U.S. DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION



National Policy

ORDER 8110.107B

Effective Date: 10/13/2023

SUBJ: 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.

In addition, this order discusses the use of the companion MSAD information technology (IT) tool designed to support these procedures and the minimum requirements needed for use of alternative IT tools.

In this revision, the FAA incorporates requirements from the Aircraft Certification, Safety, and Accountability Act (ACSAA) of 2020 and the Cybersecurity Information Sharing Act (CISA) of 2015, as well as recommended changes from the National Academies of Sciences, Engineering, and Medicine (NASEM).

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Chapter 1. General Information

1. Purpose of this Order. This order explains how to use the MSAD process and companion MSAD IT tool to analyze continued operational safety (COS) data and monitor safety in aircraft fleets throughout their life cycle.

2. Audience. All FAA AIR staff and Flight Standards Service (FS) staff responsible for monitoring and addressing aircraft safety risks.

3. Where to Find This Order. You can find this order in the Dynamic Regulatory System (DRS) at <u>https://drs.faa.gov/browse</u> and on the FAA website.

4. What This Order Cancels. This order cancels FAA Order 8110.107A, *Monitor Safety/Analyze Data*, dated October 1, 2012.

5. Explanation of Policy Changes. This revision includes the following changes:

a. Updates information based on ACSAA/National Academy of Sciences, Engineering and Medicine recommendations.

b. Adds sensitive security items and cybersecurity information.

c. Adds instructions to send TARAM information to Congress for certain fatal transport airplane accidents under Section 130(c) of the FAA ACSAA.

d. Aligns terminology with higher-level FAA Safety Risk Management (SRM) orders, such as Order 8040.4, *Safety Risk Management Policy*.

- e. Adds AIR organizational changes.
- **f.** Incorporates deviations related to 8110.107A.

6. Identifying Requirements in This Order. In this order, the use of the word "must" means a required or mandatory action(s) or step(s). The use of the word "will" does not mean a requirement. If you do not see the word "must" in a sentence, then the authors of this document did not intend it to be a requirement; there are no inferred requirements. When using this order, if you cannot meet a requirement in this order for any reason, you must contact the Organization and System Policy Branch (AIR-630) to request a deviation from the requirement before making any local interpretations or workarounds. A deviation typically drives improvements to future revisions of this order.

Chapter 2. MSAD Process

1. MSAD Process within SMS. The MSAD process addresses how AIR fulfills its part of the FAA's State Safety Program (SSP) under Annex 19 issued by the International Civil Aviation Organization (ICAO). The FAA established the following orders directing its personnel to implement SMS policy and requirements:

FAA-level	Order 8000.369, Safety Management System.	
	• Order 8040.4, Safety Risk Management Policy.	
AVS-level	• Order VS 8000.367, AVS Safety Management System (AVSSMS) Requirements.	
	• Order VS 8000.370, Aviation Safety (AVS) Safety Policy.	
	• Order 8000.377, Flight Standards Safety Management System (FSSMS) Requirements.	
Service-level	• Order 8000.368, Flight Standards Service Oversight.	
	• Order 8110.107, Monitor Safety/Analyze Data.	

a. <u>Purpose of the MSAD Process</u>. This order (8110.107) addresses AIR's SMS process through the interrelated Safety Assurance (SA) and SRM functions, as shown in figure 1 "SA and SRM processes (from FAA Order 8040.4)". In basic terms, "Monitor Safety" corresponds to SA and "Analyze Data" corresponds to SRM. The MSAD process filters, reviews, analyzes, and trends aviation safety data to help the FAA identify hazards in the in-service aircraft fleets and mitigate safety risks across the fleet. This process also identifies other causes of hazards that cannot be addressed by aircraft fleet mitigations, such as product or part design or manufacturing causes. Hazards that originate outside of AVS, should be worked with the FAA SMS Committee, which helps coordinate hazards across lines of business (LOB) or staff offices.

b. <u>SRM within AVS</u>. For safety investigations that remain within AVS, FAA Order 8040.4 permits AIR to use the MSAD process instead of nominating an issue for review by a cross LOB team through Hazard Identification, Risk Management, and Tracking (HIRMT). This includes using AIR's risk assessment methodologies, such as Transport Airplane Risk Assessment Methodology (TARAM) and Advisory Circular (AC) 39-8.

Note: Information regarding AIR's risk assessment methodologies, including FAA policy memo PS-ANM-25-05, *Risk Assessment Methodology for Transport Category Airplanes* (which defines TARAM) and AC 39-8, *Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes*, can be found in appendix C of this order.

c. <u>Sensitive Security Information (SSI) Investigations</u>. SSI investigations require a dedicated and more restricted process. This process parallels more routine SRM investigations, but limits the personnel involved and restricts access to data.

d. <u>Cybersecurity Issues</u>. Intentional unauthorized electronic interaction (IUEI) is a circumstance or event with the potential to affect the aircraft due to human action resulting from unauthorized access, use, disclosure, denial, disruption, modification, or destruction of information and/or aircraft system interfaces. Note that this includes malware and the effects of external systems on aircraft systems but does not include physical attacks or electromagnetic jamming. Safety investigations related to IUEI cybersecurity issues, or safety and security investigations (SaSI) also require similar handling as SSI, discussed in paragraph c above.

Note: For additional information, FAA personnel may contact the Cybersecurity Section, AIR-628.

e. <u>MSAD IT Tool</u>. Many of the activities within the MSAD process rely on IT tools. Where this document states you must complete an action in the MSAD IT tool (for example, document information or attach data), you must do that action, but you may use an alternative IT tool instead of the MSAD IT tool. The MSAD IT tool is the standard (default) IT tool recommended, but not required. This order discusses how the MSAD IT tool works and how to use it. It does not discuss alternative IT tools. If any AIR certification branch chooses to use something other than the standard MSAD IT tool, they must meet the minimum requirements for each alternative IT tool (see appendix E).

Note: For the purposes of this order, AIR certification branch refers to any Operational Safety, COS, certification, or validation branch in the Integrated Certificate Management Division (AIR-500) or Compliance and Airworthiness Division (AIR-700) that performs COS functions.

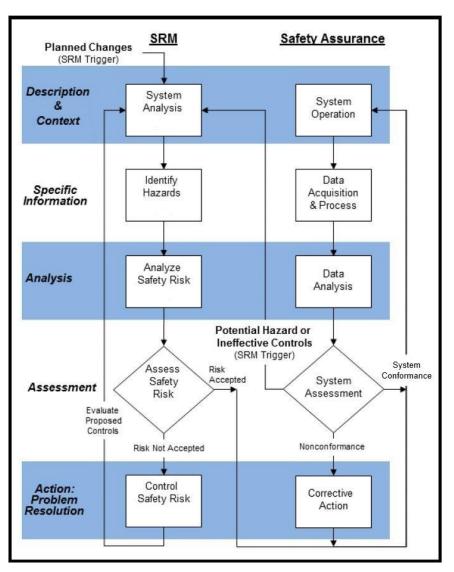


Figure 1. SA and SRM Processes (from FAA Order 8040.4)

2. Range of the MSAD Process. The MSAD process analyzes in-service fleet data to determine mitigations and identify mandatory corrective action(s) for COS issues. The MSAD process covers everything from receiving data to determining mitigation of fleet hazards. It also discusses possible follow-on actions, such as airworthiness directives (AD), special airworthiness information bulletins (SAIB), and others.

Note: If issuing mitigations and corrective actions, such as the rulemaking process, refer to the appropriate order in appendix B.

a. 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 to foster cooperative COS agreements that integrate the DAH's and MSAD's processes in a manner that is 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.

b. The MSAD process may also interface with other AIR and non-AIR FAA processes, as well as industry, to help identify non-fleet-based hazards. For example, ASEs and aviation safety inspectors (ASI) who oversee the DAH might analyze product design, production, operations, and maintenance process data to identify areas of risk within a DAH's product, as well as mitigations that reduce aircraft fleet risks. Also, FS has a process to oversee certificate holders, such as airlines, for hire companies, and repair agencies. It is a recommended practice to share product related risks with FS ASIs through FS's Safety Assurance System (SAS), just as it's important for AIR ASEs to review information coming from SAS and use their data collection tools (DCT) to track mitigations at the operator level. This ensures that data and information is kept flowing between AIR and FS to address these hazards.

Note: For an example of information obtained in DCTs that could be useful to AIR ASEs, refer to FAA Order 8900.1, Volume 10, Chapter 8, Section 1, *Certificate Holder Evaluation Process*. For the range of interfaces between the MSAD process and other FAA processes, see appendix F.

c. SaSI and SSI.

(1) SaSI within AIR would follow the same SA/SRM steps outlined by the MSAD process and involve similar personnel. However, access to investigation details and associated information is restricted compared to routine SRM investigations. Depending on the sensitivity and security of the topic, an investigation could be handled completely outside of the MSAD process. The Cybersecurity Section (AIR-628), would make the determination and it would be an exception.

(2) Safety investigations that relate to national transportation safety or security issues fall within the scope of FAA Order 1600.75, *Protecting Sensitive Unclassified Information* (*SUI*), and are defined as SSI in Title 49, Code of Federal Regulations
(49 CFR) 1520.b.7. SSI is a designation unique to the operating administrations of the Department of Transportation and Department of Homeland Security. It applies to information the FAA obtains or develops while conducting security activities, including research and development activities. Unauthorized disclosure of SSI would:

- Constitute an unwarranted invasion of privacy (including, but not limited to, information contained in any personnel, medical, or similar file);
- Reveal trade secrets or privileged or confidential information obtained from any person; or
- Be detrimental to transportation safety or security.

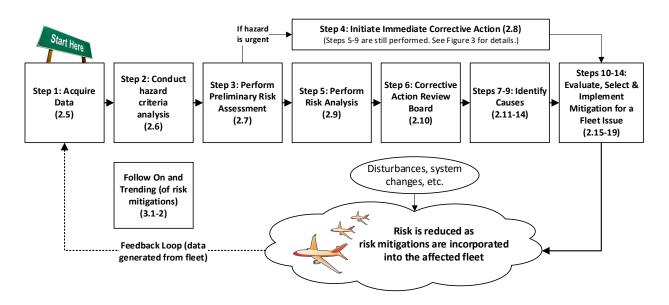
Note: For additional information, FAA personnel may contact AIR-628 as the liaison with the Office of National Security Programs and Incident Response (AXE).

3. MSAD High-Level Overview. The MSAD process provides a data-driven, risk-based approach for SA and SRM that supports aviation products throughout their life cycle. MSAD identifies potential hazards by comparing aviation safety data with product-defined terms known to indicate a hazard, called hazard criteria. An ASE following the MSAD process will perform both a risk and causal analysis of the potential hazard that led to the issue. An AD, SAIB, other mitigation, or recommendations may be initiated at several points within the MSAD process. Event data, hazard information, risk analysis, causal analysis, and mitigation data is stored as a record for future use in accordance with FAA Order 1350.14, *Records Management*.

Note: Figure 2 is a high-level overview of the entire MSAD process. Although the components are displayed sequentially, there may be situations where portions of the process are worked concurrently or out of sequence.

Figure 2. High-Level View of MSAD

Note: The numbers in parenthesis below refer to the chapter and paragraph in this order where the topic is discussed in more detail. For example, 2.5 indicates chapter 2, paragraph 5.



4. MSAD Detailed Process Flow. Figure 3 shows the entire MSAD process, with each step described in the paragraphs noted within the figure.

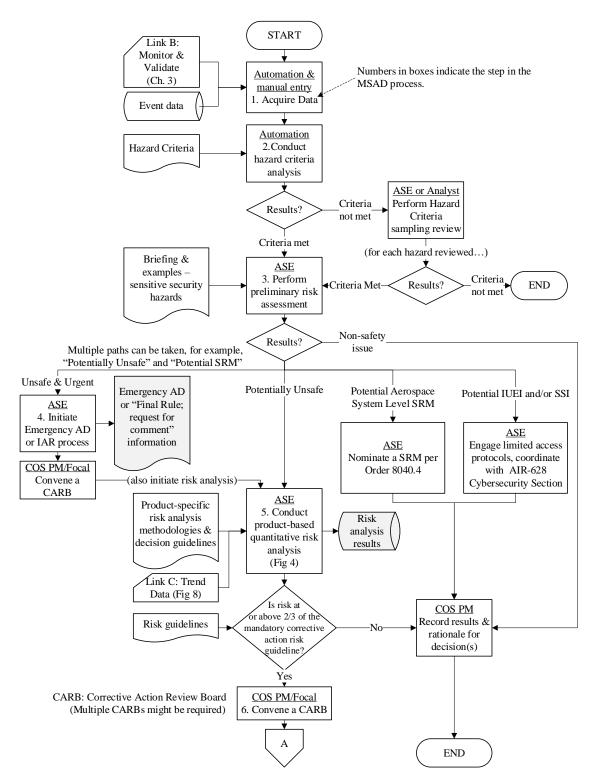


Figure 3. MSAD Process Flow – Page 1

See chapter 3 for details on link C. See figure 4 for details on step 5.

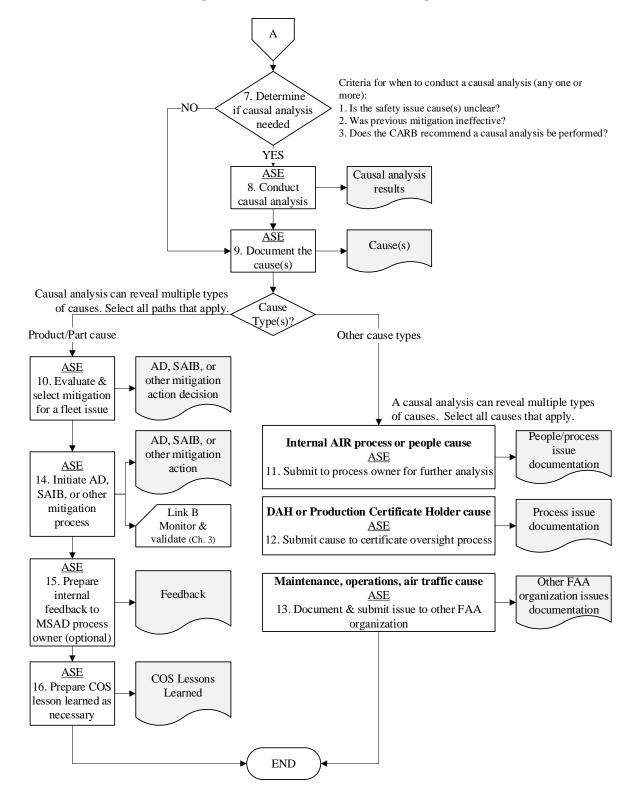


Figure 3. MSAD Process Flow - Page 2

5. Step 1 - Acquire Data.

a. ASEs have many sources of safety data to use for their analyses, including FAA databases focusing on event information. A partial list of data sources, which include failure, malfunction, and defect data, can be found in appendix D. Not all event data needs to be analyzed through the MSAD process; hazard criteria (described in paragraph 6) are used to filter out the events that do not present potential hazards.

Note: Any hazard meeting the definition of a suspected unapproved part, as described in FAA Order 8120.16, *Suspected Unapproved Parts Program*, must be reported per Order 8120.16.

b. The MSAD IT tool pulls data from certain FAA databases and submits those as event records to the responsible AIR certification branch (AIR-520, AIR-750, AIR-760, AIR-770, or AIR-780) based on make and model using an automated batch process. The IT tool also allows ASEs to manually create an event record from any data source. The COS focal may import event data from external sources via the data portal. Personnel from AIR-500, AIR-700, and the System Oversight Division (AIR-800) may also manually enter event records associated with quality escapes. The tool then generates an electronic record of event data that is sent to the appropriate AIR certification branches for review and hazard analysis (see figure 3).

c. The AIR certification branches are responsible for conducting SA and SRM reviews for hazards on products for which they have oversight and coordinating with other FAA offices as applicable (e.g., if multiple products are involved or the product type is not immediately apparent, etc.). After the event data is reviewed and appropriate action is taken, the record must be closed. A record will not show that it is fully "closed" until all AIR certification branches involved have completed their review and taken appropriate action. Sometimes more than one office might need to remedy hazards related to a single event.

6. Step 2 – Hazard Criteria Analysis. Product-specific hazard criteria are used to filter out event data automatically or manually. Filtering reduces the number of events the assigned ASE(s) review(s) for potential hazards during the preliminary risk assessment. Event data that does not meet the hazard criteria is retained and can be used for trending. Within the MSAD IT tool, automatic filtering is based on keyword, key phrase matches, or other data mining techniques of the event data by product-type. For example, a filter can be used to send any event description that contains the word "fire" to the assigned ASE(s). If the assigned ASE(s) determine(s) that the event should not have been filtered, then it should be marked as a "false positive". This assists AIR-630 in further refining the hazard criteria.

Note: The MSAD IT tool will not filter Title 14, Code of Federal Regulations (14 CFR) 21.3 reports or other safety data submitted under negotiated COS agreements since the agreement will typically include hazard criteria specific to the company providing the data.

7. Step 3 - Perform Preliminary Risk Assessment. Preliminary risk assessment is used to triage incoming events to determine how they should be handled based on their type and potential severity using any available data. It is preferred to minimize single point safety

decisions by doing multi-discipline assessments when resources permit. This assessment might be performed by a group of ASEs. If a group assessment is performed, a cognizant senior ASE for the engineering discipline most affected by the event must participate. The senior ASE or group of ASEs must address the questions outlined in table 1. Please keep in mind that more than one action might be required (e.g., a hazard might need immediate action and be considered for FAA SRM). This table may also be referred to at a later point of an investigation, as it might not be apparent that a hazard is, for example, a cross-product or aerospace system level (ASL) issue.

Questions:	Required action:
Does an urgent unsafe condition exist that requires immediate corrective action, such as an emergency AD or immediately	You must immediately assign it to an ASE and put together an emergency Corrective Action Review Board (CARB) to initiate either an emergency AD or IAR (see step 4.). Proceed to step 5 and conduct risk analysis to determine the risk posed by the hazard.
adopted rule (IAR) (issued as a "final rule; request for comment")?	Note: Urgent action requires immediate briefing to management, for communication up to executive management, and to discuss next steps to prevent catastrophic accidents. This typically requires additional actions not covered by the MSAD process.
Does this hazard potentially contain IUEI or SSI?	You must contact AIR-628 if, in your determination, the hazard involves IUEI, as defined in paragraph 1.d or addresses any one of the conditions described in paragraph 2.c(2) in this chapter.
	AIR-628 might determine that the hazard should be handled outside of the MSAD COS process for certain cybersecurity issues. It is recommended that AIR-500 and/or AIR-700, after coordinating with AIR-628, communicate(s) final risk mitigations with other ASEs and ASIs, if it is deemed appropriate and necessary to do so.
	Note: For assistance identifying IUEI cybersecurity issues and SSIs, it is recommended that persons conducting a preliminary risk assessment contact AIR-628.
Is this a potential ASL hazard that requires an FAA SRM investigation per FAA Order 8040.4?	You must contact the Safety Programs Branch (AIR-360), who must in turn work with Safety Management and Research Planning Division (AVP-300) HIRMT Oversight team to enter the hazard information into HIRMT. Also contact your <u>AVSSMS Coordination Group Representative</u> to initiate an FAA SRM assessment.
	Note: It might not be obvious during the initial phases of the investigation.
Is the event a potential hazard requiring more investigation through the MSAD process?	You must assign the hazard to an ASE to proceed with the investigation and risk analysis (see step 5).
Is the event a design-related cross-product hazard?	Identify the cross-product hazard, enter the rationale into the MSAD IT tool, and submit it to AIR-723 and other affected office(s).
Does an FAA AD exist that adequately addresses the hazard?	Note: It might not be obvious during the initial phases of the investigation. You must link the MSAD record item in the MSAD IT tool for the event to the FAA AD and reference it for future management of the issue.
Is the event a hazard of negligible risk?	You must document this determination in the system of record. The event does not move any further in the event evaluation portion of the MSAD process but is retained for trending. Events may be reopened if new information is received that suggest the risk is higher than previously analyzed.
	Note : Prior to closing the MSAD event, it is recommended that you ensure that MSAD events discovered to be false positives are marked, and that the MSAD record in the MSAD IT tool is routed to appropriate offices, as necessary.

Table 1. Preliminary Risk Assessment Questions and Required Actions

8. Step 4 - Initiate Immediate Corrective Action.

a. If a hazard is urgent, you must conduct an analysis, if possible, and brief management or conduct a CARB for a safety and corrective action determination. If so instructed, start either an emergency AD or IAR in accordance with FAA Order 8040.1, *Airworthiness Directives;* FAA Manual FAA-IR-M 8040.1, *Airworthiness Directives Manual*; and any product-specific procedures. This ensures that the risk is mitigated in a timely fashion, without waiting for the remaining MSAD process steps. The assigned ASE can delay the comprehensive risk analysis and causal analysis until after initiating the emergency AD or IAR. Once the emergency AD or IAR is initiated, the assigned ASE must continue analyzing the hazard in the risk analysis step. The COS Program Manager (PM) or the assigned ASE also might determine that an emergency AD or IAR may be necessary later in the MSAD process as new data becomes available.

b. If an AD is likely to be issued and is associated with a transport airplane accident with seating capacity of 30 people or more in which a loss of life occurred, you must send a report of findings and recommendations of the TARAM to AIR-500 or AIR-700 per applicable office procedures. They in turn must send the report to the Program Integration Branch (AIR-320) for congressional notification and copy the Policy and Standards Division (AIR-600). This is to meet requirements of ACSAA, section 130, dated December 27, 2020, as follows:

"REQUIRED NOTICE.—The Administrator shall provide notice to the congressional committees of jurisdiction on the findings and recommendations of a TARAM conducted following a transport airplane accident—

(1) in which a loss of life occurred; and

(2) for which the Administrator determines that the issuance of an airworthiness directive will likely be necessary to correct an unsafe condition associated with the design of the relevant aircraft type."

Note: ACSAA Section 137, section (6), uses the following definition: "The term 'transport airplane' means a transport category airplane designed for operation by an air carrier or foreign air carrier type-certificated with a passenger seating capacity of 30 or more or an all-cargo or combi derivative of such an airplane."

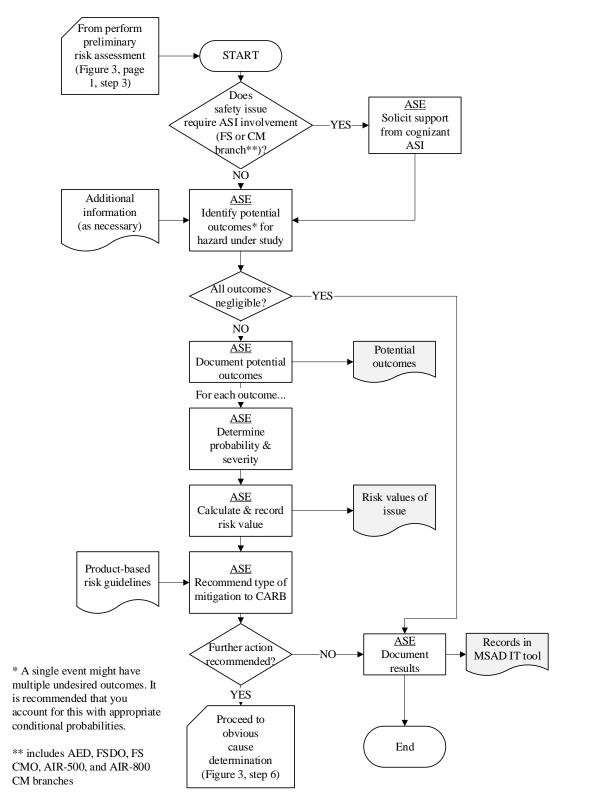


Figure 4. Record Risk Analysis Results Flow Diagram

Risk Value	Definition	Purpose	Mathematical Basis
Total uncorrected fleet risk	Predicted risk expected, over remaining life of affected fleet, if no corrective action is taken.	Provides future risk if no corrective action is taken. Helps determine if an unsafe condition may exist in future. Used to guide decisions for corrective action.	Computed by multiplying the average severity and average per- flight (or flight-hour) probability of occurrence, multiplied by the exposure (flights or flight-hours) remaining in affected fleet life. If known voluntary compliance to an existing service document is supported by data, then you can account for the existing control actions by adjusting the affected fleet numbers. If only a subset of the fleet is subject to the risk, include only that portion in the analysis. Evaluate significant variations between identifiable subsets of the fleet (different models, different usages, operational conditions, etc.) as separate populations for the individual risk.
Uncorrected individual risk	The probability of a given outcome per unit of exposure (per operation, flight hour, opportunity, etc.) because of a given hazard.	Provides future risk if no corrective action is taken. Needed for cases of low fleet exposure that result in the total uncorrected fleet risk, as defined above, to be acceptable while the risk to an individual aircraft or person is unacceptable. Helps determine if an unsafe condition might exist in future. Used to guide the decision for corrective action.	Typically based on averages that apply to the fleet. However, there might be circumstances where you can calculate individual risk including risk values for special conditions and combinations of conditions, or for subsets of the fleet, for example by model or usage. If only a subset of the fleet is subject to the risk, include only that portion in the analysis. Evaluate significant variations between identifiable subsets of the fleet (different models, different usages, operational conditions, etc.) as separate populations for the individual risk.
Time until control program risk guideline is reached	Amount of time from when the need for corrective action is determined by the CARB to the time when the fleet would exceed the control program risk guideline if no action was taken.	Provides information to assist in risk management planning, i.e., how much time is available to determine root cause, develop service information, coordinate, and process corrective action, and incorporate the corrective action in the fleet while staying within the risk guideline. See figure 5.	The period when risk accumulates in the fleet to a value that equals the control program risk guideline (Note: Control program risk guideline is discussed further in paragraph 15.b).

Table 2. Risk Value Definition, Purpose, and Mathematical Basis

9. Step 5 - Perform Risk Analysis. AIR-630 has particular risk measures and acceptable risk guidelines based on the specific product type. MSAD risk analysis objectively characterizes hazards for probability and severity to determine the risk posed by each hazard. Risk analysis combined with the risk guidelines for ADs assists the CARB in determining if mandatory corrective action is warranted. If you are an assigned ASE, you are responsible for conducting risk analysis. You must record the risk values described in table 2 and compare them to productdefined risk guidelines, as applicable, for issuing ADs or other mandatory corrective actions for the product type. In calculating these risk values, consider if the hazard is associated with an appliance, technical standard order (TSO) article or standard part. If so, the hazard could be associated with multiple product types. The assigned ASE must obtain information from the manufacturer to determine product applicability to support the risk assessment. In certain cases where the safety effect is different depending on the installation or when the appliance, TSO article, or standard part is installed on multiple product types that use different product-defined risk guidelines, the assigned ASE must re-assign the MSAD records to the cognizant type certificate (TC) or supplemental type certificate (STC) oversight office(s) to perform risk analysis and subsequent follow-on actions.

a. <u>Identify ASI Support</u>. If you need manufacturing, maintenance, or operations ASI support, it is recommended you contact an ASI responsible for the product and ask for information to support the risk analysis.

(1) The manufacturing ASIs come from a certificate management (CM) section in AIR-800 or AIR-500. Manufacturing ASIs provide vital assistance as SMEs of the manufacturing and quality control processes. AIR-800 also has aircraft certification specialists (ACS) that provide collaborative assistance and act as a liaison between offices for support.

(2) When FS ASI help is needed, ASEs must either obtain the information through the cognizant aircraft evaluation division (AED) as the primary interface with other FS ASIs in the field (Flight Standards District Office (FSDO) or FS Certificate Management Office (CMO)) or at least notify the AED that information is requested directly from the field. FS ASIs might come from an AED, FSDO, and/or FS CMO.

(3) The AED assists and coordinates with manufacturers, operators, and other FS offices and AIR certification branches on product-specific COS issues. Information regarding the roles different FS groups have for COS oversight can be found in appendix G, including getting help from the appropriate Air Carrier Safety Assurance (ACSA) or General Aviation Safety Assurance (GASA) principal inspector (PI), Safety Analysis Program Office (SAPO) that standardizes analysis techniques which is responsible for providing analytical support through the SAS program, and Regulatory Support Division (AFS-600).

b. <u>Identify Potential Outcomes</u>. You must identify and document all important potential outcomes for the hazard you are studying for further risk analysis. If you determine that the risk of an outcome is obviously negligible, there is no need to calculate it.

c. <u>General Risk Calculation Guidance</u>. To calculate the risk values of the hazard's effects, you must:

(1) Evaluate the risk based on the applicable methods and guidance for the particular product type listed in appendix C;

(2) Document the assumptions, methods, and other supporting information describing how the probability and severity were determined;

(3) Work with AIR-630 to gain conditional probability data so that they can compile a risk analysis "library data" for the applicable product (e.g., hazard ratios and injury ratios).

d. <u>Calculate the Risk Value of Each Outcome</u>. You must use the product-specific risk analysis method identified in appendix C (units convertible to fatal accidents) to calculate the quantitative probability, severity, and risk value for each important outcome. You must calculate and record the following risk values:

- (1) Total uncorrected fleet risk;
- (2) Uncorrected individual risk (per flight or per flight hour); and
- (3) Time until control program risk guideline is reached.

Note: An investigation might determine that there is negligible risk, meaning the risk is not credible and that calculation of the risk is not required. Recording of the risk values are not required if both the total uncorrected fleet risk and the uncorrected individual risk are below 2/3s of the product-specific risk guidelines. Detailed descriptions of risk values are in table 2.

e. <u>Attach document to the MSAD Record</u>. You must attach the documents to the MSAD record containing the event information that support probabilities, severities, and risk values for total uncorrected fleet risk and individual risk, per flight or flight hour.

f. Some AIR certification branches have negotiated agreements with certain DAHs to perform risk analysis on behalf of the FAA. In those cases, you must review the DAH risk analysis per the negotiated agreement to verify that their risk analysis meets the objectives of this section. The depth and scope of each review is left to the appropriate AIR certification branch to decide.

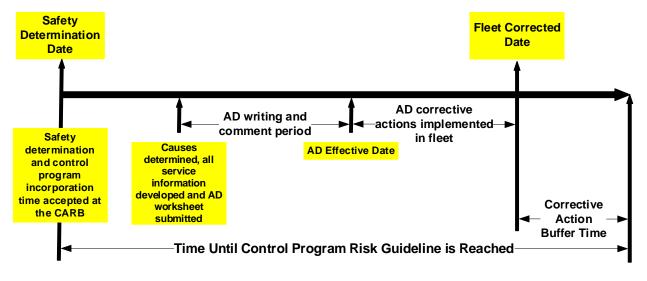


Figure 5. Corrective Action Timeline (Notional)

g. <u>Requirements for Control Program Risk Guideline</u>. You must calculate the time until the control program risk guideline is reached if either the total uncorrected fleet risk or the uncorrected individual risk is above the product-specific risk guidelines.

h. <u>Determine Necessary Action</u>. To assist the CARB in determining the type and/or need for mitigation (mandatory, non-mandatory, or no action), you must compare the risk values calculated for the hazard against the product risk guideline(s) for ADs or other mandatory corrective action. The minimum requirement is to provide an uncorrected individual risk value. See figure 6, Risk Guideline Diagram.

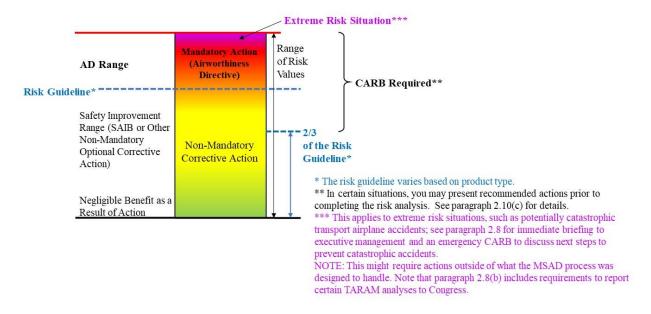


Figure 6. Risk Guideline Diagram

10. Step 6 - Corrective Action Review Board. The goal of the CARB is to improve aviation safety through better decision-making techniques achieved by:

- Reducing the number of single thread safety decisions.
- Composing the CARB of high-expertise, cross-functional, or inter-disciplinary membership.
- Fostering an environment to allow others to raise concerns and contribute knowledge about a hazard and proposed mitigation or corrective action plan.
- Facilitating real-time, open exchange of hazards across the product lifecycle among key disciplines of design, production, and operation oversight staff.
- Providing a regular forum for the review of the risk and causal analyses, as well as proposed mitigations.
- Expanding knowledge and experience of the trends and improvements in aviation risk analysis.

Note: CARB is where the appropriate decision makers assess the analysis and make informed decisions and determine the level of safety risk to accept and mitigate. CARBs are designed to precede the AD process, not replace it. CARB actions ensure a complete data package is assembled for the AD process.

a. <u>CARB Applicability</u>. The COS program manager (PM) or COS focal must bring forward the following situations to be reviewed by the CARB:

(1) Hazards with a calculated risk above two-thirds of the risk guidelines for AD or other mandatory corrective action.

(2) Recommendations for ADs or other mandatory corrective actions regardless of risk.

(3) Unilateral (FAA only) corrective action considered on foreign products and technical no action required (NAR) decisions involving mandatory continuing airworthiness information (MCAI). See Chapter 4 for further information on handling MCAIs within the MSAD process.

b. <u>Presenting recommended actions to the CARB for a safety and/or mitigation decision</u>. The assigned ASE must present to the CARB the recommended action and substantiating data. The presentation must include, at a minimum a:

(1) Description of the issue;

(2) Risk analysis efforts;

(3) Causal analysis;

(4) List of previous similar incidents (such as from the Accident Lessons Learned library), if any; and

(5) Prior risk reduction resulting from previous corrective actions, if applicable.

c. In some cases, with COS PM/focal concurrence, you may present the recommended action prior to completing all the analysis. For example, if there are challenges quantifying the risk, or it is a high-visibility hazard that needs immediate CARB awareness or attention.

d. <u>CARB evaluation</u>. The CARB will evaluate the data for completeness and coherence of the conclusion; and will provide concurrence with the recommended action, select a different course of action, or defer the issue (generally to allow the ASE time to obtain more information). Some cases may warrant several CARB sessions for further assistance in developing the assessment for final mitigation and/or corrective action. If possible, reach consensus on a safety decision. In cases where consensus cannot be reached, the AIR certification branch manager or responsible office manager has final decision authority.

e. <u>CARB Participants</u>. Each AIR certification branch manager is responsible for selecting and assigning representatives to CARBs, and for designating alternates for unavailable representatives.

(1) Mandatory Participants. The AIR certification branch must maintain a list of current representatives to select CARB participants from; and coordinate with flight test, CM branch, and AED management to facilitate representation (see table 3).

Role	Responsibility
AIR certification branch manager, Operational	Sets CARB agenda and leads CARB.
Safety Branch Manager, or International	
Validation Branch Manager.	
CARB co-leads	Ensures minutes are taken, (which must document
	CARB attendees, issues presented, and decisions
	made), records all decisions, and tracks any
	associated actions at the CARB. Administrative
	actions can be delegated to other support
	personnel.
ASE or pilot assigned and presenting the hazard.	Brings all relevant information to the CARB,
	including developing the main presentation.
At least three other ASEs, one with experience in	SMEs for the analyses or technical subjects.
the hazard and two others that support CARB	
technical discipline diversity. This can be satisfied	
using program or branch managers with the	
appropriate experience.	
Representation from flight test, AED, and CM	SMEs able to bring perspective from the
branch.	production, maintenance, avionics, or operation of
	the aircraft.

Table 3. CARB Participants Roles and Responsibilities

(2) Conditional participants:

- AIR-600 staff might participate on a case-by-case basis.
- Other optional FAA representatives (such as chief scientific and technical advisors (CSTAs) related to the discipline associated with the hazard, etc.) might attend on a case-by-case basis to provide a comprehensive view of the hazard and mitigation.
- AIR-360 as the liaison to AVP might attend in cases where there is AVP involvement or a related Accident Lessons Learned module.

f. <u>CARB Participant Training</u>. COS program managers, other COS specialists, management, and engineers within AIR, and the CARB participants must receive the appropriate level of training. Please refer to the AIR-700 On the Job Training Program through AIR-740 for further details.

g. <u>Other Factors in the CARB Decision</u>. In rare situations, the ASE or FAA management may make recommendations not consistent with risk guidelines for ADs or other mandatory corrective actions. The CARB decides whether to accept or reject these recommendations, and that decision will be documented in the meeting minutes. The risk analysis is intended to be an

objective input into the CARB decision. To maintain the objectivity of risk analyses, do not use unrelated factors as inputs to risk analyses.

h. <u>Documenting CARB Decision</u>. The CARB is accountable for its safety decisions. The CARB co-leads must confirm that the meeting minutes are available within AIR and contain the following information:

- Issues presented;
- CARB decision; and
- CARB attendees.

Note: To ensure integrity in the assessment process, it is recommended that those responsible for presenting to the CARB, including producing the risk analysis, be separate from those making the CARB decision.

11. Step 7 - Determine if Causal Analysis is Required.

The MSAD process identifies and mitigates product risk from hazards (see figure 3). The goal is to determine the cause(s) for the hazard. A structured causal analysis typically creates a diagram that shows the interconnection of causes and effects. The structured approach supports your assumptions and conclusions during the process and guides the documentation of the cause(s), effect(s), and the causal analysis report. You must document the causes, which is an important step to support future trending activity and quick identification of systemic problems when causes reoccur.

a. You must conduct a structured causal analysis when any of the following conditions are met:

(1) For high-profile hazards (such as high public interest or fatalities);

- (2) If directed by the CARB;
- (3) Previous mitigation(s) were not effective;

(4) For complex systems, such as hazards involving multiple systems or software. A complex hazard might include cases where more than one potential cause is identified from one or more certification branches; or

(5) The causes are unclear.

b. If none of the conditions in paragraph 11(a) applies, a structured causal analysis is not required for issues with obvious causes and clearly identifiable fleet solution(s). Fleet solutions include inspections, re-designs, limitations, and/or other product/part mitigations.

12. Step 8 - Perform Causal Analysis. A structured causal analysis typically creates a diagram that shows the interconnection of causes and effects. When you perform a structured causal

analysis, you trace the chain of events, identify contributing factors, and develop a list of candidate solutions. The structured approach supports your assumptions and conclusions during the process and guides the documentation of the cause(s), effect(s), and the causal analysis report.

a. Focus on identifying the part or product causes that can be addressed using fleet risk mitigations (AD, SAIB, or other optional mitigation).

b. You might also identify other causes that contributed to the event. These "contributing factors" might include design, manufacturing, operations, and maintenance failures and might have surfaced from "people" and/or "process" issues in a manufacturer, designer, or operator's organization. They might also include FAA process shortfalls. See paragraph 14.

c. Some certification branches have negotiated agreements with certain DAHs such that the DAH performs the causal analysis on behalf of the FAA. In those cases, you must review the causal analysis per the negotiated agreement to verify that it meets the objectives of this section.

13. Step 9 - Document the Cause(s). Documenting all causes is an important step to support future trending activity and quick identification of systemic problems when causes reoccur. Whether the causes were obvious based on engineering expertise and judgement or were determined through a structured causal analysis. The assigned ASE must document the causes in the MSAD IT tool using the causal taxonomy, including at least a:

- **a.** Problem statement (might be similar to the defined hazard);
- **b.** Product or part causes;
- c. People or process causes, also called "contributing factors," if applicable; and
- **d.** Causal analysis report (for structured causal analysis only).

14. Identifying Contributing Factors.

a. Causal analyses might identify contributing factors that can influence a part- or systemlevel failure. Since contributing factors are not always addressed by ADs or SAIBs, you, the assigned ASE, must submit these factors to the appropriate organization for analysis and possible action.

b. If you identify that an operational, maintenance, or manufacturing process is contributing to a hazard, you must send your analysis results and hazard information to the appropriate organization for review and action (e.g., AED, CM branch, etc.). It is recommended that you follow-up to ensure that the organization understands and has sufficient information to address the hazard.

c. If you identify a shortfall in the FAA's process, you must submit the causes to the appropriate organization for their review and mitigation.

15. Step 10 - Evaluate and Select Mitigation for a Fleet Issue. Based on the cause(s) identified and documented in steps 7 thru 9, you must identify candidate corrective action(s) and select the appropriate one(s) to reduce the fleet risk presented by the hazard.

a. <u>Identify Candidate Corrective Actions (CCAs)</u>. CCAs can range from initial mitigating to extensive final and terminating. The assigned ASE must evaluate each CCA for its appropriateness and timeliness to mitigate the safety risk. Corrective actions typically are developed by DAHs, who submit these to the FAA. The FAA has the option of accepting, rejecting, or developing alternative corrective action(s). When a DAH does not submit corrective action(s) for a concern, the FAA must develop necessary corrective action(s) to mitigate the risk to an acceptable level. Examples of CCAs include, but are not limited to:

- Inspections;
- Part repairs or replacements;
- Modification/kit installations;
- Limitations;
- Software updates;
- Rework; and
- Process or procedure changes.
- b. Determine the Corrective Action Vehicle.

(1) The assigned ASE must calculate CCA control program fleet and individual risk as defined in table 4. If the CARB decides not to follow the recommended corrective action, the decision and rationale must be documented in the CARB minutes. The assigned ASE must attach supporting documentation to the MSAD record in the MSAD IT tool.

(2) If new information becomes available late in the control program development that shows that the risk was much greater than first calculated, or if there was a significant delay in implementing the control program due to some unforeseen mistake/problem, you may find that the control program will now exceed the risk guidelines. In this case, interim action should be considered as part of the mitigation plan. Care should be taken to avoid getting into these situations. The AIR certification branch manager must make their division director aware that we are temporarily accepting this increased risk and/or extended exposure.

c. <u>Evaluate AD CCAs.</u> Use the control program fleet risk and control program individual risk guidelines (CPRGs) to evaluate AD CCAs. This applies to AD CCAs only. Skip this task if you are proposing non-mandatory mitigation. You must ensure that the CCA (or combination of mitigations) calculated control program risk is at or below both the fleet and individual CPRG.

(1) During this analysis, consider combined actions of a "bundle" of CCAs, for example interim action such as a repetitive inspection followed by a final action, such as a part replacement. Evaluate the mitigation plan for the total effect on the risk.

(2) If the risk of a CCA exceeds either fleet or individual CPRG, consider eliminating or revising the candidate by either accelerating the implementation (for example, replacing at 'B' check rather than at 'C' check, or "inspect at 100-hr vs. 200-hr intervals") and/or adding or modifying mitigations. Use the product specific CPRG analysis method to determine the action's acceptability and timing by comparing it to the control program fleet and CPIRGS.

Note: When considering compliance times for mandatory corrective action, do not unnecessarily extend the compliance time even if doing so would keep the control program fleet or control program individual risk below the CPRG. Work within existing maintenance schedules, where possible, and act as soon as reasonably practical.

Risk Value	Definition	Purpose	Mathematical Basis
Control program fleet risk	Risk within affected fleet while corrective action is taken (plus any residual risk not remedied by corrective action).	Helps ASEs evaluate candidate corrective actions against a maximum allowable risk value with respect to effectiveness and timeliness.	Computed by multiplying the average severity and average per flight or per flight-hour probability of the occurrence, multiplied by the control program exposure (predicted number of flights or flight-hours for the fleet during the time taken to accomplish the corrective actions). If only a subset of the fleet is subject to the risk (different models, different usages, operational conditions, etc.), include only that portion in the analysis if possible; otherwise include a factor representing the likelihood that a given airplane is in the affected subset. The start of the control program is when CARB determines there is an unsafe condition. The risk typically includes the exposure since that time—it includes corrective action preparation time and AD flow time, as applicable. If actual corrective action incorporation rate is unknown, estimate control program duration (flights or flight- hours) by using estimated time for AD issuance plus half the AD compliance
Control program individual risk	The probability of a given outcome per unit of exposure (per operation, flight hour, opportunity, etc.) because of a given hazard during the control program.	Needed for cases of low fleet exposure that result in the control program fleet risk, as defined above, to be acceptable while the risk to an individual aircraft or person during the control program is unacceptable. Helps ASEs evaluate candidate corrective actions against a maximum allowable risk value with respect to effectiveness and timeliness.	time. Typically based on averages that apply to the fleet during the control program. However, there might be circumstances where you can calculate individual risk including risk values for special conditions and combinations of conditions, or for subsets of the fleet, for example by model or usage. If only a subset of the fleet is subject to the risk, include only that portion in the analysis. Evaluate significant variations between identifiable subsets of the fleet (different models, different usages, operational conditions, etc.) as separate populations for the individual risk.

Table 4. Control Program Risk Value Definition, Purpose, and Mathematical Basis

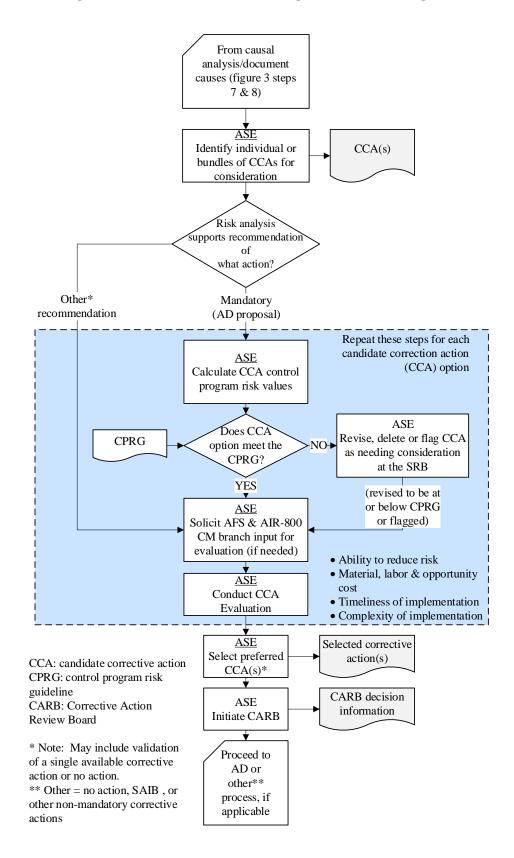


Figure 7. Evaluate and Select Mitigation(s) Flow Diagram

d. <u>CCA Evaluation</u>. Ideal candidates for corrective action are inexpensive, easy to perform, implemented quickly, 100 percent effective at reducing risk, and do not introduce a risk of unintended consequences. No situation meets these ideals. Therefore, the assigned ASE must conduct a short evaluation of each candidate action(s) that consider effectiveness, cost, timeliness of implementation, and complexity.

e. <u>Select Preferred Corrective Action</u>. After you have evaluated all candidate corrective actions against the attributes in figure 7, select the most appropriate one(s), balancing the attributes. Document and submit your recommendation with all supporting documentation for review by the CARB.

f. <u>Interim Mitigation</u>. When issuing interim mitigation, you must add a date before the control program risk guideline is reached and associated comment field to the MSAD record in the MSAD IT tool. This date will act as a reminder that the final action still needs to be issued in time to meet the control program risk guideline.

g. <u>Terminating Corrective Action</u>. When the terminating corrective action is defined, you must calculate the control program fleet and control program individual risk to ensure it meets the fleet and individual CPRGs. Proceed through the corrective action selection process as defined in figure 7. The CARB must review terminating corrective actions not previously discussed in the initial CARB.

16. Step 11 - Submit to AIR Process Owner for Further Analysis. As described in figure 3, assigned ASEs discovering causes in other AIR business processes (like certification and rulemaking) must communicate those causes to process owners for action.

17. Step 12 - Submit Cause to Certificate Oversight Process. Assigned ASEs who identify causes originating with the production approval holder (production escapes), must communicate them to the AIR certificate oversight representative for action.

18. Step 13 - Document and Submit Issue to FAA Organization Outside of AIR. The MSAD process might identify a cause or contributing factor that originates in FS, air traffic, and other non-AIR FAA organization or the companies they oversee. The condition might warrant mitigation by their organization, as determined by their business process. When such a condition is identified, the assigned ASEs must submit information to the responsible organization. If the responsible organization is FS (e.g., ACSA, GASA, FSDO, CMO, etc.), the assigned ASE must either submit the information through the AED or, at a minimum, notify the AED that information has been submitted directly to the field.

19. Step 14 – Initiate AD, SAIB, or other Mitigation Process.

a. <u>CARB Selection of Risk Mitigation</u>. The CARB must use the risk analysis outputs to guide its decision whether to choose an AD, SAIB, or other mitigation. If the CARB selects any of these options, the assigned ASE starts the mitigation process. If an AD is likely to be issued and is associated with a transport airplane accident in which a loss of life occurred, you must prepare a report of findings and recommendations of the TARAM as described in step 4.

b. <u>Initiate Corrective Action</u>. AD, SAIB, and other mitigation processes are outside the scope of the MSAD process. They are defined in appropriate orders and the quality management system (QMS) documents. Once the AD or SAIB is issued, the assigned ASE or other administrative personnel must enter the corrective action information (AD number, SAIB number, or other applicable information) into the MSAD record in the MSAD IT tool. Developing and issuing mitigations might require exchange of information and further MSAD process analysis. You must use the MSAD process to track changes to the technical decision-making.

20. Step 15 – Prepare Internal Feedback to MSAD Process Owner (optional). MSAD is part of the AIR QMS process. AVS MSAD users can submit feedback directly to AIR-630 using the form in appendix H.

21. Step 16 - Prepare Lessons Learned (optional). Lessons from events, hazards, risk analyses, or mitigation selections that are valuable teaching cases can be captured and submitted to the AVSSMS Coordination Group through AIR-360.

Chapter 3. Follow-On and Trending

1. Monitor and Validate. The cognizant ASE must validate the effects of risk mitigation in the fleet by monitoring in-service data to ensure that the risk has been properly mitigated (depicted as link B in figure 3). You can do this by identifying repeat and similar events using the MSAD IT tool record database. You must also watch for introduction of substitute risk due to unintended consequences of mitigating action.

Note: It is recommended to contact the System Approach for Safety Oversight (SASO) office in AFS-900 who can develop DCTs to help monitor mitigations, especially for ADs that are high-profile or that mitigate potentially catastrophic hazards.

2. Trending. Data trending (safety assurance) is defined as collecting and monitoring existing data to identify items that meet specific criteria or exceed established guidelines.

a. Monitoring data for trends is important because it:

(1) Enables tracking known hazards to ensure that their rate of occurrence does not cause risk to exceed established guidelines and is consistent with the intent of the certification assumptions and analyses.

(2) Allows the monitoring of the results of implemented mitigations to verify that the implementation and results are as presumed, and that new problems were not introduced by any actions.

(3) Identifies emerging hazards.

b. <u>Conducting Trending</u>. Trend analysis can be conducted by all AIR personnel responsible for monitoring and addressing product safety risks. Although MSAD trending using the MSAD IT tool records is primarily based on fleet level events, it does not prevent us from trending at the DAH management level, looking for trends in people or process causes. If trending identifies a potential hazard (see link C, figure 3), the assigned ASE must perform a risk analysis outlined in step 5. If an ASI identifies a potential hazard, the ASI must submit that information to the cognizant ASE, who will assess the fleet risk and take appropriate mitigation, as necessary. It is a recommended practice to reach out to the FS SAPO to see if they are seeing similar trends in SAS or to utilize SAS to help with your trending.

- c. <u>Identifying Trends</u>. Trending activities can include:
 - (1) Identifying items to trend (parts, products, failures, etc.);
 - (2) Analyzing cross-product trends;

(3) Tracking trends and items of significant interest;

(4) Tracking repeat events (within makes, models and series or across them) or similar failures that have occurred on multiple occasions, including repeat part failures, high part replacement, and repeat hazards;

(5) Identifying causes (during MSAD process);

(6) Identifying most common part category or system failures; and

(7) Identifying patterns or potential correlations (for example, when part A fails and part B fails, then event C occurs).

Note: Not all events necessitate a trend analysis. It is recommended you focus on anticipated concerns. Figure 8 illustrates the trending process.

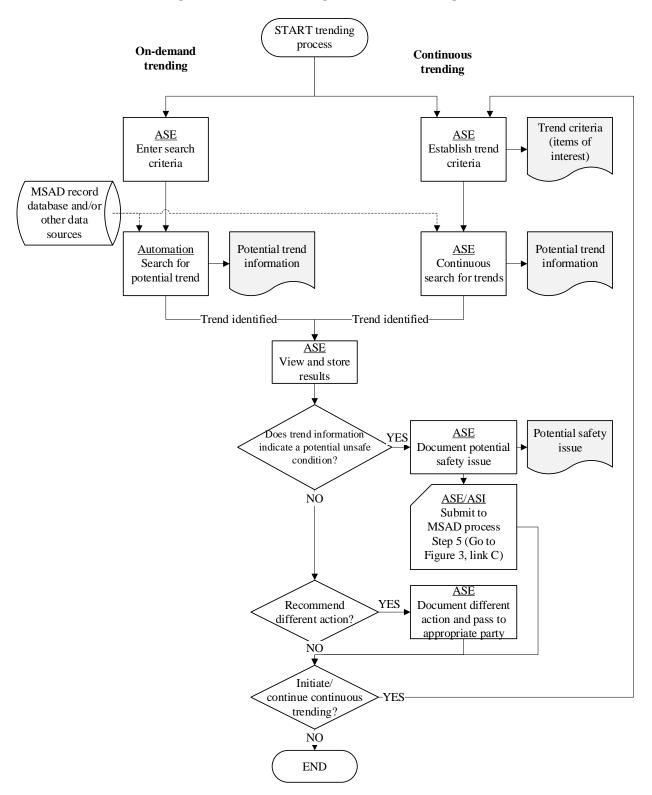


Figure 8. Data Trending Process Flow Diagram

Chapter 4. Applying MSAD to Foreign Products

1. Introduction. This chapter describes how MSAD applies to hazards on products designed and manufactured outside the United States. It covers how to handle events on these products, as well as how to review and disposition MCAI.

2. Addressing MCAI. MCAI are documents issued by other State of Design Authorities (SoDA), following ICAO Annex 8, regarding unsafe conditions on products designed or manufactured in other countries. FAA Order 8040.5, *Airworthiness Directive Process for Mandatory Continuing Airworthiness Information*, offers guidance on MCAI. Most FAA ADs following MCAI are issued in this manner.

a. After evaluating a safety concern, the FAA may choose to take unilateral action or may decide that the risk is acceptable (a FAA AD is not required). If you determine an action not aligned with SoDA decision, use table 5 to determine the necessary action.

b. For an illustrated version of how to apply MSAD to MCAIs, see figure 9.

Scenario:	ASE required action:
(1) Is unilateral action, as defined by FAA Order 8040.5, necessary?	If yes, you must enter the information into the MSAD database, creating an initial MSAD record in the MSAD IT tool. You then apply the MSAD process steps, beginning with risk analysis outlined in step 5. When requesting more technical information from the SoDA, specifically request information needed to perform the MSAD risk analysis step.
(2) Is the MCAI for an issue with low enough risk that a corresponding AD is not needed?	If yes, you must document your decision. This does not apply when decisions are made that no AD is required for administrative reasons. A typical administrative reason is when the SoDA has issued a revised or superseding MCAI and the FAA decides no AD is required for the initial or preceding MCAI, and instead writes an AD for the later MCAI.

Table 5. Handling MCAI Disagreements within MSAD

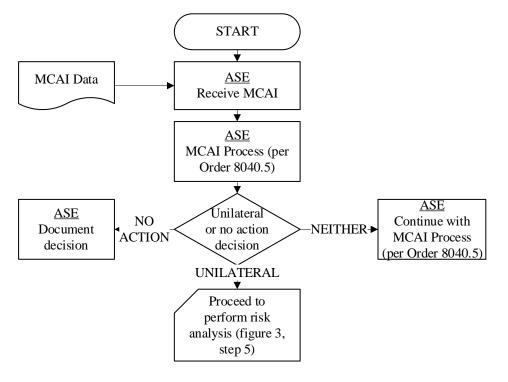


Figure 9. MSAD Process for MCAI

3. Addressing Events. Some events on foreign products will pass through the MSAD hazard criteria filter in the MSAD IT tool for a product type and will need to be reviewed by the International Validation Branch (AIR-730). If you are responsible for a foreign product, you must review and disposition all events associated with that product using the MSAD process for foreign product data described in this section. Coordinate with the SoDA as needed, ensuring they are aware of any hazards to address them.

a. <u>Hazard Criteria Analysi</u>s. Foreign product data is automatically filtered in the MSAD IT tool as outlined in step 2.

- b. Perform Preliminary Risk Assessment.
 - If you have identified a hazard requiring emergency corrective action or a potential hazard, you must coordinate the MSAD event record information, along with the results of the preliminary risk assessment, with the SoDA to determine whether they intend to address the hazard with an MCAI, are in the process of preparing an MCAI, or have already issued an MCAI.
 - If an FAA AD exists that adequately addresses the hazard, you must link the MSAD record item in the MSAD IT tool for the event to the FAA AD and reference it for future management of the issue.
 - If you determine that no further action is necessary, you must close the MSAD record in the MSAD IT tool. Retain the record for trending. Prior to closing the MSAD

event, it is recommended you ensure that MSAD events discovered to be false positives are marked.

c. <u>Take Corrective Action</u>. For cases when immediate action is warranted, you must notify the SoDA and initiate FAA corrective action. If the SoDA notifies us that they are taking no action or you determine that the SoDA action is not adequate, you must continue through the MSAD process to perform risk analysis, outlined in step 5, to determine what further action, if any, is necessary. You might need to take unilateral action following the process described in FAA Order 8040.5.

Note: It is not necessary to wait for the SoDA to act or for the eventual MCAI. Figure 10 is a depiction of the MSAD process flowchart including other SoDAs.

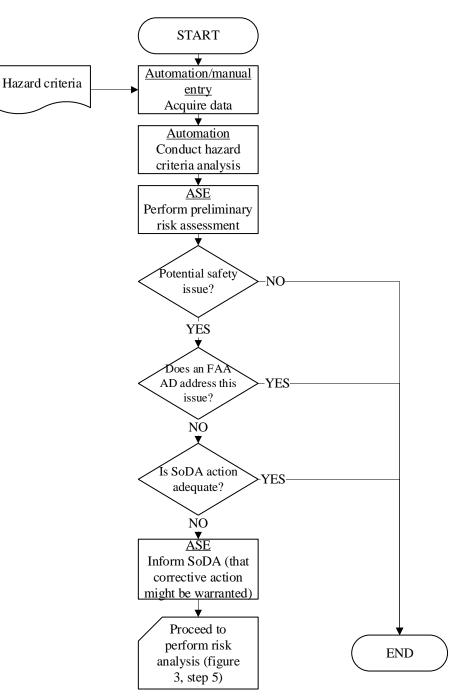


Figure 10. MSAD Process for Foreign Product Data

Chapter 5. Exceptions

1. Exceptions. When certain higher-level policies require that an AD be written, MSAD risk analysis results are optional. The policy decision to write ADs in those cases was made during rulemaking or other policy deliberations and overrides the MSAD risk guidelines. The following are the limited authorized cases of an overriding higher-level policy:

a. ADs for mandatory modifications required by the Widespread-Fatigue-Damage Rule (75 FR 69746) November 15, 2010, or later revision.

b. ADs to mandate the incorporation in the airworthiness limitations section of the maintenance manual, new or revised damage tolerance inspections, or safe-life limits required for §§ 23.571, 25.571, 27.571, 29.571, 33.14, 33.70, or 35.37.

c. ADs that are needed for fuel tank protection, ignition prevention, flammability reduction, or ignition mitigation, required for compliance with Special Federal Aviation Regulation (SFAR) 88, § 25.954, or § 25.981, as applicable.

d. ADs required by the Aging Aircraft Safety Final Rule (AASFR) (70 FR 5518) February 2, 2005, or later revisions) for changes to supplemental structural inspection programs and Corrosion Prevention and Control Programs (CPCP).

e. SSI ADs.

2. Applicability. ADs are issued to correct an unsafe condition in an aircraft, engine, propeller, or appliance (products), and have a defined applicability at the time of issuance. On occasion, after AD issuance, the FAA might discover that the applicability did not include all the affected products, and the AD is superseded to increase the applicability. When the FAA supersedes an AD solely for this reason, it is not necessary to use MSAD risk analysis results, as the supersedure will be issued regardless of the risk result to meet ICAO obligations or as general policy. This exception only applies when the unsafe condition of the superseding AD is the same (the supersedure must be solely to add applicability).

3. Exceptions.

a. For the situations defined above in paragraphs 1.a and 1.b, the following exceptions to the requirements are authorized (Steps referenced are from chapter 2):

(1) Step 5, Perform Risk Analysis.

(2) Step 7, Determine if Causal Analysis is Required.

(3) Step 8, Perform Causal Analysis.

(4) Step 9, Document the Cause(s).

4. Identifying Contributing Factors.

a. Some of the requirements defined in step 10, Evaluate and Select Mitigation for a Fleet Issue, regarding selecting mitigation for the CARB to review. See paragraph 2.b of this chapter for limitations and requirements still in effect.

b. When exceptions are made in accordance with this chapter, the following limitations and requirements remain in effect:

(1) Issue and recommended mitigation must be presented to the CARB for concurrence as outlined in step 10.

(2) CARB decision of the issue must be documented in the CARB meeting minutes as outlined in step 10.

Chapter 6. Administrative Information

1. Distribution. Distribute this order to all AVS branches and offices.

2. Authority to Change This Order. The issuance, revision, or cancellation of the material in this order is the responsibility of the AIR Organization and System Policy Branch (AIR-630). This branch will accomplish all changes, as required, to carry out the FAA's responsibility to provide guidance for the MSAD process.

3. Suggestions for Improvement. Please forward all comments on deficiencies, clarifications, or improvements regarding the contents of this order to the Directives Management Officer (DMO) at <u>9-AVS-AIR-Directives-Management-Officer@faa.gov</u>. Your suggestions are welcome. FAA Form 1320-19, *Directive Feedback Information*, is in appendix H of this order for your convenience.

4. Records Management. Refer to FAA Order 0000.1, *FAA Standard Subject Classification System*; FAA Order 1350.14, *Records Management*; or your office Records Management Officer (RMO)/Directives Management Officer (DMO) for guidance regarding retention or disposition of records.

Appendix A. Definitions and Acronyms

AASFR	Aging Aircraft Safety Final Rule	
ACS	Aircraft Certification Specialist	
ACSA	Air Carrier Safety Assurance	
ACSAA	Aircraft Certification, Safety, and Accountability Act	
AD	Airworthiness Directive	
AED	Aircraft Evaluation Division	
AIR	Aircraft Certification Service	
AMOC	Alternative Methods of Compliance	
ASL hazard	Per Order 8040.4, an aerospace system level (ASL) hazard meets one or more of the following criteria:	
	 The hazard is tracked and managed by the FAA SMS Committee; The hazard is present in the National Airspace System (NAS)^[1], its safety risk has not been accepted, and it is expected to have high risk (for example, it is identified as a result of an accident or incident, or it is assumed to have high risk but an assessment has not been completed); or The hazard has high risk and has a potentially systemic outcome (for example, the outcome crosses LOBs or the outcome impacts an industry segment rather than an individual certificate holder) Contact AVP-300 for additional information. 	
ASE	Aviation safety engineer	
ASI	Aviation safety inspector	
Assigned ASE	ASE with COS responsibilities for a specific aircraft or product hazard	
ΑΤΟ	Air Traffic Organization	
AVP	Office of Accident Investigation and Prevention	
AVS	Aviation Safety Organization	
CAAM	Continued Airworthiness Assessment Methodology	

CAAP	Continued Airworthiness Assessment Process
CARB	Corrective Action Review Board
CAST	Commercial Aviation Safety Team
Causes	Underlying circumstances, occurrences, and/or failures that contribute, or could contribute, directly or indirectly, to an event.
CCA	Candidate corrective action
Certificate Holder	Person or entity authorized by the Administrator to conduct operations as a direct air carrier
CISA	Cybersecurity Information Sharing Act
CM Branch	Certificate Management Branch (AIR). References to "Certificate Management Branch" or "CM Branch" include branches responsible for production/oversight aspects of this policy within the System Oversight Division (AIR-800) and Integrated Certificate Management Division (AIR-500).
СМО	Flight Standards Certificate Management Office
Condition	See "Hazard"
Corrected risk	Residual risk that remains after corrective action is taken. When highly effective corrective action is taken, corrected risk is zero. See also Chapter 2 for added details, as well as "Uncorrected Risk."
Corrective action	An action to eliminate or mitigate the cause or reduce the effects of a detected nonconformity or other undesirable situation.
COS	Continued operational safety
СРСР	Corrosion Prevention and Control Program
CPRG	Control Program Risk Guidelines. The upper limit of acceptable risk which assists the candidate mitigation ASE in determining the adequacy, in terms of risk reduction, of a proposed. These guidelines are characterized in terms of both fleet risk and individual risk.

Credible	A probability of an outcome at or above greater than or equal to 1×10^{-11} . If the probability of an outcome is less than 1×10^{-11} , it is considered not credible and does not need to be formally assessed or considered as part of the safety risk analysis.
Cross-product	Can be across product lines within a manufacturer, across products from various manufacturers, and/or across product-types, if parts, components, or processes are common to other aircraft or engines.
DAH	Design Approval Holder
DCT	Data Collection Tool
DRS	Dynamic Regulatory System – a comprehensive knowledge center of regulatory and guidance material from the FAA Office of Aviation Safety and other Services and Offices. <u>https://drs.faa.gov</u> .
Event	Any individual occurrence involving an aircraft or its components. Described in terms of what is observed (the symptoms) or recorded during the occurrence. Events typically trigger investigations that seek causes of a hazard. The hazard (or condition) is then evaluated for safety implications.
Expected Value	Statistical prediction of a value, for example "expected number of events, if the hazard is not addressed."
FAA	Federal Aviation Administration
Fleet	Aircraft, engine, or propeller products of a type currently in-service affected by a certain hazard.
Frequency of Occurrence	Ratio of the number of events of interest to the exposure period, for example, one event in 1 million flight hours. Frequency is often expressed with the denominator normalized to a single unit, 1x10-6 per flight hour.
FS	Flight Standards Service
FSDO	Flight Standards District Office
GASA	General Aviation Safety Assurance
Hazard	A condition or an object with the potential to cause or contribute to an aircraft accident or incident, as defined in 49 CFR 830.2.
Hazard criteria	Terms known to indicate a hazard within a specific product. This text-based mapping approach is used as basic safety performance indicators.

HIRMT	Hazard Identification, Risk Management, and Tracking
IAR	Immediately Adopted Rule
ICA	Instructions for Continued Airworthiness
ICAO	International Civil Aviation Organization
ICM Division	Integrated Certificate Management Division
LOB	Line of Business
MCAI	Mandatory Continuing Airworthiness Information
Mitigation	A means to reduce or eliminate the effects of hazards.
MSAD	Monitor Safety Analyze Data – the policy and procedures as documented in this order.
MSAD IT Tool	An enterprise-grade IT tool used to accomplish parts of the MSAD procedures.
MSAD Alternative IT Tools	IT Tool(s), typically custom developed by AIR certification branches that replace some or all functionality of the MSAD Tool
NAR	No action required
NPRM	Notice of proposed rulemaking
Outcome	Result of an event, condition, or failure at aircraft level.
Ы	Principle Inspector
PM	Program Manager
Preliminary risk assessment	An initial assessment of the risk posed by a hazard, often performed with limited data or qualitative information. This assessment is meant to quickly determine an issue's potential risk and urgency and is followed by comprehensive and quantitative analysis as data and circumstances permit unless the issue is deemed to entail very little risk.
Probability	Ratio of the number of occurrences of interest to the total number of possible occurrences. For example, "20 percent probability that an event will lead to an unsafe outcome" means that out of 100 events, we expect 20 unsafe outcomes.
QMS	

RA	Risk analysis. Process whereby hazards are objectively characterized for their severity and probability. The process is either qualitative or quantitative.
Risk	A generic expression that combines the probability and severity of a given outcome. In practice, risk is specific to an affected population, exposure, and a given hazard (individual risk, individual personal risk, collective risk, etc.) Risk might be expressed in terms of rates or probabilities. See also "corrected risk" and "uncorrected risk."
Risk assessment	Comparison of the risk analysis to the product-specific risk guideline.
Risk guideline	The upper limit of acceptable risk which assists the ASE in determining the need for AD or other mandatory corrective actions and the adequacy, in terms of risk exposure, of a proposed candidate mitigation.
Risk level	The likely operational outcome of a hazard.
Risk measure	The units used as part of the risk analysis calculations (i.e. fatal accident, fatalities, etc.).
Risk value	The result of the risk analysis for a particular risk level addressing total uncorrected fleet risk, uncorrected individual risk, control program fleet risk, control program individual risk, and time until control program risk guideline is reached.
SA	Safety Assurance
Safety issue	See "hazard"
SAIB	Special Airworthiness Information Bulletin
SAPO	Safety Analysis Program Office
SARA	Small Airplane Risk Assessment
SAS	Safety Assurance System
SASO	System Approach for Safety Oversight
SB	Service Bulletin. One type of "service document" (see below). In this order, the terms are synonymous.
SFAR	Special Federal Aviation Regulation

Service documents	Publications by a design approval holder, appliance or component manufacturer that offer information on safety, product improvement, economics and operational and/or maintenance practices. Publications include service bulletins, all-operators' letters, service newsletters and service digests or magazines. Not included in this definition are documents required for FAA type certification or approval, such as flight manuals and certain maintenance manuals. (Source: AC 20-176, <i>Service Bulletins Related to Airworthiness Directives and Indicating FAA</i> <i>Approval on Service Documents</i>)
Severity	The consequence or impact of a hazard in terms of degree of loss or harm.
SMS	Safety Management System
SoDA	State of Design Authority
SPI	Safety Performance Indicator
SRM	Safety Risk Management
SSI	Sensitive Security Information
SSP	State Safety Program
STC	Supplemental type certificate
Substitute risk	Risk of unintended consequences from implementing mitigation
TARAM	Transport Airplane Risk Assessment Methodology
Taxonomy	A standard industry language and set of definitions that improve the quality of information and communication within the aviation community.
ТС	Type certificate
TSO	Technical standard order
Uncorrected risk	Risk if no mitigation is taken for a certain hazard. See also Chapter 2 for added details, as well as "corrected risk."
UPN	Unapproved Parts Notification

Appendix B. Related Publications

The following regulations and other documents referenced in this order are available on the Dynamic Regulatory System (DRS) at <u>https://drs.faa.gov/browse.</u>

1. Title 14, Code of Federal Regulations (14 CFR).

- Section 21.3, *Reporting of failures, malfunctions, and defects.*
- Section 21.4, *ETOPS reporting requirements*.
- Section 91.1415, (CAMP: Mechanical reliability reports.)
- Section 91.1417, (CAMP: Mechanical interruption summary report.)
- Section 121.374, Continuous airworthiness maintenance program (CAMP) for twoengine ETOPS.
- Section 121.703, *Service difficulty reports*.
- Section 121.705, Mechanical interruption summary report.
- Section 135.364, *Maximum flying time outside the United States*.
- Section 135.415, *Service difficulty reports*.
- Section 135.417, *Mechanical interruption summary report.*
- Section 145.221, Service difficulty reports.
- Section 183.63, Continuing requirements: Products, parts, or appliances.

2. Advisory Circular.

AC 39-8, Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes.

3. FAA Orders.

- Order 8000.367, Aviation Safety (AVS) Safety Management System Requirements.
- Order 8000.369, Safety Management System.
- Order 8040.1, *Airworthiness Directives*.
- FAA-IR-M 8040.1, Airworthiness Directives Manual
- Order 8040.4, *Safety Risk Management Policy*.
- Order 8040.5, Airworthiness Directive Process for Mandatory Continuing Airworthiness Information.
- Order 8040.6, Unmanned Aircraft Systems Safety Risk Management Policy.

- Order 8110.100, Special Airworthiness Information Bulletin.
- Order 8120.16, Suspected Unapproved Parts Program.
- Order 8900.1, Certificate Holder Evaluation Process.

4. Other Documents.

FAA Policy Memo PS-ANM-25-05, *Risk Assessment Methodology for Transport Category Airplanes*.

Appendix C. Risk Assessment Methodologies

AIR has developed four product-specific risk assessment methodologies, reflecting the different product types for which we have design oversight responsibility. For more information for any of these methodologies, contact AIR-630.

- Continued Airworthiness Assessment Process (CAAP) covers risk determination and management during the resolution of engine, propeller, and auxiliary power units (APU) hazards and is based on AC 39-8, *Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes*. Often will be referenced as "Continued Airworthiness Assessment Methodology (CAAM)," which is primarily for engines on transport airplanes.
- Rotorcraft Risk Analysis (RA) guidance for estimating the associated risk and determining unsafe conditions for hazards on rotorcraft. The rotorcraft RA is also based on the risk analysis framework established by AC 39-8.
- Small Airplane Risk Assessment (SARA) guidance for estimating the associated risk and determining unsafe conditions for hazards on small airplanes. SARA is also based on the risk analysis framework established by AC 39-8.
- Transport Airplane Risk Assessment Methodology (TARAM) PS-ANM-25-05 contains guidance for estimating the associated risk and determining unsafe conditions for hazards on transport airplanes. It explains how to use such risk analysis calculations when making determinations of unsafe conditions, and selecting, and implementing corrective actions.

Note: These methodologies are available on the FAA internal employee's website at <u>https://my.faa.gov/org/linebusiness/avs/offices/air/sms/cos.html.</u>

Appendix D. Potential Data Sources

Depending on the type of product and investigation, there are several aviation safety data sources that can be utilized as part of the analysis and assessment of safety events, as well as tracking of any mitigations to those potential hazards. You are not expected to utilize every data source listed, but there might be some helpful data sources that you have not considered.

Note: Tables D-1 and D-2 provide an overview of various safety databases and recording systems used by the FAA. This list is by no means comprehensive but should give you a good start in finding the data you need for SA monitoring or SRM analysis.

Data or System Name	Overview
Section 21.3 Reports (also sometimes referred to as "COS Reports")	Reports of failures, malfunctions, and defects from the design or production approval holder, as required under § 21.3, or from the organization designation authorization (ODA) holder as required under § 183.63.
Accident/Incident Data System	The Accident/Incident Data System contains data records for all general aviation and commercial air carrier incidents since 1978.
Aviation Safety Action Program (ASAP)	ASAP promotes voluntary reporting of safety issues and events that come to the attention of employees of certain certificate holders. It includes enforcement-related incentives to encourage employees to voluntarily report safety issues, even though the issues may involve an alleged violation of 14 CFR.
Aviation Safety Information Analysis and Sharing (ASIAS) System	ASIAS is a data warehouse and integrated database system. It enables users to perform queries across multiple databases and display queries in useful formats. It includes accidents, incidents, and voluntary data.
Emergency Operations Network (EON)	Deployed to provide the FAA with collaborative communication, continuity of operations and adaptive situational awareness for enhanced decision support at all levels within FAA, often the first group to receive word of an incident or accident. Formerly known as the Daily Alert Bulletin (DAB) (and "Page Outs").
Extended Operations (ETOPS) Reports	Reports of failures, malfunctions, and defects on any flight under ETOPS approval for anyone voluntarily operating an ETOPS route (travelling more than one hour away from a suitable

Table D-1. Potential FAA Data Sources for SA and SRM

Data or System Name	Overview
	airport). These reports are mandatory under §§ 121.374 and 135.364 and appendix G to part 135.
FAA Safety Recommendations	FAA safety recommendations are sent directly to the Office of Accident Investigation and Prevention and disseminated to the responsible FAA office.
Mechanical Interruption Summary Reports	Monthly reports required by all operators for events that do not rise to the level of a Service Difficulty Report (SDR), but result in a flight diversion, cancellation, or interruption due to mechanical issues.
Service Difficulty Reporting System	Database containing failure, malfunction, and defect reports from operators and repair agencies as SDRs required under §§ 121.703 and 135.415, and other regulations and voluntary malfunction or defect reports. Analogous to § 21.3 reports.
Washington Operations Center (WOC)	See EON. Some reports first come through the WOC.

Table D-2. Potential External Data Sources for SA and SRM

Data or System Name	Overview
Aviation Herald	Summary of global accidents and incidents published as news articles.
Aviation Safety Network	Detailed information of global accidents and incidents.
Aviation Safety Reporting System (ASRS)	Established by NASA to identify issues in the aviation system which need to be addressed. NASA collects voluntarily submitted aviation safety incident/situation reports in the ASRS database from pilots, controllers, and other personnel. It identifies system deficiencies and issues messages to alert individuals in a position to correct the identified issues.
NTSB Accident and Incident Database	The official repository of aviation accident data and causal factors. In this database, personnel categorize events as accidents or incidents.
NTSB Safety Recommendations	Recommendations that address specific issues uncovered during investigations and specify actions to help prevent similar accidents from occurring in the future.

Appendix E. Alternative IT Tool Process

This appendix allows the use of an alternative IT tool process in addition to, or as a replacement for the MSAD IT tool. While the MSAD IT tool is recommended, it is acceptable to use alternative IT tools in addition to, or as a replacement for the MSAD IT tool, provided the following requirements are met for each alternative IT tool used:

a. AIR-740 is responsible for assisting the ASE community in analyzing safety data in support of COS processes. As part of this role, AIR-740 develops AIR-level strategies to implement and standardize usage of advanced data analytics systems (which are considered an alternative IT tool) for use by the ASE community to enhance the COS processes throughout AIR. This includes the processes associated with integration and usage of safety data sources.

b. AIR-740 approval prior to beginning development or improvements for all new and substantially updated IT tools. Contact AIR-740 with any recommendations or enhancements for consideration in the alternative IT tool process.

c. Contact the Technology Management Branch (AIR-950) so they can add the tool to their IT inventory database if the IT tool stores data. This includes establishing protocols and/or procedures to cover how to protect the IT tool and its stored data from unauthorized access, alteration, deletion, and data loss.

d. Provide AIR-630 a listing of software, IT tools, etc. required to make the alternative IT tool work (e.g., MuleSoft).

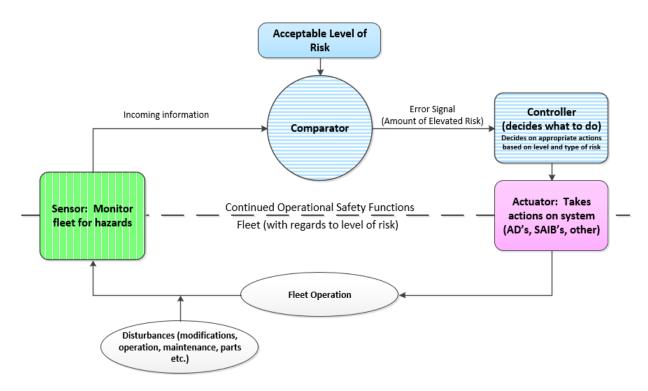
For the purposes of the requirements above, the term "IT tool" is described as:

- Tools,
- Applications,
- Software,
- Collection of tools and/or systems, and
- Possibly other terms.

The alternative IT tool might be contained on a single hard drive, operate over a local area network, or use web (internet) technologies. Certain IT tools might involve SharePoint sites, knowledge sharing network (KSN) sites, or other externally hosted platforms. There is some overlap and ambiguity with the various IT tool terms. Microsoft ExcelTM can be considered a tool, an application, and software. A certification branch that started with Microsoft ExcelTM and customized it to store and filter hazard information could refer to it as a tool, an application, or software. Regardless, the requirements above would apply.

Appendix F. MSAD Process Interactions

Our safety process can be viewed as a simple control system model (figure F-1), where green (with vertical stripes) indicates how we sense or monitor the system we are controlling; light blue (with horizontal stripes) indicates how we analyze and use our sensed signals to make decisions on what to do (how to act on our system); and pink indicates components we use to act on our system.





The MSAD process, depicted in light blue (with horizontal stripes) in figure F-2 below, interacts with many other COS processes within AIR. We have also added interactions that involve FAA personnel outside of AIR (depicted as shapes without a fill color)

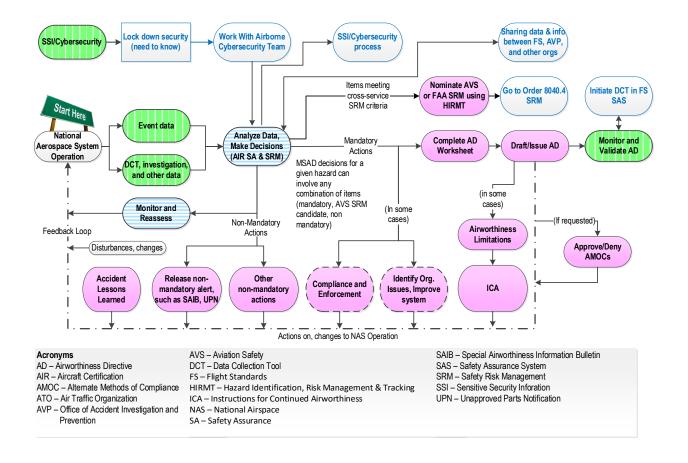


Figure F-2. FAA AIR COS System

Appendix G. FS Roles and Responsibilities in Support of MSAD Process

1. ACSA and GASA. The ACSA and GASA monitor safety and analyze data in accordance with FAA Order 8900.1 *Flight Standards Information Management System*.

2. Safety Analysis and Promotion Division, AFS-900.

a. Maintains SAS.

b. SAPO standardizes analysis techniques and is responsible for providing analytic support to AVS in support of SRM.

3. Regulatory Support Division, AFS-600. The Aviation Data Systems Branch (AFS-620) develops, delivers, and manages safety data, analysis, and reporting within systems outside of SAS.

4. AED, **AFS-100**. An AED ASI is a technical resource for an FS ASI and serves as a liaison with the responsible AIR office.

a. Obtains and assesses information and data of failures, malfunctions, and defects relevant to products and articles they are assigned.

b. Determines, using FAA Order 8120.23, if condition(s) affect the airworthiness or operation of the aircraft.

c. Confirms that DAHs are monitoring SDRS and are receiving notifications from product and article users of in-service failures, malfunctions, and defects.

d. Interfaces with aircraft manufacturers, operators, AIR certification branches, other FS offices, and industry personnel throughout the operational life of an aircraft.

Appendix H. Directive Feedback Information

Please submit any written comments or recommendation for improving this directive or suggest new items or subjects to be added to it. Also, if you find an error, please tell us about it.

Subject: FAA Order 8110.107B, Monitor Safety Analyze Data.

To: Directive Management Officer, at <u>9-AWA-AVS-AIR-DMO@faa.gov</u>.

Please mark all appropriate line items:

An error (procedural or typographical) has been noted in paragraph ______ on page

Recommend paragraph _____ on page _____ be changed as follows: (*attach separate sheet if necessary*)

In a future change to this Order, please include coverage on the following subject: (*briefly describe what you want added.*)

Other comments: I would like to discuss the above. Please contact me.

 Submitted by:

Telephone Number:

Routing Symbol:

FAA Form 1320-19 (08/21) Supersedes Previous Edition