Jurnal Iman dan Spiritualitas
eISSN: 2775-4596, Vol 6, No 3, 2026, pp. 953-968
https://doi.org/10.15575/jis.v6i3.56012

Legal Aspects of Automatic Equipment in Medical Laboratories

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Suggested Citation:

Aprianda, Adi Darma; Subhan, Mochamad; Lany, Arman. (2026). Legal Aspects of Automatic Equipment in Medical Laboratories. *Jurnal Iman dan Spiritualitas*, Volume 6, Number 3: 953–968. https://doi.org/10.15575/jis.v6i3.56012

Article's History:

Received February 2026; *Revised* May 2026; *Accepted* August 2026.

Abstract:

The advancement of technology in medical laboratory equipment has created legal challenges due to regulatory lag. Errors arising from the use of such technology may jeopardize patient safety, given the vital role of laboratory test results in diagnostic accuracy. According to ISO 15189:2022, laboratories are required to implement a series of procedures, ranging from equipment selection to the termination of its operation, as part of quality assurance efforts. Errors within these processes may lead to equipment malfunction and trigger medical disputes. Since the equipment itself is inanimate, legal responsibility lies with the individual or legal entity managing the laboratory. This retrospective normative legal study collects primary and secondary legal materials along with their legal subjects, analyzed through qualitative descriptive methods to assess the legal dimensions in reference to the principles of justice, the legal theories of lex naturalis and lex aeterna, as well as Montesquieu's concept of law. In principle, the comparative analysis between the legal framework and these legal concepts reveals a consistent alignment. The legal perspective on automated laboratory equipment thus reflects the underlying principles, theories, and legal concepts applied.

Keywords: automatic equipment; health law; medical laboratory.

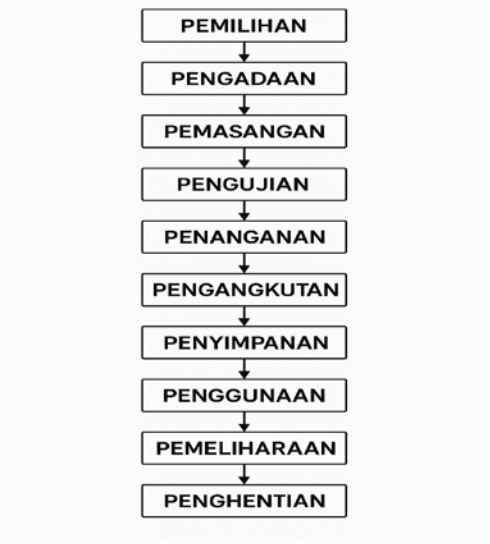
INTRODUCTION

Technological developments consistently have both direct and indirect impacts, both positive and negative, and significantly influence the attitudes, actions, and mentality of every member of society. From a criminological perspective, technology can be considered a criminogenic factor, that is, a factor that triggers a person's desire to commit crimes or facilitates their commission (Hamid, 2023). Technology also plays a crucial role in the medical world. The rapid development of medical technology has not been matched by developments in the law, resulting in many legal issues in the health sector that require careful consideration in determining regulatory solutions. Technology in medical laboratory equipment is no exception. Wilson explains the development of medical laboratory technology as follows: "The progression of medical laboratory technology has been closely tied to technological breakthroughs. Automated analyzers have considerably heightened the speed

and accuracy of diagnostic tests (Wilson et al., 2022)." Medical laboratory equipment technology is being progressively developed, with the goal of reducing staff involvement in the clinical specimen examination process, with the hope of also reducing random errors due to human error. Generally, measurement results are only estimates or approximations of a value because measurement activities contain both systematic and random errors. The true value is never known, but it is believed to be within the measured range. However, the technology of medical laboratory equipment is one of the main factors that can potentially cause errors. As explained by Westgard, Barry & Hunt (1981), the definition of possible sources of error depends on the analytical method and instrumentation used (Chan, 2025). Medical laboratories play a vital role in the world of medicine. As outlined in Article 527 Paragraph (1) of Government Regulation of the Republic of Indonesia Number 28 of 2024, which states that medical laboratories carry out the function of examining clinical specimens with the aim of obtaining information about patient health related to establishing a diagnosis, management, disease monitoring, prognosis, and prevention of diseases that can affect individual health (Wiradirja et al., 2024). Due to this vital function, examination errors that occur in medical laboratories have a high potential to become disputes that lead to repressive legal efforts.

The International Organization for Standardization (ISO) requires that laboratories have a process for the selection, procurement, installation, acceptance testing (including acceptance criteria), handling, transportation, storage, use, maintenance, and decommissioning of equipment, to ensure proper equipment function and prevent contamination or damage. The stages in the process, as outlined in ISO 15189:2022, when sequenced, will appear as shown in the following diagram:

Figure 1. Process Stage Chart of Equipment in Medical Laboratory



Source: ISO 15189:2022

The long and complex series of processes related to medical laboratory equipment actually involves many parties. Any process that is not carried out according to established regulations and/or standards has the potential to reduce/change the working method and function of the equipment itself, thus causing errors in the clinical specimen examination process in medical laboratories and resulting in inaccurate final results. Errors in clinical specimen examination results in medical laboratories caused by the use of technology integrated into methods and instrumentation can indirectly endanger patient safety (Tziakou et al., 2023). This is because laboratory results are one of the important medical information used for various purposes, as stated in Article 527 Paragraph (1) of Government Regulation of the Republic of Indonesia Number 28 of 2024 which states that medical laboratories carry out the function of examining clinical specimens with the aim of obtaining information about patient health related to establishing a diagnosis, management, monitoring disease, prognosis, and prevention of diseases that can affect individual health (Fitra et al., 2025).

Patients may experience safety threats in the form of incorrect decision-making, for example, laboratory-based diagnostic errors. Incorrect specimen examination results in medical laboratories can result in misdiagnosis that endanger patient safety (Alharbi et al., 2025). Medical errors often result in medical disputes

and drag medical laboratories into legal proceedings to resolve these disputes. A medical dispute can be defined as a disagreement that arises between a patient or their family and a healthcare professional or hospital/healthcare facility. These disputes typically arise from the outcome of the healthcare service or treatment provided, regardless of the process involved. Therefore, laboratory equipment itself is not a legal entity, as defined by Kelsen in Salim and Nurbani (2019):

> *"Humans are the subjects of rights and obligations. However, because persons are not only humans but also other entities, such as business entities, city governments, and states, persons are defined as holders of rights and obligations. Therefore, those who can function as holders are not only humans but also other entities* (Salim & Nurbani, 2019)*."*

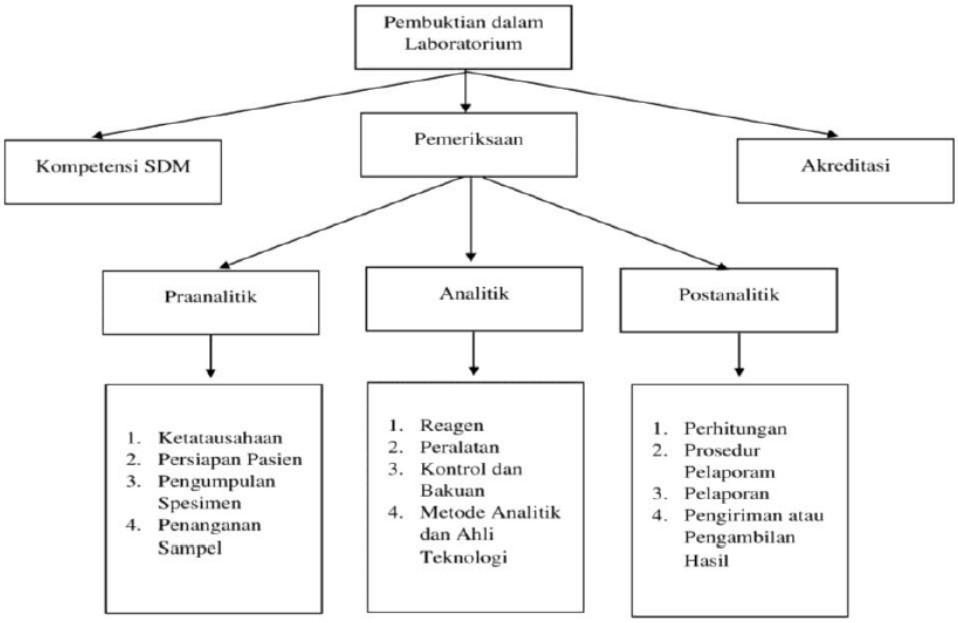
Therefore, humans and/or other entities involved in legal relationships and/or legal events can be positioned as subjects of legal efforts, both preventive (preventive) and repressive (punishment). Legal relationships, also known as the law of relationships, are conceptualized as bonds or ties related to legal interests (Dempsey et al., 2023). According to Philipus M. Hadjon, legal protection is the protection of dignity and honor, as well as the recognition of human rights held by legal subjects based on legal provisions from arbitrariness or as a collection of regulations or rules that will be able to protect one thing from another (Andriawan & Ali, 2024). There are two forms of protection, namely: (1) preventive protection and (2) repressive protection.

In determining the legal subject in a concrete legal event, it must be based on the principle of justice as contained in the 2nd principle of Pancasila, namely just and civilized humanity. According to Magnis Suseno in Prasetyo & Purnomosidi (2019), legal development can only maintain the quality of human beings if it is based on an attitude of respect for humans, recognizing the equal position of humans, not treating humans as objects of planning, never sacrificing one party for the benefit of another party and not buying progress by causing misery to others (Prasetyo & Purnomosidi, 2019). Thomas Aquinas defines justice as an equality that must be received by someone according to their portion (Porter, 2015). In line with the meaning of justice, it is also stated in the explanation of Article 6 Paragraph (1) Letter g of the Republic of Indonesia Law Number 12 of 2011 concerning the Formation of Legislation, that what is meant by "principle of justice" is that every Content of Legislation must reflect proportional justice for every citizen (Anggraeni & Moh. Saleh, 2024). In the Middle Ages, the concept of justice more broadly became St. Augustine's thought in his legal theory (Blondel, 2023). The basis of Augustine's thinking on law and order is the "eternal law" (lex aeterna), namely the eternal plan of the world, reason and divine will. In the divine order, respect for the natural order of God's creation is written in the human soul as "natural law" (lex naturalis). According to St. Augustine, lex aeterna is also the unchangeable norm or standard of all human or temporal laws (Alimi, 2024). Therefore, nothing can be called legitimate or just in the moral sense that is not derived from lex aeterna, the source of all legitimacy and justice.

The state, as a policy maker, needs to take preventative measures to minimize the potential for medical disputes. This is to ensure patient safety and security when using medical laboratory services. The Indonesian government has attempted to establish a legal framework to ensure order in the practice of medical laboratory services. One such effort is to require all medical laboratories to be accredited using standards established by the Ministry of Health. Regulations governing laboratory accreditation are outlined in Minister of Health Regulation Number 34 of 2022 concerning Accreditation of Public Health Centers, Clinics, Health Laboratories, Blood Transfusion Units, Independent Doctors' Practices, and Independent Dentists' Practices (Hertawaty Sijabat & Widjaja, 2025). A derivative of this regulation, specifically addressing the standards that must be met in medical laboratory operations, is stipulated in Decree of the Minister of Health of the Republic of Indonesia Number HK.01.07/Menkes/2011/2022 concerning Health Laboratory Accreditation Standards (Qolbi, 2024). The standards contained in the accreditation also emphasize laboratory efforts related to patient safety, followed by facility and safety management and establishing criteria for quality health laboratory examinations.

Previous research conducted by Rahmania, Kuntjoro & Suroto in 2019 entitled "Proving the Accuracy and Legal Accountability of Clinical Laboratory Examination Results Using Automated Tools" has discussed the matter of proving the accuracy of laboratory examination results using automated tools in detail and systematically (Rahmania et al., 2019). The proof scheme in the form of variables presented in a structured manner in the form of a chart, followed by an in-depth description as a discussion of each variable proves that the research was truly carried out comprehensively. The variables in the proof scheme also included an assessment of the code of ethics, professional standards and service standards, making this research can be used as a reference in professional ethics hearings to find evidence in legal proceedings.

Figure 2. Legal Evidence Scheme Diagram [14]



Source: SOEPRA Journal of Health Law 5, no. 2, 2019

From a broader perspective, previous research has comprehensively discussed only the processes occurring within the medical laboratory itself. Therefore, if no evidence of violations of the code of ethics, professional standards, or service standards is found in the legal process, no other parties can be considered legal subjects. This situation causes patients, both victims and the injured party in the dispute, to feel they have not received the justice they desire. Furthermore, this research has provided little discussion of preventive legal measures to ensure patient safety when receiving services in medical laboratories. Therefore, further research is needed to address the legal aspects more broadly, particularly preventive legal measures across all processes related to automated equipment in medical laboratories, as will be done in this study.

The analysis of the legal framework on the aspect of legal subjects and their formation refers to the definition of justice according to experts and medieval legal theories, the ideas of St. Augustine and the legal concept once stated by Montesquieu and rewritten by Muljono (2023), that good lawmakers must prioritize crime prevention over punishment (Muljono, 2023). This study aims to obtain an overview of the suitability of the legal framework related to automated equipment in medical laboratories, seen from the aspects of the proportion of legal subjects and the proportion of the objectives of legal formation to the principle of justice, the theories of lex naturalis and lex aeterna, and Montesquieu's concept of legal formation (Hösle, 2025). Based on the researcher's search, no similar research has been found, so this study was compiled as an extension and update of previous research.

METHOD

The research conducted is a retrospective normative legal study using qualitative descriptive methods (Colcelli et al., 2023). This means that the object of the research is the current legal framework, which contains legal sources relevant to the problem. Referring to the civil law system used in Indonesia, this means that the primary legal source used is positive law or written law. Therefore, the data collected consists of materials contained in these primary legal sources and their data subjects. Other data consists of secondary legal sources that will serve as a reference for understanding and analyzing the research object. To understand the relationship between legal science and positive law (in this case, written law, as it concerns normative legal research; or perhaps also recorded law), an examination of the elements of law or gegevens van het recht is necessary. For normative legal research that uses secondary data as its source, sampling procedures are not necessary (Negara, 2023). This is because, in general, secondary data in the legal field each has its own unique qualities that cannot be replaced.

RESULTS/FINDINGS

The Roman-German legal system is the system used in Indonesia. In Indonesia, it seems to be better known as the Civil Law System (Wardhani et al., 2022). Talking about the sources of law in the Roman-German legal system or civil law system, the very large role of human-made law (enacted law) or what will hereinafter be called statutory law or written law immediately appears (Baini, 2025). The government defines justice as stated in Article 6 Paragraph (1) Letter g of the Republic of Indonesia Law Number 12 of 2011 concerning the Formation of Legislation, that what is meant by "the principle of justice" is that every Content of Legislation Material must reflect proportional justice for every citizen (Chandra et al., 2022).

This research is a form of control over the legal framework established by the government, ensuring that the integrity of justice, as defined by the government, is maintained. One of the control standards used is a concept proposed by Montesquieu. Montesquieu stated that good lawmakers should prioritize crime prevention over punishment (Thorburn, 2024). However, more broadly, the basic human nature of thinking can also naturally and abstractly assess existing laws. This is in line with the eternal legal theory of lex aeterna and lex naturalis, the idea of St. Augustine. Lex naturalis according to St. Augustine is the conscious participation of rational humans in lex aeterna (Prieto López & Cendejas Bueno, 2023). The basic teachings of lex naturalis can be understood by all who are capable of correct thinking, no matter how corrupted they are because God wrote lex naturalis in the human heart. Augustine stated that "Divine" wisdom is universal law. Therefore, to understand and appreciate the deeper meaning of this "universal law" (Donato, 2023). We must realize that "law" and "order" are two terms that are correlated and often synonymous.

Categorization based on data subjects is carried out when the research involves many individuals who are data subjects. This is especially true if these subjects have certain characteristics such as gender, age, education level, and so on. Because qualitative research data has many gaps to be categorized, the more categorizations there are, the more possible relationships between the data in the study (Bouncken et al., 2025). The research data is grouped into four data variables: Primary Preventive Legal Materials, Primary Repressive Legal Materials, Secondary Legal Materials, and Legal Subjects. In the case of Legal Subjects, the researcher limits these categories based on the identification results of the Primary Preventive Legal Material data collected.

Filling out the data record sheet begins by assigning a code to each piece of data collected. As a result, the researcher has collected 17 pieces of Primary Legal Material for Prevention (codes A1–A17), 9 pieces of Primary Legal Material for Punishment (codes B1–B9), 12 pieces of Secondary Legal Material, and 4 pieces of Legal Subject.

Table 1. Primary Preventive Legal Materials
Source: Secondary data

Kode*	Bahan Hukum Bersifat Preventif (Pencegahan)
A1	Pasal 28D Ayat (1) Undang-Undang Dasar Negara Republik Indonesia tahun 1945
A2	Pasal 28H Ayat (2) Undang-Undang Dasar Negara Republik Indonesia tahun 1945
A3	Pasal 306 Ayat (3) Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 tentang Kesehatan
A4	Pasal 138 Ayat (1), Ayat (3), Ayat (4), dan Ayat (6) Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 tentang Kesehatan
A5	Pasal 140 Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 tentang Kesehatan
A6	Pasal 128 Huruf b Peraturan Pemerintah Nomor 28 Tahun 2024 tentang Peraturan Pelaksanaan Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan
A7	Pasal 677 s.d 683 Peraturan Pemerintah Nomor 28 Tahun 2024 tentang Peraturan Pelaksanaan Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan
A8	Peraturan Menteri Kesehatan Republik Indonesia Nomor 1191/MENKES/PER/VIII/2010 tentang Penyaluran Alat Kesehatan
A9	Peraturan Menteri Kesehatan Republik Indonesia Nomor 4 Tahun 2014 tentang Cara Distribusi Alat Kesehatan yang Baik
A10	Peraturan Menteri Kesehatan Republik Indonesia Nomor 42 tahun 2015 tentang Izin dan Penyelenggaraan Praktik Ahli Teknologi Laboratorium Medik
A11	Peraturan Menteri Kesehatan Republik Indonesia Nomor 54 Tahun 2015 tentang Pengujian dan Kalibrasi Alat Kesehatan
A12	Peraturan Menteri Kesehatan Republik Indonesia Nomor 20 Tahun 2017 tentang Cara Pembuatan Alat Kesehatan dan Perbekalan Kesehatan Rumah Tangga yang Baik
A13	Peraturan Menteri Kesehatan Republik Indonesia Nomor 62 Tahun 2017 tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik *In Vitro* dan Perbekalan Kesehatan Rumah Tangga
A14	Peraturan Menteri Kesehatan Republik Indonesia Nomor 15 Tahun 2023 tentang Pemeliharaan Alat Kesehatan di Fasilitas Pelayanan Kesehatan
A15	Keputusan Menteri Ketenagakerjaan Republik Indonesia Nomor 170 Tahun 2018 tentang Penetapan Standar Kompetensi Kerja Nasional Indonesia Kategori Aktivitas Kesehatan Manusia dan Aktivitas Sosial Golongan Pokok Aktivitas Kesehatan Manusia Bidang Teknologi Laboratorium Medik
A16	Keputusan Menteri Kesehatan Republik Indonesia Nomor HK.01.07/Menkes/2011/2022 tentang Standar Akreditasi laboratorium Kesehatan.
A17	Keputusan Direktur Jenderal Pelayanan Kesehatan Nomor Hk.02.02/D/632/2023 tentang Instrumen Survei Akreditasi Laboratorium Kesehatan

**Kode unik masing-masing data diberikan untuk kemudahan identifikasi*

Table 2. Repressive Primary Legal Materials

Kode*	Bahan Hukum Bersifat Represif (Penghukuman)
B1	Pasal 242 Kitab Undang-Undang Hukum Pidana
B2	Pasal 359 Kitab Undang-Undang Hukum Pidana
B3	Pasal 360 Kitab Undang-Undang Hukum Pidana
B4	Pasal 1365 Kitab Undang-Undang Hukum Perdata
B5	Pasal 1366 Kitab Undang-Undang Hukum Perdata
B6	Pasal 1367 Kitab Undang-Undang Hukum Perdata
B7	Pasal 1371 Kitab Undang-Undang Hukum Perdata
B8	Pasal 474 & 475 Undang-Undang Republik Indonesia Nomor 1 Tahun 2023 tentang Kitab Undang-Undang Hukum Pidana
B9	Pasal 306 Ayat (3) Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 tentang Kesehatan

** Kode unik masing-masing data diberikan untuk kemudahan identifikasi*

Source: Secondary data

Table 3. Secondary Legal Materials

No	Judul	Tahun	Penulis
1	Seri Hukum Kesehatan: Mediasi Nonlitigasi Terhadap Sengketa Medik dengan Konsep Win-Win Solution	2012	Ratman, D.
2	Kapita Selekta Perkembangan Hukum Pidana di Indonesia Edisi Pertama	2018	Muntaha
3	Pengantar Ilmu Hukum	2019	Salim, HS. & Nurbani, E.S.
4	Membangun Hukum Berdasarkan Pancasila	2019	Prasetyo, T., & Purnomosidi, A.
5	Teknik Pembuatan Akta Badan Huikum dan Badan Usaha di indonesia	2019	Moechtar, O.
6	Ilmu Hukum	2021	Rahardjo, S.
7	Teori-Teori Hukum	2022	Atmoko, D.
8	*Medical Laboratories – Requirements for Quality and Competence (ISO 15189:2022)*	2022	ISO
9	Asas-Asas Hukum Kontemporer	2023	Nor, A.
10	Hukum Kesehatan	2023	Siregar, R.A.
11	Pengantar Teori Kriminologi	2023	Muljono
12	Teori Hukum: Dari Teori Hukum Klasik hingga Teori Hukum Kontemporer Edisi Pertama	2024	Mardani

Source: Secondary data

Table 4. Legal Subjects

Kode*	Tahap Proses	Subjek Hukum	Sumber Hukum**
C1	Pemilihan	- Pimpinan Laboratorium	A16
C2	Pengadaan	- Perusahaan Alat Kesehatan	A12
		- Penyalur Alat Kesehatan	A8, A9, A13
		- Pimpinan Laboratorium	A16
C3	Pemasangan	- Perusahaan Alat Kesehatan	A12
		- Penyalur Alat Kesehatan	A9
C4	Pengujian	- Pimpinan Laboratorium	A11
		- Perusahaan Alat Kesehatan	A12
		- Petugas laboratorium yang kompeten & berwenang	A16
C5	Penanganan	- Perusahaan Alat Kesehatan	A12
		- Penyalur Alat Kesehatan	A9
C6	Pengangkutan	- Perusahaan Alat Kesehatan	A12
		- Penyalur Alat Kesehatan	A9
C7	Penyimpanan	- Perusahaan Alat Kesehatan	A12
		- Penyalur Alat Kesehatan	A8, A9
		- Pimpinan Laboratorium	A17
		- Petugas laboratorium yang kompeten & berwenang	A15
C8	Penggunaan	- Perusahaan Alat Kesehatan	A12
		- Petugas laboratorium yang kompeten & berwenang	A10, A15, A16
C9	Pemeliharaan	- Perusahaan Alat Kesehatan	A12
		- Penyalur Alat Kesehatan	A9
		- Petugas laboratorium yang kompeten & berwenang	A15
C10	Penghentian	- Perusahaan Alat Kesehatan	A12
		- Pimpinan Laboratorium	A17

** Kode unik masing-masing data diberikan untuk kemudahan identifikasi*
***Sumber hukum sesuai data pada Tabel 1.*

Source: Secondary data

DISCUSSION / ANALYSIS

This discussion outlines two fundamental aspects of the legal construction related to medical laboratory equipment: the proportion of legal subjects in the equipment management chain and the objectives of the legal formation inherent in the existing regulatory framework. The perspective used is a norm-based and function-based analysis, so that each stage in the laboratory equipment life cycle is not only read as a technical procedure, but also as an arena for the distribution of legal responsibility, authority, and accountability (Hejnowicz & Rudd, 2017). Through this approach, it can be traced how the roles of various legal subjects—laboratory management, laboratory personnel, medical device companies, and medical device distributors—are constructed proportionally to prevent legal, technical, and ethical risks that can arise from the use of medical devices in laboratory services.

The first stage that must be reviewed is the tool selection process (code C1), which positions the laboratory leader as a strategic decision-maker. Within the framework of health laboratory accreditation standards, the laboratory leader has full responsibility for ensuring that the selected tool is relevant to the type of examination to be performed and meets national and international quality standards (A16) (White et al., 2021). The laboratory leader's position at this stage reflects the precautionary principle, which serves as a primary preventive measure before the tool is used in clinical services (Vellela & Balamanigandan, 2024). Inappropriate selection can result in serious consequences such as inaccurate test results, a domino effect on patient diagnoses, and even potential medical disputes. Therefore, the technical and managerial knowledge of the laboratory leader is a key element underscored by existing legal policies.

At the procurement stage (code C2), there is a proportional division of responsibilities among three main legal entities: medical device companies, medical device distributors, and laboratory managers as end users. Medical device companies are responsible for producing devices according to quality standards through mandatory certification and testing (A12), while medical device distributors are responsible for distributing devices through mechanisms that comply with Good Medical Device Distribution Practices (A8; A9; A13). Laboratory managers, on the other hand, must ensure that the procurement process follows objective, transparent procedures, and meets specifications (A16). Continuity between these three parties is a legal mechanism designed to prevent the entry of illegal or inappropriate devices, ensuring that the entire procurement system operates within a framework of integrity and accountability. This process also reflects the principle of integrated governance, where each actor has complementary legal functions (Tan et al., 2022).

The next stage includes installation (C3), handling (C5), and transportation (C6), which are primarily the domain of medical device companies and distributors. Medical device companies are required to ensure that devices are manufactured and packaged according to standards to prevent damage during the logistics process (A12). Distributors are required to adhere to strict distribution protocols to ensure the devices remain safe and undamaged during transit (A9). The complexity of laboratory equipment systems, which consist of various sensitive components, makes this stage extremely critical. Even the slightest negligence at this stage can lead to a decline in the quality of the equipment or damage that is not always immediately visible but can significantly impact the accuracy of the examination. Here, legal norms demonstrate their preventive nature, namely by establishing obligations and technical procedures to ensure the integrity of the equipment before use (Zebarjad, 2024).

The testing phase (C4) demonstrates more intensive collaboration between legal entities, particularly between laboratory leaders, medical device companies, and competent laboratory personnel. Laboratory leaders are obligated to ensure that testing and calibration are conducted regularly in accordance with technical standards (A11; A16). Medical device companies are required to provide quality assurance in the form of test reports for the equipment prior to distribution (A12). Meanwhile, competent laboratory personnel are tasked with conducting initial verification and validation upon the equipment's arrival at the laboratory to ensure its safety and accuracy when used for clinical specimen examination (A16). The involvement of these three parties demonstrates the law's emphasis on the principle of shared responsibility, namely the division of responsibilities based on the competence, authority, and technical functions of each party (Monteil et al., 2022).

The storage phase (C7) involves all legal entities simultaneously. During the distribution process, medical device companies (A12) and medical device distributors (A8; A9) must ensure that the devices are stored according to stability and safety standards. Once the devices are in the laboratory, this responsibility shifts to the laboratory manager and competent laboratory personnel (A15; A17). Proper storage, including temperature and humidity control, is a determining factor in extending the device's useful life and ensuring it continues to function according to specifications. Therefore, this phase reflects the principle of sustainability of function in legal instruments while preventing material and medical losses (Mang et al., 2023). The use phase (C8) is the most critical phase because it directly relates to patient safety. At this stage, competent and authorized laboratory personnel have primary responsibility as equipment operators (A10; A15; A16). The law requires that operators be professionally registered and licensed to practice to ensure that equipment is used by individuals with genuine technical skills (Haas, 2008). Laboratory management oversees this process to ensure that equipment is not used by incompetent parties (A16). Medical device companies also remain responsible by providing complete and safe instructions for use (A12). Because the use phase is directly related to patient care, negligence at this stage not only impacts the quality of test results but can also trigger medical disputes, both criminal and civil. Legal policy at this stage is closely aligned with the principle of non-maleficence, namely the moral and legal obligation to avoid causing harm (Bifarin & Stonehouse, 2022).

The maintenance stage (C9) demonstrates the concept of dual control between the medical device company or distributor and laboratory personnel. Companies and distributors are required to provide after-sales services in the form of periodic maintenance, typically performed by authorized company technicians (A9; A12). However, competent laboratory personnel are authorized to perform basic maintenance and report any indications of damage (A15). This legal mechanism aims to maintain equipment in optimal condition and prevent damage that could interfere with test results or threaten patient safety (Ramanathan, 2014). At this point, the law plays a role as a quality control through a multi-layered maintenance system. The equipment retirement phase (C10) falls entirely within the authority of laboratory management. Based on the accreditation survey instrument (A17), laboratory management must establish procedures for discontinuing equipment that is no longer suitable

for use, damaged, or has exceeded its recommended service life (A12). The primary objective of this phase is to avoid the risk of equipment use that could compromise patient safety or produce inaccurate laboratory data. The decision to retire equipment embodies the principle of advanced precaution, which is the legal obligation to assess risks and take preventative measures even before potential damage occurs (Festa, 2025).

The overall analysis of the ten-stage process in managing medical laboratory equipment according to ISO 15189:2022 shows that the proportion of legal subjects has been arranged with a clear balance. Each legal subject performs the necessary functions to maintain equipment quality, ensure patient safety, and prevent legal disputes. This proportion also aligns with the principle of justice as defined in St. Augustine's legal theory, namely that justice is achieved when each party carries out its roles and obligations correctly and proportionally (Nicolaides, 2024). Thus, the current legal framework has been able to provide an adequate normative foundation for the operation of a safe, high-quality, and accountable medical laboratory. The purpose of establishing laws in the governance of medical laboratory equipment cannot be separated from the fundamental nature of law itself as an instrument of social regulation tasked with creating order, justice, and certainty (Campbell, 2024). In the context of medical laboratory equipment, legal formation is directed at regulating the behavior of legal subjects in both preventive and repressive ways so that patient safety, health worker security, and service quality can be guaranteed. This discussion outlines three dimensions: preventive objectives, repressive objectives, and the contribution of secondary legal materials in creating an interpretive space that allows the law to develop adaptively. The entire analysis is guided by using the principle of justice as theorized by St. Augustine (Augustine, 426) and the principle of prevention proposed by Montesquieu (Montesquieu, 1748) as a lens of legal philosophy (Parise, 2021).

Conceptually, preventive law exists to prevent violations, damage, or disputes before they actually occur (de Sadeleer, 2021). Based on the legal data collected, preventive legal materials regarding medical devices are structured from the highest level, namely the 1945 Constitution, then down to the Health Law, and then to government regulations, ministerial regulations, and national accreditation standards. This hierarchy demonstrates a pattern of legal formation that is not only systematic but also adheres to strong principles of legality and legal certainty. At this level, the 1945 Constitution serves as a source of fundamental norms that provide the basis for fulfilling the right to health and providing quality health services, while the Health Law outlines the operational principles that must be followed by all health facilities (Nampewo et al., 2022). Subsidiary regulations, such as the Minister of Health Regulation and laboratory accreditation standards, further detail technical governance. Mandatory medical laboratory accreditation standards serve as a continuous quality control mechanism, ensuring that all healthcare facilities adhere to high technical standards, including equipment management. At this point, the law functions not as a punitive tool, but as a regulatory instrument that plays a role in preventing systemic risks, ranging from equipment errors and inaccurate test results to potential medical disputes that may arise from equipment damage or malfunction (Munoz et al., 2015).

The preventive function of law also creates a standardized ecosystem for the governance of medical laboratory equipment. International standards, including ISO 15189:2022 on medical laboratory competence, ensure alignment between national practices and global standards. The establishment of prevention-oriented laws is also consistent with St. Augustine's principle of justice, which states that justice is created when each party acts according to its moral obligations and roles within a proper order (Karapetian, 2023). In this context, preventing errors from occurring in the first place is a form of substantive justice because it minimizes the risk of harm to patients, healthcare workers, and healthcare institutions. In contrast to preventive objectives, repressive objectives involve legal intervention after a violation or dispute has occurred (Bsisu & Murdie, 2022). However, based on available data, Indonesia currently lacks a repressive law specifically designed to address medical disputes related to laboratory equipment. There is no law specifically regulating the mechanism for handling medical disputes, so researchers can only refer to general articles in the Criminal Code (KUHP) and the Civil Code (KUHPerdata). The use of these two general legal codes demonstrates the general application of the Indonesian legal system, where general provisions can be applied to specific cases when there is no specific law (Hacker et al., 2023).

However, these articles cannot be applied directly. In Indonesia's legal evidentiary system, a judge can only issue a verdict based on at least two valid pieces of evidence. In medical disputes, this evidentiary process becomes more complex because most people do not fully understand medical procedures and the inherent risks of medical procedures. Medical risks are defined in Government Regulation Number 28 of 2024 as events that can occur naturally in healthcare practices and have the potential to cause negative impacts, but are not always the result of negligence (zerbo et al., 2020). Therefore, before criminal or civil provisions are implemented, a

special investigation through a professional ethics hearing is required. The professional ethics council will assess whether the actions of medical and healthcare personnel comply with professional standards, codes of ethics, and service standards (Tarzian et al., 2015). The results of this investigation produce recommendations that serve as important evidence for judges in determining whether a violation of the law has occurred. If the ethical recommendations conclude that there was negligence or noncompliance, only then can the provisions of the Criminal Code or Civil Code be enforced.

This repressive legal construction reflects the government's efforts to maintain a balance between patient rights and the protection of medical personnel. According to St. Augustine's principle of justice, a law is considered just if it does not deprive others of their rights and does not burden those practicing their profession beyond reasonable limits (Chroust, 2017). This repressive approach, which places professional ethics hearings as an initial filter, is a crucial mechanism to ensure that punishment is truly based on the violation, not on the inherent medical risks of healthcare (Phalen, 2017). This analysis demonstrates that the repressive legal structure established by the government aligns with the principles of justice. The government focuses not only on patient protection but also recognizes the rights and objective circumstances faced by medical personnel (Cardenas et al., 2021). This alignment ultimately enhances professionalism and prudence in medical laboratory service providers.

Secondary legal materials play a crucial role as a tool for interpreting and expanding the meaning of primary law. In this study, secondary legal materials, including classical and contemporary legal theories, criminological literature, and international standards such as ISO 15189:2022, serve as analytical instruments that enable a deeper understanding of the formation of national law (Joseph et al., 2025). Legal experts and academics provide a conceptual framework that helps examine whether legal formation complies with the basic principles of justice, legal certainty, and proportionality (Carlsson, 2025). International standards also play a crucial role in the Indonesian legal system, given that Indonesia adheres to a civil law system that emphasizes codification but still requires analytical references in interpretation. Through international standards, health professionals can provide technical input to the government in formulating technical regulations, ensuring that national law keeps pace with technological developments and global practices (Masum et al., 2013). Secondary legal materials also assist law enforcement officials in handling complex legal issues, particularly those related to technology and medical devices (Sharma & Sony A.L., 2021). A thorough understanding of the literature enables judges, prosecutors, and investigators to make rational, fair, and contextually appropriate legal decisions.

More broadly, the analysis shows that secondary legal materials enrich legal practice by providing a broader theoretical perspective. This function is consistent with Montesquieu's view that good lawmakers must understand the character of their society as well as the basic principles of universal justice (Petersen, 2023). Thus, secondary legal materials serve not only as a supplement but also as an intellectual foundation for adaptive legal formation. Based on an analysis of preventive and repressive aspects, it is clear that the government has established a proportional legal framework in terms of both quantity and quality. A strong preventive structure aligns with Montesquieu's idea that good lawmakers should prioritize crime prevention over punishment (Kury & Redo, 2021). Furthermore, a careful repressive mechanism based on ethical review ensures that the law does not apply arbitrarily to medical personnel. Thus, the overall legal framework established aligns with the principles of justice and St. Augustine's legal theory, which places order and proportionality at the heart of justice (Vujadinović & Zaharijević, 2024).

In a global context, the governance of medical laboratory equipment is not merely a technical and legal issue, but is also linked to the dynamics of international health, the globalization of quality standards, and the distribution of power in the medical technology economy (Adekoya et al., 2025). A comprehensive analysis of the ten stages of the medical laboratory equipment management process according to ISO 15189:2022 shows that the proportion of legal subjects in Indonesia has been clearly balanced. However, this equality needs to be interpreted within the broader context of global competition for health standardization, patient safety, and scientific legitimacy. Developed countries such as Germany, Japan, the United States, and South Korea have long considered medical laboratories a strategic infrastructure, particularly after the COVID-19 pandemic triggered major changes in the global health system (Jakovljevic et al., 2021). Under these conditions, the formation of national laws regarding laboratory equipment cannot stand alone; they must be connected, aligned, and able to negotiate with global standards, health technology trade regimes, and demands for international transparency and accountability.

The principle of justice, as defined by St. Augustine, finds relevance in these global relations: justice is achieved when each party plays its role properly and proportionally. At the global level, "each party" includes not

only individuals or national institutions, but also international health organizations such as the WHO, global accreditation bodies, multinational medical device manufacturers, and international donor agencies (Nasrullah & Rahim, 2014). As medical laboratory equipment becomes a strategic commodity, justice not only means the division of roles within a country, but also the ability of developing countries like Indonesia to access high-quality equipment, the latest diagnostic technology, and the transfer of knowledge under conditions that are not detrimental. The goal of establishing laws governing medical laboratory equipment also aligns with changes in global health geopolitics. Since 2020, the WHO has emphasized that countries must strengthen internal regulations to participate equally in the global laboratory network (Davies & Wenham, 2020). International standards such as ISO 15189:2022 have become a "common language" that enables interoperability of laboratory results across countries, particularly in the case of transboundary infectious diseases. In other words, national laws function not only as internal regulatory tools but also as tools for global health diplomacy. Campbell (2024), in his analysis of global health governance, refers to law as an instrument of harmonization, a tool for aligning national practices with international norms without compromising national sovereignty (Campbell, 2024).

The preventive objective in establishing medical laboratory laws is becoming increasingly important as the world enters an era of “high-risk technology.” Modern laboratory equipment such as real-time PCR, next-generation genetic sequencers, and AI-powered automation devices require legal governance that not only prevents operational accidents but also prevents biotechnological risks, algorithmic errors, and the misuse of genetic data (Badiger et al., 2025). Developed countries are now developing anticipatory regulation legal models—regulations that not only regulate current events but also anticipate future risks. Indonesia, through its established preventive structure, is strategically positioned to adopt a similar approach, particularly as ISO 15189:2022 itself is designed to adapt to developments in diagnostic technology (Ahern, 2025). In Indonesia's legal hierarchy, the 1945 Constitution is the fundamental source of norms governing the right to health. However, in a global context, this principle is also aligned with the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which obligates states to meet the highest attainable health standards (Ssenyonjo, 2017). Therefore, when Indonesia establishes a preventive system for managing medical laboratory equipment through the Health Law, government regulations, ministerial regulations, and accreditation standards, the state is fulfilling its legally binding international obligations. A state that fails to provide safe diagnostic devices may be deemed to be violating its citizens' right to health under global human rights standards (Lemmens & Telfer, 2012).

The global context also shows that laboratory accreditation standards are no longer merely technical but are part of the global health security architecture (Lal, 2025). Countries with standardized laboratories have a stronger bargaining position in international health cooperation. Conversely, countries with weak laboratory systems tend to rely on donor countries and are vulnerable to diagnostic dependency (Szalavitz et al., 2021). Therefore, Indonesia's preventive law regulating laboratory equipment aims not only to prevent medical errors but also to strengthen national health sovereignty within the global system. In this complex global landscape, the preventive function of law is indeed aligned with St. Augustine's principle of justice: prevention is a form of substantive justice. However, this justice also has a geopolitical dimension—namely, the state's ability to protect its citizens from the risks of imported technology (Gudalov, 2024). Many developing countries have been victims of the dumping of used medical devices, lax regulations, and aggressive marketing practices of the global medical device industry. By strengthening the preventive function of law and ensuring that all laboratory equipment complies with international standards, Indonesia prevents the entry of substandard equipment that could endanger patient safety (Putri et al., 2024).

In contrast to its preventive objectives, the repressive objectives of the Indonesian legal system still face challenges at the global level (Faisal et al., 2024). The absence of specific laws regarding medical disputes involving laboratory devices reflects a regulatory gap compared to countries such as Australia, Germany, and Canada, which have comprehensive medical device litigation systems (Mulla & Patel, 2025). In the global legal system, litigation regarding medical devices has become a crucial mechanism for ensuring the accountability of manufacturers, distributors, and healthcare facilities. Indonesia still relies on the Criminal Code and Civil Code, which are of general application. Globally, this indicates that Indonesia is still in the transition phase toward a specialized health law regime, characteristic of high-income countries (Wenham et al., 2022). The complexity of proving medical disputes in Indonesia reflects a global phenomenon called asymmetric information, which is an imbalance in understanding between medical professionals and patients (Maiti et al., 2023). Developed countries address this through health technology assessment mechanisms, specialized expert panels, and medical courts (Drummond et al., 2022). In Indonesia, professional ethics hearings serve as an initial filter before criminal or civil provisions are applied. While these mechanisms work well, in a global context, Indonesia still needs to strengthen

its repressive regulations to handle cases involving advanced diagnostic technology, particularly AI-based devices that are difficult to explain technically to the courts.

Indonesia's cautious, repressive approach aligns with a global trend known as just culture—an approach that does not punish healthcare workers for systemic errors but emphasizes continuous learning and improvement (van Baarle et al., 2022). This principle, adopted in the UK, Australia, and Canada, aligns closely with St. Augustine's principle of justice, which rejects arbitrary punishment (Cragg, 2003). In a global context, Indonesia's efforts to balance patient rights with the protection of healthcare workers are not only legally sound but also internationally ethical. At the global level, secondary legal materials are increasingly playing a strategic role as sources of legitimacy and regulatory adaptation. ISO 15189:2022, for example, is not simply a technical document, but an international consensus on what constitutes correct, legitimate, and safe practice. By incorporating international standards into national legal analysis, Indonesia not only improves regulatory quality but also positions itself in the global laboratory technology market (Bartley, 2010). Countries that adhere to ISO 15189 are generally viewed as more credible in international research collaboration, health data exchange, and participation in global laboratory networks.

Secondary legal materials such as legal theory, medical technology literature, and contemporary criminology studies enable law enforcement officials to understand the complexities of legal events involving high technology. In the context of globalization, law enforcement officials need more than just a basic understanding of the law; they must also understand biotechnology, AI, genomics, and international standard principles. Developed countries have developed interdisciplinary legal training to bridge this gap (Dai, 2025). Indonesia needs to move in the same direction if it wants to remain relevant in the increasingly complex international health ecosystem. If we examine Indonesia's overall legal framework through the lens of global health geopolitics, it is clear that a strong preventive structure and a cautious repressive structure create proportionate governance. This aligns with Montesquieu's principle that good lawmakers should prioritize prevention over punishment (Vassiliou, 2024). However, in a global context, prevention encompasses not only operational errors but also technological dependency, the weakening of health sovereignty, and global inequalities in access to quality medical devices (Eberwein & Badie, 2006). Thus, Indonesia's legal framework for the governance of medical laboratory equipment not only fulfills the principle of justice internally but also strengthens Indonesia's position within the global health system. St. Augustine's principle of justice, which emphasizes order and proportionality, finds its articulation not only in relations between national legal subjects but also in Indonesia's relations with the international community (Boas, 2012). A country capable of regulating advanced technology fairly and proportionally is a country capable of maintaining its legal dignity and health sovereignty amidst increasingly intense globalization.

CONCLUSION

Based on the results of the data analysis that has been carried out, it can be concluded that the legal framework in Indonesia related to equipment technology in medical laboratories when viewed from the aspects of legal subjects and legal formation aspects, has sufficiently described the principles contained in the definition of justice according to experts, the legal theory of lex aeterna lex naturalis and the concept of legal formation according to Montesquieu. However, because this research is a normative research that only uses secondary data, it is necessary to conduct further research using primary data, to assess the implementation of the legal framework so that a more representative picture is obtained.

REFERENCES

Adekoya, A., Okezue, M. A., & Menon, K. (2025). Medical Laboratories in Healthcare Delivery: A Systematic Review of Their Roles and Impact. *Laboratories*, *2*(1), 8. https://doi.org/10.3390/laboratories2010008

Ahern, D. (2025). The New Anticipatory Governance Culture for Innovation: Regulatory Foresight, Regulatory Experimentation and Regulatory Learning. *European Business Organization Law Review*, *26*(2), 241–283. https://doi.org/10.1007/s40804-025-00348-7

Alharbi, T., Rababa, M., Alsuwayl, H., Alsubail, A., & Alenizi, W. (2025). Diagnostic Challenges and Patient Safety: The Critical Role of Accuracy – A Systematic Review. *Journal of Multidisciplinary Healthcare*, *Volume 18*, 3051–3064. https://doi.org/10.2147/JMDH.S512254

Alimi, T. (2024). Augustine on Temporal Law and Virtue. *Political Theology*, *25*(1), 9–31.

https://doi.org/10.1080/1462317X.2023.2207771

Andriawan, H., & Ali, M. (2024). Legal Issues Against the Enforcement of Court Determination Granting Objections of Parties in Good Faith. *Jurnal Ius Constituendum*, *9*(3), 530–541. https://doi.org/10.26623/jic.v9i3.10414

Anggraeni, Y., & Moh. Saleh, M. S. (2024). The Use Of The Indonesian Language In International Contracts After The Circular Letter Of The Supreme Court Number 3 Of 2023 As Guidelines For The Implementation Of Duties For Courts. *Eduvest - Journal of Universal Studies*, *4*(5), 3938–3947. https://doi.org/10.59188/eduvest.v4i5.1198

Badiger, M., Mathew, J. A., Nandyal, A. B., Vidya, D., C., M. F., & Shaikh, R. N. (2025). *AI Revolution in Biomedicine and Biotechnology Transformative Trends and Emerging Applications* (pp. 125–146). https://doi.org/10.4018/979-8-3693-8161-8.ch007

Baini, G. M. (2025). *The Roman-Germanic Problems: In Search of the Fundamental Legal Conformation of the Right to Res Judicata* (pp. 23–51). https://doi.org/10.1007/978-3-032-07485-0_3

Bartley, T. (2010). Transnational Private Regulation in Practice: The Limits of Forest and Labor Standards Certification in Indonesia. *Business and Politics*, *12*(3), 1–34. https://doi.org/10.2202/1469-3569.1321

Bifarin, O., & Stonehouse, D. (2022). Beneficence and non-maleficence: collaborative practice and harm mitigation. *British Journal of Healthcare Assistants*, *16*(2), 70–74. https://doi.org/10.12968/bjha.2022.16.2.70

Blondel, M. (2023). The Latent Resources in St. Augustine's Thought. *Communio: International Catholic Review*, *50*(3), 596–624. https://doi.org/10.1353/cmm.2023.a933265

Boas, G. (2012). *Public International Law*. Edward Elgar Publishing. https://doi.org/10.4337/9780857939562

Bouncken, R. B., Czakon, W., & Schmitt, F. (2025). Purposeful sampling and saturation in qualitative research methodologies: recommendations and review. *Review of Managerial Science*. https://doi.org/10.1007/s11846-025-00881-2

Bsisu, N., & Murdie, A. (2022). Interventions and repression following civil conflict. *Journal of Peace Research*, *59*(2), 213–228. https://doi.org/10.1177/00223433211010857

Campbell, T. (2024). *Prescriptive Legal Positivism*. Routledge-Cavendish. https://doi.org/10.4324/9781003579533

Cardenas, D., Correia, M. I. T. D., Ochoa, J. B., Hardy, G., Rodriguez-Ventimilla, D., Bermúdez, C. E., Papapietro, K., Hankard, R., Briend, A., Ungpinitpong, W., Zakka, K. M., Pounds, T., Cuerda, C., & Barazzoni, R. (2021). Clinical nutrition and human rights. An international position paper. *Clinical Nutrition*, *40*(6), 4029–4036. https://doi.org/10.1016/j.clnu.2021.02.039

Carlsson, V. (2025). Legal certainty in automated decision-making in welfare services. *Public Policy and Administration*, *40*(2), 302–321. https://doi.org/10.1177/09520767231202334

Chan, C. W. (2025). Data analytics for error detection in clinical laboratories. *Critical Reviews in Clinical Laboratory Sciences*, 1–17. https://doi.org/10.1080/10408363.2025.2555261

Chandra, M. J. A., Febrian, F., & Anggono, B. D. (2022). The Urgency of Reharmonization in Construction of The Stage Formation of Law. *Jurnal Penelitian Hukum De Jure*, *22*(3), 311–324. https://doi.org/10.30641/dejure.2022.V22.311-324

Chroust, A.-H. (2017). The Fundamental Ideas in St. Augustine's Philosophy of Law. In *Augustine and Modern Law* (pp. 171–193). Routledge. https://doi.org/10.4324/9781315096735-9

Colcelli, V., Cippitani, R., Brochhausen-Delius, C., & Arnold, R. (Eds.). (2023). *GDPR Requirements for Biobanking Activities Across Europe*. Springer International Publishing. https://doi.org/10.1007/978-3-031-42944-6

Cragg, W. (2003). *The Practice of Punishment*. Routledge. https://doi.org/10.4324/9780203406823

Dai, X. (2025). Integrating interdisciplinary approaches in legal education: a study on enhancing problem-solving, innovation, and comprehensive legal understanding. *Artificial Intelligence and Law*. https://doi.org/10.1007/s10506-025-09445-x

Davies, S. E., & Wenham, C. (2020). Why the COVID-19 response needs International Relations. *International Affairs*, *96*(5), 1227–1251. https://doi.org/10.1093/ia/iiaa135

de Sadeleer, N. (2021). The principles of prevention and precaution in international law: two sides of the same coin? In *Research Handbook on International Environmental Law*. Edward Elgar Publishing. https://doi.org/10.4337/9781786439710.00015

Dempsey, R. P., Brunet, J. R., & Dubljević, V. (2023). Exploring and Understanding Law Enforcement's Relationship with Technology: A Qualitative Interview Study of Police Officers in North Carolina. *Applied Sciences*, *13*(6), 3887. https://doi.org/10.3390/app13063887

Donato, A. (2023). *The Origin of Laws and Utopia* (pp. 51–89). https://doi.org/10.1007/978-3-030-97016-1_5

Drummond, M. F., Augustovski, F., Bhattacharyya, D., Campbell, J., Chaiyakunapruk, N., Chen, Y., Galindo-Suarez, R. M., Guerino, J., Mejía, A., Mujoomdar, M., Ollendorf, D., Ronquest, N., Torbica, A., Tsiao, E., Watkins, J., & Yeung, K. (2022). Challenges of Health Technology Assessment in Pluralistic Healthcare Systems: An ISPOR Council Report. *Value in Health*, *25*(8), 1257–1267. https://doi.org/10.1016/j.jval.2022.02.006

Eberwein, W., & Badie, B. (2006). Prevention and sovereignty: A vision and a strategy for a new world order? *Global Society*, *20*(1), 1–24. https://doi.org/10.1080/13600820500405368

Faisal, Yanto, A., Rahayu, D. P., Haryadi, D., Darmawan, A., & Manik, J. D. N. (2024). Genuine paradigm of criminal justice: rethinking penal reform within Indonesia New Criminal Code. *Cogent Social Sciences*, *10*(1). https://doi.org/10.1080/23311886.2023.2301634

Festa, M. G. (2025). *The Standard Precautions and Behavior About Transmission-Based Precautions Isolation Techniques and Room Placement* (pp. 93–108). https://doi.org/10.1007/978-3-031-84469-0_8

Fitra, T. R., Yusof, N. B., & M. Radiamoda, A. (2025). Sanctions and Legal Compliance in Marriage Registration: A Comparative Implementation of Islamic Family Law in Indonesia and Malaysia. *Islamic Law and Social Issues in Society*, *1*(1), 47–61. https://doi.org/10.64929/ilsiis.v1i1.10

Gudalov, N. (2024). *Political Geographies of Spirit: Augustine and International Relations* (pp. 197–209). https://doi.org/10.1007/978-3-031-50407-5_16

Haas, J. (2008). Occupational Licensing Versus Company-Led Training. *European Societies*, *10*(4), 597–617. https://doi.org/10.1080/14616690701871795

Hacker, P., Engel, A., & Mauer, M. (2023). Regulating ChatGPT and other Large Generative AI Models. *2023 ACM Conference on Fairness Accountability and Transparency*, 1112–1123. https://doi.org/10.1145/3593013.3594067

Hamid, S. (2023). Rationalization of technological criminology in the era of disruption. *International Journal on Social Science, Economics and Art*, *12*(4), 221–232. https://doi.org/10.35335/ijosea.v12i4.159

Hejnowicz, A., & Rudd, M. (2017). The Value Landscape in Ecosystem Services: Value, Value Wherefore Art Thou Value? *Sustainability*, *9*(5), 850. https://doi.org/10.3390/su9050850

Hertawaty Sijabat, H., & Widjaja, G. (2025). Nurses' Responsibility for Independent Practice in Providing Nursing Care; A Study of Law Number 17 Of 2023 Concerning Health. *International Journal of Health and Pharmaceutical (IJHP)*, *5*(3), 541–548. https://doi.org/10.51601/ijhp.v5i3.441

Hösle, V. (2025). Aquinas' doctrine of natural law in the context of the history of the discipline. In *Aquinas, Natural Law, and Social Ontology* (pp. 151–182). Routledge. https://doi.org/10.4324/9781003539520-13

Jakovljevic, M., Wu, W., Merrick, J., Cerda, A., Varjacic, M., & Sugahara, T. (2021). Asian innovation in pharmaceutical and medical device industry – beyond tomorrow. *Journal of Medical Economics*, *24*(sup1), 42–50. https://doi.org/10.1080/13696998.2021.2013675

Joseph, A., Rao, I., & Singh, N. (2025). Enhancing forensic DNA quality: a comprehensive review of the integrated ISO centric standards from the crime scene to the courtroom. *Problems of Forensic Sciences*, *140*, 281. https://doi.org/10.4467/12307483PFS.24.017.21383

Karapetian, G. (2023). *St. Augustine and the Court of Justice of the European Union on Citizenship* (pp. 111–132). https://doi.org/10.1007/978-94-6265-595-9_6

Kury, H., & Redo, S. (Eds.). (2021). *Crime Prevention and Justice in 2030*. Springer International Publishing. https://doi.org/10.1007/978-3-030-56227-4

Lal, A. (2025). Towards a coherent global health architecture: perspectives on integrating global health security and universal health coverage through diplomacy and governance reforms. *Health Policy and Planning*. https://doi.org/10.1093/heapol/czaf086

Lemmens, T., & Telfer, C. (2012). Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency. *American Journal of Law & Medicine*, *38*(1), 63–112. https://doi.org/10.1017/S0098858800011576

Maiti, M., Vukovic, D. B., & Frömmel, M. (2023). Quantifying the asymmetric information flow between Bitcoin prices and electricity consumption. *Finance Research Letters*, *57*, 104163. https://doi.org/10.1016/j.frl.2023.104163

Mang, B., Oh, Y., Bonilla, C., & Orth, J. (2023). A Medical Equipment Lifecycle Framework to Improve Healthcare Policy and Sustainability. *Challenges*, *14*(2), 21. https://doi.org/10.3390/challe14020021

Masum, H., Lackman, R., & Bartleson, K. (2013). Developing global health technology standards: what can other industries teach us? *Globalization and Health*, *9*(1), 49. https://doi.org/10.1186/1744-8603-9-49

Monteil, C., Foulquier, P., Defossez, S., Péroche, M., & Vinet, F. (2022). Rethinking the share of responsibilities in disaster preparedness to encourage individual preparedness for flash floods in urban areas. *International Journal of Disaster Risk Reduction*, *67*, 102663. https://doi.org/10.1016/j.ijdrr.2021.102663

Muljono, W. (2023). *Pengantar Teori Kriminologi*.

Mulla, S. J., & Patel, M. (2025). Global Regulatory Perspectives on Sensor-Enabled and Biomaterial-Integrated Medical Devices: A Focus on India, Canada, and Australia. *Biomedical Materials & Devices*. https://doi.org/10.1007/s44174-025-00327-z

Munoz, G., Vidal-Gomel, C., & Bourmaud, G. (2015). *The Operators' System of Instruments: A Risk Management Tool* (pp. 229–247). https://doi.org/10.1007/978-3-662-45704-7_9

Nampewo, Z., Mike, J. H., & Wolff, J. (2022). Respecting, protecting and fulfilling the human right to health. *International Journal for Equity in Health*, *21*(1), 36. https://doi.org/10.1186/s12939-022-01634-3

Nasrullah, N. M., & Rahim, M. M. (2014). *CSR Practices in the Private Enterprises of Bangladesh* (pp. 75–115). https://doi.org/10.1007/978-3-319-02350-2_4

Negara, T. A. S. (2023). Normative Legal Research in Indonesia: Its Originis and Approaches. *Audito Comparative Law Journal (ACLJ)*, *4*(1), 1–9. https://doi.org/10.22219/aclj.v4i1.24855

Nicolaides, A. (2024). Waging a Just and Ethical War – Contemplating Saint Augustine, 'Just War' theory, Gaza, and other Philosophical Notions. *Pharos Journal of Theology*, *105(3)*. https://doi.org/10.46222/pharosjot.105.321

Parise, A. (2021). José Manuel Estrada (Argentina, 1842–94). In *Law and Christianity in Latin America* (pp. 304–324). Routledge. https://doi.org/10.4324/9781003020257-23

Petersen, F. (2023). Montesquieu and the Concept of the Non-Arbitrary State. *The European Legacy*, *28*(1), 25–43. https://doi.org/10.1080/10848770.2022.2106638

Phalen, R. F. (2017). *Core Ethics for Health Professionals*. Springer International Publishing. https://doi.org/10.1007/978-3-319-56090-8

Porter, J. (2015). Justice, Equality, And Natural Rights Claims: A Reconsideration Of Aquinas's Conception Of Right. *Journal of Law and Religion*, *30*(3), 446–460. https://doi.org/10.1017/jlr.2015.27

Prasetyo, T., & Purnomosidi, A. (2019). *Membangun Hukum Berdasarkan Pancasila*. Penerbit Nusa Media.

Prieto López, L. J., & Cendejas Bueno, J. L. (2023). *Projections of Spanish Jesuit Scholasticism on British Thought*. BRILL. https://doi.org/10.1163/9789004516731

Putri, A. K., Ilyas Syafiq Darul Ridzuan, Emma Ismawatie, Yulita Maulani, & Basuko Agus Wibowo. (2024). The Role of Understanding the Medicolegal Implications of Occupational Safety and Health (OSH): An Observational Study of Compliance with the Use of Personal Protective Equipment (PPE) among Single

Center Laboratory Staff at Indriati Boyolali Hospital, In. *Sriwijaya Journal of Forensic and Medicolegal*, *2*(2), 79–86. https://doi.org/10.59345/sjfm.v2i2.139

Qolbi, R. S. (2024). Pengaruh Hukum Normatif dalam Peningkatan Mutu Pelayanan dan Perlindungan Hukum Tenaga ATLM. *Jurnal Hukum Legalita*, *6*(1), 40–49. https://doi.org/10.47637/legalita.v6i1.1308

Rahmania, Y. L., Kuntjoro, T., & Suroto, V. (2019). Pembuktian Akurasi dan Pertanggungjawaban Hukum Hasil Pemeriksaan Laboratorium Klinik... *SOEPRA Jurnal Hukum Kesehatan*, *5*(2). https://doi.org/10.24167/shk.v5i2.XXXX

Ramanathan, T. (2014). Law as a tool to promote healthcare safety. *Clinical Governance: An International Journal*, *19*(2), 172–180. https://doi.org/10.1108/CGIJ-03-2014-0015

Salim, H. S., & Nurbani, E. S. (2019). *Pengantar Ilmu Hukum (Introduction to Legal Service)*. Rajawali Pers.

Sharma, S., & Sony A.L., R. (2021). eLegalls: Enriching a Legal Justice System in the Emerging Legal Informatics and Legal Tech Era. *International Journal of Legal Information*, *49*(1), 16–31. https://doi.org/10.1017/jli.2021.9

Ssenyonjo, M. (2017). The Influence of the International Covenant on Economic, Social and Cultural Rights in Africa. *Netherlands International Law Review*, *64*(2), 259–289. https://doi.org/10.1007/s40802-017-0091-4

Szalavitz, M., Rigg, K. K., & Wakeman, S. E. (2021). Drug dependence is not addiction—and it matters. *Annals of Medicine*, *53*(1), 1989–1992. https://doi.org/10.1080/07853890.2021.1995623

Tan, E., Mahula, S., & Crompvoets, J. (2022). Blockchain governance in the public sector: A conceptual framework for public management. *Government Information Quarterly*, *39*(1), 101625. https://doi.org/10.1016/j.giq.2021.101625

Tarzian, A. J., Wocial, L. D., & The ASBH Clinical Ethics Consultati. (2015). A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field. *The American Journal of Bioethics*, *15*(5), 38–51. https://doi.org/10.1080/15265161.2015.1021966

Thorburn, M. (2024). The rise of utilitarianism in criminal justice. In *Research Handbook on Law and Utilitarianism* (pp. 82–96). Edward Elgar Publishing. https://doi.org/10.4337/9781789901726.00009

Tziakou, E., Fragkaki, A. G., & Platis, A. N. (2023). Identifying risk management challenges in laboratories. *Accreditation and Quality Assurance*, *28*(4), 167–179. https://doi.org/10.1007/s00769-023-01540-3

van Baarle, E., Hartman, L., Rooijakkers, S., Wallenburg, I., Weenink, J.-W., Bal, R., & Widdershoven, G. (2022). Fostering a just culture in healthcare organizations: experiences in practice. *BMC Health Services Research*, *22*(1), 1035. https://doi.org/10.1186/s12913-022-08418-z

Vassiliou, C. C. (2024). Montesquieu. In *Research Handbook on the History of Political Thought* (pp. 381–393). Edward Elgar Publishing. https://doi.org/10.4337/9781800373808.00045

Vellela, S. S., & Balamanigandan, R. (2024). An efficient attack detection and prevention approach for secure WSN mobile cloud environment. *Soft Computing*, *28*(19), 11279–11293. https://doi.org/10.1007/s00500-024-09891-w

Vujadinović, D., & Zaharijević, A. (2024). *Gender Justice: Reassessing Theories of Justice from Feminist Perspectives* (pp. 77–105). https://doi.org/10.1007/978-3-031-75423-4_4

Wardhani, L. T. A. L., Noho, M. D. H., & Natalis, A. (2022). The adoption of various legal systems in Indonesia: an effort to initiate the prismatic Mixed Legal Systems. *Cogent Social Sciences*, *8*(1). https://doi.org/10.1080/23311886.2022.2104710

Wenham, C., Eccleston-Turner, M., & Voss, M. (2022). The futility of the pandemic treaty: caught between globalism and statism. *International Affairs*, *98*(3), 837–852. https://doi.org/10.1093/ia/iiac023

White, T. E., Wong, W. B., Janowiak, D., & Hilborne, L. H. (2021). Strategies for laboratory professionals to drive laboratory stewardship. *Practical Laboratory Medicine*, *26*, e00249. https://doi.org/10.1016/j.plabm.2021.e00249

Wilson, S., Steele, S., & Adeli, K. (2022). Innovative technological advancements in laboratory medicine: Predicting the lab of the future. *Biotechnology & Biotechnological Equipment*, *36*(sup1), S9–S21. https://doi.org/10.1080/13102818.2021.2011413

Wiradirja, I. R., Hadi Purnomo, Yulianto, A. W., Tejo, E. S., Sari, S. I., Gunawan, V., & Muhamad Rivaldi. (2024). Reviewing the Ruling of the Constitutional Court Number 90/PUU-XXI/2023 Concerning the Requirements for President and Vice President Candidates in the Perspective of Progressive Law. *International Journal of Scientific Research and Management (IJSRM)*, *12*(07), 521–531. https://doi.org/10.18535/ijsrm/v12i07.lla01

Zebarjad, Z. (2024). Elucidating the Necessity of Drafting a Legal Provision for Corruption Prevention in the Law Establishing the General Inspection Organization. *Interdisciplinary Studies in Society, Law, and Politics*, *3*(4), 166–176. https://doi.org/10.61838/kman.isslp.3.4.15

zerbo, stefania, Malta, G., & Argo, A. (2020). Guidelines and Current Assessment of Health Care Responsibility in Italy. *Risk Management and Healthcare Policy*, *Volume 13*, 183–189. https://doi.org/10.2147/RMHP.S238353