



Setting up of a Analytical laboratory

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INTRODUCTION

- To have an effective Quality control programme, we need a well equipped quality control laboratory
- Where we can analyze the various materials, such as raw materials, semi-finished, finished, stored products etc. for various chemical and bacteriological parameters, so as to see that they meet the legal and quality standards.
- Quality control laboratory should be regarded as one of the key features of any dairy plant.
- While designing a dairy plant, a due consideration should be given for the location and design of a quality control laboratory.

Types of dairy laboratories(BIS)

1. Category A

For dairies which handle 1 lakh liters or more of milk per day.

2. Category B

For dairies which handle 25,000 litres or more of milk per day, but less than 1 lakh litres.

3. Category C


For dairies which handle 10,000 liters of milk or more per day, but less than 25,000 liters.

4. Category D

For dairies which handle 5,000 liters of milk or more per day, but less than 10,000 liters.

5. Category E

For dairies which handle less than 5,000 liters per day.



For category A, B and C almost similar facilities are required. The facilities are as follows:

- Bacteriological room, sterilization and Media room, balance room, wash-up room, gas chamber, fume chamber (Fume hood or fume cupboard), Fine instrument room
- Separate rooms for quality control officer and laboratory staff, working benches etc.

For category D and E:

- Bacteriological room, Sterilization & Media room, fine instrument room are not generally required.
- These labs look like labs **only for collection centers.**

Location of QC lab in a dairy

- It should not be at a remote (far-off) place from the dairy operations.
- It should not be very close to the dairy operations where there can be lot of noise, vibrations, steam etc. In other words, it should be free from noise and vibration.
- It should preferably be away from boiler houses.
- It should be easily accessible for all the major activities of the dairy.

Layout/design of the laboratory

- Laboratory should have adequate number of rooms/chambers and benches of suitable dimensions.
- While setting up a laboratory, the possible expansion of the dairy should be kept in view.
- Every laboratory should be provided with a minimum of 2 exits.
- For each category (A, B, C, D, E) of lab, BIS has given two alternate layout plans.

General requirements for a QC lab

- ✿ Walls

- ✿ Windows

- ✿ **Lighting :**

- Northern or east - northern exposure is preferred for a satisfactory natural day light, particularly for color matching minimum average intensity of 400 to 450 lumen/m² at working level
- Direct sun light should be avoided particularly for sensitive instruments (e.g. Chemical balance)
- A roof light is helpful.
- Flooring

Flooring should be non- slippery and should be capable of cleaning easily.

- ✿ Store room: 2 store rooms

- (a) One for acids, alkalies and ammonia

- (b) Second for fine chemicals, glasswares, apparatus and equipments

☀ **Benches**

- Bench top should be made of material resistant to acid and alkali (For example, acid and alkali proof tiles or sunmica may be used).

- **A. Above bench fittings**

- Shelves should be provided above the bench to keep various solutions, chemicals, reagent bottles, glassware etc.

- **B. Under Bench fittings**

- ☀ The drawers and cupboard with shelf accommodation should be provided. The under bench unit could be of fixed or removable type and inter changeable

☀ **Cupboards**

- Protect the apparatus
- Give neat and clean appearance. wall cupboards are preferred without occupying the floor space.

☀ **Sinks**

- Glazed earthenware or vitreous ware or stainless steel. Preferable dimensions of sinks 75 x 45 x 25 cm
- Service bench or laboratory bench or working bench should be fitted beneath



☀ **Fume cupboard/ fume hood/fume chamber**

- There should be a fume cupboard provided with an efficient means of removing objectionable fumes, gases, vapors etc for carrying out operations which cause fumes etc.
- Fume chambers should have the provision for gas, water, waste outlet and electricity.



- ✿ Water supply
- ✿ Distilled water plant
- ✿ Gas
- ✿ Electric supply
- ✿ Service lines (of water, gas & electric power)
- ✿ Drainage Underground drainage system should be there.
- ✿ Fire-extinguishers
- ✿ Ventilation
- ✿ Air-Conditioners
- ✿ Chemicals, glassware & Consumable Stores
- ✿ Equipments

Integrated Pest Management

- Integrated Pest Management which is environment friendly broad ecological approach for managing pest problems.
- It encompasses pest control techniques, such as cultural, mechanical and biological with minimum dependence on chemical pesticides

IPM Inspection zones

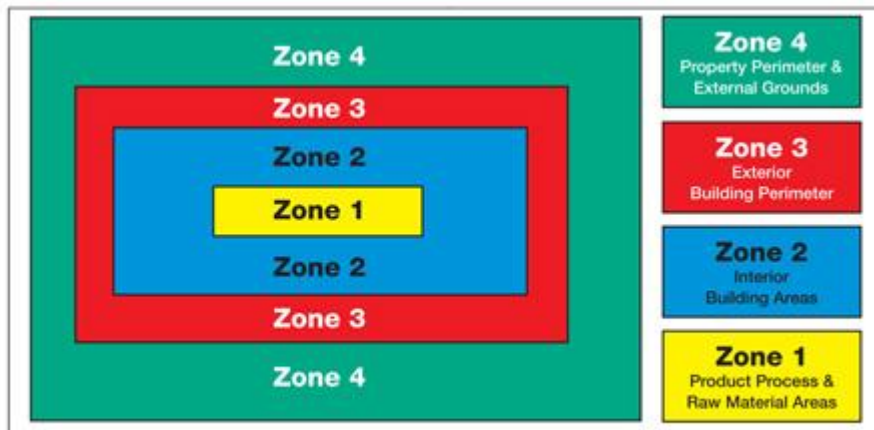


Figure 2: IPM Inspection Zones for a Manufacturing Facility

Pest prevention

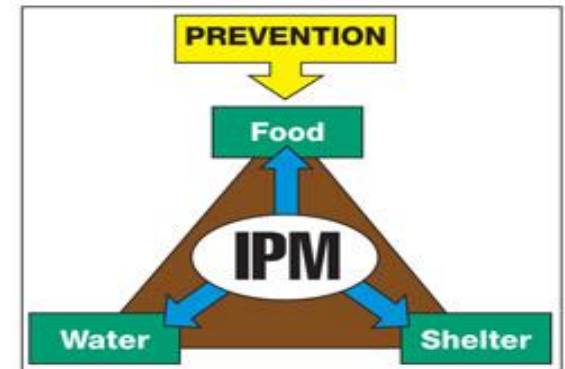


Figure 1: Pest Prevention: Controlling Food, Water and Shelter

- Pests require an available food or water source to thrive.
- It is critical that food and water sources are controlled or eliminated where possible.
- Unnecessary water sources, such as standing water and puddles, should be prevented by maintaining proper drainage and sloping of facility grounds.
- ***Controlling Shelter***
Controlling and eliminating pest shelter sites is an effective way of reducing pest pressure on the facility by removing nearby harbourage sites and eliminating breeding grounds.
- Rodent Pest Management for building capacity, creating awareness and conducting rodent control campaigns to reduce product loss and cost break up for each component under Rodent Pest Management
- Strategy for fly control in dairies

Equipments in QCL

- Mojonnier apparatus, water baths Mojonnier flask and flask stand
- Hot air oven, Hot plates
- Analytical balances, Desiccators
- Colorimeter/Spectrophotometer
- Nitrogen digestion/distillation apparatus
- Glass distillation apparatus
- Refrigerator, BOD incubator
- Microscope, Autoclaves
- Milkotester/Milko scan
- Gerber fat testing centrifuge
- Automatic measure for Gerber acid and iso- amyl alcohol
- pH meter,
- Viscometer
- Pro-milk, Infra-red Moisture tester
- General purpose centrifuge
- Solubility index apparatus
- Butyro-refractometer with circulating water bath
- Polarimeter

Special Requirements

✓ **Fat Test**

A white tiled platform of suitable dimension would be found to be useful for conducting fat test.

✓ **Wash-up Room**

In wash up rooms, it is desirable to have 3 sink units with draining board and draining rack.

✓ **Balance Room**

The balance room should be so located in laboratories that it is least affected by vibrations.

✓ **Doors**

The doors of the laboratory should be self closing

✓ **Bacteriological Room**

The bacteriological room should be dust-free and air- conditioned.

✓ **Drains**

Made of an acid-proof material, the volume of discharge, suitable traps at suitable places to prevent blockage of drains.

✓ All the rooms meant for analytical work in the laboratory should be fly-proof and rodent proof.



Concept of mobile testing laboratory

Concept of mobile testing laboratory

- The mobile laboratory is the integrated analytical platform equipped with state-of-the-art measurement systems. It is to detect, analyze and confirm the chemical and biological adulterants/contaminants in food, water, milk etc.
- This lab in real sense is full-fledged traditional laboratory in the field as a mobile unit.
- The mobile testing laboratory for the detection of food adulteration includes some rapid chemical and microbiological tests in particular.
- This lab should have proper safety features like pressurized air system, biological safety cabinet etc.
- These labs are fabricated on a specially modified mobile platform like heavy duty trucks.
- The concept of mobile testing laboratories is already in place in many developed countries as well as in some developing countries.
- In India, the newly formed Food Safety and Standards Authority (FSSAI) has taken an initiative to setup the mobile testing laboratories.
- These Mobile Labs are expected to be positioned at various locations in the country, including Delhi on the basis of risk assessment.

Objectives of Mobile Testing Laboratory

To take process of food testing to the door steps of the consumers and others.

i) The labs will visit the local markets, households, restaurants, godowns, schools and other public places, conduct tests on the spot and declare the result, thereby creating awareness among the people and also furnish feedback to the food safety authorities.

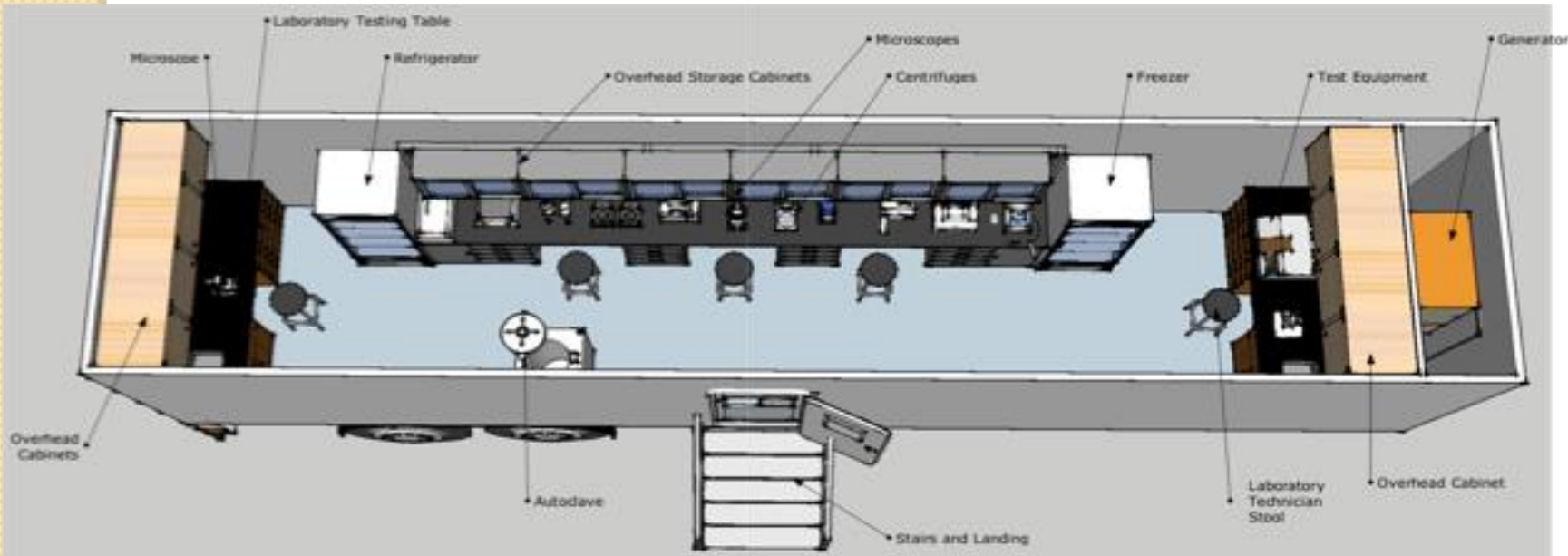
ii) Collection of information by means of testing and preparation of a data base, which can be useful in maintaining surveillance and could also be utilized by the Food Safety Officers, Laboratories and others involved in Food Safety regulation.

Design of the Laboratory

- Constructed by laminated panels with excellent insulation properties.
- Panels are mounted in a galvanized steel frame.
- External dimensions generally depend upon the type and kind of testing to be carried out in a particular laboratory.
- The container should be easily lifted by both crane, truck with container hoist and can be transported by truck, ship, train and aeroplane.
- Generally divided into two portions internally by a sliding door.

One half of the laboratory can be used for the preparation of samples and the other functions as a measurement laboratory where instrumentation can be located.

- The platform includes both rear and side entry doors with dual pan windows.
- The units should have at least two numbers generators. Both can be controlled from the outside or inside the laboratory compartment.
- There should be filtered fresh air intakes and exhaust vents to avoid contamination of environment. Fume hood, refrigerator/freezer/microwave. Lines for telephony, data, internet, e-mail.



Equipment

Type of equipment depends upon the kind of testing to be performed. The possible equipments are as:

- i) Sampling equipment and containers.
- ii) Milko tester/Milk analyzer
- iii) Ovens, Incubators.
- iv) Gerber Centrifuge and clinical centrifuge.
- v) Rapid chemical testing kit.
- vi) Rapid microbiological testing kits
- vii) Biosensor based tests for antibiotics etc.
- viii) Lactometers,
- ix) Computers (PC's), Printer
- x) Protective equipment, electronic personnel.



Laboratory accreditation

Accreditation- What?

A process by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks.

E.g. Joint commission on accreditation of healthcare organizations (JAHO), National committee on quality assurance (NCQA), NABL, CAP.

- In India NABL is authoritative body for testing and calibrating laboratories.

Laboratory accreditation

- Laboratory accreditation provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing, measurement and calibration services.
- To maintain this recognition, laboratories are re-evaluated periodically by the accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained.
- Laboratory accreditation uses criteria and procedures specifically developed to determine technical competence.
- The criteria are based on an international standard called International Organization for standardization/ International Electrochemical Commission (ISO/IEC) 17025, which is used for evaluating laboratories throughout the world.

Laboratory accreditation

- Government of India has authorized National Accreditation Board for Testing and Calibration Laboratories (NABL) as the sole accreditation body for the purpose of accreditation of Testing and Calibration laboratories.
- NABL is an autonomous body under the aegis of Department of Science and Technology, Government of India, and is registered under the Societies Act.
- NABL has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories.
- NABL is a full member of both ILAC (International Laboratory Accreditation Cooperation) and APLAC (Asia Pacific Laboratory Accreditation Cooperation).

Process of Accreditation

Stage I:

- Prepare your **laboratory's application for NABL accreditation**, giving all desired information and **enlisting the test(s) / calibration(s)** along with range and measurement uncertainty for which the laboratory has the competence to perform.
- Laboratory can apply either for **all or part of** their testing/calibration facilities.
- Formats NABL 151, NABL 152 & NABL 153 are to be used by **Testing, Calibration & Medical Laboratories** respectively for applying to NABL for accreditation.
- Laboratory has to take special care in filling the **scope of accreditation** for which the laboratory wishes to apply. In case, the laboratory finds any clause (in part or full) not applicable to the laboratory, it shall furnish the reasons.
- Laboratories are required to submit **three sets of duly filled in application forms** for each field of testing/calibration along with **two sets of Quality Manual and Application Fees**.
- NABL Secretariat on receipt of application will issue acknowledgement to the laboratory. After scrutiny of application for it being complete in all respects, a **unique Customer Registration Number will be allocated** to laboratory for further processing of application.

- NABL Secretariat shall then **nominate a Lead Assessor for giving Adequacy Report** on the Quality Manual/Application submitted by the laboratory.
- A copy of **Adequacy Report by Lead Assessor will be provided to Laboratory** for taking necessary corrective action, if any.
- The laboratory shall submit Corrective Action Report.
- After satisfactory corrective action by the laboratory, **a Pre-Assessment audit of the laboratory will be organized by NABL**. Laboratories must ensure their preparedness by carrying out its internal audit before Pre-Assessment.

Stage II

- NABL Secretariat shall organize the **Pre-Assessment audit**, which shall normally be carried by Lead Assessor **at the laboratory sites**.
- The pre-assessment helps the laboratory to be **better prepared for the Final Assessment**. It also helps the Lead Assessor to assess the preparedness of the laboratory to undergo Final Assessment.
- A copy of **Pre-Assessment Report will be provided to laboratory** for taking necessary corrective action on the concerns raised during audit, if any.
- The laboratory shall **submit Corrective Action Report to NABL Secretariat**.
- After laboratory confirms the completion of corrective actions, **Final Assessment of the laboratory shall be organized by NABL**.

Stage III

- NABL Secretariat shall **organize the Final Assessment at the laboratory site(s)** for its compliance to NABL Criteria and for that purpose appoint an assessment team.
- The **Assessment Team shall comprise of a Lead Assessor and other Technical Assessor(s) in the relevant fields** depending upon the scope to be assessed.
- **Assessors shall raise the Non-Conformance(s), if any,** and provide it to the laboratory in prescribed format so that it gets the opportunity to close as many Non- Conformance(s) as they can before closing meeting of the assessment.
- The Lead Assessor will **provide a copy of consolidated report of the assessment to the laboratory and send the original copy to NABL Secretariat.**
- Laboratory shall take **necessary corrective action on the remaining Non-Conformance(s)/other concerns** and shall submit a report to NABL within a maximum period of **2 months.**

Stage IV

- After satisfactory corrective action by the laboratory, the **Accreditation Committee examines the findings of the Assessment Team and recommends additional corrective action**, if any, by the laboratory.
- Accreditation committee determines **whether the recommendations in the assessment report are consistent with NABL requirements** as well as commensurate with the claims made by the laboratory in its application.
- Laboratory shall have to **take corrective action on any concerns** raised by the Accreditation committee.
- Accreditation committee shall make the appropriate recommendations regarding accreditation of a laboratory to NABL Secretariat.
- Laboratories are **free to appeal** against the findings of assessment or decision on accreditation by writing to the Director, NABL.
- **Whenever possible NABL will depute its own technical personnel to be present at the time of assessment** as Coordinator and NABL observer. Sometimes, NABL may at its own cost depute a newly trained Technical Assessor as "Observer" subject to convenience of the laboratory to be assessed.

Stage V

- Accreditation to a laboratory shall be **valid for a period of 2 years** and NABL shall conduct periodical **Surveillance of the laboratory at intervals of one year.**
- Laboratory shall apply for **Renewal of accreditation to it at least 6 months before the expiry** of the validity of accreditation.



THANK YOU