

# Quality management. The Engineering perspective

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# ISO 15189 of 2012

**5.2 Accommodation and environmental conditions**

**5.3 Laboratory equipment, reagents, and consumables**

## 5.2 Accommodation and environmental conditions

- **POWER SUPPLY and QUALITY**
- **WATER SUPPLY and QUALITY**
- **ERGONOMICS**
- **ENVIRONMENTAL CONDITIONS**

# POWER SUPPLY and QUALITY

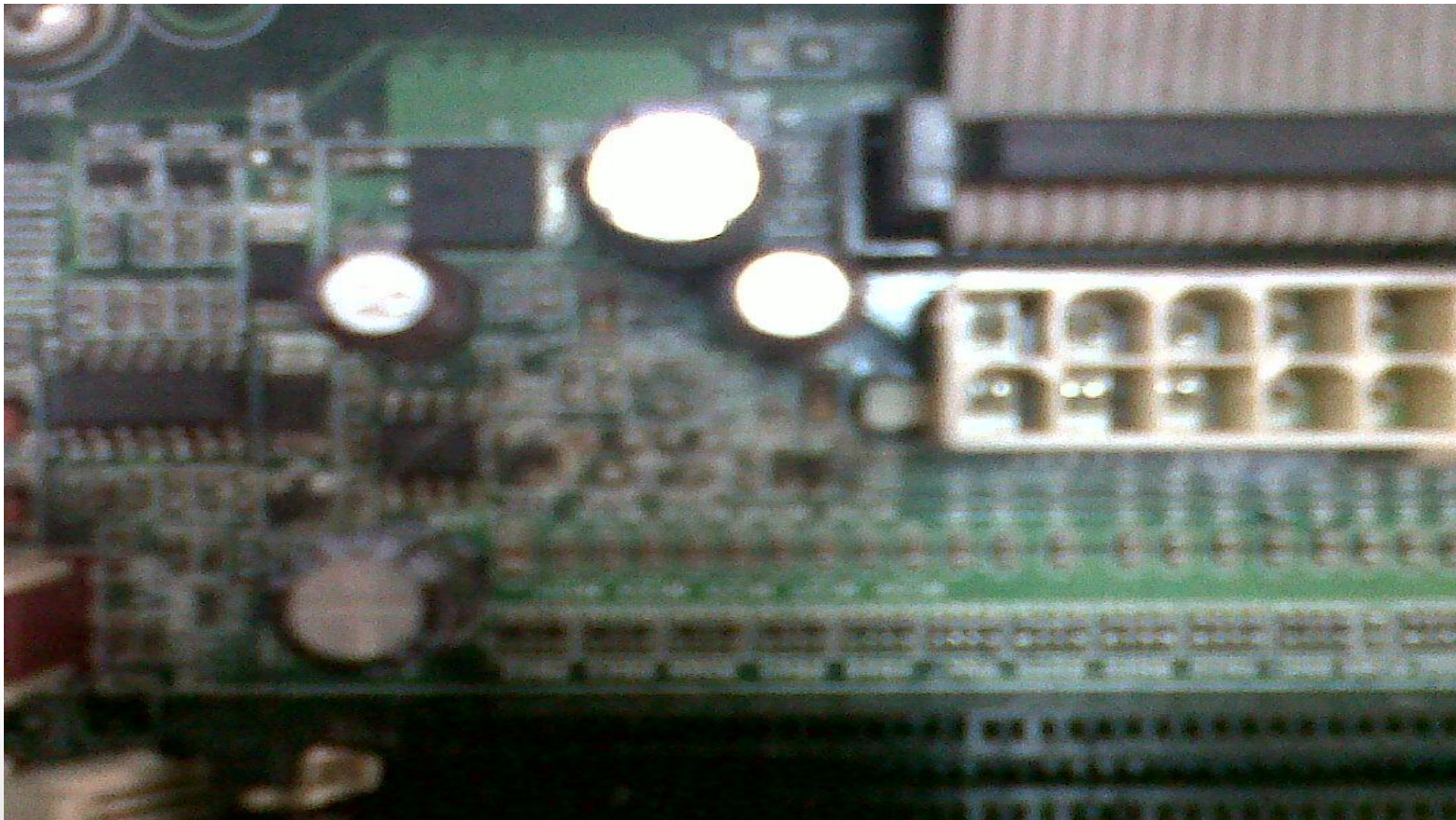
ISO 5.2.4/5.2.5

- Please keep in mind that as little as a 1 volt spike can damage sensitive electrical circuitry in a modern day analyzer .



# POWER SUPPLY and QUALITY

Damaged circuit board cost of replacement \$980-00



# WATER SUPPLY and QUALITY

## ISO:5.2.4

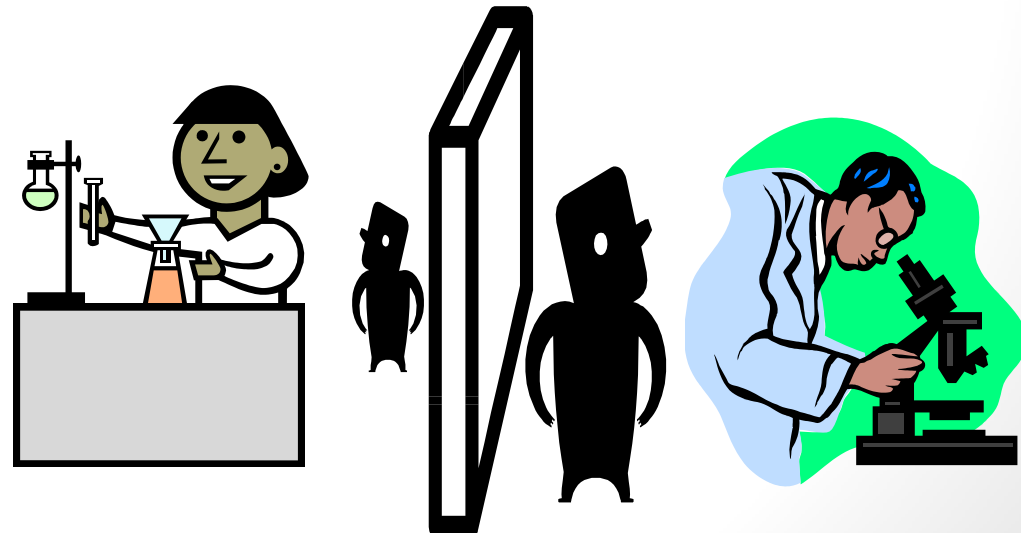
- Example of input water parameters.
- RULE OF THUMB: IF YOU WILLING TO DRINK IT USE IT TO FEED YOUR EQUIPMENTS WATER UNIT.....

Feed Water Quality Requirements	
Pressure	1 – 6 bar
Flow rate Tap water connection	> 5 L/min at 2 bar 1/2" Gaz M
Type Temperature	Potable 5 – 35 °C
Conductivity pH	100 – 2000 µS/cm at 25 °C 4 - 10
Langelier Saturation Index (LSI)	< 0.3
Free total chlorine Silt Density Index (SDI)	< 3 ppm < 12

# ERGONOMICS

ISO: 5.2.4/5.2.6/5.2.2

- Effective separation between laboratory sections that is... incompatible ,thus limiting the chances of any negative effect on result ,sample ,quality or staff health
- Micro Biology
- PCR

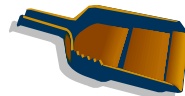


# ENVIRONMENTAL CONDITIONS



Light

Natural or artificial for reading of manual test results.



Dust

Dust is one of the major causes of mechanical and electrical failure of equipment



Fumes/aerosols



Both Chemical and Biological fumes can cause reagent chemicals to react, adversely affecting quality of results or operators health.



Vibration



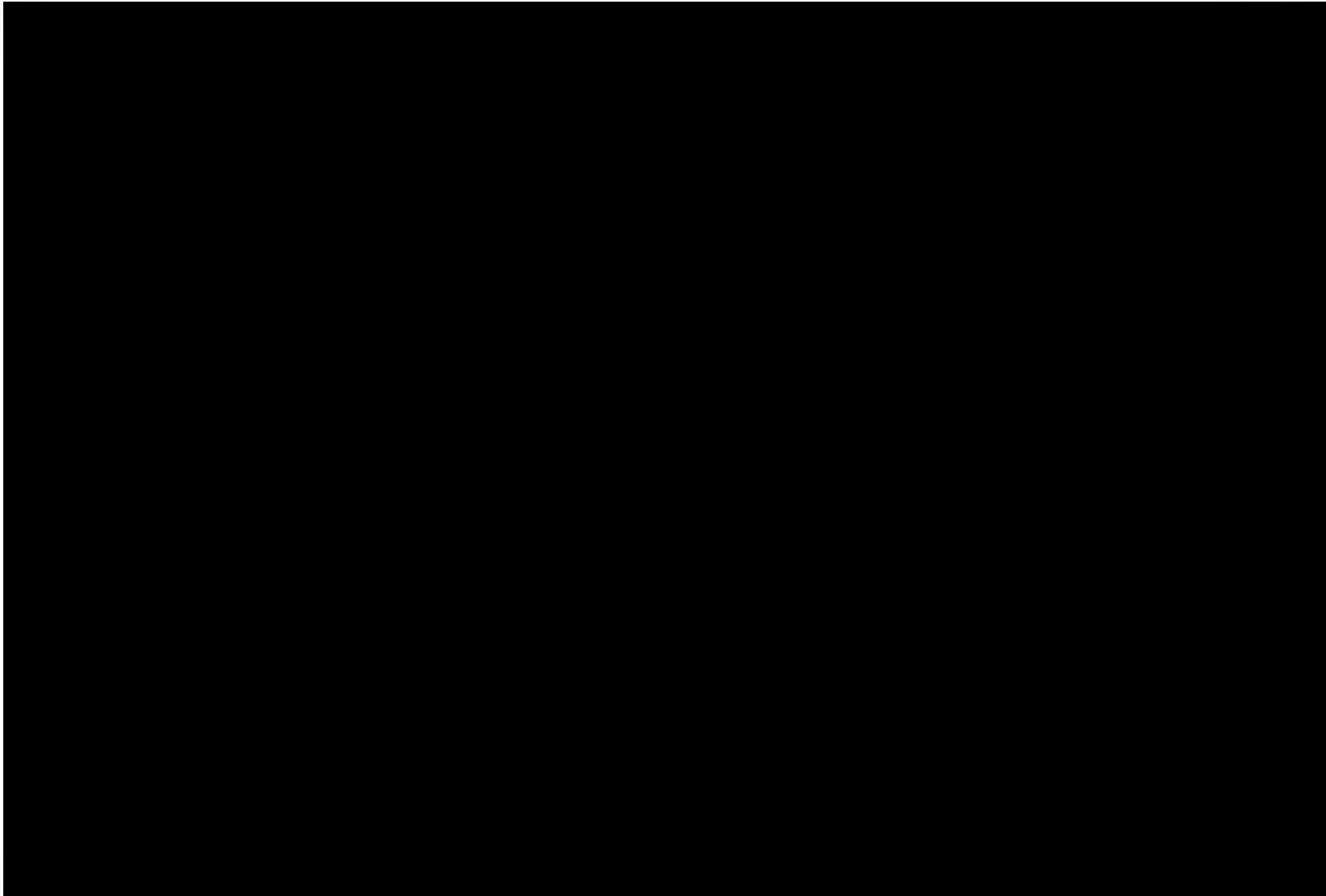
Environmental and Mechanical vibration can cause equipment to fail.

Temperature



Optimal temperature for a lab 22 degrees celcius





**Short movie before we start with equipment selection**

# 5.3 Laboratory equipment

## SELECTION

**The start of the quality journey.**

Determine the difference between

what you **WANT**

what u **NEED**

**AFFORDABILITY.**

**Yourself and END USER**

# Selecting your first instrument is similar to buying your first car.

## • INSTRUMENT

- NUMBER OF SAMPLES PER DAY
- INTENDED SCOPE OF USE
- LOCAL SUPPLIER VERSUS IMPORT
- LOCAL SERVICE SUPPORT/AGENT
- AVAILABILITY REPLACEMENT PARTS COST/
- PEER GROUP FEEDBACK
- LONGEFITY OF INSTRUMENT
- USER FRIENDLY
- MAINTENANCE INTERVALS

## • YOUR FIRST CAR

- NUMBER OF PEOPLE TO CARRY
- INTENDED SCOPE OF USE
- LOCAL SUPPLIER VERSUS IMPORT
- LOCAL SERVICE SUPPORT/AGENT
- SPARE PARTS AVAILABILITY AND COST
- CUSTOMER FEEDBACK
- LOGEFITY OF VEHICLE
- USER FRIENDLY
- MAINTENANCE INTERVALS

# Questions to ask when selecting your new equipment.

- Is the supplier going to install / commission the equipment?(ISO :5.3.1/5.3.2)
- Will a full verification be carried out post installation?(ISO:5.3.4/4.5.2/4.6.2)
- Will operators training be given ?(ISO:5.3.5)
- Will reagents and consumable for the operation of your equipment be readily available?(ISO:4.6.1/4.6.4)
- Who will carry out the scheduled maintenance of the equipment?(ISO 5.3.2/4.5.2)

# **SOME PICTURES OF BREAKDOWNS**



## **BENT PROBE ON ABX PENTRA 60**

**COST TO REPLACE \$120**

**CAUSED BY DUST BLOCKING STOP SENSOR OPERATION**



## **WRONG ROTOR FIXED TO CENTRIFUGE**

**CAUSED BY: OPERATOR TRAINING**

**COST TO REPLACE CENTRIFUGE \$20 000.00**

**COST TO FIX LAB \$ 5000.00**



## **Centrifuge stopped by hand**

**Cause: Safety switch "by passed"**

**Cost to fix equipment 1\$ /cost to fix hand \$5000.00**



# WRAP UP



- I HAVE WORKED IN SEVERAL COUNTRIES IN AFRICA  
Nigeria, Botswana ,Zambia, Zimbabwe ,Chad, DRC ,Kenya  
,Namibia, Swaziland ,Lesotho, Ivory  
coast,,Tanzania,Rwanda, ect.
- One thing that has always intrigued me ...

The amount of equipment that I found abandoned.

Reason being not following the simple points that I just shared with you!

- **Quality is not a document it's a state of mind a way of live.**
- **There is no quality without safety ,no safety without quality.**

THANK YOU