



TECHNICAL REGULATION

SANDBOX

(Courtesy translation)

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1. This Regulation identifies the requirements and procedure for the establishment of a sandbox and issuance of authorization for its management.
2. The establishment of a sandbox allows for addressing regulatory or technological challenges in order to:
 - a) test or validate new requirements, acceptable means of compliance and standards or changes thereof, or
 - b) develop new technologies, systems, services, products and business models.
3. Within the sandbox it is possible to carry out impact analyses of the activities referred to in letters a) and b), paragraph 2, on the external environment.

Art. 2 Definitions

1. For the purposes of this Regulation, the following definitions apply:
 - a) **Sandbox** - controlled physical or virtual test environment, in which activities related to regulatory and technological challenges can be experimented for a limited period of time, after opening a dialogue with ENAC. The sandbox benefits from a simplified temporary regime.
 - b) **Sandbox administrator** - legal person authorized by ENAC to manage a sandbox.
 - c) **Regulatory challenge** - attempt to:
 - i) fill regulatory gaps;
 - ii) modify rules or interpretative material and guidelines that prevent or in any case make activities inefficient in various domains of the civil aviation system or
 - iii) cope with the absence of standards or rules for the specific innovation at stake.
 - d) **Technological challenge** - attempt to:
 - i) fill technological gaps or the lack of industrial standards;
 - ii) cope with the inadequacy of industrial standards that prevent the realization of innovative products and services;
 - iii) meet the need for evaluation of new systems or
 - iv) assess the maturity of a project, product, technology or service.

Art. 3 Scope

1. This Regulation applies to activities carried out by supervised entities that pursue interests consistent with ENAC's institutional tasks and are considered worthy of protection.

2. The following activities are relevant for the purposes of this Regulation, alternatively:
 - a) significantly innovative;
 - b) require an exemption from current requirements and need experimentation and the opening of a dialogue with ENAC;
 - c) Add value to the civil aviation sector.

Art. 4**Sandbox team**

1. The sandbox team is in charge of carrying out the process of establishing the sandbox, and it consists of ENAC experienced professionals not directly involved in the approval of the sandbox's operations.
2. The sandbox team will be responsible to discuss with the applicant the challenges and the demonstration of their aviation system, to establish the relevant sandbox and to monitor its test activities and assess final results.
3. According to Article 36 of Italian Legislative Decree are used 16 July 2020, n. 76, converted into law 11 September 2020, n. 120 (so-called "Sperimentazione Italia"), in the case of tests which require the issuance of a temporary exemption from national rules, the ENAC sandbox team can be integrated by experts from the Department for Digital Transformation of the "Dipartimento per la trasformazione digitale della Presidenza del Consiglio dei ministri".

Art. 5**Sandbox administrator**

1. The sandbox administrator is a legal person with adequate organization and capacity for the purposes pursued. The sandbox administrator is responsible for ensuring the coordination of the activities of the various subjects in the sandbox, and for:
 - a) ensuring compliance with the obligations assumed upon the approval of the sandbox project by ENAC;
 - b) organizing operational activities within the sandbox in order to guarantee the efficient and optimal use of resources for the provision of activities and services of a qualitative level adequate for the purposes of the sandbox;

- c) where necessary, under the supervision of ENAC, coordinating with the other subjects authorized by ENAC and the air navigation service providers;
- d) adopting risk mitigation measures and procedures and any other measures necessary for the coordination of the subjects operating in the sandbox. The introduction of new technologies, systems, services, products and business models is such as not to introduce unacceptable risks, both within the scope of sandbox activities, and in the external environment, under both nominal conditions and degraded conditions (defect or failure).
2. The sandbox administrator shall appoint one person with the overall responsibility for the management of the relevant services and coordination of the organisation authorised to operate with the purposes of the sandbox.
3. The establishment of a sandbox and the issuance of the corresponding authorization for use in favour of a subject with a registered office in a State outside the European Union are subject to the opening of a secondary office or a representative office in Italy.
4. The sandbox administrator monitors the activities according to the challenges identified, processes the results and continuously updates the sandbox team on the progress of the program.

Art. 6**Application for a Sandbox authorization and its management**

1. An Organisation can apply for establishing or modifying a sandbox, or for an extension of its activities to ENAC.
2. The application form can be sent at any time by e-mail to:
Ente Nazionale per l'Aviazione Civile - protocollo@pec.enac.gov.it.
3. Technical data to support application shall include:
- a) detailed description of the activities and the challenges;
 - b) risk assessment and mitigation measures with the aim of reducing the systemic and operational safety risks associated with the sandbox activities;
 - c) analyses, simulations and test plans suitable for ensuring the validity of the assumptions referred to in letter b);
 - d) list of organisations/operators/person interested in operating in the sandbox.

4. Organizations/operators/person that intend operate in the sandbox shall satisfy the conditions listed in the present regulation and meet the applicable requirements, however applicable, necessary for carrying out operations.

Art. 7**Approval procedure**

1. Following the positive assessment of the application, ENAC shall establish the sandbox in favour of the sandbox administrator, and in coordination with other relevant authorities where appropriate.
2. In the sandbox testing and/or simulations could be conducted only under authorised operations by ENAC.
3. The sandbox approval specifies the methods and duration of the tests/simulations, the provisions in force, the operational procedure to mitigate the risks and the unknowns, and protect third parties, and involved parties. Timelines for completing the Sandbox process depend on the scale and complexity of the challenges. ENAC shall be informed about any change or limitations to converge towards clarity and focus on how innovation addresses the fundamentals of safety, security and consumer protection.
4. The procedure shall be comply with the Italian Law 7 August 1990, n. 241, and subsequent amendments, and with the ENAC Regulation "Individuazione dei termini dei procedimenti amministrativi di competenza dell'Ente Nazionale per l'Aviazione Civile".

Art. 8**Establishment of a sandbox on ENAC's initiative**

1. ENAC may establish a sandbox on its own initiative in compliance with the requirements and procedures established in this Regulation if understands that the existing regulations are not fit for the purpose of the novel products and services, and where there are gaps in regulations for the purpose of achieving public interests,
2. The sandbox may be managed by a legal person with adequate organization and capacity for the purposes pursued who express an interest in it, under the conditions and according to the methods established in this Regulation.

Art. 9
Analysis of results

1. The outputs and findings of the testing are documented in a Report. The Sandbox administrator shall review the evidence that has been gathered, and document the lessons learned from the testing
2. The report contains at least:
 - a) the results of the tests/simulations/activities carried out according to the challenges identified, including the occurrence reporting;
 - b) where there are gaps in regulations, the proposal of new emerging requirements need to be addressed or of change of existing requirements supported by an impact analysis and any other useful element also pursuant to article 71, § 3, Regulation (EU) 2018/1139;
 - c) where envisaged, the proposals of new acceptable methods of compliance or standard;
 - d) the proposal to adopt new regulation or modify existing rules or address technological evolutions.

Art. 10
Data collected protection

1. Data collected shall be processed by authorised staff and not to be used, in any circumstances, for other purposes than ENAC institutional purpose.

Art. 11
Occurrence Reporting

1. The provisions of Regulation (EU) no. 376/2014 apply to operations carried out within a sandbox.
2. The sandbox administrator is responsible for the collection, analysis, and management of data related to aeronautical events that occur during activities carried out in the sandbox, as well as for communicating to ENAC any other occurrence that may represent a significant risk to safety.

Art. 12**Fees**

1. The activity carried out by the ENAC sandbox team is invoiced pursuant to the ENAC "Regolamento per le Tariffe".

Art. 13**Liability and insurance**

1. The sandbox administrator is responsible for identifying and taking out, before the start of activities, an insurance policy that is appropriate for the purpose and activities to be carried out, in compliance with current legislation. Where legislation is lacking, the policy should align with the minimum parameters established by Regulation (EC) no. 785/2004, and should, in any case, be suitable for covering damage to third parties arising from the performance of activities.
2. It is the sandbox administrator's responsibility to verify that all subjects operating in the sandbox have insurance, concerning the specific operations, appropriate for the purpose and suitable for covering damage to third parties, including the pre-flight, flight and flight conclusion phases, in compliance with current legislation and, where lacking, with the minimum parameters established by Regulation (EC) no. 785/2004.
3. In the event that the insurance coverage proves to be inadequate pursuant to paragraph 1 or paragraph 2, the sandbox manager, as the sole responsible party, is obliged to respond in his own capacity, without limitation.
4. The insurance referred to in paragraphs 1 and 2 includes insurance for the Italian State, ENAC and all subjects involved in the operation.
5. In the event of damage resulting from willful misconduct, gross negligence or violation of the conditions and limitations specified in the authorization for the management of the sandbox, the manager's liability towards third parties is unlimited.
6. In the event of damage resulting from willful misconduct, gross negligence or violation of the discipline applicable to the activities of the subjects operating in the sandbox, the liability of the aforementioned operators towards third parties is unlimited.

**Art. 14
Sanctions**

1. In the event of violation of this Regulation, articles 1174 and 1175 of the "Codice della Navigazione" apply.
2. The procedure for the suspension, revocation and limitation of the provision establishing a sandbox, as well as for authorization to manage it and for the application of pecuniary administrative sanctions, is governed by the ENAC Regulation "Esercizio del potere sanzionatorio per la violazione del Regolamento (UE) n. 2018/1139 e Regolamento (UE) n. 255/2010", excluding article 7, Establishment of the committee.

**Art. 15
Data protection**

1. Documentation submitted to ENAC shall specify whether the operations carried out within the sandbox scope may involve processing of personal data.
2. The processing of personal data takes place pursuant to Regulation (EU) 2016/679 and Italian Legislative Decree no. 196 of 30 June 2003.

**Art. 16
Entry into force**

1. This Regulation shall enter into force on the day of its publication in the ENAC institutional website.