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Takehiko Hashimoto, ed. 橋本毅彦編, *Anzen kijun wa dono yō ni deki te ki ta ka* 安全基準はどのようにできてきたか [*How Have Safety Standards Been Constructed?*]

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We rarely show much interest in the basis of safety standards, although the safety of almost everything in society is built on them. The reason is simply that we assume these standards to be based on robust science. As a result, complex real-world elements have become obscured behind safety standards, and myths about safety continue to be held. We tend to regard something as perfectly safe as long as it satisfies its safety standard, and perfectly dangerous when it falls short. This attitude often results in overreactions in response to mass media reports pointing out a failure to comply with standards. Safety standards, however, are not criteria based purely on science that invariably separate safety from danger, but instead are artificial creations obliged to balance benefits and risks. Knowledge of the assumptions and processes behind the making of various safety standards is one part of the basic literacy of living successfully in this complex modern society. Based on these ideas, I started a graduate course at the University of Tokyo on how to set regulatory standards, and in 2014 I and three colleagues published a book explaining the processes of various kinds of standards. It focused on safety in foods, drinking water, air quality, and radionuclides, although it covers traffic-safety-related standards as well (Murakami et al. 2014).

The book *How Have Safety Standards Been Constructed?*, edited by Takehiko Hashimoto, was also written for a related motive: to visualize past, buried memories about the processes and disputes in developing various safety standards. It is based on the final reports of a four-year, joint research project that started in 2012 and was published in 2017, and it consists of nine chapters by eleven authors. It has two distinctive features compared with our previous works. One is its focus on such engineering fields as aviation, marine vessels, firefighting, river dikes, and nuclear facilities; the other is its adoption of a historical approach. Based on a large body of historical materials, some chapters indeed go back beyond World War II.

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This book is also a collection of case studies on real "regulatory science" (even though this is not a term the authors use). Over forty years ago, Alvin Weinberg (1972) advocated the concept of "trans-science" and defined it as the "questions which can be asked of science and yet which cannot be answered by science." The constructing of safety standards is clearly a trans-scientific activity, not something achieved solely by science, containing as it does many assumptions and inferences. Economic considerations must be included. Weinberg pointed to "engineering judgment" as one example of trans-science and stated that the compelling reason for defining it as a trans-science was that "the engineer works against rigid time schedules and with a well-defined budget" (210).

Unlike the concept of trans-science, which tends to emphasize the fact that science cannot answer all of the questions raised by policy, the concept of regulatory science, advocated in late 1980s, emphasizes the idea that science can try to answer questions raised by policy, although both look to the gap between science and policy. Activities for constructing safety standards in the field of medicine started being called "regulatory science" in the 1990s, and more recently the concept of regulatory science has been spreading to other fields, such as chemicals and food.

This book consists of nine fascinating case stories on real regulatory science in Japan, with a focus on engineering. The nine stories are divided into four categories: transport, disasters, health, and international standards.

The first addresses the development of aviation and maritime safety standards, focusing on the first half of the twentieth century. Both fields have in common that insurance companies played a critical role in developing safety standards at an early stage and that international negotiations inevitably accompanied the process.

The second section addresses the development of safety standards for mitigating fire, flood, and nuclear disaster. In the field of fire safety, several numbers were introduced. One, introduced in 1882, was the approximately two-hundred-meter cordon regulating the distance around a fire; the other (the "eight-minute fire service") required firefighters to arrive at the scene of a fire within eight minutes simply because it was assumed that the fire would spread to neighboring buildings thereafter. A common feature in the history of developing safety standards for both flood and nuclear disaster mitigation was the introduction of probabilistic risk assessment. The concept of probability was introduced just after World War II in determining the safe height of river banks, although standards were determined based on the largest recorded floods up until that time. One factor was the strict budget constraints of the day. This example clearly shows the key role of the cost element in determining safety standards. Explicit consideration of costs is often regarded as inappropriate in determining safety standards and hidden from official records in Japan. On the other hand, the safe height of seawalls is still determined based on the largest recorded tsunami, even after the 3/11 Tohoku earthquake. The methodology of probabilistic risk assessment in nuclear power plants was first proposed in 1975 in the United States and was introduced in Japan in the 1980s but was adopted in developing safety standards in 2013 after the Fukushima nuclear accident.

The third section of the book, on health, addresses the development of the Tolerable Daily Intake (TDI) of organic mercury in fish and the transition of the assumed relationship between worker health and safety and psychological traits. The first chapter covers the process of determining the TDI and the upper limit for mercury

concentration in fish, both of which have been updated several times. This study shows that these are not things that can be determined purely by science and that there is much room for political intervention. The second chapter, which does not cover concrete safety standards, instead describes the historical development of psychological explanations of worker health and safety, focusing on the period from the 1920s to the end of World War II.

The fourth and final section of the book addresses the development of international standards for medical devices and the CE Mark used in the European Union. The International Standardization Organization (ISO) plays an increasingly crucial role in developing safety regulations in our globalized world. In the medical field, the concept of "Good Practice" was born in 1962 and is the prototype of the important concepts of Good Manufacturing Practice, Good Clinical Practice, and Good Laboratory Practice. The style of safety regulations has also needed to change, from the traditional command-and-control types to performance-based ones, in response to the increase in speed of technological innovation. The CE Mark is a certification that indicates conformity with safety, health, and environmental standards, the basic idea being that regulators set only the general goal and leave regulated entities room to choose how to achieve this.

The concept of risk is indispensable in demonstrating the safety of something, since safety is defined by ISO/IEC Guide 51 (ISO/IEC 2014) as "freedom from risk which is not tolerable." And this is why the concept of probability has been introduced in developing safety standards in several cases. This book is also useful for readers with an interest in how society will accept, or sometimes reject, emerging technologies. In the past, emerging technologies such as automobiles, airplanes, and even nuclear power plants could be relatively easily introduced into society. In recent years, however, the safety of emerging technologies must be demonstrated by those who have developed or would like to sell them before their introduction. This reflects a change in the assumptions behind safety, from "when we don't understand it, we assume it's safe" in the last century, to "when we don't understand it, we assume it's hazardous" in this. In other words, society has learned lessons from the many failures of the last century and has adopted a precautionary approach to emerging technologies. For example, the safety of carbon nanotubes was vigorously investigated even before a small volume of samples was supplied for development into possible applications. So, if innovators wait for the development of safety regulations set by governments, they will surely lag behind rivals, regulators usually having little knowledge of emerging technologies. They must develop instead ways to demonstrate safety, especially methodologies of risk assessment and (voluntary) safety standards for their own technology, in parallel with the development of the technology itself, and propose them to such an international body as the ISO. In the field of the sharing economy in Japan, coregulation has been looked to as a solution to the dilemma, bringing the benefits of government approval while allowing the timely revision of rules in response to unforeseen technological changes and social problems.

When emerging technologies are introduced, there will be inconsistency with existing laws and regulations, sometimes leading to unexpected accidents. For fear that overly strict safety standards might be established in response to accidents, an emerging technology might be withdrawn, denying us of its potential benefits for some time. Moderate safety standards being established and implemented appropriately plays an

important role in reducing uncertainty in business and in supporting innovation. The importance of innovation is well recognized in Japan, but not the pivotal roles of safety standards and regulatory science.

This book will contribute to enhancing public understanding of how the safety of society has been ensured through relevant standards. Yet it covers only past experiences, hence the title. The next step for readers to consider must be, how will safety standards be constructed?, a question that will become more and more important in the case of emerging technologies such as autonomous vehicles, health care robotics, and drones.

References

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