

MODULE 6

Reporting the Audit

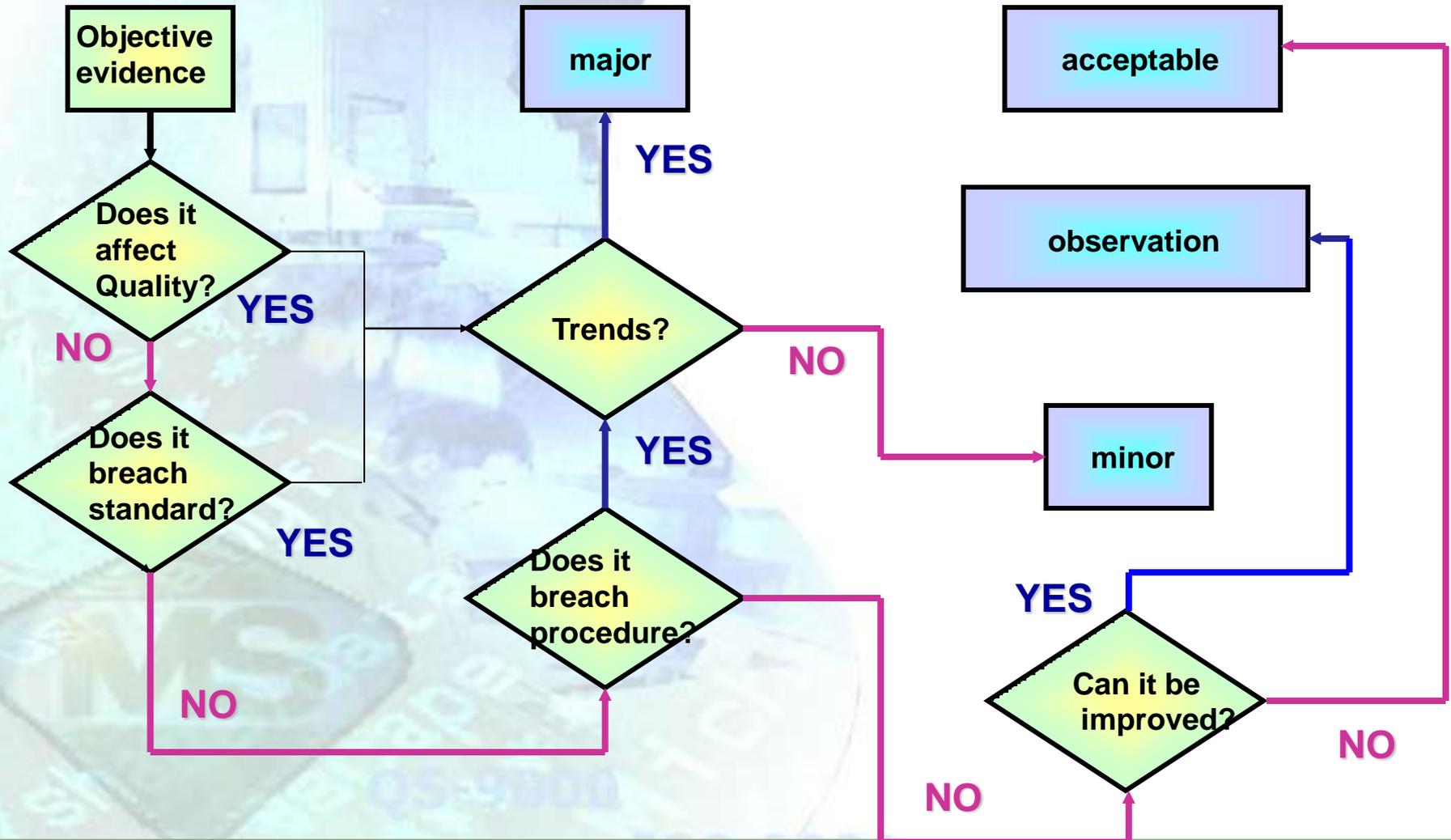


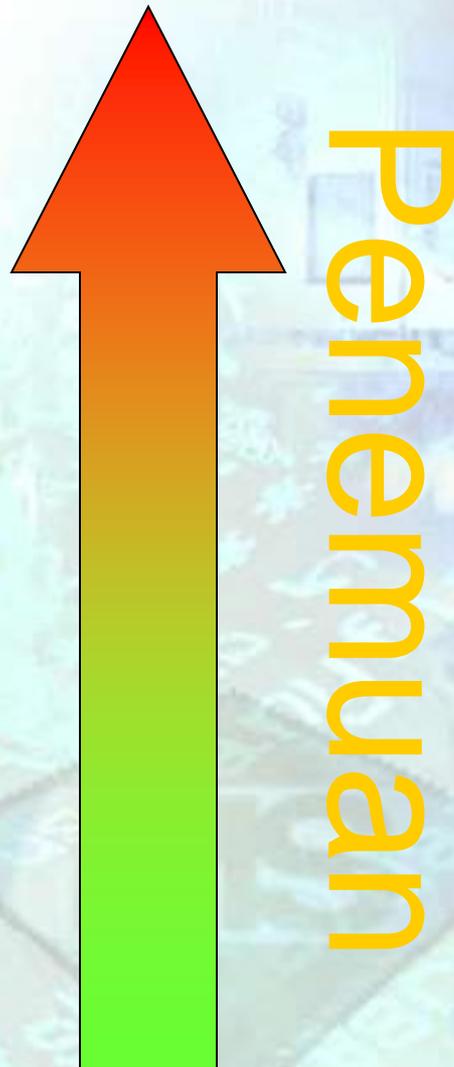
What is report writing

- Audit report is the final product
- The evidence of the audit was conducted
- Must be completely factual
- Tone must be courteous and professional
- Should be verifiable (track down the evidence)



EVALUATION FLOW CHART





Sekiranya penemuan
audit tidak mematuhi
keperluan :

Ketidakpatuhan



Kecil - tidak memberi kesan secara langsung kepada kualiti / pelanggan, kes terpencil.

Besar - secara langsung memberi kesan kepada pelanggan / kualiti.

- kes sering terjadi.

Audit Findings

Audit evidence should be evaluated against audit criteria to generate audit findings. Audit findings can indicate either:

Conformances



Non Conformances

Observations

*Opportunity for further improvement

Nonconformance Exists Because...

- The system DOES NOT COMPLY with the standard, procedure or other requirements.
- Performance DOES NOT COMPLY with the system.
- Performance is NOT EFFECTIVE.

Minor Nonconformity

Single incident observed that a requirement of procedure or system or standard not being conform to. It may be one of the followings :-

- A failure in some part of the organization's document QMS relative to ISO 17025
- A single observed lapse in fulfilling one of a company's QMS.



Major Nonconformity

- The absence of or total breakdown of a system to meet a requirement.
- A noncompliance that judgment and experience indicate is likely either to result in the failure of the QMS or to materially reduce its ability to assure controlled processes and products.
- A number of minor nonconformities against one requirement can represent a total breakdown of the system.



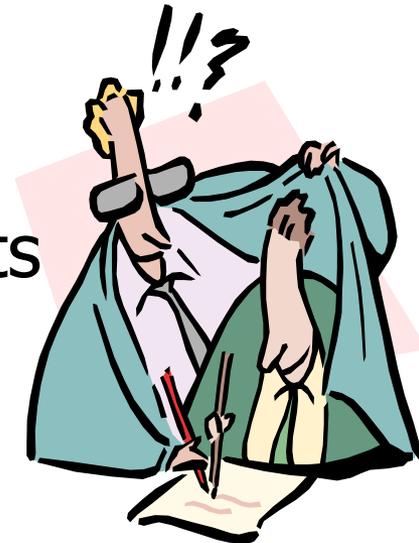
Area for Improvement

- An observed situation where there was not enough objective evidence to classify the situation as nonconformance.
- An observed situation which is NOT a major or minor nonconformity, but where results achieved, based upon the auditor's judgement and experience in that commodity, are not optimal.
- These opportunities shall be recorded in the final audit report for benefit of the laboratory.
- In support of continuous improvement, the auditor should identify quality system strengths, weaknesses and shall record opportunities for improvement.



EXAMPLE OF MINOR NONCONFORMANCE

- Isolated examples of deficient record keeping on Contract Reviews.
- Isolated examples of instruments or test equipment not maintained as scheduled.
- Isolated examples of obsolete documents retained in quality manual, procedures, manual or work instruction.
- Isolated examples of data in worksheets unchecked.



EXAMPLE OF MAJOR NONCONFORMANCE

- Management review was not conducted at all for the last one year.
- No internal audit carried out within one year cycle.
- No evidence of corrective action taken to all complaints received from customer for the last one year.
- Equipment not calibrated and lead to invalid test results.



NCR Statement

- Objective Evidence
 - Something you found and confirmed by authorized personnel
 - Be specific, where, what name, what number
 - Make it retrievable
 - Correct - check your facts
- Nonconformance - Why a nonconformance
 - Deviation against requirements
 - Deviation against system
- Requirement - cite the specific requirements
 - Reference Standard, Auditee QMS, Management requirement, Customer contract, Gov. regulations, codes of practice.

NCR statement

"Should"



"Actual"

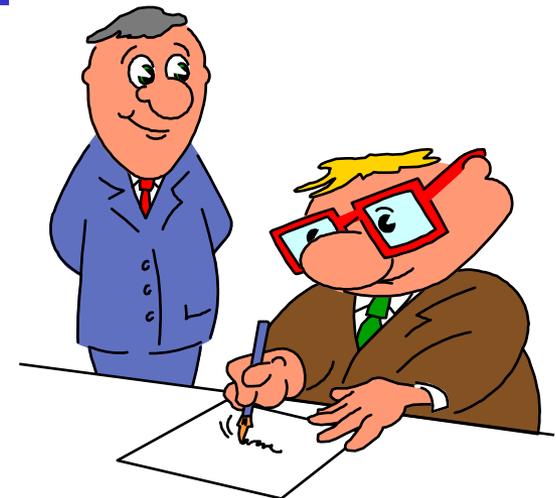
Requirement

Statement (links the two)

Evidence

How to start writing

- **It was found that.....**
- **It was noted that.....**
- **It was observed that**
- **There was no evidence that.....**
- **During the audit**



Non Conformance Statements 1

4.3 Control of Documents

 It was found that the purchasing forms from January to April (SQAS1) used is different from that in the purchasing procedure PRO/PUR/03 Issue 1, Rev 2.

Non Conformance Statements 2

4.12 Internal Audit



Procedure *QP 17* requires that the company to carry out internal audit at least once a year. It was found that three rounds of internal audits had been carried out, but the company did not audit the following elements: 4.8 Complaints, 4.12 Internal audit and 4.15 Management Review to ensure these areas are complying.

Non Conformance Statements 3

5.2 Personnel



At the time of the audit, there was no evidence to show that identification of training needs for all levels of personnel by individual department heads through annual assessment has been carried out as required by procedure *QP 18*. Consequently, no training plan for the year 2009 to show that training has been carried out on a systematic basis

AUDIT REPORT



Given at the end of an internal audit.



Summarize the audit team's *findings* and *conclusions* as to the *states* and *efficiency* of the organization management policy, system, procedures and instruction requirement.

Reporting Internal Audit Results

-  **Report significant observation and conclusion.**
-  **Distinguish between chronic and isolated incidents.**
-  **Trends of performance of the quality system.**
-  **Reveal any repetitive problem areas/departments**
-  **Reveal any repetitive findings.**
-  **Techniques used for prioritizing significant observation and conclusion.**
-  **Provides recommendations on how managers can improve performance.**
-  **Tells the managers something useful that they don't know.**

A Balanced Report

-  A statement about the compliance to the quality system.
-  A statement about any particular strong point worth of comment.
-  A statement about any area that requires strengthening to assure the organization will continue meeting them.

(Note: Report needs to be written in clear, concise and unambiguous language).

CLOSING MEETING



Is a verbal audit reporting done at the end of the audit session



The objective is to present the results of the audit & to agree on the corrective actions if they have not been agreed earlier

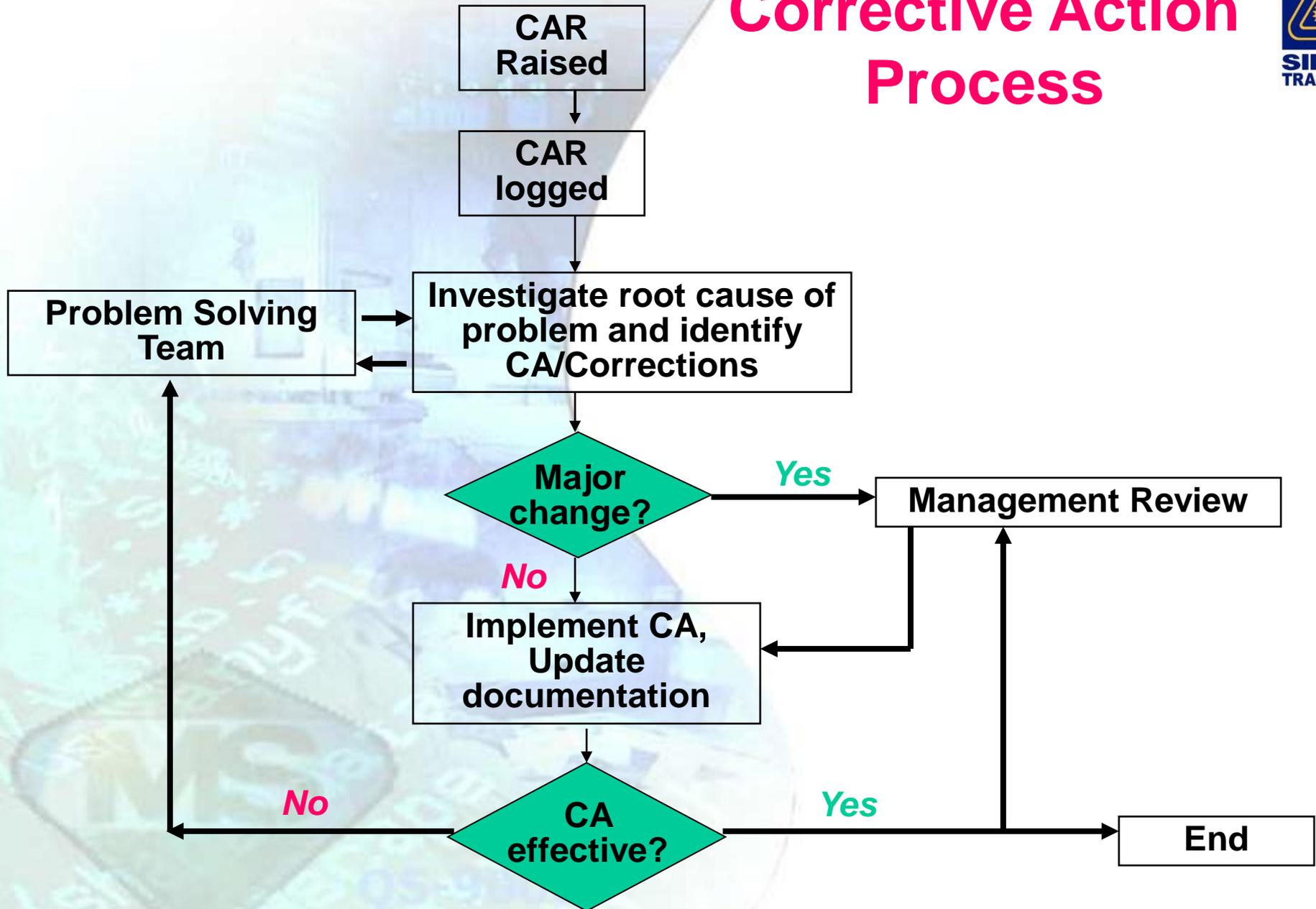
REPORTING THE AUDIT



During the closing meeting, the Lead Auditor will:

- Explain on how the audit is done.
- Give overall audit team's view of the Department's quality system.
- Indicate the strong points found by the audit team.
- Present non conformance & the agreed actions including their corrective actions.
- Recommend suggestions for improvement to the management.
- Thank auditee and the management for their cooperation.

Corrective Action Process



Correction VS. Corrective Action

- **“Correction”** refers the action to eliminate a detected nonconformity such as repair, rework, scrap or adjustment.
- **“Corrective action”** relates to the action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence.

FOLLOW-UP ON CORRECTIVE ACTION

-  **To ensure that all items agreed in the report is effectively implemented.**
-  **Revisit by the auditor to the area of non conformance to establish the implementation of corrective actions.**
-  **Either close the non conformance if deficiencies are corrected or keep the non conformance open if found otherwise.**

CLOSEOUT

- **Accept the response if there is a reasonable chance of success**
- **Request the changed or revised documents where promised document change is involved.**
- **Perform brief follow-up visit to personally verify the implementation of the promised corrective action**

END OF SESSION 6:
REPORTING THE AUDIT

THANK YOU VERY MUCH