BIPM Capacity Building & Knowledge Transfer Programme

FUTURE NEEDS FOR METROLOGY Summer School and METAS Project Placement

REPORT

Project Name	Introduction to the Laboratory Biological Analysis and References – Federal Institute of Metrology METAS
Description	This project aims to gain exposure to the Laboratory for Biological Analysis and References at the Federal Institute of Metrology METAS, with the objective of supporting the development of the Biology Laboratory at SNSU–BSN
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Motivation & Introduction

Biology Laboratory of SNSU–BSN is a newly established facility that is planning to expand its scope of activities and prepare for accreditation under ISO/IEC 17025 and ISO 17034. The METAS laboratories offer a valuable reference, as they combine metrology laboratory with accredited National Reference Laboratory (NRL). This dual role makes METAS an ideal model for guiding the development and accreditation readiness of Biology Laboratory of SNSU–BSN.

Main Objective:

1. To acquire knowledge on the fundamentals of metrology and its applications in biological analysis.
2. To gain insight into the operation and scope of the NRL for genetically modified organisms in food (NRL-GMOs) and the NRL for food-borne viruses (NRL-Viruses)
3. To understand how proficiency testing (PT) is organized by METAS and identify relevant practices for future implementation at SNSU–BSN
4. To explore the implementation of digital transformation at METAS

Research

Laboratory for Nucleic Acid Metrology

During my time at the Metrology Laboratory, I gained valuable insight into the development of highly characterized / certified reference materials (RMs), as well as the development of reference measurement procedures (RMPs).

- Plasmid-based GMO Reference Material
  The development process of a plasmid-based GMO reference material involves several key stages: DNA construct design, outsourcing of plasmid synthesis to a third party, verification of the received plasmid, and a ring trial for performance evaluation. Due to time constraints, I was only able to participate in the plasmid verification stage. The verification process included real-time PCR, gel electrophoresis, and DNA sequencing performed by an external service provider.

- GenomeMET
  The GenomeMET project aims to strengthen metrological capabilities and establish frameworks to improve the quality, reproducibility, and SI-traceability of genomic profiling measurements, thereby supporting assay validation in accordance with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746.

  The project consists of six Work Packages (WPs), with METAS being the lead of Work Package 4 (WP4), which focuses on:
  1) Revising and applying statistical approaches for determining measurement uncertainty.
  2) Evaluating uncertainties arising from bioinformatics data analysis.
  3) Developing guidance for the estimation of measurement uncertainty in genomic profiling workflows.

National Reference Laboratory (NRL)

METAS operates two National Reference Laboratories (NRLs): the NRL for Genetically Modified Organisms in Food (NRL-GMOs) and the NRL for Food-Borne Viruses (NRL-Viruses). During this project, I had the opportunity to observe the activities conducted by the NRL-Viruses team.

The NRL-Viruses regularly collects random vegetable samples from local markets in Switzerland to assess the presence of food-borne viruses in fresh vegetables such as salads. The testing workflow includes the following steps:
- Ribonucleic acid (RNA) extraction from the sample
- Reverse transcription of RNA to deoxyribonucleic acid (DNA)
- Molecular detection and quantification of viruses by Real-time PCR

RNA extraction is performed using two alternative methods: manual extraction and automated extraction using the Maelstrom 8 system. The use of Maelstrom 8 helps reduce the risk of human error, such as incorrect reagent handling or improper mixing sequence, thereby enhancing consistency and reliability in the extraction process.

Proficiency Testing

While METAS has extensive experience in organizing proficiency testing (PT) schemes for physical measurements, the Laboratory for Biological Analysis and References has not yet conducted PTs specifically in the areas of food safety or health. However, useful insights were gained from the Electromagnetic Compatibility (EMC) Laboratory – METAS, which implements two PT models that may be relevant for adaptation at SNSU–BSN.

EMC Laboratory provides PTs with individual participation principle as well as PT in inter-laboratory comparison campaigns.

- Interlaboratory Comparison (ILC) Campaign: In this model, multiple laboratories participate in the same comparison. The organizer also participates and performs its own measurements, and the reference values are calculated from the collective results of all participants. Individual results are anonymized and published in a randomized format.
- PT with individual participation: In this model, participants' results are compared directly with reference values held by the organizer. These reference values may come from previous ILCs or from repeated in-house measurements by the organizing laboratory.

Unlike SNSU–BSN's current practice of conducting PTs only with a few participants, the individual participation model offers greater flexibility. This approach could be particularly useful for initiating PTs in emerging or highly specialized fields, such as biological testing, where the number of available participants may initially be limited.

Digital Transformation

The METAS Biology Laboratory uses a Laboratory Information Management System (LIMS) called LIMSOPHY, developed by the Swiss company, Infotray. This system includes the following features:

- Equipment inventory management, including calibration and maintenance schedules
- Role-based user access control
- High customizability to meet laboratory-specific needs

LIMSOPHY allows for efficient documentation, improved traceability, and streamlined data handling, all of which are essential components of a modern, metrologically sound laboratory. This digital infrastructure serves as a valuable reference for the future implementation of LIMS or other digital tools at SNSU–BSN, in line with its goal of enhancing operational quality and accreditation readiness

Conclusions and Future Work

This project successfully provided first-hand exposure to metrological practices in biological analysis at METAS, particularly in the areas of development of RMs, RMPs, viral detection workflows, digital proficiency testing strategies, and digital laboratory systems. Key contributions included the verification of plasmid-based RM for GMO detection and the observation of workflows at the NRL-Viruses. All objectives were met. The knowledge gained will inform improvements at SNSU-BSN, particularly in RM development, viral detection, proficiency testing organization, and digital transformation.

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