Transport Category Airplane Continued Operational Safety Agreements

Aviation Rulemaking Committee

Recommendation Report
September 30, 2024

1. Executive Summary

In response to the National Academies of Sciences, Engineering, and Medicine (NASEM) review of the Federal Aviation Administration (FAA) Transport Airplane Risk Assessment Methodology (TARAM)[1], this Aviation Rulemaking Committee (ARC) was chartered by the FAA to provide industry feedback to support the FAA's response to recommendations made by NASEM in 2022. The charter[2] for this ARC tasked industry with drafting new, and clarifying existing, FAA policies and guidance for Continued Operational Safety (COS) Agreements with industry organizations. This includes drafting new, and clarifying existing, policies for quantitative ranking of alternative solutions in support of responding to NASEM Recommendation 9, review and provide feedback to the FAA's proposed response to NASEM Recommendation 6, review the FAA's study in support of NASEM Recommendation 11, and drafting new, or clarifying existing, policies for efficiently providing the FAA with the organization's safety data to support the FAA performing a TARAM.

The work of the Committee generated eleven recommendations for the FAA. Two of those recommendations are associated with the first task the Committee which was to draft new, or clarify existing, policies for the quantitative ranking of alternative solutions in support of responding to NASEM Recommendation 9. While reviewing the arguments presented by the NASEM review of the FAA TARAM, and the references[3],[4],[5] provided within the NASEM review for NASEM Recommendation 9, this Committee concludes that the recommendation to adopt quantitative ranking of alternative corrective actions within the TARAM and execution of COS is not conducive to the industry need to assess the volume of reported conditions quickly and flexibly, and may not support the best modeling of the risk. However, this committee assumes the intent of NASEM Recommendation 9 is to suggest the adoption of an objective method of assessing possible solutions to address unacceptable risk. Therefore, this committee proposes the FAA TARAM Handbook PS-ANM-25-05[6] add guidance elaborating on the evaluation of possible solutions based on the policy within MSAD Order 8110.107B, and FAA Advisory Circular (AC) 39-8.

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[1] *Evaluation of the Transport Airplane Risk Assessment Methodology*. (2022). In *National Academies Press eBooks*. https://doi.org/10.17226/26519

[2] *Transport Category Airplane COS Agreements ARC Charter*. (2023, September 1). Federal Aviation Administration. https://www.faa.gov/regulationspolicies/rulemaking/committees/documents/transport-category-airplane-cos-agreements-arc

[3] *Acceptability of probabilistic risk assessment results for Risk-Informed activities*. (2020, December 29). Federal Register.

[4] Stamatelatos, S., Dezfuli, H., Apostolakis, G., Everline, C., Guarro, S., Mathias, D., Mosleh, A., Paulos, T., Riha, D., Smith, C., Vesely, W., & Youngblood, R. (2011, December 1). *Probabilistic Risk Assessment Procedures Guide for NASA Managers and Practitioners (Second Edition)*. NASA Technical Reports Server (NTRS). https://ntrs.nasa.gov/citations/20120001369

[5] Groth, K., Wang, C., & Mosleh, A. (2010). Hybrid causal methodology and software platform for probabilistic risk assessment and safety monitoring of socio-technical systems. *Reliability Engineering & System Safety*, *95*(12), 1276–1285. https://doi.org/10.1016/j.ress.2010.06.005

[6] Federal Aviation Administration, 2011, Transport Airplane Risk Assessment Methodology (TARAM) Handbook, PS-ANM-25-05, Washington, DC: Transport Airplane Directorate ANM-100.

After the initial draft deadline for Task (a), the committee expanded to include the rest of the tasks defined within the charter. Work Groups were established with each Work Group assigned tasks or subtasks with the goal of educating committee members and Subject Matter Experts (SMEs) on high level overview of existing relationships each organization currently holds with the FAA for the transfer of data, conducting TARAM, and COS agreements in general. The outcome of the Work Groups is a set of recommendations for the FAA to consider, including a recommendation to establish general guidance for a COS Agreement outlined within Appendix C. This Committee considered providing a recommendation for the form the FAA should adopt in establishing policy for COS Agreements such as a Policy Memo or an Advisory Circular, however the committee members and SMEs concluded it is more appropriate to recommend requirements for the form and continued maintenance of COS Agreement Guidance for the FAA to determine the most advantageous authoritative document.

Five recommendations are associated with safety data sharing and include establishing information resources available to safety risk analysts, standardizing event reporting, sharing cognizant safety information with DAHs if obtained by the FAA through a third-party, and to enhance FAA feedback processes on safety decisions with the DAH. These recommendations were developed based on inefficiencies detected in Committee discussions on current practices and feedback from safety risk analysis practitioners from the FAA and industry.

The charter also tasked this committee with reviewing two FAA products responding to NASEM recommendations and providing feedback, which generated two recommendations. The FAA created a draft response to NASEM Recommendation 6 discussing the implementation of Design Assurance Levels (DALs) within the FAA TARAM, and a study addressing NASEM Recommendation 11 suggesting the FAA implement an independent peer review process. This committee reviewed the draft response to Recommendation 6 determining DAL does not translate effectively into the in-service risk analysis methods required post-certification and concurs with much of the document's conclusions; this committee disagrees with the draft's commentary on the usefulness or accessibility of 14 CFR 25.1309 principles and suggests the FAA engage with the Design Approval Holders (DAHs) to obtain the pertinent information as required. This committee reviewed the study prepared by the FAA to respond to NASEM Recommendation 11 which assesses the options and viability of incorporating an independent peer review of TARAM with the process. The study outlines several options for independent peer reviews and concludes such a practice is already in place through the FAA's Corrective Action Review Board (CARB). This committee agrees with the FAA's reasons but disagrees with the FAA's conclusion and suggests incorporating a step for vetting the TARAM with the DAH before presenting to the CARB.

Lastly, one of the goals of this Committee was to identify best practices that can be incorporated into a COS Agreement and the variability in the implementation of safety decision guidance values is a potential driver for divergent application of the COS process across the industry. A recommendation is made for a harmonized risk standard that would better drive convergence towards consistent flight safety standards, and risk mitigation decisions, at the industry level.

2. Background

The NASEM was chartered to provide a third-party non-advocate review of the FAA's TARAM. NASEM published a report in 2022 with 13 recommendations. NASEM Recommendation 3 suggested the FAA form an industry advisory committee to harmonize COS agreements between the FAA and DAHs. In reply to this recommendation, the FAA chartered an ARC to accomplish the suggested action and help formulate industry response to the NASEM Recommendations 6, 9, and 11.

The charter for this ARC focused heavily on the review of existing guidance for COS Agreements seeking industry input for improving existing guidance and drafting new guidance as appropriate. Guidance was reviewed by the industry members and weighed for appropriateness to the COS risk management. Emphasis was placed on quantitative methods of establishing importance rankings of prospective mitigating actions, supporting the FAA's accomplishment of TARAM, and improving efficiency of transmitting safety data to the FAA. Due to the NASEM recommendation timelines, the ARC charter prioritized drafting guidance for importance ranking of prospective mitigating action to be accomplished by February 29, 2024. This Committee then continued to refine the guidance and construct industry input to support the FAA's response to the NASEM recommendations with the goal of completion by September 30, 2024.

While this committee performed research through sharing COS agreement best practices, it was determined that COS agreements are not unique or limited to just part 25 DAH; several part 33 DAH also have a COS agreement or equivalent in place to facilitate the shared responsibility of risk analysis, risk management, and data sharing. As a result, the subject of COS agreements within this report is considered applicable to both part 25 and part 33 DAH.

3. Summary of ARC Activities

In addition to the published and publicly available documentation, the committee discussed practices used by the organizations they represent. These verbal discussions were general descriptions of practice without disclosing proprietary information. The dialogue on practice was used to benchmark industry organizations to provide guidance and feedback in executing the ARC charter tasks.

To facilitate the completion of the ARC Charter, this committee assigned the tasks to four working groups composed of ARC members and Subject Matter Experts (SME):

- Working Group 1 (WG 1) - Task a, b.i, b.iv, b.vi
- Working Group 2 (WG 2) - Task b.ii
- Working Group 3 (WG 3) - Task b.iii
  - Note: WG 3 combined efforts with WG 1 due to significant overlap in tasks
- Working Group 4 (WG 4) - Task b.v

In addition to regular WG meetings, the ARC members and SMEs met in plenaries with all WGs involved. The first plenary took place from June 25-26, 2024, for WG status sharing and recommendation development, and the second from September 4-5, 2024, for resolving comments on the ARC Recommendations Report and to ratify the report.

Due to the complexity of both the tasks chartered to this committee, and the recommendations from this committee, the table below was compiled to correlate the recommendations to the relevant task.

Table 1: ARC Report Section to Chartered Task Matrix

Report Section / Task	a	b.i	b.ii	b.iii	b.iv	b.v	b.vi
4.1. Response for NASEM Recommendation 9	X						
4.2. COS Agreement Guidance		X	X	X	X	X	X
4.3. Data Sharing Practices					X	X	X
4.4. Feedback to Draft NASEM Recommendation 6 Response			X				
4.5 Feedback on FAA NASEM Recommendation 11 Response Study Report				X			
Appendix C.1 General Guidance		X		X			
Appendix C.2 Scope of COS Agreements		X		X			
Appendix C.3 Monitoring and Event Reporting		X		X		X	
Appendix C.4 Potential Unsafe Condition Identification		X		X		X	
Appendix C.5 Risk Analysis and Decision Making	X		X		X		X
Appendix C.6 Risk Management Plan	X		X		X		X
Appendix C.7 Coordination/Communication		X			X	X	
Appendix C.8 SMS Integration		X					

4. Recommendations

While performing the tasks chartered to this ARC, this committee found there is opportunity to provide recommended improvements to existing FAA policy and documentation for COS risk management, suggested structure for the construction of COS Agreements, and feedback for FAA draft responses to NASEM recommendations. The following sections elaborate on the recommendations from this committee.

Some recommendations contain suggested text to insert into existing documents. This is represented by italicized text within the recommendation to clearly communicate the suggested content.

4.1. Response for NASEM Recommendation 9

Intent

Address NASEM Recommendation 9 by developing guidance which enables flexibility and speed for COS decisions by providing the factors to be considered in selecting corrective actions rather than to mandate any specific quantitative process.

Scope (ARC Charter)

Within the tasks of the ARC Charter, Task (a) states "regarding the TARAM Handbook, address recommendation 9 (risk importance ranking methods) of the NASEM report. Draft guidance to clarify and reinforce existing policies as well as develop any appropriate new guidance on quantitative ranking of alternative corrective actions and risk-informed inspections."

Discussion

While reviewing the arguments presented by the NASEM review of the FAA TARAM, and the references provided within the NASEM Recommendation 9 review, this committee concluded that the recommendation to adopt quantitative ranking of alternative corrective actions within the TARAM and execution of COS is not conducive to the industry need to assess the volume of reported conditions quickly and flexibly, and may not support the best modeling of risk.

The risk priority methods highlighted in the NASEM report use fault tree analysis methods not as common in COS analyses. Most COS assessments start with a known initiating event leading to possible unsafe outcomes and do not require a full fault tree assessment that is more typical for the certification of new systems. Often the corrective actions are limited and obvious, and thus any extensive quantitative analysis requirement could be counterproductive to safety. However, the committee assumed the intent of NASEM Recommendation 9 was to suggest the adoption of an objective method for assessing possible solutions to address unacceptable risk.

The committee found that that existing policy documents provides a good balance for considerations when multiple corrective actions are being evaluated, including FAA MSAD Order 8110.107B[8], FAA Advisory Circular 39-8[7], and EASA EU 748/2012 - Part 21.A.3B[10]. These documents provide considerations for selecting corrective actions that are useful while not being intrusive and time-consuming in the COS process where timeliness is an utmost concern. The guidance identified in these documents contain the follow considerations:

1. The risk mitigation effectiveness of the corrective action considering both interim and final actions
2. Implementation timelines, complexity, and cost
3. Availability of resources (shop capacity, material availability, personnel availability)

Therefore, to address NASEM Recommendation 9 and Task (a) of the ARC Charter, the committee proposes the FAA TARAM Handbook add guidance elaborating on the evaluation of possible solutions (Recommendation 1) as well as expanding the guidance within MSAD Order 8110.107B (Recommendation 2). The committee also proposes incorporating this guidance into COS Agreements and offered expanded considerations to be given to the selection of possible solutions therein (Section 4.2, Recommendation 3, Appendix C.6).

Recommendation 1

Within TARAM Handbook PS-ANM-25-05 Section 6.4 - Aviation Safety Engineering (ASE) Risk Management, it is recommended that additional information be included within the sub-bullets for step 3 as follows:

> *In some cases, the corrective action for an issue may be simple and obvious based on established industry experience. Any requirement to compare alternatives in this case may be counterproductive to making efficient safety decisions and deploying corrective action as soon as reasonably practicable.*

When multiple Candidate Corrective Action (CCA) sets are being considered, the optimum solution set can be assessed through qualitative, experience-based judgements and supported by quantitative data where available, based on:

- *The risk mitigation effectiveness of the corrective action considering both interim and final actions*
- *Implementation timelines, complexity, and cost*
- *Availability of resources (shop capacity, material availability, personnel availability)*

Recommendation 2

Within MSAD Order 8110.107B Chapter 2 Section 15.c - Evaluate Airworthiness Directive (AD) CCAs, additional information is to be included immediately after Step 2 as follows:

(3) In some cases, the corrective action for an issue may be simple and obvious based on established industry experience. Any requirement to compare alternatives in this case may be counterproductive to making efficient safety decisions and deploying corrective action as soon as reasonably practicable.

(4) When multiple Candidate Corrective Action (CCA) sets are being considered, the optimum solution set can be assessed through evaluation of risk mitigation effectiveness, timeliness/complexity, and impact on resources. Ranking, achieved with qualitative, experienced based judgements and supported by quantitative data where available, should be based on:

- *The risk mitigation effectiveness of the corrective action considering both interim and final actions*
- *Implementation timelines, complexity, and cost*
- *Availability of resources (shop capacity, material availability, personnel availability)*

4.2. COS Agreement Guidance

Intent

Through the review of the FAA policies, orders, and guidelines about Continued Operational Safety it is clear the FAA requires the partnership of the Design Approval Holders, Operators, and other organizations within the industry to ensure aviation products maintain a minimum level of safety. This section provides a framework and content for guidance of COS Agreements including value added practices being captured from industry experts. The section recommends the FAA task the creation of an industry guide to create the right level of documentation for the inculcation of COS Agreements[7].

[7] While this Committee does not direct a specific document to author, discussions in working meetings suggested that an industry-reviewed document like The FAA and Industry Guide to Product Certification might be the appropriate place to capture this guidance.

Scope (ARC Charter)

The Objective of this ARC, as stated in the Charter, was to "assess and develop improvements to current FAA requirements and guidance material for establishing detailed COS agreements between the FAA and design approval holders (DAHs) of transport category airplane type certificates."

Additionally, Task (b.i) of the Charter stated "Assess current FAA requirements and guidance material for establishing detailed COS agreements. Develop new guidance material as needed."

Therefore, the scope of this section is limited to findings and recommendations associated with existing FAA requirements and guidance material for COS Agreements, and the construction of recommended guidance.

Discussion

The members and SMEs of this committee reviewed existing FAA guidance and policies for COS Agreements and discussed existing COS Agreements or equivalents held by the organizations represented by this committee. Based on the reviews this committee has noted both observations and recommendations.

Each section of Appendix C.1 through Appendix C.8 represents a category of recommended guidance for COS Agreements, with findings, recommendations, and rationale pertinent to the section's subject.

While there is demonstrated practice for COS Agreements, or equivalent, between the FAA and Design Approval Holders, the requirement and guidance for the adoption of a COS Agreement is implicit. This committee finds value in establishing a standard for COS Agreements so there is a common framework between the FAA and Design Approval Holders for transferring significant safety-related data and managing in-service risk. Additionally, this committee believes there are opportunities for the FAA to use the Design Approval Holder as a partner resource for analyzing and managing in-service risk.

A critical component of the COS Process is risk mitigation, and therefore agreement on a methodology for risk management is a crucial element of a COS Agreement. Managing in-service risk must be considered within the constraints of available resources, complexity of implementation, cost, and risk mitigation effectiveness to be able to down select the corrective action which is most reasonably practicable for a given safety condition. The sharing of the methodology and inputs into that methodology should occur as fleet corrective actions are defined.

The committee also identified that best practice sharing across DAHs is valuable, and incorporating future learnings is critical to sustaining the guidance identified for COS Agreements. Therefore, the guidance should be updated with agility as best practices and learnings are encountered across the range of experiences between DAH and FAA organizations. Continued maintenance of the guidance should also consider any evolution to FAA policies or guidance. The content identified for COS Agreements is appropriate for an industry body tasked by the FAA to publish and maintain.

Recommendation 3

This committee recommends the FAA task an industry group to publish and maintain a COS Agreement Guide[8]. That industry body should utilize the information in Appendix C as the basis for publishing the COS agreement guidance document. This guidance will provide the information the committee identified as the basis for a successful COS agreement. This product will serve to inculcate COS agreements into the relationship between FAA and the organizations they oversee.

4.3. Data Sharing Practices

Intent

The intent of data sharing recommendations is to improve the availability and quality of relevant input data for FAA and industry safety risk assessments.

Scope (ARC Charter)

Within the tasks of the ARC Charter, Task (b.v) states "Provide recommendations for making transferring safety-related data (such as data related to Title 14 of the Code of Federal Regulations 21.3 and 183.63) more efficient.

In addition, the ARC Charter objective provides a focus on NASEM Recommendation 3 which includes the statement: "The agreements should explicitly define the monitoring and analysis process, including the type of data collected and the collection process necessary, to improve the completeness, accessibility, quality, and maintenance of TARAM input data for supporting the COS process."

Discussion

To understand opportunities to improve safety data sharing efficiency, the committee commissioned a survey of FAA TARAM practitioners and interviewed operators. This information yielded a variety of recommendations ranging from creating accessible databases for standard safety risk analysis inputs, modernizing and standardizing the method to collect reportable information, expanding the sharing of reportable event information with cognizant stakeholders, and improving FAA methods to provide information to the DAH on safety related decisions.

One of the findings from the survey of FAA practitioners was that a major source of uncertainty of TARAM input was obtaining data for failure rates (F) and conditional probability (CP). Additional feedback was obtained through a discussion with Operators which highlighted their difficulty in obtaining data needed for their safety risk management assessments. These discussions also revealed a lack of clarity of where to request this type of data within the FAA.

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[8] This committee recommended an industry group and guide to help establish guidance and provide updated guidance based on industry lessons learned, like *The FAA and Industry Guide to Product Certification*

A dedicated FAA database that contains aggregated safety data could provide useful data to aid in developing input assumptions for safety risk analysis purposes. This committee recognizes limitations and the need for each safety issue to be assessed on its own merit and context, but having a standard can be helpful for use or validation in input assumptions. An industry group forum could vet proposed parameters to ensure universally applicable parameters are published.

The FAA Analyze Safety Performance Insight Results Environment (ASPIRE) database has shown the capability of aggregating fleet utilization data from multiple sources which can be utilized to establish and validate fleet assumptions. Utilization assumptions are key safety risk analysis inputs given they define the exposure to risk outlook, in combination with the expected remaining aircraft life.

Review of current industry practices for submitting reportable information to the FAA found a wide variation by DAH in complying with the regulation. Review of global regulator practices identified opportunities for the FAA to modernize the method and standardize the collected information which can enable improved monitoring and data usefulness and accessibility. The FAA ASPIRE tool has promising capability in this area. The COS agreement guidance in the Appendix to this report also includes a suggested section on common taxonomy to be used throughout the course of a COS investigation, which can help reduce variation and provide clarity when DAH's make initial and subsequent COS reports.

Current FAA reporting requirements could be enhanced and aligned with Safety Management System expectations by ensuring DAH are informed of reported issues on their products. By DAH having increased awareness and context around product defects, COS processes will be enhanced.

Finally, COS agreements are effective, and efficient, with mutual transparency between the DAH and FAA. The committee sees an opportunity for the FAA to enhance their processes for providing feedback to the DAH. This allows the DAH to have better visibility of the FAA decision making process. This feedback will foster better communication and harmonization between the DAH and the FAA on each respective risk assessment processes.

Recommendation 4

Develop and maintain an FAA database which contains an accessible inventory of common and meaningful input parameters for safety risk analyses. For example, collecting frequently used operational factors, such as the occurrence rate of low altitude go-arounds, or obstacle limited take-offs, would provide useful source data for developing probabilities for safety issues vulnerable in these critical flight points. The FAA should utilize an industry group forum, such as done with the Continued Airworthiness Assessment Methodologies (CAAM) Committee for propulsion system hazards to aircraft, to identify relevant parameters (hazardous conditions, conditional probabilities, failure rate magnitudes, operational factors, etc.).

Recommendation 5

The FAA should develop a consolidated database with information on aircraft and fleet utilization data that can be accessible by industry, which takes into consideration of proprietary disclosure of operating usages (e.g., summarized by aircraft model/fleet rather than by operator). The FAA and industry access can help align on safety risk assessment assumptions which is important to achieve consistent risk assessment results. The FAA should use an industry group forum to help select and maintain pertinent parameters for the database. The industry group forum can help monitor to identify trends that would drive updates to the database.

Recommendation 6

The committee recommends the FAA develop and maintain a harmonized standard for initial reporting procedures for DAH. The standard should outline a preferred format, medium, and with a method approved by the Administrator. A European Union Aviation Safety Agency (EASA) reporting tool is an existing process that can be used as an example for FAA consideration. The interface should accommodate multiple DAH capabilities, such as the ability to either have input from DAH or capability for FAA to retrieve information from DAH systems.

Recommendation 7

Recommend the FAA revise its policies to include sharing information. Where reports external to the DAH are reported to the FAA and for items which manufacturers have a vested interest in (e.g., products built by the DAH), the FAA will push applicable reports to the DAH to increase visibility of issues that may affect their product and with sufficient information to take action. The intent is not to provide duplicate data back to the DAH.

Applicable instances include:

- Occurrences/Events that directly involve a DAH’s product (within applicable investigation NTSB protocols and beneficial for COS)
- Submittal of a Service Difficulty Report from Part 91, 121, 135, and 145 operators
- Submittal of Voluntary Disclosure Reports from Part 121, 135, and 145 operators (With express permission of operators, deidentified, with non-pertinent parts redacted)

Recommendation 8

It is recommended that the FAA develop, within their safety issue tracking system (ASPIRE), a feedback mechanism to DAH’s concerning FAA risk assessments, safety decisions, and AD creation status. As the DAH is exercising its COS process, the COS agreement should allow transparency on the data being evaluated, assessments done on that data, decisions made based on the assessment and actions taken. It is recommended that the FAA develop processes to provide similar information flow back to the DAH on its decision-making processes, closure status of issues, and, within ex-parte protocol, status of AD creation and implementation timing, triggered by status/phase changes within COS decisions or AD publication dates.

4.4. Feedback on Draft FAA NASEM Recommendation 6 Response

Intent

This section contains the consolidated committee feedback on the FAA proposal for addressing NASEM Recommendation 6, which advocates for the usage of certification methodologies when conducting the in-service safety process. The FAA proposal can be found within Appendix D.

Scope (ARC Charter)

ARC Charter Task (b.ii) - Review and provide feedback on the proposal the FAA NASEM Recommendation 6 Work Group will develop for improving the TARAM process, including its risk calculations, decision-making procedures, and the usage of current certification data. As part of its review, the ARC should consider how to incorporate these improvements into the COS agreements.

The scope of this section focuses only on providing feedback to the FAA proposal. Considerations for improvements within the COS agreements are provided in separate relevant sections within this report.

Discussion

This committee finds value in utilizing certain certification methodologies for the in-service safety process but cautions that the data utilized be evaluated for appropriateness to the specific event or condition being analyzed. Further, this committee reinforces that any methodology determined appropriate should also foster timely evaluations without adding unnecessary burden.

This committee agrees with the FAA position that Hybrid Causal Logic (HCL) appears promising but is not yet sufficiently mature for widespread usage within the Transport Category Airplane industry.

This committee agrees with the FAA position that quantitative metrics associated with software reliability (also referred to as "software failures") are not appropriate. This committee also agrees that software development robustness tools are aimed at providing various levels of confidence and are not linked to quantitative principles for failure rates.

This committee disagrees with implementation of Design Assurance Level (DAL), also referred to as Development Assurance Level, within the TARAM improvements. Although DALs can be correlated to the severity of an aircraft/system level failure condition, they are derived from existing hazard classifications within the Functional Hazard Assessment (FHA). Understanding the event or condition hazard classifications within the FHA are a necessary aspect to be used as a reference during the in-service safety process and including DAL assignments would be redundant and provide limited value.

All committee feedback and recommendations are grounded in increasing flexibility within the in-service safety process where appropriate while promoting accurate and efficient analysis.

Recommendation 9

This committee reviewed the FAA proposal and compiled feedback into Table 2. Committee feedback is categorized into either observations or recommendations with the following definitions:

- Observation – Committee members noted relevant vantage points which may differ from the FAA Draft Response to NASEM Recommendation 6. The committee requests the FAA to consider this information during revisions of associated guidance material.
- Recommendation – committee members advocated for specific changes to the FAA Draft Response to NASEM Recommendation 6. The committee urges the FAA to incorporate the identified changes.

Note: For any statements not explicitly identified within the table, the committee agreed with the FAA proposal.

Table 2: Committee Feedback to Relevant Sections of the FAA Draft

FAA Proposal Section – Relevant Statement	Committee Feedback
The committee review began with a general overview of the in-service safety processes used within the industry along with the specific guidance currently offered within the TARAM handbook.	**Observation 1** – Prior to the TARAM methodology, which was implemented in 2011, Advisory Circular 39-8 and 1E-09 catastrophic probability concepts were utilized. **Observation 2** – 25.1309 principles can serve as a useful tool for rapid triaging and are considered acceptable methodologies within other regulatory agencies. **Observation 3** – 25.1309 principles can validate concerns and relationships comparable to causal chain linkage without introducing additional steps to the in-service safety process. **Observation 4** – 25.1309 principles include some conservative assumptions used during design approval, such as aircraft weight, center of gravity position, operational speeds, and environmental conditions (temperature, humidity, degree of turbulence, etc.), that are always considered at the critical state. However, in-service risk may consider better estimates for the specific scenario under evaluation. 25.1309 principles may not always be appropriate, noting structural defects, wear-out, damage tolerance, and human reliability are examples of aspects not accounted for within the framework of 25.1309.
Section 3.1 - "The use of certification safety data may require an infrastructure FAA does not currently have."	**Observation 5** – This response could be interpreted as insinuating that the FAA develops the assessment without DAH input. This does not align with practical implementation of the TARAM, which heavily involves DAHs. Assessment without DAH involvement may create difficulties in validating and verifying Fault Tree Analyses (FTAs) used by the DAH and may also be burdensome for the DAH and FAA within the lower-level FTA details. The DAH is responsible for aiding the FAA by providing germane data to support a risk analysis which can include relevant excerpts of certification FTAs.
Section 3.1 - "A fault tree analysis (FTA) is a knowledge repository of how systems fail to work correctly...can be used to identify pertinent casual chain (C.C.) data."	**Observation 6** – There is general agreement with this statement if FTA data is available and noting that the understanding should not be a requirement to generate new 25.1309 analyses. **Observation 7** – 25.1309 provides a good basis for the assessment's construct but should be evaluated for appropriateness prior to usage. This may include modifying the FTA architecture such that it is representative of the event or condition being evaluated and is sufficiently specific for the in-service safety process.
Section 3.1 - "We are accomplishing a TARAM risk assessment because something in the certification process has presumably failed us."	**Recommendation 9.1** – Safety data generated for certification represents a snapshot in time with assumptions made for scenarios known at that time. In-service events or conditions can evolve that understanding, but do not invalidate the certification efforts. It is recommended that the statement, "... because something in the certification process has presumably failed us" be considered for revision to "... because a condition has been identified which is

	applicable to the in-service fleet and may represent a safety concern." **Observation 8** – It is noted that a finding during the in-service safety process may also trigger modifications to the type design should system interactions or latencies invalidate the type design.
Section 3.1 - "FTAs and other design certification data used for showings of compliance to 14 CFR 25.1309 do not reside within FAA access or control."	**Observation 9** – When a DAH is involved in the analysis, the expectation is that the DAH extracts and provides relevant 25.1309 details to the FAA when requested. The FAA also has the authority to request any relevant data which relates to the in-service safety process.
Section 3.1 - "The focus of the COS causal chain risk assessment is not the same as that used in the certification process so the additional quantitative data may be of limited value."	**Recommendation 9.2** – Leveraging 25.1309 analyses can be useful in support of the in-service safety process for triaging. Certification analyses should not be used without an evaluation of necessary modifications. Fault trees provide a regimented approach consistent with certification methods to quantify the probability of a failure condition. Failure analyses can and should be updated as appropriate within the in-service safety process to account for new information, human factors, operational considerations, etc. It is recommended that "of limited value" be revised to clarify specific challenges and to avoid misinterpretation.
Section 3.1 - "While the FTA method and process is well described in consensus industry practice and widely used, each applicant and their system suppliers may select from a wide variety of FTA software tool vendors to accomplish an FTA on any specific program. FAA acquisition, maintenance, and training on the use of these various toolsets would become problematic."	**Observation 10** – The standard industry practice of DAH and FAA working together for the in-service safety process alleviates many of these challenges. DAHs should provide relevant extractions of the FTA in a standardized format conducive to the FAA's needs and the ability for rapid triaging, as needed. **Observation 11** – The 25.1309 analysis would be leveraged only for the impacted failure conditions, limiting the scope of which portions of the FTA need to be assessed.
Section 3.1 - "The use of a software based quantitative analysis tool, such as an FTA or event tree, would only calculate a small portion (i.e. frequency of occurrence portion of the fleet risk component) of the needed TARAM risk data."	**Observation 12** – There is general disagreement with the premise that the FTA provides only a small portion of the data needed for the in-service safety process. The top event of the certification FTA will often capture both Frequency of Occurrence and hardware-related Conditional Probability values needed for TARAM. The analyst may need to adjust rates and/or expand the existing architecture of the certification FTA to model an in-service failure condition appropriately.
Section 3.2 - "TARAM improvement recommendations will therefore focus on the capture of appropriate development assurance level assignments at the aircraft/system level (Functional DAL) and AEH or SW (Item DAL) levels and document their potential interactions for contribution in the causal chain."	**Observation 13** – FDAL and IDAL principles apply to newer aircraft designs, only. Consideration should be given to how best to incorporate older aircraft designs during TARAM handbook revision. **Observation 14** – DAL may be more appropriately considered as part of certification and compliance rather than part of the in-service safety process. An incorrect DAL does not imply that the software is unacceptable. Rather, it only indicates that the level of development rigor to certify was not commensurate with the appropriate assurance requirements.
Section 4.1 - "You may need to formally construct a representative causal chain or other similar event model, such as a fault tree, event tree, concept diagram, etc."	**Recommendation 9.3** – The proposed update to TARAM Handbook 4.1 removes the referenced verbiage and simplifies the message to "or other similar model". It is recommended that these explicit references be reintroduced in some form such that the analyst realizes the principles are acceptable. Doing so more explicitly illustrates flexibility for the in-service safety process.
Section 4.1 - "The TARAM Analyst should work with the product manufacturer and their pertinent equipment suppliers to gather failure modeling information."	**Recommendation 9.4** – The following sentence modifications are recommended. "The TARAM Analyst should work with *<u>operators</u>,* the product manufacturer and their pertinent equipment suppliers*, <u>as appropriate</u>,* to gather failure modeling information."
Section 4.1 - "Pertinent information used for showings of compliance to 14 CFR 25.1309, if available should also be evaluated. Compliance information may include but is not limited to the following:"	**Recommendation 9.5** – As stated, the sentence appears to instruct the analyst to evaluate 25.1309 data every time it is available, when sometimes this may be unnecessary. It is recommended that the sentence be revised as follows. "Pertinent

	information used for showings of compliance to 14 CFR 25.1309, if available *could also be evaluated, as appropriate*."
Section 4.1 - "Compliance information may include but is not limited to the following: Definition of functional failure sets created during assignment of FDALs and IDALs"	**Observation 15** – Criticality is defined as part of the FHA hazard classification process and DALs are assigned based on the hazard classification, not vice versa. Understanding the hazard classifications within the FHA is a necessary aspect of the in-service safety process and including DAL assignments would be redundant and provide limited value. **Recommendation 9.6** – It is recommended that instructions to the analyst for evaluations of FDALs or IDALs within the in-service safety process be removed.
Section 4.1 - "This information will be used enhance the understanding and modeling of the event."	**Observation 16** – "to" is missing from this sentence after "used". "This information will be used *to* enhance the understanding and modeling of the event."
Section 4.1 - "It will provide opportunities to identify and contrast system assumptions and/or characteristics assumed at certification from those associated with the in-service event under analysis."	**Recommendation 9.7** – It is recommended to add a sentence immediately following the referenced which states "*Relevant extractions from the certification analysis may be requested from the product manufacturer.*"
Section 4.1 - "An example of potential causal chain improvement using design stage FTA modeling information could be provided in TARAM Appendix C."	**Recommendation 9.8** – It is recommended that "could be" is changed to "is" if an example will be provided or remove this sentence if an example will not be provided.
Section 4.1 - "Another potential source complicit in the causal chain is the potential sources of error which may cause or contribute to the condition under study. Each of the system and implementation elements of a complex system should have been assigned a development assurance level during the development stage of the project. This Functional DAL or FDAL established the rigor with which the objectives of the development process were accomplished. Letter designations from A thru E were assigned to the function based on the worst severe failure effects this function may have on the aircraft. Similarly, airborne electronic hardware and software were assigned Item DALs or IDAL to establish the objectives for the implementation domain to accomplish. An evaluation of the functional failure sets and compatibility of the associated assigned FDALs and IDALs, associated with the condition under study should be documented. Any potential interactions of lower-level development rigor supporting higher level severity classifications should be evaluated."	**Observation 17** – Insufficient DAL assignments should be treated equivalent to a lack of appropriate DO-160 testing. Neither have any bearing on the probability of equipment failure. These processes provide confidence that the equipment design is acceptable. Correlation between DAL and failure probability is not possible. Inappropriate DAL assignments may have compliance implications, but do not directly impact the in-service safety process. **Observation 18** – Criticality is defined as part of the FHA hazard classification process and DALs are assigned based on the hazard classification, not vice versa. Understanding the condition hazard classifications within the FHA are a necessary aspect of the in-service safety process and including DAL assignments would be redundant and provide limited value. **Recommendation 9.9** – It is recommended that instructions to the analyst for evaluations of FDALs or IDALs within the in-service safety process be removed from the TARAM handbook.

4.5 Feedback on FAA NASEM Recommendation 11 Response Study Report

Intent

NASEM Recommendation 11 advised the FAA to conduct a study to determine the requirements and viability of an independent peer review and quality assurance process for the results from the TARAM analysis of significant in-service safety issues and the COS decisions resulting from TARAM outputs. As an output from this study, the FAA Aircraft Certification Service's authored a report summarizing the options of implementing an independent peer review within the FAA's COS process and provided the report to this committee. The ARC Charter Task (b.iii) requested this committee review the study and provide recommendations that can be incorporated into COS Agreements to support the FAA's implementation of a peer review.

Scope (ARC Charter)

The ARC Charter Task (b.iii) states "Review the study the FAA NASEM Recommendation 11 Work Group will prepare and recommend how to document the independent peer review and quality assurance process in COS agreements between manufacturers and the FAA. The ARC should ensure that COS agreements address monitoring and analysis of operational safety performance that meets recommendation 3 of the NASEM report."

The findings and recommendations within this section are focused on the study from the NASEM Recommendation 11 Work Group, and how to document the outcome of that study within COS Agreements as appropriate.

Discussion

The FAA report defined an independent peer review of the TARAM occurs when one or more qualified individuals who did not perform the TARAM evaluates the analysis. With that definition in mind, the report considered four options for executing an independent peer review and established criteria to evaluate the four options based on speed, robustness, qualifications of peer reviewers, and logistics. The report elaborates on the study's evaluation of the options with those criteria in mind and constructed a decision matrix to identify which options met which criteria.

Of the four options, the report recommends adopting a standardized peer review process that includes a multi-level FAA internal review of all TARAM analyses and at least three annual audits of COS decisions. Under this plan, FAA employees would act as peer reviewers of risk assessments and COS decisions, and states the FAA already includes an independent peer review process in the form of a Corrective Action Review Board (CARB). The annual audits recommended within the report elaborate on the positive impacts of conducting routine audits and suggest the FAA Office of Accident Investigation and Prevention (AVP) conduct them.

After reviewing the report, this Committee has the following findings:

- This committee agrees that the FAA's MSAD Order 8100.107B and implementation of a CARB, along with the study's recommendations, provide a valuable peer review of the COS risk analysis.
- This committee disagrees that the review structure is independent as the reviews are still performed by the organizations responsible for conducting and managing the TARAM, and the FAA CARB acts as a decision-making body instead of the independent peer review it claims to be within the study.
- This committee recognizes both the value and the need to ensure the peer reviews are performed by individuals that are knowledgeable of the FAA's process, knowledgeable of TARAM, and knowledgeable of the aviation product being evaluated, while ensuring adequate protection of any proprietary information.

- This committee recognizes a truly independent peer review is not reasonably conducive to the needs of the FAA or the industry. But there is a need to mitigate potential cultural bias through seeking peer reviews from group(s) outside the FAA organization responsible for performing the risk analysis and resulting decision-making.
- This committee agrees with the study recommendation for the FAA AVP to conduct routine audits.

While a truly independent peer review is desirable, it is recognized as not reasonably achievable. The reasons provided within the study are valid. This committee believes there is another option to be explored by using the Design Approval Holders or the product's owners being evaluated in the peer review process. It is not reasonable to expect the FAA to have the expert knowledge of the systems and design of a product of every issue they assess. A peer review with the DAH of the product or system under review prior to CARB would reduce the potential for cultural bias leading into a CARB decision and provide valuable product expert knowledge while not introducing excessive time, cost, or additional infrastructure.

Recommendation 10

It is recommended the FAA include a step within its review process, prior to CARB, for a peer review beyond the FAA organization responsible for performing the TARAM. This committee suggests that additional peer review include at least a representative of the Design Approval Holder (DAH) of the product or system being assessed, if possible. Any feedback from this review not incorporated into the risk analysis should be noted in the final assessment provided to the CARB.

The obligation for a DAH to support this peer review should be included within any COS Agreement. Within the review, the DAH should function as a technical advisor for the product and/or system being assessed and provide any data required to help refine the analysis as needed.

4.6 Standardizing Acceptable Risk Assessment Methodologies

Intent

To improve consistency in flight standards through convergence towards a standardized risk assessment methodology or set of acceptable methodologies used in developing a TARAM analysis.

Scope (ARC Charter)

Task (b.i.) of the ARC Charter is to assess current requirements and guidance material for establishing detailed COS agreements. As part of that evaluation, this committee noted there is no standardized methodology used across DAHs. Additionally, ARC Charter Task (b.vi). requires the drafting of “guidance regarding how the risk analysis...will be used to influence the TARAM analysis.”

Discussion

MSAD Order 8110-107B provides direction and guidance for a structured and standardized COS management process with TARAM being a foundational piece of that effort.

The committee found that TARAMs were routinely developed based on the risk assessments performed by a DAH and while the output may be in a consistent format, the inputs which form the basis of TARAM may be developed under different methodologies or with a different safety risk threshold.

To better understand how COS was implemented across the industry for both airframe and engine manufacturers, committee members were asked to provide a high-level briefing of their respective COS processes. This included general risk measures to which an analysis can be compared to inform a final safety determination. The committee found that there is not standardized guidance across the industry for what constitutes an unsafe condition.

One of the goals of this committee is to identify best practices that can be incorporated into a COS Agreement and the variability in the implementation of safety decision guidance values is a potential driver for divergent application of the COS process across the industry. A harmonized risk standard would better drive convergence towards consistent flight safety standards at the industry level.

Recommendation 11

The committee recognizes that there is currently no single standardized risk assessment methodology in the industry. FAA AC 39-8, FAA TARAM, and EASA AMC & GM 21A.3B are some examples of risk standards currently used between a DAH and the FAA. To improve consistency in flight safety standards, this committee recommends that the FAA continue to work towards a harmonized acceptable risk standard for use across the industry.

5. Consensus

At the time of the report publication, no ARC members had expressed dissenting opinions.

6. Conclusion

This committee appreciates the FAA chartering this ARC and assembling organizations which broadly represents aviation industry airframers and engine manufacturers. The ARC was an invaluable exercise facilitating candid dialog about improving data sharing for aviation Continued Operational Safety. The breadth of FAA and industry organization experts enabled this committee to have diverse perspectives in executing the tasks and identifying best practices to recommend for FAA and industry consideration.

In executing the tasks assigned in the charter of this ARC, multiple regulatory and industry documents were reviewed to assess opportunities for industry to provide recommendations for policy improvements to the FAA. Through the Work Groups and Plenaries identified in Section 3 of this document this committee executed the charted tasks and provides the recommendations articulated in Section 4. While the overarching goal of the ARC focused heavily on the review of existing COS Agreement policy and guidance, and the authoring of new guidance as appropriate, the charted tasks provided specific direction for needs to be addressed by this ARC. The committee provided eleven recommendations in total to the FAA within Section 4 of this report.

ARC Charter Task (a) requested the committee to evaluate NASEM Recommendation 9 and provide industry feedback on the inclusion of risk importance ranking within TARAM to facilitate identification of the most impactful solution. The committee's review found the suggestion to incorporate risk importance ranking within TARAM to not be conducive to the speed and agility required within the aviation industry for risk analysis, and instead provided two recommendations to the FAA to reiterate existing guidance found within the FAA Advisory Circular 39-8 into both the TARAM Handbook and MSAD Order 8110.107B.

ARC Charter Task (b) had six sub-tasks for Continued Operational Safety Agreements requested the committee review existing policies and guidance, provide recommendations for the existing policies and guidance, and author new policy and guidance as appropriate. The sub-categories provided additional direction for the committee to review and provide feedback on the FAA's draft response to NASEM recommendation 6, and the FAA's study for NASEM recommendation 11. Additionally, the committee was tasked to provide recommendations for making the transfer of safety data more efficient.

The committee provides nine recommendations to the FAA to address the Task (b) sub-tasks (b.i-vi.), and authored Appendix C as draft guidance for the FAA to use in the interim until a more permanent solution is put in place. One recommendation is for the FAA to task an industry body with the ongoing maintenance of COS Agreement guidance, five recommendations are to enhance data sharing, one recommendation, with sub-recommendations, for enhancing the FAA's draft response to NASEM Recommendation 6, one recommendation in response to the FAA's study related to NASEM Recommendation 11, and one recommendation to evolve an industry standard for assessing in-service risk. Appendix C provides practices industry has identified as valuable for establishing a COS Agreement with the FAA, including guidance for event reporting, potential unsafe condition identification and investigation, risk mitigation, and FAA engagement.

The committee provides these recommendations and draft guidance to the FAA to enhance the symbiotic relationship between the FAA and the DAH, and to continuously improve the safety of the aviation industry. The committee appreciates the FAA making the request of industry and looks forward to the ongoing evolution of Continued Operational Safety.

Appendix A: ARC Membership List

The below list are the ARC members identified by the FAA.

Dan Elgas, *AIR-600, Federal Aviation Administration, FAA Co-Chair*
Brennen Roberts, *AIR-633, Federal Aviation Administration, ARC Coordinator*
Seth Bird, *The Boeing Company, Industry Co-Chair*
Tim Yee Lee, *Bombardier*
Fabien Bourmaud, *ATR Aircraft*
Doug Ritchie, *Gulfstream Aerospace Corporation*
Philip McKee, *Gulfstream Aerospace Corporation*
Felipe Eudes Pontes Fernandez, *Embraer*
Guilherme Arioli Fernandes, *Embraer*
Julie Elpers, *GE Aerospace*
Robert L. Ramey, *Textron Aviation*
Fabienne Sauron, *Airbus*
David McDermott, *Pratt & Whitney*

In addition to the members, Subject Matter Experts from the FAA, the represented organizations, and industry groups were asked to participate as needed to support research and development of the content of the report.

Aitor Larrazabal, *Airbus*
Jon Mardaras, *Airbus*
Marc Rieugnie, *Airbus*
Patrice Chassard, *Airbus*
Fran Heil, *Airlines for America*
Nicolas Brevot, *ATR Aircraft*
Brian Durham, *Boeing*
Darian Wood, *Boeing*
Michael Germani, *Boeing*
Tak Lee, *Boeing*
John Dulski, *Bombardier / Learjet*
Eduardo Sanches Cerdeira, *Embraer*
Guilherme Moreschi Valente dos Santos, *Embraer*
Sergio Augusto Viana de Carvalho, *Embraer*
Bobbie Kroetch, *FAA*
Brett Portwood, *FAA*
Chris Spinney, *FAA*
Eugene Kang, *FAA*
Francis, Carandang, *FAA*
Gayarthri Barathamani, *FAA*
Herman Mak, *FAA*
James Gray, *FAA*
Jeff Palmer, *FAA*
Jim Cashdollar, *FAA*
John Craycraft, *FAA*
Keith Lardie, *FAA*
Krysten Urchick, *FAA*
Melanie Violette, *FAA*
Michael Barton, *FAA*
Michael Bumbaugh, *FAA*
Nathan Weigand, *FAA*
Peter Jarzomb, *FAA*
Philip Windust, *FAA*
Sanford Proveaux, *FAA*
Shelia Mariano, *FAA*
Susan Monroe, *FAA*
Thomas Tiernan, *FAA*
Walter Desrosier, *GAMA*
Melanie Cox, *GE Aerospace*
Sarah Knife, *GE Aerospace*
Wendy Merkelz, *GE Aerospace*
Brittnee Kikolski, *Gulfstream*
Juan Ramires, *Gulfstream*
Michael Curran, *Gulfstream*
Doug Banach, *Pratt & Whitney*
Ken Adams, *Pratt & Whitney*
Mike Short, *Pratt & Whitney*
Todd Martin*, *Alaska Air*
Cory Boese*, *Southwest Airlines*

* Participated in an interview conducted by Work Group 4.

Appendix B: COS Agreement ARC Charter

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
Aviation Rulemaking Committee Charter

Effective Date:
7/19/2023

SUBJECT: Transport Category Airplane Continued Operational Safety Agreements Aviation Rulemaking Committee

1. **PURPOSE.** This charter establishes the Transport Category Airplane Continued Operational Safety (COS) Agreements Aviation Rulemaking Committee (ARC), according to the Administrator's authority under Title 49 of the United States Code § 106(p)(5). The sponsor of the ARC is the Associate Administrator for Aviation Safety. This charter outlines the ARC's organization, responsibilities, and tasks.

2. **BACKGROUND.** Section 130 of the Aircraft Certification, Safety, and Accountability Act of 2020[1] (ACSAA) requires the Federal Aviation Administration (FAA) to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM) to develop a report regarding the methodology and effectiveness of the Transport Airplane Risk Assessment Methodology (TARAM) process used by the FAA. In accordance with the ACSAA section 130 requirement, the NASEM conducted a review of the TARAM and prepared a report[2] that provides 13 recommendations for improving the TARAM process used by the FAA. The FAA has established work groups to address the recommendations. As part of its report, NASEM recommended that the FAA establish a committee to develop regulatory guidance material for establishing detailed COS agreements. In response, the FAA committed to chartering an ARC to assess and develop improvements to current FAA requirements and guidance material for establishing detailed COS agreements.

3. **OBJECTIVES OF THE ARC.** The objectives of the ARC are to assess and develop improvements to current FAA requirements and guidance material for establishing detailed COS agreements between the FAA and design approval holders (DAHs) of transport category airplane type certificates. The ARC will focus primarily on recommendation 3 of the NASEM report but also will help address recommendations 6, 9, and 11.

4. **TASKS OF THE ARC.** The tasks of the ARC are:

    a. By February 29, 2024, regarding the TARAM Handbook, address recommendation 9 (risk importance ranking methods) of the NASEM report. Draft guidance to clarify and reinforce existing policies as well as develop any appropriate new guidance on quantitative ranking of alternative corrective actions and risk-informed inspections.

    b. By September 30, 2024, regarding COS agreements between the FAA and DAHs of transport category airplane type certificates, the ARC should:

        i. Assess current FAA requirements and guidance material for establishing detailed COS agreements. Develop new guidance material as needed.

[1] Division V, Title 1 of Consolidated Appropriations Act, 2021. Public Law 116-260 (Dec. 27, 2020)
[2] National Academies of Sciences, Engineering, and Medicine. 2022. Evaluation of the Transport Airplane Risk Assessment Methodology. Washington, DC: The National Academies Press. https://doi.org/10.17226/26519.

ii. Review and provide feedback on the proposal the FAA NASEM Recommendation 6 Work Group will develop for improving the TARAM process, including its risk calculations, decision-making procedures, and the usage of current certification data. As part of its review, the ARC should consider how to incorporate these improvements into the COS agreements.

iii. Review the study the FAA NASEM Recommendation 11 Work Group will prepare and recommend how to document the independent peer review and quality assurance process in COS agreements between manufacturers and the FAA. The ARC should ensure that COS agreements address monitoring and analysis of operational safety performance that meets recommendation 3 of the NASEM report.

iv. Include DAHs Safety Review Board Assessments and trade studies in COS agreements for inclusion in the TARAM analyses.

v. Provide recommendations for making transferring safety data (such as data related to Title 14 of the Code of Federal Regulation §§ 21.3 and 183.63) more efficient.

vi. Draft guidance regarding how the risk analysis and data from COS agreements will be used to influence the TARAM analysis.

c. Submit the TARAM Handbook and COS Agreement recommendations by the stated deadlines in paragraphs 4a and 4b to the Industry Co-Chair, who sends the recommendation reports to the FAA Co-Chair and the Director of the Office of Rulemaking.

i. The FAA Co-Chair determines when the recommendation reports and records, pursuant to paragraph (8), will be made available for public release.

5. ARC PROCEDURES.

a. The ARC acts solely in an advisory capacity by advising and providing written recommendations to the FAA Co-Chair.

b. The ARC may propose related follow-on tasks outside the stated scope of the ARC to the FAA Co-Chair.

c. The ARC may reconvene following the submission of the recommendation report for the purposes of providing advice and assistance to the FAA, at the discretion of the FAA Co-Chair, provided the charter is still in effect.

6. ARC ORGANIZATION, MEMBERSHIP, AND ADMINISTRATION. The FAA will establish a committee of members representing a diverse set of aviation stakeholders, including DAHs of transport category airplane type certificates, manufacturers, their suppliers, and aircraft operators, as well as members of the COS community. Subject matter experts from the FAA, other federal agencies, and foreign civil aviation authorities may be requested to participate as observers and to provide technical support to the ARC members.

The provisions of the August 13, 2014, Office of Management and Budget (OMB) guidance, "Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards, and Commissions" (79 FR 47482), continue the ban on registered lobbyists participating on Agency Boards and Commissions if participating in their "individual capacity." The revised guidance allows registered lobbyists to participate on Agency Boards and Commissions in a "representative capacity" for the "express purpose of providing a committee with the views of a nongovernmental entity, a recognizable group of persons or nongovernmental entities (an industry, sector, labor unions, or environmental groups, etc.) or state or local government." For further information, refer to the OMB Guidance at 79 FR 47482.

Membership is limited to promote discussion. Attendance, active participation, and commitment by members is essential for achieving the objectives and tasks. When necessary, the ARC may set up specialized and temporary working groups that include at least one ARC member and invited subject matter experts from industry and government.

a. At the request of the Sponsor, the Director of Policy and Standards Division will function as the FAA Co-Chair and will:

   1) Select and appoint industry members based on their familiarity and experience with transport category airplane COS,
   2) Ensure that membership is balanced in viewpoints, interests, and knowledge of the committee's objectives and scope,
   3) Select the Industry Co-Chair from the membership of the ARC,
   4) Select the FAA participants and ensure FAA participation and support from all affected lines-of-business,
   5) Provide notification to the members of the time and place for each meeting, and
   6) Receive any status report(s) and the recommendations report.

b. As stated in paragraph 6(a)(3), the FAA Co-Chair will select and appoint the Industry Co-Chair from the membership of the ARC. Once appointed, the Industry Co-Chair will:

   1) Coordinate required ARC meetings in order to meet the objectives and timelines,
   2) Establish and distribute meeting agendas in a timely manner,
   3) Keep meeting notes, if deemed necessary,
   4) Perform other responsibilities as required to ensure the objectives are met and tasks achieved,
   5) Provide status reports, as requested, in writing to the FAA Co-Chair, and
   6) Submit the recommendation report to the FAA Co-Chair and the Director of the Office of Rulemaking.

7. **PUBLIC PARTICIPATION.** Meetings are not open to the public. Persons or organizations outside the ARC who wish to attend a meeting must secure approval in advance of the meeting from the Industry Co-Chair and the FAA Co-Chair.
8. **AVAILABILITY OF RECORDS.** Subject to applicable Freedom of Information Act (FOIA) Exemptions pursuant to Title 5, U.S.C., § 552, the FAA will make records provided by the ARC to the FAA available for public inspection and copying. Available records will be located at the Office of Aircraft Certification Service, FAA Headquarters, 800 Independence Ave. SW,

Washington, D.C. 20591. Fees will be charged for information furnished to the public according to the fee schedule published in Title 49 of the Code of Federal Regulations, part 7.

You can find this charter on the FAA Committee Database website at: http://www.faa.gov/regulations_policies/rulemaking/committees/documents/.

9. **DISTRIBUTION.** This charter is distributed to: Office of the Associate Administrator for Aviation Safety, the Office of the Chief Counsel, the Office of Assistant Administrator for Policy, International Affairs, and Environment, and the Office of Rulemaking.

10. **EFFECTIVE DATE AND DURATION.** The ARC is effective upon issuance of this charter and will remain in existence until June 30, 2025, unless the charter is sooner suspended, terminated, or extended by the Administrator.

Issued in Washington, D.C. on July 19, 2023.

Kathryn B. Thomson
Acting Deputy Administrator

Appendix C: COS Agreement Guidance

C.1. General Guidance

The FAA and Design Approval Holders (DAH's) have a shared responsibility to maintain the Continued Airworthiness of the products used in the National Airspace System (NAS). To be achieved, this requires systems for monitoring data, identifying hazards and risks associated with those hazards, evaluation tools to quantify those identified risks and processes for mitigating those risks to an acceptable level, when required. There are several regulatory requirements that mandate certain notifications and data sharing between the DAH and the FAA.

These include the following regulations:

> **14 CFR 21.3 Reporting of failures, malfunctions, and defects.** This regulation requires the holder of a type certificate to report whenever they determine one of thirteen specific occurrences (hazard or safety events/precursors) has or could occur with their product.
>
> **14 CFR 21.99 Required design changes**. When the FAA makes a determination of an Unsafe Condition that requires a design change, this regulation requires the Type Design Holder, upon request of the FAA, to submit the appropriate design changes for approval necessary to correct the unsafe condition.
>
> **14 CFR 183.63 Continuing requirements:** Products, parts, or appliances. This regulation requires the holder of an Organization Designation Authorization (ODA) to report any condition in a product, part or appliance that could result in the finding of unsafe condition by the administrator, or a product, part or appliance not meeting the applicable airworthiness requirements for which the ODA Holder has obtained or issues a certificate of approval. This regulation requires the ODA Holder to investigate, at the request of the FAA, any suspected unsafe condition or finding of noncompliance with the airworthiness requirements and report to the administrator the results of the investigation and any actions taken or proposed. Additionally, the regulation requires the ODA Holder to submit the information necessary to implement corrective action needed for the safe operation of the product, part, or appliance.
>
> **14 CFR Part 5 Safety Management Systems**. This regulation requires DAHs to have processes and procedures in place, in part, to identify hazards, develop risk controls and a process for conducting risk assessment that allows for the determination of acceptable safety risk.

In addition to the regulations relating to Continued Operational Safety noted above, the FAA provides the following guidance on risk identification, analysis, and mitigation:

> **Partnership for Safety Plan.** Many DAHs have established formal Partnership for Safety Plans (PSPs) alongside the FAA with the goal of laying the foundation from which to build confidence, leadership, teamwork, and communication around certification activities. One of the components of a PSP is Continued Operational Safety (COS). The FAA Product Certification Guide states the following:
>
> > "The PSP should be written with the expectation that DAH COS methods are consistent with the FAA methodology, as a means to leverage DAH resources

and enhance reliance on DAH COS risk analyses. This approach will permit the leveraging of FAA resources through risk management and will focus on safety oversight of systems and processes. This process applies to the product's design/production and its operation, maintenance, modification, and repair. This process should identify potential safety-related issues and relay the information to the appropriate organization in the FAA for further analysis and corrective actions, when appropriate. This process:

a. Produces timely, data-driven, risk-based corrective actions for safety issues in the in-service aircraft fleets.
b. Produces a structured risk analysis of potential safety issues.
c. Performs a root cause analysis, when appropriate.
d. Initiates the appropriate corrective actions."

Additionally, the Product Certification Guide states, "Safety is a continuum, and each party must proactively monitor their fleet and act appropriately to mitigate unacceptable risk. This section of the PSP should document the Applicant's commitment to monitor and take timely action to mitigate unacceptable risk."

Advisory Circular 21-9B, Manufacturers Reporting Failures, Malfunctions, or Defects. This AC describes an acceptable means of complying with the reporting requirements of 14 CFR 21.3. However, there are several conditions that may lead to an unacceptable hazard, or Unsafe Condition, which are not addressed by the thirteen conditions listed in 14 CFR 21.3. Many DAHs have voluntarily expanded the items they will report to the FAA to address these gaps.

FAA Order 8100.15B, Organization Designation Authorization Procedures. This FAA Order states that procedures for monitoring service information, investigation, and FAA notification must be included in the procedures manual. However, Continued Operational Safety and the identification and resolution of Unsafe Conditions is not an authority delegated by the FAA. Additionally, not all DAHs have an ODA.

FAA Order 8110.107B, Monitor Safety/Analyze Data. This order describes how the Aviation Safety Organization (AVS) staff use the Monitor Safety/Analyze Data (MSAD) process within the Aircraft Certification Service (AIR) Safety Management System (SMS) to help identify safety issues and manage risk in aviation products throughout their life cycle. The Order also states:

"Certain design approval holders (DAHs) have their own processes to filter, review, analyze, and trend aviation safety data on their products. If DAHs want to use their internal processes to support this order, it is recommended that the responsible AIR certification branch coordinate DAH processes with the Operational Safety Branch (AIR-720) focal and AIR-630. The FAA expects the AIR certification branches to continue fostering cooperative COS agreements that integrate the DAH's and MSAD's processes in a way compatible with this order. In those instances, the DAH might accomplish many of the steps defined in this order to address the safety of their products

> in accordance with existing product risk assessment methodologies with the AIR certification branch aviation safety engineer (ASE) performing an oversight role."

The cooperative COS agreements noted above are meant to outline how the DAH and FAA risk management processes interact and work together. These cooperative COS agreements could be established in different forms, depending on the authorizations held by the DAH. For those DAHs who do not hold an ODA, this agreement could be contained in the PSP or as a standalone document. For those DAHs who hold an ODA, this agreement could be contained in the ODA Manual. Many DAHs have established detailed COS agreements as an addendum or external supplement to the ODA Manual, since COS is not a delegated authority by the FAA, and it allows for timely revisions and process improvements should they be needed. Whatever method is used to establish a cooperative COS agreement between the DAH and the FAA, it should include a maintenance plan and/or update schedule. This process will allow for continuous improvement and evaluation to ensure the expectations of the FAA and DAH are being met.

A COS agreement between the DAH and the FAA can be used as a method of compliance with the regulations identified above, outlining how each organization's COS activities will interact. Foundational to this agreement is transparency between the DAH and the FAA on fleet monitoring, hazard identification, assessment of risks associated with those hazards, establishing risk mitigation plans where needed and supporting the FAA in the issuance of Airworthiness Directives. Detailed COS agreements between the FAA and DAHs will aid both parties in fulfilling their obligations to maintain the continued airworthiness of the fleet.

C.2. Scope of COS Agreements

An effective COS agreement should identify key expectations of the DAH and the agency throughout a typical COS investigation. A COS investigation is the result of identifying safety precursors, typically identified as part of the reporting requirements of 21.3 and 183.63(a). These expectations include but are not limited to roles and responsibilities, reporting criteria, the types of findings which meet the criteria of a potential safety issue, communication of expectations, and the risk management process.

The COS agreement should clearly identify the products that are subject to the expectations in the COS agreement and can be identified as: the entirety of the type design products owned by the DAH, a listing of the products which apply, and/or the consortia products which apply.

The COS agreement should also consider defining expectations for the following scenarios, Security/Cybersecurity Issues, Third Party Type Design/Supplemental Type Certification (STC) Issues, and Maintenance/Improper Usage Issues:

> **Security/Cybersecurity Issues:** Security issues are those which involve malicious intent. Given the sensitive nature of security issues, these investigations should include limited personnel and restricted access to data. Cybersecurity issues, or intentional unauthorized electronic interaction with malicious intent, require similar handling as security issues. While security issues and cybersecurity issues may also contain product safety concerns, the sensitive nature and malicious intent aspects create difficulties when applying standard COS methodologies. The DAH should

have a separate method to identify expectations and communications with FAA when security/cybersecurity issues are identified that necessitate communication/coordination with the FAA. That method could be outside of a COS agreement but should be agreed upon between the DAH and the relevant personnel at the agency.

Third Party Type Design/Supplemental Type Certification (STC) Issues: When the DAH has determined that a reportable event/finding that they made was ultimately due to a third-party design issue (such as a Parts Manufacturer Approval (PMA) part, or due to a third party STC modification), the DAH is not likely to have the necessary data, and will not have the authority, to complete the COS investigation process for that finding. However, the DAH should communicate to the FAA their findings and should provide the data for how they assessed that the PMA part or STC design was the cause of the event/finding. Additionally, if the finding was a potential safety issue, the DAH should state why that condition does not apply to the Type Design.

Maintenance/Improper Usage Issues: While maintenance/improper usage issues are exempt from the reporting criteria (see 21.3(d)(1)(i)), maintenance/operation issues which lead to a reportable event can in fact be a safety precursor. An event/finding could show that inadequate maintenance and operating instructions exist which could affect continued operational safety. However, while the tracking of maintenance errors or improper operation can highlight potential issues, it can also result in a significant increase in reports that may be of low severity or low value in reporting. Because of this, the DAH should coordinate with the FAA to identify the reporting expectations (if any) regarding maintenance/operation issues. It should be based on previous experience with their products and be included in their individual COS agreement.

C.3. Monitoring and Event Reporting

The COS agreement should include clear reporting criteria, defining the types of events/findings that are reported to the FAA. The DAH should coordinate with the FAA to agree on those reportable events/findings. The agreed-to event reporting should include those events/findings that meet or exceed the regulatory requirements per 14 CFR 21.3-and include the failure, malfunction, and defect (FMD) criteria that is explicitly defined in the regulations and those that have been historical safety precursors for the DAH's products.

The DAH should have company processes for monitoring events/findings to determine reportability. The COS agreement should include the definition of key roles and responsibilities of the personnel involved in the COS process and identify who monitors events/findings, who makes the determination of reportability, who makes the report, and the required reporting timeline once the reportable criteria has been determined to be met. The agreement should also list the primary data sources the company monitors for events/findings.

Initial reports to the FAA should include the following minimum information, if known (Note: data marked with an asterisk (*) are required per 14 CFR 21.3):

- Event Description/Initial Findings*
- Date of event/finding
- Name of product/Type Certificate number*

- Aircraft and/or Engine serial number
- Applicable reporting criteria*

More data can be added to the list of minimum information through the COS Agreement negotiation. Some examples include:

- Age of component which failed (e.g., cycles since new)
- Time since last shop visit/maintenance activity of the product (e.g., cycles since shop visit/maintenance interval)
- Location of event/finding

If an event/finding is determined to meet reportable criteria, but the details are limited, the report should still be provided and can be updated once additional information is available. Periodic COS investigation updates support alignment between the DAH and FAA as an issue progresses through the respective safety processes. Transparency regarding the investigation status and safety process progression has been identified as a best practice.

After the initial event/finding report, subsequent COS report updates should provide clear information on the investigation's progression, as well as expected next steps and timelines. The timing of the information to be provided may be considered commensurate with the level of risk – for example, those which are clear safety precursors may necessitate more frequent and urgent updates, while those that are not, may have less frequent updates.

To increase standardization of follow-on COS reports provided by the DAH to the FAA, best practice should be to utilize a common taxonomy for certain common elements of a COS investigation. Suggested elements are listed below. For those elements without suggested taxonomy, the list will be product specific (such as in the case of Event Symptoms or Root Cause Component), or COS Agreement specific (such as in the case of Reporting Criteria Met). A COS Agreement should include the agreed upon taxonomy, drawing from the ADREP taxonomy utilized by International Civil Aviation Organization (ICAO) as much as possible:

- Event Symptoms
- FMD Reporting Criteria Met
- Potential Hazard Identified
- Root Cause Status: Not Started, In Process, Completed, Not NeededRoot Cause: Maintenance Error, Human Factors, Engine/Component Failure, Icing, Inclement Weather, Structural Failure, Design, Manufacturing, Maintenance/Repair/Alteration, Operational, Other.
- Root Cause Component
- Containment Plan Status: Not Started, In Process, Completed, Not Needed
- Containment Action: Design Change, Service Bulletin - Removals, Service Bulletin - Maintenance/Inspection, One-Time Inspection, Repetitive Inspection, One-Time Replacement, Repetitive Replacement, Revised Limits, Software Change, Manual Change, Modification, Other, Not Needed.
- Corrective Action Status: Not Started, In Process, Completed, Not Needed
- Corrective Action: Design Change, Service Bulletin - Removals, Service Bulletin - Maintenance/Inspection, One-Time Inspection, Repetitive Inspection, One-Time Replacement,

Repetitive Replacement, Revised Limits, Software Change, Manual Change, Modification, Other, Not Needed.

- Company Safety Determination: Non-Safety, Potential Safety, Safety.

C.4. Potential Unsafe Condition Identification

The COS Agreement should include a process for the identification of potential unsafe conditions for which a risk analysis will be performed. This process fulfills the 14 CFR 183.63(b1) requirement to notify the FAA of potential unsafe conditions and should also be considered for inclusion in Partnership for Safety Plans. Not all reportable events require a safety risk analysis. To facilitate the identification of potential unsafe conditions, the definition of an unsafe condition from Advisory Circular 39-8 is used: a condition which, if not corrected, is reasonably expected to result in one or more serious injuries.

A key point in this definition is “reasonably expected.” This does not include every outcome which is physically possible. The range of failure outcomes which are “reasonably expected” will vary with the analyst, and so it is critically important to use representative, realistic conditional probabilities (hazard ratios) when assessing the likelihood of hypothesized outcomes. “Reasonably expected” can be assessed to both continued airworthiness standards and applicable design / certification standards.

The process to escalate a reportable issue to a potential unsafe condition may include all events applicable to the Failure, Malfunction, and Defect (FMD) criteria, or may apply escalation criteria that is more narrowly defined than the broader FMD reporting criteria. For example, the FMD criteria may include any occurrence of “a complete loss of more than one electrical power generating system or hydraulic power system during a given operation of the aircraft,” as specified by FAR 21.3. However, the escalation criteria may exclude such events where the issue was only identified as “temporary loss of electrical power that is regained with normal crew procedures,” since this type of issue would not be expected to result in unsafe conditions.

Potential Unsafe conditions can result from hazardous conditions and may require a risk assessment. The following list of hazardous conditions, as defined by 14 CFR 33.75, is provided for exemplary purposes in assessing unsafe conditions:

- Non-containment of high-energy debris;
- Concentration of toxic products in the engine bleed air intended for the cabin sufficient to incapacitate crew or passengers;
- Significant thrust in the opposite direction to that commanded by the pilot;
- Uncontrolled fire;
- Failure of the engine mount system leading to inadvertent engine separation;
- Release of the propeller by the engine, if applicable; and
- Complete inability to shut the engine down.

It is suggested the COS agreement specifies that most reportable events are provided for information only with no follow-up required or expected by the FAA or the DAH. Follow-up is generally only expected for those items which meet the criteria for escalation as Potential Unsafe Conditions. Any report that is not escalated should include rationale. The FAA should establish reciprocal communication acknowledging reports not escalated. This could potentially provide a path for the FAA to use the COS agreement steps to satisfy MSAD tasks for Hazard Criteria Analysis or similar.

C.5. Risk Analysis and Decision Making

The fundamental goal of an effective COS process is to identify and mitigate safety risks. Risk Analysis is an important aspect of a robust SMS and is initiated following identification that a Potential Unsafe Condition exists.

Risk can be characterized as the relationship between severity and likelihood for which there should be an inverse relationship. The DAH should work with the FAA to establish the appropriate risk assessment methodology and risk acceptance thresholds. Consideration should be given to the type of methodology that not only satisfies internal DAH objectives, but also those of the FAA. The FAA utilizes the Transport Airplane Risk Assessment Methodology (TARAM) or the CAAM methodology described in AC 39-8. Alternative methodologies may be appropriate as MSAD Order 8110.107B provisions for the FAA to use a DAH risk assessment, so long as there is concurrence between the parties that the approach is acceptable.

The TARAM process establishes risk guidance values that can be adopted and utilized by a DAH for risk informed safety determinations or a DAH may elect to define a different level of risk acceptability within a COS Agreement. In these cases, it is prudent to recognize how, or if, this could impact safety conclusions between the two parties. A DAH may still be requested by the FAA to provide inputs to, or perform, the TARAM. A COS Agreement should establish when a TARAM is expected to be performed and the expected level of DAH involvement in the TARAM development. For scenarios when an issue can be dispositioned without the use of TARAM, the COS Agreement should identify the appropriate progression path.

A COS Agreement should define how/when the results of a risk analysis are compared against acceptable risk criteria, what the potential decision outcomes are (Safety Issue, Not a Safety Issue, etc.) and which stakeholders within an organization maintains responsibility for making safety-related determinations (i.e., appropriate levels of leadership involvement).

Issues found to have unacceptably elevated levels of risk require corrective action to mitigate. The risk analysis performed as part of the COS assessment should be leveraged to help define the mitigation timeline and the adequacy of proposed mitigating actions. See the Risk Management Plan section for further details.

The establishment of defined communication channels for sharing of safety related information (including COS Safety determinations by the DAH and the FAA) is a best practice and should be included within a COS Agreement. See the Coordination/Communication section for further details.

C.6. Risk Management Plan

Risk mitigation is an integral part of an effective COS process and as such a COS Agreement should define a process for managing issues if the risk levels exceed the organization's or the FAA's risk thresholds/guidance levels. The process should include guidance for the development and selection of potential corrective actions.

Corrective action options will typically fall into one of the following categories: operational limitations, part replacement, part/system redesign, increased inspection frequency, additional operator training or awareness, or improved maintenance practices or crew procedures. Identifying root cause is an important step in defining the appropriate course of action.

There may be multiple acceptable options for addressing the issue and a COS Agreement should discuss the process that will be followed to select the final solution. This process should include consideration of the following factors, which are additionally discussed in MSAD Order 8110-107B, AC 39-8 and EASA EU 748/2012 - Part 21.A.3B:

- **Risk mitigation effectiveness of the corrective action considering both interim and final actions**
    - First, candidate solutions should be considered based upon their capacity to reduce the future risk to acceptable levels, including confidence in the effectiveness of the corrective action.
- **Implementation timelines, complexity, and cost**
    - While difficult to quantify, the risk associated with implementing the proposed change, sometimes referred to as transition risk, may be significant and should be considered in the down-select process.
    - Complex solutions that are difficult to implement can increase transition risk.
    - Compressed implementation timelines which require increased production rates or out of sequence maintenance actions can increase transition risk.
    - Some highly effective options may prove not to be in the public interest if the cost to implement them exceeds the potential benefits.
- **Availability of resources (shop capacity, material availability, personnel availability)**
    - Like implementation timelines and solution complexity, the availability of resources can also affect transition risk.
    - A solution that utilizes existing shop capacity, material availability, and personnel availability will minimize transition risk.
    - Attempts should be made to ensure proposed service actions target routine airline maintenance intervals where accomplishment of the corrective action could be performed with existing resources and minimal operational disruption.

Integrating these factors provides the basis of the selection process from a list of Candidate Corrective Actions (CCAs) to a selected solution.

COS Agreements should also accommodate the ability to prioritize multiple, concurrent safety concerns. An organization may have more than one issue found to have unacceptable risk at a given point in time. Considering resource limitations, it may not be feasible for a DAH to mitigate multiple issues in parallel with the same level of urgency. The maximum allowable control program timeframe gathered for each safety concern can be useful in establishing the risk ranking for multiple, concurrent safety concerns. This priority should be aligned with mitigating issues as soon as reasonably practicable and within the maximum allowable risk timeframe.

A Risk Management Plan defines how an unsafe condition with unacceptable levels of risk will be resolved. It should:

- Have a means to establish an issue's urgency by defining the timeframe until the maximum allowable amount of risk is accrued.
  - In situations where the urgency does not allow for the minimization of transition risk, there should be a mechanism for creating interim action, which can provide temporary risk reduction while the final corrective action is developed and/or implemented into the fleet.
- Include a recommendation for corrective action to be incorporated as soon as reasonably practicable.
- Provide a means to validate the effectiveness of a proposed solution. This can be done by modifying the initial risk analysis to show how a proposed corrective action solution would effectively mitigate the safety concern.
- Account for regulatory rule-making time, as appropriate.
- Include a high-level schedule identifying milestones for the development of corrective action, communication to operators, regulatory rule-making time, and fleet incorporation.
- Link to a process related to root cause investigation.

Active tracking of fleet implementation can provide insight into the effectiveness of the selected solution.

The Risk Management Plan should also identify the medium in which corrective actions are communicated to the fleet. This can include Service Bulletins, Service Letters, Messages to Operators, etc. The FAA may issue an Airworthiness Directive (AD) to mandate compliance actions or other non-mandatory guidance for safety issues, such as a SAIB. A COS Agreement should establish the process used to communicate a proposed risk management plan to the FAA. It should also identify how/when information related to risk management is exchanged between the DAH and the FAA.

C.7. Coordination/Communication

A primary purpose for a COS agreement is to establish clear roles and responsibilities for sharing data and information necessary for Continued Operational Safety. The COS agreement should identify the methods, the parties, and the triggers (e.g., 21.3+ criteria) for communication between the DAH and FAA.

- **Mechanisms of communication**
  - Each DAH must have a well-defined communication channel/tool (email, web page, etc.) suitable to provide information necessary for the DAH to provide to the FAA the information supporting the organization’s COS investigation. This includes providing the organization’s risk analysis as needed, or for the DAH to provide the information FAA needs to perform its own COS Risk Analysis (a.k.a. TARAM).
- **Two-way DAH / FAA communication**
  - COS agreement must establish the correct area/department/person (and backup) inside DAH and FAA to handle such information
  - It is each organization's responsibility to advise the other one if there is any change in the area/department/person in charge of such communications and update accordingly
  - It is good practice to also communicate:
    - COS process health metrics

    - COS process changes
- **Foreign Civil Aviation Authority**
  - The COS agreement should include the process for addressing inquiries by foreign authorities. Foreign (validation) civil aviation authority may ask for FAA to be involved/informed also. If a foreign civil aviation authority contacts a DAH directly, the DAH should direct the request to the FAA and support as directed by the FAA. Nevertheless, it is paramount that FAA is copied in all communications between DAH and Foreign civil aviation authority
- **Investigative bodies**
  - The COS agreement should include the process for communications during formal ICAO Annex 13 investigations. When NTSB opens an investigation process, COS agreement must consider that DAH communication with investigative bodies must follow ICAO Annex 13. Summarizing, the Investigator in Charge (IIC) is the main coordinator and information manager and will control all information flow. All communication about the event exchanged between DAH and civil authority must be agreed with IIC. There should be an understanding that even in the context of an Annex 13 investigation, the FAA still needs to manage COS in parallel to the investigation. According to FAA Order 8020.11, the FAA may require information in addition to that required by the NTSB or more quickly than the NTSB to address urgent unsafe conditions.
- **Communications Triggers**
  - The COS agreement should establish expected triggers for updates between the DAH and FAA, including:
    - DAH Internal processes must define when determination of a "safety condition" meets the COS agreement reporting criteria, and that determination should be communicated to the agency in a timely manner commensurate with the level of risk
    - Any substantive updates to the root cause understanding of the failure mode integral to the hazard
    - Significant updates to expected completion/progression of the COS investigation timelines
    - Any substantive updates to the suspect population, including any subpopulations
    - Safety risk assessments approved for release and associated with recommended corrective actions, and updates to those risk assessments if it changes the timeline needed for corrective actions
    - Recommendations for corrective actions, or refinements to corrective action plans
    - Information associated with the implementation of corrective actions that would indicate additional actions may be necessary to achieve compliance with the defined plan
    - Other than mandatory reporting requirements, updates should occur as needed, not necessarily on a set periodic schedule, unless otherwise specified

C.8. SMS Integration

The mission of COS is to manage risk in aviation products throughout their lifecycle. Therefore, COS is recognized as a critical sub-system in support of the overall SMS for Part 21 organizations. Specific guidance can be found in the FAA Advisory Circular 21-58 for incorporation of COS as a critical sub-system of t for incorporation of COS as a critical sub-system of the SMS environment for Part 21 organizations pursuing compliance with 14 CFR Part 5 SMS.

The COS agreements should consider how the COS process interfaces with SMS processes by providing a systematic approach to identifying hazards and mitigating aviation safety risks in support of achieving the desired levels of product safety performance. There are also tenets of an SMS worth modeling into the COS process to include identification of COS responsibilities, risk decision-making and delegations, training plans, safety performance monitoring, and auditing.

Appendix D: FAA Draft Response to NASEM Recommendation 6

The FAA proposed response to NASEM Recommendation 6 is provided within this Appendix for traceability purposes. This draft was utilized expressly for the purpose of executing ARC Charter Task (b.ii) and should not be construed as the FAA final response to NASEM Recommendation 6. The Committee's feedback on this proposal can be found in Section 4.4.

NASEM Recommendation 6 Evaluation

1) Scope

This evaluation provides the FAA response to National Academies of Sciences, Engineering and Medicine (NASEM) evaluation of recommendation number 6 to the FAA Transport Airplane Risk Assessment Methodology (TARAM) Handbook (NASEM, 2022) (FAA, 2011). The full transcript of the NASEM recommendation 6 summary and narrative are provided in Annex I.

2) Evaluation Summary

The FAA has evaluated NASEM Recommendation number 6 proposal to identify or develop and implement methods and computational tools that leverage 14 CFR 25.1309 compliance for use in conducting the in-service safety process. Recommendation 6 advocated that these methods and tools should take advantage of Development Assurance Level (DAL) assessments of software/airborne electronic hardware, Fault Tree analysis, and other probabilistic risk assessment methodologies.

Based on the evaluation highlighted in section 3 herein, revisions to TARAM Handbook section 4.1 are proposed. An example of using certification safety data to improve a casual chain model will be considered for incorporation into TARAM Handbook Appendix C.

Finally, it is recommended that the Hybrid Causal Logic (HCL) modeling technique be further investigated to fully integrate causal chains, fault tree analysis and the man-machine interfaces into a more comprehensive evaluation solution.

3) Recommendation Evaluation Detail Discussion

Two virtual discussions, with the NASEM Community of Experts (COE) were held to enable a better FAA understanding of the number 6 recommendation. During the virtual discussions, it was highlighted by COE members that the summary contained two different recommendations; 1) Use certification safety assessment tools to add clarity to the logic created for the causal chain and 2) Calculate a software failure rate probability to enhance unsafe condition risk calculations.

This evaluation will discuss these two recommendation elements in the following paragraphs.

3.1. Use of Certification Safety Tools in TARAM

The NASEM TARAM evaluation noted that the TARAM Handbook discusses the relationship of 14 CFR 25.1309 to post-certification risk assessment but does not discuss how to apply it (NASEM, 2022) Section 3, page 3-3.

It is important to remember the goal of establishing a causal chain is to rapidly assess the potentials for unsafe outcomes and make the necessary corrective action decisions. An unsafe condition that is readily understood does not require a comprehensive causal chain model with accurate risk parameter calculations.

A number of reasonable observations were presented in the recommendation report and voiced during the two NASEM COE – FAA virtual meetings. These observations included:

- "The integration of TARAM's causal chains and the 14 CFR 25.1309's fault trees could help identify missing failure conditions and highlight potential design gaps. This integration would also provide a more comprehensive probabilistic risk assessment that could help address the lack of data for the conditional probabilities (CPs) in the TARAM causal chains."
- The use of certification safety data may require an infrastructure we (FAA) currently do not have.
- A fault tree analysis (FTA) is a knowledge repository of how systems fail to work correctly. We can use the FTA to identify pertinent casual chain data.
- Caution is advised on FTA use since the FTA may be incomplete or modeled at a different hierarchical level than the causal chain.
- "We are accomplishing a TARAM risk assessment because something in the certification process has presumably failed us."

The civil certification process, from the safety characteristics perspective, involves a two-path approach. Errors, which may result in failures, are addressed using a structured and scalable qualitative development assurance approach. Implementation failure mechanisms are addressed using analyses which may be shown to satisfy quantitative criteria.

The recommendation to use the numerical (quantitative) 14 CFR 25.1309 certification analyses (e.g FTA) in a TARAM COS risk assessment is challenged by a number of factors:

- FTAs and other design certification data used for showings of compliance to 14 CFR 25.1309 do not reside within FAA access or control. Once a certification process is complete, any submitted certification information is returned to the Applicant and removed from FAA storage media.
- The focus of the COS causal chain risk assessment is not the same as that used in the certification process so the additional quantitative data may be of limited value.
- While the FTA method and process is well described in consensus industry practice and widely used, each applicant and their system suppliers may select from a wide variety of FTA software tool vendors to accomplish an FTA on any specific program. FAA acquisition, maintenance, and training on the use of these various toolsets would become problematic.
- The use of a software based quantitative analysis tool, such as an FTA or event tree, would only calculate a small portion (i.e. frequency of occurrence portion of the fleet risk component) of the needed TARAM risk data.

Incidents which arise out of product manufacturer notifications or service-difficulty reports currently afford the FAA and product manufacturer the opportunity to cooperatively investigate the causal chain using the safety design data (e.g FTA, SSA). In other cases, this data may be requested from the manufacturers depending upon urgency of condition under study.

However, a promising methodology emerged during a review of the NASEM report references. The Hybrid Causal Logic (HCL) advanced probabilistic risk assessment combination of event sequence diagrams, fault trees and Bayesian networks provides a unique way to evaluate complex systems and human event interactions. Figure 6-1 presents a high-level summary of the HCL method. Each layer of the HCL applies an appropriate method to model and capture the risk. Event sequence diagrams (ESD) capture the possible end states and the related sequences of intermediate events emerging from the same initiating event. Some of the ESD can be decomposed into physical failure elements for which fault tree analyses (FTA) model the associated risk. Finally, Bayesian Network (BN) nodes are used to model the human causal relationships directly. In the HCL diagram, BN nodes can be linked to FT basic events and to any initial or intermediate evets in the ESDs.

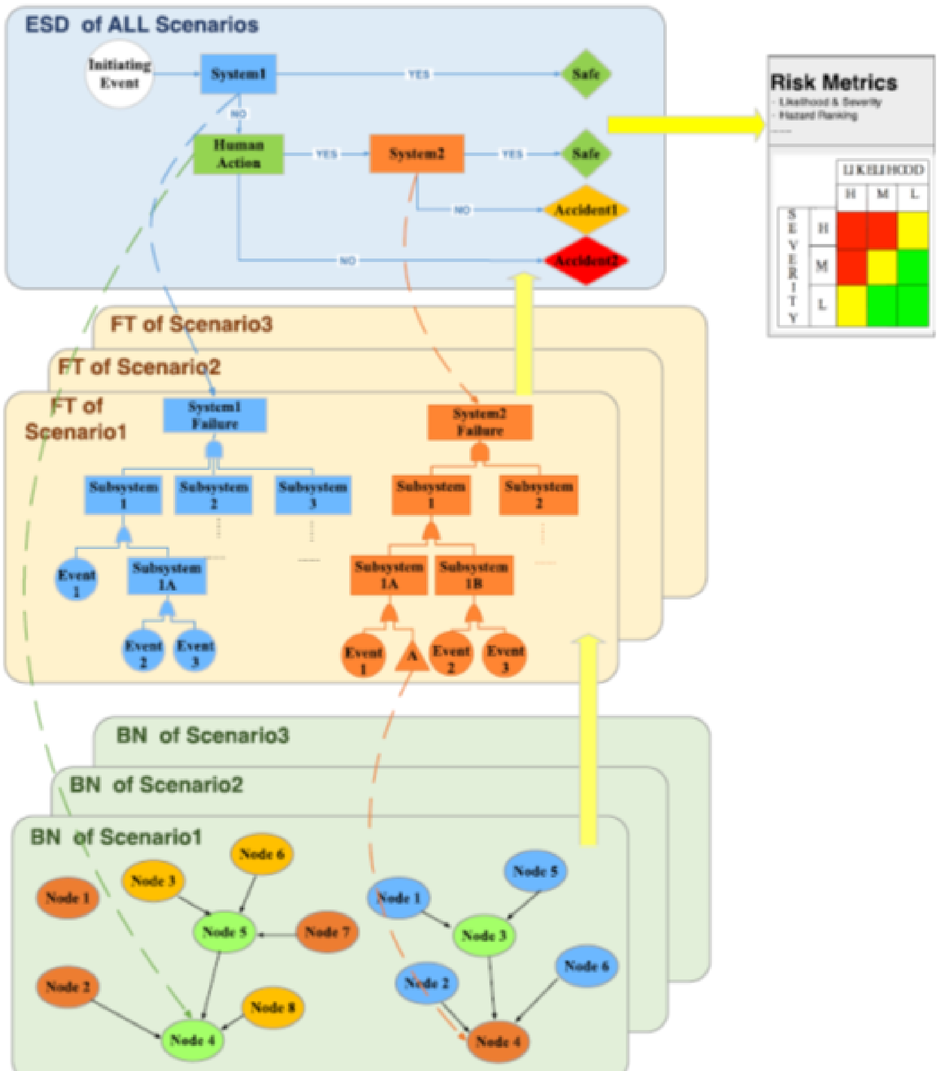

Figure 6-1 Structure of an HCL Model (Wang, 2020)

Unfortunately, due to unavailability of key HCL reference materials and recommendation response timelines, a complete TARAM application revision could not be formulated for HCL. However, the HCL technique will be recommended for continued development and incorporation into the TARAM Handbook as the approach can be matured.

Additional guidance on the proposed use of certification FTA modeling data could be added to the TARAM handbook in section 4.1 (see section 4 herein).

3.2. Software failure rate calculation

The FAA does not concur with the supposition that software "fails" and that therefore a quantitative software reliability metric must be calculated or measured and subsequently used as part of an event risk analysis. System failures (see Figure 2) may be attributable to software faults which arise due to the presence of an error. There are two primary sources of software error; human introduced, or tooling introduced.

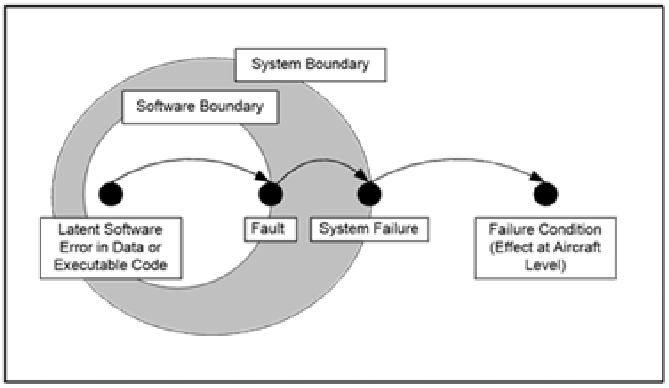

Figure 2 – Error to System Failure Progression (RTCA, Inc., 2011)

The civil aviation industry has over 35 years of experience in the development of digital systems and fielding software-based functionality. Throughout this timeframe, the process of developing this software functionality has continually evolved and matured. A software-based function in today's avionics, which satisfies the objectives identified in the recommended development process, has a high level of confidence that it will perform its required behaviors correctly. There is no implication that a software function, developed to DO-178 C Level A objectives, will provide a safe function with a probability of erroneous behavior equivalent to 1 in a billion. The completion of the development process objectives has no connection to safety and provides only a level of confidence in the software that it will provide the required functionality and behavior when it is required without error. The largest contributor to the malfunction of software hosted functionality in service is missing or incomplete behavior requirements. The sole contributor to this error source is human.

As the NASEM COE identified in the TARAM evaluation report "*The different methods developed by the U.S. NRC and NASA, however, still require further evaluation as they are facing a number of challenges.*"

Therefore, the recommendation to add a quantitative software error calculation to the TARAM risk evaluation will be rejected in favor of extending the current qualitative evaluation context.

It is reasonable to include documentation and evaluation of the development assurance assignments and objectives associated with the functions, airborne electronic hardware elements and software elements. There is potential, in any aircraft of today's complexity, to have a mismatch of development assurance level objectives which may be a potential risk source to be considered.

TARAM improvement recommendations will therefore focus on the capture of appropriate development assurance level assignments at the aircraft/system level (Functional DAL) and AEH or SW (Item DAL) levels and document their potential interactions for contribution in the causal chain.

4) TARAM Recommendations

The following TARAM revision recommendations have been formulated based on the described evaluation of NASEM recommendation number 6 herein.

It should be noted that the TARAM Handbook already advocates using certification information associated with showing of compliance to 14 CR 25.1309 (if available) to be used to enhance the causal event model. But as the NASEM report highlighted, there is no guidance or examples of how this process could be achieved nor identification of the potential benefits.

In response to this recommendation, the following TARAM event definition process enhancements to TARAM Handbook section 4.1 are proposed:

> **4.1 Understanding the Causal Chain**
>
> The first step in using the TARAM is to develop and/or understand the causal chain that leads directly from the condition under study to foreseeable unsafe outcomes for which an injury ratio is known (see TARAM section 3.5 and Figure 3). Creation of a representative causal chain or other similar model is encouraged, especially in cases where the relationships between the condition under study and the associated outcomes are complex or not well-understood. The causal chain diagram enables visual depiction of the logical paths leading to unsafe conditions for enhancing communications and discussion to fully understand the nature and effect of the condition under study.
>
> The TARAM Analyst should work with the product manufacturer and their pertinent equipment suppliers to gather failure modeling information. Pertinent information used for showings of compliance to 14 CFR 25.1309, if available should also be evaluated. Compliance information may include but is not limited to the following:
>
> > Fault tree analysis of failure condition associated with condition under study,
> > Definition of functional failure sets created during assignment of FDALs and IDALs,
> > System safety assessment evaluations (PASA, PSSA, SSA or ASA),
> > Functional failure modes and effects analyses.
>
> This information will be used enhance the understanding and modeling of the event. It will provide opportunities to identify and contrast system assumptions and/or characteristics assumed at certification from those associated with the in-service event under analysis.
>
> Care should be taken when evaluating any certification data for causal chain use. The depth of analysis accomplished in the certification data, how the safety data is partitioned, estimates of specific failure mechanisms and rates and exposure times may vary drastically from the COS study

parameters. An example of potential causal chain improvement using design stage FTA modeling information could be provided in TARAM Appendix C.

Another potential source complicit in the causal chain is the potential sources of error which may cause or contribute to the condition under study. Each of the system and implementation elements of a complex system should have been assigned a development assurance level during the development stage of the project. This Functional DAL or FDAL established the rigor with which the objectives of the development process were accomplished. Letter designations from A thru E were assigned to the function based on the worst severe failure effects this function may have on the aircraft. Similarly, airborne electronic hardware and software were assigned Item DALs or IDAL to establish the objectives for the implementation domain to accomplish. An evaluation of the functional failure sets and compatibility of the associated assigned FDALs and IDALs, associated with the condition under study should be documented. Any potential interactions of lower-level development rigor supporting higher level severity classifications should be evaluated.

Based on knowledge drawn from the causal chain, if more than one unsafe outcome is foreseeable for the condition under study, a TARAM worksheet should be filled out for each unsafe outcome, and Part 2 of an additional, constant-failure-rate summary worksheet should be prepared. Use this additional summary worksheet to document the risk factors associated with all of the unsafe outcomes, for that specific condition, added together (or, if the outcomes are not independent, combined as appropriate). Only Part 2 need be filled out on the additional summary worksheet. The additional summary worksheet is not necessary if there is a single outcome with a known injury ratio in the causal chain leading to all subsequent unsafe outcomes.

As an example, if the only injury ratios known were those associated with unsafe outcomes A and B in TARAM Handbook Figure 3, the analyst would prepare a worksheet for each of those unsafe outcomes, then add (or combine as appropriate) the results together on a summary worksheet Part 2 to obtain the combined risk. If an injury ratio for Condition A1 is known, only one worksheet would be necessary with the Condition, A, listed in the unsafe-outcome-description block of the worksheet.

Annex I NASEM Recommendation Number 6

Annex I.1 Recommendation Number 6 Summary

Recommendation #6: Within 18 months of receipt of this report, the Federal Aviation Administration (FAA) should identify or develop and implement methods and computational tools that leverage 14 CFR 25.1309 (SAE ARP4761) compliance for use in conducting the in-service safety process. These methods and tools should take advantage of Development Assurance Level (DAL) assessments of software/airborne electronic hardware, Fault Tree analysis, and other probabilistic risk assessment methodologies that support software reliability analyses. (NASEM, 2022) Page S-5 FAA Response: Within 12 months, the FAA will review, evaluate and draft guidance for inclusion in the TARAM handbook current certification data usage in the TARAM process and improvements to TARAM risk calculations and decision-making.

Annex I.2 Excerpt from Section 5 of NASEM Report

IMPROVING SYSTEMATIC RISK MODELING IN THE TARAM PROCESS (NASEM, 2022) Section 5, Page 5-1

In Section 4.1 of the Handbook, TARAM discusses the creation of a causal chain, which starts with the "condition under study" and ends with the "unsafe outcome(s)." This causal chain describes a series of airplane-level events which may result in unsafe outcome(s). In the probabilistic risk assessment (PRA), utilized for other technological systems such as nuclear power plants [1] and space exploration, [2] a causal chain is commonly modeled by event trees. Event Trees have inductive logic and are used to model (using Boolean logic) the chronological sequences of system-level events from an initiating event to an end state. In PRA, fault trees have deductive logic and are used to model (using Boolean logic) the causal and functional relationships between system-level events in the event trees and their underlying subsystems and component/equipment. Similarly, 14 CFR 25.1309 fault trees or other probabilistic analysis could be integrated with the causal chains in TARAM. This integration of TARAM's causal chains and the 14 CFR 25.1309's fault trees could help identify missing failure conditions and highlight potential design gaps. This integration would also provide a more comprehensive probabilistic risk assessment that could help address the lack of data for the conditional probabilities [3] (CPs) in the TARAM causal chains. Although the TARAM Handbook indicates the potential use of FTs from the design certificate to support the lack of data for CPs—this is being estimated based on engineering judgment.

Finding: TARAM analysis has no referencing to 14 CFR 25.1309 fault tree analysis for failure conditions, which may need to be integrated with field data.

Finding: TARAM's causal chains needs to build from 14 CFR 25.1309 fault tree analysis (or other probabilistic analyses) to provide a more complete assessment of risk-contributing causal factors.

TARAM currently utilizes worksheets for calculating and presenting the risk outputs. To integrate the airplane-level causal chain with fault trees, a software tool is needed for the derivation of minimal cut sets in Boolean logic, event sequence quantification, and risk calculation. There are a number of existing software tools available that have the capability to perform these functions. For instance, the fault tree analysis in the type certification utilizes the Computer Aided Fault Tree Analysis System (CAFTA) software tool,[4] which also has the functionality of building and quantifying event tree models to represent the airplane-level causal chain and integrate the event trees with the fault trees. As another example, the U.S. Nuclear Regulatory Commission (U.S. NRC) utilizes the Systems Analysis Programs for Hands-on Integrated Reliability Evaluation (SAPHIRE) software tool [5] to develop a standardized PRA model by integrating event trees and fault trees for each operating nuclear power plant.

When the data to quantify component/equipment-level inputs (such as failure probabilities for basic events in fault trees) are unavailable or insufficient, one option would be to integrate explicit models of failure mechanisms underlying the component/equipment-level events with event trees and fault trees as was done, for instance, in the development of the Integrated Risk Information System (IRIS) software tool for a previous Federal Aviation Administration (FAA)-funded research project.[6] The IRIS software integrates an airplane-level causal chain (modeled by an Event Sequence Diagram) and fault trees with a Bayesian Belief Network (BBN) that models the underlying causal factors. The BBN is an acyclic graphical modeling technique, where the causal factors and their influence paths are represented by nodes and edges, respectively. The causal relationship between two factors is quantified using conditional probabilities, typically estimated based on data and subjective judgment. As another example of software code, recent research in the nuclear power domain has developed an Integrated PRA (I-PRA) methodology[7] to integrate event trees and fault trees with simulation models of underlying failure mechanisms by generating a probabilistic interface equipped with key functions to convert the simulation data to the PRA inputs considering uncertainty analysis and dependent failure analysis. The I-PRA methodology models the underlying causation using a system performance simulation rather than translating the system behavior to a probabilistic graphical model as done in IRIS. For instance, as stated in Chapter 4 and in the previous section of this chapter, if the wear-out failure TARAM analysis lacks sufficient data to fit the Weibull distribution for calculating the expected value "DA,"[8] additional data could be generated by simulation modeling for the physical degradation mechanism of concern using the probabilistic physics-of-failure (PPoF) approach.[9] In this case, the PPoF model could be interfaced with event trees and fault trees using the I-PRA methodology.

For risk estimation, adequate treatment of dependency is crucial. In risk analysis, scenarios are represented by the intersections of multiple events; hence, risk quantification requires the calculation of their joint probabilities. If the events (E1, E2, …, EN) are independent, their joint probability[10] can be calculated by multiplying their marginal probabilities, Pr(E1, E2, …, EN) = Pr(E1) * Pr(E2) * … * Pr(EN). Meanwhile, if the events are not independent, the joint probability must be computed using the chain rule of probability, Pr(E1, E2, …, EN) = Pr(E1) * Pr(E2 | E1) * … * Pr(EN | E1, E2, …, EN–1). In the context of risk analysis, most often, the existence of dependency tends to increase the conditional probability of a failure event, given its preceding failure event(s), compared to the marginal probability, for instance, Pr(E2 | E1) > Pr(E2). Therefore, inadequate consideration of known dependencies in risk quantification can result in underestimating risk and, ultimately, lead to an unsafe decision.

In the current TARAM, risk scenarios are represented by an intersection of airplane-level events in the causal chain.[11] The dependency among those airplane-level events is addressed by directly estimating the CPs of unsafe outcomes, given the condition or event being analyzed, as input to the TARAM risk calculations. This approach can work if adequate data is available to support the airplane level CP estimation. However, it is not always feasible to find either sufficient relevant data for the simultaneous occurrence of multiple events at the airplane level or operational data for the airplane-level scenarios that have led to a catastrophic outcome; thus, reliance on the data-driven CP estimation can result in inaccurate risk outputs and significant uncertainties. The TARAM Handbook states that, when historical or test data are not available, CPs can be estimated based on design and certification fault tree analyses. Based on the presentations provided to the committee by the FAA, the lack of data for CPs is, however, mainly addressed by using engineering judgment.

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9 M. Azarkhail and M. Modarres, 2012, The evolution and history of reliability engineering: Rise of mechanistic reliability modeling, International Journal of Performability Engineering, 8(1):35–47.
10 The joint probability of events A and B is represented as the probability of their intersection $P\ (A \cap B)$.
11 FAA Transport Airplane Directorate, 2011, Transport Airplane Risk Assessment Methodology (TARAM) Handbook, 2011.

Annex I.3 Excerpt from Section 5 of NASEM Report

INCORPORATING SOFTWARE RELIABILITY ANALYSIS IN TARAM PROCESS (NASEM, 2022) Section 6, Page 5-8

Until now, efforts to improve software reliability on commercial airplanes mainly centered around software fault-avoidance and fault-tolerant technologies.[34] These fault-avoidance technologies are common in software reliability engineering as they rely on a compliance with formal development guidelines, design requirements, and testing and validation procedures to reduce ambiguity, uncertainties, and potential software faults. Meanwhile, fault-tolerant technologies [35,36] often include (1) single-version methods that equip software with mechanisms to detect and recover from faults; and (2) multi-version methods that implement diversity measures (e.g., separate development teams, different algorithms, and different programming languages/tools) to defend against common cause software error.

The Safety Assessment Processes utilized for 14CFR 25.1309 Type Certification compliance include a consideration of errors in the development of functions, software, and airborne electronic hardware (AEH). The process defined in SAE ARP4754A describes a methodology to determine the level of rigor—

Development Assurance Level (DAL)—to apply to the development of functions, software, and AEH, based on the failure condition to which those elements are associated. These DALs guide the development process by increasing the rigor applied to the development based on the severity of the failure condition. As the severity increases, so does the rigor. These DALs are utilized in the structured software development process defined in RTCA/DO-178 [37] and AEH in RTCA/DO-254.[38] While not quantitative demonstrations of software and AEH reliability, the DAL used for the development of these items can be used to demonstrate if the DALs of the item support an unsafe condition that the TARAM process may identify.

Characterization and quantification of software errors in the TARAM process need a probabilistic modeling approach to account for unavoidable uncertainties associated with the process and its variables.[39] TARAM, in its current form, does not offer a documented approach to analyze software errors in a probabilistic manner especially when the software is a source of latent failure, or the software contributes to progression of the scenarios after the occurrence of the condition under study (represented by CPs).

In other domains, there have been efforts to develop probabilistic models for software reliability to support risk assessment. For example, the U.S. NRC has been conducting research on the identification and development of methods, analytical tools, and regulatory guidance for probabilistically modeling the reliability of digital instrumentation and control systems and including them in PRAs of nuclear power plants.

A review of available quantitative software reliability methods (QSRMs) was conducted,[40] where the existing methods are grouped into four major categories including software reliability growth methods, Bayesian Belief Network [BBN] methods, test-based methods, and other methods such as the Context-based Software Risk Model [CSRM]). The BBN and the test-based methods were eventually selected for further development. The BBN method can incorporate expert judgment and information about the software's lifecycle activities into the evaluation of safety-critical software. In addition, the BBN provides a mathematical framework for propagating epistemic uncertainties while calculating the software error probabilities. Meanwhile, the test-based method uses standard statistical methods with software testing and operating data (if available) and includes the treatment of parameter uncertainties. The two methods were then combined to develop a Bayesian updating algorithm in which a prior distribution of the software error probability is first developed via the BBN approach (or using a noninformative prior distribution) and the test-based method is then used to generate data needed for the Bayesian updating.[41] To incorporate software reliability into the current PRA frameworks, software functions or components are modeled as events on the PRA model's event trees and/or fault trees. The failure probabilities of these events, estimated by using methods such as the above-mentioned Bayesian updating algorithm, are then used for PRA quantification. In parallel to these efforts, the U.S. NRC also sponsored research to investigate the modeling of digital systems using dynamic PRA methods, as detailed in NUREG/CR-6901,[42] NUREG/CR-6942,[43] and NUREG/CR-6985.[44]

In the space exploration domain, NASA suggested using the CSRM method.[45] CSRM combines event tree and fault tree techniques of traditional PRA with an advanced modeling approach (e.g., the dynamic flowgraph methodology) to integrate the contributions of both hardware and software into an overall system risk model. With this design, CSRM is not specifically an approach to estimate the failure probability or failure rate of a particular software error mode and, therefore, other classical QSRMs or context-based, risk-informed testing could be relied upon for such estimation. CSRM targets logic errors triggered by off-normal system conditions, which are considered the dominant contributors to system risk from software errors yet are often overlooked by classical QSRMs.

The different methods developed by the U.S. NRC and NASA, however, still require further evaluation as they are facing a number of challenges including

(1) the BBN methods require a substantial development effort and depend significantly on the expertise of the BBN developers, expert opinion, and availability and quality of software development documentation;

(2) the test-based methods and any other QSRM that rely on test data (e.g., software reliability growth methods) require a large number of software tests and are susceptible to the uncertainty that the testing designs and conditions may not represent the actual environment in which the software is operated;

(3) the CSRM approach also relies on context based, risk-informed testing for scenarios that involve off-nominal conditions for which a substantial amount of time and resources would be needed; and

(4) many software reliability growth methods rely on empirical formulas of the expected number of failures as a function of time, yet these assumed empirical formulas are not applicable for all situations.

Owing to these limitations, further research is required to advance the existing QSRMs for the safety critical applications.

In a relevant area of research and development, efforts in the nuclear industry have been initiated to address software-related technical challenges that emerge from the introduction of digital technologies (e.g., automation, digital instrumentation, and control). These technical challenges include but are not limited to:

(1) new potential software-based hazards/failures in critical safety and control functions;
(2) common mode failure and common cause failure in software; and
(3) increased complexity in human software-hardware interactions leading to possible programming errors and incorrect outputs.

While addressing the first two challenges requires software reliability analysis and its integration into a risk assessment framework, the third challenge falls under the umbrella of software trustworthiness evaluation. A line of research [46] has recently been initiated within the Department of Energy Light Water Reactor Sustainability Program Plant Modernization Pathway to develop a generic (instead of technology specific) methodology to evaluate and improve automation trustworthiness. This methodology extends the scientific usage of epistemic uncertainty to generate sufficient evidence for verifying that the automation would be explainable, trustworthy, and operationally acceptable.

Finding: TARAM does not offer a documented approach to analyze software errors in a probabilistic manner especially when the software is a source of latent failure, or the software contributes to progression of the scenarios after the occurrence of the condition under study (represented by CPs). In support of Recommendation 6, research needs to be conducted to evaluate the feasibility of the existing methods for the probabilistic assessment of software reliability in TARAM and, if any of the existing methods can satisfy the needs, they can be adopted for TARAM; otherwise, new methods/tools may need to be developed to analyze software reliability in support of the COS decision-making.

In the current TARAM, the risk outputs are calculated and presented in spreadsheets. When the scope of TARAM is expanded based on the recommendations in this report, the current spreadsheet format may not be practical in the light of timely analysis and decision-making. The computational tools that fit the practical needs in the COS analysis would need to be evaluated and, if any of the existing ones are relevant, they can be adopted for TARAM; otherwise, a new computational tool may need to be developed for TARAM leveraging the existing tools.

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Annex II Acronyms, Terminology and Definitions

AEH – Airborne Electronic Hardware

ASA – Aircraft Safety Assessment

BN – Bayesian Network

COE – Community of Experts

CP – conditional probabilities (NRC, 2007)

DAL – Development Assurance Level (SAE S18, 2010)

Failure – A loss of function, or a malfunction, of a system or a part thereof. (AC 25.1309-1A)

Failure - An occurrence which affects the operation of a component, part, or element such that it can no longer function as intended (this includes both loss of function and malfunction). Note: Errors may cause failures, but are not considered to be Failures. (Arsenal Draft AC 25.1309)

FDAL – Functional Development Assurance Level

FTA – Fault Tree Analysis

HCL – Hybrid Causal Logic (Wang, 2020)

IDAL – Item Development Assurance Level

PASA – Preliminary Aircraft Safety Assessment

PRA – Probabilistic Risk Assessment (NRC, 2007)

PSSA – Preliminary System Safety Assessment

SACO – Seattle Aircraft Certification Office

SSA – System Safety Assessment

SW - Software

TARAM – Transport Airplane Risk Assessment Methodology

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Appendix E: AIR Analysis of NASEM Recommendation 11

The AIR Analysis of NASEM Recommendation 11 is provided within this Appendix for reference. This document was utilized expressly for the purpose of executing ARC Charter Task (b.iii). The Committee's feedback on this study can be found within Section 4.5.

AIR Analysis of The National Academies of Sciences, Engineering, and Medicine Academy Recommendation 11

Implementing Peer Reviews and Quality Assurance Functions into TARAM

October 11, 2023

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Aircraft Certification
Signature Page

AIR STUDY
AIR Analysis of NASEM Recommendation 11

Approved by:

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Implementing Peer Reviews and Quality Assurance Functions into TARAM

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EXECUTIVE SUMMARY

This study provides The FAA Aircraft Certification Service's (AIR) response to The National Academies of Sciences, Engineering, and Medicine (The National Academies) (NASEM) Recommendation 11, along with the rationale supporting recommendations for changes to AIR's continued operational safety (COS) process.

NASEM Recommendation 11 requested AIR to document a study to determine the requirements and viability of an independent peer review and quality assurance process for (1) the results from the Transport Airplane Risk Assessment Methodology (TARAM) analysis of significant in-service safety issues and (2) the COS decisions resulting from TARAM outputs.

As outputs from this study, AIR recommends the following changes that will strengthen and standardize COS processes across the East, Central and West Aircraft Certification Branches (AIR-700) and the Integrated Certificate Management Division (AIR-500). Those changes are:

1. AIR should adopt a standardized approach to implementation of the peer review requirements described in FAA Order 8110.107A, Monitor Safety/Analyze Data (MSAD). This standardized approach should include a multi-level review of all TARAM analyses.
2. To provide additional quality assurance oversight, the Aircraft Certification Fleet Safety Section (AIR-723) will conduct a minimum of 3 annual deep dive reviews of AIR COS decisions and present the results of those reviews to the FAA Office of Accident Investigation and Prevention (AVP).

1

1 OVERVIEW

1.1 Background

The National Academies of Sciences, Engineering, and Medicine (the National Academies) published a consensus study report, "Evaluation of the Transport Airplane Risk Assessment Methodology (2022)" containing recommendations for action by the Federal Aviation Administration (FAA) Aircraft Certification Service (AIR). The origin of the National Academies (NASEM) study was a mandate contained within the Aircraft Certification, Safety, and Accountability Act, signed into law on December 27, 2020. As a result of The Act, the FAA entered into a contract with the National Academies to conduct a study to assess the Transport Airplane Risk Assessment Methodology (TARAM) process used by the FAA.

The NASEM report identified several recommendations for improving the quality of COS decision-making process when using the TARAM results. NASEM stated that in order to support the quality of COS decision-making, a review process is required to continuously evaluate:

1. the adequacy of the TARAM analysis to generate risk results, and,
2. the adequacy of the use of the TARAM results in the COS decision-making process.

NASEM also posited that the review process could consist of multiple layers of reviews at different phases of the COS decisions involving various stakeholders to provide evaluations from diverse perspectives. Accordingly, NASEM provided Recommendation 11 as a means to ensure the integrity of decisions made through the TARAM processes.

Recommendation 11 states:

> *Within 12 months of receipt of this report, the Federal Aviation Administration (FAA) should conduct and document a study to determine the requirements and viability of an independent peer review and quality assurance process for (1) the results from the Transport Airplane Risk Assessment Methodology (TARAM) analysis of significant in-service safety issues and (2) the continued operational safety (COS) decisions resulting from TARAM outputs. Details of the independent peer review and*

quality assurance process should be documented in the COS agreements between the manufacturers and the FAA.

1.2 AIR Organization Description

The Federal Aviation Administration (FAA) Aircraft Certification Service (AIR) is part of the Office of Aviation Safety (AVS) and includes more than 1,500 engineers, scientists, inspectors, test pilots, and other experts responsible for oversight of design, production, airworthiness certification, and continued airworthiness programs for all U.S. civil aviation products and foreign import products. AIR collaborates with the International Civil Aviation Organization (ICAO) and other Civil Aviation Authorities (CAA) to maintain and further the safety of the international air transportation system. Accountable to the American public and FAA stakeholders, AIR strives to reach the next level of safety, efficiency, environmental responsibility, and global leadership. This includes responsibility for evaluating continued operational safety (COS) for aircraft operating in the national airspace system (NAS) and aircraft where the United States is the state of design.

1.3 Study Scope

This study necessitated a complete understanding of the TARAM process, how it is implemented within AIR, the inputs that are needed, the source of these inputs, and who executes the TARAM process itself.

2 Peer Review

The FAA examined the requirements and viability of peer review as a component in the development of TARAM analyses for significant in-service safety issues and the associated COS decisions informed by TARAM outputs. In conducting this study, the FAA considered information in the proposed American National Standard: Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications (https://www.nrc.gov/docs/ml0037/ML003733342.pdf) and US Nuclear Regulatory Commission Regulatory Guide 1.200, Rev 2, (https://www.nrc.gov/docs/ML0904/ML090410014.pdf) as industry benchmarks for peer review of risk assessments.

2.1 Definitions

For the purposes of this study, an *independent peer review of a TARAM analysis* occurs when the inputs, assumptions, analytical methods, and outputs for a TARAM analysis are evaluated by one or more qualified individuals who did not perform the TARAM analysis. An *independent peer review of a COS decision* occurs when a regulatory action (or a decision to not initiate regulatory action) associated with a TARAM analysis is evaluated by one or more qualified individuals who are not the decision-authority for that regulatory action.

2.2 Alternatives Considered

This study considered a variety of means by which peer reviews might be accomplished in the context of a TARAM analysis and its associated COS decision. Four options are outline in the following table:

Options for Peer Review of Risk Assessments and Safety Decisions

ID	Approach
1	FAA employees serve as Independent Peer Reviewers of FAA risk assessments and safety decisions developed by a company or other FAA employees.
2	Establish requirements for design approval holders to acquire Independent Peer Reviews of their Risk Assessments prior to submission to the FAA (e.g., risk assessment designees).
3	Obtain Independent Peer Review of FAA risk analysis and COS decision by hiring risk assessment consultants (e.g., MITRE Corp.)
4	Utilize other Government Agency Experts (e.g., NASA, Nuclear Regulatory Commission, Department of Defense) as independent peer reviewers of FAA risk analyses and COS decisions

2.3 Criteria for Evaluation

In evaluating these Options, the FAA considered the following criteria:

Speed vs Robustness of Review: The continued operational safety decision process can often allow several weeks for an issue to be analyzed and a decision to be reached regarding the handling of a potential safety issue. But the process must also accommodate the handling of more urgent safety issues which must be addressed in a matter of hours or days. The process needs to balance robustness of the review process relative to the speed with which the safety decision process can be completed.

Qualifications of Peer Reviewers: As noted by the Nuclear Regulatory Commission, "Each member of the peer review team must have technical expertise in the PRA elements he or she reviews, including experience in the specific methods that are used to perform the PRA elements. This technical expertise includes experience in performing (not just reviewing) the work in the element assigned for review. Knowledge of the key features specific to the plant design and operation is essential." (Rev 2 of RG 1.200, Pg. 34). For continued operational safety issues handled by the FAA, the peer reviewer(s) will need to have sufficient knowledge of both the TARAM method and the particular aircraft and equipment associated with the issue under investigation.

Logistics: Each peer review option presents a different set of logistical challenges which would need to be addressed.

2.4 Evaluation of Options

The following paragraphs provide a detailed evaluation of each option:

For Option 1, at least one FAA employee develops a risk assessment and recommended safety decision based on information and recommendations obtained from a company. Multiple FAA employees serve as the Independent Peer Reviewers of risk assessments and COS decisions recommended by the lead FAA employee(s) conducting the risk assessment. This approach provides the FAA with flexibility in managing the speed and robustness of the peer review relative to the circumstances of the particular safety issue. The robustness of this approach can be established if policy assures use of individuals with significant expertise for the aircraft/equipment as well as the TARAM methods. Logistically, this approach is simple to implement and maintain since it relies on FAA employees who can be directed and deployed relatively easily. The FAA employee peer reviewers would be expected to have high familiarity with the aircraft/equipment involved with the safety issue, and significant levels of expertise in TARAM methods.

For Option 2, the FAA would need to establish requirements for design approval holders to acquire an Independent Peer Review of their Risk Assessments prior to submission to the FAA (e.g., risk assessment designees). This approach would increase the robustness of a company's risk assessment process, and could provide high speed of response once such a program is established and mature. Logistically, this approach is very complex. It would require justification and establishment of new requirements for companies, which could require rulemaking. A cadre of readily available independent consultants trained in TARAM methods and familiar with a variety of aircraft systems and equipment does not presently exist. The FAA would likely need to develop a program to evaluate and credential individuals who are qualified to serve in this capacity.

For Option 3, the FAA would obtain Independent Peer Review of FAA risk analysis and COS decision by hiring independent risk assessment consultants to support each project. This approach would increase the robustness of the FAA's risk assessment process through the inclusion of a fully independent perspective. However, this approach could slow down the FAA decision process due to inherent logistics associated with acquiring and tasking consulting services in support of government activities. The qualifications of consultants in TARAM methods can likely be established at a high level, but it may be difficult for independent FAA consultants to maintain a high degree of familiarity with aircraft systems and equipment due to proprietary concerns. Logistically, this approach is somewhat complex. It would require implementation and maintenance of new contract vehicles with independent consultants and the development of a cadre of TARAM experts which does not currently exist.

For Option 4, the FAA would utilize other government agency experts (e.g., NASA, Nuclear Regulatory Commission, Department of Defense) as independent peer reviewers of FAA risk analyses and COS decisions. This approach would increase the robustness of the FAA's risk assessment process by introducing expertise from beyond the civil aviation community. This approach would likely slow down the decision process to some degree due to the interagency nature of the review. The reviewers under this approach would likely have less expertise in TARAM methods but may have substantial expertise in general risk assessment methods. The reviewers likely would not have significant expertise in the affected aircraft systems and equipment. Logistically, this approach would introduce some complexity due to the need for interagency agreements and the development of a network of qualified risk assessment reviewers.

The following table summarizes the FAA's assessment of each option. A "+" indicates that the associated criterion is a relative strength for that option:

Evaluation of Peer Review Options

ID	Option	Speed	Robustness	Peer Reviewer Qualifications	Logistics
1	Multiple FAA reviewer	+	+	+	+
2	Independent Company Consultants	+	+	+	
3	Independent FAA Consultants		+	+	
4	Independent Government Consultants		+	+	

2.4 Recommendations for Peer Review

Each of the options evaluated offer some potential benefits. However, while Options 3 (Independent FAA Consultants) and 4 (Independent Government Consultants) each would provide the FAA with increased robustness of review through access to expertise not resident within the FAA and freedom from potential cultural biases within the FAA organization, these options present significant logistical challenges through the establishment of a new government program with associated funding and interagency complexities. Both of these options also potentially slow down the safety decision process, negating any benefits for the most critical, time-sensitive agency decisions. As such, it is recommended that Options 3 and 4 are not viable approaches for peer review of FAA COS decisions.

Option 2 (Independent Company Consultants) presents several potential benefits. The introduction of certified, independent reviewers into a design approval holder's process could significantly improve the quality of analysis and decision recommendation generated by companies. And by introducing this peer review within the corporate process, it can likely be accomplished faster than it would be accomplished within the context of government contracting and interagency procedures. However, this approach is not immediately ready for implementation. Significant effort would be required to develop the cadre of consultant reviewers and the procedures for approval necessary for this approach to be effective. As such, Option 2 is not recommended for near-term action, but might be considered as a possible future enhancement to the COS system.

Option 1 is recommended as the most viable, near-term approach to enhance the peer review of FAA TARAM analyses and associated COS decisions. FAA Monitor Safety/Analyze Data (MSAD) policy already includes an independent peer review process in the form of a Corrective Action Review Board (CARB).

Per sections 2-7. and 2-9. of the MSAD Order, 8110.107A, the preliminary risk assessment is evaluated by a *senior COS ASE*, and the risk analysis and determination of corrective action is performed by an *assigned ASE*. Then as outlined in section 2-10. of 8110.107A, the risk analysis and corrective action is presented to a CARB (sometimes several times) for concurrence, with the goal to *improve safety through better decision making* by:

- *Improving robustness by reducing the number of single thread safety decisions.*
- *Providing for cross-functional review, allowing others to raise concerns and contribute knowledge about a safety issue and proposed corrective action plan.*
- *Facilitating real-time, open exchange of safety issues across the key lifecycle disciplines among ACO, MIDO and [AED] staff.*
- *Providing a forum for the review of the preliminary risk analysis, risk analysis, causal analysis and corrective action(s) for a product type, leading to acceptance, rejection or revision of the proposed corrective action.*
- *Increasing knowledge and experience in the AVS community.*

When implemented effectively, the MSAD Order provides a robust, independent peer review framework utilizing existing FAA resources. The preparations for a CARB include multiple layers of peer review for a TARAM analysis; utilizing not just one ASE, but supplementing that work with support from senior engineers, section managers, COS program managers and COS technical advisors. Then the CARB itself provides multiple deliberations and discussions on the TARAM inputs, outputs and the proposed corrective actions for Transport Category aircraft by highly-qualified, multidisciplinary stakeholders (i.e. Engineering, Flight Test, Aircraft Evaluation Division (AED), senior management, etc.) that participate in these meetings.

The MSAD Order and CARB provide an excellent framework for effective independent peer-review, but the quality and nature of this CARB-based independent peer review has not been standardized across FAA offices. This study recommends adoption of the following standard practices across AIR offices:

- TARAM analysis will be completed by an ASE familiar with both the TARAM method and the aviation product being evaluated. A COS Program Manager will support the ASE and determine when the risk assessment is ready for final review.
- Prior to CARB presentation, the ASE's TARAM results and associated recommendations will be peer reviewed by a COS Technical Advisor.
- During CARB presentation, the peer-reviewed TARAM results and associated recommendations will be presented for feedback and discussion. At a minimum, the following personnel will participate in each CARB: at least one COS Program Manager, at least one COS Technical Advisor, at least one Senior ASE representing the technical discipline for the aviation product being evaluated, at least one manager responsible for approving the COS decision, and at least one senior staff member or manager from each technical section, the flight test branch, flight standards, and other affected organizations. The rationale for this attendance is to ensure at least two leadership-level individuals with a focus on COS processes and risk assessment guidance (COS PM and COS TA), and at least two leadership-level individuals with a focus on the safety of the product being evaluated (Senior ASE and Manager), and at least one safety advocate from each of the other technical disciplines to ensure cross-functional effects are considered (additional senior staff members).

3 Implementing a Quality Assurance Process

A study of the current COS processes evaluated the benefits enabled by a quality assurance (QA) process. The study considered both:

- The value of implementing a QA process
- The mechanism for incorporation

3.1 Definitions

For the purpose of this study, *Quality Assurance* is a mechanism for providing oversight of a target process to ensure it achieves a desired level of performance.

3.2 Existing Quality Assurance Capabilities

The FAA's AVS organization has implemented quality assurance activities for many years as part of an organization-wide Quality Management System (QMS). As such, AIR's COS decision-making processes have been supported by AVS QMS quality assurance activities for many years. This study evaluated a reinvigoration of FAA quality assurance activities as applied to AIR's COS decision-making process.

3.3 QA Process: Value Proposition

The study determined that enhancing the COS processes with a reinvigoration of the quality assurance function would be beneficial. The analysis of Peer Review alternatives discussed above highlighted that AIR has had significant variability in performance of the MSAD process as implemented across various offices. A quality assurance function could assist in reducing that variability and assuring reliably effective performance in COS decision-making.

With the level of peer reviews proposed within this study, a quality assurance function is unlikely to result in better technical outcomes on individual COS issues, but rather, the increased process scrutiny should drive additional accountability to achieve consistent process adherence across all COS issues. The peer review will assure the outcome of each COS decision is appropriate, and quality assurance will ensure that we follow our processes and document our activities, raising confidence that we are consistently making good COS decisions. Some of the rationale supporting greater accountability are:

1. A QA function drives accountability by providing a structured and systematic process to assess, verify, and report on AIR's compliance with established standards, policies, or regulations.
2. The QA function in the form of periodic audits (i.e., periodic audits), utilizing predefined criteria ensures that individuals or branches are held to the same set of standards, furthering consistency across AIR.
3. Identification of Deviations: Audits identify deviations from established standards or compliance requirements. This includes detecting errors, inconsistencies, or non-compliance with the process.
4. Documentation and Reporting: QA findings are documented in reports that outline the areas of concern and the extent of deviations.

5. Preventing Future Issues: Audits not only focus on current compliance but also help identify weaknesses in systems and processes. By addressing these weaknesses, audits contribute to preventing future problems.
6. Transparency: Audits promote transparency by providing stakeholders, whether internal or external, with insights into AIR's operations and adherence to standards.
7. Continuous Improvement: Regular audits encourage a culture of continuous improvement. Organizations and individuals are motivated to strive for better performance and higher levels of accountability over time.
8. Feedback and Learning: Audits provide valuable feedback that can be used for learning and development. Mistakes or shortcomings can be turned into opportunities for growth and improvement.

All of these outcomes are beneficial in assuring effective performance of AIR's COS decision-making process.

3.4 QA Process: Mechanism for Incorporation

AIR employs individuals in many parts of the organization with expertise in QA-related functions. These individuals have a deep knowledge of analyzing compliance to standards, criteria and processes, documentation and record keeping, and continuous monitoring. The study considered leveraging a specific branch to conduct the QA function, along with utilizing regional certification branches to verify activities completed in other regions. In total the study considered options from building a dedicated team staffed with personnel from various parts of the organization or employing Branches from across the organization, including:

AIR-510 Certification Program Management Branch
AIR-520 Continued Operational Safety Branch
AIR-540 Integration & Performance Branch
AIR-570 Certification Branch
AIR-580 System Operation & Oversight Branch
AIR-600 Policy and Standards Division
AIR-720 Operational Safety Branch
AIR-740 Integration & Performance Branch
AIR-750 East Certification Branch
AIR-760 Central Certification Branch
AIR-770 West Certification Branch

After reviewing the above and in consideration with the accountability principles identified in Section 3.2, the study recommends utilizing quality assurance capabilities within the full AIR organization, supplemented by oversight beyond AIR. The study proposes utilizing the FAA's Office of Accident Investigation and Prevention (AVP) to provide greater accountability at the AVS-001 Associate Administrator for Aviation Safety executive level.

As noted in NASEM Recommendation 1, AIR's COS decision-making process, as documented in FAA Order 8110.107A, is an implementation of the FAA's overall safety risk management policy as described in FAA Order 8040.4B. As the organization accountable for the performance of the FAA's safety risk-management policy, the AVP organization is well-positioned to provide quality assurance oversight of AIR's MSAD process.

This study recommends the following quality assurance support activities in oversight of AIR's COS decision-making process:

1) Each year, the AIR-723 Fleet Safety Section will conduct a minimum of 3 post-performance "deep dive" reviews of significant safety issues addressed by AIR's MSAD Order to assess effectiveness of the risk assessment activities (i.e., TARAM) and the COS decision-making process.
2) AIR-723 will present the results of these reviews to the AVP organization to verify that AIR's COS decision-making process is fulfilling the objectives of FAA Order 8040.4B Safety Risk Management Policy.

Appendix F: Consolidated Recommendations

Appendix E contains a matrix of all recommendations made within this report with reference to the correlating section and page number the recommendation is from.

Table 3: Consolidated Recommendation Matrix

Number	Recommendation	Section	Page
1	Within TARAM Handbook PS-ANM-25-05 Section 6.4 - Aviation Safety Engineering (ASE) Risk Management, it is recommended that additional information be included within the sub-bullets for step 3 as follows: *In some cases, the corrective action for an issue may be simple and obvious based on established industry experience. Any requirement to compare alternatives in this case may be counterproductive to making efficient safety decisions and deploying corrective action as soon as reasonably practicable.* *When multiple Candidate Corrective Action (CCA) sets are being considered, the optimum solution set can be assessed through qualitative, experience-based judgements and supported by quantitative data where available, based on:* *o The risk mitigation effectiveness of the corrective action considering both interim and final actions* *o Implementation timelines, complexity, and cost* *o Availability of resources (shop capacity, material availability, personnel availability)*	4.1	7
2	Within MSAD Order 8110.107B Chapter 2 Section 15.c - Evaluate Airworthiness Directive (AD) CCAs, additional information is to be included immediately after Step 2 as follows: *(3) In some cases, the corrective action for an issue may be simple and obvious based on established industry experience. Any requirement to compare alternatives in this case may be counterproductive to making efficient safety decisions and deploying corrective action as soon as reasonably practicable.* *(4) When multiple Candidate Corrective Action (CCA) sets are being considered, the optimum solution set can be assessed through evaluation of risk mitigation effectiveness, timeliness/complexity, and impact on resources. Ranking, achieved with qualitative, experienced based judgements and supported by quantitative data where available, should be based on:* *o The risk mitigation effectiveness of the corrective action considering both interim and final actions* *o Implementation timelines, complexity, and cost*	4.1	8

	o Availability of resources (shop capacity, material availability, personnel availability)		
3	This committee recommends the FAA task an industry group to publish and maintain a COS Agreement Guide. That industry body should utilize the information in Appendix C as the basis for publishing the COS agreement guidance document. This guidance will provide the information the committee identified as the basis for a successful COS agreement. This product will serve to inculcate COS agreements into the relationship between FAA and the organizations they oversee.	4.2	10
4	Develop and maintain an FAA database which contains an accessible inventory of common and meaningful input parameters for safety risk analyses. For example, collecting frequently used operational factors, such as the occurrence rate of low altitude go-arounds, or obstacle limited take-offs, would provide useful source data for developing probabilities for safety issues vulnerable in these critical flight points. The FAA should utilize an industry group forum, such as done with the Continued Airworthiness Assessment Methodologies (CAAM) Committee for propulsion system hazards to aircraft, to identify relevant parameters (hazardous conditions, conditional probabilities, failure rate magnitudes, operational factors, etc.).	4.3	11
5	The FAA should develop a consolidated database with information on aircraft and fleet utilization data that can be accessible by industry, which takes into consideration of proprietary disclosure of operating usages (e.g., summarized by aircraft model/fleet rather than by operator). The FAA and industry access can help align on safety risk assessment assumptions which is important to achieve consistent risk assessment results. The FAA should use an industry group forum to help select and maintain pertinent parameters for the database. The industry group forum can help monitor to identify trends that would drive updates to the database.	4.3	11
6	The committee recommends the FAA develop and maintain a harmonized standard for initial reporting procedures for DAH. The standard should outline a preferred format, medium, and with a method approved by the Administrator. A European Union Aviation Safety Agency (EASA) reporting tool is an existing process that can be used as an example for FAA consideration. The interface should accommodate multiple DAH capabilities, such as the ability to either have input from DAH or capability for FAA to retrieve information from DAH systems.	4.3	16
7	Recommend the FAA revise its policies to include sharing information. Where reports external to the DAH are reported to the FAA and for items which manufacturers have a vested interest in (e.g., products built by the DAH), the FAA will push applicable reports to the DAH to increase visibility of issues that may affect their product	4.3	12

	and with sufficient information to take action. The intent is not to provide duplicate data back to the DAH. Applicable instances include: - Occurrences/Events that directly involve a DAH's product (within applicable investigation NTSB protocols and beneficial for COS) - Submittal of a Service Difficulty Report from Part 91, 121, 135, and 145 operators - Submittal of Voluntary Disclosure Reports from Part 121, 135, and 145 operators (With express permission of operators, deidentified, with non-pertinent parts redacted)		
8	It is recommended that the FAA develop, within their safety issue tracking system (ASPIRE), a feedback mechanism to DAH's concerning FAA risk assessments, safety decisions, and AD creation status. As the DAH is exercising its COS process, the COS agreement should allow transparency on the data being evaluated, assessments done on that data, decisions made based on the assessment and actions taken. It is recommended that the FAA develop processes to provide similar information flow back to the DAH on its decision-making processes, closure status of issues, and, within ex-parte protocol, status of AD creation and implementation timing, triggered by status/phase changes within COS decisions or AD publication dates.	4.3	12
9	This committee reviewed the FAA proposal and compiled feedback into Table 2. Committee feedback is categorized into either observations or recommendations with the following definitions: • Observation – Committee members noted relevant vantage points which may differ from the FAA Draft Response to NASEM Recommendation 6. The committee requests the FAA to consider this information during revisions of associated guidance material. • Recommendation – committee members advocated for specific changes to the FAA Draft Response to NASEM Recommendation 6. The committee urges the FAA to incorporate the identified changes. Note: For any statements not explicitly identified within the table, the committee agreed with the FAA proposal.	4.4	14
10	It is recommended the FAA include a step within its review process, prior to CARB, for a peer review beyond the FAA organization responsible for performing the TARAM. This committee suggests that additional peer review include at least a representative of the Design Approval Holder (DAH) of the product or system being assessed, if possible. Any feedback from this review not incorporated into the risk analysis should be noted in the final assessment provided to the CARB.	4.5	18

	The obligation for a DAH to support this peer review should be included within any COS Agreement. Within the review, the DAH should function as a technical advisor for the product and/or system being assessed and provide any data required to help refine the analysis as needed.		
11	The committee recognizes that there is currently no single standardized risk assessment methodology in the industry. FAA AC 39-8, FAA TARAM, and EASA AMC & GM 21A.3B are some examples of risk standards currently used between a DAH and the FAA. To improve consistency in flight safety standards, this committee recommends that the FAA continue to work towards a harmonized acceptable risk standard for use across the industry.	4.6	19

Appendix G: Acronyms

AC	Advisory Circular
AEH	Airborne Electronic Hardware
AD	Airworthiness Directive
AIR	Aircraft Certification Service
AOG	Aircraft on Ground
ARC	Aviation Rulemaking Committee
ASE	Aviation Safety Engineering
ASPIRE	Analyze Safety Performance Insight Results Environment
CAA	Civil Aviation Authority
CAAM	Continued Airworthiness Assessment Methodologies
CARB	Corrective Action Review Board
CCA	Candidate Corrective Actions
CFR	Code of Federal Regulations
COS	Continued Operational Safety
CP	Conditional Probability
DAH	Design Approval Holder
DAL	Design Assurance Level
EASA	European Union Aviation Safety Agency
F	Failure Rates
FAA	Federal Aviation Administration
FDAL	Functional Design Assurance Level
FHA	Functional Hazard Assessment
FMD	Failure, Malfunction, or Defect
FTA	Fault Tree Analysis
HCL	Hybrid Causal Logic
ICA	Instructions for Continued Airworthiness
IDAL	Item Design Assurance Level

IIC	Investigator in Charge
ICAO	International Civil Aviation Organization
MOC	Means of Compliance
MSAD	Monitor Safety/Analyze Data
NAS	National Airspace System
NASEM	National Academies of Sciences, Engineering, and Medicine
ODA	Organization Designation Authorization
PMA	Parts Manufacturer Approval
PSP	Partnership for Safety Plan
SAE	Society of Automotive Engineers
SME	Subject Matter Expert
SMS	Safety Management System
SRM	Safety Risk Management
STC	Supplemental Type Certification
SW	Software
TARAM	Transport Airplane Risk Assessment Methodology

Appendix H: Definitions

Candidate Corrective Actions – A set of actions that potentially resolve the safety issue/unsafe condition in the affected fleet. The set may all be implemented or there may be a down selection based on an evaluation of timeliness of implementation, cost, effectiveness, or other considerations.

Continued Airworthiness – The processes that ensure an aircraft remains operable, safe, and complies with applicable regulations.

Continued Airworthiness Assessment Methodologies – Guidance which provides quantitative event probabilities to perform risk assessment and is further defined in AC 39-8.

Continued Operational Safety Agreement – Agreements between a DAH and a Civil Aviation Authority (CAA) that define the process for monitoring and reporting in-service events, evaluating those events for unacceptable risk, and implementing corrective actions in a timely manner to manage risk to acceptable levels.

Design Approval Holder- An organization that develops an aircraft or engine design and shows it meets applicable airworthiness regulations.

Hybrid Causal Logic – A risk modeling approach which combines traditional risk modeling techniques such as event sequence diagrams and fault trees and combines them with Bayesian belief networks to model non-deterministic influences, such as human and organizational influences. (Groth, et al)

Partnership for Safety Plan – Agreement between the DAH and the FAA that defines the working relationship and communication between the two parties. PSPs vary in scope but can include guidance for obtaining and maintaining certification, continued airworthiness, auditing, and training.

Potential unsafe condition/potential safety issue – Events that meet the reporting criteria under the COS agreement, and which may constitute a safety concern, but require further evaluation to make that determination.

Safety Management System– SMS is the formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk. (faa.gov)

Transport Airplane Risk Assessment Methodology – The risk management process used by the FAA and some DAH for calculating a numerical value for risk associated with a transport airplane fleet, which is used to make safe/unsafe determinations.

Unsafe Condition - a condition which, if not corrected, is reasonably expected to result in one or more serious injuries. [AC 39-8]

Appendix I: References

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Appendix J: COS Agreement ARC Member Concurrence

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Seth Bird
Voting Member Organization	Boeing

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Seth Bird Date: September 27, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Tim Yee Lee
Voting Member Organization	Bombardier Canada

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Tim Yee Lee Date: September 25, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Fabien Bourmaud
Voting Member Organization	ATR Aircraft

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Date: September 27, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Doug Ritchie
Voting Member Organization	Gulfstream Aerospace Corporation

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Doug Ritchie Date: September 28, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Philip McKee
Voting Member Organization	Gulfstream Aerospace Corporation

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: *Philip McKee* Date: September 29, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	FELIPE EUDES PONTES FERNANDEZ
Voting Member Organization	EMBRAER

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

DocuSigned by:

Voting Member Signature: Date: SEPT 25, 2024

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2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date: SEPT 25, 2024

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date: SEPT 25, 2024

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Guilherme Arioli Fernandes
Voting Member Organization	Embraer

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Guilherme A. Fernandes Date: September 27, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Julie Elpers
Voting Member Organization	GE Aerospace

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Julie A Elpers Date: 9/25/24

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	Robert Ramey
Voting Member Organization	Textron Aviation

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Robert L. Ramey Date: September 30, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

**Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence**

Voting Member Name	Fabienne SAURON
Voting Member Organization	Airbus SAS

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: Fabienne Sauron Date: September 26, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date:

Transport Category Airplane Continued Operational Safety Agreements
Aviation Rulemaking Committee (ARC)
Recommendation Report Statement of Concurrence / Non-Concurrence

Voting Member Name	David McDermott
Voting Member Organization	Pratt & Whitney

As a voting member and full participant of the Transport Category Airplane Continued Operational Safety Agreements ARC, I hereby acknowledge that I have reviewed the Final Report and recommendations and make the following statement (*choose the applicable option*):

1. Concur with the Final Report as written.

Voting Member Signature: David P. McDermott   Date: September 27, 2024

2. Concur with Comment or Exception(s):

Provide comment or exception in the text box above or submit a separate paper on company letterhead if additional space is required. Separate papers may not exceed 2 pages in length.

Voting Member Signature: Date:

3. Non-Concur. Letter of Dissent must be provided. (*Letter of Dissent must be on company letterhead and may not exceed 2 pages in length.*)

Voting Member Signature: Date: