



Recommendations on Regulatory Cooperation and Standardization Policies

Revised Edition

P Recommendation P on Risk Management in Regulatory Systems¹

The Working Party on Regulatory Cooperation and Standardization Policies,

Recognizing the role of technical regulation, conformity assessment and market surveillance in preventing and addressing crises in various fields,

Noting that some risks are almost impossible to identify, and that all risks, even if identified, cannot be totally mitigated,

Recognizing the common interest of all regulatory stakeholders, including economic operators and consumers, in developing and applying tools that allow to effectively anticipate, and if necessary, resolve situations of crises,

Recognizing that international and national crises may require different treatment,

Recognizing the need to take decisions despite lack of information and the speed of change of the crisis,

Stressing that in many cases crises have led to imposing disproportionate regulations,

Underlining that risks that are identified and accepted within a regulatory system require developing or updating contingency plans that can be applied by regulators and other stakeholders,

Stressing that “crisis management” is an integral function of the risk management process of any regulatory framework,² and that effective preparedness and/or response to crises requires systemic management of risks, and vice versa,

Taking into account international and national standards related to risk management, such as, for example, current editions of ISO 31000, IEC 31010, AS/NZS 5050, ISO 9001 and ISO 27001, ISO 22301, ISO 26000, ISO 23313, ISO 22316, (see <https://www.iso.org/covid19> for relevant free ones), ISO 15801, ISO 20395, ISO/IEC 20000, ISO/IEC 17000 and other standards relevant to the healthcare system,

And **with the objective of** promoting a culture of responsible management of risks, increased preparedness for and management of crises, including more effective coordination among all parties that can be involved in crises,

1 Recommendation P adopted in 2011 and revised in 2020.

2 The definition of crisis management is one that is used in the respective sector/industry.

Recommends that:

- P.1** Regulatory authorities should recognize that there are situations which are beyond the capacity of normal organizational structures and processes. This situation can best be managed when sufficient resources are available and prior planning in accordance with available international best practice has been made.
- P.2** Regulatory authorities should design and implement crisis management functions as an integral part of the risk management process of a regulatory framework.
- P.3** Regulatory authorities, taking into account the internal and external context of a regulatory system, available resources, regulatory objectives, communication technologies, lessons learned, and other factors, should design the crisis management function so that it provides effective coordination of the actions taken by various stakeholders, including conformity assessment bodies, market surveillance authorities, economic operators and citizens in a situation of a crisis. The crisis management processes should permit managing the following phases: preparation for a crisis, stabilization, continuing critical functions, recovery and follow-up.
- P.4** Crisis management should be described in the legislation that establishes regulatory practice.
- P.5** A crisis management unit (or any other form of assigning responsibility for crisis management) functioning within a regulatory system should be endowed with the necessary resources and authority, which may include:
- (a) Access to emergency funding;
 - (b) People with the required skills, experience and competence;
 - (c) Tools, methods and supporting infrastructure for managing a crisis;
 - (d) Communication systems;
 - (e) Information and knowledge management systems;
 - (f) Delegated and defined authority for decision-making;
 - (g) Authority to reduce regulatory interventions that have “compliance costs” that impede the delivery of an essential service, or supply of products, out of proportion to the risks they address during the crisis;
 - (h) Participation in international and cross-jurisdictional information sharing and activities to coordinate response to the crises.
- P.6** A recovery planning and management unit functioning within a regulatory system should be endowed with the necessary resources, which may include:
- (a) People with the required skills, experience and competence;
 - (b) Tools, methods and supporting infrastructure for planning and managing a recovery;
 - (c) Communication systems;
 - (d) Information and knowledge management systems;
 - (e) Delegated and defined authority for decision-making;
 - (f) Participation in international and cross-jurisdictional information sharing and activities to coordinate recovery planning.
- P.7** Regulatory authorities establish contingency plans and build contingent capacity that can be quickly released in a crisis as a tool to reduce the impact of a crisis. Regulators, in coordination with relevant stakeholders, develop, test and implement:
- (a) Generic contingency plans with general responses for risks, whether they were identified, to allow effective responses to any incidents in the early hours of a crisis;
 - (b) Where appropriate, specific contingency plans for risks identified and processed within the system.

Contingency plans specify:³

- (i) Version, date and issuing authority;
 - (ii) Purpose and scope;
 - (iii) Activation criteria;
 - (iv) Cross-reference and linkages to other plans;
 - (v) Roles, accountabilities and responsibilities;
 - (vi) Process descriptions;
 - (vii) Details for accessing resources;
 - (viii) Communication and consultation requirements;
 - (ix) Schedules of critical information including contact lists, maps and plans;
 - (x) Description of possible techniques for:
 - Stabilization;
 - Continuing critical functions;
 - Recovery;
 - Implementation of lessons learned.
- (c) Regulatory authorities as a part of implementation of contingency plans organize training for personnel to ensure that:
- (i) The staff is familiar with the procedures;
 - (ii) The contingency plans are realistic, complete and uploaded.

P.8 Regulatory authorities prepare communication and consultation processes as a part of crisis management in order to:

- (a) Build awareness, confidence and understanding of crisis management processes by regulatory system stakeholders;
- (b) Effectively exchange information and consult with stakeholders in situations of crises, to provide information to stakeholders in early hours after the crisis occurs;
- (c) Encourage, where appropriate, the use of opportunities provided by alternative media.

P.9 Regulatory authorities ensure that in situation of a crisis appropriate mechanisms are established for, at least, the following:

- (a) Providing immediate focus on affected individuals;
- (b) Launching and using reliable data collection processes;
- (c) Activating a crisis management team (which may include subject experts, top management, crisis people, affected individuals, etc.);
- (d) Organizing a review of the effectiveness and lessons learned from the management and recovery from a crisis.

P.10 In organizing a review of a crisis, regulatory authorities should gather the related data and analyse the causes of the crisis, the effectiveness and relevance of actions taken during the immediate response period as well as the recovery period. Data related to a crisis constitute an input into regular risk identification

3 For details, please see AS/NZS 5050:2010.

performed within a regulatory framework.⁴ Adoption and continuation of regulatory measures related to crisis are subject to the normal review processes.

- P.11** Regulatory authorities should participate in regional and international cooperation efforts to develop and build capacity in the field of international best practice in crisis management.
- P.12** Donors should give top priority to capacity-building activities for crisis management and contingency planning, especially to train officers responsible for technical regulation, conformity assessment and market surveillance activities.

4 See ECE/TRADE/C/WP.6/2011/4 (draft of the general recommendation "Risk Management in Regulatory Systems").