

R³ Report | Requirement, Rationale, Reference

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Published for Joint Commission-accredited organizations and interested health care professionals, *R3 Report* provides the rationale and references that The Joint Commission employs in the development of new requirements. While the standards manuals also may provide a rationale, *R3 Report* goes into more depth. The references provide the evidence that supports the requirement. *R3 Report* may be reproduced if credited to The Joint Commission. Sign up for [email](#) delivery.

New and Revised Requirements for Infection Prevention and Control for Laboratories

Effective July 1, 2025, The Joint Commission approved new and revised requirements for the “Infection Prevention and Control” (IC) chapter for laboratories. The IC chapter underwent a full rewrite and will replace the current IC chapter.

In keeping with the ongoing initiative to simplify requirements and provide more meaningful evaluations of organizations, The Joint Commission simplified the content and structure of the IC chapter and eliminated requirements that do not add value to accreditation surveys. The new and revised requirements focus on the structures that are essential for quality and safety and identify a framework for a strong infection prevention and control program, while aligning requirements more closely to the Centers for Disease Control and Prevention (CDC) Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings.

After a review of the literature and consultation with a technical advisory panel on emerging infectious diseases preparedness, The Joint Commission has introduced new Standard IC.07.01.01 and two new elements of performance (EPs) to enhance laboratories’ preparedness for high-consequence infectious diseases or special pathogens. The recent history of infectious disease outbreaks, including severe acute respiratory syndrome (SARS), H1N1 influenza, Middle East respiratory syndrome (MERS), Ebola, and actively ongoing global outbreaks (clade I mpox, Marburg virus) have clearly demonstrated that emerging infectious diseases pose a real threat to human health and can cause significant disruptions in health care delivery systems on local, national, and global scales. The new requirement’s standardized protocol-based approach to preparedness for high-consequence infectious diseases or special pathogens is founded on fundamental infection control principles and serves to protect laboratory staff and the public.

Engagement with stakeholders, customers, and experts

In addition to an extensive literature review and public field review, The Joint Commission sought expert guidance from the following groups:

- [Technical Advisory Panel \(TAP\)](#) of subject matter experts on emerging infectious diseases and emergency response, infectious disease epidemiology, and occupational safety from various government, health care, academic, and professional associations.
- [Standards Review Panel \(SRP\)](#) comprised of clinicians and administrators who provided a “boots on the ground” point of view and insights into the practical application of the proposed standards.

The prepublication version of the requirements will be available online until June 30, 2025. After July 1, 2025, please access the new requirements in the E-dition or standards manual.

Infection Prevention and Control (IC) Chapter

Requirement: Standards IC.04.01.01 and IC.06.01.01

Standard IC.04.01.01 The laboratory has an infection prevention and control program for the prevention and control of communicable diseases and infections.

EP 1: The laboratory's infection prevention and control program is under the direction of a designated and qualified professional who has training in infection control.

EP 3: The laboratory has written policies and procedures to guide its activities and methods for preventing and controlling the transmission of infections and communicable diseases. The policies and procedures are in accordance with applicable law and regulation, nationally recognized evidence-based guidelines, and standards of practice, including the use of standard precautions.

Note: Standard precautions include hand hygiene, environmental cleaning and disinfection, injection and medication safety, use of personal protective equipment (PPE), minimizing potential exposures, and reprocessing of reusable medical equipment or devices. For full details on standard precautions, refer to the Centers for Disease Control and Prevention's (CDC) Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings <https://www.cdc.gov/infection-control/hcp/core-practices/>.

Standard IC.06.01.01 The laboratory implements its infection prevention and control program through prevention and control activities.

EP 1: The laboratory identifies risks for infection, contamination, and exposure that pose a risk to patients and staff based on the following:

- Blood and infectious materials and associated equipment handled by the laboratory staff
- Locations where lab services are provided
- Workflows or practices for sample acquisition, handling, transport, preparation, and disposal
- Relevant infection control issues identified by the local, state, or federal public health authorities that could impact the laboratory
- Laboratory staff contact with patients, if applicable

Note: Risks may include organisms with a propensity for transmission within health care facilities (for example, norovirus, respiratory syncytial virus [RSV], influenza, COVID-19) and airborne pathogens (for example, tuberculosis [TB]).

EP 2: The laboratory reviews identified risks at least annually or whenever significant changes in risk occur (for example, in response to local infectious diseases outbreaks).

EP 3: The laboratory implements activities for the prevention and control of contamination, infections, and communicable diseases. (See also NPSG.07.01.01, EP 1)

EP 4: The laboratory implements its policies and procedures for reporting of communicable diseases and outbreaks in accordance with state and local public health authorities' requirements.

EP 5: The laboratory implements policies and procedures to minimize the risk of communicable disease exposure and acquisition among its staff, in accordance with law and regulation. The policies and procedures address the following:

- Screening and medical evaluations for infectious diseases
- Immunizations
- Staff education and training
- Management of staff with potentially infectious exposures or communicable illnesses

Rationale for Standards IC.04.01.01 and IC.06.01.01

According to the Centers for Disease Control and Prevention's (CDC) *Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings*, effective operation and administration of the infection prevention and

control program requires a qualified and trained leader who has direct oversight of the implementation of infection control policies and procedures. Such an approach supports consistency, competence, and occupational safety among staff.

Note: For laboratories located inside hospitals and integrated into the hospital's infection prevention and control program, the hospital's qualified infection preventionist(s) or infection control professional(s) may be designated to direct the laboratory's infection prevention and control program. In such case, the laboratory must coordinate infection prevention and control activities with the hospital's infection preventionist(s) or infection control professional(s).

In addition to establishing policies and procedures, laboratories need to conduct a proactive risk assessment to determine the appropriate level of infection prevention and control activities and anticipate training needs. While risk assessment is foundational to safety, there is no perfect method to identify all sources of risk. Therefore, laboratories must continuously implement standard/universal precaution strategies to minimize infection risks from laboratory procedures for patients and staff.

References and Resources for Standard IC.04.01.01 and IC.06.01.01:

- Centers for Disease Control and Prevention. (2024, April 12). *CDC's core infection prevention and control practices for safe healthcare delivery in all settings*. Retrieved February 12, 2025, from <https://www.cdc.gov/infection-control/hcp/core-practices/>
- Centers for Disease Control and Prevention. (2024, December 6). *Biosafety in microbiological and biomedical laboratories (BMBL) 6th edition*. Retrieved February 12, 2025, from <https://www.cdc.gov/labs/bmb/index.html>
- Centers for Disease Control and Prevention. (2011, April 15). Guidelines for biosafety laboratory competency. *Morbidity and Mortality Weekly Report*, 60. <https://www.cdc.gov/mmwr/pdf/other/su6002.pdf>
- Centers for Disease Control and Prevention. (2021, January 6). Guidelines for safe work practices in human and animal medical diagnostic laboratories. *Morbidity and Mortality Weekly Report*, 61. <https://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
- Centers for Disease Control and Prevention. (n.d.) *Risk assessment in clinical laboratories* [Video]. YouTube. <https://www.youtube.com/watch?v=3itXV7YPvRY>
- Centers for Disease Control and Prevention. (2024, September 21). *Biological risk assessment process*. Retrieved February 12, 2025, from <https://www.cdc.gov/safe-labs/php/biological-risk-assessment/process.html>
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- Forney, J.R. (2021) *Infection Control in the Clinical Laboratory Environment* [White paper]. The Joint Commission. <https://www.jointcommission.org/-/media/tjc/documents/accred-and-cert/lab-and-pbm/lab-infection-control-whitepaper-final-sep-22.pdf>
- Occupational Safety and Health Administration. (n.d.). Worker protections against occupational exposure to infectious diseases: Comparing the universal precautions of OSHA's Bloodborne Pathogens standard to the standard precautions and the transmission-based precautions used by healthcare practitioners for infection control. Retrieved February 12, 2025, from <https://www.osha.gov/bloodborne-pathogens/worker-protections>

Not a complete literature review. For more information on IC resources, visit [Infection Prevention and Control Resource Center | The Joint Commission](#)

Requirement: Standard IC.07.01.01**Introduction to Standard IC.07.01.01**

While there is not a standardized definition for high-consequence infectious diseases or special pathogens, expert consensus defines these as novel or reemerging infectious agents that are easily transmitted from person-to-person, have limited or no medical countermeasures (such as an effective vaccine or prophylaxis), have a high mortality, require prompt identification and implementation of infection control activities (for example, isolation, special personal protective equipment), and require rapid notification to public health authorities and special action. Examples of high-consequence infectious diseases or special pathogens include MERS, novel influenzas, clade I mpox, and Ebola or other viral hemorrhagic fever diseases. This list may change, however, to reflect current regional or global outbreaks or to include future emerging agents.

Standard IC.07.01.01 The laboratory implements processes to support preparedness for high-consequence infectious diseases or special pathogens.

EP 1: The laboratory develops and implements protocols for high-consequence infectious diseases or special pathogens. The protocols are readily available at the point of use and address the following:

- Procedures for specimen or sample collection, labeling, preparation, handling, packaging, transport and secure specimen containment and disposal
- Required personal protective equipment and proper donning and doffing techniques
- Infection control procedures to support safe specimen collection and management while the patient is in isolation using the hierarchy of controls (for example, the use of dedicated point-of-care devices for routine laboratory testing)
Note: See the Glossary for a definition of hierarchy of controls.
- Procedures for waste management and cleaning and disinfecting spaces, surfaces, and equipment
- Procedures for informing public health authorities and key staff

EP 2: The laboratory develops and implements education and training and assesses competencies for staff who will implement protocols for high-consequence infectious diseases or special pathogens.

Note: Training, education, and competency assessment occur as required by laboratory policy or in accordance with law and regulation.

Rationale for Standard IC.07.01.01

Throughout recent outbreaks and pandemics, including the 2014 Ebola outbreak, hospitals and clinical laboratories were on the frontline of the response, providing medical care and necessary diagnostic testing. Each specimen handled in a clinical laboratory presents an unknown hazard. Universal precautions, when implemented consistently, reduce risk; however, a standardized approach to preparedness for high-consequence infectious diseases and special pathogens is also needed in clinical laboratories to ensure appropriate management and necessary precautions along the specimen management chain.

References for Standard IC.07.01.01:

- Centers for Disease Control and Prevention. (n.d.) *Outbreaks*. Retrieved February 12, 2025, from <https://www.cdc.gov/outbreaks/index.html>
- Cornish, N.E., Anderson, N.L., Arambula, D.G., Arduino, M.J., Bryan, A., Burton, N.C., Chen, B., Dickson, B.A., Giri, J.G., Griffith, N.K., Pentella, M.A., Salerno, R.M., Sandhu, P., Snyder, J.W., Tormey, C.A., Wagar, E.A., Weirich, E.G., & Campbell, S. (2021). Clinical laboratory biosafety gaps: Lessons learned from past outbreaks reveal a path to a safer future. *Clinical Microbiology Reviews*, 34(3), e00126-18. <https://doi.org/10.1128/cmr.00126-18>
- National Emerging Special Pathogens Training and Education Center. (n.d.). Lab resources. Retrieved February 12, 2025, from <https://netec.org/education-training/covid-19-educational-resources-training/labs/>

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Not a complete literature review. For more information on IC resources, visit [Infection Prevention and Control Resource Center | The Joint Commission](#)

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