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Technical Authorization in the Biomedical Laboratory: Rationale and Key Concepts

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1. Introduction

The staff of Pathology and Laboratory Medicine Services (across various specialties), Transfusion Medicine, Pharmaceutical Galenics, Zooprophylactic Institutes, and other biomedical laboratories includes numerous professional figures, all essential to meet clinical and patient needs, address the rapid development of informatics, and keep pace with advances in medical and biological research.

Historically, in Italy, each of these professions evolved independently, developing specific competencies and contractual roles. However, this has also led to significant and sometimes unjustified areas of overlap.

Performing one's duties effectively requires a profound understanding of the purpose and objectives of the work. The way each professional applies their skills greatly impacts the entire laboratory process.

This recommendation aims to clarify the key role that ***Biomedical Laboratory Healthcare Technologists (TSLB)*** play, or should play, within the analytical, preparative, and productive contexts of Italian laboratories. It provides a comprehensive explanation of the concept of Technical Authorization and its practical significance, which is vital for this profession.

The goal is to prevent unnecessary professional downgrading, eliminate organizational inefficiencies, and contribute to better human resource allocation.

2. European and International Qualification Framework

The *European Qualifications Framework (EQF)* defines "reference levels" to express learning outcomes, such as knowledge, skills, and autonomy-responsibility. These levels indicate what individuals know, understand, and are capable of doing upon completing a study program.

In Italy, to become a *TSLB* — internationally known as *Biomedical Scientist (BS) or Biomedical Laboratory Scientist (BLS)* — a first-level university degree (Bachelor's degree) from a Faculty of Medicine and Surgery is required.

The Italian academic qualification corresponds to EQF Level 6, which includes:

- Advanced knowledge in a field of work or study, involving a critical understanding of theories and principles;
- Advanced skills demonstrating mastery and innovation, necessary to solve complex and unpredictable problems in a specialized field;
- Ability to manage technical or professional activities/projects, assuming responsibility for decision-making in unpredictable work or study contexts, as well as responsibility for professional development within teams.

International professional associations, such as the *European Association for Professionals in Biomedical Science (EPBS)* and the *International Federation of Biomedical Laboratory Science (IFBLS)*, also require a minimum core curriculum equivalent to EQF Level 6 for entry into the profession.

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3. Rationale for Technical Authorization

The clinical utility of laboratory test results heavily depends on the quality of analyses. Measurement inaccuracies — whether methodological, analytical, or disease-predictive — must be minimized and maintained within "state-of-the-art" standards, which are continuously updated through *Evidence-Based Laboratory Medicine (EBLM)*. This is the primary mission of Clinical Laboratories.An erroneous result can generate diagnostic delays, mislead clinical reasoning, and cause harm to patients.

As the primary executor and manager of analytical processes, the TSLB plays a crucial role in ensuring test result quality. Technical Authorization represents the final and qualifying act of their work.
The rationale for Technical Authorization can be summarized through the following key concepts:

- Judgment
- Evaluation
- Responsibility
- Ethics
- Collegiality
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- Traceability

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4. Technical Authorization as a Formalized Judgment

Technical Authorization constitutes a formalized judgment representing the final act of the analytical or preparative process managed by the TSLB, certifying that results conform to predefined quality standards. It authorizes the data for official reporting or subsequent procedural steps.

To ensure traceability and maintain analytical quality, Technical Authorization should be formally expressed through a digital or traditional signature by the TSLB who performed the procedure.

When multiple individuals are involved in a single analytical process, the organization of work should allow clear attribution of responsibilities and separate authorization of significant outcomes, even if only for internal documentation purposes.

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5. Technical Authorization Originates from a Performance Evaluation Process

Technical Authorization results from a systematic evaluation of empirical and cognitive data concerning every aspect of the work managed by the TSLB: the suitability of the received sample, the method used (and its limitations), instrument functioning, calibrations, quality control results, test readings, plausibility of results (such as panic values), environmental and operational factors (temperature, humidity, space, timing, unforeseen events, workload, etc.).
If the evaluation identifies critical or doubtful situations that might impact the clinical utility of laboratory data, the TSLB must document the issues electronically or manually and take appropriate corrective actions (CAs), when possible. Corrective actions, such as test repetition or sample recollection, are normally agreed upon with the Laboratory Director, based on the laboratory's specific functions and organization (e.g., Hub or Spoke facilities, telemedicine services, point-of-care testing (POCT), night-time emergencies).Failure to properly record criticalities and non-conformities may compromise clinical outcomes and hinder subsequent corrective actions. Therefore, if the Laboratory is not already equipped with an *Electronic Laboratory Notebook (ELN)*, the use of a structured, sector-specific Lab-Book (paper- based) is highly recommended.It is also essential that manuals, updates, and safety notices *(FSN, Field Safety Notice and FSCA, Field Safety Corrective Action)* related to in vitro diagnostic medical devices (IVDs) vigilance systems be promptly and directly received by the TSLBs in their original form.

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6. Technical Authorization as an Act of Personal and Ethical Responsibility

Since Technical Authorization is a judgment based on empirical and operational data known only by the person who performed the procedure, it constitutes an act of personal responsibility for the TSLB. Therefore, it cannot be bypassed or delegated, even to management personnel.

Assuming responsibility for Technical Authorization strengthens professional ethics and increases the guarantees of process reliability, ensuring accountability toward users and patients.

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7. The Formalized Technical Authorization in a Collegial Healthcare Process

"Collaboration" means working together with others to achieve a shared benefit and common goal. In Laboratory Medicine, it signifies focusing on the patient's health needs by ensuring effective and efficient diagnostic processes.

The formal act of Technical Authorization helps delineate and clarify overlapping competencies and responsibilities within the Clinical Laboratory team, thus optimizing its performance.

Moreover, it allows each professional to concentrate on their core competencies, enhancing their ability to manage and deepen the areas pertinent to their specialized training, fostering loyal collaboration and mutual respect.

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8. Technical Authorization as a Formal Act That Must Be Tracked

Technical Authorization must not be confused with the "signature" of the final clinical report, which remains the responsibility of the Laboratory Director or delegate. However, it is one of the necessary preconditions.

Like all significant Laboratory operations, Technical Authorization must be traceable, either digitally or manually (via registers, personal stamps, etc.). It is the responsibility of Company Management and the Laboratory Director to implement measures ensuring that this becomes standard practice, also supporting accreditation and certification processes.

Where possible, the Technical Authorization signature should appear alongside that of the Laboratory Director on the final report delivered to clinicians.

All laboratories are encouraged to adopt a mandatory digital traceability and signature system for TSLB personnel, ensuring a high standard of *Information Technology (IT)* security (smart cards or better).

APPENDIX: Special Cases of Technical Authorization

It is impossible to list all the problems that might arise regarding Technical Authorization across different laboratories, instruments, or tests. Thus, highly trained and continuously updated TSLB professionals are essential.

Three notable cases are outlined below.

CoreLab and Expert Laboratory Systems

CoreLabs aim for high production efficiency while maintaining top qualitative-quantitative standards. Automation, high-throughput chains, expert software systems, and artificial intelligence tools increasingly position TSLBs as complex systems managers rather than mere test executors. Human control and Technical Authorization remain indispensable for system reliability.

Where multiple operators are involved, significant steps should be individually authorized to ensure responsibility attribution.

Telemedicine

Telemedicine supports equitable healthcare access in remote areas and enables expert consultations from "Hub" facilities to "Spoke" centers or basic laboratories. Here, Technical Authorization ensures the quality of images and data transmitted for diagnostic purposes. Even without a supervising physician, formalized Technical Authorization is often sufficient to guarantee test quality, reserving specialist interpretation for complex cases.

Reorganization of Laboratories and Near-Patient Testing (NPT)

Recent reorganizations based on the Hub-and-Spoke model, while efficient, risk compromising urgent diagnostic needs and *TAT (Turnaround Time)*, especially during nights and holidays.

The spread of NPT in care settings often involves non-specialized personnel. Clinical Laboratory Directors attempt to manage these through *Laboratory Information System (LIS)* integration and remote supervision. However, the legal responsibility for Technical Authorization must remain clear. Unauthorized use of non-TSLB personnel on non-waived instruments could constitute "unauthorized practice of TSLB profession," with serious consequences.

All near-patient tests must comply with the EU Regulation 2017/746 regarding in vitro diagnostic devices.