

**Clearance Record**  
**DOCUMENT COMMENT LOG**

<b>Originating Office:</b> AIR-140	<b>Document Description:</b> Draft Order, Monitor Safety/Analyze Data	<b>Project Lead:</b> Brett Portwood	<b>Reviewing Office:</b>	<b>Date of Review:</b>
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<b>Company &amp; Group</b>	<b>Page &amp; Paragraph</b>	<b>Comment</b>	<b>Rationale for Comment</b>	<b>Recommendation</b>	<b>Disposition</b>
Boeing	Cover page	<p>FAA: We describe how the Office of Aviation Safety (AVS) staff uses MSAD within the AIR Safety Management System (SMS) to identify and manage risk in aviation products.</p> <p><i>Comment: FAA needs to clarify how the MSAD order relates (or doesn't relate) to existing FAA Orders regarding SMS, and to potential future SMS regulation.</i></p>			<p>Concur. Words added to chapter 6 referencing order 8000.367.</p> <p>MSAD is an SMS sub process. Accordingly MSAD only relates to high level FAA SMS documents in that it adheres to and supports SMS principles.</p>
Boeing	<b>Para 2-3 (Page 2)</b>	<p><i>Comment: The high level view of MSAD depicted in Figure 1 on Page 3 indicates that an FAA Senior COS Aviation Safety Engineer (ASE) will work with other FAA AIR and AVS experts to "identify and evaluate candidate corrective actions...". While we recognize the need for FAA oversight, when the identified safety concern involves an aviation product discrepancy, the determination of appropriate and effective corrective action almost</i></p>			<p>Non-concur. The FAA agrees that significant involvement by the certificate holder is highly desired. Indeed, it is expected and understood that for the typical case the candidate corrective action being assessed by the FAA will have been provided by the certificate holder. Also note that the MSAD order describes an FAA internal</p>

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		<p><i>always requires the expertise of the product manufacturer or certificate holder and cannot be accomplished independently by the FAA. Shouldn't the substantial interaction between the FAA and the manufacturer be represented in Figure 1. High-Level View of MSAD?</i></p>			<p>process, so not all interactions with processes that are outside of the control of the FAA are shown. See para 2-2.b., which discusses industry involvement.</p>
Boeing	<p><b>Para 2-4 (Page 3)</b></p>	<p><i>Comment 1 of 2: The Draft MSAD Order shows an "MSAD record database" (Figure 2. MSAD Process Flow – Page 1) and indicates that "all event data, decisions, calculations, and information related to the MSAD process will be stored in the MSAD record database." While the concept of a national database that could aggregate aviation safety data and information from a variety of sources certainly is one way of advancing the data situation, the implementation presents considerable potential problems. Currently, in the course of considering and evaluating potential continued operational</i></p>			<p>Partially concur. The commenter may not have understood that the MSAD record database is for FAA internal use only (non-FAA entities will not have direct access to it), and all FAA employees are bound by strict data protection requirements. The FAA understands that some certificate holders may still have concerns and has provided a means to limit the access to voluntarily submitted MSAD records to a local FAA office. However, it is hoped that certificate holders would recognize that broader visibility within the FAA has safety</p>

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		<p><i>safety issues, the FAA legitimately requests and receives proprietary data and information from manufacturers. It is assumed that the FAA's intent would be to include proprietary data and information received from the manufacturer in the MSAD record database. Storage of manufacturers' proprietary data in a nationwide electronic database would create significant data protection concerns that would have to be addressed.</i></p>			<p>benefits, and would not demand these additional restrictions as a condition of continued submittal of voluntary reports and data.</p>
Boeing	<p><b>Para 2-4 (Page 3)</b></p>	<p><i><u>Comment 2 of 2:</u> Because of concerns over data protection, Boeing cover letters include the following conditional statements when proprietary data is transmitted to the FAA:</i></p> <p><i>“The information being forwarded to the FAA, by or with this correspondence, is considered proprietary to The Boeing Company, and is provided on a confidential basis. The data provided should be returned to Boeing immediately following use</i></p>			<p>No changes recommended, therefore no action required. The FAA agrees that there are significant concerns about data protection and that Boeing includes a standard conditional statement on proprietary correspondence.</p>

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		<p><i>by the FAA, including any copies thereof, which the FAA may be required to make in the course of its review. Boeing does not authorize the FAA to retain any portion of the materials being supplied.”</i></p>			
Boeing	<p><b>Para 2-5 (Page 6)</b></p>	<p><i><u>Comment 1 of 3:</u> The Draft MSAD Order proposes to collect and aggregate data from a variety of sources, presumably including mandatory reports from certificate holders, voluntary reports, and other sources. There is no standard taxonomy in current widespread use, nor required for mandatory reports. Modification of submitted reports to fit taxonomy standards could result in unintended changes to the meaning of reports, the potential for incorrect or misleading reports and resulting analysis, and the possibility for inappropriate action.</i></p>			<p>Partially Concur. The purpose of a standard taxonomy is to minimize misinterpretation of safety event data. We will not be modifying submitted reports.</p> <p>The database maintains separate fields for the as-submitted and the standardized taxonomy versions of the information. Restructuring reports into a standard taxonomy format will very rarely, if ever, result in changes to the factual information. The FAA also hopes that major contributors of COS data will voluntarily structure reports using the standard taxonomy.</p>

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Boeing	Para 2-5 (Page 6)	<p><i>Comment 2 of 3: The FAA states that the MSAD taxonomy is consistent with the FAA's CAST and ICAO common taxonomy team (CICTT) taxonomy. The CICTT has issued several taxonomy documents, including Phase of Flight Definitions and Aviation Occurrence Categories. Presumably, it's the latter to which the FAA is referring. Given that, it's not clear what value there may be in using a taxonomy that was developed to categorize accidents for event reporting.</i></p>			<p>Nonconcur. The MSAD development team evaluated all of the various existing taxonomies in use and determined that the CICTT provided the most value for our process. Although it may have been developed primarily for accidents, it can be used for describing other non-accident events in the fleet. The taxonomy gives us a standardized method of classifying and categorizing event data. Although CICTT is now limited in scope, the FAA intends to influence CICTT to add more detailed sub-taxonomies. In the meantime, MSAD will supplement the existing CICTT with other taxonomies, such as terms derived from the Service Difficulty Reporting (SDR) system.</p>

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Boeing	Para 2-5 (Page 6)	<p><i>Comment 3 of 3: The Draft MSAD Order describes a one-way data flow from the field to the database based on predetermined criteria. Many potential safety concerns require the gathering of data not normally considered reportable under the pre-established criteria, but required to accurately assess the potential of the perceived hazard. Without this supplemental data gathering ability, the true threat may be unquantifiable. In addition, investigative data such as DFDR, component failure analysis, etc., which is not initially available are usually required to establish cause scenarios which are essential to calculating hazard probabilities.</i></p>			<p>Non-concur. The initial event record is a one-way data flow, but once an investigation begins, the FAA expects to communicate with, and obtain significant data from, the certificate holder as required by FAR part 21. In addition, the FAA will communicate with and obtain data from airlines, operators, and other non-FAA entities.</p>
GE Aviation	Page 6 2.5c	<p>“We expect industry sources to increase as cooperative data sharing increases”, <i>once mechanisms to sanitize and protect data are finalized.</i></p>	<p>Concerns regarding data control and protection are widespread in the industry, and present a significant concern for increased data sharing.</p>	<p>Add italicized text</p>	<p>Partially concur. The commenter may not have understood that the MSAD record database is for FAA internal use only (non-FAA entities will not have direct access to it), and all FAA employees are bound by strict data protection</p>

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					<p>requirements. The FAA understands that some certificate holders may still have concerns and has provided a means to limit the access to voluntarily submitted MSAD records to a local FAA office. However, it is hoped that certificate holders would recognize that broader visibility within the FAA has safety benefits, and would not demand these additional restrictions as a condition of continued submittal of voluntary reports and data.</p>
Boeing	<p><b>Para 2-6 (Page 6)</b></p>	<p><i>Comment: The Draft MSAD Order proposes to utilize hazard (aka 'threat') criteria developed by each directorate standards staff to automatically or manually filter event data. Utilizing fixed criteria can potentially reduce workload, but safety data analysis and utilization still ultimately relies on trained, experienced, and knowledgeable individuals to effectively accomplish hazard identification.</i></p>			<p>Concur, no change requested or required. Furthermore the FAA recognizes that the organizations in the best position to accomplish hazard identification through review by skilled individuals are the certificate holders that have the capability. Because of this recognition, the MSAD database will not filter out any records coming</p>

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					from such a certificate holder (e.g., in accordance with a formal COS working agreement).
GE Aviation	Page 7 2.7	<p>“The assessment should take advantage of whatever data is immediately available”</p> <p><i>Quantitative risk assessment may not be possible at this stage.</i></p>	<p>In some cases, there is insufficient data available to provide any kind of risk assessment immediately after the event. The process as a whole should take this into account, and allow for action without a risk assessment, a delay in action while information is gathered to enable a risk assessment, and also a change in corrective action as new information becomes available. A good discussion is available in section 6 of AC 39-8</p>	Add italicized text	No action required. See definition of preliminary risk assessment in glossary.
GE Aviation	Page 7 Para 2-7b(1)	<p>Add specifics to the step “Is this a potential safety issue?” The definitions of “event” and of “safety issue” are currently so broad that they include almost everything.</p>	<p>Risk assessment is a valuable tool in shaping consistent, rational response to in-service issues. It is also a very labor intensive process, typically requiring many iterations before a stable understanding</p>	<p>Change the wording “Is this a potential safety issue” to “Would this issue in isolation likely result in a fatal accident? Would it likely result in a fatal accident in combination</p>	<p>Nonconcur. Although we agree risk assessment can be a labor intensive process, we expect the appropriate level of effort to be achieved thru training and coordination with industry. Note that at this point</p>

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			<p>of failure mode, root cause and risk level is arrived at. Universal application of the MSAD process could overwhelm both FAA resources and industry data infrastructure, and divert attention from the highest priority risks. Limiting the scope of the events to be analyzed – at least for the initial version of the order – will allow FAA personnel to become experienced in the process and to identify gaps and areas for improvement, before universal application of the process.</p>	<p>with one frequently encountered adverse circumstance, or with one Probable additional failure?” (The bounding criteria above were selected, in part, to allow twin engine aircraft to fly.)</p>	<p>in the process, you are still in the preliminary risk assessment phase, not the more thorough, quantitative risk assessment that occurs later in the process.</p>
GE Aviation	Page 8 2.9	<p>“you perform the risk analysis by determining the total uncorrected fleet risk and the uncorrected individual risk (per flight or per flight-hour) and comparing them to directorate-defined risk <i>guidelines</i> for the product type. “</p> <p>Clarification is needed here</p>	<p>The term “uncorrected fleet risk” is ambiguous. It can be interpreted as “the risk if no control action – past or future – were in place”, which will give an unrealistically inflated risk. More realistically, it can be interpreted as “the risk if already existing control actions are/ continue to be implemented”</p>	<p>Instead of the term “uncorrected”, say “fleet risk with existing control actions.” Or provide clarification in a footnote. Also, correct the glossary and table 1.</p>	<p>Non-Concur. If voluntary compliance to an existing SB is established and supported by data, then you can account for the existing control actions by adjusting the affected fleet numbers.</p>

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Boeing	Para 2-9 (Page 8)	<p><i>Comment: The Draft MSAD Order proposes that FAA will continuously accomplish safety risk analysis activity (e.g. quantification of safety risk) to identify potential airworthiness and safety concerns regarding delivered products, and safety risk assessment (determination of acceptability of the risk) for identified concerns. FAA should retain this analytical capability as part of exercising effective oversight of manufacturers, but should not intend to duplicate in every case the analysis and assessment that should be routinely accomplished by the manufacturer. FAA should propose to inspect, review, audit, and oversee a manufacturer's safety risk analysis activity. FAA should maintain the capability to independently accomplish safety risk analysis, and should do so in some cases, but should not intend to duplicate each safety analysis which should be accomplished by the manufacturer. In fact, in Chapter 1, there is the stated</i></p>			<p>Concur, no action required.</p> <p>The FAA does not intend to duplicate in every case the analysis and assessment of certificate holders. Ideally certificate holders would submit useable analysis in a timely manner; in cases when they do not the FAA must be able to intervene and either work to obtain suitable analysis from the certificate holder or independently perform the analysis. Since some safety issues are very critical and urgent, the FAA's ability to quickly identify cases where it needs to intervene must be maintained.</p> <p>The FAA agrees that the certificate holders are ultimately responsible for safety and that the FAA's role is to regulate and to oversee. However, in many cases, FAA needs in terms of</p>

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		<i>expectation that the ...industry... take responsibility for the safety of their products.</i>			the content of a risk analysis and the necessities of regulatory risk management are wider in scope and supplement those addressed by a single certificate holder's processes.
Boeing	<b>Para 2-9 (Page 8)</b>	<i>Comment: The Draft MSAD Order instructs the FAA ASE to compare the total uncorrected fleet risk, and uncorrected individual risk to "directorate-defined risk guidelines for the product type." The result would presumably be used to determine the necessity of mandating corrective action (e.g. by Airworthiness Directive). The directorate-defined risk guidelines would become de-facto regulation (without public comment) defining an acceptable level of safety for in-service products, and prescribing AD action for issues where the guidelines are not met.</i>			Non-concur. Airworthiness Directives in accordance with part 39 are, and will remain a discretionary prerogative of the Administrator. The MSAD risk analysis and risk guidelines serve only to provide additional data to assist in making informed discretionary decisions. There are currently no regulations that limit or even hint at any limitation to the Administrator's prerogatives in this regard. Further, there will be no de facto regulation without public comment, as each individual AD goes through a formal rulemaking process which includes public comment

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					either before rulemaking or after rulemaking in those cases where the urgency of the issue precludes an advance comment period.
GE Aviation	Page 8 figure 3	The term “negligible” is not defined anywhere in the document	Is the outcome negligible based on severity? On probability? On comparison to guidelines?	Clarify the intent of the term	Partially concur. The negligible risk is based on severity and probability as compared to the risk guideline. Sentence added to 2-9.e. to clarify.
GE Aviation	Page 8 figure 3	The flowchart requires consideration of combinations of outcomes. This is hard to interpret. The flowchart should be clarified.	The outcomes may be mutually exclusive, so that combinations are not physically possible. Or outcome combinations may be physically possible, but highly unlikely. The intent of the flowchart is unclear.	Reword flowchart footnote to say ” A single event may have multiple undesired outcomes; this should be accounted for with appropriate conditional probabilities”	Concur. Footnote changed to recommended wording
Boeing	<b>Para 2-9 (Page 9)</b>	<i>Comment: The Draft MSAD Order, in Table 1, provides a definition, purpose, and mathematical basis for calculation of uncorrected fleet risk, uncorrected individual risk, and control program fleet risk. The Draft Order, as written, insinuates that a single, correct numerical</i>			Partially concur.  The FAA does not believe that there is a single, correct numerical answer. These are probabilistic calculations that have varying amounts of associated uncertainty (and

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		<p><i>answer is available as the result of a simple calculation for each issue. Quantitative safety risk calculations used for evaluating continued operational safety issues typically involve multiple indeterminate variables and require experienced judgment for accomplishment, and critical review for the acceptance of analytical results and resulting recommendations. Much more detailed guidance would be required for the safety analysis practitioner, and a formalized review process would be necessary to reliably benefit from the analysis results.</i></p>			<p>the answer and the uncertainty can change as more data becomes available). Also the mathematical model of any given safety issue is dependent upon the qualitative understanding of the issue by the analyst. These points are understood by the FAA.</p> <p>The order is not intended to provide all the guidance needed to learn and perform risk analysis; additional training and guidance will need to be provided separately, and there is a plan to do so.</p> <p>MSAD requires a Corrective Action Review Board (CARB) for all AD issues; one of the functions of the CARB is to review the risk analysis.</p>

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Boeing	Para 2-9 (Page 9)	<p>FAA: c. Determine the Risk Value of each Outcome. 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 these risk values:</p> <p><i>Comment: Risk value in units that are “convertible” to fatal accidents implies that some measure other than the probability of an accident is the default risk measure. See comment on ‘defacto regulation’ in Para 2-9 (Page 8) above.</i></p>			<p>Partially concur. The implication that there are other measures than the probability of a fatal accident was intended.</p> <p>See disposition of de facto regulation above.</p>
Cessna	Pg 8 para2-9.c.	<p>In Section 2.9c, the draft MSAD referred to quantitative probability, severity, and risk value for safety items. Although the MSAD is the oversight organization, how much of the quantitative risk analysis will be pushed to be worked by the OEMs? The data that the MSAD would be looking for is usually proprietary to the manufacturers,</p>			<p>No action required. There is no requirement at this time to required OEMs to perform risk assessments on behalf of the FAA. However, we encourage that the ACOs work with their major TCHs in developing local COS partnership agreements. Many ACOs</p>

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		and is not meant for public knowledge.			<p>already have such agreements in place. Future requirements may be promulgated based on the one-rule SMS ARC activity that has recently been started. The MSAD data is for FAA internal use only (non-FAA entities will not have direct access to it), and all FAA employees are bound by strict data protection requirements. The FAA understands that some certificate holders may still have concerns and has provided a means to limit the access to voluntarily submitted MSAD records to a local FAA office. However, it is hoped that certificate holders would recognize that broader visibility within the FAA has safety benefits, and would not demand these additional restrictions as a condition of continued submittal of voluntary reports and data.</p>

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GE Aviation	Page 11 2.9e	<p>“Calculate the safety issue’s risk values using all the important risk values calculated for each outcome. You will use both the total uncorrected fleet risk and the uncorrected individual risk (per flight or per flight hour). When determining the risk value, define severity units so they can be converted to fatal accidents.” Add the following notes: Risk models should be consistent with observed experience. Underlying assumptions, data, and analytic techniques should be identified and justified</p>	As noted in AC 39-8 section 7, justification of the inputs to a risk model is important in order to get accurate results.	Add wording: Risk models should be consistent with observed experience. Underlying assumptions, data, and analytic techniques should be identified and justified	Partially concur. Similar wording added to 2.9e.
GE Aviation	Page 13 2-11	Causes identified by the causal analysis should be specific to the issue, verifiable and actionable.	The more general the cause, the less closely it is associated with the issue and the more difficult it is to develop corrective action. Causes such as « fatigue », « complacency » or « organizational structure » are frequently alleged, difficult to verify or rule out, and almost impossible to address.	Add wording “Causes identified by the causal analysis should be specific to the issue, verifiable and actionable. »	Partially concur. No action required. Although the primary purpose of MSAD is to address acute safety issues at the aviation product level, a secondary purpose is to dig deeper into the causal chain for the purposes of documenting underlying issues. Although these underlying issues are difficult to address using AD’s, they can be trended

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					using the MSAD database and addressed using more strategic corrective action such as rulemaking, industry outreach programs, etc.
GE Aviation	Page 13 2-11 and 2-12	Causes should be identified by stating the problem, rather than jumping to a solution.	By stating the cause in terms of a solution, options to address the cause may be neglected. Example: "Lack of training in recognizing engine surge" presupposes a solution "training"; other options such as automation might also be effective.	Add wording "Causes should be identified by stating the problem, rather naming a solution."	Nonconcur. Nowhere in the order do we state that you identify the cause by 1 <sup>st</sup> identifying a solution. The order states that you trace the chain of events (which characterizes the causal path), which describe the problem then develop a list of candidate solutions, which could be training, automation, etc.
Cessna	Pg 14 para 2-14	In Section 2.4 Step 9, do the OEMs bear the responsibility for causal analysis and potential corrective actions, or does the MSAD process allow the FAA to propose their version of corrective action and hold the OEMs to that proposal? I believe the intent was to define the level of corrective action (AD, SAIB, etc), but the wording is vague and may be interpreted any number of ways.			Partially concur. Para 2-14 edited to clarify. The CCAs can be developed by certificate holders just like current practice. These are submitted to the FAA and the FAA has the option of accepting, rejecting or developing their own CCA(s). All CCAs, whether they come from a certificate holder or other source are

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					evaluated. There is no intent to negate this current practice. However, the MSAD process documents this more rigorously.
GE Aviation	Page 16	Evaluation of candidate corrective action should also consider the risk of unintended consequences.	Corrective actions involving line maintenance intervention have introduced maintenance error in the past, resulting in higher risk than the original issue and sometimes causing fatal accidents	Modify table 2 to clarify that substitute risk is included, not just risk of ineffective execution of the corrective action	Partially Concur. Although Table 2 was removed, we included substitute risk in the new word.
GE Aviation	Page 16	Candidate corrective actions may be based upon existing actions such as manufacturers service documents.	This approach reduces conflict and confusion.	Add wording “Candidate corrective actions may be based upon existing actions such as manufacturers service documents.”	Concur. We added similar language to para 2-14.a.
Boeing	<b>Para 2-14 (Page 16)</b>	<p>FAA: Note: Choose control program compliance times to reduce the risk at the earliest reasonable opportunity. Don’t unnecessarily extend the times, even if doing so would keep the control program risk below the CPRG (control program risk guideline).</p> <p><i>Comment: Reduce risk at the</i></p>			Partially concur. The definition of “earliest reasonable opportunity” was deliberately left vague as it is a discretionary determination. Even so, the FAA would welcome more data to help it make this determination.

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		<p><i>earliest reasonable opportunity – there is no guidance provided for “reasonable” opportunity. In addition, there is no mention of manufacturer or operator input – timing of available hardware, time to perform the task, rework scheduling, etc., all require consideration in order to not generate an unnecessary burden on the operators.</i></p>			<p>Certificate holder input will be considered.</p>
Boeing	<p><b>Para 2-14 (Page 17)</b></p>	<p>FAA: f. Select Preferred Corrective Action. Once you have evaluated all candidate corrective actions, select the most appropriate one, balancing the attributes and emphasizing risk reduction. Document and submit your recommendation with all supporting documentation for review by the corrective action review board (CARB).  <i>Comment: The FAA does not often develop or select solutions for airplane related issues. It is suggested that this paragraph be re-worded to better differentiate FAA and manufacturers’ roles</i></p>			<p>Concur. Words added to various paragraphs to convey Safety Risk Management and Safety Assurance principles. The FAA agrees. The FAA expects the typical case to be that the certificate holder has performed trade studies and is recommending one corrective action plan to the FAA for evaluation.</p>

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		<i>when selecting corrective action.</i>			
Boeing	<b>Para 3-1 (Page 20)</b>	<p>FAA: Monitor and Validate. If you're an ACO ASE, you should monitor and validate the effects of corrective action in the fleet by monitoring in-service data.</p> <p><i>Comment: It is suggested that this paragraph be re-worded to better define 'monitoring', since specific queries (of airlines) may be necessary for some high-risk issues, as opposed to 'passive monitoring'.</i></p>			Nonconcur. The types of specific queries that Boeing mentions are outside of the MSAD process and are mostly conducted by our flight standards counterparts.
GE Aviation	Page 20 3-2	Trend data should be critically reviewed to avoid changes in reporting being mistaken for changes in fleet behavior		Add wording from comment.	Nonconcur. No action required. Good point, but we already address in para 3-2 a. (3) that you have to carefully decide which data you'll trend and act on. This can be addressed thru training, not necessarily as a requirement in the order

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Boeing	<b>Para 3-2 (Page 20 and Figure 6, Page 22)</b>	<p>FAA: Trending.</p> <p><i>Comment: Developing and validating trending tools is not a trivial task. It probably should have its own block on Figure 6.</i></p>			<p>Partially concur. No action required. We agree that trending is not a trivial task. However, as trending is currently envisioned within MSAD, a special block is not needed, since the MSAD process and database already allows for trending data for a wide variety of safety issues.</p>
Boeing	<b><u>Chapter 4, pg 23</u></b>	<p><i>Comment: It isn't clear how the underlying risk assessment methodology developed by the TAD would be applied to airplanes of non-US design (e.g. COSM); this point is important as a world-wide standard should be the direction of the future.</i></p>			<p>Non-concur. In most cases the airworthiness authority of the country of manufacture is, by bilateral agreement, responsible the continued operational safety of aviation related products. Accordingly those authorities will use the internal process of their choosing. The MSAD process will only apply to foreign products when the FAA considers unilateral airworthiness action on a foreign product or disagrees with the foreign authority's determination in a particular case.</p>

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Boeing	<b>Para 5-3 (Page 26)</b>	<p>Directorate Responsibilities. Each directorate is responsible for developing and maintaining the supporting MSAD processes for their product type.</p> <p>5-3.b. Directorates will develop risk analysis methods and guidelines.</p> <p><i>Comment 1 of 2: By allowing each directorate to establish their own risk analysis methods and guidelines, Boeing may be held to different safety thresholds depending on which directorate they're dealing with, typically TAD or EPD. Safety standards should not be up to each individual directorate. Those standards need to be coordinated between TAD and EPD so that there is one regulated standard of safety that fits within the design regulations that were applied to certified airplanes.</i></p>			<p>Nonconcur.</p> <p>Having different risk guidelines for airplanes and for engines does not pose any significant difficulty, as only one directorate (either the TAD or the EPD) will ultimately be responsible for the AD.</p> <p>Part 21 makes a clear distinction between meeting certification standards and the FAA's discretionary determination that the product is "safe." For example, to receive a type certificate in accordance with part 21.21 it is required that all airworthiness requirements be met (deterministic determination) <i>and</i> that no feature or characteristic make it unsafe (discretionary determination). To receive airworthiness certificate in accordance with part 21.183 requires conformance to the type design (deterministic</p>

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					determination) <i>and</i> being in a condition for safe operation (discretionary determination). ADs in accordance with part 39 are, and will remain, discretionary—there is no threshold or standard for their issuance. The only criteria necessary for an FAA unsafe condition finding (discretionary determination) is that the unsafe condition exists in a product and is likely to exist or develop in another product of the same type design.
Boeing	<b>Para 5-3 (Page 26)</b>	<i>Comment 2 of 2: Risk analysis methods and guidelines are already well established in the industry and have been validated by service experience.</i>			Nonconcur. Although some certificate holders have quasi-numerical, probabilistic risk guidelines in place, and the FAA has generally agreed with the certificate holder recommendations, it is also not uncommon for the FAA to disagree with the certificate holder's initial

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					<p>recommendation, and to require a faster or more extensive corrective action program; this is especially noteworthy in urgent cases. Therefore, the level of safety achieved is not due solely to the certificate holder's guidelines.</p> <p>Furthermore, there is no uniform risk analysis methodology or guidelines used throughout industry. The actual application varies between certificate holders</p>
GE Aviation	Page 27 6-2b	Delete " <i>MSAD is defined so that MSAD process steps, except the decision and issuance of an AD or SAIB, could be taken by industry for us when appropriate.</i> " Replace by . " <i>The existence of this order does not place any requirement on the certificate holder to collect data, to follow the MSAD process or to perform any specific risk analysis.</i> "	By defining the MSAD process very closely, and creating an expectation that industry perform will perform the process on behalf of the FAA, the order is equivalent in impact to rulemaking outside of process. Rulemaking on this subject is being instigated as part of the SMS rule; the process outcome should not be anticipated.		Nonconcur. The MSAD order does not place requirements on industry. No rulemaking is being performed with the MSAD order. The sentence as written does not mandate any actions, and includes the word "could" to indicate the actions are optional at this time.

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Boeing	Para 6-2.b (Page 27)	<p>FAA: 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.</p> <p><i>Comment: We agree with the notion of harmonized processes (related to) . . . risk guidelines and methods.. The concern is related to the apparent opposite point made several times in other paragraphs, that of each directorate developing their own risk guidelines</i></p>			<p>Non-concur.</p> <p>By “harmonizing” we mean “by product type”. It was never intended that there is a single method and guideline for all products since each product has it’s own unique hazards and levels of acceptable risk.</p> <p>However, the FAA desires as much standardization as possible, and expects coordination between the directorates to occur over time.</p>
Boeing	Para 6-2.b (Page 27)	<p>FAA: MSAD is defined so that MSAD process steps, except the decision and issuance of an AD or SAIB, could be taken by industry for us when appropriate.</p> <p><i>Comment: We agree with this</i></p>			Concur. No action required.

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		<i>point; development of action is the manufacturers' responsibility, and the process steps inherent in much of MSAD already exist at Boeing.</i>			
Boeing	<b>Para 6-3. (Page 27)</b>	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.  <i>Comment: The MSAD process will not ensure that AIR COS process evolves to a more risk-based process without working together with the OEMs.</i>			Concur. No action required. In working together, the FAA must maintain its role of regulator and overseer. This is the fundamental tenet of SMS: that industry supports SMS by providing FAA the appropriate level of data to support risk-based decision making.
GE Aviation	General concern	The MSAD process outlined is very labor intensive. The FAA may not have the resources or data to execute sound, defensible risk assessments for the range of issues raised. There is a potential for the number of risk assessments performed to adversely affect the validation of each assessment. There should be a process whereby the quality of risk assessments is	Risk assessments typically progress iteratively; first with very simple assumptions and minimal data, and then – if needed – progressively better researched assumptions and additional data. The process of iteration, of refining assumptions and collecting additional data, is labor intensive and time consuming.	Introduce an audit process for the assessments conducted under MSAD, in accordance with the National SMS Standard.	Nonconcur. Internal auditing is normally part of an external quality process outside the scope of a business process order and is covered within the AVS QMS environment. Also the CARB is another method that could result in improvement of RA. The FAA will also be

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		<p>validated (i.e. the calculated risk is of the correct order of magnitude). An audit process should be developed for identifying and correcting systemic errors or systemic unrealistic assumptions in assessments (if multiple assessments from one source have an unrealistic risk prediction, this should not be allowed to continue.)</p>	<p>It is important that risk assessments used to determine action be valid predictions of fleet behavior, rather than simplified worst-case bounds on risk. (Getting the correct order of magnitude is important – third significant figure of risk is less so). Each assessment must find a balance between timeliness and refinement of the risk model.</p>		<p>working with qualified certificate holders who perform the risk analysis on behalf of the FAA.</p>
Boeing	General comment	<p>This Draft Order appears to confuse the boundaries between the FAA, the OEMs and the airlines, in the sense that it seems to assume that the FAA has a completely independent ability to assess risk. While we agree that the FAA must maintain its independence, much of the data and information needed to assess and mitigate risk comes from the OEMs and the airlines. For this reason, the FAA has traditionally played an oversight role. Boeing plays a similar role with the engine OEMs. When Boeing deals with engine issues, we typically use the</p>			<p>Partially-concur. No changes incorporated</p> <p>The FAA agrees that much of the data and information needed to assess and mitigate risk comes from the OEMs and the airlines (for airline related products). The FAA encourages certificate holders (OEMs) to provide a suitable risk analysis and supporting data for FAA review, or analyses data for direct FAA use,. Also note that the MSAD process is for</p>

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		<p>engine manufacturers' risk assessment analyses because we recognize that they have the most detailed information necessary to perform those analyses.</p>			<p>all product types, and there are occasions when certificates have been surrendered. There may be other occasions where a certificate holder is not adequately carrying out their continued operational safety responsibilities. For those occasions the FAA must have the ability to independently assess risk.</p> <p>The FAA disagrees. Transport Airplanes and airplane engines have separate and unique type certificates and have unique considerations for how they are managed. Having different risk guidelines for airplanes and for engines does not pose any significant difficulty, as only one directorate (either the TAD or the EPD) will ultimately be responsible for an AD.</p>

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Cessna	General	<p>This proposed process encompasses many organizations within the FAA. Would this have the potential of slowing down the corrective actions that Cessna usually takes when determining a field issue? Safety-of-flight items are usually resolved and the resulting Service Bulletins mailed and partially implemented before an AD is ever issued. If the FAA now has the opportunity to propose corrective action, would Cessna then need to wait to deploy its solutions?</p>			<p>Clarification. No action required.</p> <p>There is no intention of delaying service bulletin issuance. It is expected that the cert holders will continue to work with their local ACOs in developing corrective action to address safety issues in the fleet.</p> <p>Coordination that has traditionally occurred on the safety issue will continue to occur.</p> <p>It is expected that the ACOs will work towards more negotiated agreements with their cert holders such that any of the MSAD steps will be performed by the cert holder, based on their safety management capability maturity. In this case, the efficiency of fielding corrective actions should improve.</p>

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Boeing	General comments	<p>In addition, though it is commented on below in the by-paragraph section, it's so important that it should be mentioned in these general comments as well – paragraph 2-9 discusses the idea that each directorate would define their own risk guidelines. While this may be appropriate for different aircraft types (say, large transports vs. helicopters), it is not appropriate for related-type directorates. For example, the Seattle ACO and the New England ACO should have like risk guidelines, as the products they oversee are 'like-types'.</p>			<p>Partially-concur. No changes incorporated</p> <p>The FAA agrees that much of the data and information needed to assess and mitigate risk comes from the OEMs and the airlines (for airline related products). The FAA encourages certificate holders (OEMs) to provide a suitable risk analysis and supporting data for FAA review, or analyses data for direct FAA use,. Also note that the MSAD process is for all product types, and there are occasions when certificates have been surrendered. There may be other occasions where a certificate holder is not adequately carrying out their continued operational safety responsibilities. For those occasions the FAA must have the ability to independently assess risk.</p>

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					<p>The FAA disagrees. Transport Airplanes and airplane engines have separate and unique type certificates and have unique considerations for how they are managed. Having different risk guidelines for airplanes and for engines does not pose any significant difficulty, as only one directorate (either the TAD or the EPD) will ultimately be responsible for an AD.</p>