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Malpractice Law Update on Radiologists' Liability in Cases of Diagnostic Errors and Standards of Practice

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Abstract: The development of modern medicine places radiology as a crucial pillar in the diagnostic process, but on the other hand, it opens up the potential for misdiagnosis with legal implications. Radiologists have a professional responsibility to establish accurate diagnoses based on medical practice standards. However, negligence or deviations can lead to malpractice issues. Legal reforms in Law Number 17 of 2023 concerning Health bring significant changes to the concept of responsibility for medical personnel, including radiologists, by more firmly regulating criminal, civil, administrative, and disciplinary liability mechanisms. Furthermore, technical regulations such as Minister of Health Regulation Number 24 of 2020 concerning Clinical Radiology Services, as well as regulations of the Indonesian Medical Council and the Nuclear Energy Regulatory Agency (BAPETEN) regarding radiation safety, provide a comprehensive normative foundation for professional standards and patient safety. This study uses a normative-juridical method with a statutory regulatory approach and analysis of jurisprudential cases to examine the extent to which legal reforms provide certainty and protection for both patients and medical personnel. The study's findings indicate that despite increasingly clear legal frameworks, there remains overlap in the application of criminal and administrative sanctions, as well as challenges in distinguishing inherent medical risks from criminally punishable negligence. Therefore, regulatory harmonization, strengthening of radiology practice standards, and a fair and balanced medical dispute resolution mechanism are needed.

Keywords: Medical Malpractice, Radiology Physician, Legal Liability

INTRODUCTION

Radiology is a branch of medicine that plays a strategic role in the diagnosis process and medical decision-making (Fathoni, Anwar, & Setiawan, 2024). Advances in imaging technologies such as CT scans, MRIs, and PET scans have enabled doctors to detect various diseases earlier and more accurately (Prayogi et al., 2023). However, these technological advances also carry the consequence of increasing the risk of misinterpretation of medical images, which can lead to misdiagnosis and incorrect treatment (Roderud et al., 2025). This situation makes the role of radiologists not only technical but also carries a high legal and

ethical responsibility for patient safety (Anwar et al., 2023). Even the slightest error in the interpretation stage can have serious medical consequences and give rise to potential lawsuits against the medical personnel involved.

The rapid development of radiology creates new complexities in the relationship between medical personnel, patients, and the law (Andhani et al., 2024). The involvement of various artificial intelligence-based digital technologies in the process of interpreting radiology results has increased the burden of responsibility on doctors to ensure accurate diagnoses (Putra, 2024). The use of software to support medical image analysis often raises new questions regarding who is responsible for diagnostic errors (Sari, 2024). This situation highlights the urgent need to strengthen regulations and clarify the boundaries of radiologists' legal liability to avoid uncertainty for both patients and medical personnel.

Lawsuits against radiologists tend to increase in line with growing public awareness of patient rights and transparency in healthcare services (Widjaja & Sijabat, 2025). Patients now have broader access to information and greater courage to seek justice if they feel harmed by medical procedures deemed erroneous. Furthermore, radiologists are often in the difficult position of having to interpret medical images that are probabilistic, not absolute (Lubis & Soejoko, 2020). It has given rise to debate about the boundary between tolerable professional error and criminal negligence. These tensions underscore the need for legal reforms that are more adaptive to the complexities of modern medical practice.

The enactment of Law Number 17 of 2023 concerning Health represents a major step in reforming Indonesia's health legal system. This law replaces several outdated norms previously stipulated in Law Number 29 of 2004 concerning Medical Practice, particularly regarding the responsibilities and protection of medical personnel (Widjaja & Sijabat, 2025). This reform more strictly regulates the mechanisms for criminal, civil, administrative, and disciplinary liability for medical personnel, including radiologists. The 2023 Health Law also introduces the principle of balancing patient protection with legal guarantees for healthcare workers to prevent criminalization in carrying out their profession (Maulana & Avrillina, 2024). This reform marks a significant transformation in the national health legal paradigm.

Research into malpractice law reform is relevant because there is still an overlap between various sectoral regulations governing the medical profession. In practice, many cases of misdiagnosis cannot be categorized clearly as negligence or a reasonable medical risk. These differing interpretations often create legal uncertainty, especially when law enforcement officials do not fully understand the characteristics of radiology (Pujiyono, 2023). Harmonized regulations are needed to ensure that each form of radiologist liability has a proportional boundary between technical error and intentional negligence. This harmonization will strengthen legal certainty while maintaining public trust in the medical care system.

The theory of professional responsibility serves as the primary conceptual basis for assessing the actions of radiologists. Professional responsibility is based on the principle that every medical professional is obliged to perform their work according to the standards of competence, expertise, and reasonable care required by their profession (Abdi et al., 2022). In the theory of medical negligence, errors are viewed not only in terms of the consequences but also in the decision-making process and adherence to practice standards (Jannah et al., 2025). Radiologists are required not only to be technically proficient but also to be ethically and legally responsible for their interpretations. This concept emphasizes that professional responsibility is inherent in a doctor's expertise in providing medical services (Sulistiyani & Syamsu, 2015).

Medical malpractice is essentially a violation of professional standards that results in harm to patients (Widhiantoro, 2021). This action occurs when a doctor fails to meet the standards of care, skill, or diagnostic accuracy expected of a competent professional (Daeng

et al., 2023). In radiology, malpractice can include misreading images, making incorrect medical recommendations, or failing to follow radiation safety procedures (Lubis et al., 2024). The distinction between malpractice and medical risk needs to be clearly understood so that not all diagnostic errors are considered legal violations. This understanding is crucial so that the legal system is not merely repressive but also educational and oriented towards improving the quality of care.

Law Number 17 of 2023 concerning Health provides a new legal basis for enforcing the responsibilities of medical personnel. Provisions in Chapter XVIII concerning Criminal Provisions clarify the classification of violations and dispute resolution procedures. These regulations also emphasize the need for ethical and disciplinary mechanisms before entering the criminal realm, to prevent the criminalization of medical actions that actually constitute professional risks (Amaliah et al., 2024). In the context of criminal law, the provisions of Articles 359 to 361 of the Criminal Code remain applicable to assess elements of negligence that cause injury or death (Rikmadani, 2023). Furthermore, in the civil realm, Article 1365 of the Civil Code remains the basis for patients to sue for compensation for unlawful acts committed by medical personnel.

Technical regulations governing radiology practice play a central role in defining the limits of the authority and responsibility of radiologists. Minister of Health Regulation Number 24 of 2020 concerning Clinical Radiology Services provides operational guidelines regarding the implementation, safety, and qualifications of radiologists. In addition, the Indonesian Medical Council issued KKI Regulations No. 50 of 2017 and No. 93 of 2021, which regulate the education standards, competencies, and professional ethics of radiologists. Meanwhile, the Nuclear Energy Regulatory Agency (BAPETEN) established regulations on medical radiation safety and mandatory reporting of incidents related to the use of imaging equipment. These regulations complement each other to create a comprehensive legal framework for radiology practice in Indonesia.

Professional ethics is an essential element that cannot be separated from medical practice, including in radiology. The Indonesian Code of Medical Ethics (KODEKI) emphasizes that every physician must uphold integrity, honesty, and professional responsibility in providing services to patients. This code of ethics serves as a moral guideline that complements positive legal regulations, as not all ethical violations are punishable by written law (Abdullah & Binarsa, 2025). In practice, violations of the code of ethics can be grounds for disciplinary sanctions by the Indonesian Medical Council, although they do not necessarily constitute a legal violation. Consistent application of professional ethics is one of the most effective measures to prevent malpractice.

The competency standards for radiologists serve as the primary reference for assessing whether a medical procedure aligns with the expertise required of a professional. These standards encompass technical, scientific, and ethical aspects that must be met from the educational stage through clinical practice. Clinical audits then serve as an evaluation mechanism for the implementation of these standards so that any errors can be identified and corrected without having to wait for legal disputes to arise (Nurdahniar, 2022). With an audit system, hospitals can assess whether a diagnostic error was caused by negligence or an unavoidable medical risk. The implementation of transparent and objective clinical audits can strengthen public trust in the medical liability system in Indonesia.

The elaboration of theories, norms, and professional ethics in the study of radiology malpractice law demonstrates that legal reform is not merely a regulatory change, but also a paradigm shift in understanding the relationship between medicine and law. Radiologists are required to operate based on the principle of utmost care while being protected from disproportionate criminalization. The legal system must be able to objectively assess medical actions, taking into account scientific standards and the complexity of diagnoses. The

integration of positive law, professional ethics, and technical policies is key to achieving a balance between patient protection and legal guarantees for medical personnel. Comprehensive legal reform will create a more equitable, transparent, and professional healthcare ecosystem.

METHOD

This study uses a normative legal research method that aims to analyze the legal norms governing the responsibilities of radiologists in malpractice cases due to diagnostic errors. The approaches used include a statutory approach and a conceptual approach. The statutory approach is conducted by examining various relevant legal provisions, such as Law Number 17 of 2023 concerning Health, Law Number 44 of 2009 concerning Hospitals, the Criminal Code (KUHP), the Civil Code (KUHPerdata), and technical regulations such as Regulation of the Minister of Health Number 24 of 2020 concerning Clinical Radiology Services and the Nuclear Energy Regulatory Agency (BAPETEN) regulation on medical radiation safety. Through this approach, the research focuses on examining the hierarchy, principles, and interrelationships between regulations to determine the consistency and effectiveness of applicable legal norms. Meanwhile, a conceptual approach is used to understand and elaborate key concepts such as medical malpractice, professional negligence, legal liability, and standards of radiology practice, both from the perspective of legal theory and the ethical doctrine of the medical profession. The combination of these two approaches allows for an in-depth analysis of how positive law regulates the responsibilities of radiologists and how the concepts of justice and legal certainty can be applied proportionally between patient protection and medical personnel protection.

RESULT AND DISCUSSION

Forms of Legal Responsibility in Radiology Malpractice Cases

Enforcing criminal liability against radiologists is fundamentally based on the principle of negligence or professional negligence that results in legal consequences for patients. Under Indonesian law, the element of negligence is expressly stipulated in Articles 359, 360, and 361 of the Criminal Code (KUHP). Article 359 states that "Any person whose negligence causes the death of another person shall be punished by a maximum imprisonment of five years or a maximum imprisonment of one year." This provision provides the basis for criminal liability in medical incidents resulting in death due to professional negligence. When a radiologist makes a mistake in interpreting imaging results that results in a fatal outcome for a patient, the element of negligence can be satisfied if it is proven that the action deviated from the standard of professional care that should be exercised by competent medical personnel.

Criminal liability depends not only on the consequences but also on the fulfillment of the elements of *mens rea* (inner intent) and *actus reus* (physical action). In radiology malpractice cases, the *mens rea* element often manifests as gross negligence, not intent, because the doctor did not intend to cause harm but ignored standard professional procedures. Law Number 17 of 2023 establishes criminal provisions regarding medical negligence in Article 440. Article 440 paragraph (1) stipulates criminal sanctions for medical personnel or health workers if their negligence results in serious patient injury; paragraph (2) stipulates a more severe criminal penalty if such negligence results in the patient's death. For other violations related to health services, there are separate articles (e.g., provisions regarding mandatory first aid, unlicensed practice, and so on) also included in the criminal chapter of the Health Law. This provision emphasizes that professional negligence now has a specific basis for sanctions in the health sector as *lex specialis* of the Criminal Code.

The relationship between the Criminal Code and the 2023 Health Law demonstrates that modern health law strives to distinguish between professional misconduct and criminal negligence. The 2023 Health Law stipulates that in enforcing criminal penalties against medical personnel, the assessment must first go through the disciplinary enforcement mechanism of the Indonesian Medical Council. This mechanism demonstrates that criminal law serves as the *ultimum remedium*, a last resort after proving a violation of professional ethics or discipline. Therefore, criminal liability for radiologists can only be imposed if there is strong evidence that negligence exceeded the limits of reasonable medical risk.

Civil liability for radiologists is rooted in the principle of unlawful acts as stipulated in Article 1365 of the Civil Code (KUHPerdata). This article states that every unlawful act that causes harm to another person requires the perpetrator to compensate for that loss. In the medical field, this liability arises when a doctor fails to carry out their professional obligations with due care, resulting in harm to a patient. A patient or their family can file a civil lawsuit seeking compensation for material and immaterial losses resulting from a radiological misdiagnosis that resulted in mistreatment.

The burden of proof in civil lawsuits involving radiological malpractice is often challenging. Patients often face difficulties proving a causal link between the misdiagnosis and the harm they have suffered. However, the development of the doctrine of *res ipsa loquitur*—meaning "the facts speak for themselves"—is beginning to be adopted in Indonesian judicial practice. This doctrine allows judges to assess negligence based on concrete evidence, such as errors in reading radiological images that violate professional standards of competence. Nevertheless, judges still objectively assess whether the radiologist's actions constitute professional misconduct or simply an unavoidable medical risk.

Administrative accountability for radiologists is a crucial legal instrument for ensuring compliance with licensing and service standards. Law Number 17 of 2023 concerning Health stipulates, in Articles 305 to 309, administrative sanctions for medical personnel who violate licensing provisions, professional obligations, or the provision of healthcare services. Sanctions can include written warnings, administrative fines, suspension of practice permits, or even license revocation. This provision aligns with Minister of Health Regulation Number 24 of 2020 concerning Clinical Radiology Services, which requires every radiologist to possess a valid Registration Certificate (STR) and Practice License (SIP) and to comply with patient safety standards.

Oversight of radiology practice falls under the authority of the regional Health Office and the Indonesian Medical Council (KKI). The Health Office plays a role in monitoring healthcare facilities' compliance with operational permit requirements, while the KKI has the authority to assess physicians' competency and professional ethics. If administrative violations or indications of disciplinary violations are found, the KKI can recommend corrective action or impose sanctions according to the severity of the offense.

Oversight of radiology practice falls under the authority of the regional Health Office and the Indonesian Medical Council (KKI). The Health Office is tasked with monitoring health care facilities' compliance with operational and practice permit requirements, as stipulated in Article 410 paragraph (1) letter a of Law Number 17 of 2023 concerning Health, which stipulates that every health care facility must have a permit to operate in accordance with statutory regulations. Meanwhile, the KKI has the authority to develop, supervise, and improve the quality of the medical profession, as stipulated in Article 16 of Law Number 17 of 2023, which states that the Central Government is assisted by the Council and/or Collegium in implementing the development and supervision of medical personnel.

The disciplinary aspect of the profession serves to maintain the dignity and integrity of medical personnel, including radiologists. Types of disciplinary sanctions include written

warnings, mandatory additional education, suspension of registration, and revocation of practice permits. These sanctions are administrative-professional in nature and do not preclude the possibility of criminal or civil law enforcement if more serious violations are found. This disciplinary enforcement mechanism aims not only to provide a deterrent effect but also to improve the quality and prudence of radiologists in their professional practice.

Disciplinary enforcement in radiology cases has been implemented in several jurisdictions, demonstrating that professional misconduct does not always result in criminal penalties. For example, in cases of violations of radiology examination procedures that result in delayed diagnosis, the Indonesian Medical Council (MKDKI) often imposes sanctions in the form of coaching and mandatory retraining. This pattern demonstrates that the disciplinary enforcement approach is directed more toward professional correction than punishment. This effort strengthens the internal accountability system in medicine while supporting the principle of substantive justice for patients and medical personnel.

Analysis of the Responsibility of Radiologists in Cases of Diagnostic Errors and Practice Standards

Radiology services are a vital part of the healthcare system, demanding a high level of precision and a strong sense of professional responsibility. The primary principle of radiology practice is to provide safe, accurate services in accordance with medical professional standards. Every examination procedure must follow standard protocols established by the Ministry of Health and guidelines from professional organizations such as the Indonesian Association of Radiology Specialists (PDSRI). Implementing a double-reading system is an important method for reducing the risk of misinterpretation of medical image results. The radiologist's responsibility extends beyond reading the images; it also encompasses timely and clear communication of diagnostic results to the referring physician.

The implementation of a double-reading system serves as a form of internal oversight of radiology diagnostic results. Every interpretation should ideally be reviewed by colleagues to ensure there are no misperceptions that could lead to legal or medical consequences. This accuracy is part of the service standards stipulated in Minister of Health Regulation Number 24 of 2022 concerning Medical Records and Professional Standards for Medical Personnel. When diagnostic results are used as the basis for clinical decision-making, even small errors in interpretation can have a significant impact on the medical treatment taken. Therefore, the application of the principle of due care and complete documentation is a key indicator of a radiologist's professionalism.

Radiological diagnostic errors are often caused by human factors that cannot be ignored. Fatigue, work stress, and time constraints in reviewing numerous examination results can reduce diagnostic accuracy. Furthermore, a lack of technical competence due to a lack of advanced training can exacerbate the risk of misinterpretation. Radiologists are required to continually update their knowledge as medical imaging technology advances rapidly. Failure to keep up with these developments can be categorized as a form of professional negligence, potentially leading to legal liability if it results in harm to patients.

In addition to human factors, hospital work systems also significantly contribute to the potential for diagnostic errors. High workloads, busy examination schedules, and inefficient internal communication systems often hinder the accuracy of radiology results. Inaccuracies in standard operating procedures, such as incomplete image transmission or incorrect patient labeling, can lead to fatal errors. Hospital management has the administrative responsibility to ensure the availability of supporting infrastructure, including a radiology information system (RIS) and a Picture Archiving and Communication System (PACS), so that the entire service process can run effectively and be well-documented.

Technological factors are also a crucial factor influencing the accuracy of radiological diagnoses. Deteriorating imaging equipment quality, improper machine parameter settings, or technical glitches in digital systems can result in unrepresentative images. It necessitates regular maintenance programs and equipment certification by authorities such as the Nuclear Energy Regulatory Agency (BAPETEN) to ensure radiation and imaging are within safe and accurate limits. Failure to comply with these technical standards can have legal implications, particularly if proven to cause harm or medical errors that could have been avoided with proper equipment maintenance.

Evaluation of diagnostic errors is conducted through clinical audits, which serve as a mechanism for reflection and professional learning. These medical audits involve a thorough assessment of the diagnostic process to determine whether negligence occurred or was simply a reasonable medical risk. Medical Committees in healthcare facilities play a crucial role in ensuring that any errors are handled professionally, not merely through sanctions but also as a basis for evaluation to improve service quality. This mechanism is also regulated in Law Number 17 of 2023 concerning Health, which emphasizes the importance of continuous development and evaluation of medical personnel to ensure patient safety and professional integrity.

Regular clinical audits can help distinguish between errors resulting from systemic factors and errors resulting from individual negligence. This process allows hospital policymakers to objectively assess whether errors are the result of procedural failures or professional negligence. Audit results serve as the basis for the Indonesian Medical Association (KKI) in recommending disciplinary sanctions or proportionate coaching for the medical personnel involved. Thus, medical audits serve not only as a monitoring tool but also as a means of collective learning to improve the overall quality of national healthcare services.

The relationship between violations of practice standards and the legal liability of radiologists is closely linked and complex. When a physician fails to meet professional standards or acts beyond the scope of their competence, the elements of legal error may be met, as stipulated in Articles 304 to 309 of Law Number 17 of 2023 concerning Health. The distinction between errors of judgment and gross negligence is key in assessing whether an error is criminally liable. An error of judgment refers to a mistake in judgment that falls within reasonable professional limits, while gross negligence indicates gross negligence that cannot be justified ethically or legally.

Clarifying the boundaries between professional misconduct and legal violations is necessary to ensure legal protection for doctors without violating patients' rights to safety and justice. The legal system must provide space for doctors to exercise scientific judgment without fear of excessive criminalization. However, when there is strong evidence that professional and ethical standards are being ignored, legal sanctions become a crucial instrument for maintaining the integrity of the medical profession.

Efforts to prevent radiological diagnostic errors need to be directed at harmonizing regulations between institutions and the relevant authority. The Ministry of Health, the Indonesian Medical Association (KKI), and BAPETEN need to synergize policies to avoid overlapping competency oversight, equipment certification, and radiology practice licensing. Integrating information systems between regulatory agencies and healthcare facilities is also a strategic step to accelerate early detection of potential standard violations. Strengthening ongoing training, transparent documentation of examination results, and improving communication between healthcare professionals can be crucial foundations for reducing the risk of malpractice in radiology.

Prevention of radiological malpractice should be supported by policies that promote a culture of patient safety. Every healthcare professional should feel safe reporting errors

without fear of disproportionate sanctions, as long as the error does not involve gross negligence. Hospitals need to develop a medical incident reporting system that is both educational and constructive. This way, every error can be used as a lesson for improving the service system, rather than simply as a basis for punishment. A learning-based and preventative approach is believed to create a more accurate, professional, and equitable radiology service system.

CONCLUSION

Legal reforms through Law Number 17 of 2023 concerning Health have provided clearer direction for the framework of responsibility for medical personnel, including radiologists, in carrying out their professional practice. This regulation emphasizes the importance of professional standards and the principle of prudence in all diagnostic procedures, but its implementation still faces obstacles due to overlapping administrative and criminal sanctions. Provisions regarding disciplinary violations and professional negligence are often not clearly distinguished from reasonable medical risks, creating the potential for criminalization of physicians who have actually worked according to procedures. This situation demonstrates the need for more comprehensive legal reforms that emphasize not only accountability but also provide legal protection for medical personnel who work in good faith within their professional competence.

Improvements to the legal system in radiology must be directed at harmonizing regulations between the Health Law, the Minister of Health Regulation on radiology practice, technical provisions from BAPETEN, and ethical and disciplinary guidelines issued by the Indonesian Medical Council (KKI). This integration is expected to establish a uniform, fair, and effective oversight system. Medical dispute resolution mechanisms need to be strengthened through non-litigation channels such as mediation and ethics forums to prevent disputes from always ending in criminal proceedings. Furthermore, improving the quality of education and training for radiologists, emphasizing patient safety and mastery of modern imaging technology, should be a priority. Revisions to medical practice guidelines are also crucial to ensure that medical actions within professional boundaries are not misinterpreted as malpractice, thus ensuring a balanced justice for patients and medical personnel.

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