L11 Non-conformance management

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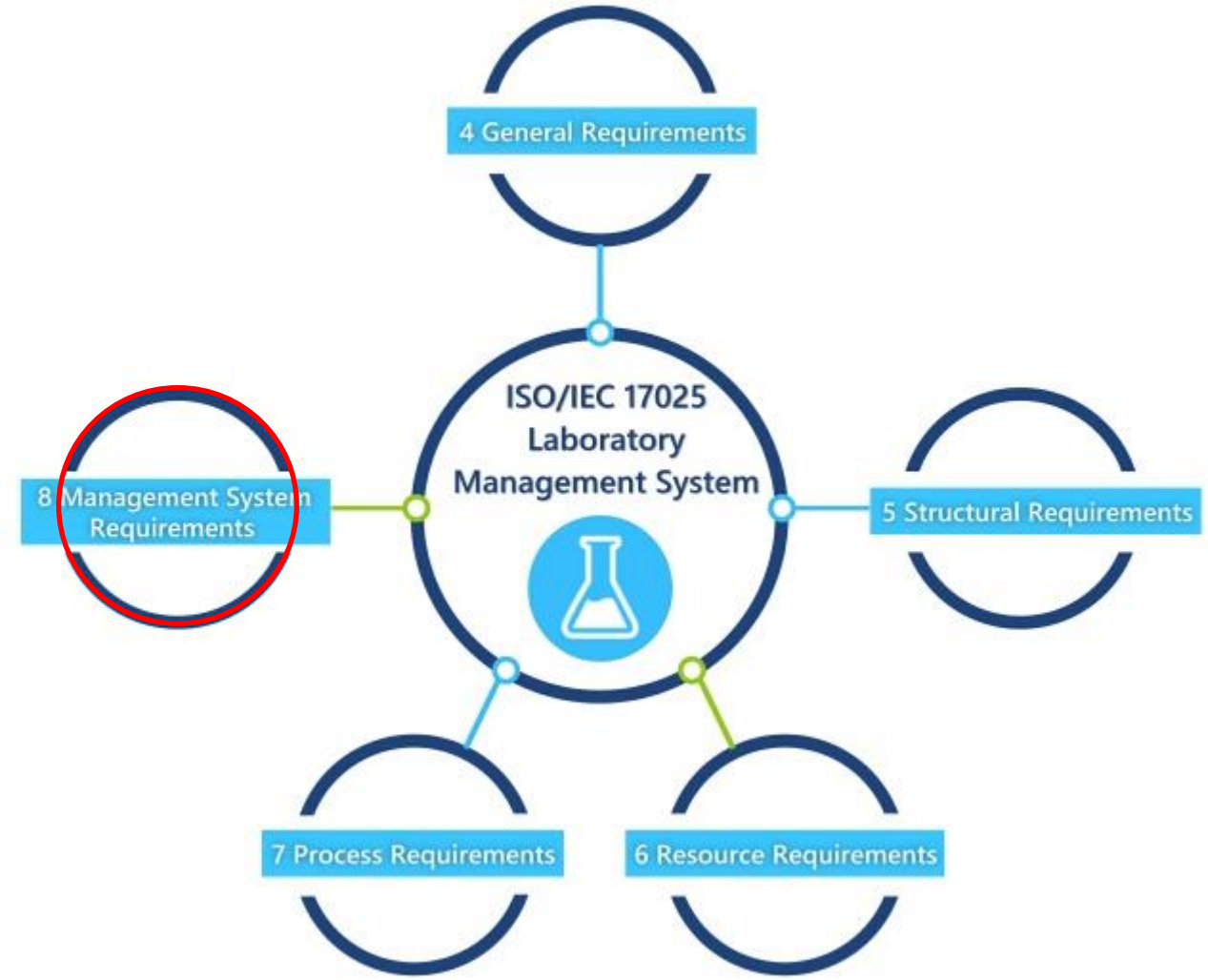
International Atomic Energy Agency

8 Management System Requirements



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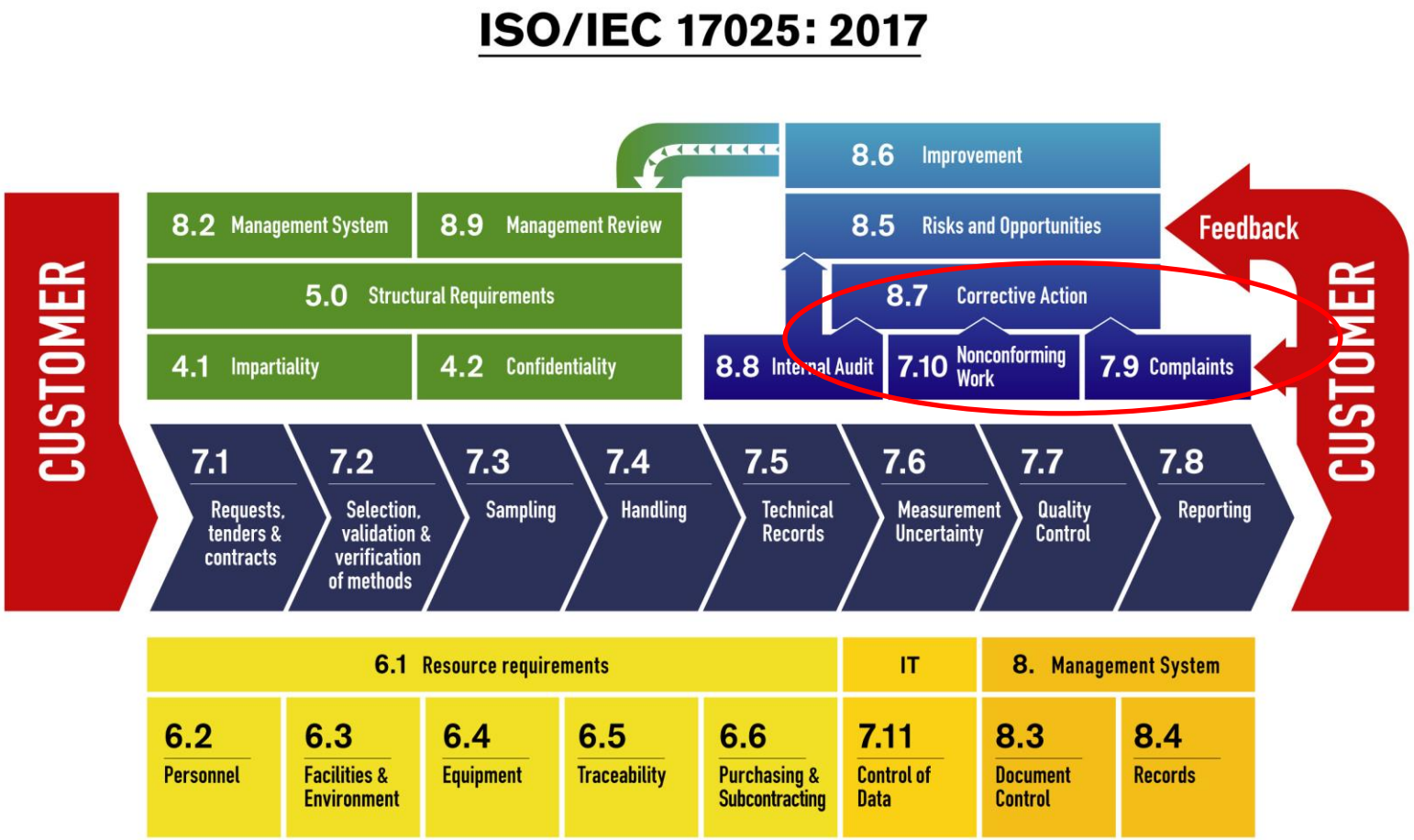
Structure


ISO/IEC 17025: 2017
8.6 Improvement
8.2 Management System
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8.5 Risks and Opportunities
Feedback
5.0 Structural Requirements
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CUSTOMER
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CUSTOMER
7.1 Requests, tenders & contracts
7.2 Selection, validation & verification of methods
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IT
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7.11 Control of Data
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8.4 Records

Objectives

In this lecture we will discuss :

- Preventing nonconformities
- Finding nonconformities
- Correcting nonconformities
- Dealing with customer complaints & feedback

- This lecture applies to all nonconformities found within the organization referring to managerial or technical issues or found outside of the organization through customer complaints & feedback

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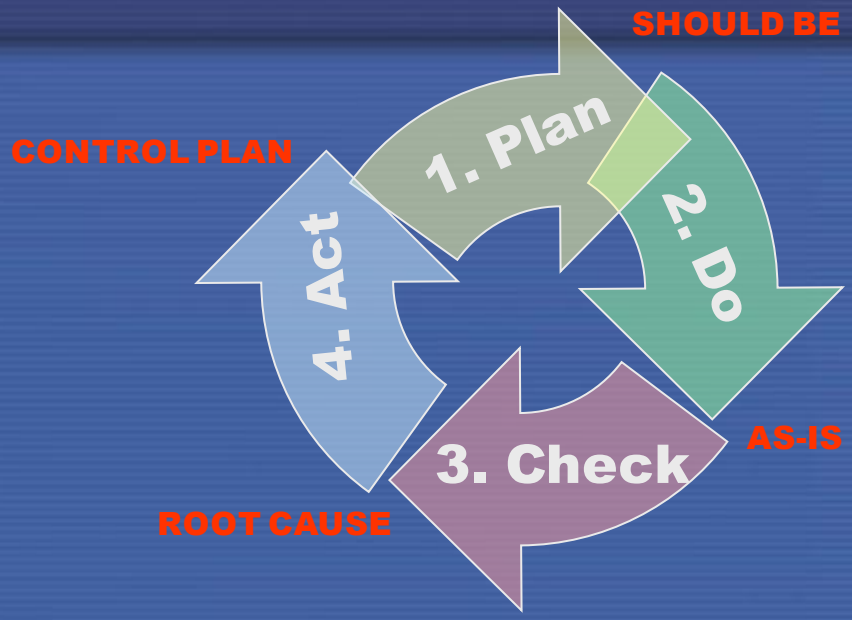
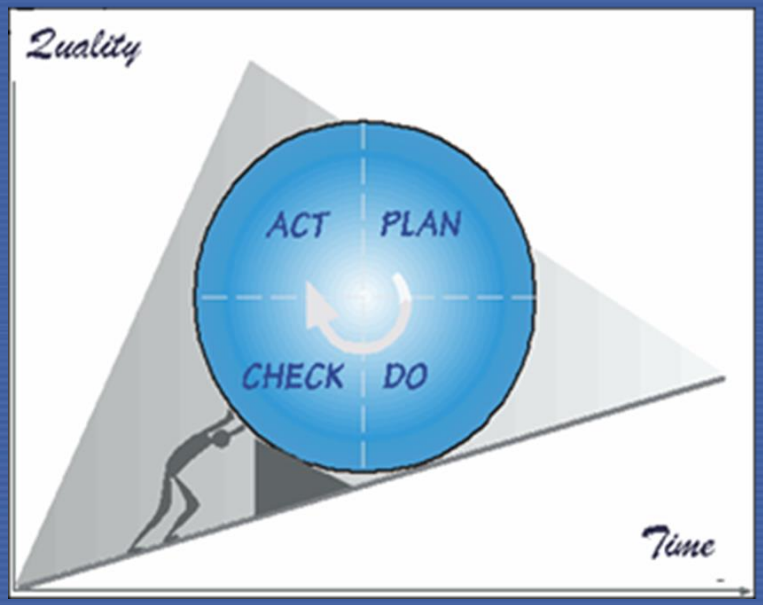
Non conformance management is based upon the the PDCA Cycle .



1. **Plan** what you will do
2. **Do** what you planned
3. **Check** what you actually accomplished
4. **Act** on the gap between the plan and the accomplishment



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Definition: i. A. non-conformity

A nonconformity is any failure to meet a requirement.

- A requirement can be that of a customer's, statutory or regulatory body, ISO/IEC 17025 or your organization's (i.e. failure to follow a procedure).
- There are two types of non-conformaties, major and minor. A major nonconformance is classified when there is an absence or a complete breakdown in your QMS, preventing you from meeting requirements with major impact on the results given to customers. A minor nonconformance is defined as an incident that does not meet requirements, but that does not have any major consequences. This means, that the nonconformance will not result in a failure or majorly weaken your QMS.

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Nonconformities ??

For radiation protection services this could include:

- incorrectly entered raw data;
- results arrived at by applying incorrect algorithms;
- incorrect calibration data or factors;
- measurement results produced using instruments out of their application range;
- calibration data arrived at by using incorrect irradiation conditions; etc.

Definition ii. A correction

Action taken to eliminate a detected nonconformity

A correction may involve repair, rework, regrade

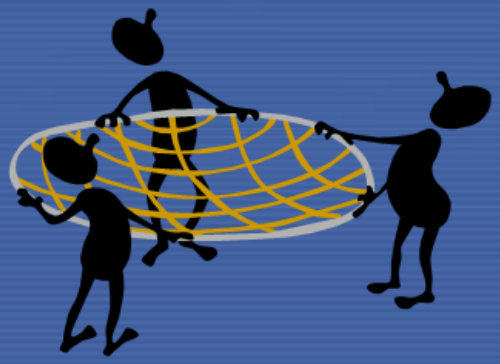
= remedial action

Definition ii. A corrective action

Action taken to eliminate the cause of a detected non-conformity or other undesirable situation.

Corrective action is taken to prevent recurrence.

There is a distinction between correction and corrective action. A correction may or may not be made in conjunction with a corrective action.



Non conformance management

- When a nonconformity occurs, you must react to it by either controlling and correcting it or dealing with the consequences. Then you must determine the root cause(s), evaluate the need to eliminate the cause(s) so the nonconformity does not reoccur and implement any corrective action necessary. Remember, a corrective action is defined as the action taken to prevent recurrence of a nonconformity and as such works on the root cause of the problem.

Definition iii. A preventive action

Preventive action:

Action taken to eliminate the cause of a potential non-conformity or other undesirable situations.

- Proactive process to identify opportunities for improvement (= prevention of errors) rather than reaction to identification of problems or complaints e.g. a preventive maintenance plan for a reader
- In ISO/IEC 17025:2017 addressed as part of the risk & opportunity paragraph 8.5

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8.6 Improvement

- 8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.
  - NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

- 8.6.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.
  - NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

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Customer Satisfaction Surveys

CUSTOMER-SATISFACTION SURVEYS

1. How would you rate your level of satisfaction with our laboratory's customer service?
   - ❑ Very satisfied—no improvement necessary
   - ❑ Satisfied—needs minor improvement
   - ❑ Dissatisfied—needs a few improvements
   - ❑ Very dissatisfied—needs considerable improvements
2. How would you rate your interactions with our laboratory's employees?
   - ❑ Very satisfied—always friendly and helpful, tend to go the extra mile
   - ❑ Satisfied—mostly friendly and helpful
   - ❑ Dissatisfied—often abrupt and appear unconcerned
   - ❑ Very dissatisfied—unfriendly and unhelpful
3. How would you rate the overall quality of your relationship with our laboratory?
   ❑ Excellent ❑ Good ❑ Fair ❑ Poor
4. Please list one aspect of customer service you wish our laboratory would improve.

Physician-specific questions

1. How would you rate the ease and availability of consultative services offered by our laboratory?
   ❑ Excellent ❑ Good ❑ Fair ❑ Poor
2. How would you rate the quality of interaction you receive during consultations with our laboratory?
   ❑ Excellent ❑ Good ❑ Fair ❑ Poor

Nursing-specific questions

1. Do you receive adequate feedback when there is a problem with a specimen?
   ❑ Yes ❑ No ❑ If no, please explain:
2. Is laboratory staff available and helpful?
   ❑ Yes ❑ No ❑ If no, please explain:

Outreach client-specific questions

1. Please rate your level of agreement with the following statements:

	Strongly Agree	Agree	Disagree	Strongly Disagree
I believe ABC Laboratory values my business.	❑	❑	❑	❑

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8.7 Corrective actions

8.7.1 When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable take action to control and correct it and address the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

- reviewing and analysing the nonconformity;
- determining the causes of the nonconformity;
- determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

8.7 Corrective actions

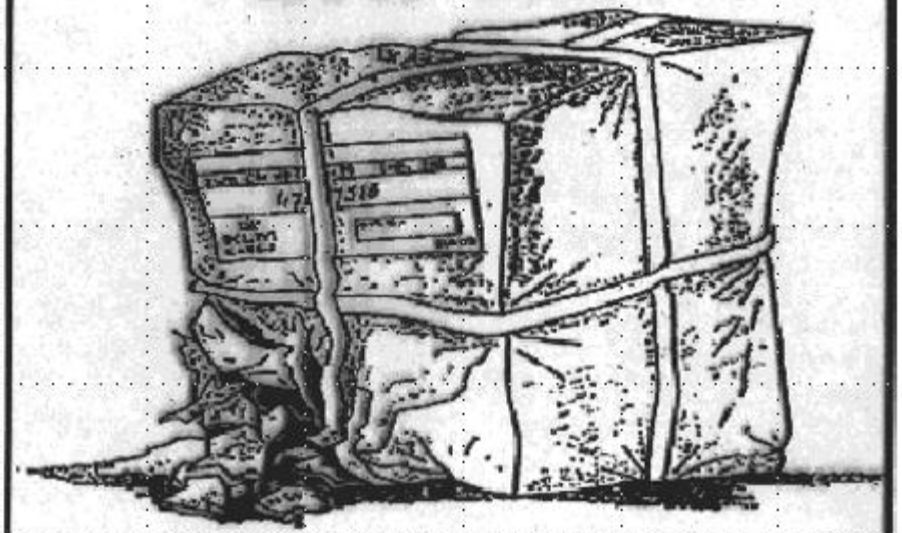
8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

not
WHO
did it...



...but
WHAT
has to be done!

7.10 Nonconforming work

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are defined;

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.10 Nonconforming work

7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

7.9 Complaints

7.9.1 The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

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7.9 Complaints

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

NOTE This can be performed by external personnel.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

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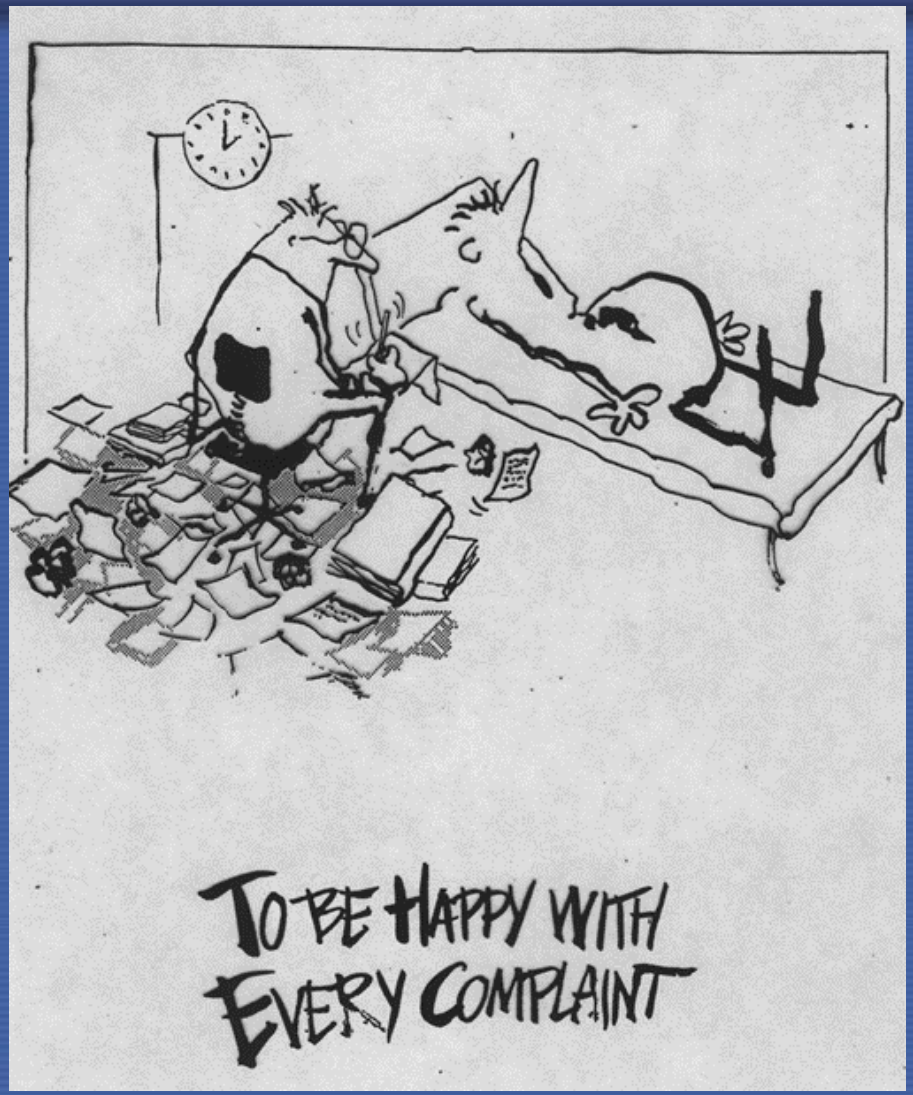

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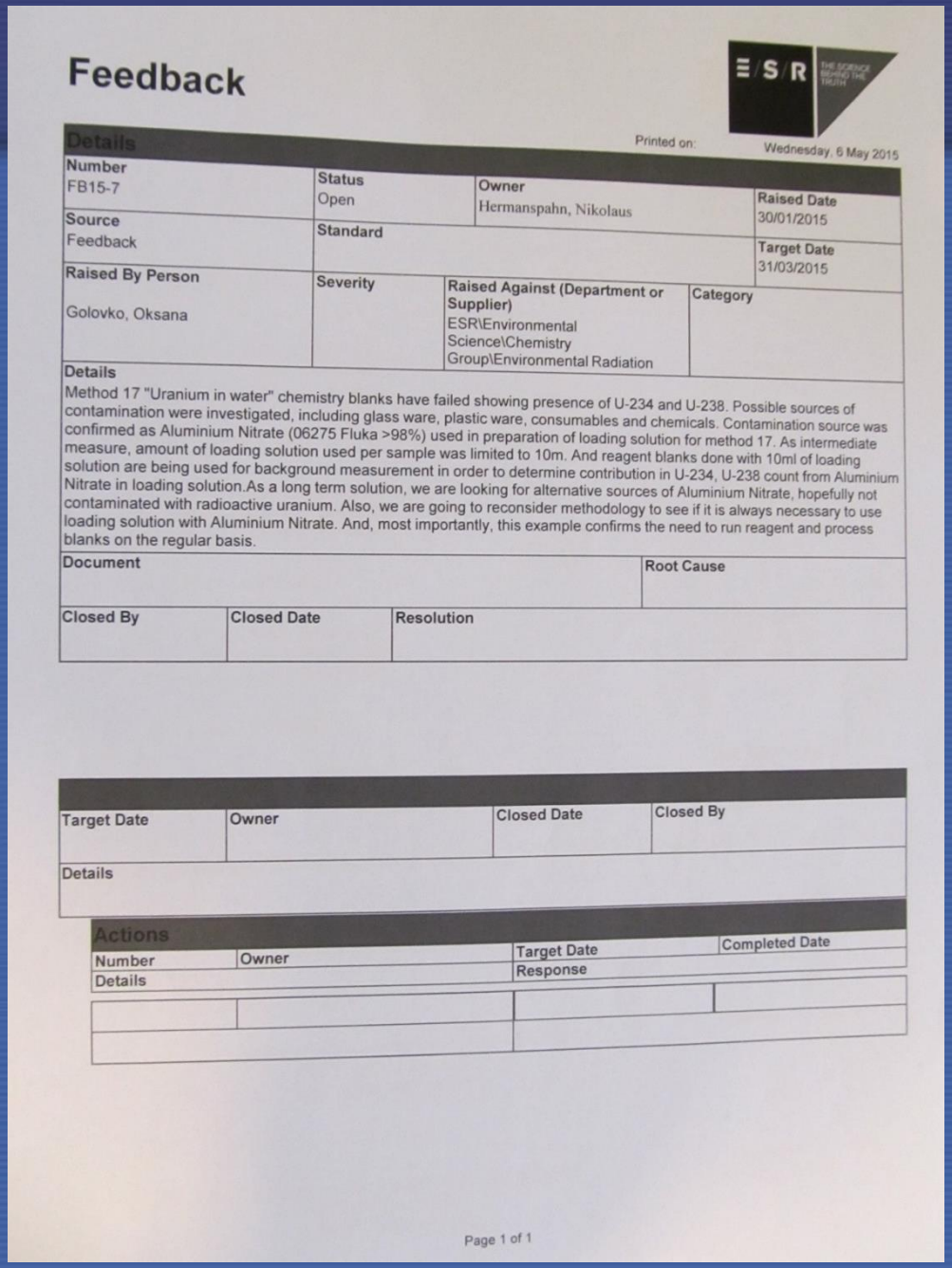
Complaints



Feedback

Printed on: Wednesday, 6 May 2015

Details

Number	Status	Owner	Raised Date
FB15-7	Open	Hermanspahn, Nikolaus	30/01/2015

Source	Standard	Target Date
Feedback		31/03/2015

Raised By Person	Severity	Raised Against (Department or Supplier)	Category
Golovko, Oksana		ESR\Environmental Science\Chemistry Group\Environmental Radiation	

Details

Method 17 "Uranium in water" chemistry blanks have failed showing presence of U-234 and U-238. Possible sources of contamination were investigated, including glass ware, plastic ware, consumables and chemicals. Contamination source was confirmed as Aluminium Nitrate (06275 Fluka >98%) used in preparation of loading solution for method 17. As intermediate measure, amount of loading solution used per sample was limited to 10m. And reagent blanks done with 10ml of loading solution are being used for background measurement in order to determine contribution in U-234, U-238 count from Aluminium Nitrate in loading solution.As a long term solution, we are looking for alternative sources of Aluminium Nitrate, hopefully not contaminated with radioactive uranium. Also, we are going to reconsider methodology to see if it is always necessary to use loading solution with Aluminium Nitrate. And, most importantly, this example confirms the need to run reagent and process blanks on the regular basis.

Document	Root Cause

Closed By	Closed Date	Resolution

Target Date	Owner	Closed Date	Closed By

Details

Actions

Number	Owner	Target Date	Completed Date

Details	Response

Page 1 of 1

The Non-Conformance Report

- A Non-Conformance Report (NCR) is a document that addresses specific deviations or work that fails to meet the quality standard. This document is created to allow the lab to take action to correct the nonconformity and to eliminate the cause. In essence, the report is used as part of a quality control process be detailing the nonconformity, relaying how it occurred, and how to prevent it from occurring again.

Part A: Registration of non-conformance

Requirement or expectation: *SOP GAMMA/01*	Performance or observation *Complaint from customer Food control* *Results are approximately 1000 times too high*
Signature: *Lab Head*	ID: *CMM* Date: *2002-02-17*

Use Part E if more space is required

Part B: Root cause analysis

Investigating team: *Lab Head*		
Findings: *An error in the formula for the calculation of the result in the Excel Spreadsheet lead to an overestimation of 1000.*		
Signature: *Lab Head*	ID: *CMM*	Date: *2002-02-18*

Part C: Correction/Corrective/Preventive action

Correction:	*1. A new corrected report has been sent on 2002-02-18* *2. An analysis of previous measurements shows that no previous measurements have the same error. (2002-02-18)*		
Corrective action:	*1. Adapt the formula in the Excel sheet.*		
Name: *Lab Technician*	*DLa*	Target date: *2002-01-18*	
Closure (Name): *Lab Head*	*CMM*	Date:	*2002-01-19*
Preventive action:			
1. Check the other spreadsheets to check if the same error exists there also.			
Name: *Lab Technician*	*DLa*	Target date: *2002-01-19*	
Closure (Name): *Lab Head*	*CMM*	Date:	*2002-01-19*

Part D: Non-conformance follow-up

The Spreadsheets and all other related Spreadsheets were checked and the error was corrected. The problem should not occur any more.		
Closure (Quality Manager): *QAM*	*PVe*	Date: *2002-03-30*

Laboratory Name Instrument identification code: ***LAB-XCF-***

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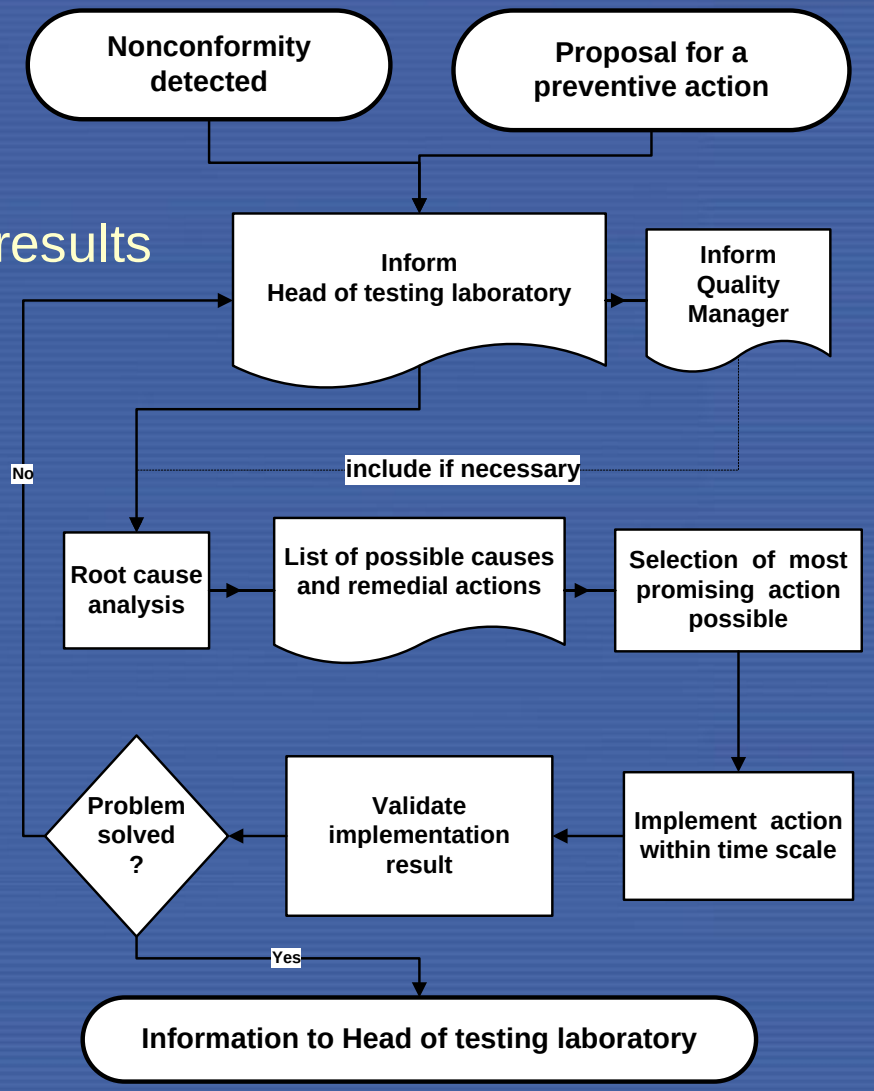
Corrective action

- Determine the root cause(s)
- Determine the impact, also on previous results
- Use graded approach (minor; major; repetitive, …)
- Define & Implement proposed solution: correction & corrective actions
- Monitor effectiveness of solution.
- Update risk register, if needed
- Document the results.



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