

1. REQUEST

Enquiry title:	Tracking (identification, recording and closing) of issues and non-compliances by the AsBo
Enquiry description:	It is not clear which information the AsBo should share with the proposer concerning the issues and non-compliances the AsBo identifies during the independent safety assessment activities.
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Country:	France
Date of submission:	26/06/2018
Related documents:	Regulation 402/2013, Article 6 Explanatory Note on the roles and responsibilities of the AsBo

2. TRACEABILITY

RFU number:	11
Version number:	1.0
Version comment:	First version, voted by the plenary

3. SOLUTION

1.	There should not be any form imposed for fulfilling this requirement.
2.	Applying the working method described in the RFU 1.1, the AsBo should keep a history log with all issues and non-compliances identified with respect to : <ul style="list-style-type: none"> (a) the provisions of the risk management process in Regulation 402/2013; (b) the description of the project organisation⁽¹⁾, project management, proposer's risk management and roles of all involved actors (including the sub-contractors [if any] and the actors impacted through the interfaces); (c) the proposer's safety and quality processes;
3.	The information in the history log should include the following: <ul style="list-style-type: none"> (a) minimum basis as evidence of the identified issue(s) and/or non-compliance(s); (b) reporting (i.e. communication) of the issue(s) and/or non-compliance(s) to the proposer and systematic formal recording in the history log referenced to in the independent safety assessment report; (c) assessment of the proposer's remedial actions for the identified issue(s) and/or non-compliance(s).
4.	This RFU leaves thus freedom to each AsBo to keep using its own templates/tools for fulfilling this need.

⁽¹⁾ The term organisation refers here to the proposer's (project) organisation, including the safety and quality processes and assigned resources and responsibilities, actually put in place by the proposer for managing the development, the risk assessment and risk management of the significant change under assessment. It does not refer to the overall organisation of the proposer's company.

Where the CENELEC 50126, 50128, 50657 and 50129 standards are used as Codes of Practice for controlling the identified hazards, the project organisation is expected to describe how the compliance with the CENELEC Safety Integrity Levels, and the associated levels of independency of project development activities, is achieved for the hazards and risks arising from the change under assessment. By virtue of point § 3.3 in Annex I of Regulation 402/2013, the AsBo is required to independently assess whether the project organisation matches with the applicable Safety Integrity Levels.

4. DECISION

Cooperation decision:	Accepted
Plenary meeting nr:	9
Date of decision:	5 November 2020

5. ANNEX

Additional details on the solution: No further details needed	
Annex documents:	There are no annexed documents