Interim evaluation report (draft): Legal System Research Group

1. Objectives

The objectives of this research project are to analyze and study, in a cross-sectional manner in relation to safety systems, a variety of legal systems for ensuring safety (e.g., traffic safety, medical and pharmaceutical safety, food safety, nuclear safety, and disaster prevention, etc.), with the cooperation of researchers in the engineering/medical research groups representing various sectors of the mission programs. By so doing, we aim to clearly demonstrate the basic methods/techniques for the review, design, and operation of a uniform safety legal system.

2. Members

Name	Affiliations
Hideaki Shiroyama	Associate Professor, Graduate School for Law and Politics, the University of Tokyo
Mitsuo Kobayakawa	Professor, Graduate School for Law and Politics, the University of Tokyo
Hisakazu Hirose	Professor, Graduate School for Law and Politics, the University of Tokyo
Ryuji Yamamoto	Associate Professor, Graduate School for Law and Politics, the University of Tokyo
Toshihiro Kawade	Associate Professor, Graduate School for Law and Politics, the University of Tokyo
Tomoyuki Tanabe	Chief Researcher, Central Research Institute of Electric Power Industry
Takako Nakajima	Part-time Instructor, International Christian University
Ryoko Hatanaka	Researcher, Research Institute of Science and Technology for Society
Kengo Hattori	Graduate School for Law and Politics, the University of Tokyo

3. Target achievements

3-1. Construction of a cross-sectional knowledge base covering existing legal structures for safety

Based on a comprehensive examination of existing safety-related legal systems, we will establish common perspectives and make cross-sectional comparisons. As a result,

we will clearly reveal the overall picture of the existing legal structure on safety (that could not be seen in its entirety until now due to its historic complexity, etc.), as well as the breadth of the tools used.

3-2. Case study on safety laws: Extraction of implicit knowledge in legal structures related to safety and its limitations

By building up a store of detailed case studies in a bottom-up style, based on dialogues with on-site business personnel and technicians, we will clearly show the implicit knowledge in legal structures related to safety as well as their limitations.

3-3. Construction of a method for designing legal structures for promoting safety

Through investigations of the technical and social characteristics of various sectors related to safety, as well as their relationship with the design of legal structures, we will categorize the guidelines (e.g., options as well as legal, political, and administrative consideration items related to each option) to ease the design of systems suited to various sectors.

3-4. Specific science and technology for society = Proposal of legal structures designed to promote safety

Starting from our cross-sectional knowledge base covering existing safety laws, case studies of safety laws, and temporary safety law design techniques, we will propose several legal structures designed to promote safety to serve as specific science and technology for society while cooperating with the mission program groups representing various sectors.

4. Status and self-evaluation

4-1. Construction of a cross-sectional knowledge base covering existing legal structures designed to promote safety (progress rate: 80%)

With respect to the construction of a cross-sectional knowledge base on existing legal structures related to safety, we have more or less completed a comprehensive investigation of the existing legal structures in the transport sector (aviation and vehicular transport), medical and pharmaceutical sectors, housing disaster-prevention sector, food safety sector, nuclear safety, etc. We are currently categorizing the issues and analyzing them based on common perspectives (a. A system for gathering information on accidents, breakdowns/failures, and safety; b. Collaboration and

allotment of responsibilities of countries, industries, academic societies, international organizations and foreign countries in establishing the standards; c. Collaboration and allotment of responsibilities of the administration, private sector, international organizations and foreign countries in implementing tests; d. A victim relief system).

4-2. Case study on safety laws: Extraction of implicit knowledge in legal structures related to safety and its limitations (progress rate: 60%)

(1) Aviation safety: We investigated the relationship between surveys conducted by aviation accident investigation committees in Japan, US and Europe, and criminal procedures. From here on, we plan to extend our studies on European case examples and continue our studies on system design.

(2) Nuclear safety: We investigated the role which a system of whistle-blowing plays in ensuring safety, the process of stoppage and operational resumption of nuclear reactors, and the procedures and systems of establishing, certifying and accrediting the standards. Henceforth, we plan to extend our studies on accreditations and certifications, and to continue our studies of system designs.

(3) Medical safety: We investigated the provision of information for ensuring safety, certification of the quality of medical institutions, the role of expert/professional organizations, and a system for compensation and reparation. From here on, we plan to accumulate more case studies focusing on the analysis of the systems and operations implemented in the US and Europe to ensure the quality and safety of medical treatments, then examine system designs.

(4) Food and pharmaceutical safety: We investigated the roles of experts as well as industrial organizations, and the establishment and operation of the Food Safety Commission, using the Kanemi Oil Poisoning incident and the Morinaga Powdered Milk incident as examples. From here on, we hope to continue studying cases reported by the Food Safety Commission as well as cases pertaining to already-approved pharmaceuticals.

(5) Chemical safety: In the fall of 2002, we conducted a joint overseas survey (UK) with the Chemical Process Safety Research Group to investigate the role that chemical information plays in establishing various criteria and the role of private organizations in the process of establishing certification/accreditation of standards. We also conducted similar surveys on present conditions in Japan. From here on, we hope to propose an even more detailed system design.

(6) Product safety: We investigated the operation/management of legal structures on product safety in Japan, the US and Europe. Studies of cases in the US and Japan

are also steadily under way. From here on, we hope to investigate system designs while taking into account the relationship with insurance, etc.

(7) Insurance systems: We have more or less completed a historical analysis of insurance systems as well as standards that serve as insurance's undertaking conditions. From here on, we hope to conduct further case studies on the allotment of roles of insurance and regulations in various specific sectors, and to present a framework.

4-3. Construction of a method for designing legal structures that promote safety (progress rate: 20%)

We have presented a hypothesis through cross-sectional comparisons of existing legal structures designed to promote safety. From here on, we will categorize the guidelines (e.g., options as well as legal, political, and administrative consideration items related to each option) for the design of systems specifically suited to various sectors.

4-4. Specific science and technology for society = Proposal of legal structures designed to promote safety (progress rate: 50%)

Starting from our cross-sectional knowledge base covering existing safety laws, case studies of safety laws, and temporary safety law design techniques, we will propose several legal structures designed to promote safety that will serve as specific science and technology for society, while cooperating with the mission program groups representing various sectors.

(1) A system for supporting the elimination of inappropriate (disaster-prone) houses that have already been built

We have collaborated with the Seismic Disaster Prevention and General Research Groups in conducting a joint study on the issue of repairing/rebuilding existing inappropriate (disaster-prone) houses to make them earthquake-resistant. As the Legal System Research Group, we aimed at gaining a clear understanding of the current status and problems associated with legal structures and insurance systems, and plan to propose new legal structures. Our study focused especially on the balance between usage restriction systems and the protection of people's freedoms and rights, as well as the subsidy system and the shouldering of financial burdens by the government and municipalities. We conducted comparative studies on a number of specific systems.

(2) Legal structures promoting chemical safety and the role of private-sector

organizations (corporations and expert/professional organizations)

A joint research project is currently under way with the Chemical Process Safety Research Group. We have reached the stage of completing an analytical paper that may become the basis for future system proposals. From here on, we plan to conduct further discussions on system design with the collaboration of legal researchers, engineering researchers, and business personnel.

(3) Legal structures regarding nuclear safety and the role of private-sector organizations (corporations and expert/professional organizations)

Basic analyses of procedures related to the establishment of standards, whistle-blowing, and the operational suspension/resumption of nuclear power plants, etc., are currently being completed. At present, we are studying methods for proposing future system designs. In so doing, we plan to collaborate with the Nuclear Safety Research Group and the General Research Group.

(4) Accident investigations and pursuit of responsibility in complex systems

Basic analyses of procedures related to investigations of air accidents and the pursuit of specific responsibilities, gathering of information on malpractice accidents, etc., are close to completion. At present, we are studying methods of proposing future system designs. As part of this process, we plan to collaborate with the Failure Study Research Group.

(5) Legal tasks facing the clinical navigator system

We have studied, from the legal structure perspective, the significance and problems associated with the clinical navigator system that is currently being developed primarily by the Medical Safety Research Group. One issue that is likely to become especially problematic from the legal perspective should this type of system be introduced is its relationship with the protection of personal medical information. The following specific points at issue have been identified: While there is a need, from the personal interest/benefit perspective, for a system that provides accurate information to patients and gains their understanding, there also is a need, conversely, from the public interest perspective, for a system that enables mutual collaboration between different medical institutions and ensures the use of the broadest range of medical information. We plan to conduct more detailed studies henceforth.

4-5. Self-evaluation

In this research project, we analyzed and studied, in a cross-sectional manner, a variety of legal systems designed to ensure safety (e.g., traffic safety, medical and

pharmaceutical safety, food safety, nuclear power safety, and disaster prevention, etc.), with the cooperation of researchers in the engineering/medical research groups representing various sectors of the mission programs (by taking advantage of our status as a member of a mission group that includes diverse engineering/medical research groups). By so doing, we believe that we have been able to demonstrate clearly the basic methods/techniques relating to the design and operation of a uniform safety legal system. We were also able to show a major step in direction of reconstructing these systems.

In carrying out our studies, as mentioned earlier, we held regular and frequent study meetings (over 50 times over a 20-month period), in addition to holding close discussions among the members. The latter in itself was a valuable experience as a cross-sectional project covering various sectors of our university's Graduate Schools for Law and Politics. Through operations such as these, we were able to spend time conducting substantive, cross-sectional discussions (which under normal circumstances we rarely have time to engage in), which we feel to be highly significant. First of all, especially during the initial year (2001), we were able to conduct highly focused discussions with individual groups within the mission program (groups such as Seismic Disaster Prevention, Medical Safety Research, Failure Study Research, Chemical Process Safety, and Traffic Safety Research), and to compare the awareness of the issues held by legal experts concerning legal structures designed to promote safety with that of engineers and physicians. Second, we have continued to hold study meetings with the Seismic Disaster Prevention and Medical Safety Research Groups, and are producing joint findings and results.

Pertaining to the mission program as a whole, our Legal System Research Group has played a central role in active research exchanges on a daily basis as well as in three mini-symposiums covering the whole range of mission programs. As a result of these activities, we believe that we were able to contribute to stimulating and inducing cross-sectional discussions.

In conducting this research, moreover, we are collaborating with similar programs being implemented in the US and the UK. The results are steadily being incorporated into the educational programs at the University of Tokyo Graduate Schools for Law and Politics and other institutions.

From here on, we hope to continue conducting case studies on safety laws that are based on actual sites where these laws are enforced, and to proceed with joint research (that is highly specific, detailed and personal) with legal, engineering, and medical researchers such that we are able to set forth clearly items that have up to now been

regarded as implicit knowledge. At the same time, we hope to capitalize on those operations to construct a method for designing these types of legal structures to ensure safety. In the course of implementing such processes, we hope to collaborate with the engineering and medical research groups in studying and making system proposals on issues such as the system of accident investigations and pursuit of where responsibilities lie, the system of regulations pertaining to chemical processes and nuclear power, and the system of quality control in the medical sector.