corrective actions that avoid recurrence of the same non-compliances. This approach provides a long term perspective for the improvement of the system where both auditor and auditee focus on addressing the root causes of the shortcomings in the system.

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When used as part of the internal audit process, Root Cause Analysis can lead to more specific conclusions and/or recommendations for process and system improvements. However this should not be perceived as placing the internal auditor in the role of management; their respective roles and responsibilities are different and distinct:

- The auditor uses Root Cause Analysis to determine the appropriate systems-based conclusions and recommendations to address the underlying cause of the issue in the long term (possibly why it happened).

The knowledge obtained through the Root Cause Analysis helps auditors to assess the action plan proposed by the auditee and its suitability to mitigate the underlying causes in the long term.



- The auditee carries out Root Cause Analysis with the objective of identifying and/or confirming the root causes (why it happened) and the specific preventative and/or mitigation actions (what needs to be done to correct it).

The auditee's knowledge of the system audited may enable the identification of additional or more specific root causes of the issues mentioned in the audit report; this Root Cause Analysis should be reflected in the action plan leading to a more effective outcome to the audit.

III. WHEN TO USE ROOT CAUSE ANALYSIS

When should Root Cause Analysis be used?

- If a non-compliance is identified at a system level.
- Where evidence of issues of significant concerns is found (such as issues related to effectiveness or suitability of controls).

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- When factors giving rise to the issue are not immediately apparent.

When to stop Root Cause Analysis?

- When root cause lies beyond the limits of the system being audited (it is external to it and therefore cannot be directly addressed by the auditee).
- When no longer proportionate to the issue at hand (cost-benefit and linked to the seriousness of the issue).

When looking for root causes the following considerations should be taken into account:

Characteristics of Root Causes	Approach to follow	Benefits
Underlying causes	The goal should be to identify specific underlying causes of the issue.	The more specific the underlying causes are, the easier it will be to arrive at effective conclusions and/or recommendations (auditor) or actions (auditee) that will prevent recurrence or mitigate the impact
Causes that can reasonably be identified	Investigating issues must be cost beneficial. Information required should be readily available/ accessible and the time/resources allocated for the analysis must be proportionate to the severity of the issue.	Structured Root Cause Analysis makes efficient use of the time and resources invested in the investigation.
Specific solutions	Root causes should be addressed by specific solutions. Analysts should avoid using general cause classifications such as human error, equipment failure or external factor. These are too vague and may be indicative that more effort is needed to identify the specific cause in order to allow management to make effective changes.	Root Cause Analysis, by identifying exactly why an issue occurred, helps management to take action to prevent re-occurrence or to mitigate the impact of the issue.
Causes over which management has no power to take action	The causes must be within the control of the management so attributing a root cause to factors totally outside their control should be avoided.	Root causes that focus on issues where management can produce effective actions will assist in developing strategies for prevention or mitigation of future problems that stem from the root cause.

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IV. HOW TO DO ROOT CAUSE ANALYSIS

Steps before performing Root Cause Analysis

Because an audit team has a limited budget for resources and time it has to make choices on which issues are worth investigating to establish the root causes.

The first step is to state clearly/ identify the issue. It is important to be specific and describe the issue strictly in terms of what was found or observed. Avoid defining the issue in terms of a possible solution, e.g. inspection procedures are not sufficient, because this could prejudice both the decision to carry out Root Cause Analysis and the outcome of the analysis.

Secondly, the audit team should be able to distinguish (based on their skills, training and experience) between an isolated issue which has a low or no impact on the overall performance of the official control systems (audits focusing on "person") and an issue that has a clear and significant impact on the performance of the control system. For isolated or low impact issues a finding of non-compliance or shortcoming should be sufficient.

Thirdly review the evidence collected/available to estimate the extent and the likely impact/consequences of the issue. This will determine if the issue is worthy of further investigation to determine the root cause.

Another consideration is the feasibility of carrying out a short Root Cause Analysis and reaching the result in a quick and efficient manner without compromising the overall performance of the audit.

Performing Root Cause Analysis

Once it has been decided that an issue requires some Root Cause Analysis the audit team can start by brainstorming possible causes, focusing on the issue and why it may have happened rather than the symptoms. It can be helpful to list or chart the steps in a process leading up to the issue to help identify a causal chain. Root Cause Analysis should be approached with an open mind in order to consider alternative root causes where appropriate and not just to confirm an auditor's belief as to why the issue arose.

It is important to work as a team, and not as a stand-alone auditor, and to exchange information because knowledge and insight into the possible root cause can be found in previous audits or experiences of the members. Quick and easy access, where needed, to technical experts improves efficiency and outcomes.

Where, during an audit, the possibility arises for brainstorming involving the audit team and the auditee to investigate possible causes for an issue, this provides an opportunity to obtain information which may be useful for the Root Cause Analysis.

When using Root Cause Analysis the audit team should not focus on the person/persons performing the task giving rise to the issue and their individual shortcomings. These are

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symptoms rather than a cause of the issue. The Root Cause Analysis should focus on the system or environmental factors that led to that issue. For example:

- *Competence of personnel*; not how competent the individual was, but on the measures in place to ensure that staff:
 - have the appropriate qualifications.
 - performing controls acquire/maintain skills.
 - are kept up to date with legal and technical requirements.
- *Completeness or clarity of procedures*, instructions, check lists etc., including up-dating of procedures and measures to ensure staff have ready access to up to date versions.
- *Supervision*, particularly with regard to compliance with planned arrangements and consistency/uniformity of activities.
- *Coordination*, particularly with regard to consistency of approach, sharing of information and scheduling of activities..
- *Technology or tools*, adequacy to the tasks to be performed.
- *Organisation (or departmental) environment*, such as working conditions, culture and morale of the organisation which may impact on staff performance.
- *Resources* (e.g. budget or personnel).
- *Actions in the case of non-compliance*, particularly the responsibility and authority of the staff to take action the level at which decisions regarding sanctions are made and factors influencing these processes.

Methods of Root Cause Analysis

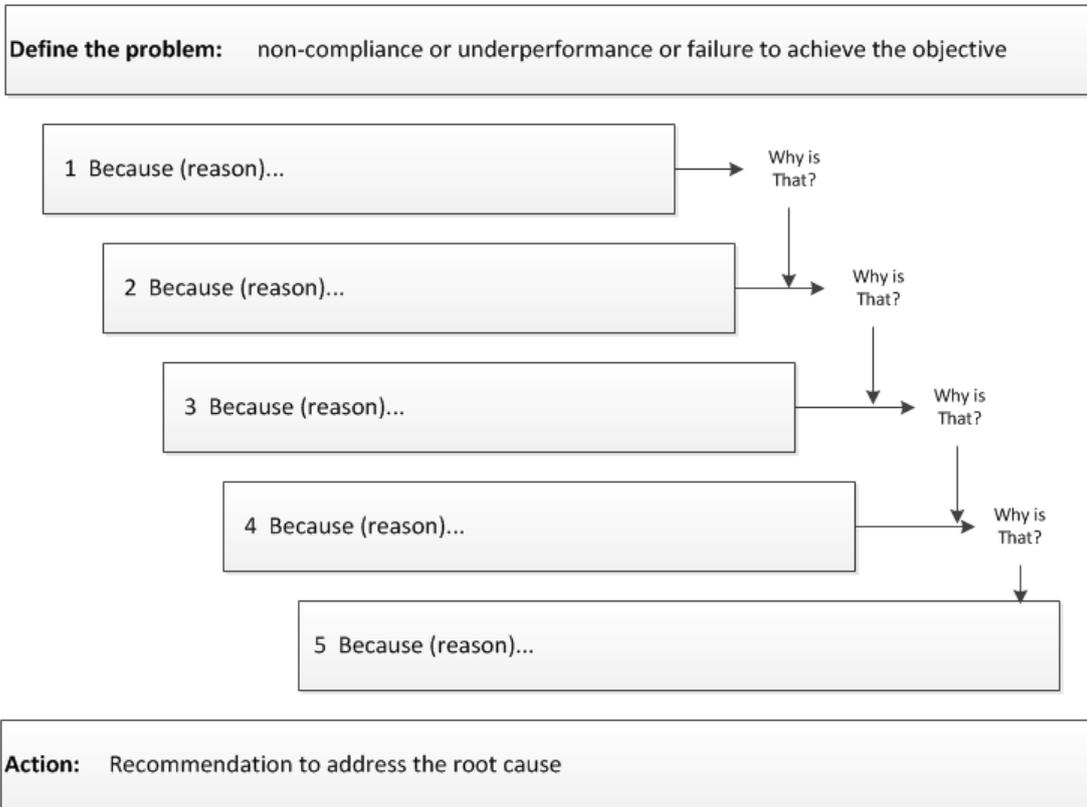
There are many methods for conducting Root Cause Analysis, ranging from relatively simple generic methodologies to complex specific ones requiring specialist approaches. Some methods are more suited to industrial products (manufacturing) and other for processes (as service providers).

For the purpose of this document some of the simpler generic methods that can be adapted for application to official controls are described:

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A. 5 Whys

This method consists of the practice of asking, five times⁴, why the failure has occurred in order to get to the root cause/causes of the issue. See Annex II



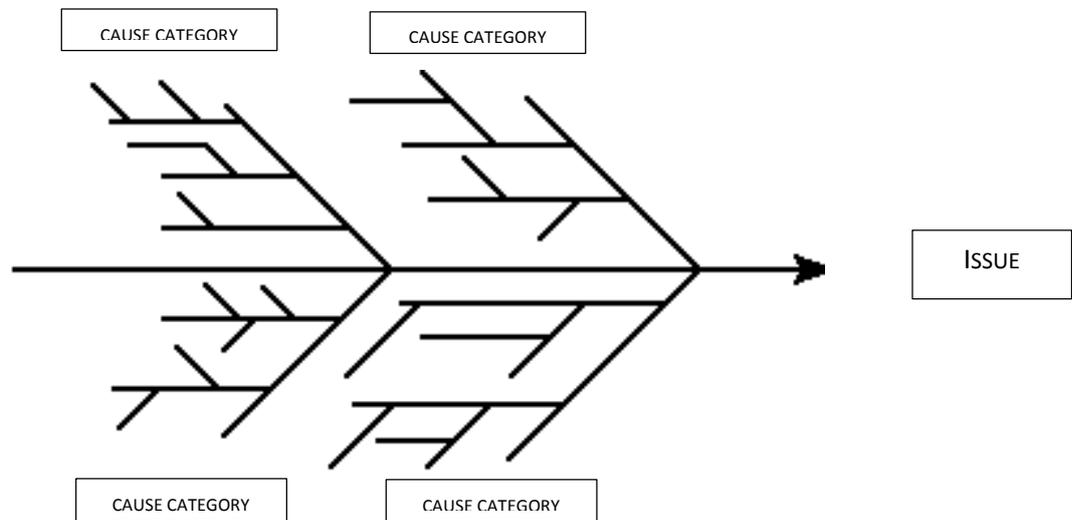
Using this method you track back on each possible reason for the issue. If you identify more than one possible reason at the same level you track each reason separately unless you decide to prioritise and follow the most significant one. If the last answer is beyond the control of the auditee, go back to the previous answer and base the recommendation on this point.

⁴ Five is an arbitrary number, it may take more or less to get to the root cause of the issue. You should attempt to answer five whys using multiple paths to ensure you have reached the root cause.

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B. Ishikawa Cause-and-effect-diagram, “Fishbone”

This technique uses a visual (diagram-based) approach to look at the cause and effect of an issue. It is known as a *fishbone diagram* because of its shape.



The issue is displayed at the "head of the fish" and the cause categories (headings) on the "bones" where the possible cause of the issue may be found. Possible contributing causes can be listed on smaller “bones” of the main cause categories.

Categories/headings are not fixed for this technique and can be selected to suit the issue under investigation although it is quite common to find:

- Manpower, Methods, Materials, Management or Measurement and Machinery (known as 5Ms) used as main categories when dealing with a product/manufacturing issue, and
- Place or Processes, Policies, Procedures, and People or Personnel (known as 4Ps) as main categories when dealing with administration and service issues.

Therefore categories /headings can be selected to suit the scope of the audit and the line of investigation. For example a fishbone diagram can be organised along the main Regulation (EC) No 882/2004 requirements or, following the PDCA cycle. See Annex III for examples.

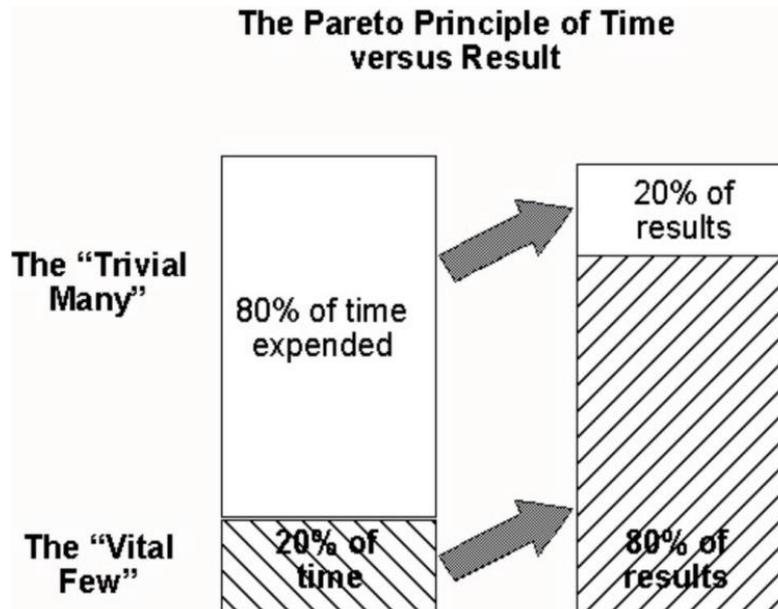
The fishbone chart approach to cause and effect analysis can be used to structure brainstorming, to identify possible causes of an issue and to sort ideas into useful categories. It is a more structured approach than some other tools available for brainstorming causes of an issue. It can also be helpful in identifying possible causes that might not otherwise be considered, by directing those involved to look at the categories and think of alternative causes.

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Other methods which can be used include:

C. Pareto Principle

The Pareto Principle categorises the frequency of a certain type of issue.



It is helpful in the case of patterns of small non-compliances to identify links and whether the rate of occurrence points to a system failure. This method is particularly useful for desk-based activities and if looking at effectiveness of controls.

See Annex IV for a practical application.

D. Failure Mode and Effects Analysis (FMEA)⁵

FMEA is a method used in industry to make an inventory of all the possible failures during a production process and therefore predict their consequences in order to measure potential risks.

To measure the criticality of failures, three quantitative criteria are taken into account:

- The seriousness of the fault (SEV),
- The frequency of occurrence of the failure (OCC), and
- The failure detection capability (DET).

The risk priority number (RPN) of an issue is the product of the values of the criteria ($RPN = SEV \times OCC \times DET$), which represents the potential risk.

⁵ This method is more likely to be used by auditees.

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Associated with FMEA, the QRQC ("Quick Response, Quality Control") method is very effective to solve quickly the issues that occur during a production cycle. It provides solutions directly to employees, who can apply the adequate action in response to the fault.

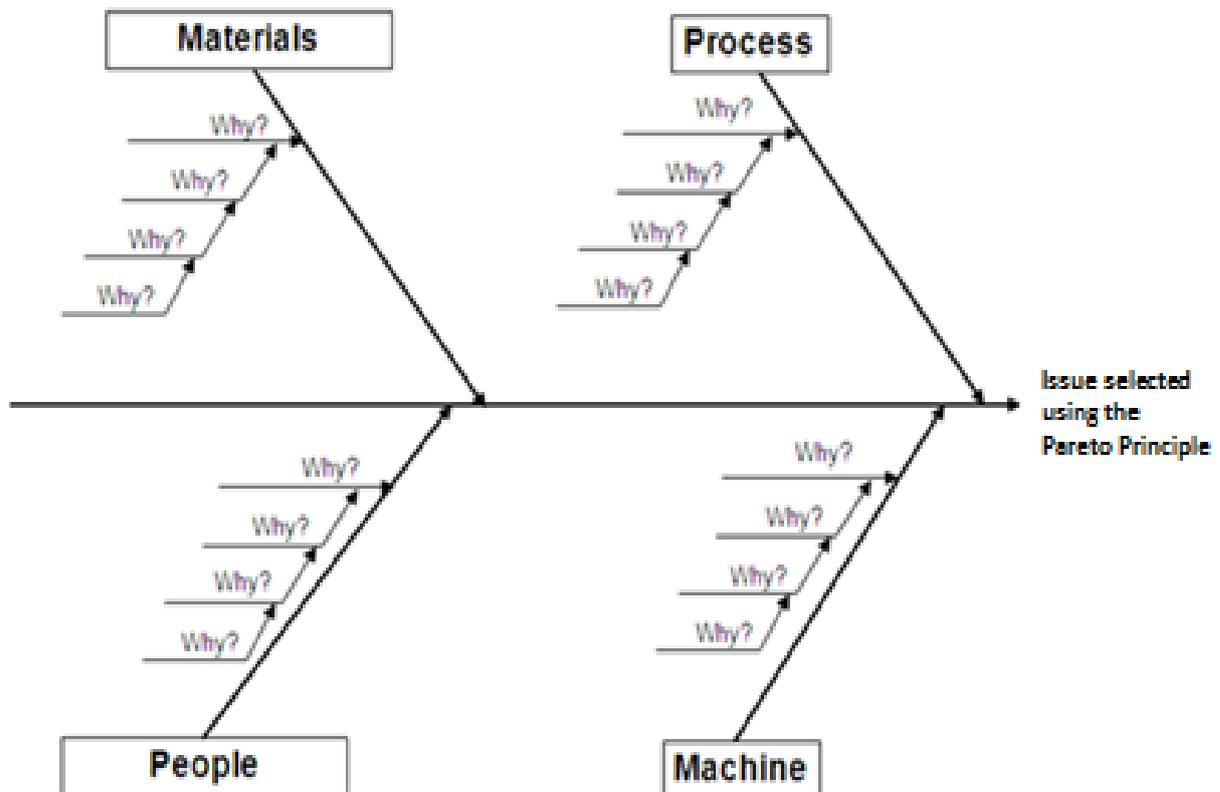
In the field of internal audit, the maturity level (or existence) of QRQC illustrates the maturity level of internal control, as well as the implementation of an FMEA.

Regarding the use of the method by the audit team, the first requirement is to fully understand how the system and its environment work. The FMEA will then be formalized with an analysis grid. This process is therefore long and preferably used in the desk study phase, in particular if the auditee does not have a formalized risk approach to lean on.

See Annex V for a practical example.

E. Combining Methods

Frequently Root Cause Analysis methods are combined, the synergies resulting in the optimum result (see example and Annex I).



V. Documentation of the process

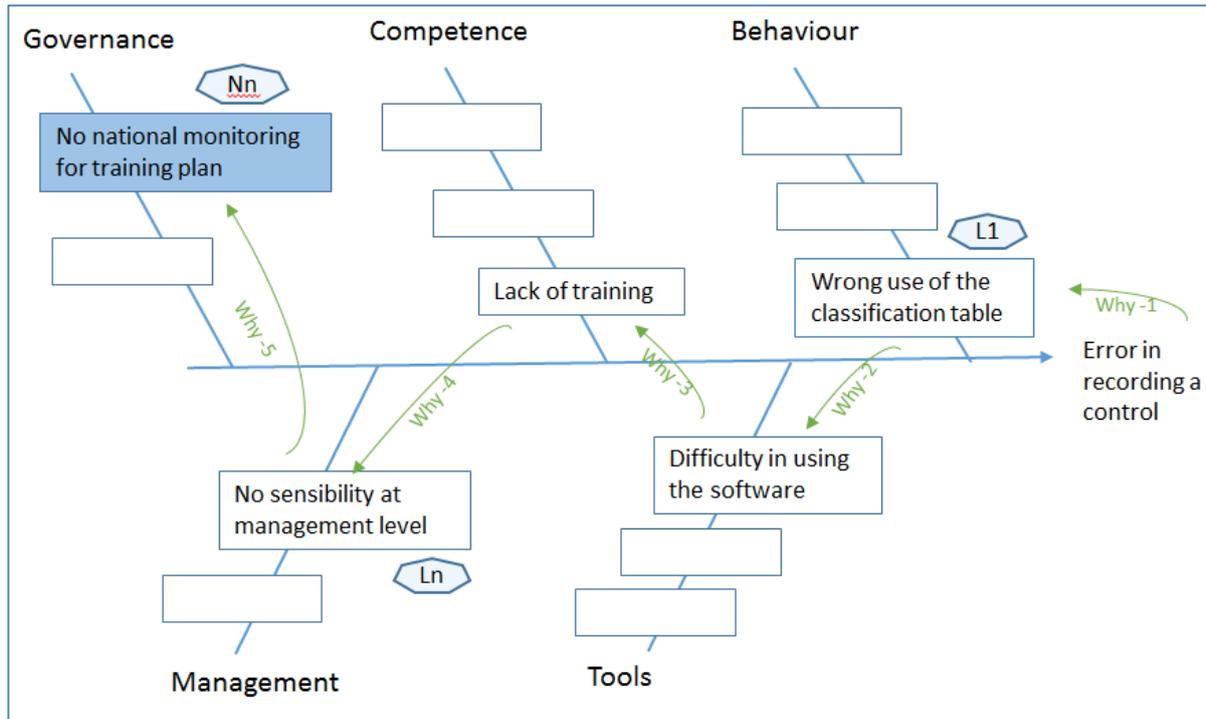
Regardless of the method used it is important to document in some way the steps taken in the Root Cause Analysis to be able to fully explain to the auditee how the root cause was found because in some cases it may be perceived as not linked to the initial issue identified.

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Annex I – Common Root Cause

The purpose of this example is to show how you can "jump" from one to another branch. For reasons of clarity the diagram only shows the main decisions and not all the possibilities that have been "cleared" by the audit team, for example through a decision tree.

Case 1:



The audit team, in the first unit audited, finds a non-compliance due to an error of “recording the control” made by an inspector (on the right of the diagram), *i.e. recording a control for labelling under the category for hygiene*.

Why 1 : Wondering on the cause of the situation, it appears that the inspector made a wrong use of the table (it isn't a dysfunction of the program for example), this is an obvious cause, signalled as L1 because it is a local issue concerning a single agent.

Why 2 : Looking again for the cause of the situation, it appears to the audit team members that the presentation of the different screens of the program is not totally logical.

Why 3 : Nevertheless a deeper investigation leads to the fact that the inspector has had no training on the program and on the fact that the senior inspectors found the presentation of the information useful and convenient. It also shows that the users have been consulted for the organization of the information on the screens, so that the IT service is not concerned with that matter.

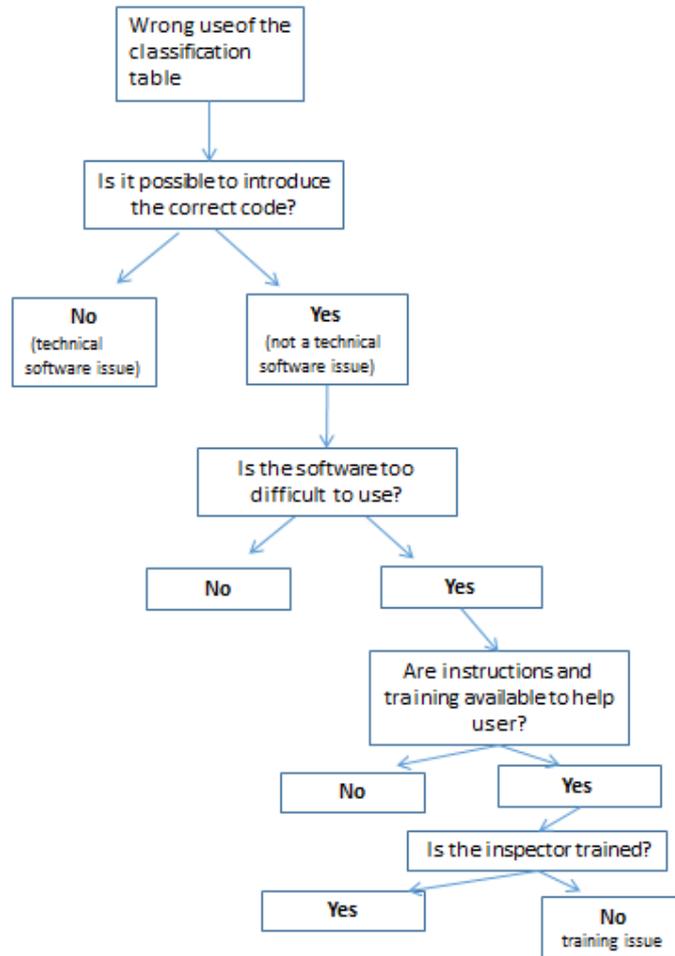
Why 4 : The fourth time the why question is asked, leads to the fact that the lack of training of the inspector is due to a lack a sensibility on the subject of the local manager. Therefore we can see that if the situation remains local, it can now concern all the members of his team (situation Ln).

Why 5 : The last try for a root cause leads to the fact that on a national basis there is no evaluation of the training made locally, so that managers only act on their goodwill, and are not directed by a national objective of performance of training. We reach a cause addressing a national issue

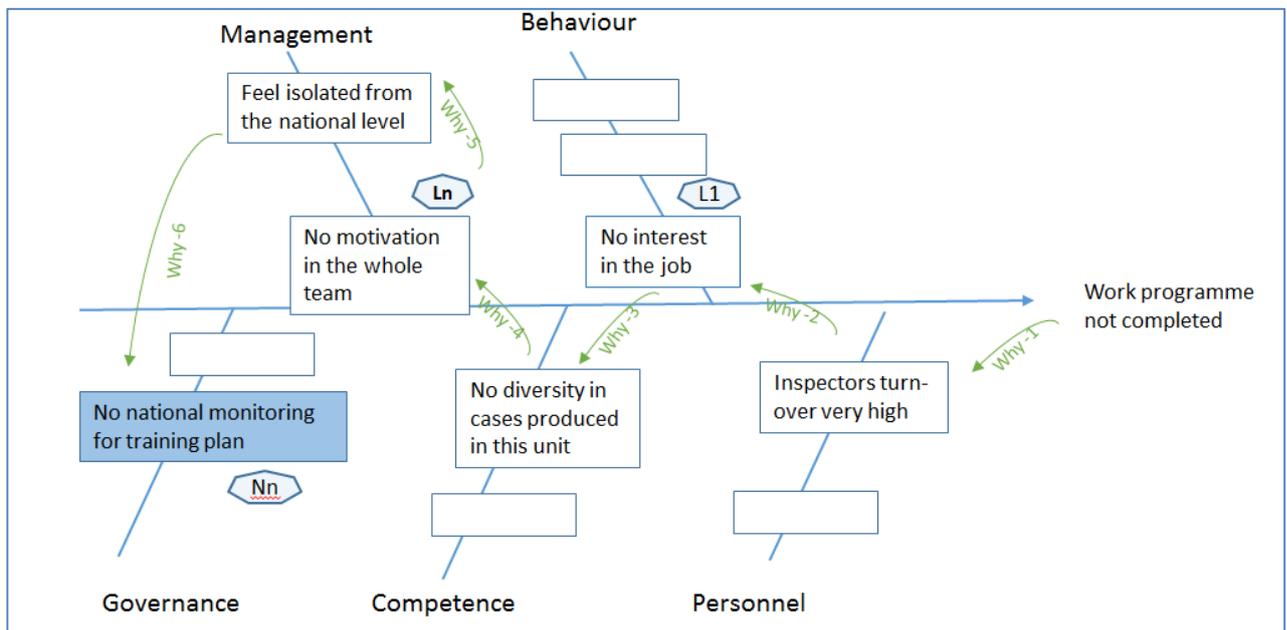
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concerning a lot of inspectors (Nn), it can be considered as a root cause to be addressed by the audit team. The plan to correct the situation belongs to the auditee.

Decision tree for *Tools* branch (using the 5Whys technique):



Case 2 :



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The audit team, in the second unit audited, finds that the programme is not being completed.

Why 1: The first why shows that it is not a non-compliance, but an out-of-range rate of departure among the inspectors of this unit. As it is strange the cause is sought.

Why 2: The second why shows, in the documented letters and evaluations that the inspectors talked of the poor interest of the job before resigning or asking for a geographical mobility.

Why 3: Pursuing the investigation the audit team finds that there are no interesting cases raised in that unit. It can explain the poor interest of the job.

Why 4: It could be due to a weak local level of activity in the area of this unit, but the fourth why of this situation shows a general lack of motivation, even among the inspectors in place. It then appears that the local cause is not individual but collective.

Why 5: The following why leads to the cause of this collective depression: the team feels isolated and forgotten from the national level, even if it has the standard level of exchange with the national boards.

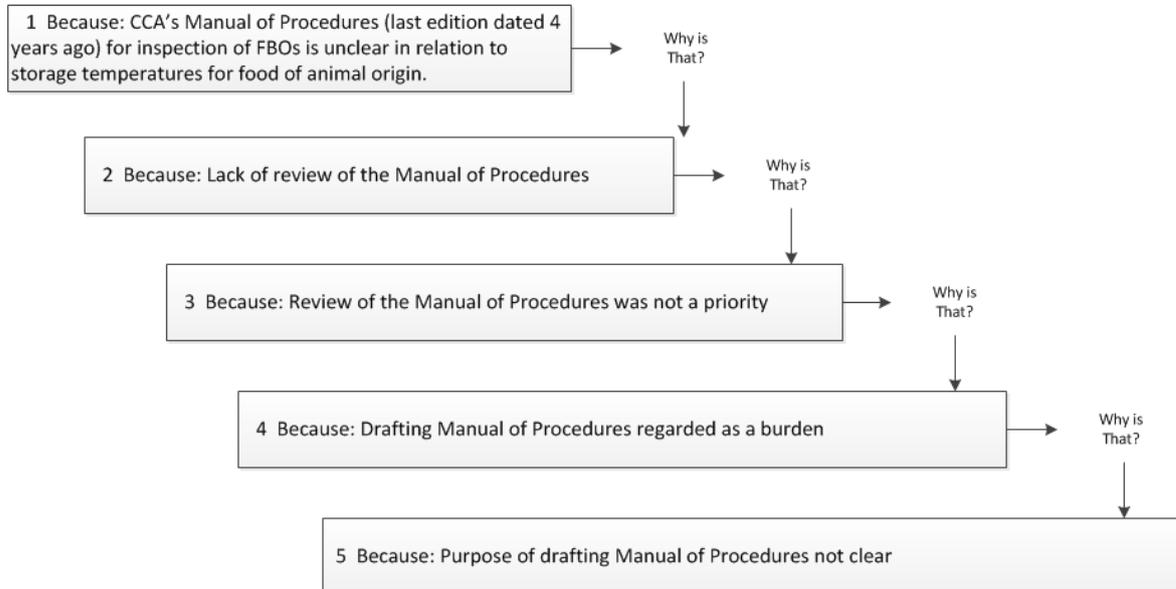
The last why reveals that there is no exchange with the training service, therefore people don't benefit new technics, never meet colleagues or share experience. This general mood has not been locally identified and treated and everybody feels abandoned and plays an individual strategy for his career, explaining the turn-over.

Note: these two cases illustrate how by addressing a common root-cause a single recommendation can solve two known issues and potentially several others not looked at.

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Annex II - 5 Whys

Define the problem: Food of animal origin stored for long periods, in several FBOs, at temperatures above the regulatory limits. Different regional CAs audited did not take corrective actions.

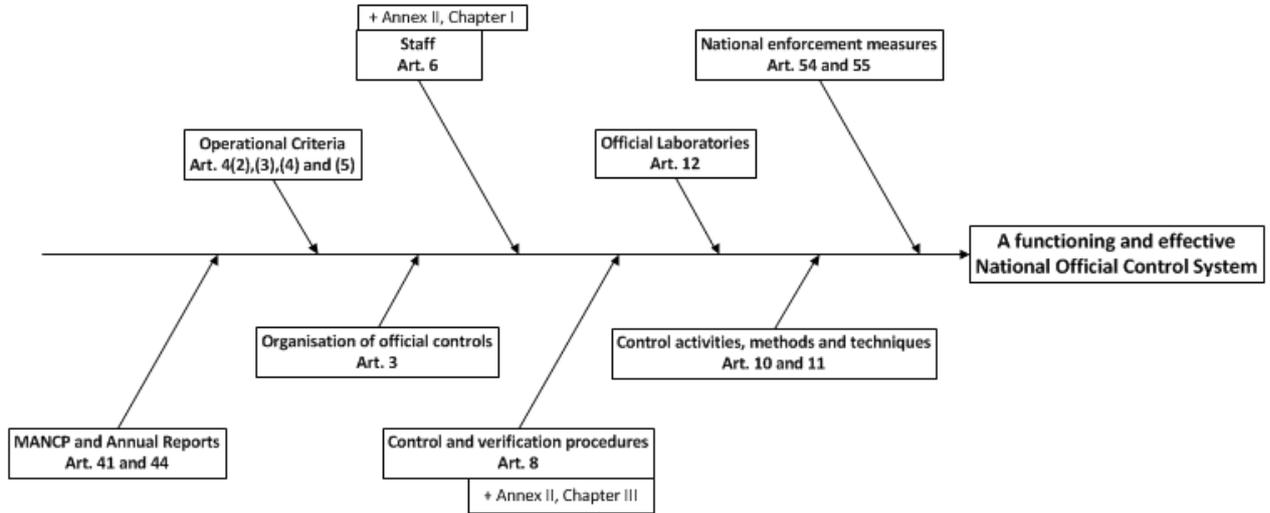


Action: CCA should define a policy for drafting and keeping Manual of Procedures updated. CCA should ensure that staff at all levels follow the most updated version of the Manual.

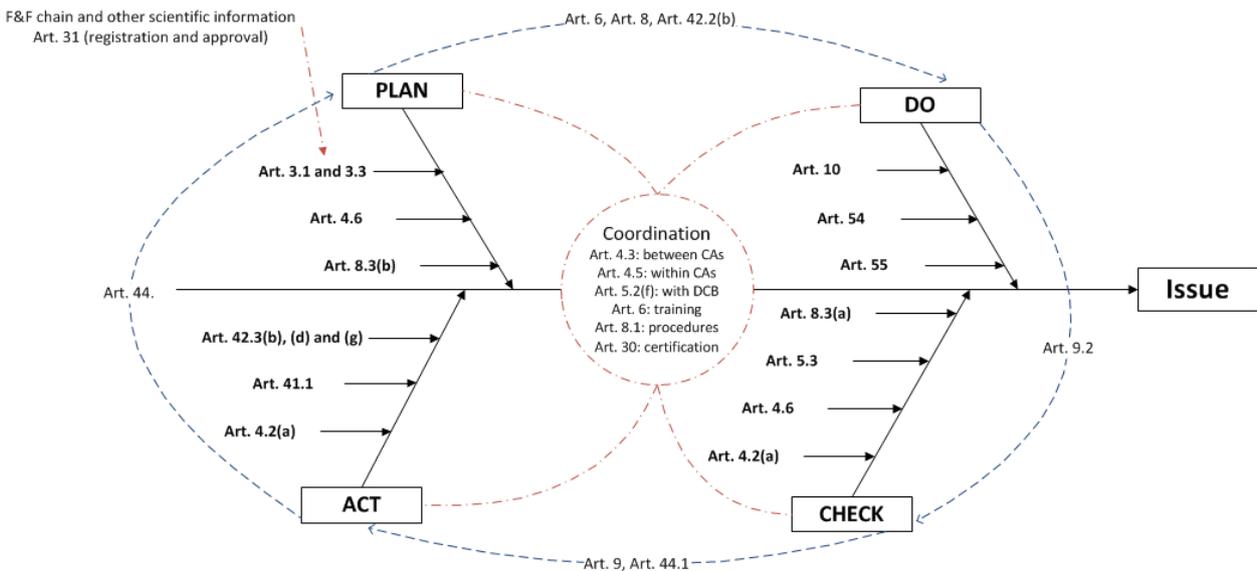
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Annex III - Fishbone

882 Fishbone "cause and effect" diagram



PDCA/882 Fishbone "cause and effect" diagram



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Annex IV - Pareto principle

The Food Standards Agency (FSA) was responsible for implementing Official Controls in 1500 approved meat establishments in Great Britain (England, Wales and Scotland). FSA Internal Audit conducted audits of official controls in 200 establishments each year, issuing a report highlighting non-compliances with Regulation (EC) No 882/2004 identified for each establishment and a corrective action report.

Non-compliances (NC) were classified according to type. For example NC1 representing official controls for animal welfare and health, NC2 representing official controls for animal by-products etc. In the practical example only 10 NC types are shown.

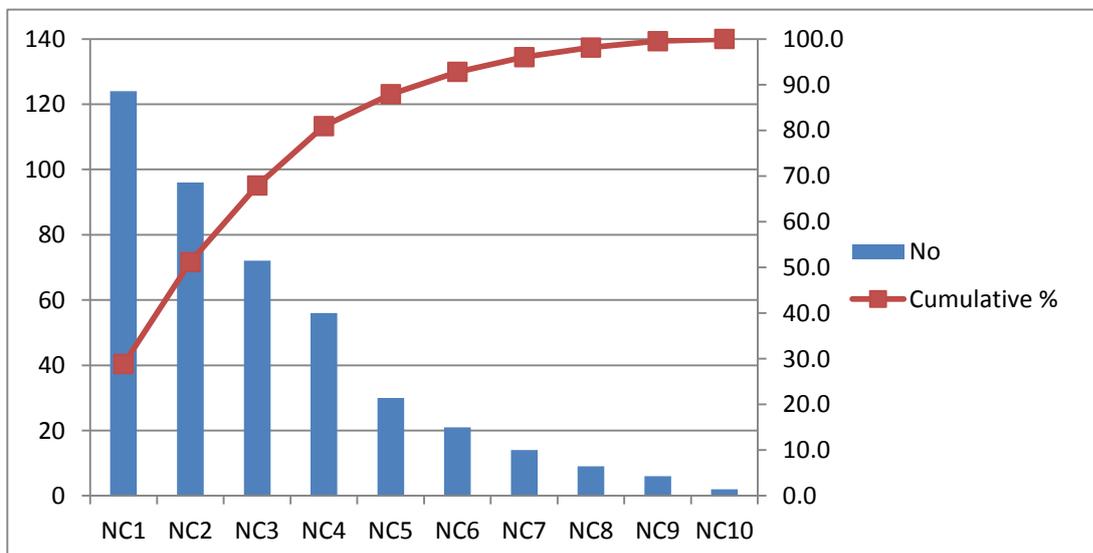
Every six months, the Internal Audit presented a summary report to management which highlighted the number of times (frequency) each type of non-compliance had been identified. This is illustrated in the table and bar-chart below.

Applying Pareto principles to the data would help Internal Audit to demonstrate to management that addressing the root causes of the four most frequent non-compliances could eliminate 80% of the non-compliances identified by auditors in the establishments audited.

The technique does not pin-point the root cause but helps to focus effort in dealing with the root causes.

Non-compliances in approved meat establishments

Non-compliance type	No	Cumulative Count	Cumulative %
NC1	124	124	28.8
NC2	96	220	51.2
NC3	72	292	67.9
NC4	56	348	80.9
NC5	30	378	87.9
NC6	21	399	92.8
NC7	14	413	96.0
NC8	9	422	98.1
NC9	6	428	99.5
NC10	2	430	100.0



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Annex V – Failure Mode and Effects Analysis, FMEA

The following table is an example of FMEA applied to the procedure of reception by the lab of the chilled samples.

Example of QRQC : At the reception of a sample from an external transporter temperature data are lacking or non-readable. The answer explains to the lab employee that he has to contact the transporter to obtain the lacking data and in the same time, the sender so that he can treat the case within its own sub-contract of transportation.

FMEA for Lab cold sample reception

Function or Process Step	Failure Type	Potential Impact	SEV	Potential Causes	OCC	Detection Mode	DET	RPN
<i>Function, step or item being analyzed</i>	<i>What has gone wrong</i>	<i>What is the impact</i>	<i>How severe is the effect</i>	<i>What causes the key input to go wrong</i>	<i>Frequency of occurrence</i>	<i>What are the existing controls that either prevent the failure from occurring or detect it should it occur</i>	<i>How difficult to detect</i>	<i>Risk priority number</i>
Lab reception procedure of insulated box	Invalid data from the thermo button	Invalid sample for analysis	10	Button failure Button touch the holding plate	3	Check the button before putting in the box Put it in the middle of the sample Control the temperature with the Lab calibrated thermal probe	4	120

Recommended Actions	Responsibility	Target Date	Action Taken	SEV	OCC	DET	RPN
<i>What are the actions for reducing the occurrence of the cause or improving the detection</i>	<i>Who is responsible for the recommended action</i>	<i>What is the target date for the recommended action</i>	<i>What were the actions implemented? Now recalculate the RPN to see if the action has reduced the risk.</i>				
Policy of annual calibration of the buttons Return to the sender the difference with the calibrated measure Extra button given to the teams	Sender	From immediate effect	Information procedure Software modification to transmit to the senders the measured temp. Extra budget for buttons	10	1	3	30