INTRODUCTION TO TROUBLESHOOTING

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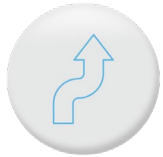
GET THE FUNDAMENTALS RIGHT

- Effective and regular sanitation program – all zones
- Validation and verification of Sanitation program
- Sanitary equipment design & preventive maintenance
- Elimination of microbial harborages
- Control of vectors: GMPs, traffic control, pest elimination
- Pest Elimination program
- Training and education
- Participation, accountability, and commitment from everyone
  - Management
  - Supervisors
  - All Employees
- RESPECT FOR THE PRODUCT

GUIDELINES TO TROUBLESHOOTING

- Work safely
  - Follow good personal safety rules

- Teamwork
  - Getting multiple viewpoints



- Plan the work
  - Random shotgun approach loses time and is not efficient.
  - Is your investigation giving you new information?

- Document what has been done
  - There is no substitute for experience, but documentation comes close.
  - Erratic failures can often be difficult to identify without documentation.

STEPS OF TROUBLESHOOTING

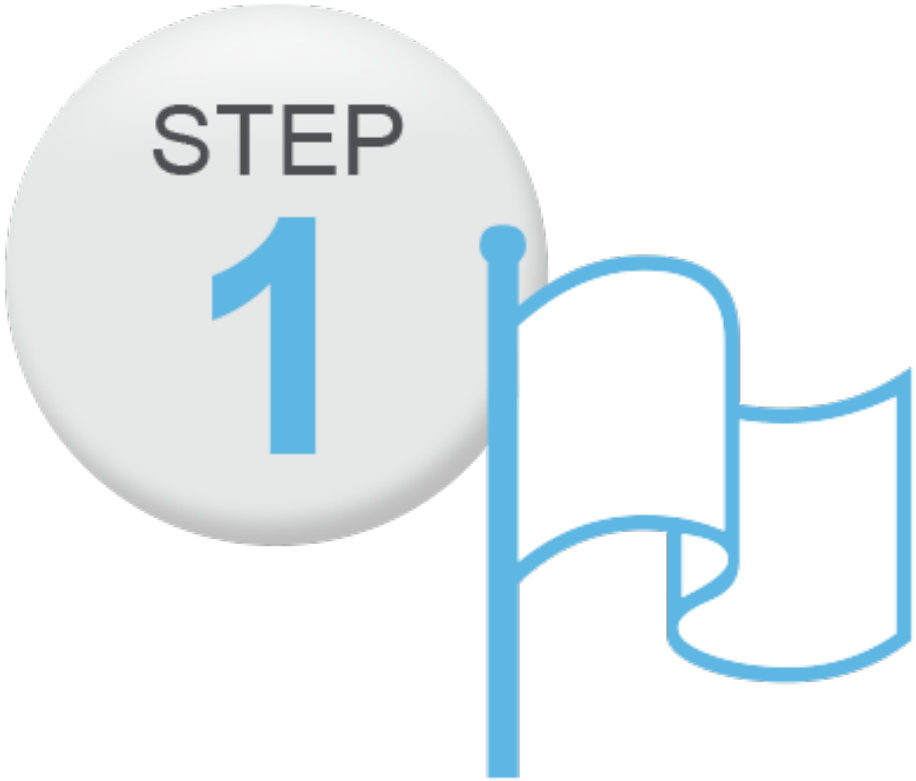
IDENTIFY the problem

COLLECT and INTERPERT data

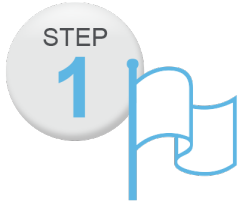
CORRECT the problem

FOLLOW UP to prevent further trouble

IDENTIFY THE PROBLEM



IDENTIFY THE PROBLEM



- Identify the problem
  - What testing or observation indicated a problem?
  - What are the symptoms?
- Identify the scope of the problem
  - How long has this been going on?
  - How serious is this problem? Is it urgent?
  - Is there a history?

SUGGESTIONS

STEP 1

- Assemble a timeline with events
- Observe area of positive
  - Traffic patterns
    - People
    - Equipment
    - Materials
  - Observe Production, Sanitation, Maintenance, etc.
- Write out the problem statement

COLLECT AND INTERPRET DATA

COLLECT AND INTERPERT DATA

STEP 2

- Data collection
  - What data is existing?
  - What data needs to still be generated?
- Look at data in a few different ways
  - Spreadsheet vs. table
  - Full data set vs. summary
- Identify quick wins or “low hanging fruit”
- Collect clues but don’t get locked on one abnormality
  - Let the data be your guide

SUGGESTIONS

- What inputs are in your system?
  - People
  - Ingredients
  - Equipment
- Zoning maps – traffic flow patterns show overlaps of activities and traffic
- Talk with the employee that took positive swab and observe area of positive
- Look at historical issues in area
  - What has changed?

INPUTS

STEP 2

- People
  - Training of new and existing employees
  - Supervision
- Traffic patterns
- Equipment design and maintenance
- Ingredients
  - Supplier programs and controls
- Changes in production schedule
  - On-season vs. off-season

OBSERVATION

- Direct observation on the floor during all stages
  - Production, Sanitation, Maintenance work, etc.
  - GMPs
  - Potential cross-contamination
- Observe practices and review documentation
  - Routine sanitation
  - Master sanitation
  - Preventive maintenance
- Collect clues but don’t get locked on one abnormality
  - Let the data be your guide

EQUIPMENT

STEP 2

- New or “new to you” equipment
- Recent maintenance activity
- Preventative maintenance work
  - Compliance to schedule
  - PM work executed in a sanitary manner
- Hard to clean or access areas
- Product hang-up areas
- Cleaners and sanitizers match current product mix and cleaning frequency

TESTING

STEP 2

- Agree on testing needs
  - What data exists?
  - What data should be generated?
  - Identify and list potential contributing factors
- Look at lab procedures
  - Were samples taken aseptically?
  - Are proper lab procedures being followed?
  - Any changes in method or lab?
    - Your lab results or someone else's? If both, do they agree?
- Do not make testing method changes during a corrective action

USE THE TOOLS AVAILABLE

- Chemical
- Microbiological
- Sensory
- Other Technology

CORRECT THE PROBLEM

The short-term solution

CORRECT THE PROBLEM

STEP 3

- Try quick wins for things that are obviously wrong and easy to fix
- Teamwork is important here
- Follow the data
  - DO NOT make the data fit your ideas
- Go back to Step 2 if the solution doesn't solve the problem

SUGGESTIONS

- Create a list of possible sources of trouble
  - Look at documentation of other like problems to help create the list (troubleshooting aid)
  - Rank the list using probability
  - Begin testing or fixing items on the list
- Document results of the attempted fix
  - Failures are just as important as successes
- Use multiple samples to confirm the problem is corrected
  - Three in a row is often used as a guideline

FOLLOW UP TO PREVENT FURTHER TROUBLE

The long-term solution

FOLLOW UP TO PREVENT FURTHER TROUBLE

- Can you demonstrate the root cause was corrected?
- If so:
  - Is the correction valid over time?
  - Is the fix sustainable in the long term?
  - What could be done to prevent this problem from occurring again?
- A temporary fix to a problem is just that, temporary
- Correct the root cause of the problem and not just the symptoms

SUGGESTIONS

- Plan to reverify after weeks or months
  - Confirms this was not just temporary
- Watch-out for seasonal impacts or temporary supplier changes
- Is intensified cleaning a corrective or preventative action?
  - Master Sanitation activity
  - Is it feasible to continue as a preventative action
- Use teamwork to get the best solution

EQUIPMENT

STEP 4

- Preventive maintenance
- Sanitary design improvement
- Repair
- Replace
- Training

DOCUMENTATION

STEP 4

- Update any SOPs or protocols that have been modified
  - Including MSS and PM programs
- Goal of documentation should be to make it easier to troubleshoot the next time this problem occurs
- Lets you share your experience with others
- Standardize the documentation to make it easier to use

FINAL THOUGHTS

- What is the problem?
- What is your short-term solution to get back to negative?
- How would you monitor the “fix”?
- What modifications could be done to make sure this particular incident doesn’t happen again?

QUESTIONS?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