Understanding Root Cause Analysis

BRC Global Standards

June 2012

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1. What is Root Cause Analysis?

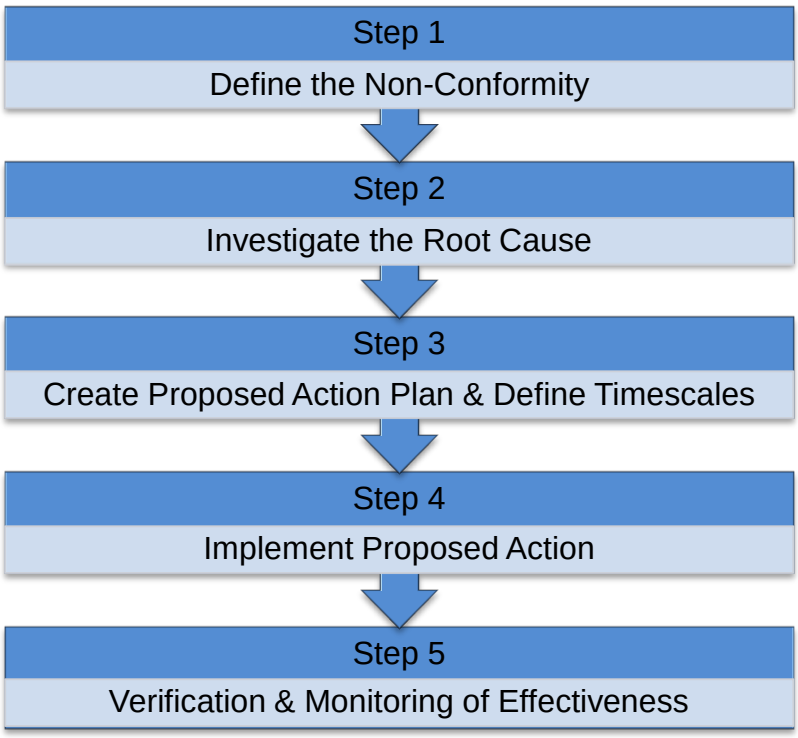
Root cause analysis is a problem solving process for conducting an investigation into an identified incident, problem, concern or non-conformity. Root cause analysis is a completely separate process to incident management and immediate corrective action, although they are often completed in close proximity.

Root cause analysis (RCA) requires the investigator(s) to look beyond the solution to the immediate problem and understand the fundamental or underlying cause(s) of the situation and put them right, thereby preventing re-occurrence of the same issue. This may involve the identification and management of processes, procedures, activities, inactivity, behaviours or conditions.

The benefits of comprehensive root cause analysis include:

- Identification of permanent solutions
- Prevention of recurring failures
- Introduction of a logical problem solving process applicable to issues and non-conformities of all sizes

Steps to Root Cause Analysis



It should be noted that this is a simplified process flow, which is typical of the majority of situations required by the BRC Standards. However, for a complex non-conformity, such as a serious incident involving a microbiological outbreak, root cause analysis will become proportionally more detailed, require extra activities and can require considerable time. For example, some or all of the following steps may be required:

- Establish a root cause team to investigate the issue
- Compilation of a summary of the event or non-conformity (ie a summary of what was wrong)
- Confirmation of the sequence of events (for example if a customer illness, led to product analysis, which subsequently led to a raw material investigation then the dates and results of each step may provide useful information)
- List of dates/times (for example when the non-conformity was discovered and when the last acceptable monitoring result of the implicated process was obtained)
- A list of implicated products/ingredients (raw materials) or processes
- A summary of any incident management or immediate corrective action that has been completed
- Any other relevant data or information (for example records, test results, information from staff in the relevant area or complaints)

- Collation of all available information
- Investigation of possible scenarios & collation of information (for example this may include product or environmental testing or liaison with technical experts and regulatory authorities).

2. Where in the Standard is RCA Required?

An important part of any non-conformity management is the identification of the root cause and the implementation of suitable action. There are a number of requirements in the BRC Standards for root cause analysis:

Food Standard Issue 6:	
Clause	**Requirement**
1.1.10	Senior management to ensure the root cause of audit non-conformities have been effectively addressed to prevent recurrence.
3.7.1	Identification of the root cause of non-conforming products and implementation of any necessary corrective action.
3.10.1	Root cause analysis and associated actions relating to customer complaints.
Audit Protocol 9.2 & 9.2.2	Following an audit, the root cause of non-conformities shall be identified and an action plan to correct this, including timescales, must be provided to the Certification Body.
Consumer Products Standard Issue 3	
2.4.2	Review of risk assessment and evaluation of complaints / incidents
3.7.4	Corrective actions and prevention of re-occurrence
3.12.4	Analysis of complaint data
Packaging Standard (Issue 4)	
	There are no requirements for root cause analysis in the Packaging Standard, but sites are required to state “corrective action taken (with consideration of root cause)” in the audit report.

3. How to Complete Root Cause Analysis?

There is no single prescribed method of conducting root cause analysis and any structured approach to identifying the factors that resulted in the non-conformity could be used, many tools and methods have therefore been published (two popular methods are highlighted below). The choice of root cause methodology may be a matter of personal choice, company policy or dependent on the type of issue/non-conformity being investigated. Some companies

find different tools work better for different types situations, for example based on the size or complexity of the incident or the type/source of data.

Whichever method of root cause analysis is used it is usually necessary to commence with, and record the known facts. Depending on the situation these may include:

- What the non-conformity is
- When it occurred and when it was discovered
- Implicated products/processes
- Any immediate corrective action completed

Throughout the process it should be remembered that the key question that root cause analysis is seeking to answer is: What system or process failed so that this problem could occur?

On some occasions the reason is straightforward – 'Why did this occur?'

- 'The documented policy didn't include the requirement' or
- 'The procedure wasn't trained to staff'

In these situations the subsequent steps of the investigation and action can be planned immediately.

On other occasions the cause is not immediately clear and investigative steps will be required, for example:

- Does the operator understand the procedure?
- Does the method laid out in the policy work if followed precisely?
- Does the specified time/temperature achieve the expected outcome?

In these situations it is necessary to gather and collate evidence, for example:

- Talk to the operator to establish the level of understanding
- Take the method into the appropriate factory area and follow it through precisely as written
- Review the original shelf life or processing data
- Where appropriate complete new or additional tests (for example on raw materials, final product, factory environment or the process)

Once this information is collated, it should be possible to draw conclusions or to establish the areas where further focus/questions are required.

Once the underlying cause has been established, the next stage of the process is to establish a proposed action plan, indicating the action that will be taken to prevent the non-conformity recurring. The action plan should include a defined timescale in which the action will be completed and define who is responsible for completion.

An important final step of an effective root cause analysis is to consider monitoring or verification activity. This is necessary to ensure that the changes to (or new) activity or

procedures is fully operational, that it is effective in managing the root cause and that it does not inadvertently introduce any additional problems. Example activities could include:

- Internal audits covering the new process
- Check sheets to be completed at the time of the changed process
- Line start up checks
- Investment in new technology
- End of production/shift countersigning by production or line manager

Once it is demonstrated that an action is fully embedded and effective, a review can consider whether the additional monitoring is still required or can be reduced to a lower frequency.

4. Methods of Root Cause Analysis

4.1 The '5 Whys':

The '5 Whys' is the simplest method for structured root cause analysis.

It is a question asking method used to explore the cause/effect relationships underlying the problem. The investigator keeps asking the question 'Why?' until meaningful conclusions are reached.

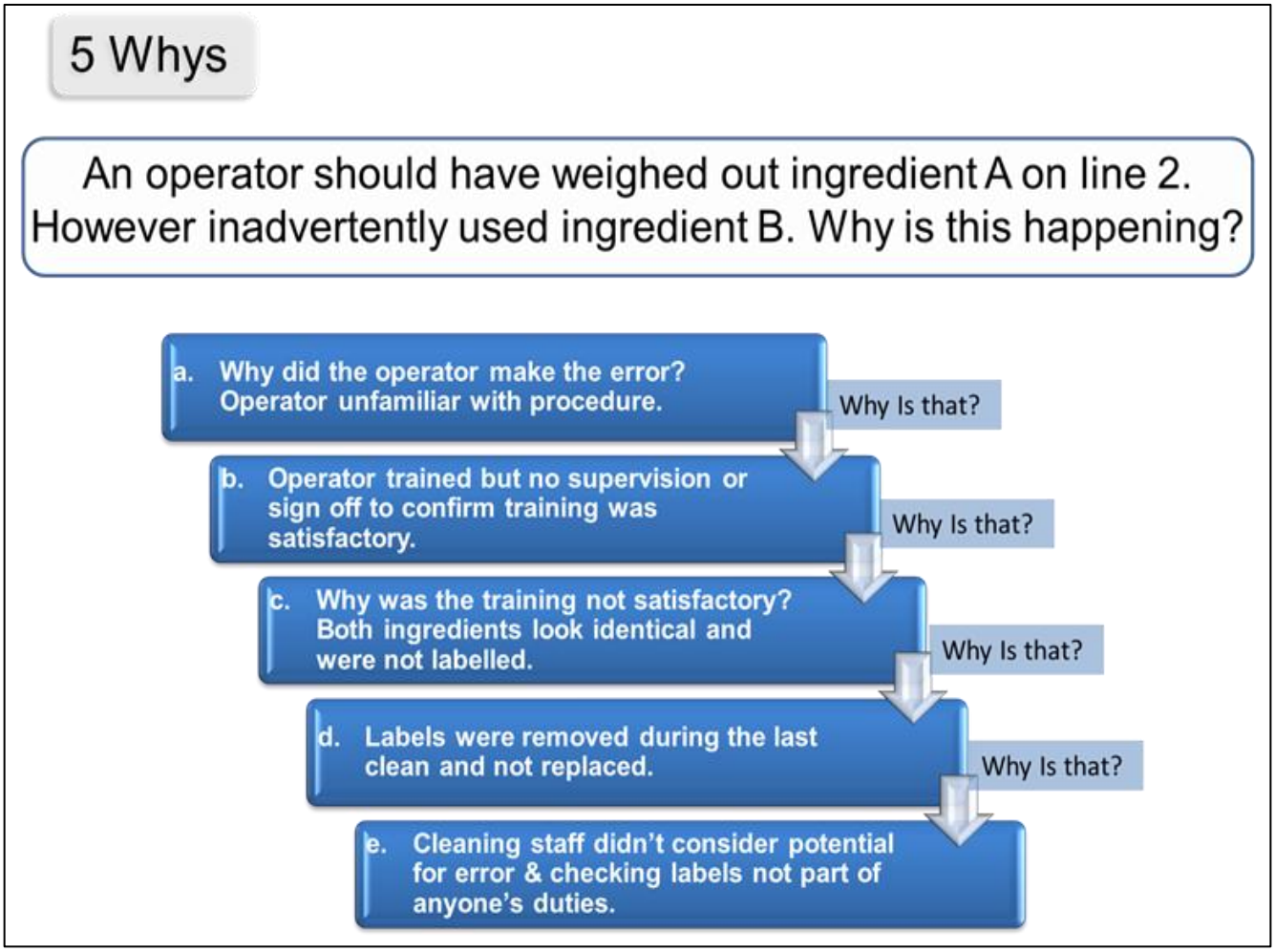
It is generally suggested that a minimum of five questions need to be asked, although sometimes additional questions are required or useful, as it is important to ensure that the questions continue to be asked until the real cause is identified rather than a partial conclusion.

As previously mentioned it is usually necessary to obtain information or objective evidence at each stage of the process, it is also sometimes necessary to re-phrase a question or make it more specific to obtain meaningful data, for example, instead of simply asking 'why?', ask 'why was the operator not trained?' or 'why did the training process fail?' or 'why was the training process not effective on this occasion?'

An example of root cause analysis using the '5 Whys':

An operator is instructed to perform a simple action 'weigh out ingredient A', however the operator inadvertently used ingredient B instead.

An immediate reaction will probably suggest this was caused by an operator error. Whilst this may be accurate, it does not establish the reason why the error occurred or prevent it happening in future. The root cause analysis must ask a series of 'Why?' questions (and obtain answers), for example:



In this example it would be easy for the investigator to stop the analysis part way through thinking that all the conclusions had been reached (ie that this was purely a training issue), however, the further questions reveal useful information about the nature of the cause and therefore the appropriate action.

The issue actually had a number of causes that contributed to the incident:

- Incomplete training procedure
- A faulty cleaning process
- Lack of post-cleaning check procedures

Proposed action can now be planned, for example:

- Update training procedure to ensure sign off (& possibly a supervision step)
- Replace ingredient labels – if practical with ones that cannot be removed.
- If labels must occasionally be removed, ensure that post cleaning line checks include

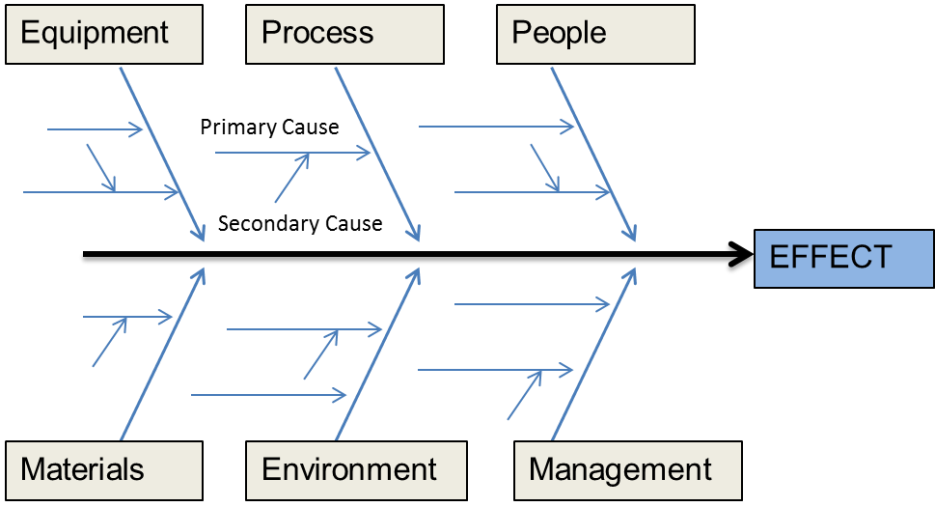
a check of labels.

- Ensure an individual (eg the production manager) is authorised and responsible for post-cleaning line sign off.
- Ensure cleaning staff fully understand and are trained in the need to return labelling (and all equipment) in a fully operational state.

4.2 Fishbone Diagrams:

A second commonly used method of root cause analysis, is the use of fishbone diagrams (sometimes referred to a Ishikawa models or Herringbone diagrams). They are most useful when the '5 whys' is too basic, for example, where a complex issue needs to be considered in bite size pieces or where there is a lot of data that needs to be trended.

In the diagram, the various causes are grouped into categories (such as equipment, materials or processes) and the arrows in the image indicate how the causes cascade or flow toward the non-conformity.



The categories are not pre-defined but common ones include:

- Equipment – this should include consideration of all equipment that could have a role in the non-conformity, for example, production line, facilities, computers or tools
- Processes or Methods – how work is performed, policies, procedures, rules or work instructions
- Measurements – any data collection or measurement, either from a process or subsequent to the non-conformity, for example metal detection records, check weights or final product analysis
- Materials – any information relating to raw materials or final products, for example raw material specification or goods receipt checks for a specific batch of ingredient.
- Environment – The location, time, temperature, culture, standards of cleanliness or available time, for an activity.
- People – Any role involved in the implicated process.

This type of root cause analysis is a causal process, it seeks to understand the possible causes by asking ‘what actually happened?’, ‘When?’, ‘Where?’ ‘Why?’, ‘How?’ and ‘So what?’ in other words a possible cause is identified and the consequences and significance is investigated for each of the group categories.

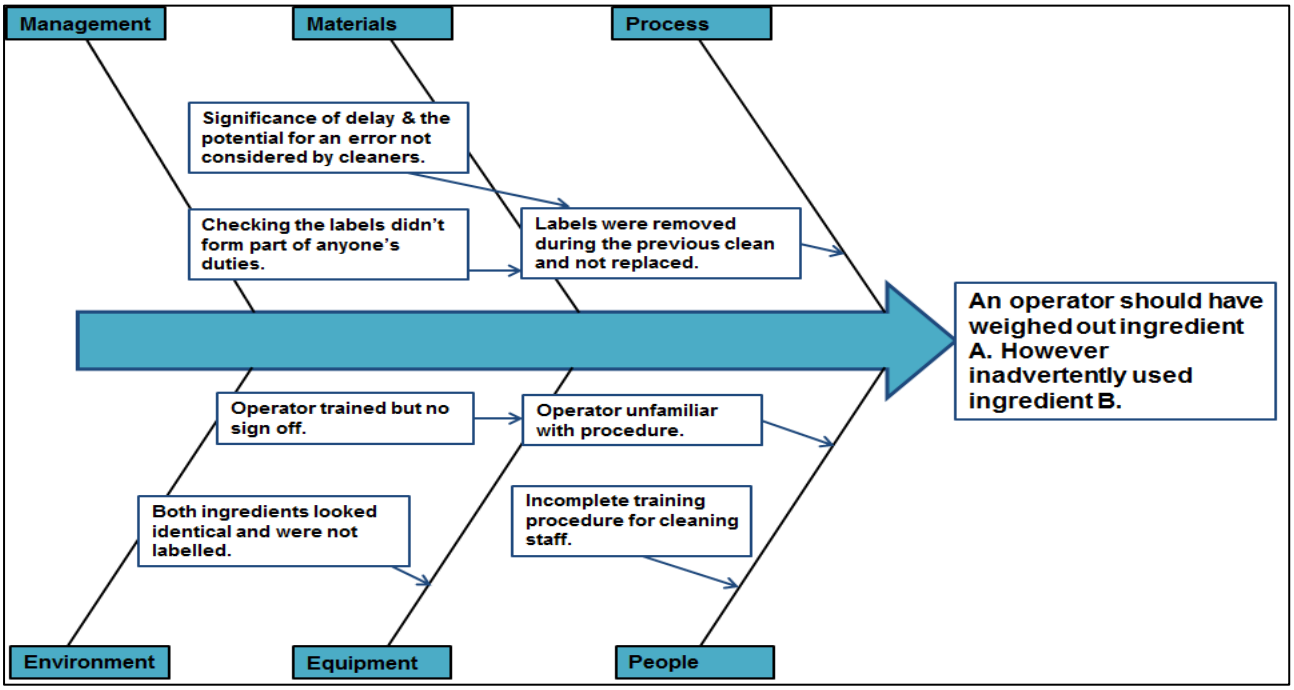
For example:

- What happened? - Procedure was not followed correctly
- Why? - Staff member was untrained in the procedure
- When? - Monday morning
- Where? - Line 2
- How? - Staff shortages
- So what? (ie is this important) - The safety of the product could be implicated if the procedure is not followed correctly. Training processes have not been followed correctly.

As with the ‘5 Whys’ it is important to initially investigate the cause and then examine the cause of the cause to ensure the root cause has been correctly identified (fishbone diagrams sometimes refer to this as examining primary and secondary causes).

Example of root cause analysis using the Fishbone Diagram:

Using the same scenario as for the ‘5 Whys?’ in which an operator is instructed to perform a simple action ‘weigh out ingredient A’, however inadvertently uses ingredient B. The causes would be tabulated as discovered and proposed action developed:



5. Common Mistakes

To help users avoid a number of common mistakes, which are known to hinder the formation of quality proposed action plans, an explanation of each mistake given below. This explanation includes an example of the incorrect approach (indicated by an '**X**'), which is immediately followed by the same non-conformity being accurately investigated, leading to a better proposed action plan (indicated by a '✓').

5.1 Unmanageable Conclusions

The root cause should be something that can be managed or changed, which means that it normally relates to a system or process and occasionally an alterable behaviour. For example, it is often tempting to reach a conclusion such as 'they forgot', 'not enough time', 'not enough money', 'not enough staff', 'staff sickness' or 'made a mistake', these answers may be true, but in most cases they are out of our control, whereas root cause analysis should lead to controllable, manageable or adjustable processes. If these answers are evident it is worth going back into the process to establish whether there is any other cause, for example by asking specific questions such as, 'Why did the process fail?' or 'What system allowed the mistake to be made?'

For example:

	Details of Non-conformity	Corrective action taken	Root cause analysis and proposed action plan (PAP)
✗	Internal audit of supplier management systems scheduled for January had not been carried out.	Audit completed. All scheduled audits completed and up to date.	**Root Cause:** Lack of resource in technical department due to long term sickness. **PAP:** Resource issues to be

			discussed in monthly management review.
✓	Internal audit of supplier management systems scheduled for January had not been carried out.	Audit completed. All scheduled audits completed and up to date.	**Root Cause:** Procedures didn't recognise the need for deputies and therefore no alternative staff had the appropriate qualifications/training when key staff were on long term sickness. **PAP:** Internal audit process/policy updated to incorporate deputies. The size of the internal audit team will be increased to include sufficient deputies. These staff will be trained, as appropriate, for the systems to be audited.

This example again highlights that in practice there may be more than one cause (no deputies, out of date policy and a lack of training) and therefore the proposed corrective action plan may require multiple actions.

5.2 Duplication of the Immediate Corrective Action

It is important that immediate action is taken to correct a non-conformity. However, this is separate from the root cause analysis and proposed action plan. The purpose of root cause analysis is to look beyond the immediate non-conformity, to investigate what system or process allowed the non-conformity to occur. Once this is established, the proposed action plan can focus on ensuring that the system or process is amended such that the fault cannot occur in future. Therefore the proposed action plan should not be a repeat of the immediate corrective action.

For example:

	Details of Non-conformity	**Corrective action taken**	**Root cause analysis and proposed action plan (PAP)**
✗	Acceptance and rejection criteria have not been defined for calibrated devices. Therefore the actions to take, if the device is incorrect or out of calibration range were not defined.	Acceptance and rejection criteria defined and documented. Actions in case of an out of calibration device documented.	**Root Cause:** Requirement not documented. **Action Plan:** Calibration procedure has been updated and information added.
✓	Acceptance and rejection criteria have not been defined for calibrated devices. Therefore the actions to take, if the device is incorrect or out of	Acceptance and rejection criteria defined and documented. Actions in case of an out of calibration device	**Root Cause:** Neither HACCP procedures, calibration procedure nor installation policies documented the need to define these criteria before use of new equipment.

	calibration range were not defined.	documented.	**PAP:** HACCP procedures reviewed and updated to ensure that all steps are documented and the requirement to validate any changes to CCPs is documented in the policy. Policies regarding the purchase and installation of new equipment also updated to reflect requirement. All relevant staff (HACCP team and production managers) trained in new requirements

5.3 People

It is sometimes tempting to reach a conclusion such as; 'oversight', 'mis-understood', or 'forgot', however people are rarely the true root cause and the investigator will need to establish what system, policy or process allowed the human error to occur.

For example:

	Details of Non-conformity	**Corrective action taken**	**Root cause analysis and proposed action plan (PAP)**
✗	CCP control records were not signed by the person completing the monitoring.	Training completed on the correct completion of monitoring sheets and their importance.	**Root Cause:** Inexperience **PAP:** Raise staff awareness.
✓	CCP control records were not signed by the person completing the monitoring.	Re-training designed using a number of worksheets where staff were asked to identify 'good and bad' records (ie those that were completed correctly and those that had missing information)	**Root Cause:** Effectiveness of training for newest members of staff was not assessed. CCP worksheets were not checked by either technical team or internal audits. (The reason for this should also be subject to root cause analysis) **PAP:** Examples of correctly completed, annotated CCP worksheet included in work instructions (copies of which are available in production areas). Specific checks on CCP monitoring added to the internal audit schedule. **Verification:** Line or production manager to countersign CCP record sheets at end of shift/production.

In a few situations where individuals are the root cause, for example, a site new to certification could, during its first audit, discover it has mis-understood a clause of the Standard, there will often be a need for additional training or methods to gain experience or competence (for example attending additional training, using an experienced consultant, etc)

Where re-training is considered to be a necessary part of the proposed action plan, consideration should be given to the format of the training. If the initial training was not effective then just repeating the same ineffective training, is unlikely to achieve the desired effects. Consider for example; the use of workshop or example based activity, use of pilot plant (where available), work-based training such as observing an experienced colleague, use of external training providers, language in which the training is provided, etc.

Throughout the process it must be noted that root cause analysis is not designed to establish who is to blame for a non-conformity, but to correct the underlying cause and prevent re-occurrence.

5.4 Proposed Action Plan Doesn't Prevent Re-occurrence

Occasionally, despite root cause analysis and the implementation of a proposed action plan the non-conformity re-occurs. There are a number of potential reasons why this might happen, including:

- Incomplete initial root cause analysis
- Incorrect root cause conclusions (ie the true root cause was not established)
- Multiple root causes (the proposed action plan needs to manage every root cause)
- Proposed action plan not fully implemented or trained to staff

In these situations it may be necessary to re-visit the root cause analysis and identify additional causes and appropriate controls.

Example 1:

	Details of Non-conformity	Corrective action taken	Root cause analysis and proposed action plan (PAP)
✗	The company procedure states that weekly production meetings are held to verify the effectiveness of the HACCP plan. However, there is no evidence available to demonstrate that these meetings are being held.	Procedure changed to monthly meetings.	**Root Cause:** Weekly meeting not sustainable **PAP:** Change to monthly meetings
✓	There is no evidence available to demonstrate that these meetings are being held on a weekly or monthly basis.	A meeting was carried out.	**Root Cause:** Meetings occurred on an ad hoc basis but didn't have agenda or minutes. **PAP:** Formalise meetings with agenda and minutes. Identify team member responsible for agenda and minutes. Schedule meetings for

			the year ahead and put the dates/times and locations into the team members diaries.

Example 2:

	Incident	Details of Non-conformity	Corrective action taken	Root cause analysis and proposed action plan (PAP)
✗	Product released with incorrect allergen information	Dairy dessert was packed into non-dairy packaging and released to customers (Non-dairy dessert does not contain milk which could cause a reaction in an allergic individual)	Product withdrawn and customers notified.	**Root Cause:** Multiple sets of packaging are retained in the vicinity of the packing line. **PAP:** All packaging (except that currently in use) to be kept in the storage area until needed. **Verification:** Manual checks of packed product at regular intervals during packing operations.
✓	Manual checks on packed products indicate that mis-packs still occur.	Product mis-packed. The previous root cause analysis has not prevented re-occurrence of the non-conformity.	Implicated product captured and corrected before it left the packing line.	**Root Cause:** Several products have similar packaging artwork and are therefore not visually distinct. Unused part packs of similar packaging are all stored together. **PAP:** Re-design storage areas to ensure similar packaging has separate areas. Ensure new procedures are documented and trained. Investigate opportunities to redesign some products (or discuss options with brand owners). **Verification:** Introduce additional packaging checks at line start up and when changing packaging on the line. Maintain system of manual checks of packed product, but also investigate options for automatic bar code scanners.

This example again highlights that once actions have been implemented best practice is to introduce monitoring or verification activity to demonstrate that the action has effectively prevented re-occurrence of the non-conformity. (It should be noted that clause 1.10.1 of the Food Standard requires senior managers to ensure that the root causes have been effectively addressed, monitoring and verification activity can be used as evidence, not only to the site's management, but also for the auditor).

5.5 Extra Checks

Whilst extra checks are often required for verification or monitoring (refer to section 3), it is preferable that the proposed action plan is not solely an extra check(s). The reason for this is twofold:

- Whilst it should prevent a re-occurrence, a check is only monitoring the non-conformity; it is not addressing the true cause of the problem.
- Extra monitoring requires on-going investment, in terms of time (and therefore cost), whereas proposed action plans may require an initial investment, but should not require continuous on-going investment.

For example:

	Details of Non-conformity	Corrective action taken	Root cause analysis and proposed action plan (PAP)
✗	Water used for hand washing, in the production area, was cold	Check for hot water introduced (completed by QA at start of day)	**Root Cause:** Boiler turned on too late for first shift. **PAP:** Added as part of start- up checks.
✓	Water used for hand washing, in the production area, was cold	Check for hot water introduced (completed by QA at start of day)	**Root Cause:** Switching the boiler on was forgotten on the day of the audit. Investigation has demonstrated that the boiler must be on by 7am to be sufficiently hot for the first shift. The current system relies on the first person arriving to switch on the boiler. It is not one particular colleague's responsibility. **PAP:** Company will invest in an automatic time control for switching on boiler. In the meantime the QA manager will be responsible for switching on boiler by 7am. (This has been documented in the policy on QA start-up checks).

6. Preventative Action

Although not specifically required by the BRC Standards, good practice is to ensure that once a root cause and proposed action plan is identified, consideration is given to whether any other systems, processes or procedures are susceptible to the same failure. Where appropriate, this provides an opportunity to introduce preventative action on these other systems before a non-conformity actually occurs.

7. Additional Documentation

When documenting the root cause investigation and output good practice is to include:

- A summary of the non-conformity
- Details of products/ingredients/etc implicated
- Details of any immediate corrective action eg withdrawal of product, laboratory analysis, stopping of production, etc.
- Time of non-conformity and when the root cause analysis commenced/concluded
- Conclusions reached
- Proposed action plan with expected completion dates
- Consideration of preventative action
- Verification or monitoring

8. Glossary of Terms

Root Cause: The underlying cause of the problem which, if adequately addressed, will prevent a recurrence of that problem.

Corrective Action (Immediate Corrective Action): Action taken to manage a non-conformity (the non-conformity may originate from any source, for example, a product incident, site audit or product testing). Corrective action should be completed as soon after detecting the non-conformity as possible (this is particularly important where the non-conformity could affect product safety, integrity or quality).

Corrective Action Plan: Following an audit, sites in the Enrolment Programme are required to develop a Corrective Action Plan which outlines the non-conformities observed during the audit and the action that has/will be taken to address the non-conformity.

Proposed Action Plan: Following root cause analysis, the site must develop a proposed action plan to correct each of the root causes, such that they prevent recurrence of the non-conformity.

Preventative Action: On some occasions, root cause analysis will identify an underlying cause that indicates systems or processes other than that with the current non-conformity, are susceptible to the same failure. In these situations, in additional to the normal proposed action plan, it is good practice to complete preventative action on the implicated systems before a non-conformity actually occurs.

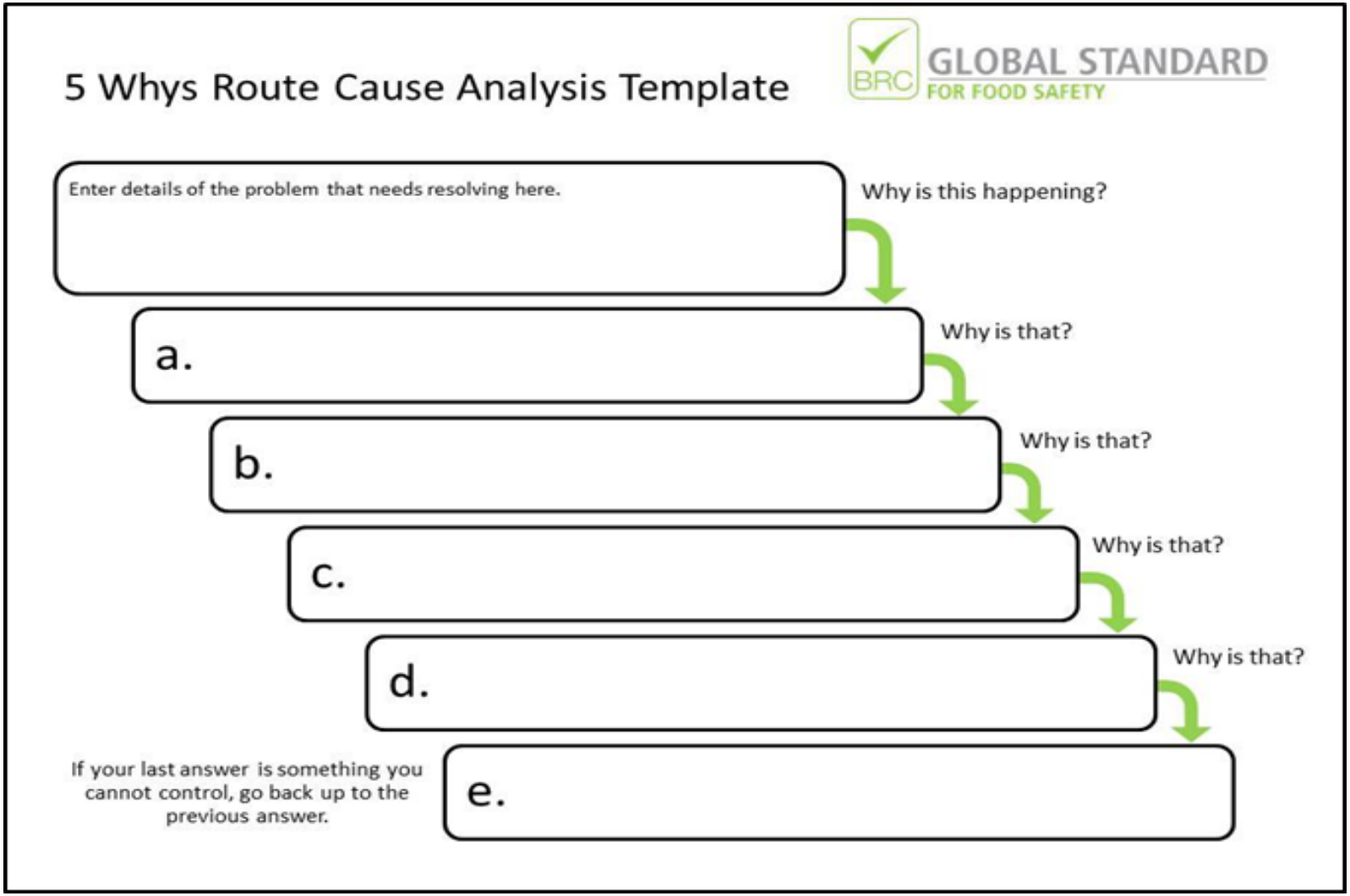
9. Appendices

9.1 Inclusion of Root Cause Analysis in the Audit Report

Following an audit the relevant information must be included in the audit report. For the Food Standard this will include a summary of the root cause analysis and proposed action plan. An example of the completed non-conformity section of the food audit report, complete with root cause analysis and proposed action plan is show below:

Minor						
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Reviewed by and Date reviewed**
1	3.4.1	Internal audit of supplier management systems scheduled for January had not been carried out.	Audit now completed as have audits scheduled for October, November and December.	**Root Cause:** Procedures didn't recognize the need for deputies and therefore no alternative staff had the appropriate qualifications/ training when key staff were on long term sickness. **Proposed Action**: Internal audit procedures updated to incorporate deputies. The size of the internal audit team will be increased to include sufficient members. These staff will be trained, as appropriate, for the systems to be audited.	Copy of audit reports	M Oliver 06/08/ 2012
2	3.11.2	Incident management procedure was not up to date, included J Read and R Smith who have left the company.	Procedure reviewed and fully updated.	**Root Cause:** 1) Procedures didn't recognize the need for deputies and therefore not reviewed to schedule due to the previously mentioned long term sickness. (NB This is the second non-conformity with a similar root cause which implies a wider issue may exist that should be investigated and managed). 2) The incident procedure is written in such a way that it need frequent updating (ie every time a staff member leaves or changes role) **Proposed Action:** 1) procedures updated to incorporate deputies. The size of the internal audit team will be increased to include sufficient members. These staff will be trained. 2) Review format of Incident procedure to facilitate less frequent or easier updates. For example, by including roles (& deputies) in the main procedure and appending a spreadsheet with names, contact details etc.	Copy of new procedure	M Oliver 06/08/ 2012

9.2 '5 Whys' Route Cause Analysis Template



9.3 Fishbone Diagram Template