

U.S. DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION National Policy



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SUBJ: Monitor Safety/Analyze Data

This order introduces the Monitor Safety/Analyze Data (MSAD) process, designed to promote data-driven, risk-based continued operational safety decision-making. MSAD supports aviation products through their life cycle.

We describe how the Office of Aviation Safety (AVS) staff uses MSAD within the Aircraft Certification (AIR) Safety Management System (SMS) to identify and manage risk in aviation products.

MSAD uses product defined hazard criteria to surface potential hazards from aviation safety data. MSAD uses a standard taxonomy for organizing continued operational safety (COS) data, promoting quick identification of emerging safety trends through dependent variable analysis.

In addition, MSAD establishes a causal analysis approach. This approach may identify underlying contributing factors, such as process breakdowns, which we then communicate to the appropriate AVS oversight business process owner.

The MSAD process is heavily based on existing industry best practices. MSAD builds a safety risk management model that sets the example for what we expect industry to evolve to, in taking responsibility for the safety of their aviation products.

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Chapter 1. General Information

1-1. Purpose of this Order. This order explains how you'll use the Monitor Safety/Analyze Data (MSAD) process to analyze continued operational safety (COS) data and monitor safety in aircraft fleets. In this order we describe the steps of the process, the tasks within those steps, and the responsibilities incumbent on all process users for all product types.

1-2. Audience. We, the Federal Aviation Administration (FAA), wrote this order for aviation safety engineers (ASEs), aviation safety inspectors (ASIs), aircraft certification offices (ACOs) staffs, directorate standards staffs, and all AIR and aircraft flight standards (AFS) personnel responsible for monitoring and addressing product safety risks.

1-3. Applicability to Certificate Holders. Compatible certificate holder processes that are acceptable to the FAA ACO can be used in lieu of functions identified for FAA personnel throughout this order. The ACO, AIR-140 and the appropriate directorates should coordinate to ensure these processes provide an adequate oversight role for the ACO in ensuring that the objectives of this order are met.

1-4. Effective Date: This order is effective September 15, 2010.

1-5. Where to Find This Order. You can find this order on the FAA's Regulatory and Guidance Library (RGL) website at <u>http://rgl.faa.gov</u> or the MyFAA Employee website at <u>https://employees.faa.gov/tools_resources/orders_notices/</u>.

Chapter 2. MSAD Process Overview

2-1. Purpose of the MSAD Process. We designed the MSAD process to filter, review, analyze and trend aviation safety data. The MSAD process helps us identify safety issues in the in-service aircraft fleets, and identify corrective actions to mitigate safety risks across the fleet. The process also identifies other causes of safety issues that can't be addressed by fleet (product/part) corrective actions. MSAD users should submit these causes to the appropriate organization and/or process owner (whether inside or outside AIR) for further analysis and action.

2-2. Range of the MSAD Process.

a. We intend the MSAD process to analyze in-service data to determine corrective action for COS issues. The MSAD process ranges from the point of receiving data up to the point of determining fleet corrective action. *Issuing* the corrective action, including the notice of proposed rulemaking (NPRM) process, is outside MSAD, and is part of the airworthiness directive (AD), special airworthiness information bulletin (SAIB), and/or other FAA actions or recommendations processes.

b. Certain certificate holders have their own processes to filter, review, analyze and trend aviation safety data on their products. We expect the ACO's will continue to foster cooperative COS agreements which integrate the certificate holders processes with the MSAD process in a manner that is compatible to this order. In those instances, the certificate holder will often be accomplishing many of the steps defined in this order to address the safety of their products with the ACO ASE performing an oversight role.

c. MSAD may also interface with other AIR processes, non-AIR FAA processes, and industry, to help identify non-fleet-based problems. For example, while staffs using MSAD are analyzing aircraft in-service data to identify fleet risks and product corrective action, ASEs and ASIs who oversee the certificate holder are analyzing product design, production, operations and maintenance process data to identify certificate holder risks and corrective actions that should reduce aircraft fleet risks.

2-3. MSAD Overview. As an ASE following the MSAD process, you perform both a risk analysis of the potential safety issue, and a causal analysis. Following the MSAD process, you initiate the AD or SAIB (or other corrective actions or recommendations) as required. When you complete the process, you store event data, safety issues, risk analysis, causal analysis and corrective action data for future use. Figure 1, on the next page, is a high-level view of the entire process. Although we display and describe the components sequentially, you may encounter situations where portions of the process are worked concurrently or out of sequence.



Figure 1. High-Level View of MSAD

2-4. The MSAD Process Flow. In figure 2 on the following pages is the entire MSAD process in fifteen steps. Subsequent paragraphs explain every step. We will expand some steps, like risk analysis, into more detail as we discuss them.



Figure 2. MSAD Process Flow Page 1

Note: See Chapter 3 for details on link C.



Figure 2. MSAD Process Flow - Page 2

2-5. Step 1.0 - Acquire Data. Data is acquired from existing FAA databases using an automated batch process. Acquired data can also be manually input, such as a report satisfying a Title 14 of the Code of Federal Regulations (14 CFR) § 21.3 requirement. In both cases, the data goes to an electronic form called the MSAD record. Not all event data will be analyzed through the MSAD process. Hazard criteria (described in paragraph 2-6) are used to filter out the events that don't present potential safety issues. However, the events that are filtered out can still be used for trending purposes.

a. Responsible Office. MSAD software sends event data to the responsible office for the applicable product-type. When event data applies to more than one product-type, MSAD software sends it to all responsible directorates and ACOs based on the make and model. If all directorates indicate they are not responsible for the event data, the software will send the event data to AIR-140 for resolution. When the event data does not contain any product-type data that is directly traceable to an aircraft, engine, or propeller, such as an appliance, the software sends it to AIR-140 for resolution. An MSAD record will not show that it's fully "closed" until all offices involved have completed their review and made some input to the record. Sometimes more than one office may need to remedy safety issues related to a single event.

b. Taxonomy. MSAD taxonomy is aligned with the FAA's Commercial Aviation Safety Team (CAST) and International Civil Aviation Organization (ICAO) common taxonomy team (CICTT) taxonomy. MSAD taxonomy goes to greater depth and detail than CICTT, because CICTT terms are currently top-level event descriptors only. MSAD supplements CICTT taxonomy with lower-level event descriptions, part name, and other details. CICTT taxonomy is still evolving. New terms and changes in hierarchy may or may not fit the MSAD application. However, we intend to keep MSAD aligned with CICTT taxonomy as it matures.

c. Event Data Sources. Sources of safety data include FAA databases focusing on event information. We expect industry sources to increase as cooperative data sharing increases. ASEs should include any data sources that benefit the MSAD process. Automation will pull data from certain databases and submit those as event records to the cognizant ACOs and directorates based on the make and model. ACO and directorate personnel can manually enter event records from any data source. We anticipate that automation will be modified to add additional data sources. Sources of MSAD data may include:

(1) National Transportation Safety Board (NTSB) accident and incident reports, primarily "Preliminary Report" and "Factual" versions,

(2) Service difficulty reports (SDRs),

- (3) Accident and incident data (AID) reports (from the AIDs database),
- (4) Daily alert bulletins (DABs), and
- (5) Data reported per 14 CFR § 21.3, or data provided under negotiated agreements.

2-6. Step 2.0 - Hazard Criteria Analysis. Hazard criteria are used to automatically or manually filter event data. Filtering reduces the number of events that the senior COS ASE must review for potential safety issues during the preliminary risk assessment. Automatic filtering is based on keyword, key-phrase matches, or other data mining techniques of the event data for the product type. For example, a filter might be one that sends forward any event description that includes the word "fire." Event data that doesn't meet the hazard criteria is retained and can be used for trending.

Note: Automation will not filter § 21.3 reports or other safety data submitted under negotiated agreements since the agreement will typically include the hazard criteria.

a. Product Type Hazard Criteria. Each directorate standards staff must develop and maintain their own hazard criteria to filter event data about their product type.

b. Manual Sampling. Automated hazard criteria should continue to mature over time. The criteria list will be a living document. Directorate-assigned COS representatives must review, at least annually, samplings of events filtered by the hazard criteria to ensure the criteria stay valid. The rate and frequency of events they sample may vary, based on process maturity and directorate/ACO needs.

2-7. Step 3.0 - Perform Preliminary Risk Assessment. The purpose of the preliminary risk assessment is to quickly identify any safety issues needing an emergency AD or "Final rule; request for comment" (FRC). It also determines whether an event indicates a potential safety issue requiring more investigation through the MSAD process. The assessment should take advantage of whatever data is immediately available.

a. Review by Other Offices. Here, or at any other point in the MSAD process, a senior COS ASE or assigned ASE may decide that there's a cross-product issue, and that other offices need to review the information. The senior COS ASE or assigned ASE must enter the rationale in the MSAD record and submit to the appropriate office(s).

b. Questions for the Senior COS ASE. As the senior COS ASE, you must review the safety event to answer two key questions:

- (1) Is this a potential safety issue and
- (2) Does an urgent unsafe condition exist that requires immediate corrective action?

c. Preliminary Risk Assessment Answers. The answers to those two questions determine the remaining steps in the process.

(1) If you, the senior COS ASE, determine that there is a potential safety issue, you must define it and submit action to the assigned ASE to proceed with the risk analysis. If you're the cognizant engineer for this product, you can assign this potential safety issue to yourself.

(2) If you, the senior COS ASE, identify an urgent unsafe condition that requires immediate corrective action, you must define the safety issue and assign it to an ASE to initiate

either an emergency AD or FRC (Go to step 4.0 and initiate emergency AD/FRC). The assigned ASE can delay the comprehensive risk analysis and causal analysis until after starting the emergency AD or FRC. Once the emergency AD or FRC starts, the assigned ASE must continue analyzing the safety issue in the risk analysis step. You or the assigned ASE may determine that an emergency AD or FRC is necessary later in the MSAD process as new data becomes available.

Note: An emergency AD or FRC can be started based on an FAA estimate that the time in which the action is required is too short to allow the time necessary for public comment. (Reference FAA Manual FAA-IR-M 8040.1 *Airworthiness Directives Manual*.)

(3) If you, the senior COS ASE, determine that no further action is necessary, you must document that determination. The event doesn't move any further in the event evaluation portion of the MSAD process, but is retained for trending.

2-8. Step 4.0 - Initiate Immediate Corrective Action. If you're an assigned ASE, you must start either an emergency AD or FRC per FAA Order 8040.1, *Airworthiness Directives*, FAA Manual FAA-IR-M 8040.1 *Airworthiness Directives Manual*, and any directorate-specific procedures. This ensures that the risk is mitigated in a timely fashion, without waiting for the remaining MSAD process steps.

2-9. Step 5.0 - Record Risk Analysis Results. MSAD risk analysis objectively characterizes hazards for probability and severity, and determines the risk posed by each hazard associated with a given safety issue. Each directorate may have particular risk *measures* based on their product type. If you're an assigned ASE, you are responsible for the risk analysis, and you must record the total uncorrected fleet risk and the uncorrected individual risk (per flight or per flight-hour) and compare them to directorate-defined risk *guidelines*, as applicable, for issuing ADs or other mandatory corrective actions for the product type. If the safety issue is associated with an appliance, technical standard order (TSO) article or standard part, the safety issue could be associated with multiple product types and the assigned ASE must contact the manufacturer to obtain available information to determine product applicability to support the risk assessment. The risk guidelines for AD or other mandatory corrective action assist the assigned ASE in determining if mandatory corrective action is warranted. The risk analysis process (step 5.0) is defined in the next paragraphs, and is illustrated in figure 3 on the next page.



Figure 3. Record Risk Analysis Results Flow Diagram

*A single event may have multiple undesired outcomes. This should be accounted for with appropriate conditional probabilities.

**includes AEG, FSDO, CMO and MIO

a. Identify Aviation Safety Inspector (ASI) Support. If you, the assigned ASE, need manufacturing, maintenance or operations ASI support, you must contact an ASI responsible for the product, and ask for information to support the risk analysis. Those ASIs may come from an aircraft evaluation group (AEG), flight standards district office (FSDO), certificate management office (CMO), manufacturing inspection district office (MIDO) and/or manufacturing inspection office (MIO).

Note: When ASEs solicit information from flight standards ASIs in the field (i.e. FSDO, CMO), ASEs must either obtain the information through the cognizant AEG or notify the AEG what information is being requested directly from the field.

b. Identify Potential Outcomes. You, the assigned ASE, must identify and document all important potential outcomes for the potential safety issue you're studying for further risk analysis. You may determine that the risk of an outcome is obviously negligible and in those cases there is no need to calculate or document it.

c. Calculate the Risk Value of Each Outcome. You, the assigned ASE, must use the directorate-specified product-specific risk analysis method (resulting in units convertible to fatal accidents) to calculate the quantitative probability, severity, and risk value for each important outcome. Calculate and record these risk values:

- (1) Total uncorrected fleet risk and
- (2) Uncorrected individual risk (per flight or per flight hour).

d. See table 1 on the next page for detailed descriptions of risk values. You, the assigned ASE, must attach the documents produced to calculate probabilities, severities and risk values for total uncorrected fleet risk and uncorrected individual risk (per flight or per flight hour) to the MSAD record containing the event information.

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 as the product of 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.
Uncorrected individual risk	Predicted risk per flight or per flight- hour.	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 may exist in future. Used to guide the decision for corrective action. 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, etc.) as separate populations for the individual risk.	Typically based on averages that apply to the fleet. However, there may 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.

e. Risk Analysis Requirements. You, the assigned ASE, must calculate the safety issue's risk values as specified in table 1 for each outcome in measures defined by the product

directorate and record in the MSAD record. Additionally, when calculating total uncorrected fleet and uncorrected individual risk, the units must be convertible to the number of fatal accidents for comparative purposes, whether or not an uncorrected risk guideline exists.

(1) To calculate the risk values of the issue you:

(a) Must evaluate the risk based on the directorate's methods and guidance for the particular product type.

(b) Must document the assumptions, methods and other supporting information describing how the probability and severity were determined.

(c) Must use risk analysis units consistently (e.g. events per flight hour or flight cycle).

(d) Must work with the applicable product directorate to gain conditional probability data that the directorate may compile as risk analysis "library data" for its products (e.g. hazard ratios, injury ratios).

(2) Some ACOs have negotiated agreements with certain certificate holders such that the certificate holder performs the risk analysis on behalf of the FAA. In those cases you must selectively review certificate holder risk analysis per the negotiated agreement to verify that the risk analysis meets the objectives of this section.

f. Determine Necessary Action. To assist you, the assigned ASE, in determining the type and/or need for corrective action (mandatory, non-mandatory or no action), you must compare the risk values calculated for the safety issue against the product directorate's risk guideline(s) for ADs or other mandatory corrective action. (The directorate's minimum requirement is to provide an uncorrected individual risk guideline). See figure 4, Risk Guideline Diagram.





2-10. Step 6.0 - Is Safety Issue Cause(s) Obvious. Getting back to figure 2, the MSAD process identifies and mitigates product risk from safety issues. The goal is to determine the product-related cause(s) for the safety issue. If the cause(s) is initially unclear, you, the assigned ASE, must conduct a structured causal analysis. "Structured" causal analysis means a causal analysis using a tool like Apollo root cause analysis (RCA) software. A structured causal analysis is not required on issues with an obvious cause and clearly identifiable fleet solution(s). Nonetheless you must still document the cause(s) using a non-structured approach applying engineering expertise and judgment. Fleet solutions include inspections, re-designs, limitations and/or other product/part corrective actions. In addition, consider doing a structured causal analysis in all cases for complex and/or high-profile safety issues. 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.

2-11. Step 7.0 - Perform Causal Analysis. As we stated, safety issues where cause(s) are not obvious and/or product/part corrective actions not easily identifiable require a structured method

to identify causes. The MSAD process prescribes this structured causal analysis approach. When you perform a structured causal analysis, you trace the chain of events, identify contributing factors and develop a list of candidate solutions.

a. Focus on identifying the part or product cause(s) that can be addressed using a "fleet" corrective action (AD, SAIB or other optional corrective action).

b. You may also identify other causes that contributed to the event. These "contributing factors" may include design, manufacturing, operations and maintenance failures. They may have surfaced from "people" and/or "process" issues in a manufacturer, designer or operator's organization. Causes may also include FAA process shortfalls. You should submit the causes to the appropriate organization for their review and corrective action. You should contact the appropriate product ASI when manufacturing, maintenance or operations issues are identified in the causal analysis.

c. Some ACOs have negotiated agreements with certain certificate holders such that the certificate holder performs the causal analysis on behalf of the FAA. In those cases you must selectively review the causal analysis per the negotiated agreement to verify that it meets the objectives of this section.

2-12. Step 8.0 - Document the Cause(s). Document the causes in the MSAD record using the causal taxonomy. MSAD requires you to document the output of a causal analysis, including at least:

- **a.** A problem statement (may be similar to the defined safety issue),
- **b**. Product/part causes,
- c. People/process causes, also called "contributing factors", if applicable, and

d. A causal analysis report (for structured causal analysis only), which is typically a document produced by a causal analysis tool in a standard format.

2-13. Identifying Causes and Contributing Factors

a. Causal analyses may 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, should submit these factors to the appropriate organization for analysis and possible action.

b. If you, the assigned ASE, identify that, outside MSAD, an operational, maintenance or manufacturing process is contributing to a safety issue; you should send your analysis results and safety issue information to the appropriate organization for review and action (e.g. AEG, MIO, MIDO, etc). You should follow-up to ensure that the organization understands and has sufficient information to address the safety issue.

2-14. Step 9.0 – Evaluate and Select Corrective Action for a Fleet Issue. You, the assigned ASE, based on the candidate solutions identified in Step 7.0, must identify candidate corrective action(s) and select the appropriate ones to reduce the fleet risk presented by the safety issue.

a. Identify Candidate Corrective Actions. Actions can range from initial mitigating to extensive final and terminating. You, the assigned ASE, must evaluate each candidate corrective action for its appropriateness and timeliness to mitigate the safety risk. Corrective actions typically are developed by certificate holders. Certificate holders typically submit these to the FAA and the FAA has the option of accepting, rejecting or developing alternative corrective action(s). When a certificate holder 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. Candidate corrective actions can include:

- (1) Inspections,
- (2) Part repairs or replacements,
- (3) Modification/kit installations,
- (4) Limitations,
- (5) Rework, and
- (6) Process/procedure changes.

b. Determine the Corrective Action vehicle. You, the assigned ASE, must calculate candidate corrective action (CCA) control program fleet and individual risk as defined in table 2 on the next page using paragraph 2-9.e.(1):

Risk Value	Definition	Purpose	Mathematical Basis
Control program fleet risk (See figure 5)	Risk within affected fleet while corrective action is taken (plus any residual risk not remedied by corrective action).	Helps risk managers evaluate candidate corrective actions against a maximum allowable risk value with respect to effectiveness and timeliness.	Computed as the product of 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 actual corrective action incorporation rate is unknown, estimate corrective action flights or flight-hours by using estimated time for AD issuance plus half the AD compliance time.
Control program individual risk	Predicted risk per flight or per flight- hour 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 risk managers evaluate candidate corrective actions against a maximum allowable risk value with respect to effectiveness and timeliness. 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, etc.) as separate populations for the individual risk.	Typically based on averages that apply to the fleet during the control program. However, there may 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.

Table 2 – Control Program Risk Value Definition, Purpose, and Mathematical Basis

Note: If you decide not to follow the recommended corrective action, you must document your decision and what you based it on. Attach supporting documentation to the MSAD record.





* Other = No action, or SAIB, or other optional corrective actions.

** NOTE: May include validation of a single available corrective action or no action.

*** All safety issues with a risk above two-thirds of the risk guideline or if recommending mandatory action must be reviewed by the CARB.

c. Evaluate AD candidate corrective actions using the Control Program Fleet Risk and Control Program Individual Risk Guidelines (CPRGs). This applies to AD candidate corrective actions only. Skip this task if you're proposing non-mandatory corrective action. You, the assigned ASE, should ensure that the candidate corrective action (or combination of corrective actions) 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 candidate corrective actions as a whole. Evaluate the corrective action plan for the total effect on the risk.

(2) If the risk of a candidate corrective action exceeds either fleet or individual CPRG, consider eliminating or revising the candidate by either accelerating the implementation (e.g. replacing at 'B' check rather than at 'C' check, or "inspect at 100-hr vs. 200-hr intervals") and/or adding/modifying corrective actions. Use the directorate-established CPR analysis method to determine the action's acceptability and timing by comparing it to the control program fleet and control program individual risk guidelines.

Note: When considering compliance times for mandatory corrective action, don't unnecessarily extend the compliance time even if doing so would keep the control program fleet or control program individual risk below the CPRG. Strive as possible to work within existing maintenance schedules.

d. Candidate Corrective Action Evaluation. You, the assigned ASE, must evaluate each candidate corrective action. Ideal candidates are inexpensive, easy to perform, implemented quickly, 100 percent effective at reducing risk and do not introduce substitute risk (risk of unintended consequences). Most situations don't meet these ideals. Therefore, you must conduct a short evaluation of candidate action(s) using effectiveness, cost, timeliness of implementation and complexity.

e. Select Preferred Corrective Action. Once you, the assigned ASE, have evaluated all candidate corrective actions against the attributes in paragraph 2-14.d., select the most appropriate one(s), balancing the attributes. You must document and submit your recommendation with all supporting documentation for review by the corrective action review board (CARB).

f. Interim Corrective Action. When taking only interim corrective action and developing no terminating corrective action, you must add a date and associated comment field to the MSAD record to revisit MSAD safety issue.

g. Terminating Corrective Action. When the terminating 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 paragraph 2-14.e. The CARB must review terminating actions not previously discussed in the initial CARB.

2-15. Corrective Action Review Board (CARB).

a. You, the assigned ASE, must present your recommended action, along with your risk analysis, causal analysis and quantitative evaluation of the risk reduction of corrective actions to the CARB for concurrence. The assigned ASE can elect to bring a given safety issue to the CARB prior to completing all analyses to provide awareness and obtain preliminary feedback. The goal of the CARB is to improve safety through better decision making. It does this by:

(1) Improving robustness by reducing the number of single thread safety decisions.

(2) Providing for cross-functional review, allowing others to raise concerns and contribute knowledge about a safety issue and proposed corrective action plan.

(3) Facilitating real-time, open exchange of safety issues across the key lifecycle disciplines among ACO, MIDO and AEG staff.

(4) 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.

(5) Increasing knowledge and experience in the AVS community.

Note: CARBs are designed to precede the AD process, not to replace it. CARB actions ensure a complete data package is submitted to the AD process.

b. CARB Applicability. All safety issues with a risk above two-thirds of the risk guidelines for AD or other mandatory corrective action, or if recommending mandatory corrective action when the risk is below two-thirds of the risk guidelines for AD or other mandatory corrective actions, must be reviewed by the CARB. Emergency ADs and FRCs can initially bypass a CARB review. However, after immediate actions are taken, the safety issue must go through the rest of the MSAD process, including the CARB. In rare cases where a CARB would be significantly delayed by lack of members and alternates, *and* where we must issue an AD, SAIB or other corrective action without further delay, the applicable ACO may allow a temporary bypass of the CARB. The CARB must review the corrective action during the next meeting. The CARB meeting minutes must be documented, and include attendees, subjects discussed, and decisions made.

c. ACOs Select CARB Participants. If you are an ACO manager, you're responsible for selecting and assigning representatives to CARBs, and for designating alternates for unavailable representatives. The ACO manager should coordinate with MIDO and AEG management to facilitate MIDO and AEG representation. The CARB should consist of the following personnel:

(1) ACO or responsible office manager.

(2) ASE or pilot assigned and presenting the safety issue.

(3) At least three other ASEs, one with experience in the safety issue and two others that support CARB technical discipline diversity. This requirement can be satisfied using program or branch managers with the appropriate experience.

(4) Representation from the AEG and MIDO/CMO.

(5) Other optional FAA representatives (such as standards staff, chief scientist and technical advisor, etc.) for a range of inputs to the safety issue corrective action.

d. CARB Attributes. The CARB should:

(1) Permit open discussion and not suppress dissenting technical opinions.

(2) Convene regularly as determined by the ACO manager (or their delegate) to ensure timely review of safety issues and enable participants to attend.

(3) If necessary, share resources across organizations and offices, and

(4) If necessary, use Web cast conferences and teleconferences to support the proper mix of expertise.

(5) If possible, reach consensus on a safety decision. In cases where consensus cannot be reached, the ACO or responsible office manager has final decision authority.

e. Factors not related to risk analysis. In rare situations, the ASE or FAA management may, based on factors unrelated to the risk analysis, make recommendations not consistent with risk guidelines for AD or other mandatory corrective actions. The decision to accept or reject these recommendations is made during the CARB. When this happens, the assigned ASE documents final decisions in the MSAD record. Factors not related to risk analysis must not be used to influence the objectivity of risk analyses. Remember that the risk analysis is intended as objective input into the decision.

f. Initiate Corrective Action. AD, SAIB and other corrective action processes are outside MSAD. They are defined in appropriate orders and the Quality Management System (QMS) process. Once the AD or SAIB is issued, the assigned ASE enters the corrective action information (AD number, SAIB number or other applicable information) into the MSAD record.

2-16. Step 10.0 - Submit to Process Owner for Further Analysis. Returning to step 10.0 of figure 2, assigned ASEs discovering causes identified in other AIR business processes (like certification and rulemaking) should communicate those causes to process owners for action.

2-17. Step 11.0 - Submit Cause to Certificate Oversight Process. Assigned ASEs who identify causes in the certificate oversight process, like design and production escapes, should communicate them to the certificate oversight representative for action.

2-18. Step 12.0 - Document and Submit Issue to External Organization. Flight standards, air traffic and other non-AIR FAA staffs may receive causal information from the MSAD process that identifies a specific condition in their business process or the certificate holders they oversee. The condition may warrant corrective action, as determined by their business process.

Note: When assigned ASEs submit information to flight standards ASIs in the field (i.e. FSDO/CMO), the assigned ASEs should either submit the information through the cognizant AEG or, at a minimum, notify the AEG what information is being submitted directly to the field.

2-19. Step 13.0 - Initiate AD, SAIB or other Corrective Action Process.

a. You, the assigned ASE, should use the risk analysis outputs to guide your decision whether or not to choose an AD, SAIB or other corrective action. If you select any of these options, start the corrective action process.

b. Developing and issuing corrective actions may require exchange of information and further MSAD process analysis. You, the assigned ASE, must use the MSAD process as a tool to track changes to the technical decision-making.

2-20. Step 14.0 - Prepare Internal Feedback to MSAD Process Owner (Optional). MSAD is part of the AIR QMS process. AVS MSAD users can submit feedback to the MSAD QMS procedure and associated work instructions by submitting a corrective action request (CAR), preventive action request (PAR) or nonconformance record (NCR) through AVS QMS Information Technology Support (QMITS) system.

2-21. Step 15.0 - Prepare COS Lessons Learned, as Necessary. Either a senior COS or assigned ASE must consider all safety issues to determine if the events, safety issues, risk analyses or corrective action selections are valuable teaching cases. If so, use the "Prepare COS Lessons Learned" function to capture the lessons.

Chapter 3. Follow On, Trending and Addressing Safety Events

3-1. Monitor and Validate. If you're an ACO ASE, you must monitor and validate the effects of corrective action in the fleet by monitoring in-service data to ensure that the risk has been properly mitigated (link B, figure 2). You can do this by identifying repeat and similar events using the MSAD record database. Also be alert for introduction of substitute risks due to unintended consequences of mitigating action.

3-2. Trending.

a. Data *trending* means collecting and monitoring existing data to identify items that meet specific criteria or exceed established guidelines. There are important reasons for trending data:

(1) Trending enables tracking known items to ensure that their rate of occurrence is not above established guidelines, and is consistent with the intent of the certification assumptions and analyses.

(2) As we said earlier, it's important to monitor the results of implemented corrective actions. We do this to verify that the implementation and results are as presumed, and that new problems weren't introduced by the actions.

(3) Finally, trending routine data can identify emerging safety issues. Note that this is challenging to implement. Items may appear to be an issue, but very few would likely result in an accident if uncorrected. Therefore, you have to carefully decide which data you'll trend and act on. If you, the assigned ASE, identify a potential safety issue (link C, figure 6), perform a risk analysis per paragraph 2-9. If you, the ASI, identify a potential safety issue, you must submit that information to the cognizant ASE, who will assess the fleet risk and take appropriate corrective action, as necessary.

b. Who Conducts Trending. Trend analysis can be conducted by all AIR personnel responsible for monitoring and addressing product safety risks, as needed. Although MSAD trending is primarily based on fleet level events, it doesn't prevent us from trending at the certificate management level, looking for trends in people/process causes. Safety events can initiate trending, or management can assign it periodically.

c. Identifying Trends. Trending activities can include:

- (1) Identifying items to trend (parts, products, failures and so forth).
- (2) Analyzing cross-product trends.
- (3) Tracking trends and items of significant interest.
- (4) Tracking repeat events similar failures that have occurred on multiple occasions.

Examples include:

- (a) Repeat part failures (within makes, models and series or across them),
- (b) High part replacement rates (within makes, models and series or across them),

and

- (c) Repeat safety issues (within makes, models and series or across them)
- (5) Identifying causes (during MSAD process).
- (6) 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. You should focus on anticipated concerns.

d. Figure 6 on the next page illustrates the trending process.



Figure 6. Data Trending Process Flow Diagram

Chapter 4. Applying Mandatory Continuing Airworthiness Information (MCAI) to Foreign Products

4-1. Introduction. At this point we have covered products designed and manufactured in the United States. This chapter clarifies how this order applies to safety issues on products designed and manufactured outside the United States.

4-2. Addressing MCAI. Mandatory continuing airworthiness information (MCAI) are documents issued by the civil aviation authority (CAA) of the other State of Design authorities, per ICAO Annex 8, to provide information regarding unsafe conditions on products designed or manufactured in other countries. FAA Order 8040.5, *Airworthiness Directive Process for Mandatory Continuing Airworthiness Information*, offers general guidance on MCAI. The FAA is reviewing the application of the MSAD process to foreign product COS oversight, and may make future changes to this order. Until such time, the ASE should use the guidance in FAA Order 8040.5 in addressing foreign product event data and not the guidance contained in this order. However, since the safety information contained in the MSAD event records, for foreign type certificate products, is routed to the cognizant office, the cognizant ASE may use this information to initiate dialogue with the foreign CAAs per FAA Order 8040.5.

Chapter 5. Roles and Responsibilities

5-1. Process Owner Responsibilities (AIR-140). The Delegation and Airworthiness Programs Branch (AIR-140) will organize inter-directorate meetings at least annually to review and discuss MSAD information and lessons learned. The agenda may include MSAD process support--make/model lists, hazard criteria, risk analyses methods and risk guidelines--which the directorates are responsible to develop and maintain. The agenda may also include any cross-product issues identified as part of the MSAD process. These meetings can be combined with other meetings, and must be documented in meeting minutes.

5-2. AIR-120 and AIR-130 Responsibilities. The Technical Programs and Continued Airworthiness Branch (AIR-120) and the Avionic Systems Branch (AIR-130) will have access to the MSAD data to determine if the TSO process or specific TSOs need changes to address emerging safety issues in the aviation fleet. Both branches will also participate in the interdirectorate meetings described in paragraph 5-1.

5-3. Directorate Responsibilities. Each directorate is responsible for developing and maintaining the supporting MSAD processes for their product type.

a. Develop hazard criteria. Directorates will develop a list of hazard criteria by product type and perform sampling per paragraph 2-6.b.

b. Develop risk measures and risk guidelines. Directorates will develop risk measures, risk guidelines and specify risk analysis methods.

c. Establish conditional probabilities. Directorates will establish for their product type (with assistance from ACOs) conditional probabilities of aircraft-level outcomes given a base event occurrence.

d. MSAD Process Maintenance

(1) Directorates must support the inter-directorate meetings described in paragraph 5-1.

(2) Directorate COS representatives must review hazard criteria samples (at least annually) and update hazard criteria as needed for their product type concerns. The results of this review should be recorded.

(3) Each directorate, coordinating with industry, may adapt their risk analysis methods and risk guidelines, as needed.

(4) Directorates must determine how often their conditional probability data is reviewed and revised.

5-4. ACO Responsibilities:

- **a.** Perform the MSAD process consistent with the product type.
- **b**. Develop and maintain fleet size and age estimates (cycles or hrs) for each model.
- c. Develop and maintain model utilization rates.
- **d**. Develop other basic data needed for risk analysis.
- e. Support the directorates as necessary in accomplishing their responsibilities.

Chapter 6. Background

6-1. AIR Safety Management System (SMS). The AIR SMS vision states, "AIR manages safety through a comprehensive systems safety approach, maximizing our value to aviation safety through influence and response to the changing aviation environment."

a. AIR SMS supports and aligns with AVS SMS requirements document 8000.367, *Aviation Safety (AVS) Safety Management System Requirements*, by establishing the MSAD process, which provides a safety risk management and safety assurance approach to AIR's continued operational safety mission. To achieve the AVS SMS vision and supporting goals, AIR decision-making processes need to evolve into an approach that's both quantitative and risk-based.

b. A mature AIR SMS will give AIR a holistic approach using risk-based processes to support an enhanced focus on safety. SMS represents the first time AVS and AIR have attempted to manage risk throughout the product life cycle. Before this, much of FAA risk analysis had been an isolated qualitative activity, lacking standard methods for analyzing and managing risk over time.

c. FAA Order 8040.4, *Safety Risk Management Policy*, establishes our safety risk management policy and requires all FAA lines of business to establish and implement a formal risk management program consistent with their role in the FAA. The order states:

"The FAA shall use a formal, disciplined, and documented decisionmaking process to address safety risks in relation to highconsequence decisions affecting the complete life cycle."

d. AIR SMS addresses the requirements in Order 8040.4. After setting up an FAA SMS that uses risk-based decision making tools and processes, we expect that industry will develop or coordinate a corresponding SMS compatible with our model and tailored to each company's needs.

6-2. Industry Interface and Applicability. MSAD effectiveness relies heavily on in-service data from operators, manufacturers and other certificate holders. This data sharing approach is risk-based, reflecting the SMS principle of being proactive by using data-driven analysis.

a. Accordingly, we have to develop MSAD interfaces with industry to foster data sharing. We expect that AIR offices, including headquarters, directorates and ACOs, will promote good working relationships with their respective industry stakeholders.

b. In addition, since certificate holders are routinely responsible for developing corrective actions for product or part hazards in the fleet, we should harmonize industry and FAA processes as much as we can. Harmonized processes promote common understanding of the fundamentals of continued operational safety: data analysis, hazard identification, risk analysis methods, risk guidelines, causal analysis and appropriate corrective actions. MSAD is defined so that MSAD process steps, except the decision and issuance of an AD or SAIB, could be performed by

industry for us when potential future SMS regulations that are applicable to certificate holders are in place. Some ACOs are working towards, or have in place, negotiated agreements with their certificate holders in which the certificate holder goes beyond statutory requirements and performs data analysis, hazard identification, risk analysis, causal analysis and corrective action development in accordance with the product directorate's MSAD objectives. In these cases, the FAA plays a critical oversight safety assurance role, as opposed to a safety risk management role.

6-3. Benefits of the MSAD Process. MSAD and its supporting tools and methods allow the current AIR COS process to evolve to a more risk-based, systemic, decision-making system. MSAD:

a. Identifies safety issues and related causes that determine product-related corrective actions.

b. Submits underlying process and people safety issues to certificate management, rulemaking and other business processes to enable a more complete aircraft life-cycle COS environment.

c. Enables consistent standardized measurable risk-based decision making for COS across AIR.

d. Quickly identifies safety trends using analysis of dependent variables (MSAD database).

e. Builds a COS model that exemplifies what the FAA would like to see from industry in the future.

6-4. MSAD Tool Support.

a. This order defined MSAD minimum *process* requirements, not *tool* requirements. The MSAD database, however, is a tool used to store event data according to MSAD-required taxonomy. An assigned ASE conducts the MSAD process using the database and other support tools to:

- (1) Access, collect and store safety information,
- (2) Guide users through the process,
- (3) Track completion of the process steps, and
- (4) Support risk, causal and corrective action analyses.

b. The database is intended to store all information input by the user, including calculations, analyses performed and technical decisions made for the MSAD record.

Appendix A. Definitions and Acronyms

Aircraft Certification Office (ACO)	The aircraft certification directorate's engineering operational element. This office administers and secures compliance with agency regulations, programs, standards, and procedures governing the type design of aircraft, aircraft engines, or propellers. It offers certification expertise on investigating and reporting aircraft accidents, incidents, and service difficulties. The term "ACO" refers to the Engine Certification Office (ECO), the Rotorcraft Certification Office (RCO), the Special Certification Office (SCO), the Airplane Certification Office (ACO), Military Certificate Office (MCO) and all other ACOs.
14 CFR	Title 14 of the Code of Federal Regulations
AD	Airworthiness directive
AEG	Aircraft evaluation group
AFS	Aircraft flight standards
AID	Accident and incident data
ASE	Aviation safety engineer
ASI	Aviation safety inspector
Assigned ASE	Directorate or ACO ASE with COS responsibilities for a specific aircraft or product safety issue.
AVS	Office of Aviation Safety
САА	Civil aviation authority
CAR	Corrective action request
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.
ССА	Candidate corrective action
CICTT	CAST/ICAO Common Taxonomy Team
СМО	Certificate management office

Condition	See "Safety Issue."
CPRG	Control program risk guideline. The upper limit of acceptable risk which assists the ASE in determining the adequacy, in terms of risk reduction, of a proposed candidate corrective action. These guidelines are characterized in terms of both fleet risk and individual risk.
Corrected risk	Residual risk that remains after corrective action is taken. When highly effective corrective action is taken, residual risk is considered to be zero. See also "Uncorrected Risk."
Corrective action	Any action to mitigate a safety issue. Includes mandatory actions like ADs and rule changes, to correct an unsafe condition. Includes non-mandatory actions and recommendations like SAIBs and Aviation Alerts. Includes actions that either directly corrects the safety problem and/or mitigates risk with operational limitations or restrictions, like grounding a product from further flight.
COS	Continued operational safety
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.
DAB	Daily alert bulletin
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 safety issue. The safety issue (or condition) is then evaluated for safety implications.
Fleet	Aircraft, engine or propeller products of a type currently in service affected by a certain safety issue.
FRC	Final rule request for comment
FSDO	Flight standards district office
Hazard	Any existing or potential condition that can lead to injury, illness or death to people; damage to or loss of a system, equipment or property or damage to the environment. A hazard is a condition that is a prerequisite to an accident or incident.
ICAO	International Civil Aviation Organization
IMS	Information management system. This refers to the MSAD workflow

	application and database, which constitutes the MSAD tool.
MCAI	Mandatory continuing airworthiness information
MIDO	Manufacturing inspection district office
ΜΙΟ	Manufacturing inspection office
MSAD	Monitor Safety/Analyze Data
NCR	Nonconformance report
NPRM	Notice of proposed rulemaking
NTSB	National Transportation Safety Board
Outcome	Result of an event, condition, or failure at aircraft level.
PAR	Preventive action request
Preliminary risk assessment	An initial assessment of the risk posed by a safety issue, 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 actual occurrences to the number of possible occurrences. For example, 1 in 1 million flight hours. Probability is often expressed with the denominator normalized to a single unit; therefore, 1×10^{-6} per flight hour. Probability can also be evaluated against total exposure of the fleet (or other relevant parameter); as in "40% probability that a failure will occur", or "an expected number of events, if the hazard is not addressed".
QMITS	Quality Management Information Technology Support
QMS	Quality management system
RCA	Root cause analysis
Risk analysis	Process whereby hazards are objectively characterized for their severity and probability. The process can be either qualitative or quantitative.
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 corrective action.
Risk	Expression of the severity and probability of an undesired event. See also "corrected risk" and "uncorrected risk."
Safety issue	Cause(s), contributing factor(s), or finding(s) that led to, or could lead to, an unsafe outcome. Safety decisions are rendered on issues/causes, not events. For example, investigation of an uncommanded flight control surface movementan eventmight reveal that the cause was a circuit failure in the autopilot's computer. Circuit failure is the safety issue/cause to evaluate for safety implications, and to take corrective action against.
SAIB	Special airworthiness information bulletin
SDR	Service difficulty reports
Senior COS ASE	The assigned ASE who performs the preliminary risk assessment and who has experience in COS duties. This person is not equivalent to senior engineers that exist in the ACOs. However, senior engineers may be qualified as senior COS ASEs.
Service bulletin (SB)	One type of "service document" (see below). In this order, the terms are synonymous.
Service documents	Publications by a type certificate 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 are flight manuals and certain maintenance manuals required for FAA type certification or approval. (Source: AC 20-114, Manufacturers Service Documents)
Severity	The consequence or impact of a hazard in terms of degree or loss or harm.
SMS	Safety management system
Taxonomy	For the purposes of MSAD, a standard industry language and set of definitions that improve the quality of information and communication within the aviation community.
TSO	Technical standard order
Uncorrected risk	Risk that accumulates over time in the affected fleet if no corrective action is taken for a certain safety issue. See also "corrected risk."

Appendix B. Administrative Information

1. Distribution. Distribute this order to the Washington headquarters division and branch levels of the Aircraft Certification Service and Flight Standards Service, to the headquarters division and regional divisions of the Flight Standards Service, to aircraft evaluation groups, to all Aircraft Certification Service Directorates and certification offices and branches. Distribute to manufacturing inspection offices (MIO), manufacturing inspection district offices (MIDO), manufacturing inspection satellite offices (MISO), all flight standards district offices (FSDO), aircraft certification and airworthiness branches of the FAA Academy, and the International Policy Office, AIR-40.

2. Authority to Change This Order. The issuance, revision, or cancellation of the material in this order is the responsibility of the AIR Delegation and Airworthiness Programs Branch (AIR–140). This branch will accomplish all changes, as required, to carry out the FAA's responsibility to provide guidance for the Monitor Safety/Analyze Data (MSAD) process.

3. Suggestions for Improvement. If you find deficiencies, need clarification or want to suggest improvements to this order, send FAA Form 1320-19, Directive Feedback Information, (written or electronically) to the Aircraft Certification Service, Administrative Services Branch, AIR-510, Attention: Directives Management Officer. You can also send a copy to the Aircraft Engineering Division, AIR-100, Attention: Comments to Order 8110.103. If you urgently need an interpretation, contact Delegation and Airworthiness Programs Branch (AIR–140) at 405-954-4374. Always use Form 1320-19, in appendix C, to follow up each verbal conversation.

4. Records Management. Refer to Orders 0000.1, FAA Standard Subject Classification System; 1350.14, Records Management; and 1350.15, Records, Organization, Transfer, and Destruction Standards; or your office Records Management Officer or Directives Management Officer for guidance regarding retention or disposition of records.

5. Related Federal Regulations and Publications.

- **a.** 14 CFR Part 39.
- b. FAA-IR-M 8040.1, Airworthiness Directives Manual.
- c. FAA Order 8040.1, Airworthiness Directives.
- d. FAA Order 8040.4, Safety Risk Management.

e. FAA Order 8040.5, *Airworthiness Directive Process for Mandatory Continuing Airworthiness Information.*

f. FAA Order 8110.100, Special Airworthiness Information Bulletin.



Federal Aviation Administration

Appendix C. Directive Feedback Information

Please submit any written comments or recommendations 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: Order 8110.107

To: Directive Management Office, AIR-510

(Please check 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 directive, 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:	Date:
Telephone Number:	_ Routing symbol:

FAA Form 1320-19 (10-98)