DOI: 10.7860/JCDR/2026/81447.22378

Review Article

Pathology Section

Essential Steps for Establishing a Molecular Pathology Lab: A Narrative Review

ANAND MOHANRAJ[1]

ABSTRACT

Molecular pathology has emerged at the forefront in the era of personalised and targeted therapy. Molecular testing is essential to identify actionable therapeutic targets, especially in oncology. There is an increasing need to integrate routine histopathology and hematology laboratories with molecular techniques. A slow but definite shift is occurring toward incorporating molecular diagnostics into routine traditional pathology services. However, there remains a significant gap in knowledge and technical know-how regarding the integration of molecular diagnostic practices within routine histopathology services. With very few regulatory bodies and limited guidelines for day-to-day practice, there is considerable confusion about establishing and operating molecular laboratories. Molecular pathology also includes several subdivisions, such as cytogenetics {Fluorescence In Situ Hybridisation (FISH) and karyotyping}, molecular diagnostics {Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and Next Generation Sequencing (NGS)}, and protein studies (mass spectrometry). The latter is primarily research-based and lies outside the purview of this review article. Immunohistochemistry (IHC) is also considered an integral part of molecular work-up. Each of these individual subdivisions has its own technical, infrastructural, and personnel requirements. NGS, in particular, requires bioinformatics support and stringent quality control measures. In this review article, the necessary infrastructure, instruments, laboratory personnel, and support staff required for establishing and running a molecular laboratory are discussed. Currently, there are very few guidelines and review papers available for setting up molecular pathology laboratories. Through the present review, the authors aim to outline the essential steps involved in establishing and operating a molecular laboratory.

Keywords: Fluorescence In Situ Hybridisation, Next generation sequencing, Polymerase chain reaction, Requirements

INTRODUCTION

The era of precision medicine is upon us, with increasing applications in both diagnosis and treatment. Precision medicine has been defined as a new approach to disease prevention and treatment that adopts an individualised strategy, taking into account genetic variability to enable tailored and targeted therapy for each patient [1]. One of the most significant applications of precision medicine is in oncology-through improved diagnosis, targeted therapy, and monitoring of disease burden following treatment [1].

In modern histopathology laboratories, there is a growing need to integrate molecular techniques with routine histopathological practices. The era of molecular pathology began with the completion of the Human Genome Project in the early 2000s [2]. Integrating molecular practices into histopathology has introduced new challenges for pathologists, including the need to design laboratories suited for molecular testing. Additional challenges include training pathologists and technicians in molecular testing, interpretation, and quality assessment [3].

Although there are no universally established guidelines for setting up molecular pathology laboratories, several basic criteria [4] are essential for their establishment. These criteria are fundamental for standardisation and quality reporting. In the present paper, the authors review the basic requirements for establishing a molecular pathology laboratory.

Establishing Space: An Ideal Infrastructure

The major requirement when planning the space and infrastructure for a molecular pathology laboratory is the prevention of contamination. Polymerase Chain Reaction (PCR) forms a fundamental step in almost all molecular investigations. PCR-based techniques are particularly prone to contamination. PCR is a rapid, powerful, and cost-effective Deoxyribonucleic Acid (DNA) amplification method. The basic principle of PCR is that extremely small amounts of target DNA can be amplified into large quantities in vitro. In simple terms, the target DNA is unwound, and each strand is used to produce a complementary "daughter" strand [5]. However, this same property can also lead to the amplification of even minute amounts of contaminant DNA, resulting in incorrect reports, loss of credibility, compromised performance, and increased financial burden [5]. In general, strict adherence to proper laboratory techniques can effectively prevent contamination.

PCR is particularly susceptible to contamination by DNA molecules present in the laboratory environment. One of the primary quality control measures to prevent such contamination is proper laboratory organization. It is necessary to physically divide the laboratory into separate compartments for different PCR-related activities [6]. Failure to separate these activities can result in cross-contamination due to sample overlap, amplicon carryover from previous reactions, simultaneous preparation of different reactions, and reagent contamination with DNA templates. These issues can be avoided by performing each step of the PCR process in distinct sections of the molecular laboratory [6].

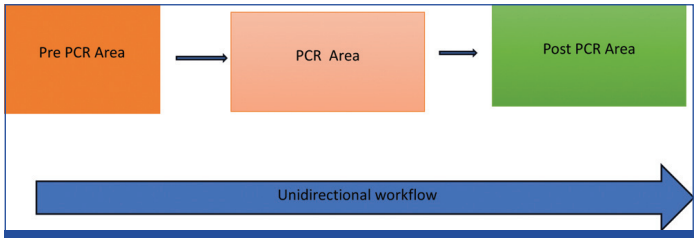
A molecular laboratory is usually divided into two major areas: the Wet Lab and the Dry Lab. The wet laboratory handles biological samples and is usually subdivided into:

- Sample receiving area
- Salts, buffer, and gel preparation area
- Pre-PCR area
- PCR setup area
- Post-PCR area

The dry lab is used for data analysis, data storage, and reporting. The pre-PCR areas should maintain positive atmospheric pressure to prevent the entry of contaminants and aerosols. The PCR and post-PCR working areas should maintain negative atmospheric pressure to prevent the escape of PCR product aerosols into surrounding

areas. Proper ventilation systems should also be available in the PCR and post-PCR areas [7].

The most important principle in designing a molecular pathology laboratory is that the workflow should be unidirectional - i.e., Pre-PCR → PCR → Post-PCR [Table/Fig-1]. Consumables and Personal Protective Equipment (PPE) that have been introduced into the post-PCR room should never be taken back into the pre-PCR room without thorough decontamination [8]. Ideally, technologists who have worked in the post-PCR area should not return to work in the pre-PCR section. However, this may not always be practical in a busy molecular pathology laboratory. If one must move against the unidirectional flow, PPE-including lab coats and gloves-must be changed. Gloves are essential as they prevent Deoxyribonucleic acidases (DNases) and Ribonucleic acidases (RNases) present in human skin or sweat from contaminating clinical specimens or PCR mixes [8].



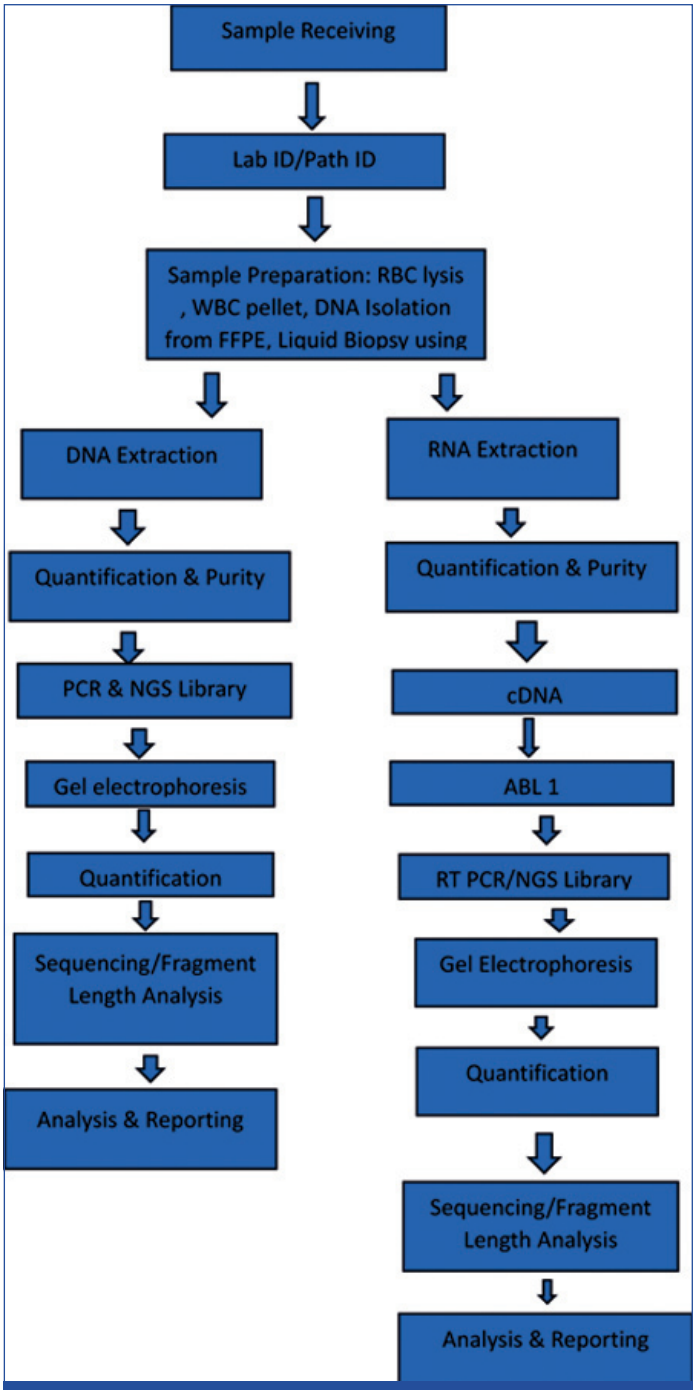
[Table/Fig-1]: Work flow of Lab.

The pre-PCR areas include the sample preparation room and reagent preparation room. Ideally, four separate rooms are recommended: the sample preparation room, reagent preparation room, PCR room, and post-PCR room. Post-PCR areas may not be necessary in molecular pathology laboratories performing only RT-PCR, as post-PCR data analysis is not required. However, post-PCR areas are essential in setups that include NGS [9].

The [Table/Fig-2] illustrates the normal workflow of a molecular pathology laboratory. The reagent and buffer preparation room is used for preparing reagent stocks, buffers, and gels. It is also used to aliquot stock reagents into small usable portions [9]. This room typically contains instruments such as a Potential of Hydrogen (pH) meter, weighing balance, and magnetic stirrer with a hot plate. Other common equipment includes a horizontal gel electrophoresis unit, oven, gel documentation system, ethidium bromide dye, DNA ladder, salts, Milli-Q water system, water bath, and autoclave. The reagent preparation room must remain free of biological materials such as DNA, Ribonucleic Acid (RNA), and PCR products to prevent contamination of reagents and buffers [9].

The sample preparation area includes kits for DNA, RNA, and cell-free DNA extraction, such as Promega Rapid Sample Concentrator (RSC), Maxwell, Qiagen, and Kingfisher systems. Other necessary instruments include a Nanodrop, Qubit, and Bioanalyzer for DNA and RNA quantification and quality checks. Essential equipment such as centrifuges, mini-centrifuges, vortex mixers, dry baths, biosafety hoods, pipettes, -80°C deep freezers, and 4°C refrigerators are also required [9].

The PCR area is used for PCR reagent storage, master mix preparation, and NGS library preparation. This area must remain free of amplicons at all times. It should have positive air pressure, restricted entry, and controlled movement. Only authorised staff should be allowed entry, with separate PCR workstations equipped with UV lights. A dedicated area for template addition should be provided with air-lock doors. Master mixes must be stored in airtight containers, and the laboratory temperature should be maintained between 18-22°C. Equipment in this area includes master cyclers for Complementary DNA (cDNA) synthesis and NGS library preparation, PCR hoods for master mix and cDNA preparation, liquid handling systems, quantification and quality control tools for NGS workflows,



[Table/Fig-2]: Molecular pathology lab workflow.
RBC: Red blood cells; WBC: White blood cells; FFPE: Formalin-fixed, Paraffin-embedded ADL1 - ABL proto-oncogene 1; Non-receptor tyrosine kinase

dedicated pipette sets, mini centrifuges, vortex mixers, TE buffers, and plate centrifuges [9].

The post-PCR area houses thermal cyclers for amplification and any equipment necessary for post-PCR analysis. To maintain environmental control, this area should be equipped with air-lock doors. Instruments placed here include thermal cyclers (for PCR, library preparation, RT-PCR, and digital PCR), pipettes, magnetic stands, sequencers (including Sanger and NGS systems), -20°C and 4°C storage units, dry baths, vortex mixers, and centrifuges [9].

Ideally, the NGS area should be a separate space with strict movement control, accessible only to designated personnel. It should include a dedicated area for cleanup, library quantification, and loading. Master mixes must be stored in airtight containers, and the temperature should be maintained at 18-22°C. Protection from vibration, temperature fluctuations, and humidity is crucial, as sequencers are highly sensitive to vibration-from nearby instruments, door movements, or unstable benches [10].

Excessive heat can affect the performance of the sequencer. There should be adequate cooling capacity in the room where the instrument is housed, as the sequencer can become overheated and generate heat during operation. Direct sunlight can also impact the instrument; therefore, it is recommended to use screens or shading during operation. Humidity can likewise affect instrument function, and it should be maintained within the range of 20-60% for optimal performance [10].

Additional equipment required for NGS testing, apart from the sequencer, includes nucleic acid quantifiers such as the Qubit fluorometer and Nanodrop fluorometer. For assessing nucleic acid quality, instruments such as the Agilent Bioanalyzer or TapeStation are used to measure DNA fragment sizes, library sizes, or insert sizes. Both sets of instruments are essential, as the quality and quantity of DNA available for sequencing are critical quality parameters. The Bioanalyzer is more economical but requires the use of a chip to process up to 12 samples at a time. The TapeStation, on the other hand, uses strip tubes, offering greater flexibility in the number of samples analysed. When processing only a few samples, the TapeStation may be more cost-efficient, considering the price of consumables [11].

For FISH and karyotyping, a separate room is required for slide preparation, along with a dark room equipped with a FISH microscope for analysis and reporting of FISH and karyotyping slides.

Information Technology Considerations

Information Technology (IT) support is essential for NGS at every step of the workflow. IT personnel should be consulted early in the planning phase. Their support is required for instrument setup, data storage, data streaming, and software installation [12].

Data storage is a crucial aspect of molecular laboratory design, as sequencing generates large volumes of data that must be securely stored and backed up. Several options are available for data backup and storage. One option is the use of external hard drives, which require minimal involvement from the IT department. However, this approach has drawbacks, including the physical space needed for storage and the risk of virus transmission between devices, which can compromise data integrity and retrieval [12].

The most commonly used option is cloud storage. Different sequencing platforms provide their own cloud services. For instance, Illumina offers BaseSpace, a proprietary cloud-based storage and analysis platform. Data streamed from the instrument can be stored, analysed, and shared with authorised users. Adequate data storage capacity is typically available; for example, BaseSpace provides 1 Terabyte (TB) of storage, with additional capacity available for purchase. In institutions with well-developed local file storage infrastructure or data security concerns regarding external streaming, laboratories may instead use local servers, scalable clusters, or custom-designed storage systems for NGS data analysis [13].

Data Streaming

Data streaming is an important component of sequencing workflows, allowing laboratories to upload sequence data for storage and sharing with various databases. A critical requirement during data streaming is the removal of patient identifiers before uploading any sequence data [13]. Data streaming can expose the laboratory network to security breaches. This risk can be minimised by implementing one-way data flow, using a dedicated network for data streaming, and employing Secure File Transfer Protocol (SFTP) systems. Networks used for data streaming must be capable of handling large data volumes. Platforms like Illumina's BaseSpace and other cloud services enable real-time data uploads, which are more manageable and efficient [13].

Ventilation

Air circulation between PCR rooms is a major potential source of contamination. Air pressure control is therefore critical for contamination prevention. Positive pressure means that the pressure inside the room is higher than outside, preventing the entry of unwanted particles. Negative pressure, conversely, allows air to enter the room but prevents it from escaping, thus containing contaminants within. Accordingly, the Pre-PCR room should be maintained at positive pressure, while the Post-PCR room should be maintained at negative pressure [14].

Avoiding Contamination

Ultraviolet (UV) radiation helps eliminate contaminating DNA that can arise during the addition of DNA templates. UV irradiation is an effective technique for sterilising the Pre-PCR laboratory. Most work surfaces should be equipped with ultraviolet lights [15]. Safety precautions for working with UV light must be clearly explained to laboratory personnel and strictly implemented.

UV irradiation works by cross-linking with thymidine residues in DNA [15]. Therefore, sequence specificity plays a role in determining its effectiveness. DNA in a dry state is less sensitive to UV irradiation; thus, dry surfaces are less effectively decontaminated by UV light. A byproduct of UV irradiation is ozone, which must be efficiently removed through proper ventilation. Ozone buildup reduces the efficacy of UV irradiation by depositing on UV bulbs [15].

Another important measure to prevent the transfer of PCR products from the Pre-PCR area to the Post-PCR area is to maintain separate supplies and instruments for each section. Laboratory personnel should wear distinct gloves and lab coats in each area.

Reagents and solutions should be prepared using Type I water, defined by strict pH, ionic, and contamination specifications [15]. All reagents should be stored as small aliquots to minimise repeated sampling from the same container. The use of negative controls (e.g., water or DNA-free buffers) at the end of each run helps assess cross-contamination and verify the integrity of PCR reactions [16].

The most common source of contamination is amplified DNA from previous positive reactions, which may occur when reaction tubes are opened after amplification. To minimise this risk, PCR tubes should be microcentrifuged before opening. Cross-contamination of pipettes and aerosol generation can be avoided by using aerosol-barrier tips for all PCR steps, especially during Pre-PCR work.

Cleaning the workspace before and after each procedure with 10% bleach followed by 70% ethanol is another essential practice [17]. Periodic swab testing of laboratory surfaces should be performed to detect environmental contamination. Another useful quality control measure is to monitor positivity rates for specific tests-an unexpected increase may indicate contamination [16].

Laboratory Personnel

For efficient functioning of a molecular pathology laboratory, well-trained personnel are essential. As molecular pathology is still an evolving field, there are no universally established criteria for personnel qualifications and training. However, several professional bodies, such as the Association for Molecular Pathology (AMP) and Clinical Laboratory Improvement Amendments (CLIA), have outlined regulations and recommendations for molecular laboratories [17].

According to CLIA guidelines, the laboratory director must be a licensed physician (MD) or hold a doctoral degree in biological, chemical, physical, or medical sciences, with a minimum of two years of experience managing a high-complexity laboratory. The director is responsible for the overall operation and administration of the laboratory. The technical supervisor is accountable for maintaining quality standards by selecting and validating methods and instruments, as well as documenting the competency of laboratory personnel [17]. All laboratory staff should possess

Good Laboratory Practice (GLP) Certification, which is required for participation in clinical trials and related projects.

The training period for laboratory personnel varies depending on their educational background and the range of tests performed in the laboratory. Given the diversity of molecular techniques-especially those involving NGS-it may be necessary to train certain technicians for specific procedures [18].

It is generally recommended that at least two staff members specialise in training and mastering sequencing protocols. If a laboratory already has a technician proficient in NGS sequencing, training may involve the trainee observing the procedure performed by the experienced technician [18]. Once the trainer confirms that the trainee is competent, the trainee performs the procedure independently under immediate supervision to ensure accuracy.

Ideally, a trainee should perform each procedure at least three times under supervision to achieve competency [18]. However, this may vary depending on laboratory policies and procedural complexity. Trainees may also be evaluated using blinded samples to assess the accuracy of their results. Annual competency testing is essential, and all results must be properly documented [18].

Equipment

Based on the laboratory profile and the types of tests performed, equipment requirements may vary. A detailed inventory is essential. Most molecular pathology laboratory instruments were initially designed for research purposes and later adapted for clinical use. For low-volume laboratories, nucleic acid extraction can be performed manually [19]. However, for high-volume laboratories, automated nucleic acid extraction systems are often more feasible and efficient. A list of essential equipment required for a molecular pathology laboratory is shown in [Table/Fig-3].

List of equipment and appliances
-20°C Freezer
+4°C Refrigerator
Automated Pipetting System
Class II Biosafety cabinet
PCR cabinet
Dry Heat block &/or water bath
Spectrophotometer
Thermal cycler
Electrophoresis system
Gel Imaging System (ultraviolet light based or computed)
Vortex mixer
Refrigerated centrifuge (minimum 5000 rpm)
Microcentrifuge (minimum 15000 rpm for 1.5 mL tube)
Magnetic stirrer
Analytical Balance
pH meter
Microwave
Relevant plastic and glass instruments
-80°C freezer
Ice machine
DNA sequencer
Water deionizer system
Hybridizer
Fume hood

[Table/Fig-3]: List of equipment in molecular pathology lab.
Rpm: Rotations per minute

Automated systems are increasingly being incorporated into molecular laboratories, as they significantly reduce Turnaround Time (TAT), minimise human error, and save technician time. It is essential to establish service and maintenance contracts for all major equipment.

Maintenance procedures are usually defined by the manufacturer and may include periodic temperature checks of PCR wells in thermal cyclers and calibration of pipettes. If manufacturer guidelines are unavailable, the laboratory should develop its own maintenance protocols in consultation with the manufacturer [19].

Quality Assessment

Quality assessment focuses on the analytic validity of the testing process to ensure the accuracy and reliability of test results. Quality Control (QC) and Quality Assurance (QA) are essential at every stage of molecular testing [20]. The CLIA state that "The laboratory must establish and follow written QC procedures for monitoring and evaluating the quality of the analytic testing process of each method to assure the accuracy and reliability of patient test results and reports" [20].

Specific requirements include adherence to the manufacturer's instructions for instrument operation and test performance, maintaining an up-to-date procedure manual, performing and documenting QC results, keeping detailed records of all QC activities, and verifying performance specifications [21]. QC procedures should be designed to detect, prevent, and minimise errors throughout the testing process [21].

The key components of quality assessment and control include:

- Test validation-verification of test performance and characteristics.
- Analytic validity assessment.
- Use of internal and external controls.
- Preventive equipment maintenance.
- Participation in quality assessment programs.
- Training and proficiency testing.
- Routine laboratory testing and review [22].

Enrollment in External Quality Assurance (EQA) programs is a crucial part of QA activities, and regular participation is recommended. Molecular laboratories should also seek accreditation with recognised bodies, as accreditation ensures compliance with International Organisation for Standardisation (ISO) standards and periodic assessment by independent authorities [22].

Immunohistochemistry (IHC)

Immunohistochemistry has long been a part of routine histopathology diagnostic services. It also falls within the scope of molecular testing, especially with the advent of immunotherapy and the use of Programmed Death-Ligand 1 Immunohistochemistry (PD-L1 IHC) (with its various clones) and Mismatch Repair Immunohistochemistry (MMR-IHC). The presence of well-trained technicians, competent in their techniques, along with the judicious selection and interpretation of markers, is essential for ensuring accurate results [23].

FISH and Karyotyping

In situ hybridisation (ISH) is similar to IHC; however, unlike IHC, ISH detects nucleic acid sequences rather than proteins. FISH and Karyotyping each have their own specific requirements within a molecular laboratory.

Trained laboratory personnel are essential for performing these procedures. Appropriate infrastructure is also required, including a designated technical room for slide preparation and a dark room for microscopy and image interpretation.

Essential equipment for a FISH/Karyotyping laboratory includes:

- FISH microscope
- Hybridizer

- Bench-top centrifuge
- Reagents (e.g., 25X SSC)
- Probes (e.g., ZytoVision, MetaSystems)

Temperature and humidity control are critical for both FISH and Karyotyping procedures. Dehumidifiers may be necessary, especially in coastal regions. Software for image analysis and interpretation is usually integrated into the system {e.g., Applied Spectral Imaging (ASI) software, IKAROS, ISIS, etc.}. A -20°C freezer is also required for storing FISH slides, as they tend to lose fluorescence at room temperature [24].

CONCLUSION(S)

With the increasing need to establish molecular laboratories for patient diagnosis, treatment, and prognostication, this review aims to provide a fundamental overview of the principles and requirements involved in setting up a molecular pathology laboratory. The necessary equipment and quality assurance measures for ensuring valid and accurate results have been discussed, along with the training and educational requirements for technical staff and the information technology needs, including laboratory information systems essential for modern molecular diagnostic workflows.

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PARTICULARS OF CONTRIBUTORS:
1. Professor, Department of Pathology, Saveetha Medical College and Hospital, Chennai, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Anand Mohanraj,
D1, Praveen Viraja Apartments, Valluvar Salai, Arumbakkam, Chennai-600106, Tamil Nadu, India.
E-mail: dranandmohanraj@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jul 06, 2025
- Manual Googling: Aug 14, 2025
- iThenticate Software: Aug 18, 2025 (8%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jul 03, 2025**
Date of Peer Review: **Jul 16, 2025**
Date of Acceptance: **Aug 20, 2025**
Date of Publishing: **Feb 01, 2026**