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Transforming Occupational Health and Safety Regulation: Strategic Pathways in the Era of Industry 4.0

Takenori MISHIBA

Abstract: This paper examines the impact of Industry 4.0 (I4.0) technological innovations on occupational health and safety (OHS) and explores appropriate regulatory approaches based on a literature review. While I4.0, with its introduction of autonomous robots powered by AI, is expected to improve operational efficiency and reduce risks, it also brings new risks—especially psychosocial risks—and regulatory challenges. Under I4.0, traditional rules are insufficient as regulations struggle to keep pace with technological evolution. A co-regulation framework is needed, where programmers and manufacturers are entrusted with risk management responsibilities. Additionally, health monitoring through wearable technologies, risk prediction using big data, and appropriate—not merely reinforced—data management to safeguard privacy are critical requirements. In conclusion, OHS regulations should be preventive and flexible, balancing the need to avoid hindering technological development while fully leveraging the benefits of new technologies. This requires establishing guidelines and safety nets that facilitate innovation. It is also necessary to adopt and enforce the principle of assigning risk management responsibilities to those capable of predicting and managing risks (broadly defined risk creators). This principle extends risk prevention responsibilities to designers, manufacturers, platforms, and clients commissioning work in part. Notably, clients should ensure that contractors have the capacity to perform work safely and sustainably. Finally, addressing psychosocial risks requires an approach that emphasizes compatibility between individuals and organizations, as well as alignment of skills and values.

Key words: Industry 4.0, Occupational health and safety, Regulation, Law and policy, Human-machine collaboration, Smart machines, Wearable devices

1. Purpose

Industry 4.0 (hereafter referred to as I4.0) has the potential to exert both positive and negative impacts on Occupational Health and Safety (hereafter referred to as OHS) (e.g., EU-OSHA 2022).[1] However, at this stage, there are few

1) There is a study that categorizes the (positive and negative) impacts of I4.0's core technologies on OHS into four types: (1) work organization, (2) OHS legal regulations, (3) OHS management systems, and (4) OHS risk management systems (Badri 2018).

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Faculty of Law, Kindai University, Higashi-Osaka, Osaka, Japan
Corresponding author: Takenori Mishiba. Department of Law, Kindai University, 228-3 Shin-kamikosaka, Higashi-Osaka, Osaka 577-0813, Japan
Email: t-mishiba@jus.kindai.ac.jp

papers that specifically examine the impact of I4.0 on OHS (Savković 2021 share a similar view), and even fewer papers that delve into the legal regulations adapting to I4.0.

This paper, therefore, examines the industrial landscape brought about by I4.0, changes in workstyles and OHS risks, and the legal regulations adapting to I4.0 in that order, based on a literature review. The objective is to provide policymakers in governments and international organizations, as well as researchers in relevant fields, with reference material for discussions on legal regulations adapting to I4.0. Due to the author's residence in Japan, Japanese materials are actively included in the review, and the discussion is based on Japan's current circumstances.

This paper is a position paper and, while grounded in a literature review, does not adopt a rigid structure or empirical analysis. As several recent review articles are included in the referenced works, this paper also carries the characteristics of a meta-review.

2. Methods

To outline I4.0, representative works such as Klaus Schwab (2017)[2] and a vision of a new industrial structure developed by Japan's Ministry of Economy, Trade, and Industry (METI 2017) were reviewed.

Next, to search for literature on I4.0, OHS, and legal regulations, keywords such as "health," "safety," "industry 4.0," "work," "law," "policy," and "regulation" were used in an and combination to search Google Scholar. Scopus, which primarily hosts peer-reviewed articles, was not used due to its field-specific search structure, which may overlook relevant literature categorized under unexpected fields, and because much of the literature indexed in Scopus also appears in Google Scholar. Additionally, as the subject pertains to cutting-edge issues, non-peer-reviewed articles also needed to be reviewed.

Approximately 12,500 hits were obtained through keyword searches, and the selection process that followed was conducted manually and at my discretion. Initially, the results were sorted by relevance to the keywords, and about 200 of the top entries were reviewed. Many articles did not mention the relationship between I4.0 and OHS at all, while others mentioned it but lacked substantial content. Additionally, many did not address legal regulations. Therefore, articles published after 2018, when the term I4.0 began to gain attention, were selected. This reduced the number of hits to approximately 11,500. From the top 200 articles by relevance, we manually selected those that were not limited to specific industries or themes and were either review articles or based on a review of at least 10 sources. Given the limited research on the relationship between I4.0 and OHS, the pool was narrowed to approximately 30 articles at this stage. From these, articles that directly addressed "law," "regulation," or closely related terms such as "standards," or provided significant implications for them, were selected through visual inspection, resulting in seven articles.

To supplement with the latest literature, the same search criteria were applied on ResearchGate, a platform where authors can upload their works, yielding two additional sources.

2) The concept of Industry 4.0 was proposed by the German government in 2011 and later systematized by Professor Schwab and others (Leso 2018). Similar initiatives have also been undertaken by countries such as the US, France, the UK, Japan, and China (Liu 2020).

Furthermore, EU-OSHA (2022), which provided insights on worker management and OHS management under I4.0, was reviewed. Based on this report's suggestion that worker management and OHS management converge under I4.0, Japan's METI (2022) vision of Human Resource Management (HRM) under a new industrial structure was also reviewed.

For areas lacking sufficient prior research, personal insights were incorporated.

3. The Industrial Landscape, Workstyles, and OHS (Regulations) Under I4.0

3.1 The Overall Impact on Industry

In my understanding, I4.0 represents a phase where machines, primarily equipped with generative AI, engage in production activities like living beings, autonomously and flexibly responding to their environment.[3] It focuses on innovations in manufacturing. The emphasis on machines "primarily equipped with generative AI" reflects the role of AI with learning capabilities in supporting the flexibility and autonomy that characterize I4.0. Examples include autonomous vehicles that detect obstacles with sensors and transport passengers to their destinations and cobots (collaborative robots) that adjust their speed to operate safely in the same space as humans without barriers. Traditional industrial robots required halting, repairing, or resetting in unexpected situations, whereas cobots can select optimal actions in real-time based on information (Hanna 2022).[4]

In a smart factory, machines are interconnected through a network, enabling one machine to convert video data and other inputs recognized by sensors into analyzable formats. The machine not only controls its own operations based on this analysis but also transmits the data to other machines, facilitating mutual coordination of movements. This allows the entire factory to produce outputs tailored to customer needs.[5,6] While humans can specify and adjust basic operational guidelines, the production activities are primarily carried out autonomously by the machines. Equipped with generative AI, the machines refine their pre-established response models based on the data collected, ensuring autonomy and adaptability.

This phase of interaction through "data," where humans, objects, and environments communicate and influence each other, defines

3) Pinto (2023) describe Industry 4.0 as the integration of cutting-edge IT technologies with production methodologies, characterized by the use of cyber-physical systems as its technical foundation. They highlight the unique feature of data linking humans to objects and objects to each other, enabling mutual interactions. Leso (2018) define Industry 4.0 as a system where the entire value chain is integrated (connected) through digital information. This integration is broadly categorized into vertical integration, which connects different layers of the value chain, and horizontal integration, which links different companies or departments.

4) However, at present, there are concerns about poor cost-performance due to insufficient development, the effort required to provide instructions to cobots, and incompatibilities with existing systems (Hanna 2022).

5) The following devices and functions are used to control machinery:
Programmable Logic Controller (PLC): Supports the stable operation of manufacturing line equipment with features such as program debugging, troubleshooting, and update capabilities.
Smart Sensors: High-performance sensors that collect, analyze, and automatically transmit data.
Online Data Analysis Function: This function collects data from the internet and performs trend analysis. It supports automation by reflecting the analysis in machine operations.

6) The term "smart enterprise" has also emerged. In this context, all workers and machines are connected to a digital network, where data generated by machines is stored in the cloud, compared with past data, and used to identify issues (Savković 2021).

I4.0.[7,8] Through such interactions, waste in materials, time, and effort is minimized. For example, production optimization minimizes material use, and matching products with consumers reduces waste. Humans can focus on high-value-added tasks.[9]

The data collected or generated by autonomous machines hold significant market value, contributing to the development of new machinery and products (METI 2017). About ten years ago, global investments in I4.0 were projected to grow from about $20 billion in 2012 to over $500 billion by 2020 (ERPS 2015).

Technological advances also transform individual workstyles and organizational management practices (Badri 2018). They also reshape societal and economic frameworks (METI 2017).

Economic shifts include the rise of decentralized autonomous organizations (DAOs) facilitating direct transactions between suppliers and consumers or investors and borrowers in digital spaces without intermediaries. Labor demand decreases, and personal interests shared in digital media spaces gain importance. The global population dynamics see declines, with a shift from dense populations in East/Southeast Asia toward South/Central Asia and Africa, before transitioning to global population declines around 2060. Japan, in particular, faces a rapid population decrease (Kawai 2021).

Thus, improving labor productivity, especially in Japan, is essential. Additionally, as populations age,[10] environments and technologies catering to older workers become increasingly necessary.

However, this process risks expanding economic and social disparities between those capable of producing intellectual or emotional value (e.g., those driving new ventures or coordinating relationships) and those who cannot.

Corporate management structures are expected to shift from hierarchical pyramid-based models to flat, collaborative structures, with each

7) Following Industry 4.0, it is predicted that Industry 5.0 will emerge, leveraging the core technologies of Industry 4.0 to address challenges faced by individuals, businesses, and society as a whole. These challenges include achieving both economic growth and environmental protection, enhancing workers' well-being, supporting mobility for the elderly, and addressing shortages in caregiving personnel (Milea 2024). While the need to thoroughly analyze workers, workload, tools, and working environments, as well as to implement risk assessment and management suited to new risks, remains unchanged from Industry 4.0, the necessary components of Occupational Health and Safety Management System (OHSMS)—such as policy decisions by management, education, and consultations with workers—should also be incorporated. However, greater emphasis will be placed on ergonomically designed workplaces and tasks, monitoring and managing health risks, protecting workers' personal information, and integrating OHS with human resources and labor management (Ibid).

8) The highly intelligent cycle that collects data from the physical world, analyzes it in the cyber world, and feeds the results back to the physical world for optimization and other purposes is known as a cyber-physical System (CPS). Autonomous machines, such as self-driving cars and intelligent items like those in smart factories, are supported by this system.

9) Leso (2018) state that under Industry 4.0, workers will focus on intellectual and creative labor that generates added value, based on the freedom to choose their working time and location.

10) The global average life expectancy in 2021 was approximately 69 years for men and 74 years for women, with healthy life expectancy at about 61 years for men and 63 years for women (WHO 2024). During roughly the same period, Japan's average life expectancy was approximately 81 years for men and 87 years for women, with healthy life expectancy at about 72 years for men and 75 years for women (Sato 2022).

project operating autonomously. This transition will likely be accompanied by greater flexibility in workers' hours and locations, as well as an increase in de-employment (outsourcing).

The rapid pace of AI and other technological developments makes it difficult for regulations to keep up (e.g., Pinto 2023). As a result, legislative authorities may need to delegate regulatory responsibility to developers, requiring them to self-regulate and report on their practices, thereby enabling effective co-regulation.[11] Additionally, adopting private standards, which can be swiftly established, as legal benchmarks is a potential strategy. However, to avoid hindering business, small mistakes in the development process should be tolerated (METI 2017). At the same time, addressing inequalities by establishing safety nets and providing intellectual, human, and financial support to small enterprises will play a crucial role.

In the era of I4.0 and beyond, the unique strengths of humans in relation to AI and robotics will lie in qualitative aspects such as value judgment, persuasion, creation from scratch, and embracing diversity. While humans have inherent limitations, preferences, and emotions, collaboration can enable distinctive innovation and production.

3.2 Transition to I4.0: From Industry 1.0 to 3.0

Reflecting on the progression from Industry 1.0 to 3.0, the following trends are observed (Milea and Cioca 2024; Badri 2018):

3.2.1 Industry 1.0 (circa 1760–1900)

This phase marked the mechanization of production via steam engines. While industries like textiles, metallurgy, chemicals, and mining thrived, major occupational risks included physical hazards (e.g., machinery contact, explosions), ergonomic risks (e.g., unnatural postures), and health risks (e.g., long working hours). OHS regulations were minimal, with labor unions taking the lead in improving working conditions.

3.2.2 Industry 2.0 (circa 1900–1960)

With the advent of electricity, mass production became feasible, and machine sizes reduced. Factory systems became the norm. Alongside earlier risks, new issues like viral infections emerged. During this phase, fragmented OHS standards began forming in various countries. The establishment of the ILO marked the start of international efforts to improve labor conditions.

3.2.3 Industry 3.0 (circa 1960–2000)

Characterized by IT and digital production, this era saw industries like steel, automotive, and consumer electronics dominate. Ergonomics enhanced production processes, and industrial robots became more common. Key occupational risks involved unsafe behaviors, excessive workload, machinery-related hazards, and environmental factors (e.g., noise, vibrations). Robust national-level OHS regulations and specialized enforcement bodies emerged. Internationally, the ILO adopted the Occupational Health and Safety Framework Convention (Convention No. 155) in 1981, and in 1989, the European Union adopted the Occupational Health and Safety

11) The Sunak Conservative Government in the UK (2023) has also emphasized prioritizing the utilization of AI and other emerging technologies in business over excessive regulation.

Framework Directive (89/391/EEC),[12] with the EU-OSHA established in 1994.

Recent categorization of OHS measures includes the following:

- Safety 0: Relied on human attention and judgment.
- Safety 1.0: Focused on installing safety measures in machinery and isolating workers from hazards.
- Safety 2.0: Emphasized collaborative safety with Industry 4.0 technologies, where humans and machines work interactively to ensure safety.

Key implementation examples include robotic suits that assist movements based on human intentions by reading bioelectric signals, robots that gradually reduce their operational speed as a person approaches, and inspection devices capable of analyzing defects in all products, not just samples and detecting worker errors through image recognition and AI. These technologies are also said to contribute to productivity improvement (Mukaidono 2016, 2019; Goto 2021).[13] Recently, a more dynamic OHS conceptual

12) This directive primarily aimed to harmonize and strengthen economic competitiveness within the EC area, while including the following provisions (selected excerpts):

1) Primary Responsibility for Risk Management:

Employers bear the primary responsibility for risk management. Their fundamental duties include risk assessment, worker education, information dissemination, consultation with workers, appointment of competent occupational health and safety (OHS) personnel, and ensuring their ability to operate effectively.

2) Worker Obligations:

Workers are obligated to perform tasks appropriately under the employer's instructions, report hazards, and cooperate with the employer.

3) Principles of Risk Management:

These include minimizing risks where their elimination is difficult, adapting work to fit workers, and conducting reviews when working conditions change.

Guidance on Risk Assessment at Work (published by the EU Commission in 1996)

The guidelines for the directive include the following provisions (selected excerpts):

1) Dual Requirements for Employers:

Employers must ensure compliance with legal requirements and the effectiveness of OHS measures. Risk assessment serves as the key to achieving both.

2) Comprehensive Risk Management:

All foreseeable risks in individual workplaces should be managed. Employers should also consider risks related to external contractors and visitors when conducting assessments.

3) Qualifications for Competent OHS Personnel:

The OHS personnel appointed by employers should possess general knowledge of risk assessment, the ability to apply it to the specific workplace, and the capacity to recognize their limitations and seek support from others when necessary.

4) Information Provision to OHS Personnel:

Employers must provide the appointed OHS personnel with relevant information, including the scope of duties related to risks, feedback from workers (or their representatives), data sheets provided by machinery manufacturers, OHS monitoring records, and anonymized data from medical examinations.

13) However, there are studies that propose different classifications. For example, Liu (2020) categorize the historical evolution of safety management into distinct phases:

Safety 1.0, which occurred between Industry 1.0 and 2.0, when occupational accident prevention laws were enacted, and regulatory oversight began in various countries.

Safety 2.0, which emerged during the Industry 3.0 period, characterized by extensive exploration of accident causes and prevention measures, resulting in the development of numerous safety theories.

Safety 3.0, which corresponds to the Industry 4.0 era, marked by advancements in accident and accident prevention measures through the use of automation technologies such as IoT.

framework, based on a new, more personalized, and dynamic risk management paradigm, has been proposed to address the complexities of production processes under I4.0 (Podgórski 2017). The concept of "deliberative safety" has also been introduced, wherein machines equipped with AI determine and select various safety measures, ranging from perimeter safety[14] based on human-machine separation to planned safety[15] and active safety[16] (Hanna 2022).[17]

In any case, it is emphasized that ergonomics and human studies are essential for OHS under I4.0 (Siemieniuch 2015).

3.3 Impacts on Specific Sectors and Occupations

I4.0-driven industries like advanced manufacturing (e.g., autonomous vehicles, wearable devices), software development, cybersecurity, biotechnology, and life sciences are expected to grow (METI 2017). Traditional industries incorporating cross-sectoral innovations may also sustain growth.

Service and retail sectors face automation, limiting human roles to consulting or managing high-value products and systems. Smart factories minimize labor needs, optimize material use, and match production with consumer demands. Energy production will transition to eco-friendly power generation systems, such as renewable energy sources, through integration with IoT (Internet of Things) technology (METI 2017). In the construction industry, although demand will decline due to population decreases, there will be a corresponding increase in the need for building renovations, supported by technological advancements. The use of autonomous heavy machinery will further enhance efficiency in construction projects. In the financial sector, the advancement of Financial Technology (FinTech) will lead to the widespread adoption of digital monetary transactions, with increasing integration of systems for corporate accounting and investment. Revenue is expected to primarily come from fees. In the education industry, demand will decrease due to population decline, while

14) A safety assurance method that stops the machine when a human is present within the machine's operating area.

15) A method that ensures safety by pre-planning the movements of both humans and machines. In case of unforeseen circumstances, it can be respond by re-planning by humans.

16) A safety measure that detects human movements, predicts human actions using prediction algorithms based on past data, and flexibly adjusts the machine's trajectory or work procedures. Unlike Perimeter Safety or Planned Safety, which involve "unidirectional interaction" where machines operate based on human decisions, this approach embodies "bidirectional interaction" between humans and machines (Leso 2018).

17) This paper provides an example of collaboration in kitting, a process where necessary components are prepared before product assembly. If a cobot drops a component, the operator covers for it while the cobot slows down its movement speed (Reactive Safety: a safety measure that reduces the robot's operating speed to facilitate human intervention. The robot does not recognize humans, and intelligent control is not applied). If the cobot fails to prepare components within the allocated time, it switches to Planned Safety mode, using lights to indicate the tasks that require operator action. When the cobot and operator work in close proximity, Active Safety is employed. After kitting is completed, the task of transporting components to the line, which is straightforward and requires speed, is handled using Perimeter Safety. Ultimately, when adaptation to situational changes is necessary and feasible, flexible and intelligent safety measures are adopted. Notably, the cobot autonomously interacts with humans to change modes, showcasing its ability to operate in a dynamic and adaptive manner.

the use of video-based and AI-driven teaching is likely to expand. Although there will be an increase in demand for problem-solving skills development, as well as recurrent and reskilling education, the number of educators capable of meeting this demand will be limited. In agriculture, the introduction of farming robots will enable operations to be carried out systematically, based on data (METI 2017). In social welfare, care robots will be utilized, leading to a bifurcation between standard services relying primarily on robots for assistance and high-value-added services involving significant human intervention.

Across sectors, labor demand decreases, with human roles focusing on intellectual and emotional value creation and supporting robotic tasks. While technology reduces physical strain, high-level intellectual tasks, especially in AI development, may see a decline in peak worker age.

3.4 Workstyles, OHS Risks, and Basic Countermeasures

In I4.0, human labor divides into tasks that are superior to and subordinate to new technologies:

Jobs positioned above new technologies will likely include development roles, such as programming and software development, and management roles, such as maintaining delivered programs and AI-embedded machinery. Conversely, jobs positioned below new technologies will involve tasks monitored or directed by these technologies.

Among the former, development tasks pose risks of overwhelming intellectual pressure, necessitating health monitoring through wearables. Management tasks may involve addressing bugs, handling inquiries from less knowledgeable individuals, and ensuring proper responses to avoid significant impacts on production and safety. This can result in severe fatigue and stress, especially when staffing is insufficient, leading to heavier burdens on individual workers. To address this, a system based on established standards should be implemented to verify whether a contractor has secured adequate personnel for the tasks at hand, thereby enabling clients to place orders with confidence.

For jobs monitored by machines, risks include surveillance pressure, privacy invasion (highlighted by EU-OSHA 2022; UK Sunak Conservative Government 2023; and Leso 2018), technostress from adapting to machine-driven workflows, and pressure from the potential repercussions of errors (as noted by Leso 2018). For example, such risks may arise when humans must compensate for malfunctions in care robots. Countermeasures might include adjusting the speed of AI-embedded machinery to match human capabilities or developing work methods within a Plan-Do-Check-Action (PDCA) cycle that minimize human errors in collaborative scenarios.

In contrast, certain jobs, such as those in customer service, which are less reliant on AI, will persist. These are generally classified as emotional labor (Russel 1983) and may often lead to excessive stress, including risks of harassment from customers or colleagues.

Workers' locations and schedules are expected to become more flexible, and employment arrangements will increasingly shift towards de-employment (outsourcing). In the near future, international transactions conducted in virtual marketplaces using cryptocurrencies may become commonplace. As the number of sole proprietors grows, economic regulations akin to antitrust and subcontractor protection laws will need to evolve to provide remedies and support for businesses. The responsibility for OHS may also need to extend beyond employers to any party capable of recognizing and managing risks (Mishiba 2023).

It may also be worthwhile to consider shifting the scope of labor law protection from employees to workers who, under Industry 4.0, face difficulties in exercising bargaining power.

Under these transformations, OHS regulations are likely to focus on physical risks associated with machinery utilizing new technologies[18)] and psychosocial risks.[19)] The latter may arise from challenges such as responding to unexpected situations with automated machinery, solving problems without predefined answers, navigating complex communication requirements, and dealing with significant responsibilities. Other causes may include the weakening of interpersonal relationships in machine-centric production systems (Leso 2018) and the potential erosion of work-life balance due to mobile work (Ibid.).

Focusing on psychosocial risks would require effective countermeasures that extend to improvements in organizational and task management, as well as the quality of HRM, thereby bringing OHS management closer to worker management (as also noted by EU-OSHA 2022).

Some literature highlights the OHS risks arising from the rapid organizational changes brought about by implementing Industry 4.0 technologies (Badri 2018). Particular emphasis is placed on psychosocial risks, such as high-skill requirements, intensive communication demands, problem-solving challenges, and job insecurity (Leka 2010). The use of new technologies to enhance inter-organizational collaboration and improve work efficiency has been proposed as a solution (Badri 2018).

Additionally, several issues have been identified by experts (Pinto 2023):

1) Invisibility of Disaster Causes in Data Processing: Computerized data handling can obscure the root causes of disasters, complicating alternative resolutions. This issue requires developers and programmers to devise countermeasures.

2) Lack of Resources for New Technology Implementation: Insufficient funding and knowledge for adopting new technologies necessitate policy-driven financing and the structuring and dissemination of knowledge by safety and health administrations.

3) Workplace Accidents Due to Overconfidence or Rule Violations: Addressing this requires raising literacy about the risks of new technologies and employing vision systems to mitigate such incidents.

3.5 Benefits of Industry 4.0 for Occupational Health and Safety (OHS)

The core technologies of Industry 4.0 (I4.0) are advancing OHS technologies (Kaivo-oja 2015; Badri 2018).

New technologies enable workers to wear wearable devices that monitor their health conditions (examples of early methods and their

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18) A typical example includes collisions between humans and cobots due to sensor malfunctions or incidents where humans get caught in machinery. When human operation of machinery is required, ergonomic risks arising from the difficulty of operation have also been pointed out (Brocal 2015; Geraci 2010).

19) DJP Automação (2020) states that Industry 4.0 reduces physical labor but accelerates work rhythms, leading to increased stress. Additionally, the core technologies of Industry 4.0 contribute to improvements in OHS but require highly skilled professionals.

performance are discussed in Mattsson 2016, and recent developments in Tani 2024). If a wearable device detects potential health risks, it can alert the user. Anonymized aggregate data can also be collected and analyzed by individual organizations, social insurance bodies, or governments to implement preventive measures. Sensors in these devices can measure hazards in the working environment, such as heat, gas, fire, or hazardous substances, and alert workers when limits are exceeded (Leso 2018).

In Japan, a framework called the Personal Health Record (PHR) has been introduced to digitize and centrally manage individuals' health, medical, and caregiving information (Ministry of Health, Labor and Welfare 2020). Currently, the system is intended to enable individuals to use their data portably—for example, to share it with healthcare providers or insurers.[20] In the near future, however, anonymized aggregate data may be used by governments or employers to implement preventive measures.

In Japan, employers are already required by law to conduct health checkups, even for items unrelated to occupational diseases. Employers can also stipulate additional health checkups through work regulations within reasonable limits.[21] Therefore, the collection and appropriate management of workers' health information using new technologies for health management purposes may be more permissible in Japan than in other countries.

In the healthcare sector, large volumes of medical claim data are accumulated under the universal healthcare system. There are also health checkups for lifestyle-related diseases under regional health systems, with data similarly accumulated. Given the increasing financial strain on social security systems, health insurance premiums may be differentiated based on individual efforts to improve health (METI 2017).

Other countries could establish data management platforms outside companies (e.g., run by governments or municipalities) to prevent employers from handling raw data directly, instead ensuring that they are provided with only the necessary recommendations. Collecting, cross-referencing, and analyzing medical, health, and caregiving data from both workplaces and local areas will be critical.

Furthermore, future regulations may "require" clients to verify the health conditions of contractors and their employees to ensure task execution capabilities.

Regarding psychosocial risk management, the author emphasizes the importance of matching individual abilities and values with organizational needs (Mishiba 2024) and suggests leveraging new technologies for this purpose.

Safety Management and Technology Adoption

New technologies are beginning to be utilized in safety management as well.

New technologies primarily developed to enhance productivity also contribute to safety management. For example, automation and intelligent systems in smart factories reduce process errors such as human data entry mistakes or improper machine operation, thereby

20) This may also enable the possibility of Precision Medicine.

21) *Obihiro Telegraph and Telephone Office of Nippon Telegraph and Telephone Public Corporation case*, First Petty Bench of the Sup.Ct. March 13, 1986, Labor Case Reports No. 470, p. 6.

lowering accident risks (Lv 2017). Automated guided carts (AGCs) autonomously controlled by a central system can prevent collisions with workers, as in the case of forklifts (Hanna 2022).

In construction, remotely operated heavy machinery enables safer and more efficient operations, even across hundreds of kilometers (Miura 2024). Robots handling repetitive tasks reduce physical strain, enabling older workers with physical limitations to work safely (Pinto 2023).

New technologies are also directly applied to safety management itself.

- Big Data Analysis: AI can analyze disaster-related big data (including unstructured data captured by sensors) for real-time risk assessment (Savković 2021; Liu 2020; Vogl 2019).
- AI-Powered Equipment: Construction machinery equipped with AI cameras, trained on past disaster mechanisms, can notify operators or halt operations when detecting hazards through video analysis (Goto 2021).

Remote digital audits of OHSMS implementation are becoming possible, enabling main contractors to manage subcontractor safety conditions digitally (Pinto 2023).[22)]

To ensure traffic safety for gig economy drivers and riders working under algorithms, Dynamic Maps (High-Definition Maps) can be utilized (METI 2017).

To reduce behavior-related accidents caused by unsafe human actions, AI could be employed to analyze the results of tests on individual workers' knowledge and thought processes, identifying those with competencies that may predispose them to accidents.

Additionally, Japan's Ministry of Health, Labor and Welfare possesses occupational accident data, which could be utilized to establish a system that provides real-time feedback to support the safe design of autonomous machines.

In Germany, the Bau Berufsgenossenschaft (Construction Employers' Liability Insurance Association) collects environmental data on occupational accidents, such as climate information, from observation points nationwide, as well as information from inspectors on high-risk industries and companies. By cross-analyzing these data, they actively apply preventive policies to enhance workplace safety. Preventive policies may, when necessary, also extend to the structure of machinery and other equipment. The association is reported to appropriately utilize new technologies in this process (Kort 2024).

Potential Applications of Emerging Technologies

The following emerging technologies have potential applications, some of which are already in use. (Savković 2021):

1) IoT: Machines detect and control abnormalities in other machines.
2) Cyber-Physical Systems: Analyze production and operational progress data in the

22) Therefore, it has been pointed out that under Industry 4.0, the focus of safety shifts from human safe behaviors to the robustness of information systems (Pinto 2023). Regarding this, Dr. Fujiwara from the Japan National Institute of Advanced Industrial Science and Technology has highlighted that the reliability of AI safety is 99.9%, which does not meet the Safety Integrity Level (SIL) 2 required by IEC 61508. He also noted that AI analysis is statistical and probabilistic, making it weak in addressing edge cases and difficult to judge gray-area issues (Fujiwara 2024).

cyber realm, detect anomalies, and provide feedback.

3) Exoskeletons: Wearable mechanical devices for workers that reduce physical strain during heavy labor. These can be considered advanced Personal Protective Equipment (PPE), helping mitigate musculoskeletal disorders (Barreto 2017; Pinto 2023).
4) Virtual Reality (VR): Simulates and evaluates work-related risks in a virtual space or provide experiential safety training to workers.
5) Augmented Reality (AR): Uses digital elements like visuals and sounds to enhance real-world tasks and training.

These advancements underscore the potential of I4.0 technologies in enhancing both productivity and safety within the workplace.

3.6 Trends in Regulations Adapted to Industry 4.0

OHS regulations have historically lagged behind industrial revolutions (Milea 2024). As of now, no country has fully developed OHS regulations tailored to the core technologies of I4.0.

However, the EU-OSHA report provides several suggestions regarding the impact of AI technologies on OHS and the necessary adaptations to OHS regulations (EU-OSHA, 2022):

(i) Human-Centric AI Technology Usage:

- The adoption of AI technology should be promoted, but humans must remain at its center. To achieve this, it is essential to:
- Foster dialogue between employers and employees:
- Minimize the collection of workers' data.
- Ensure transparency in AI-based Worker Management (AIWM) systems.
- Assign oversight responsibilities to designated individuals or stakeholders.

(ii) Addressing Psychosocial Risks in a Digital Society:

- Psychosocial risks shall be a key focus of OHS, particularly in a digitalized society. Preventing bullying and ensuring fairness—especially concerning well-being—are integral parts of this. As such, worker management (direction, evaluation, discipline), OHS, and well-being are inherently interconnected.

(iii) Risk of Worker Dehumanization:

- AI collects various types of data on workers, including biometric information, facial expressions, and body language. While this information is useful for worker management and OHS, it also poses risks of worker dehumanization and potential privacy infringements.[23)] AI should support humans, not replace, subordinate, or manipulate them.

(iv) Workers' Rights Regarding AI:

Workers must be guaranteed:

- The right to refuse AI-based data collection.
- The right to disconnect from AI systems.
- The right to request explanations for decisions made by algorithms.

(v) Improving AI Literacy:

- Both employers and employees should enhance their understanding of AI technologies and their implications.

23) However, whether the collection of personal information by machines constitutes a violation of privacy is a matter that requires discussion.

(vi) Accountability of AIWM System Providers:

- Providers of AIWM systems must inform users about the system's functions and risks. If the system is found to be harmful, its shutdown should be facilitated.

(vii) Effectiveness of Regulations Against AIWM's Adverse Effects:

- Current regulatory frameworks addressing AIWM's potential negative impacts include:

a. EU Directive 2002/14/EC:

This provides the legal basis for labor-management consultations concerning AI adoption.

b. General Data Protection Regulation (GDPR), Article 22:

This ensures individuals are not subjected solely to decisions based on automated data processing.

c. EU Charter of Fundamental Rights and the European Convention on Human Rights:

These guarantee respect for human rights and prohibit discrimination.

d. Proposed EU AI Regulation (December 2023)[24]:

Recently agreed upon in principle by the European Parliament, this legislation categorizes AI systems for HR purposes—such as hiring, promotion, job assignments, and dismissal decisions—as high-risk, mandating safety measures in their design, development, and use.

e. Germany's AI Strategy (Die Bundesregierung, 2018):

This highlights the need for legal amendments addressing data protection and co-determination in AI applications for labor.

f. Spain's Riders Law (Royal Decree-Law 9/2021):

This law establishes employment rights for food delivery workers and ensures algorithmic transparency in platform-based employment.

These developments underscore the need for a proactive approach to integrate OHS regulations with the transformative technologies of Industry 4.0.

4. Conclusion

Based on the above considerations, an active preliminary discussion on legal regulations adapting to I4.0 will be presented.

4.1 Fundamental Regulatory Methods

The core technologies of I4.0, such as AI, exert both positive and negative impacts on OHS. Governments must explore effective OHS regulations that do not hinder business development enabled by these technologies.

Existing OHS regulations are based on the analysis of past major occupational accidents and include vast amounts of knowledge and standardized practices applicable even to small businesses. These practices encompass standardized work procedures, training, risk assessments, and mechanisms for worker participation (Badri 2018).

However, they lack compatibility with operational systems and mechanisms for constant monitoring of workers and work environments (Badri 2018). Furthermore, the rapid pace of new technological development makes conventional regulatory methods inadequate.

Thus, developers, programmers, and machinery manufacturers (hereafter referred to

24) It was published as The EU AI Act on June 12, 2024. For details, please refer to https://artificialintelligenceact.eu/the-act/, accessed December 10, 2024.

as "developers") should be required to design OHS-focused regulations,[25] report their contents and operational conditions to administrative authorities, and receive oversight and support for effective regulations. This approach constitutes a method of "co-regulation."

Developers and governments must anticipate risks and aim for prospective and speculative regulations. To ensure specialization and agility, it is necessary to delegate authority for setting standards to specialized administrative agencies focused on OHS.

An alternative method is to develop standards created by non-state actors such as International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), British Standards Institution in the UK (BSI), and Japanese Industrial Standards Committee (JIS). These standards could then be incorporated into legal regulations. For instance, businesses complying with such standards could be deemed compliant with national regulations and exempt from inspections.

It is desirable to enrich these standards at the design stage of equipment, operational processes, and products (Hanna 2022), as managerial measures during the operational phase are more limited and costly (Pettitt 2016; Badri 2018; Leso 2018).

Most existing inspection standards are insufficient for autonomous machines capable of self-replanning routes during operations (Hanna 2022). While some norms such as the Machinery Directive 2006/42/EC, ISO 10218:1, ISO 10218:2, and ISO/TS 15066, which adopt the so-called Three-Step Method,[26] are to some extent adaptable to new technologies; however, they do not account for autonomous machines. Autonomous machines require risk evaluations for the entire system, not just the machinery itself. Existing norms often fail to address this requirement, meaning CE Marking,[27] compliance does not always guarantee safety. Moreover, current standards are criticized for rigidity, requiring reevaluation whenever robots' installation locations or equipped tools change (Hanna 2022).

However, emerging standards like IEC 61508 hint at adaptations to new technologies, suggesting permissible risk levels for autonomous decision-making in cyber-physical systems (Kuschnerus 2015).

Human-robot collaboration will require standards reflecting human cognitive and psychological functions (Hanna 2022).[28] Promoting

25) To encourage developers of new technologies to engage in self-regulation for safety and health management, one potential approach is to seek investments from private insurance companies and health and accident insurers that benefit from reductions in workplace accidents.

26) Here, the three-step method refers to the following:
Step 1: Intrinsic safety measures during the design phase
Step 2: Additional protective measures through safeguarding and similar mechanisms
Step 3: Providing information, such as signals, instructions, or training, and requiring users to take residual risk measures, such as using personal protective equipment.

27) It is a mark that indicates certain products meet EU unified standards and serves as a kind of passport for distribution within the European market.

28) For example, Lasota (2017) argue that safety between humans and robots includes not only physical safety but also psychological safety. They identify four necessary strategies for ensuring this safety: control, motion planning, prediction, and psychological consideration. The focus here is primarily on the potential for robots to cause psychological discomfort to workers, which may result in negative effects impacting both the physical and mental well-being of the worker, either directly or indirectly. It is also noted that psychological harm can arise from remote interfaces.

system standards legally is also critical, as Occupational Health and Safety Management Systems (OHSMS),[29] which integrate safety and operational processes for continuous organizational improvement, can contribute to the both also under I4.0 (Badri 2018).

Performance-based standards, which leave means of achievement to the regulated entities, may effectively encourage the development of standards compared to uniform specification-based requirements (Kajiya 2024).

4.2 Legal Foundations for Information Sharing

Providing legal foundations for sharing information on occupational accidents and risks is crucial.

As demonstrated by Germany's example mentioned above (Kort 2024), creating platforms to consolidate occupational accident data and related environmental information (e.g., climate conditions) and using them for rapid policymaking cycles is legally viable. It should also be legally promoted to immediately reflect occupational accident data in programming and manufacturing of machinery operated by AI. Developers must bear a duty to provide users with risk-related information, which should be integrated into a data platform for analysis and operational use.

To prevent trade secrets from leaking, the obligation to provide information could be limited to risk-related data. However, even if leaks cannot be entirely avoided, safety should take precedence over confidentiality. Shared information should reasonably include predictions derived from AI learning. Developers could also be obligated to explain safety concerns reasonably. Employers should be required to obtain risk-related information and conduct risk assessments. Inspectors should include experts in new technologies to verify compliance with these duties.

4.3 Promoting Risk Assessment and Digital Literacy

Promoting risk assessments by employers and developers remains effective under I4.0. Establishing a comprehensive OHSMS that continuously improves organizational and operational processes could yield certain benefits (Badri 2018).

However, as automation advances, risks become less visible,[30] complicating human-conducted risk assessments. AI safety also faces challenges in handling edge cases and gray areas (Fujiwara 2024). Therefore, developers of new technologies may need to develop verification technologies akin to antidotes for their creations.

Improving digital literacy among both labor and management is essential. Training on the functions of AI and cobots, methods of verification, collaborative practices, and responses

29) Regarding the elements of OHSMS, ISO identifies three key components: (1) policy formulation, (2) a systematic management mechanism to identify and minimize occupational health and safety risks, and (3) raising risk awareness throughout the organization (ISO 2015). The primary objective is to minimize the risks of occupational accidents and diseases, but it also includes the prevention of work-related illnesses and health issues. However, it has not yet fully addressed the challenges posed by Industry 4.0 (Pinto 2023).

30) Pinto (2023) point out that one of the drawbacks of computer-based data processing is that the causes of accidents can become less discernible. Additionally, they highlight the difficulty of resolving issues through alternative measures when problems arise.

to malfunctions should be mandatory for businesses. Training to differentiate human capabilities from new technologies and enhance those capabilities should also be encouraged.

4.4 Providing Frameworks for Proper Use of Wearables

Using wearables to measure workers' health parameters (e.g., blood pressure, brain waves, and stress levels) may cause privacy concerns or psychological pressure but can be justified when balanced against health management needs.

Wearable monitoring may be justified for tasks involving health risks or workers with pre-existing conditions. Wearables collecting and analyzing data, notifying workers, and sharing only anonymized group data with employers can also be justified, provided qualified managers oversee their use. In countries where conducting health examinations is legally mandated, this method could potentially serve as a substitute for traditional health checkups.

The measurement of working environments using wearables should be treated in the same manner as measurements conducted with personal exposure samplers under conventional legally prescribed methods. If current laws limit the scope of measurements, the utilization of new technologies should be employed to expand the scope wherever feasible.[31)]

4.5 The Role of Law

In addition to resolving disputes and punishing crimes, law plays a preventive role. It can mandate solutions based on past failures and successes,[32)] establish frameworks for safety and management systems, and promote technological development.

The fundamental role of OHS regulation under I4.0 includes establishing frameworks for risk investigation and management, preventing privacy infringements and discrimination, and providing safety nets. As noted by the UK Sunak Conservative Government (2023) and EU-OSHA (2022), such regulations should harness the benefits of new technologies without stifling innovation.

Integrating safety management into equipment and production planning stages is crucial, as OHSMS systems can contribute to continuous improvement of both safety and operational processes under I4.0 (Badri 2018).[33)]

4.6 Principle of Liability for Risk Creators

Revisiting OHS liability is a vital legal issue. As suggested by the ILO Occupational Safety and Health Convention (No. 155), employers have traditionally borne primary OHS responsibility. However, this is not necessarily because employers have complete control over OHS. Rather, it is likely due to the socio-engineering rationale that assigning responsibility to employers

31) It has been noted that the use of new technologies, such as wearables, not only expands the scope of data collection but also enables immediate analysis of the collected data to predict and manage workplace risks (Leso 2018). In Japan, the current *Occupational Environment Measurement Act* does not include risks such as outdoor heat, gas, or fire as measurement targets, but these might become measurable in the future.

32) However, in post-industrial countries, there has been a shift from reactive measures focused on mandating recurrence prevention of workplace accidents to preventive approaches (Badri 2018).

33) Pinto (2023) argue that the evolving aspects of OHSMS under Industry 4.0 include document management, stakeholder awareness, risk communication, risk identification, and auditing. Technologies such as AR, autonomous robots, and artificial intelligence are highlighted as playing particularly critical roles.

makes it "easier" to prevent workplace accidents. On the other hand, under I4.0, various stakeholders—such as platforms, programmers, machinery manufacturers, decision-makers for new technology adoption, AI data providers, and approvers of AI decisions—play increasingly critical roles in risk management.

Thus, the principle of risk-creator management responsibility[34)] is required. This principle holds that responsibility for managing risks lies with those who create the risks (including those who can "recognize" and "manage" them), regardless of whether they are employers (Mishiba 2023). However, centralized supervision by labor inspection agencies is challenging, necessitating coordination among relevant administrative bodies.

Among risk creators, clients/orderers are likely to bear greater OHS responsibilities than before. Legal frameworks could be introduced to impose on them the duty to verify whether contractors have the capacity (in terms of personnel, systems, and technology) to complete tasks safely and healthily.[35)] Additionally, new laws could support the establishment of third-party institutions to evaluate such capacities.

4.7 Addressing Psychosocial Risks

Addressing psychosocial risks is a particularly critical challenge for OHS under I4.0. However, it is questionable whether emphasizing employer responsibility to address such risks as obligations alone can fully resolve the issue. Risks such as those arising from human–machine interactions, the weakening of interpersonal relationships in machine-centered production systems, malicious harassment, and prolonged excessive working hours should indeed be prevented as part of employer responsibilities.

However, when addressing issues related to compatibility between human–human, human–organization, and human–work relationships, a flexible mental health approach that focuses on enhancing the strengths of both individuals and organizations is likely to be more effective. This approach would involve improving personnel and labor management—particularly in terms of selection, job design, training, motivation, and communication—as well as operational management. Aligning workers with their roles, colleagues, and supervisors, as well as harmonizing workers' skills and values with organizational expectations, would often yield better outcomes (Mishiba 2024).

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2. The FY2019–FY2021 Ministry of Health, Labour and Welfare Science Research Grant (Comprehensive Research on Occupational Health and Safety), "A Legal

34) Australia's *Model Work Health and Safety Act* embodies this principle to a significant degree.

35) As a relevant example, the UK's *The Construction (Design and Management) Regulations* can be cited. Article 8(3) imposes an obligation on construction project designers and principal clients to verify the capacity of contractors. Article 8(2) prohibits contractors without sufficient capacity from undertaking construction work.

Study for the Revision of the Occupational Health and Safety Act" (Principal Investigator: Takenori Mishiba).

Conflict of Interest Statement

There are no conflicts of interest to declare.

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