Corrective Action and Root Cause Analysis

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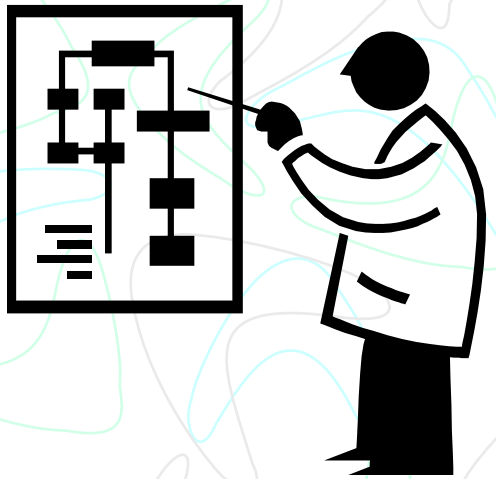
Quality Assurance

“Normal people... believe that if it ain't broke, don't fix it. Engineers believe that if it ain't broke, it doesn't have enough features yet.”

Scott Adams



What is Corrective Action?

An action taken to eliminate the initiating cause of a detected nonconformity.

Note: *Corrective action is designed to eliminate the reoccurrence of a nonconformity, where as a preventive action is designed to eliminate the occurrence.*

What Needs Corrective Action?

- Nonconforming work
- Audit deficiencies
- Complaints
- Departures from Policies and Procedures
- Proficiency Test failures
- Equipment failure

Nonconforming Work

Work that does not meet the defined requirements and requires rework.

- Quality control failure
- Reporting error

Audit Deficiencies

Nonconformity detected during an internal audit, or audit from an external organization such as;

- NPDN
- NAHLN
- AAVLD
- A2LA

Complaints

A Nonconformity detected and communicated back to the laboratory.

- Data entry error
- Wrong test performed

Departures from Policies and Procedures

Nonconformity caused because the policies and procedures of the organization were not followed.

- Incomplete Communication, not adhering to Chain of custody protocol
- Untrained employees performing testing

Proficiency Test Failures

A nonconformity detected through proficiency testing.

- Aphis, PPQ
- VLA (Veterinary Laboratory Association)
- CAP (College of American Pathologists)

Equipment Failure

Recurring equipment failure leading to frequent and prolonged down times.

- Poorly maintained equipment
- Aging equipment

“Failure is the opportunity to begin again more intelligently.”

Henry Ford, (1863 – 1947)

The Corrective Action Process

- Define the nonconformity
- Communicate and assign responsibility
- Correct the immedi
- Investigate
- Identify the initiating cause
- Identify appropriate corrective action
- Implement and monitor for reoccurrence

Root Cause

Define the Nonconformity

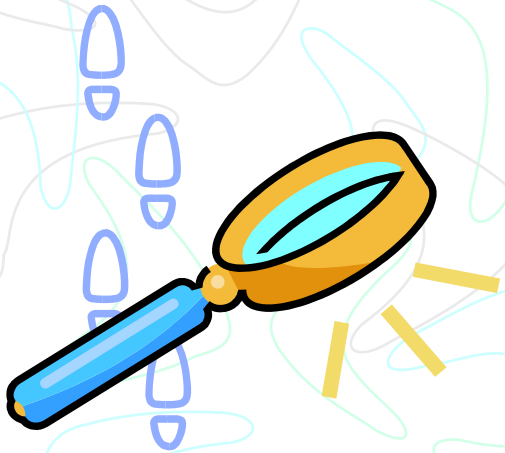
- Document the event
  - Concise
  - Only the facts
  - Don’t point fingers
- Communicate and Assign Responsibility
  - Supervisor
  - Quality Assurance
  - Management

Correct the Immediate Problem

- The immediate correction may include;
  - performing rework.
  - contacting the client.
  - issuing a corrected report.

Investigate

- Use available documentary evidence
  - Maintenance logs
  - Control charts
  - Corrective action logs
  - Customer complaint logs
  - Proficiency test results
  - Training logs
  - Test Reports
  - Etc…



Identify the Root Cause

- Investigate
  - Use available documentary evidence
  - Interview
- Involve the appropriate individuals
- Use available root cause tools

Identify Appropriate Corrective Action

- Brainstorm
  - No bad ideas
  - Evaluate ideas for feasibility
- Document all corrective actions identified during the investigation.
- Select the corrective action that will eliminate or greatly reduce the recurrence of the nonconformity.

Implement Corrective Action

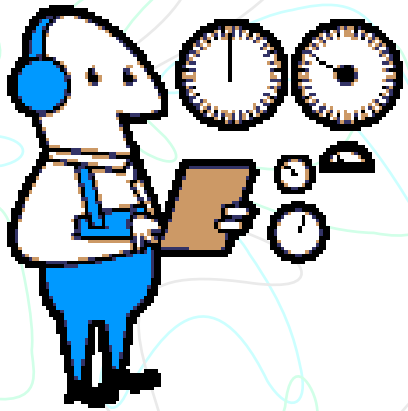
- Create a project plan
  - Assemble ideas into a workable process
  - Determine budget
  - Assign responsibilities
  - Set deadlines

Implement Corrective Action

- Complete projects
  - On time
  - On budget
- Revise documentation (*Policies, SOPs, Forms*)
- Train
- Communicate
- Support

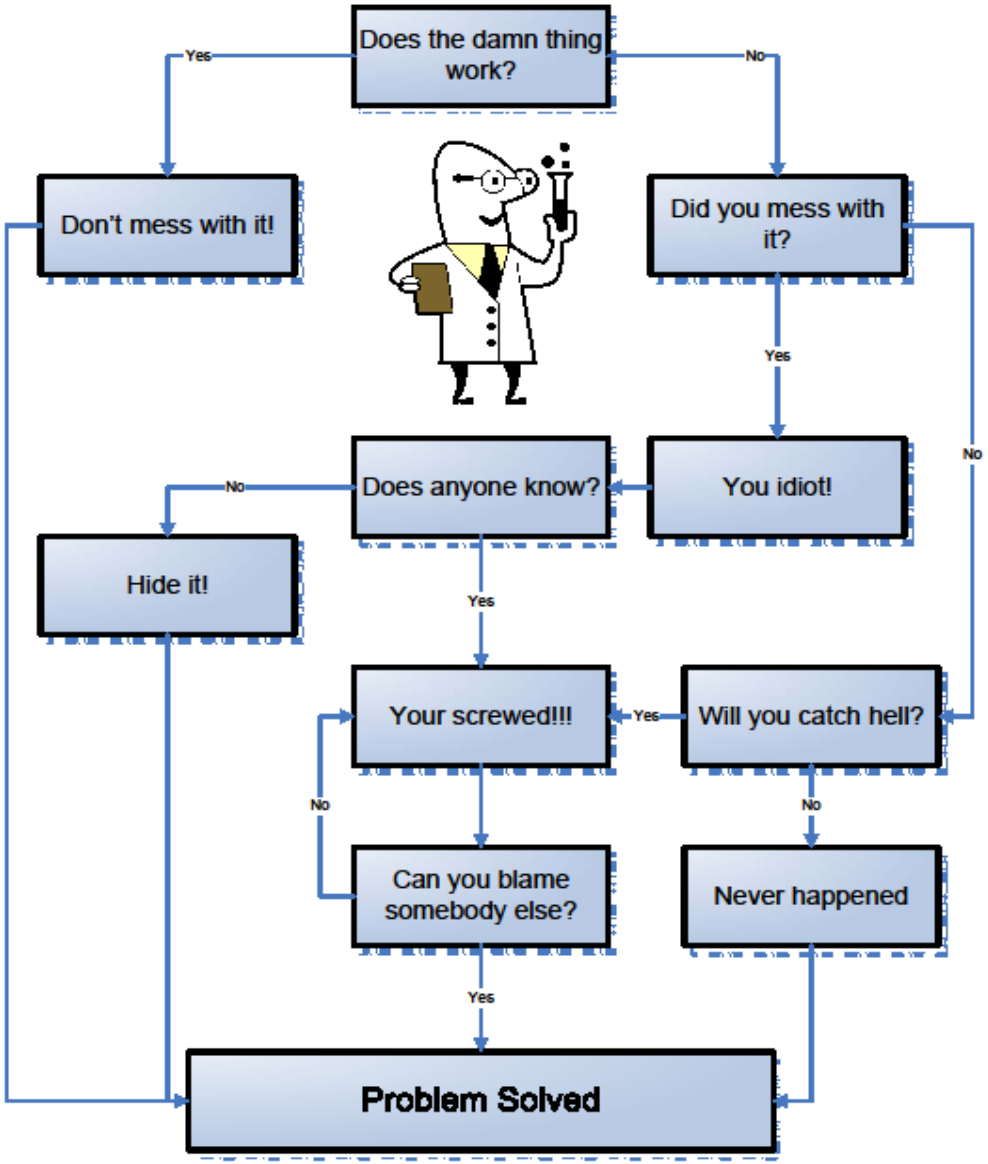
Monitor for Effectiveness

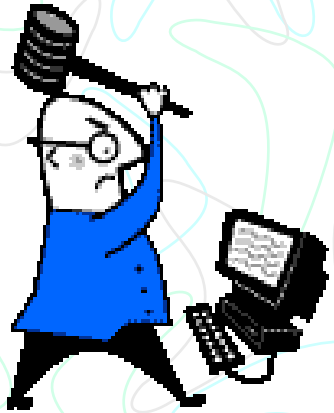
- Different for each corrective action
  - Review for reoccurrence *(fault monitoring)*
    - Ongoing quality control
    - Proficiency testing
    - Internal audits
    - Management reports
    - Etc…



Root Cause Analysis

Root Cause Analysis





Definition

- Root Cause Analysis (RCA):

A technique used to identify the conditions that initiate the occurrence of an undesired activity or state.

US Government Accountability Office (GAO)

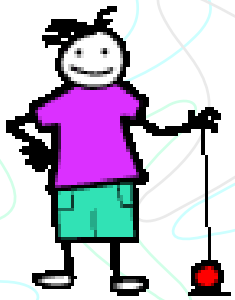
The process of problem solving used to identify the underlying or initiating source of a nonconformance.

American Association of Veterinary Diagnosticians (AAVLD)

“A tragedy of this magnitude has to be somebody's fault, …”

George Wilson, (Character)

Dennis the Menace (1993)



Investigate

- Interview
  - Don’t be a cop
  - No personal agenda
  - Be friendly
  - Explain the process
  - Listen

Examine the Evidence

- Understand how the process is intended to work.
- Evaluate all evidence for nonconformance.
- Involve individuals independent from the process if possible.

Identify Contributing Causes

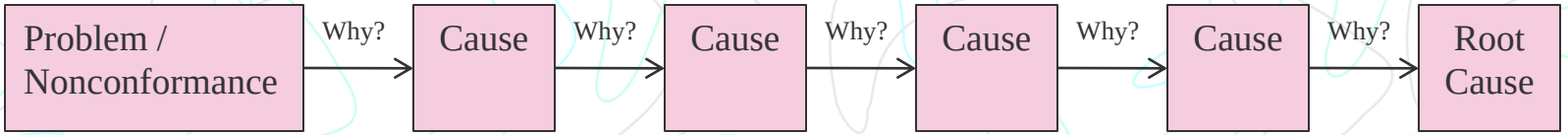
- Use data gathered
  - Documentary evidence
  - Interview
- Don’t stop at;
  - human error
  - insufficient training

Tools

- Cause Analysis
  - 5 Whys
  - Fishbone Diagram (Ishikawa)
  - Fault Tree Analysis
- Risk Assessment
  - Pareto analysis (80/20 rule)
  - Failure mode and effects analysis (FMEA)

5 Whys

Cause and effect



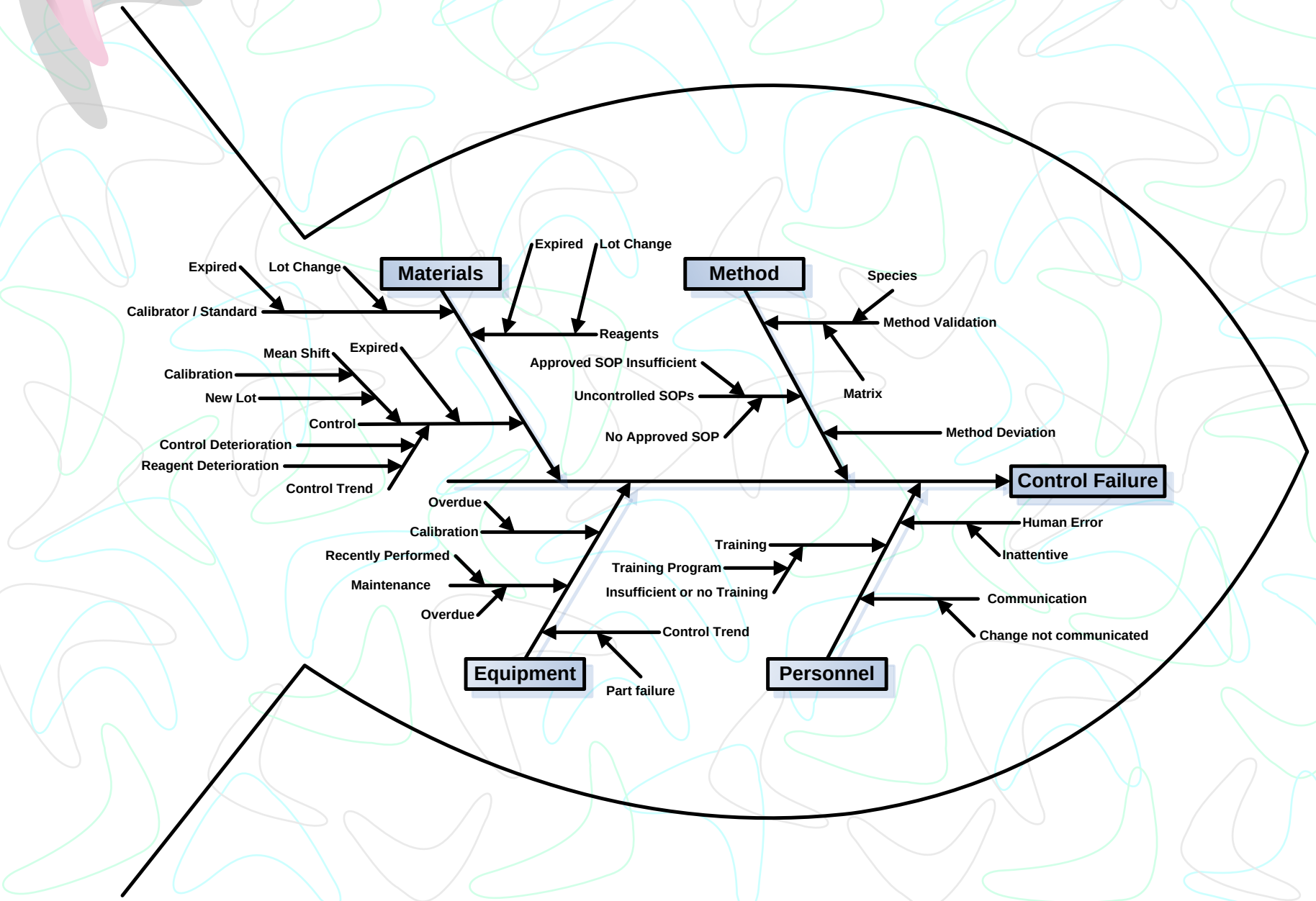
5 Whys

Example:

1. Why won't the car start?
   The engine won't turn over.
2. Why won't the engine turn over?
   The battery is dead.
3. Why is the battery dead?
   The alternator is not functioning.
4. Why is the alternator not functioning?
   The belt is broken.
5. Why is the alternator belt broken?
   The belt was not replaced according to the manufacturer's maintenance schedule.

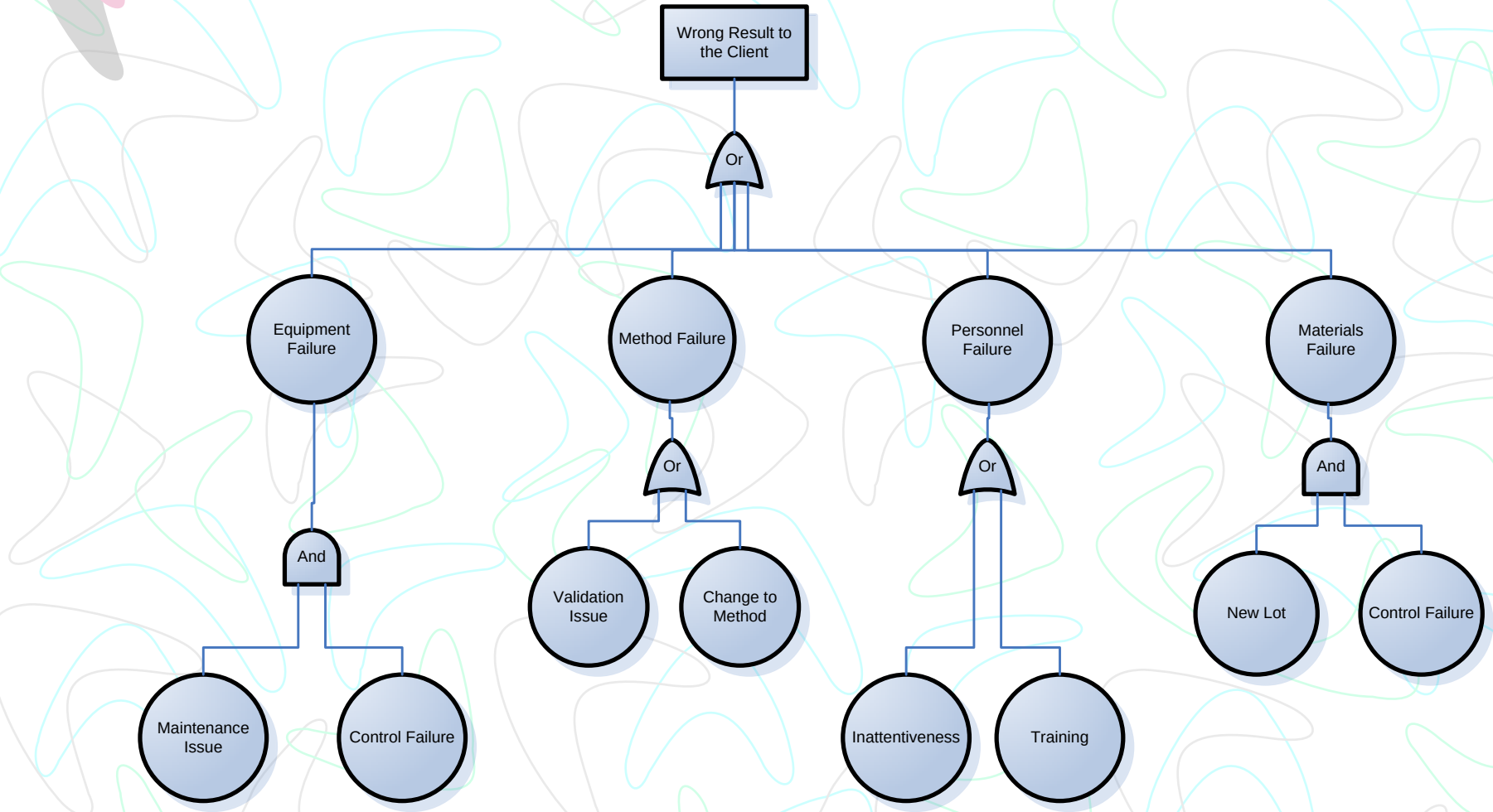
Fishbone Diagram

- The system failure is described in a box to the right of the diagram.
- Add Bones
  - Categories (4 M's)
    - Man Power (Personnel)
    - Machines (Equipment)
    - Materials (Reagents and Supplies)
    - Methods
  - Primary Causes
  - Secondary Causes


Materials
Expired
Lot Change
Calibrator / Standard
Expired
Lot Change
Reagents
Mean Shift
Expired
Calibration
New Lot
Control
Control Deterioration
Reagent Deterioration
Control Trend
Method
Species
Method Validation
Matrix
Approved SOP Insufficient
Uncontrolled SOPs
No Approved SOP
Method Deviation
Control Failure
Overdue
Calibration
Recently Performed
Maintenance
Overdue
Control Trend
Part failure
Equipment
Training
Training Program
Insufficient or no Training
Human Error
Inattentive
Communication
Change not communicated
Personnel

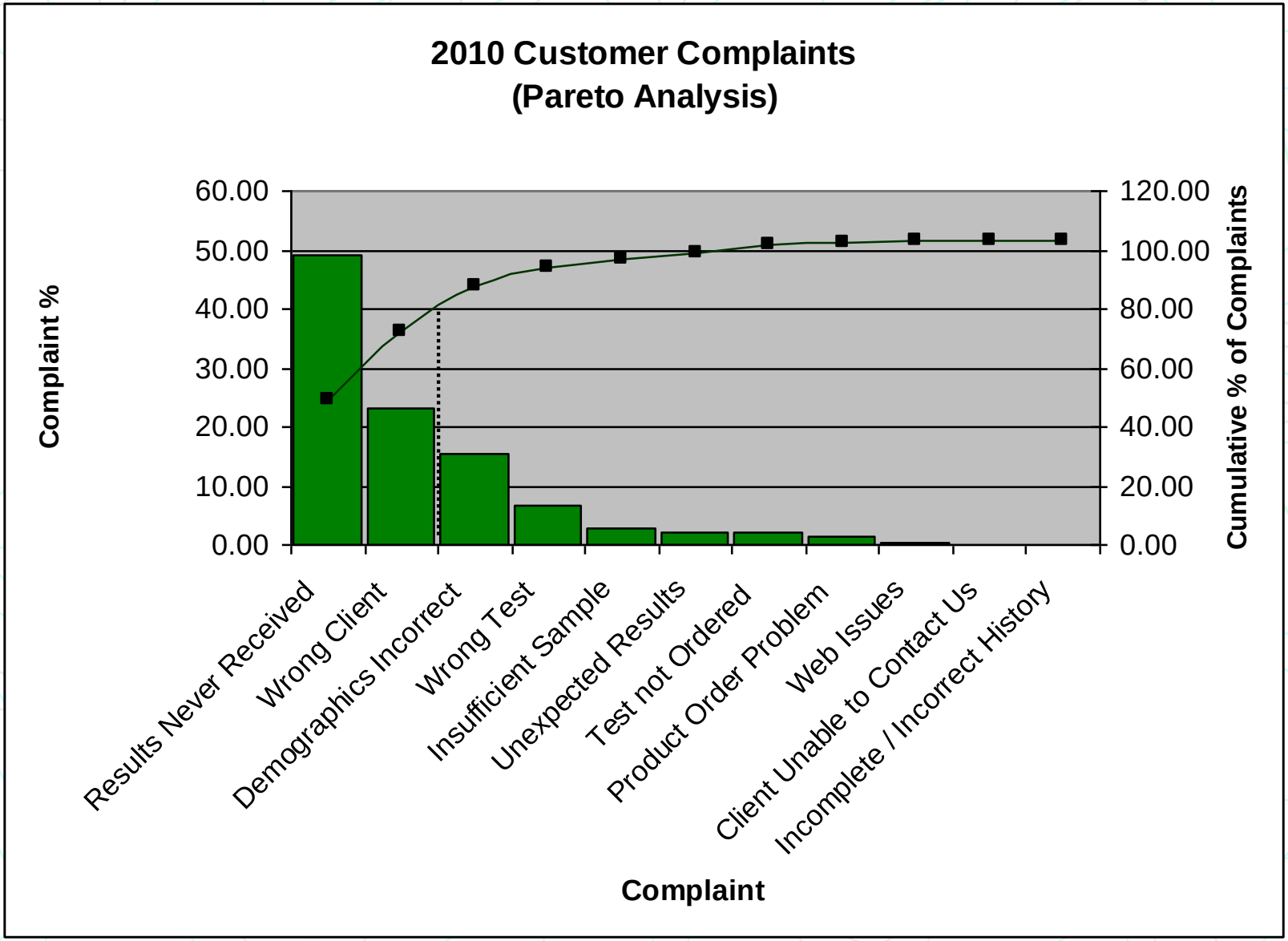
Fault Tree Analysis

- Top down analysis.
- Start with the system failure and work down to the root cause.
- Uses common logic symbols.


Wrong Result to the Client
Or
Equipment Failure
Method Failure
Personnel Failure
Materials Failure
And
Or
Or
And
Maintenance Issue
Control Failure
Validation Issue
Change to Method
Inattentiveness
Training
New Lot
Control Failure

Pareto Analysis

- 80% of the problems are produced by 20% of the possible causes.
- 80% of the customer complaints arise from 20% of our services.


2010 Customer Complaints
(Pareto Analysis)
Complaint %
Cumulative % of Complaints
60.00
50.00
40.00
30.00
20.00
10.00
0.00
120.00
100.00
80.00
60.00
40.00
20.00
0.00
Results Never Received
Wrong Client
Demographics Incorrect
Wrong Test
Insufficient Sample
Unexpected Results
Test not Ordered
Product Order Problem
Web Issues
Client Unable to Contact Us
Incomplete / Incorrect History
Complaint

Failure mode and effects analysis (FMEA)

Evaluate each of the possible system failures utilizing the following.

- Severity of Failure (Rank 1 – 10)
- Probability of Reoccurrence (Rank 1 – 10)
- Ability to Control (Rank 1 – 10)

(Severity) x (Probability) x (Control) = Risk Priority

Failure mode and effects analysis (FMEA)

Failure	Severity	Probability	Control	Risk
Wrong Client Selected at Data Entry	8	3	7	**168**
Client Does not Receive Results, but are on Web View	4	4	7	**112**

“Make failure your teacher not your undertaker.”

Zig Ziglar

Examples:

Example

A client calls and has received results for a BVD by ELISA when he had ordered a BLV by ELISA.

- Correction:
  - A BLV by ELISA was run and reported to the client.
  - The client was credited for the BVD by ELISA that was performed.
- Root Cause:
  - The current submittal form requires the client to write in the test requested.
- Corrective Action:
  - A new submittal form is developed.

Example

A new laboratory employee failed to follow the appropriate communication protocol for a pest of concern.

- Correction:
  - Review the chain of custody policy and procedure with the employee who failed to follow the protocol.
- Root Cause:
  - Insufficient training program for new employees.
- Corrective Action:
  - The Policy and procedure for training new employees are reviewed and revised. The new process is implemented with additional training provided for all employees.

Example

Quality control failed following lamp replacement on the Advia 120 hematology analyzer.

- Correction:
  - Recalibrate analyzer.
  - Rerun controls.
  - Rerun any patient samples.
- Root Cause:
  - Manufacturers guidelines for calibration following lamp replacement were not part of the laboratories maintenance SOP describing lamp replacement.
- Corrective Action:
  - SOP was revised to include calibration language.

Scenario A

Failure:

Incorrect lab results are released to clients.

Evidence:

- It was suspected that two samples had been switched.
- Rerunning the samples confirms the suspicion.
- Further evaluation indicated that the samples had been mislabeled.

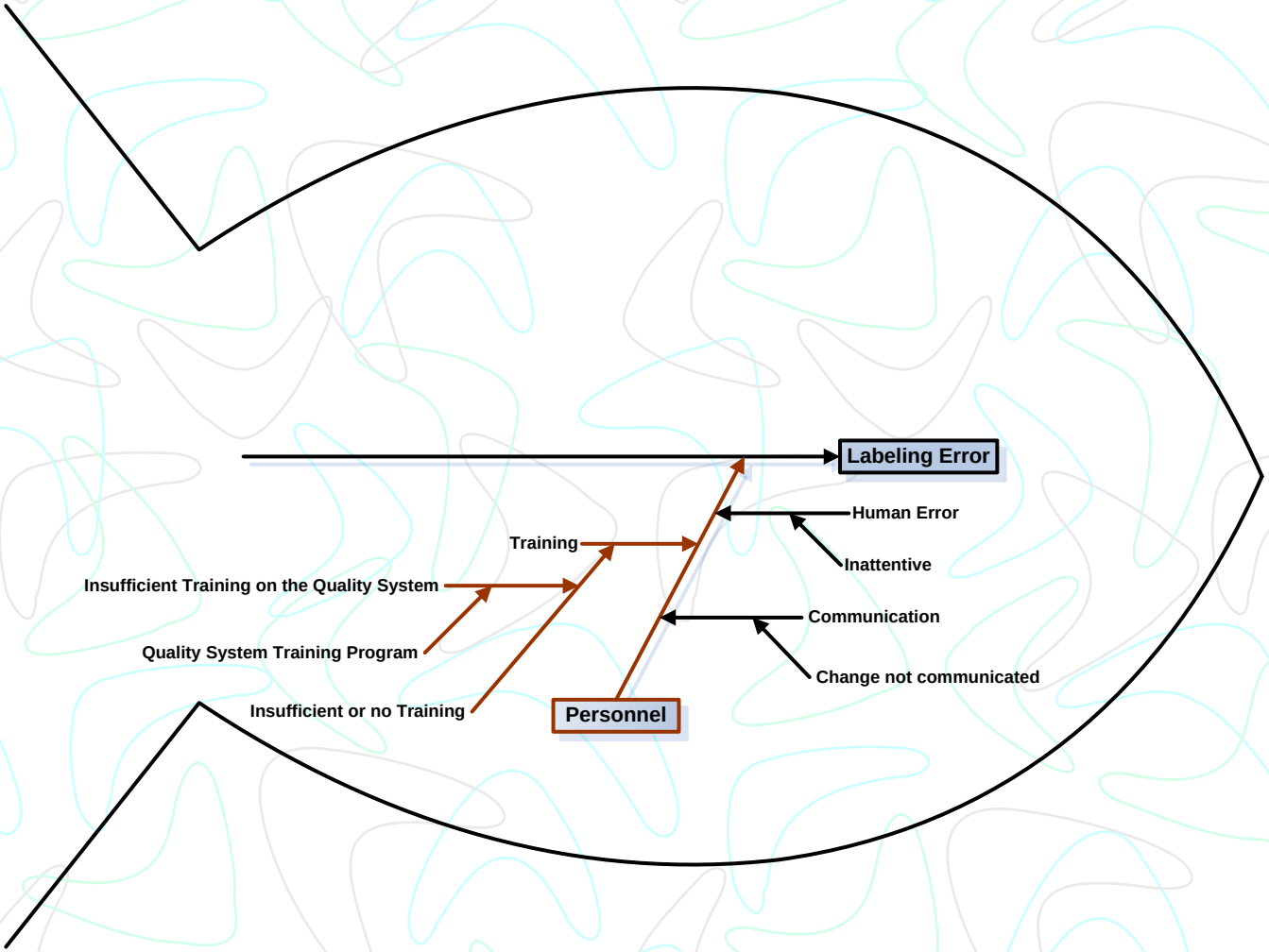
Action taken:

Samples are relabeled and corrected reports are released on the two samples.

Was the Root Cause Identified?

- Over the next two weeks mislabeled samples surface in Virology and Nutrition.
  - *On further evaluation it was determined that in each case:*
    - *The mislabeled tubes were ordered by the same data entry employee.*
    - *The employee had been on the job for only 6 weeks.*
    - *A procedure audit reveals that the employee had deviated significantly from the procedure.*
  - Conclusion:

    Insufficient quality system training program.


Labeling Error
Human Error
Inattentive
Communication
Change not communicated
Personnel
Training
Insufficient Training on the Quality System
Quality System Training Program
Insufficient or no Training

Scenario B

Failure:

A client complains because they have received a 25 page report for the laboratory results on 25 equine samples submitted.

Evidence:

- It was determined that the case was entered as individual animals and not as a multiple animal case.
- No combine report number was entered on any of the encounters on the case.

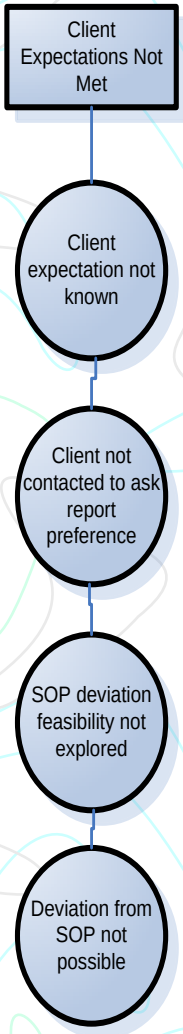
Action taken:

The employee responsible for entering the case was reprimanded. A combine report number was added to the case and a new report was issued.

Was the Root Cause Identified?

- 3 Weeks later a similar case occurred when 22 dogs were submitted.
  - *On further evaluation:*
    - *A procedural audit indicated that the employee performed to expectations.*
    - *The multiple animal data entry procedure clearly states that canine and equine submissions are to be entered as individual animals.*
  - Conclusion:

    Client expectations were not met.


Client Expectations Not Met
Client expectation not known
Client not contacted to ask report preference
SOP deviation feasibility not explored
Deviation from SOP not possible

Scenario C

Failure:

A client complains because they have not received test results for the BLV ELISA that was submitted two weeks ago.

Evidence:

- It was determined that reagent was not available and was on order and would arrive in two days time.
- An apology was issued to the client and was told that they would have results by the end of the week.

Action taken:

A daily manual inventory was instituted to evaluate critical reagent levels.

Was the Root Cause Identified?

- Over the next 3 months Virology places 4 additional orders for BLV ELISA on top of the existing standing order. Finally a notice arrived from the manufacturer recalling the current lot of BLV ELISA kits.
  - *On further evaluation:*
    - *It was determined that there was a significant increase in BLV reruns due to control failure with this lot of kits.*
    - *The trend had been difficult to recognize because the control values were filed with the patient results.*
  - Conclusion:

    Control values were not being logged in a manner that was conducive to review for trends or failure rates.

1. Why were the clients results delayed?

   There was no reagent to run the assay.

2. Why was there no reagent?

   Reagent was being utilized at an increased rate..

3. Why was the reagent being used at an increased rate?

   Control failure was causing rerun of patient samples.

4. Why were the controls failing?

   Inconsistent reagent lot.

5. Why did we continue to use the inconsistent reagent?

   A process was not in place to properly identify control trends.

Scenario D

Failure:

The technologist reports to the supervisor that they are unable to report serum albumin values due to control failure.

Evidence:

- Albumin controls have failed on both low and high levels.
- A repeat of the controls has also failed.
- Controls run after a recalibration of albumin have also failed.

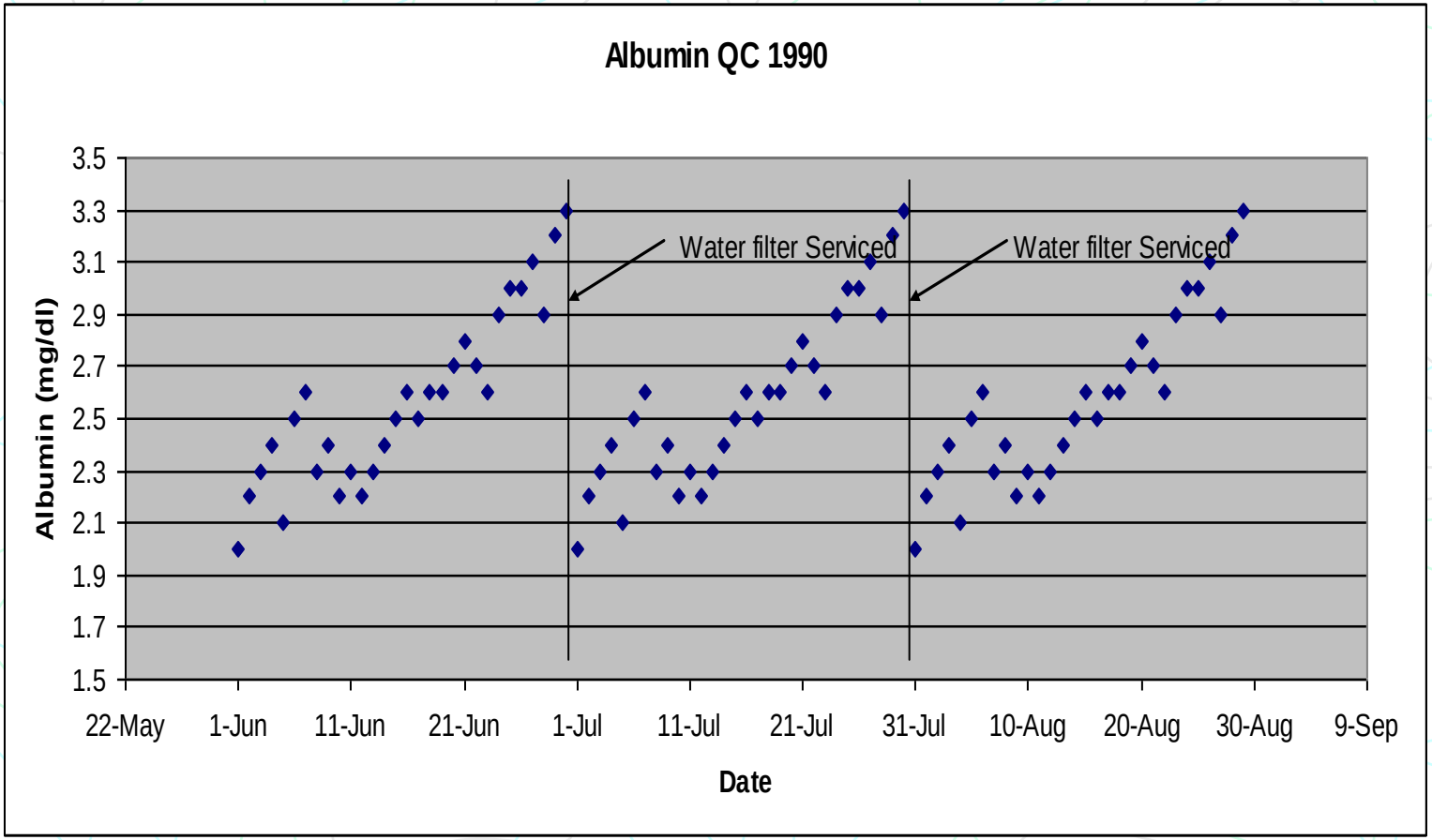
Action taken:

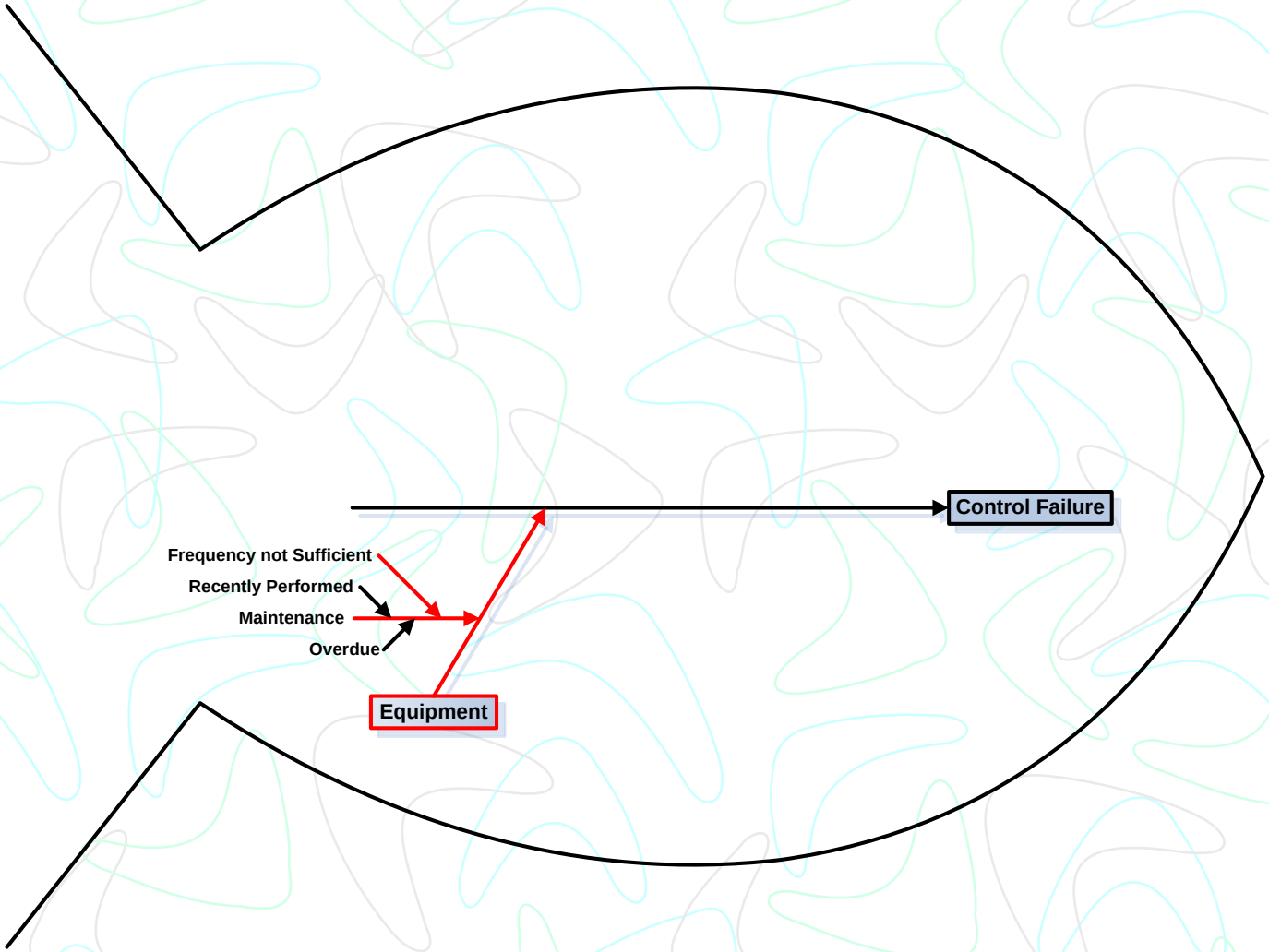
The following steps are taken:

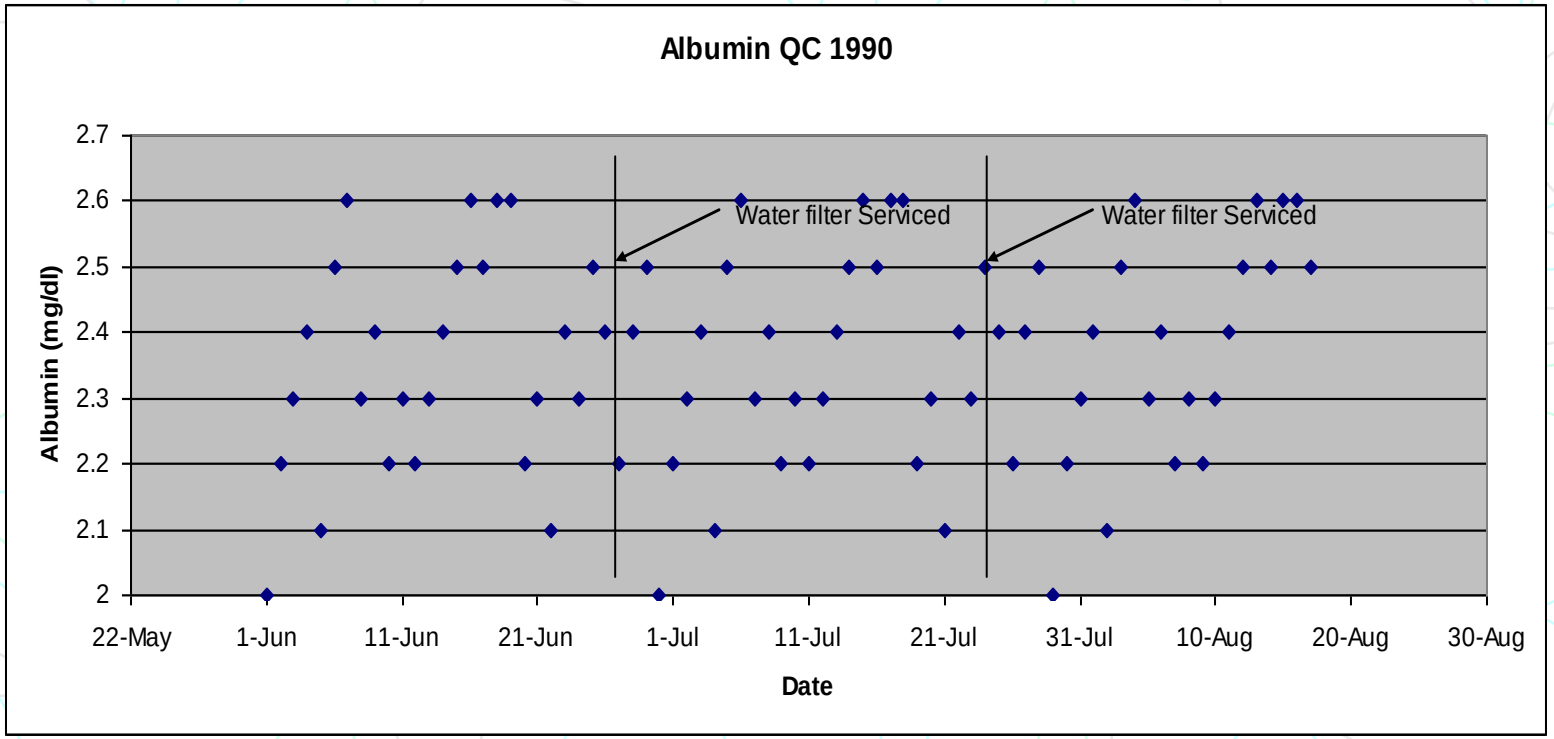
- New reagent
- New lot of reagent
- New controls
- Controls finally are within limits.
- The root cause is determined to be control deterioration.

Was the Root Cause Identified?

- 1 Month later albumins fail in a similar manner. Even after making new controls the technologist finds that the run of albumins fail.
  - *On further evaluation:*
    - *Control charts for the past 6 months are evaluated in conjunction with maintenance records.*
    - *The trend is that just before the water filtration system is serviced, albumin control values trend high.*
    - *During the previous months problem with albumin, it was observed that the water filtration system was serviced.*
  - Conclusion:
    - *Routine maintenance frequency on the water filtration system was not sufficient*


Albumin QC 1990
Albumin (mg/dl)
3.5
3.3
3.1
2.9
2.7
2.5
2.3
2.1
1.9
1.7
1.5
Water filter Serviced
Water filter Serviced
22-May
1-Jun
11-Jun
21-Jun
1-Jul
11-Jul
21-Jul
31-Jul
10-Aug
20-Aug
30-Aug
9-Sep
Date


Control Failure
Frequency not Sufficient
Recently Performed
Maintenance
Overdue
Equipment


Albumin QC 1990
Albumin (mg/dl)
2.7
2.6
2.5
2.4
2.3
2.2
2.1
2
Water filter Serviced
Water filter Serviced
22-May
1-Jun
11-Jun
21-Jun
1-Jul
11-Jul
21-Jul
31-Jul
10-Aug
20-Aug
30-Aug
Date

Key Things to Remember

- It’s the process not the people.
- Corrective actions are part of continual process improvement.
- Good record keeping makes root cause analysis easier.
- Involve management.

“Be a yardstick of quality. Some people aren't used to an environment where excellence is expected.”

Acknowledgements

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