**Introduction to using this guide**

SMS regulations require organisations to have a Management of Change process to document and assess the impact any organisational or operational change has on safety. This evaluation guide provides CAA staff with a framework to assess the Management of Change documentation. It is intended to be used to enable the CAA to be satisfied that a valid assessment of the change has been documented. It also provides a record of our evaluation.

This change documentation may come under different titles depending on the organisation and the regulatory requirements but commonly these may be called safety cases, safety risk assessments and aeronautical studies.

The Assessor will need to judge the depth of the evaluation and whether the processes and procedures used by the organisation would be sufficient to uncover any significant flaws in the change.

Due to the depth and complexity of many organisational changes it is recommended a sampling approach is used as not every aspect can be fully assessed. The extent of the sample depends on the judgement of the assessor. In addition, a judgement of the organisation’s capability and competence in managing the change safely and the assessor’s confidence in the organisation’s management system should be considered. There is a set of questions to determine the level of regulatory involvement at the start of the evaluation tool.

The evaluation has six interrelated steps:

1. **Assessment of the nature, scope and impact of the proposed change**

Review the submitted documentation to understand the change, has been adequately described, including the context and its impact internally and externally.

1. **Assessing hazard and consequence identification.**

Ensure that an appropriate hazard identification process has been carried out and the range of consequences have been identified and documented.

1. **Evaluation of the way that the risk has been assessed and accepted.**

Review and evaluate the probability and severity are classifications are appropriate and justified and is applied consistently to manage risks to an acceptable level.

1. **Assessing the risk mitigation actions**

Evaluate the risk mitigations to determine the effectiveness of the actions taken to control the risk.

1. **Assessing the justification and, supporting evidence.**

Assessment of any supporting evidence and arguments used to justify that and the change is valid and does not have an adverse effect on safety

1. **Assessing the assurance plan to manage the residual risk**

Review how the organisation plans to monitor the change implementation and verify that risks mitigations are effectively managed after the change has been completed.

Each step includes a series of actions to be taken by the assessor. For each action there is guidance to assist the assessor and a comments box to record what was sampled and any comments. The assessor does not have to review against each action but should indicate those that have been assessed and those that haven’t by identifying ‘not assessed’ in the comments column.

**Regulatory Requirements**

There may be specific regulatory requirements on how a safety case or safety risk assessment are formally accepted from existing regulatory obligations. These should always be followed and this guide supports that formal acceptance.

This guide should always be used to record the CAA evaluation of a change. It is used to guide the inspector to assess the proposed changes by the organisation and to demonstrate our assurance that the change and its supporting documentation was given an appropriate level of evaluation.

The Summary Observation Form may be used to track any issues raised with the submitted documentation.

**Management of Change Evaluation Record**

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| **Organisation:** | **Title of Change:** |
| **Point of Contact:** | **Revision / issue** **No.** |
| **CAA Assessors:** | **Date:** |
| **Project/File Ref:** | **Date received:** |

**Determining Regulatory Involvement**

To determine the level of regulatory involvement is needed in the safety case evaluation the matrix could be used (record here the chosen level of involvement by marking the matrix):

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| **What level of confidence does the CAA have that the organisation can successfully manage the proposed change?** | **Low** |  |
| **Medium** |
| **High** |
|  | **Low** | **Medium** | **High** |
| **What is the impact of the change in respect to the organisation and the aviation system?** |

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Note 1: Past oversight and the organisation’s capabilities should be considered when determining the level of confidence.

Note 2: Novelty, Complexity and scope of the change should be considered as part of the impact of the change.

The evaluator should review their assessment in the above matrix to determine their level of involvement. The further to the top-right of the matrix, the greater the level of involvement. Additionally, there may be little or no authority involvement necessary if the assessment is in the lower left corner of the matrix above, however consideration of regulatory obligations may still demand regulatory involvement. A low level of involvement could result in a greater use of sampling. In such case, the approach to sampling should be identified and recorded.

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| **Level of authority involvement**  | Mark the matrix above | **Record justification:****Sampling approach used:** |
| **Is further regulatory involvement needed?** | Yes | Proceed to Step 1. |
| No | **Record justification:** |
| **Date:** | **CAA Inspector / Surveyor:** |

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| **Step 1 – Assessment of the nature, scope and impact of the change** Review the submitted documentation to understand the change has been adequately described, included the context and its impact internally and externally. |
| **Actions** | **Evaluation guidance** | **Comments:** |
| 1.1 Review the documentation to determine whether it adequately describes the nature and scope of the change.  | Who is making the change?What is being changed?Why is it being changed?How is it being changed?  |  |
| 1.2 Review the documentation to determine whether the change has considered the environment in which the organisation / services operate. | Have the following been considered?People and ProceduresEquipmentStakeholdersPhysical environmentOrganisational cultureapplicable rulesExternal threatsInternal / external interfaces |  |
| 1.3 Review the documentation to determine whether it provides an adequate understanding of the change. | Is it; clear?Complete?Appropriate?Consistent?Unambiguous? Does it make sense? |  |
| 1.4 Review the documentation to determine whether the direct and indirect impact of the proposed change has been defined. | Do the defined impacts consider:• Direct interactions with what has been changed?• Knock-on effects from the direct interactions?• Indirect impacts through shared resources? |  |
| 1.5 Review the documentation to determine the organisation considered the cumulative effects of the change. | Have multiple changes been considered on individuals or systems? |  |
| 1.6 Does the impact of the change have an effect on compliance with standards and regulations? | Is this a proposal for an alternative means of compliance (AltMOC), meeting a rule or standard?Does this support a permission, exemption or approval? |  |
| 1.7 Does the change need other CAA departments or specialist involvement? | Where the change has a direct or indirect impact on another part of the aviation system additional CAA staff may need to be involved in the evaluation. |  |
| 1.8 Determine whether the documentation makes a clear conclusion for the safety of the proposed change and has been signed and accepted by an appropriately authorised person in the organisation? | Are there invalidated assumptions?For significant changes, you would expect to see the Accountable Manager signing off the change. |  |
| **Step 2 – Assessing hazard and consequence identification**Ensure that an appropriate hazard identification process has been carried and the range of consequences have been identified and documented. |
| **Actions** | **Evaluation Guidance** | **Comments** |
| 2.1 Is the hazard and consequence identification process documented? | Confirm that this it has been documented or that existing procedures have been followed.  |  |
| 2.2 Determine who were the people involved in the process? | Evaluate whether the right people were selected (this may include subcontractors and external stakeholders).Have departments/ organizations identified as interfaces been involved in the hazard identification process?  |  |
| 2.3 Ensure the methods used enable a comprehensive hazard and consequence identification? | Evaluate the methodology to ensure it identifies hazard and related consequences.Evaluate whether identified hazards and consequences are appropriate. Consider if any hazards or consequences have been missed.Review suitability of data used  |  |
| 2.4 Confirm whether human performance related hazards and their consequences been identified? | Have the following been considered; CompetencyFatigueAttention Working environment Distractions Communication Human physiologyHuman to machine interface Stress Error tolerance |  |
| 2.5 Confirm that the identified hazards and their consequences are recorded. | Sample some of the identified hazards and consequences. This may be included as part of the change documentation or held separately (but cross referred). |  |
| 2.6Determine whether hazards associated with interfaces and external organisations have been considered? | Ensure hazards related to internal and external interfaces outside of the control of the organisation have been considered? |  |
| 2.7 Determine whether hazards associated with the transitional phase have been considered. | Ensure that hazards that could arise during the implementation of the change have been considered. |  |

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| **Step 3 – Evaluation of the way that the risk has been assessed and accepted**Review and evaluate that probability and severity classifications are appropriate, justified and applied consistently to manage risks to an acceptable level. |
| **Actions** | **Evaluation Guidance** | **Comments** |
| 3.1 Have appropriate likelihood and severity definitions been defined and used to classify the consequences?  | Are they the same as that used in the organisation’s SMS?This may be qualitative definitions supported by expert judgement or Quantitative definitions when data is available. |  |
| 3.2 Has a risk tolerability matrix been defined and used? | Is it the same as that used in the organisation’s SMS? |  |
| 3.3 Have the likelihood and severity for each consequence been recorded and the level of risk assessed? | Is the likelihood, severity and risk assessed before and after mitigating action has been taken? Consider whether the likelihood and severity identified are reasonable and appropriate. |  |
| 3.4 Has the review of likelihood and severity taken into account the effectiveness of existing barriers and defences? | Does the organisation use bow tie models, event tree analysis, fault trees etc? |  |
| 3.5 Determine whether the risk is adequately controlled or has the justification for the risk acceptance been recorded? | Where a risk remains tolerable has the decision to accept a risk been made my an appropriately authorised person and the reasoning behind the acceptance been recorded? |  |

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| **Step 4 – Assessing the risk mitigation actions** Evaluate the risk mitigations to determine the effectiveness of the actions taken to control the risk. |
| **Actions** | **Evaluation Guidance** | **Comments** |
| 4.1 Check that the appropriate risk mitigations are implemented, recorded and will continue to be effective. | Confirm that risk mitigations are appropriately documented. Some hazards will have more than one mitigation.  |  |
| 4.2 Determine who was involved in establishing the risk mitigations  | Were appropriate people involved in the decision making and is there appropriate ownership of the risk controls? |  |
| 4.3 Review the risk mitigations, are they appropriate, achievable and is the residual risk considered appropriate after the risk reduction strategies? | Are the mitigations reasonable and robust?Are the mitigations practical and realistic? Has the residual risk been calculated after taking into consideration all risk mitigations? |  |
| 4.5 Determine whether the risk mitigations have created any new risks or affected existing risk mitigations? | Do the mitigation actions impact directly or indirectly impact any existing risk mitigationsor other safety requirements? |  |
| 4.6 Have Human Factors principles been considered in the choice of risk mitigation?  | Is there an over reliance on human action as a risk mitigation? Is the mitigation action fail safe and error tolerant?  |  |

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| **Step 5 – Assessing the justification and supporting evidence.**Assessment of any supporting evidence and arguments used to justify that the change is valid and does not have an adverse effect on safety. |
| **Actions** | **Evaluation Guidance** | **Comments** |
| 5.1 Review any supporting evidence that is presented to justify that the change is safe to implement | Is it possible to reject the evidence presented?Does it provide an equivalent level of safety? Has the proposed change been audited and assessed by the organisation? Have they addressed everything? Confirm that any evidenceis appropriate and relevant.Confirm that there is sufficient evidence to support the change. |  |
| 5.2 Confirm that transitional risks have been considered and addressed? | Additional hazards and risks may be associated with the transition from the existing operation to the changed operation and will need to be identified and addressed. |  |
| 5.3 Determine whether conclusions for the change been included? | Review the Conclusions:Ensure that the conclusion states that the change and the transitional arrangements can be implemented safely. |  |
| 5.4 Some mitigations take the form of statutory requirements defined in legislation that are applicable to the change under consideration.  Have these been captured and addressed in the change documentation? | Statutory requirements may come from EU Regulations, EASA or the CAA |  |

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| **Step 6 – Assessing the assurance plan to manage the residual risk****Review how the organisation plans to monitor the change implementation and verify that risks mitigations are effectively managed after the change has been completed.** |
| **Actions** | **Evaluation Guidance** | **Comments** |
| 6.1 Check that the organisation has identified the critical steps and risk controls that will be subject to checking and who is responsible? | There may be critical steps or phases in the change that require additional monitoring. Some of the risk controls will be more critical than others so should be highlighted. Critical in terms of:* Impact.
* Robustness of the controls.
* Number of remaining barriers in place

Check who is responsible for the monitoring activities and verification checks.  |  |
| 6.2 Review how the organisation intends to confirm the risk controls are effective?  | Has an appropriate plan for checking the risk controls been defined? Have performance indicators been established?Are there adequate contingency plans in place? |  |
| 6.3 Determine how the organisation will verify that any assumptions made in the change are valid? | How are they going to monitor and review the assumptions after the change has taken place?Will there be sufficient data available to support the claims? |  |
| 6.4 Review when the change will be reviewed and how frequently?  | The original justifications made in the change documentation may be affected by changes in the system, environment or organisation. |  |

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| **Change Acceptance** | **Date** | **CAA Staff** | **Business Area** |
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| **SUMMARY OBSERVATION FORM** | **Version: Date:**  |
| **Change Brief (project name):** | **Assessors:** | **File Ref:** |
| **Evidence Assessed (documents reviewed)** (name/date/issue**[shorthand ref]**)**:** |

| **Obs Ref No.**(Initial & Number) | **Date Raised** | **Assessor(s)** (Initials) | **Observation & Evidence**(Enter shorthand reference here & full document name/date/issue in ‘Evidence Assessed’ above) | **Safety Concern or Non-compliance** | **Update/Closure Rationale**(date & initial responses from the organisation & CAA updates) | **Closed date/init** |
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