DISPOSITION OF PUBLIC COMMENTS

POLICY MEMO. NO. ____________________, TITLE Transport Airplane Risk Assessment Methodology

General Response to Public Comments
We wish to thank all those who took the time to provide constructive comment to the *Transport Airplane Risk Assessment Methodology (TARAM) handbook*. As noted below, we have considered all comments and implemented those suggested changes that will lead to improvement of the process. Some of the provided comments are philosophical in nature and/or outside the scope of the guidance contained in the handbook. Many of these types of comments would have been better addressed during the comment period for FAA Order 8110.107, *Monitor Safety – Analyze Data* (MSAD), issued March 12, 2010, and effective September 15, 2010. The risk-analysis process described in the TARAM handbook reflects requirements contained in the MSAD Order and cannot be changed in a manner that would conflict with that order. Some comments reflect an incomplete understanding of Title 14, Code of Federal Regulations (14 CFR) and associated guidance, or FAA Transport Airplane Directorate (TAD) policy concerning those regulations. Accordingly, we have prefaced this comment disposition with brief descriptions of regulations, guidance, and policy in areas that were frequently misinterpreted, per misstatements in the comments.
G-1 – Monitor Safety – Analyze Data (MSAD) All commenters requested changes to the TARAM that would not be consistent with the requirements of the MSAD process. In 2004, the FAA Aircraft Certification Service (AIR) began an initiative to revise internal processes to introduce a Safety Management System (SMS) philosophy and structure. As part of that initiative, the MSAD Order was issued on March 12, 2010, after public review, and became effective September 15, 2010. The order defines a standardized Continued Operational Safety (COS) process to be used throughout FAA AIR. The order is based on and adheres to the SMS concepts and precepts required of an AIR SMS process. In line with AIR SMS requirements, the MSAD process requires that each AIR product directorate develop a risk-analysis methodology and accompanying risk guidelines. The risk analysis must be developed such that it is quantitative or able to evolve to being quantitative. Also, the result of the analysis processes must be convertible to risk in terms of the probability of a fatal accident so risk can be compared across AIR products and services. The risk-analysis process must be applicable to any potentially unsafe COS issue, e.g., airplane systems, structures, flight controls, etc. Beyond the high-level AIR SMS requirements outlined above, the MSAD Order also contains requirements for the risk factors that must be calculated and recorded when a safety issue reaches the risk-analysis stage of the process. Those risk factors, as defined in the MSAD Order, are: Total Uncorrected Fleet Risk, Uncorrected Individual Risk, Control Program Fleet Risk, and Control Program Individual Risk. Calculation and documentation of the specified risk factors, in a manner compliant with the high-level, risk-analysis requirements described above, is not optional in the MSAD Order. The TARAM handbook fully supports and complies with all of the risk-analysis requirements in the MSAD Order. The handbook defines a risk-analysis process that is quantitative to the extent possible for each situation, and it will become more quantitative as additional supporting data is obtained. The TARAM handbook also contains risk guidelines structured to reflect the goals of the FAA in terms of risk (reduce the present accident rate) while also limiting the risk to individuals aboard transport airplanes. The risk values calculated using the TARAM are directly convertible to the risk of a fatal accident as required by AIR SMS and the MSAD Order.

G-2 – Development of TARAM and AIR SMS Risk Analysis Requirements

GE, Boeing, Bombardier, and AIA/GAMAamma question how the COS risk-assessment approach fits into a SMS approach.

In the past decade, the FAA began to recognize that traditional approaches to assessing the risk associated with transport-airplane COS issues were not adequate in two major areas:

1. In cases of high-profile, high-severity, potential safety issues where traditional risk-assessment methods could be applied, the results were not specific or granular enough to provide any value to FAA management in determining the urgency or scope of response necessary, e.g., conservative analyses in terms of hazard categories generalize risk and blur the actual differences between hazards.
2. No correlation exists between traditional risk assessment practices across functional areas such as structures and systems. A result of this disconnect was further confusion regarding the relative urgency and scope of response necessary between cross-disciplinary COS issues.

Due to the rapid and unprecedented growth of the transport-airplane fleet, the FAA recognized that major changes would be necessary in the COS area. It was apparent that the FAA needed to have better processes for identifying and correcting emerging safety issues to accomplish agency safety goals. With transport-fleet growth and increased safety emphasis, the FAA also recognized that continued use of conservative and extremely risk-adverse approaches to safety decision-making would overburden both the resources of TAD and those of industry and operators.

As a result, in 2002, TAD chartered a multi-directorate team to develop a COS risk-analysis process that, to the extent possible, could be applied uniformly for all transport-airplane COS issues. The process was also required to be granular and specific enough to fulfill FAA management needs for high-profile, high-severity, potential safety issues. Another goal for the process was to facilitate much finer and more detailed risk-level decision-making in transport-airplane COS so as to better balance FAA/industry resources and FAA safety goals. The methodology outlined in the TARAM handbook represents the results of that team's work.

As outlined in G-1 above, in 2004, AIR began an initiative to revise internal processes to introduce an SMS philosophy and structure to all AIR internal processes. AIR undertook the SMS initiative for very much the same reasons as the TAD chartered the original risk-analysis-methodology development team. AIR recognized that, without major changes in the processes used within the service, fleet growth would eventually overburden AIR resources in ways that could affect overall fleet safety, and that implementation of an SMS was the best way to address that issue.

A major feature of an SMS is decision-making based primarily on risk. Accordingly, a large part of developing AIR SMS processes was the development of a risk-assessment methodology within each process. AIR developed a Risk Analysis Specification (RAS) to guide the development of AIR SMS-process risk analyses. To accomplish AIR SMS goals with respect to risk analysis, the RAS requires that risk-analysis processes be quantitative (in both probability and severity) or structured in such a way that they can evolve to be quantitative as necessary data is obtained. The RAS also requires that the results of AIR SMS risk-analysis processes be (quantitatively) convertible to the probability of a fatal accident for comparison across AIR products and processes.

It is very important to understand the difference between the FAA's internal SMS activities and the SMS that is being explored for application within design and manufacturing organizations. Specifically, through the MSAD Order, the FAA has defined an internal process by which we will conduct structured risk management, including the methodology to be used by Aircraft Certification Offices, to determine whether in-service events represent unsafe conditions and the appropriate timeframe within which mitigating action should occur.

As applied to design and manufacturing organizations and the SMS pilot project activities, the FAA is looking to explore how SMS implementation would benefit overall safety within the national airspace system. A basic tenet of this activity is that the FAA is developing performance-based standards that allow companies maximum latitude in developing their own internal procedures. It is also important to note that we are focusing on hazard identification at design and manufacturing organizations well upstream of the in-service events that are the focus of the MSAD activity. We do not see any conflict between those two activities. In fact, if SMS is properly implemented within the design-and-manufacturing community, resulting in early hazard identification and appropriate risk controls, we expect a reduced need for the FAA to exercise MSAD-related risk analysis because hazards will already be mitigated before an event occurs in-service.

G-2 – Development of TARAM and AIR SMS Risk Analysis Requirements (cont.)

One feature of the TAD risk-analysis process that has not changed since early in development was the characterization of risk in terms of fatal injuries. The TAD position (see AC 39-8 Appendix E), for many years, has been that the severity of transport-airplane outcomes is directly proportional to the associated fatal injuries. Accordingly, the risk factors and guidelines defined in the TARAM handbook are all structured in terms of the rate, probability, or expectation of fatal injuries. While opinions may vary on the use of fatalities as a risk-analysis severity measure, the TAD believes that it is the best quantitative measure for accomplishing TAD, AIR SMS, and MSAD Order risk-analysis requirements.

G-3 - 14 CFR Part 21 Regulations

GE, Boeing, Fokker, Embraer, AIA/Gamma, and Bombardier implied that a compliant airplane is, by definition, a safe airplane, and that a continued operational safety program should be focused on restoring compliance. Part 21 provides the regulatory requirements that direct FAA type design, manufacturing, and airworthiness approvals. In accordance with part 21, the FAA issues an approval when the applicant complies with the associated specific requirements *and* the FAA (Administrator) finds that the product or part is “safe” for the intended use. Paraphrasing § 21.21, the FAA issues a type certificate when the applicant shows that the product meets all the applicable CFR requirements and, ***§ 21.21(b)(2) For an aircraft, that no feature or characteristic makes it unsafe for the category in which certification is requested.*** This separation of the concepts of overall airplane safety and certification compliance is echoed throughout part 21. No 14 CFR regulations limit, in any way, the criteria the FAA can or should use to make such safety determinations. Assuring compliance to the airworthiness regulations is a very important part of aviation safety; however, nowhere in part 21 or anywhere else in the regulations is it stated or implied that compliance with the airworthiness regulations *alone* is sufficient to establish the safety of an aircraft. The wording and separate statement of the requirement outlined in § 21.21(b)(2) clearly means that a fully conforming and regulation-compliant design can be found to be “unsafe” by the FAA. Through § 21.21(b)(2), the FAA can require elimination of any known unsafe features prior to certification even when those features comply with the regulations. When the FAA determines that an unsafe condition exists after type certification, the provisions contained in part 39 require corrective action. In such cases, part 21 has regulations that outline type-certificate-holder responsibilities.

It is long-standing TAD policy that corrective action can and should be required when an unsafe condition is determined on a type-certificated, fully compliant airplane model. Conversely, per § 21.99, the TAD does not use part 39 to enforce the continued compliance of type certificated transport-airplane models, e.g., a discovered airworthiness regulation noncompliance is not automatically deemed unsafe and remedied by mandatory corrective action unless the noncompliance is determined to be an unsafe condition.

G-4. § 25.1309 Certification Requirements

GE, Boeing, Fokker, Embraer, AIA/Gamma, and Bombardier state that severity, characterized in terms of broad hazard categories and the probabilities provided in AC 25.1309-1A, should be the basis for the methodology and risk guidelines in the TARAM handbook. The certified safety level actually required for § 25.1309 compliance is quantitative, very stringent, and doesn't allow a design with an anticipated "catastrophic failure condition" in any given period of operational time. We evaluated the possibility of using the design risk assessments and design thresholds for COS, but determined that the level of conservatism is widely variable from one analysis to another, which would blur differences between hazards. Consequently, we were not able to develop a way of achieving consistent, comparative MSAD Order-compliant risk values using design-certification risk-assessment methods.

Regarding the quantitative numbers used as part of the § 25.1309 compliance process outlined in Advisory Circular (AC) 25.1309-1A: the provided values are not and never have been FAA goals or thresholds for the actual risk of as-built transport airplanes. Per the explicit wording in the AC and the documented intent of the authors, the quantitative values "may" be compared to risk values derived using the explicitly conservative analytical methodology outlined in the AC. That comparison, again as outlined in the AC, is ***"used to support experienced engineering and operational judgment and to supplement qualitative analysis"*** during certification of certain airplane systems. The AC-defined process is qualitative and based on the "fail-safe" design philosophy. It includes consideration of design documentation (drawings, test results, etc.), qualitative analysis (e.g., common cause, failure modes and effects, human factors, etc.), and design assurance (e.g., software, complex hardware). The overall finding "may" be supported by a prescriptively conservative quantitative analysis. The result is a finding that each catastrophic failure condition that could result from the functionality of the system being analyzed, alone, is "extremely improbable" and, likewise, each major failure condition is improbable. As defined in the AC, "extremely improbable" means that a (functional) catastrophic failure condition is **"not anticipated to occur during the entire operating life of all airplanes of one type."** The finding ***does not*** mean that the likelihood is less than 1e-9 per flight hour. We expect that due to all the additional considerations and the conservative quantitative analytical approach that the actual probability of a particular failure condition will be far less thatn the ones listed in the AC. Further, we expect the probability of an actual airplane outcome, which might be termed a "catastrophe" as the result of a "catastrophic failure condition," to be even less. This expectation has been validated by the operational history of systems certified based on the means of compliance provided in AC 25.1309-1A. Accordingly, declaring the AC numbers to be safety thresholds, even in certification, would be a step back from the actual achieved safety level.

In accordance with the intent and actual wording of AC 25.1309-1A, the TAD has published policy stating that a quantitative analysis that compares favorably to the quantitative values in the AC, alone, is not sufficient to show compliance for the requirements in § 25.1309(b).

Again, just as the TAD does not recognize the quantitative values in AC 25.1309-1A as the expected probability of occurrence of system failure conditions, or as the definitive of the qualitative safety requirements in § 25.1309, those values have not been, and are not accepted as, definitive safety thresholds in COS decision-making for transport-category airplanes.

G–5 - AC 39-8, Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes

AC 39-8 provides guidance that is limited to powerplant installations. The guidance describes a COS risk-analysis/management process with accompanying risk-level thresholds for use within the scope of application of the AC. Embraer, Bombardier, Fokker, and Bob Mattern asked why we did not use the same risk-management methodology and thresholds as provided in AC 39-8. Conversely, Bombardier took issue with the perceived similarity between AC 39-8 and the TARAM handbook.

Risk-level thresholds are provided in AC 39-8 for risk levels up to CAAM level 4. The CAAM levels are generally comparable to the hazard categories in draft versions of AC 25.1309-1 and in EASA guidance, e.g., CAAM level 4 is analogous to the “Hazardous” category (the implied-severe major category in AC 25.1309-1A) and CAAM Level 5 is defined in AC 39-8 as the same as the “Catastrophic” hazard category in AC 25.1309-1A. AC 39-8 does not contain risk-level thresholds for CAAM Level 5. Embraer implied that the risk-level guidelines, defined in the AC for CAAM level 4, should be acceptable for CAAM level 5 (extremely severe) hazards. The FAA does not accept a 10% probability of an extremely severe transport-airplane outcome for any period of time regardless of the risk-analysis methodology used.

The TAD considered the approach in AC 39-8 when developing a COS risk-assessment method, and determined that this approach does not provide the granularity desired for determining priorities and compliance times. For example, all other things being equal, we want to correct a condition leading to in-flight break-up prior to less-severe outcomes. So, rather than bucketing diverse outcomes into levels, we use the single event probability of fatality, i.e., “injury ratio,” to characterize severity, which essentially creates a continuous scale of “levels” based on the historical severity of the potential outcomes.

GE and Bob Mattern asked how the TARAM handbook and associated processes impact users of AC 39-8. The risk-analysis methodology and guidelines contained in Advisory Circular (AC) 39-8 (with some additional considerations) remain in effect for transport airplane Engine and Auxiliary Power Unit COS issues, e.g., those issues administered and resolved under the direction of the AIR Engine and Propeller Directorate (EPD).

Accordingly, the impact that the TAD policy will have on present practices at transport-airplane engine manufacturers will be minimal.

G-6 – Individual Risk

GE, Boeing, Bombardier, Bob Mattern, and AIA/Gamma requested various changes to the way the Individual Risk values in TARAM are determined. FAA Order 8110.107 requires that Uncorrected Individual Risk and Control Program Individual Risk be calculated and documented as part of the risk analysis process. Individual Risk is defined in the MSAD Order as, "Predicted risk per flight or per flight hour" – 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." In line with the MSAD Order requirements, Individual risk in the TARAM handbook is calculated in terms of the probability per flight hour that an exposed individual will be fatally injured. The TARAM handbook provides guidance for how "you can calculate individual risk including special conditions and combinations of conditions, or for subsets of the fleet, for example by model or usage" are considered. To preclude theoretical calculation of unrealistic "worst case" individual-risk scenarios, the TARAM handbook explains that only "special conditions and combinations of conditions" that significantly increase the risk per flight hour, and that are known to occur on a reasonable number of future flights, should be considered.

Although several commenters have assumed that the guidance calls for calculation of individual risk in terms of the specific risk to "individual" airplanes, the handbook does not. Specific risk associated with individual airplanes is not the intended result either in the MSAD Order requirements or the TARAM handbook guidance. Other commenters have suggested that the term, "a reasonable number of future flights" be objectively defined. Based on commenter concerns we have added additional guidance in the TARAM handbook explaining that, when calculating individual risk, a reasonable number of future flights is 10 or more.

Other commenters have taken issue with the guidelines for individual risk in the TARAM handbook, labeling the guidelines "arbitrary" and "extremely conservative." We do not agree with either characterization of the guidelines. Based on NTSB data over the last five years, the average risk of individual fatal injury per flight hour, experienced by passengers on transport airplanes operated within the U.S., is on the order of 1e-8. To achieve that average, we assume that commercial airplanes in the U.S. generally operate in a one-order-of-magnitude risk band around that average, e.g., between a fatal-injury risk level of 1e-9 and 1e-7. Accordingly, we did not believe that the risk associated with a single COS issue should result in risk above 1e-7. We did not separately factor in the contribution of airplane related causes into the average fatal injury rate. Had we done so, the band would have been at least an order of magnitude smaller (1e-10 to 1e-8).

The FAA then considered what individual risk level might necessitate consideration of urgent action. We did not believe that commercial passengers expect or should be exposed to risk levels on the order of 1e-5. That life-risk level is comparable to that experienced by motorcycle riders, and those 80 years old and above. We concluded that urgent action should be considered halfway between the 1e-5 level and the 1e-7 safety level, or 1e-6. Again, we did not include the lesser contribution of airplane related causes to the average fatal injury rate or the cumulative risk aspects associated with other, uncorrected safety issues. Accordingly, we believe the risk levels to be generous rather than extremely conservative and they were not arbitrarily selected.

G-7 – EASA GM 21A.3B(d)(4)

Fokker, Bombardier, Bob Mattern, and Boeing questioned why we did not adopt or harmonize with the EASA method documented in GM 21A.3B(d)(4). We considered this approach in 2002 when we began development of TARAM, and determined that this approach did not meet our needs. First, the EASA part 21 rules are not consistent or harmonized with the wording and intent of the requirements in 14 CFR part 21, so adoption would have been contrary to existing FAA rules and policy. Secondly, the EASA method, like AC 39-8 (as outlined in G-5 above), did not meet FAA needs with regard to the granularity and accuracy when determining the need for FAA action. In addition, the risk thresholds provided in the EASA guidance, when compared to values derived using a non-conservative risk-analysis methodology, are not consistent with the safety goals of the FAA. Finally, the EASA-defined methodology does not meet the risk-analysis requirements in FAA Order 8110.107.

DISPOSITION OF PUBLIC COMMENTS

POLICY MEMO. NO. ____________________, TITLE Transport Airplane Risk Assessment Methodology

Comment	Requested Change	Disposition
Commenter: General Dynamics, Letter A&C-11-089, dated February 22, 2011		
GD-1a **General Policy Document Comments** On Page 16, in the table CP = Conditional Probability has foot note 4 shown, but there is no foot note 4 in the document.		The FAA concurs with the commenter and will correct this item.
GD-1a-i On Page 25, referenced foot note 7 refers to paragraph 5.2 for risk variable definitions. Paragraph 5.2 is Process Overview, while paragraph 5.3 is Definitions & Formulas which contains the risk variable definitions.		The FAA concurs with the commenter and will correct this item.
GD-1a-ii On Page 50, paragraph E.2.3, Frequency. Math in paragraph seems to be incorrect. The example given in the paragraph references a Acme fleet with approximately 36,000 flight hours and that there are two PECU's on each aircraft and therefore the accumulated PECU flight hours was 4 X 720,000 = 2,880,000. This just does not seem correct.		The FAA concurs with the commenter. The ACME Model 10P has four PECUs and the FAA will change the description accordingly.

DISPOSITION OF PUBLIC COMMENTS

POLICY MEMO. NO. ___________________, TITLE Transport Airplane Risk Assessment Methodology

Comment	Requested Change	Disposition
GD-1b **General Policy Comments** The intent of this policy document is to provide detailed directions for performing COS analyses, and includes guidance on corrective action requirements based on the outcome of the analyses. This implies that when the analysis procedures are followed appropriately, the recommendations that are generated will be accepted by the FAA. However, the policy then states that the FAA reserves the right to make a determination regardless of the analysis outcome. This statement appears to rescind the guidance in the policy.		The guidance in the TARAM handbook supports the safety decision-making process described in FAA Order 8110-107, MSAD (see G-1, above). In that process, risk is the primary consideration, however it is not the only one. In some cases, it may be in the public interest to require corrective action for issues with risk lower than the TARAM handbook risk guidelines. Conversely, in some cases, the FAA will choose to accept higher risk than the TARAM risk guidelines indicate because of other considerations such as cost, industry disruption, national interest, etc.
Commenter: GE Aviation, Letter, dated February 24, 2011		
GE-1a … past successful introduction of quantified risk assessment has been preceded by extensive research and consensus-building on the data forming the basis of risk assessment assumptions. We are concerned that implementation of TARAM may be hindered by major technical disagreements unless this consensus dataset is prepared in advance.		See G-1 and G-2, above.
GE-1b We would also like to better understand the relationship between TARAM and SMS implementation. SMS is currently being positioned as allowing the use of existing systems and processes with equivalent functionality. If TARAM is being introduced to facilitate the FAA's internal implementation of SMS, does this introduction reduce the ability of manufacturers to use their existing Continued Airworthiness processes?		See G-1 and G-2, above. The FAA is implementing an internal SMS as described. By doing so we are not restricting the ability of manufacturers to use their existing COS processes. We want manufacturers to be aware of how the FAA will be assessing COS issues with regard to risk. We encourage manufacturers to perform their own assessments, and take actions they feel are appropriate, in addition to those that the FAA mandates.

DISPOSITION OF PUBLIC COMMENTS

POLICY MEMO. NO. ____________________, TITLE Transport Airplane Risk Assessment Methodology

Comment	Requested Change	Disposition
GE-2 Handbook; 3.1 and other paragraphs "Total uncorrected fleet risk. The number of weighted events statistically expected in a defined timeframe (the remaining life of the affected fleet) if no corrective action is taken as a result of the identified hazard." **Uncorrected risk:** The workbook is framed to address the necessity for FAA action to control the risk. The role of the TC holder and operator in controlling the risk should also be taken into consideration. The TC holder may have instigated their own risk control program before the FAA addresses the issue, such as by issuing a service bulletin or changing the production design. If this is the case, then calculating an "uncorrected risk" as though these measures were not in place will artificially inflate the apparent risk. This question has led to considerable debate in the past. We also suggest that the risk assessment take into account normal fleet maintenance processes, even if not mandated by CMR or AD, provided that a realistic effectivity or compliance percentage is assigned to those processes.	We suggest that the phrase "uncorrected risk" not be used, since it introduces ambiguity, and that some other phrase such as "current risk" be used.	The FAA partially concurs with the commenter. The risk-factor names used in the TARAM handbook are the same as those required by FAA Order 8110-107 (see G-1, above). It would be inappropriate to describe risk factors differently in the handbook, a supporting, lower-level document. We agree that TC-holder actions and normal fleet-maintenance processes should be accounted for in the calculation of uncorrected risk values. The risk factors are defined as uncorrected only from the viewpoint of what the risk would be if the FAA takes no action, e.g., does not issue an AD. The TARAM risk analysis should fully account for any voluntary actions that have been, or will be, accomplished in the affected fleet. We have addressed this issue during TARAM training within the FAA and clarified the expectation in the handbook.

Comment	Requested Change	Disposition
GE-3 Handbook section 5.5 "…..It may be necessary in some cases to apply the data and assumptions in the analysis to predict past events and compare the result to the actual historical record to determine the validity of the risk values." We would like stronger emphasis to be placed on consistency of the risk model with the events which have actually occurred.	: We propose the following wording from AC 39-8 be incorporated into the handbook." *If a quantitative method is used, it is essential that the analysis calibrate with the experience to date. A quantitative risk analysis cannot be expected to credibly predict into the future if it does not calibrate to actual experience*."	The FAA partially concurs with the commenter. We agree that, when possible, TARAM risk values should be validated against the applicable historical record. We expect such validation to occur whenever engineering judgment is used to a large extent in determining TARAM risk values. In many cases, TARAM risk values will be calculated based on relevant historical data for both probability and severity. Such calculations are a direct extrapolation of the past into the future and are self-validating. In other cases, not enough relevant historical data will be available to effectively validate the risk analysis results. We will clarify the wording in section 5.5 to further describe validation expectations although, rather than the AC 39-8 wording, we will use wording more reflective of the TARAM.
GE-4 Handbook 3.1 and elsewhere "90-day uncorrected risk" and "Control program uncorrected risk." The number of *fatalities* statistically expected in a defined timeframe (90 days & throughout the control program) as the result of an identified hazard. The requirement to estimate 90 day risk should be re-evaluated. When a potential safety issue initially arises, the technical details – root cause, failure mode and statistical failure characteristics – are often unknown, and a period of data-gathering is necessary before risk analysis can be performed. The "90 day risk" concept assumes that all the data necessary for a risk assessment is immediately available, which is generally not the case.	Add the wording from AC39-8, "*It is quite possible that, immediately following a potentially severe event, the likelihood of its recurrence cannot be adequately estimated. If it is possible to take immediate, practical, mitigating action while an initial assessment is being made, that action should be taken.*"	As outlined in G-1 above, the MSAD process defined in FAA Order 8110.107 provides direction for how COS issues are administered in the FAA. The MSAD Order directs the responsible engineers to take immediate corrective action for urgent unsafe conditions (see Order 8110.107, paragraph 2-7). The TARAM risk assessment occurs later in the MSAD process (see Order 8110.107, paragraph 2-9) at a point in that process where enough information has been obtained to accomplish the TARAM analysis, and can occur after the issuance of an emergency AD or immediately adopted rule. Note: The 90-day risk value provides a snapshot of the current risk (90 days was chosen, but any relatively short time period could have been used). This value is used only for prioritization of safety issues within the TAD and is not used in the MSAD process for safety decision-making.

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GE-5 Handbook 1.1 and elsewhere “The risk guidelines described here do not, and are not intended to, correspond with or correlate to any airworthiness rule, standard, or guidance” The risk guidelines should be compatible with initial certification; the intention is to control risk until the product can be returned to the level of safety intended at certification. In particular, a newly certified product with no identified concerns should not immediately require an AD to meet the TARAM guidelines. It appears that the guidelines, by attempting to address instantaneous peak risk on individual tail numbers, may conflict with the initial certification requirements.	The risk guidelines should be reviewed to ensure that they are compatible with initial certification requirements for risk.	See G-3 and G-4, above. The FAA has no probabilistic 14 CFR part 25 certification requirements, nor any part 25 requirements that pertain to the as-built safety of any transport airplane. There is also no provision in 14 CFR part 21 that equates certification alone to overall product safety. The FAA believes that the safety level intended at certification is the one achieved within the U.S. type-certificated transport-airplane fleet operated within the United States. Accordingly, the guidelines contained in the TARAM handbook are structured to be commensurate with that demonstrated safety level. Paragraph 1.1 in the TARAM handbook contains wording that precludes its use in certification or re-certification. The disclaimer was added to allay the type of concerns expressed here. The FAA believes such concerns arise from misunderstandings about 14 CFR part 25 airworthiness requirements (see G-3 and G-4 above) and the role the TARAM handbook plays in the COS process (See G-1 and G-2 above). TARAM will not be applied outside FAA ~~discretionary~~ safety determinations made as part of Order 8110.107. We agree that a newly certified product with no identified concerns should not require an AD to meet TARAM guidelines. We have not found any realistic situation in which this would occur, nor has any commenter presented us with such a situation. The TARAM handbook does not attempt “to address instantaneous peak risk.” See G-6 above.

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Comment	Requested Change	Disposition
GE-6 Handbook table 1, "uncorrected individual risk : "The highest probability per flight hour that an exposed individual will be fatally injured that is expected to occur during a reasonable number of future flights." The intent not to expose any passenger at any time to undue risk is clear. However, the ability of statistical tools to estimate risk degrades as finer discrimination is requested, either by time or by sub-population (the confidence bands expand rapidly to the point where prediction is impracticable). Fleet or sub-fleet average risk is likely to be more meaningful (a closer estimate to reality) than is an attempt to estimate individual aircraft risk.	Remove the expectation of calculating risk to individual aircraft. We also request that the phrase "*reasonable number*", which appears several times in the handbook, be clarified, since what is "reasonable" varies greatly between individual perceptions.	The FAA partially concurs with the commenter. See G-6, above. Individual risk, as required by the MSAD Order and defined in the TARAM handbook, does not represent an attempt "to estimate individual aircraft risk." The intent of the analytical process defined in the handbook is that individual risk be based on fleet average frequency and probability unless significantly higher risk factors are associated with "special conditions and combinations of conditions.[1]" If that is the case, the higher values are used to calculate individual risk. Individual risk in the TARAM handbook is not, nor intended to be, analogous, or similar to the certification related term "specific risk." We will further clarify this in the TARAM handbook wording.
GE-7 Handbook section 5.3, footnote: "The term "fleet" refers to all airplanes on which the condition under study could occur and that are similar enough in equipage, design, and/or operation that they can be considered together in a risk analysis. The term can refer to all transport category airplanes or to a single, identifiable airplane." Statistical approaches are inherently based on addressing a population rather than an individual. Estimates of risk applied to very small populations acquire very large confidence bands, so that the estimate becomes of very limited use. In particular, we do not believe that management of risk by selecting an individual perceived as "high risk" for corrective action is an effective strategy. We recommend that the proposal to assess risk for an individual airplane be removed, to ensure statistical validity.	Replace by "the term can refer to all transport category airplanes or to a much smaller subfleet; attempts to estimate risk should address populations rather than individuals."	The FAA partially concurs with the commenter. See GE-5 and G-6, above. The TARAM handbook does not define a method for calculating the risk associated with an individual airplane within a group. In the referenced footnote, the term "fleet" is defined within the context of exposure to the "condition under study." We removed the reference to a "single airplane" because the FAA does not issue ADs for single airplanes, however, if the same failure, defect, or malfunction can only occur on a small number of airplanes, then that small number constitutes the fleet. Alternately, if the same failure, defect, or malfunction can occur on multiple models of transport airplane, they all represent the "fleet" and require a single risk analysis or multiple risk analyses that cumulatively cover all the affected airplanes. To avoid further confusion, the FAA reworded the footnote.

[1] FAA Order 8110.107, MSAD

Comment	Requested Change	Disposition
GE-8 Handbook Appendix A, definitions: ***"Foreseeable—****A qualitative expression of likelihood. It signifies a greater likelihood than "physically possible," but less likelihood than "not expected to occur in the life of the affected fleet." An event or condition is foreseeable if it is theoretically possible, and if knowledgeable persons cannot reasonably rule out its occurrence during the exposure in question."* Defining "foreseeable" as so unlikely that it would never occur in the life of the fleet appears contrary to normal usage and historic practice. A foreseeable event is defined (Merriam-Webster Legal) as "*such as reasonably can or should be anticipated: such that a person of ordinary prudence would expect to occur or exist under the circumstances*" Since the proposed definition appears to introduce significant controversy, and since the term foreseeable has been used extensively within the regulations, it would be better to avoid introducing a new understanding of the term by a handbook definition. If a definition is desired, Chapter 1 would be an appropriate location for a generally used term.	Remove definition of "foreseeable"	The FAA concurs with the commenter.
GE-9 Handbook Appendix E, example E.2: " Acme determined that the fleet had approximately 36,000 flight hours on the incident date. Since each Acme 10P airplane has two PECUs the accumulated PECU flight hours was 4 x 720,000 = 2,880,000 ….The ASE then determined the expected time between burn through failures to be 2,880,000/2 = 1,440,000."	Arithmetic error; the accumulated PECU hours would be 2 x 36,000. The rest of the calculation would be changed accordingly. Suggest that the remaining calculations and formulae should be re-checked also. Suggest that the wording of the example be clarified to distinguish more clearly between failures, burnthrough failures and burnthrough failures leading to fires.	The FAA partially concurs with the commenter. The ACME Model 10P has four PECU's and the FAA will change the description accordingly. We believe that the wording in E 2.1 and E 2.2 sufficiently distinguishes between burn-through failures and burn-through failures leading to fires in the example problem.

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POLICY MEMO. NO. ___________________, TITLE Transport Airplane Risk Assessment Methodology

Comment	Requested Change	Disposition
Commenter: Fokker Services Letter 11.51015, dated 24 February 2011		
FS-1a In aviation industry it is a common rule to use the 25.1309 approach for assessing risks. Thanks to this common standard, the aviation industry stakeholders have been able to promote and to attain a safety level which is unmatched in any other business.		See G-1, G-2, G-3, and G-4, above. The FAA agrees that, prior to the TARAM handbook, the FAA had no published method for assessing continued-operational-safety risk for transport-category airplanes, and that some in the industry have used a modified AC 25.1309-1A safety-assessment method as part of their internal COS programs. The FAA has never employed an AC 25.1309-1A, e.g., “25.1309 approach” in making safe/unsafe determinations for transport airplanes.
FS-1b Assessing risks and safety promotion are thus closely connected to each other. Fokker Services is therefore surprised about this sudden "change of insight" and complete new philosophy about assessment of risks in the so called "TARAM Handbook".		See G-1, G-2, G-3, and G-4, above. The TARAM handbook provides guidance for accomplishing the risk analysis step in the MSAD Order Process for transport airplane COS. The TARAM handbook does not reflect a “change of insight” or “complete new philosophy.”
FS-1c-i The guideline states e.g. *"The risk guidelines described here do not, and are not intended to, correspond with or correlate to any airworthiness rule, standard, or guidance",* which is unacceptable for Fokker Services. This complete disconnection between the design safety standards and the TARAM Handbook approach for judging in-service events cannot be justified by any reasonable consideration.		See G-1, G-2, G-3, and G-4, above. The method outlined in the TARAM handbook for “judging in-service events” is required by FAA Order 8110.107. We will clarify this statement in the handbook to further explain that the approach to design-certification is different and not comparable to the TARAM approach to assessing COS risk as required by FAA Order 8110.107. Our intent in the subject sentence is to reassure the public that TARAM results would not be used for design certification.

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FS-1c-ii Accepting this would mean that the Authority can apply this TARAM Handbook while industry must use the common 25.1309 approach. This can lead to conflicts between the two and will certainly not contribute to an increase in safety. On the contrary, it will most probably create a gap between industry and authorities leading to a decrease in safety due to misunderstanding and differences of insight.		As required by FAA Order 8110.107, the FAA will use the TARAM handbook as part of MSAD process when performing the ~~discretionary~~ safety-decision responsibilities defined in 14 CFR part 21 and 39 (see the G-3 disposition, above). Industry is required to show compliance to § 25.1309 for design certification, and the method in AC 25.1309-1 is one approach to compliance; however, the FAA has no requirement for industry to use a design-certification approach when evaluating the safety of in-service events. (See G-1, G-2, and G-4, above.)
FS-1d Next to this difference between the FAA and the industry, applying this Handbook will also create a gap between the FAA and the EASA. EASA is following IR 21 A.3B(d)(4), which is fully in line with the 25.1309 approach for judging in-service events and AD decisions. Consequently, the worldwide aviation industry would be confronted with two different standards which is an additional burden to the aviation industry as well as that it can have a detrimental effect on aviation safety for the same reason as given above.		EASA IR 21 A.3B(d)(4) is a non-harmonized approach to COS that was not consistent with FAA regulation and policy at inception (see G-3, G-4, and G-7, above.) The gap between FAA regulations and EASA regulations and guidance on COS existed prior to the release of FAA Order 8110.107. However, as described in TARAM handbook paragraph 1.2, the continued operational safety of the Fokker fleet will continue to be the responsibility of EASA per ICAO Annex and bilateral agreement.
FS-1e The Handbook contains useful explanations of various statistical methods and should be used for that reason only. To avoid any conflicts between the FAA on one hand and the industry or other Authorities on the other side, Fokker Services would like to ask the FAA to reconsider the TARAM Handbook and to focus on a 25.1309 philosophy instead for further development of a risk assessment based AD decision guidance document.		See G-1 and G-4, above.

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Commenter: Embraer Letter GCH-O02012011 - 1 12, dated February 24, 2011		
E-1a The Memorandum ANM-117-10 summarizes the applicability of the proposed Risk Assessment Methodology and explains that it intends to fill the need for transport airplane COS risk guidance. As the TARAM will complement current advisory material, it should provide a guidance consistent with the AC 39-8 and AC 25.1309, but the proposed uncorrected fleet risk of .02 is barely achieved for large aircraft fleets at the AC 25.1309 certification baseline threshold of 1.0E-9/h. Considering for instance, an outcome with IR=1 in compliance with the 25.1309 threshold of 1.0E-9/h, in a fleet of 300 aircraft with a foreseeable average retirement life of 50000hs per aircraft, results an UFR of .015, which appears to be an indication that the identified risk limits are probably too restrictive.		See the G-1, G-2, G-3, and G-4 dispositions, above. As noted in the general comments, the risk values in the TARAM handbook are ***not*** calculated using design estimates, and cannot be realistically compared to values derived via the conservative analytical methodology outlined in AC 25.1309-1A. As noted in G-4, if there were a real issue that resulted in an IR=1 (e.g., uncontrolled crash) that was actually occurring in the given fleet with the frequency in the example, that issue would not meet the requirement of § 25.1309 that a (functional) catastrophic failure condition is extremely improbable – **"not anticipated to occur during the entire operating life of all airplanes of one type."** We have not encountered any real-life situation where a certified system with no in-service issues would have a risk greater than the TARAM guidelines, nor has any commenter presented us with such a situation.
E-1b For medium to high capacity airplanes, the proposed control program fleet risk also may be considerably lower than the AC 39-8 short term acceptable risk. The TARAM handbook says that current aviation safety levels were considered when determining the risk level guidance, but does not explain the reason for a more stringent risk guideline than current industry practice and also the Handbook does not contain a clear explanation of the mathematical variables that lead to the establishment of the "control program fleet risk factor" of 3. Additional analysis and clarification is necessary, including the industry impact evaluation and the expected safety benefits.		See G-1 and G-5, above As an aside, AC 39-8, *Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes*, as the title states, provides guidance that is limited to powerplant installations. The comment implies that the guidance was intended to be effective outside the stated scope of use. Regarding "additional analysis," etc., see G-1 and G-2, above.

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E-1c Regarding the Risk Analysis procedure, all assessment is based on the injury ratio and according to the Handbook, the historical injury ratios for a variety of conditions and outcomes are available. But it is not clear how the data have been collected and classified. The injury ratio is the core of the process and a better clarification regarding databank management is essential. It is also important to evaluate how this historical data will reflect the technological and safety improvements of new airplane types.		An injury ratio, as defined in the TARAM handbook, is the single-event probability of fatal injury. Injury ratios are derived by obtaining a random, statistically significant number (or all) occurrences of a specific airplane-level outcome involving U.S. type certificated transport airplanes. An injury ratio for each occurrence is calculated by dividing the number of fatalities that occurred as a result of the outcome (including fatalities on the ground) by the number of people aboard the airplane. Those injury ratios are averaged, and statistical methods are used, to derive the best statistical estimate of injury ratio for future occurrences of the outcome. The technological and safety improvements of new airplane types will be reflected over time in the injury ratios, as those airplanes are involved in unsafe outcomes, and the results will be incorporated into the calculation. However, historically, technological and safety improvements have resulted in a lower probability of unsafe outcomes rather than a lessening of the severity of those outcomes. Accordingly, technological and safety improvements will be more applicable to the specific TARAM analyses parameters affecting the probability of the outcome.
E-1d The safety risk management process is already in use by some manufacturers with different methodologies. Embraer has been using a similar process for years, including the risk assessment and control program definition for various issues. This practical experience from the industry is valuable when defining a new methodology and we strongly suggest a wider discussion, taking in consideration the Industry best practices for establishing a standard for transport airplane continued safety risk assessment.		See G-1 and G-2, above We intend to have further discussion with industry, over time, with the goal of developing a mutual understanding of industry versus regulatory agency needs for risk analysis and to share best practices. However, we cannot delay implementation of TARAM because the analysis process is required by FAA Order 8110.107, which is already released and in effect.

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Comment	Requested Change	Disposition
Commenter: Boeing, Letter B-H001-REG-31-TLM-15, dated February 28, 2011 (General Comments)		
B-1a Boeing fully endorses the intent of the MSAD Order, and considers it a welcome enhancement to our shared mission to ensure the continued safety of the flying public. However, we are concerned with potential unintended adverse effects that could arise from application of the TARAM Handbook as it is currently proposed.		See G-1 and G-2, above. The FAA has been applying the TARAM handbook to safety issues on Boeing aircraft for more than four years for most technical disciplines. In the majority of cases, the FAA's TARAM results and Boeing's safety-program results have been in agreement on the nature of the both the safety issue and the compliance time needed to address the issue.
B-1b The Summary section of the proposed policy memo describes the MSAD Order's requirement for each FAA aircraft directorate to develop data-driven, risk-based analysis methods in terms of a statistical probability of a fatal accident. The final two sentences within the Summary section imply that the design approval holder or certificate holder may be asked to perform elements of the TARAM process. However, MSAD Order 8110.107, Chapter 1, Paragraph 1-3, allows acceptable certificate holder processes to be used in lieu of functions identified for FAA personnel throughout the Order. Boeing maintains that the current FAA-Boeing Working Agreement on COS involving the COS Program (COSP) and In-Service Safety Issue Management processes have been, and continue to be, effective and acceptable processes with which to manage safety risk in the in-service fleet. These processes are identified in the BCA Organization Designation Authorization Procedures Manual. Further, MSAD Order 8110.107, Chapter 2, Paragraph 2-2.b., provides the expectation that the FAA aircraft directorates will integrate the certificate holder's processes with the MSAD process in a compatible manner with the Order. We again maintain that our current aforementioned safety processes have been and continue to be successful in effectively managing and reducing the risk of accidents. Our existing safety processes accomplish a majority of the MSAD Order process steps and allow the FAA's ACO Aviation Safety Engineers (ASE) to perform an oversight role.		MSAD Order 8110.107, Chapter 1, Paragraph 1-3, was not intended to allow certificate-holder processes to be used "instead of" the prescribed MSAD processes. Paragraph 1-3 allows an ACO to delegate accomplishment of all or part of the MSAD process where that delegated function will effectively and reliably accomplish what is required in the MSAD Order. The FAA-Boeing COS Working Agreement is very valuable and beneficial to the FAA. However, Boeing's internal risk-analysis processes are not structured in the manner required by MSAD, do not result in the risk values required to be calculated and recorded within the MSAD process, are not accomplished uniformly for all issues, and do not have associated risk guidelines in terms of the MSAD-required risk values. Accordingly, Boeing's internal risk-assessment processes are not compatible with the MSAD Order and cannot be accepted in lieu of risk analysis that is structured to fulfill MSAD requirements. In addition to being MSAD-compliant, TARAM provides the FAA with a tool to evaluate and more-effectively assess Boeing's safety recommendations under the existing working agreement.

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B-1c Additionally, the FAA is currently considering regulation that would potentially require certain product design and manufacturing organizations to have a Safety Management System (SMS). The FAA Aircraft Certification Service has initiated a pilot project to evaluate the issues involved with regulation and oversight of SMS in the design and manufacturing sector. Boeing supports this effort. Any Transport Airplane Directorate guidance that requires FAA offices and personnel to use one specific methodology in making determinations of unsafe condition, without the latitude to recognize existing mature COS processes, would potentially circumvent these efforts to evaluate, develop, and deploy SMS regulation and policy in the design and manufacturing sector.		See G-1 and G-2, above. The FAA considers this comment to be outside the scope of this TARAM review. MSAD Order 8110.107 defines the requirements for a compliant risk-analysis process and the TARAM handbook provides guidance for implementing those requirements. The MSAD Order very specifically mandates TAD guidance that requires FAA offices and personnel to use “one specific methodology in making determinations of unsafe condition.” The MSAD Order does not provide any “latitude to recognize existing mature COS processes” that do not meet the risk-analysis requirements contained in the MSAD Order. Providing transport airplane risk determination guidance in a form that supports accomplishment of the MSAD Order is not optional for the TAD.
B-1d-i **Industry cost of TARAM implementation should be formally evaluated – Boeing considers it to be significant:** • Since the proposed policy memo states that design approval holders may be asked to perform all or part of the TARAM process, there may be significant recurring and non-recurring resource impacts.		The draft policy memo and the MSAD order only directs FAA actions. It does not (and cannot) impose any requirements on industry. Design-approval holders may be asked to perform all or part of the TARAM process; however, the design-approval holders may refuse, leaving accomplishment of an MSAD order compliant risk analysis to FAA engineers.

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B-1d-ii • Extremely conservative individual risk thresholds defined in TARAM have already imposed significant hardship on some operators in specific instances, and are likely to continue to be an issue if not modified. We note that these thresholds have been established without Industry input.		See G-6, above. The FAA does not agree that the risk guidelines provided in the TARAM handbook are conservative or conservatively derived. Boeing has not provided us with a specific instance where significant hardship on operators was driven by the individual risk guideline. Safety management based on individual risk, as required by the MSAD order, is a new concept in safety decision-making, and some controversy should be expected. However, the individual risk guidelines have not proven to be a significant point of controversy during the four years that the TARAM process has been tested in the Seattle and Los Angeles Aircraft Certification offices. In some cases, because of TARAM analysis results, the FAA has decided not to require corrective action even though corrective action has traditionally been required in similar cases. Such cases have lessened the burden on operators. If, in the future, it is shown that the guidelines do not effectively represent the safety goals of the FAA, those guidelines will be changed.
B-1d-iii • Boeing recommends that the FAA continue to work closely with Industry to develop appropriate policy that would allow Industry to follow proven in-service risk assessment practices. Separate guidance could be maintained as tutorial reference and to assist service providers with voluntary activities that exceed minimum regulatory standards.		See G-1, G-2, G-3, and G-4, above.

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B-1e-i **TARAM is not consistently applied across Industry, resulting in an unlevel playing field and a divergence of safety standards across Industry worldwide:** • Non-US manufacturers and operators are largely exempt. • This could result in a large competitive disadvantage to Boeing and to US-based operators.		See G-1, G-2, G-3, G-4 and G-7, above. The FAA considers the discussion of harmonization of safety standards to be outside the scope of this TARAM review. This comment implies that common airplane-level COS standards in place now would be negated by the implementation of the MSAD order and TARAM. No worldwide COS standards exist; MSAD and TARAM will not change that.
B-1e-ii • The “Effect of Policy” section (first paragraph, first sentence) of the proposed policy memo indicates that the TARAM methods do not change or contravene the guidance in Advisory Circular (AC) 39-8, “Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes.” We foresee powerplant or APU issues where AC 39-8 data-driven decisions are different from TARAM data-driven decisions.	We therefore request that further instructions be provided where AC 39-8 guidance and methods will overlap TARAM methods.	~~The two methodologies will have no unresolved overlap.~~ AC 39-8 (as amended to meet the requirements of the MSAD Order) will be used to guide accomplishment of the risk-analysis portion the MSAD process when powerplant-related COS issues are being resolved within the jurisdiction of the FAA Engine and Propeller Directorate. Likewise, COS issues within the jurisdiction of TAD will be resolved within MSAD using the guidance of the TARAM handbook. ~~All ADs are ultimately within the jurisdiction of a single Directorate, with no overlap.~~ <u>For the rare cases where an issue is in the jurisdiction of both EPD and TAD, if either method indicates an unsafe condition is present, then issuance of an AD is warranted. Both methods provide guidelines, not hard and fast thresholds, so both methods allow for latitude in decision-making.</u>
B-1f-i **TARAM risk management thresholds and philosophies represent significant changes relative to current Industry standards and practices:** • Individual risk philosophies and resulting thresholds are overly conservative and have not been appropriately vetted with Industry.		See G-1, G-2, G-3, G-4, G-6, and B-1d-ii, above.

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B-1f-i • Fatality-based control program calculations are not supported by regulation, are inconsistent with current Industry practice, and can result in unreasonably short compliance time limits for Boeing airplanes compared to some competitors.		Regarding regulation: see G-3 and G-4, above. No regulations preclude FAA consideration of fatalities in determining acceptable control-program risk. As a past-practice reference, AC 39-8 contains guidance for considering fatalities when establishing corrective-action times for resolution of CAAM level 5 hazards. Experience obtained to date, using the TARAM process, has resulted in few, if any, cases where controversy has arisen about control-program compliance times that were established based on risk level alone. To provide some control on the cumulative risk associated with multiple unresolved-safety issues, the TARAM handbook provides guidance indicating that corrective action should be accomplished as quickly as reasonably practical within the timeframe associated with the control-program fleet risk-level guidance. This is very much the same guidance for establishing control-program timeframes provided in AC 39-8. In some cases, the practicalities of specific, corrective-action timeframes have been contested and we concur that the TARAM guidance should be expanded in this area. We very much welcome input from industry and operators in developing additional guidance for FAA engineers when determining appropriate “reasonably practical” corrective-action times.

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B-1f-ii • Fatality-based control program calculations produce significantly different results for passenger airplanes and cargo airplanes, and result in compliance recommendations that would support increased accident rates for cargo airplanes. We do not consider this to be in the public's best interest.		The FAA believes that the severity of unsafe transport airplane outcomes is directly proportional to the number of people expected to be fatally injured. We also believe that the public would concur. This is the premise used when justifying FAA rulemaking per executive Order 12866, i.e., a large part of rulemaking justification is the valuation of the number of lives saved. Accordingly, from a cost/benefit standpoint, the FAA can justify safety-related rulemaking for larger transport airplanes that isn't possible for smaller airplanes. Airplane size (carriage) is also reflected in the structure and contents of the 14 CFR airworthiness and operational rules. Within the limits of the individual risk guidelines and with *all other factors being equal*, we believe corrective action should occur more quickly on the airplanes expected to carry the most passengers. Individual risk guidelines, required by the MSAD Order, limit the risk that transport-airplane occupants (including the flightcrew on cargo airplanes) should be subjected to and include provision for increasing the urgency of corrective action based on risk to individuals alone. See G-6, above.
B-1g **Implementation of TARAM may actually result in reducing fleet safety:** • Increased resource expenditures on lower risk issues that have marginal impact on fleet safety may siphon finite resources from more significant safety-related activities, including implementation of Commercial Aviation Safety Team (CAST) initiatives.		See G-1, above. To the contrary, based on experience to date, FAA data, research, and analyses show that use of MSAD supported by TARAM analysis allows more objective risk-informed safety decision-making. This has resulted in fewer perception-based ADs to correct issues that represent very low actual risk, and more focused resolution of higher-risk issues.

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B-1h **The TARAM quantitative approach to structural issues is not sufficiently mature enough to allow direct implementation:** • TARAM structural methods are technically appropriate for issues where sufficient good data exist; however, it has been Boeing's experience that, for many types of structural events, there is often little data available to support a strictly statistical approach. Examples where this may be the case are: airplane decompression resulting from skin cracking, or certain crack initiation and crack growth cases, such as corrosion damage and plating cracking.		See G-1, above. The MSAD Order contains no provision for delaying implementation of MSAD-compliant risk analysis in any area. As required by the MSAD Order, the TARAM-defined quantitative approach is presently being used to establish the risk associated with structural issues. These analyses have been very effective in characterizing the risk associated with the majority of structural-safety issues addressed to date. Valuable risk analyses have also been accomplished for issues associated with some of the example areas cited in this comment. As with any quantitative analytical approach, data-acquisition and data-analysis refinement are the keys to improving risk-analysis results. The FAA agrees that some structural-safety issues would benefit from more and better data. To that end, TAD is sponsoring research and development projects to identify and improve the data used in structural risk analysis. The Boeing Company is the research contractor for one such project. However, both sufficient data and analytical techniques are available to perform structural risk analysis for most COS issues. We do not agree (nor is it allowed by the MSAD Order) that such data should be ignored in favor of a qualitative approach merely because data is lacking in other areas.
Commenter: Boeing, Letter B-H001-REG-31-TLM-15, dated February 28, 2011 (Specific Comments)		

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<table>
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Page 7
Section 3.1 The Concept of Risk
The proposed text states:

3.1 The Concept of Risk
To properly use the TARAM, you must understand the concept of risk. This handbook defines the following measures of risk:
Total uncorrected fleet risk. The number of weighted events statistically expected in a defined timeframe (the remaining life of the affected fleet) if no corrective action is taken as a result of the identified hazard. The events are weighted by the injury ratio (IR).
“90-day uncorrected risk” and “Control program uncorrected risk.” The number of fatalities statistically expected in a defined timeframe (90 days & throughout the control program) as the result of an identified hazard.
Consistency with the rest of the document – the terms “Control program uncorrected risk” and “90 day uncorrected risk” are not used anywhere else in the document.</td><td>Change “90 day uncorrected risk” to <u>“90 day Fleet risk”</u> and “Control program uncorrected risk” to <u>“Control Program Fleet Risk</u>.”</td><td>The FAA concurs with the commenter.</td></tr>
</table>

Comment	Requested Change	Disposition
B-3 Page 7 Section 3.1 The Concept of Risk The proposed text states: ***3.1 The Concept of Risk*** *To properly use the TARAM, you must understand the concept of risk. This handbook defines the following measures of risk:* ***Total uncorrected fleet risk.*** *The number of weighted events statistically expected in a defined timeframe (the remaining life of the affected fleet) if no corrective action is taken as a result of the identified hazard. The events are weighted by the injury ratio (IR).* ***"90-day uncorrected risk" and "Control program uncorrected risk."*** *The number of fatalities statistically expected in a defined timeframe (90 days & throughout the control program) as the result of an identified hazard.* The 90-uncorrected and control program fleet risks use "exposed occupants" in their calculation, whereas total uncorrected fleet risk does not. The methodology should be standardized, and should not be based on exposed occupants. There is the potential for significant confusion due to the change in units between "total uncorrected fleet risk" and the 90-day and control program fleet risk indices, and there is no apparent justification or need for the expression of the 90-day and control program risks in terms of fatalities.	Eliminate use of expected fatalities for determination of safety and urgency of corrective action and use a consistent methodology that does not rely on occupancy for all three fleet risk values – total fleet risk, 90 day fleet risk, and control program fleet risk.	See B-1f-i, above

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B-4 The proposed text states: ***3.3 Individual Risk*** *Individual risk, as used in the TARAM, is the largest result of the number of times a condition under study is likely to occur, the conditional probability of an outcome as a result of that condition, and the fatality rate per outcome, that will occur on future flights, (e.g. the largest frequency coupled with the largest conditional probability expected to occur together during a reasonable number of actual flights.) [footnote below]* ***Footnote:*** *Individual risk is not based on the 'worst case' that can be hypothesized. It represents the actual frequency of known conditions that can reasonably be expected to occur during actual flights.* Although the footnote says individual risk is not based on worst case, tables 1 and 2 use terms such as 'highest', 'oldest' and 'largest'. Use of the worst conditions will cause a distortion of priorities in fleet issues. Also using the age of the oldest aircraft in assessing a wear-out condition may cause fleet action (such as grounding) when no airplane part will necessarily reach an age where wear-out actually becomes a factor. Individual risk as described in the TARAM Handbook is defined as the **highest** probability per flight hour, while MSAD Order 8110.107 defines individual risk as the **average** probability per flight hour. The TARAM handbook must align with the MSAD Order definition of individual risk to avoid unintentional misapplication.	Change Section 3.3 and Tables 1 and 2 to use average individual risk	The FAA partially concurs with the commenter. See G-6 above. We will further refine the wording in the TARAM handbook to make it clear that individual risk, as actually defined in the MSAD Order, typically is based on averages that apply to the fleet. However, in some circumstances it is calculated "including risk values for special conditions and combinations of conditions." In the majority of cases, average frequency and conditional probability will be used in the calculation of individual risk due to no known factors that significantly increase the risk. However, when known conditions significantly increase the risk, those conditions should be included. Traditionally, structures fatigue (wear-out) has always recognized increased risk with increased age. Most compliance programs for wear-out issues have an age threshold (in flights or hours). Only airplanes past the threshold (older airplanes) would be at risk of "grounding," and then only if the issue were severe enough to require immediate action for those older airplanes. Airplane parts that don't reach the age at which wear-out becomes a factor would not be affected by the compliance program. Boeing and the FAA have used this approach to wear-out issues for decades, and TARAM does not change this. Boeing, in some cases, has used a tiered compliance-time approach, with multiple thresholds and shorter compliance times for older airplanes. TARAM can accommodate this approach in assessing control-program risk, each tier being assessed separately against the control-program individual-risk guidelines. However, the riskiest airplanes should be protected accordingly. For a wear-out issue, the riskiest airplanes are the oldest airplanes within the timeframe being assessed (e.g., the control program), and an individual-risk calculation needs to be performed to ensure that adequate corrective actions are taken for these old airplanes.

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Comment	Requested Change	Disposition
B-5 Page 8 Section 3.5 Non-Fatal Injuries The proposed text states: *3.5 Non-Fatal Injuries* *This handbook addresses analysis and management of risk in terms of the cumulative probability of outcome related fatalities within a fleet, the number of fatalities expected in a specific period of time, and the individual risk of fatal injury per flight. However, unsafe condition determination can result from an unacceptable rate of passenger or crew injuries that are not expected to be fatal. Even though such injuries are not the focus of the TARAM, conditions that would result in routine injuries and/or life-threatening injuries to passengers or crew are unacceptable. Such cases should be addressed by applying the MSAD process, with the risk calculated as described in this handbook and the particular injury(s) used as the severity. Applying the process in this way will produce data representing the cumulative probability of non-fatal injuries, the number of specific non-fatal injuries expected in the timeframes defined for each risk factor, and the per-flight-hour probability of individual non-fatal injury. Since the type and nature of such injuries vary, it is not feasible to establish acceptable risk guidelines. Each office, in consultation with the TAD Safety Management Branch, will determine, on a case-by-case basis, whether the risk of injury associated with any given condition justifies corrective action.* This section is in contradiction to the MSAD intent of establishing clear, documented guidelines for making safety determinations, and opens the possibility for future inconsistent application between different airplane models, manufacturers, or operators.	If non-fatal injuries are to be considered under MSAD, the guidance for acceptable risk in this area needs to be clearly established - not determined ad-hoc on a case-by-case basis. Any such guidance material should be adequately vetted with Industry participants and be defined through appropriate rulemaking methods.	See G-3, above. TARAM handbook paragraph 3.5 addresses those cases where it may be in the interest of the FAA to reduce the risk associated with nonfatal injuries. It provides recognition that such risk can and should be considered. There is some frequency at which almost any passenger or crew injury can be considered unacceptable; however, the types of injuries and the circumstances under which such injuries can occur are so varied and unique that it is impractical at this time to establish standardized risk criteria to address them. Accordingly, each office must address such safety issues on a case-by-case basis, as has always been done. We are not changing current practice in this regard. Over time, as such issues arise and are resolved, and further data is obtained, we will improve the guidance in the TARAM handbook to support more objective, non-fatal-injury safety decision-making.

DISPOSITION OF PUBLIC COMMENTS

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Comment	Requested Change	Disposition
B-6 Page 17 Section 5.3 Definitions and Formulas The proposed text states: *The variables used in determining the Transport Airplane risk values are defined as follows:* ***Conditional Probability (CP) —*** *the probability that an unsafe outcome, for which an injury ratio is known, will result from a particular condition under study. The conditional probability is the product of the individual conditional probabilities for all of the conditions that must occur after* Without a good understanding of the details of the event under consideration, erroneous conclusions may be drawn from the output of the tool. The example above assumes that the event assessment can be represented by a one branch fault tree Logically ANDED with other independent branches. However, it is not atypical for a component failure interaction to involve Logical OR's or Logical Exclusive OR's which would result in a Conditional Probability that cannot be calculated by simply multiplying terms.	The TARAM process needs to ensure that the ASE performs an appropriate assessment of the event architecture before they begin to populate the Excel spreadsheet. It is important to fully understand the contributing factors to a potential safety issue, as well as the interactions between these factors. One way to do this is to construct an Event Tree (similar to a fault tree used for certification). This should be a required first step prior to filling in the spreadsheet. The concern is that the TARAM handbook has provided a level of instruction and a set of tools that may lead to a "plug-in-the-numbers" application approach. Without requiring a good understanding of the details of the event under consideration, erroneous conclusions may be drawn from the output of the tool. This can be corrected by adding a step in the process to create an event tree, or something similar that fully represents the problem, prior to completing the TARAM worksheet.	The FAA partially concurs with the commenter. We agree wholeheartedly with the spirit of this comment and recommendation. We will add wording in the TARAM handbook to recommend that, when the circumstances surrounding a safety issue are complex and/or not well understood, it would be good practice to construct a representative causal chain (event tree) to better understand the details of the event. We will also clarify the physical meaning of "multiplication of conditional probabilities," and discuss appropriate calculations for other situations. The TARAM handbook presently emphasizes the importance of understanding the problem fully prior to conducting the analysis.

Comment	Requested Change	Disposition
B-7 Page 14 Table 1. Risk Value Definition, Purpose, and Mathematical Basis Row: Total uncorrected Fleet Risk - Mathematical Basis The proposed text states: *For a constant failure rate issue the total uncorrected fleet risk is obtained by computing the product of the frequency of the condition under study per flight or flight hour (based on the estimated remaining affected fleet life), the conditional probability that the condition under study will result in a defined outcome, and the average severity probability (injury ratio) of the outcome. A comparable calculation using failure forecasts is performed for wear out issues.* *This computation is performed for each* ***reasonably expected*** *outcome for which an injury ratio is known. The result of the total uncorrected fleet risk computation for each outcome is usually summed together to obtain the total uncorrected fleet risk associated with the condition under study.*	The term “reasonably expected” is used in the Handbook in several locations. The use of this term in the phrase above leaves great latitude for interpretation by the FAA Aviation Safety Engineer (ASE). Further, this phrase when used with the term “highest” or “largest” as seen throughout the Handbook, seems to imply that some judgment takes place, leading to inclusion of some conditional probabilities but not others (e.g., “do not stack unrealistic worst-case combinations of conditions”). These value judgments can have an overwhelming impact on the resulting risk values, and are subject to interpretation by the user without any significant guidance. Boeing recommends that the FAA review the use of this phrase “Reasonably expected” throughout the Handbook and either define it explicitly or provide more detailed guidance to bound its interpretation.	The FAA partially concurs with the commenter. The guidance contained in the TARAM handbook is intended for aviation-safety engineers. Good engineering judgment is necessary to properly, efficiently, and effectively accomplish the risk-analysis methodology described just as it is in any similar type of engineering analysis. Accordingly, we assume that those performing or overseeing risk analyses have the capabilities outlined in TARAM handbook paragraphs 6.4 and 6.5. We also expect that both the MSAD process and associated TARAM risk analysis are collaboratively performed, and any analysis has the benefit of engineering judgment from several sources. Accordingly (and as described several places in the TARAM handbook), the term, “reasonably expected” and other qualitative terms are meant to be interpreted within the context of good engineering judgment. In the cited use, the “reasonably expected” provision is included so an ASE can forgo analyzing outcomes that are theoretically possible but where the risk will obviously be so low as to not affect the outcome of the analysis. If the ASE chooses to include those very-low-probability outcomes, it will not have an “overwhelming impact” on the resulting risk values. The FAA will, based on the comments received, bound the term, “reasonably expected” where it is used to define the scope of individual-risk-value determination.

Comment	Requested Change	Disposition
B-8 Page 14 Table 2. Risk Value Definition, Purpose, and Mathematical Basis Page 16 Table 2. Basic Risk Formulas and Variables Page 20 Table 3. Risk Guidelines Page 11 Section 5 Risk Analysis / Section 5.1 General Description And throughout the Handbook where ever "90-day or control program fleet risk" is used. The use of an allowable fatality count for calculating compliance intervals has undesirable consequences with respect to public perception and potential media misinterpretation, and is not supported by Industry. It is not logically consistent to argue that a compliance interval for a 300 passenger airplane should be an order of magnitude shorter than the compliance interval for a 30 passenger airplane (assuming the basic probability of the event of interest is the same for both airplanes) simply because the theoretical probability of producing 3 fatalities is greater for the larger airplane – in either instance, there will be 0 fatalities until there is an actual accident event. If the probability for the basic event is the same for both airplanes, and if it is controlled to a sufficiently low probability of occurrence, neither airplane fleet will experience ANY fatalities, irrespective of the theoretically calculated differences in expected fatality count. Conversely, in the case that an actual event was to occur, the resultant number of fatalities could easily exceed the desired threshold value of 3, even for the smaller airplane.	We request not basing compliance intervals on number of expected fatalities; base them instead on controlling the risk of occurrence of a fatal airplane accident.	See B-1f-i, above. The FAA does not expect undesirable consequences with respect to public perception and potential media misinterpretation. On a far larger and more visible scale, we had no public perception or media misinterpretation when the FAA, as an agency, changed the safety-goal metric for commercial air travel to a fatality-rate measure. We agree that if the probability of the outcome is controlled at a sufficiently low level, an actual outcome will not be anticipated on either airplane in the example stated. However, the "risk" (probability and severity) associated with a defined outcome for the two airplanes is very different, i.e., based on the historical severity of past outcomes of the same type, the expectation is 10 times more fatalities on one of the airplanes. Accordingly, the FAA position is that a control program based on risk should be more urgently accomplished for the 300-passenger airplane, *all other factors being equal*.

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Comment	Requested Change	Disposition
B-9 Page 16 Table 2. Basic Risk Formulas and Variables Footnotes There appears to be a missing footnote on page 16 (footnote 4) and may be unintended footnotes on page 17 (footnote 2 within definition of Time Period and footnote 5 within definition of Number of Aircraft).	EDITORIAL COMMENT: Correct footnotes for Table 2	The FAA concurs with the commenter. The item will be corrected.

Comment	Requested Change	Disposition
B-10 Page 20 Table 3 – Risk Guidelines To avoid creation of multiple safety standards worldwide. The control program fleet risk criteria is based on a fatality limit (>3) that is not supported by regulation or Industry, and appears to diverge from the Industry-wide efforts to focus and prioritize activities based on the accident rate. TARAM methods include a calculation element related to airplane size, which is not only inconsistent with 14 CFR part 25 requirements, but also inconsistent with other worldwide regulatory agencies' continued airworthiness methods. The inclusion of a methodology that depends on airplane passenger count will create an unlevel playing field and diverge from a single worldwide safety standard. Boeing maintains that the alignment of Industry-wide efforts globally will be of the greatest value to aviation safety. Individual risk threshold values have not been vetted with Industry, and are philosophically inconsistent with similar specific risk approaches as recommended by recent ARAC committee activities.	To avoid creation of multiple safety standards worldwide. To maintain a "level playing field" for all manufacturers and operators.	The FAA considers the comment to be outside the scope of this TARAM review. Regarding multiple safety standards, see G-1, G-7, and B-1e, above. Regarding "… not supported by regulation," see G-3, G-4, and B-1f-, above. Regarding "… not only inconsistent with 14 CFR part 25 requirements, but also inconsistent with other worldwide regulatory agencies' continued airworthiness methods," see G-1, G-3, G-4, G-7, and B-1f, above. Regarding "… will create an unlevel playing field and diverge from a single worldwide safety standard," see G1, G2, G4, G-7, and B-1e, above. Regarding "Boeing maintains that the alignment of Industry-wide efforts globally will be of the greatest value to aviation safety," see G-1, G-2, and G-7 above. Regarding "Individual risk threshold values have not been vetted with Industry, and are philosophically inconsistent with similar specific risk approaches as recommended by recent ARAC committee activities," see G-1, G-3, and G-6, above. Also note that no ARAC committees are involved in developing as-built, airplane-level COS standards. See G-4 above. Individual risk, as defined in MSAD Order 8110.107, is not analogous to the concept of specific risk. See G-1 and G-6, above. We welcome Boeing's constructive comment on the TARAM handbook risk guidelines, particularly on the topic of individual risk, which is a new COS consideration required by the MSAD Order.

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Comment	Requested Change	Disposition
B-11 Page 20 Proposed Section 6.3 The proposed text states: 6.3 Risk Level Guidance Justification The risk level guidelines presented here correlate, in general, with those used during an extended period of COS program testing in certain branches, including Mechanical and Electrical Systems and Propulsion within the Seattle Aircraft Certification Office (ACO) and Los Angeles ACO. That testing found that risk results align well with decisions made by the COS Board and the Service Difficulty Board, respectively, for those branches. This alignment with ongoing continuing operational safety programs shows the risk level guidance presented here to be generally consistent with the historic level of safety maintained by the transport airplane AD process. As TARAM is employed in the remaining Seattle and Los Angeles ACO branches and in the rest of the ACOs across the country; we will monitor the results of the analyses and associated safety decisions to ensure that the methodology and guidance reflect the risk management policy of the Transport Airplane Directorate as well as AIR SMS. *When determining the risk level guidance for uncorrected individual risk, we considered current aviation safety levels, as well as the type of life risk data illustrated in Figure 6. The life risk data in this table provides a contrast between individual risk calculated according to the guidance in this handbook and the risk associated with various aspects of daily life.* Transport Airplane risk level guidance can and will change based on changing agency goals and expectations.	Handbook Section 6.2, Table 2, defines risk guidelines, while Section 6.3 states that the guidelines correlate with those used during an extended period of COS program testing in certain branches. However, the correlation data is neither included as an Appendix nor shared with Industry for review. Further, the methods and guidelines presented diverge from Industry-wide and worldwide standards of managing accident rates. Boeing requests FAA share the data used to support this correlation.	As a part of the TARAM test programs carried out in the Seattle and Los Angeles Aircraft Certification Offices, the FAA has monitored ~~both the rate of~~ safety-decision disagreements between the FAA and Boeing and the specific causes of those cases where issues have arisen as a direct result of risk-analysis results. We are also aware that Boeing has likewise monitored the same ~~rates and~~ issues. FAA study shows that the rate of safety-decision disagreements that existed prior to testing, and now full MSAD/TARAM usage in those offices, has remained unchanged. Furthermore, we know of only one case where TARAM analysis and guidance was a significant factor in an FAA safety decision with which Boeing strongly disagreed. We are not aware of any cases where controversy has arisen about control-program compliance times that were established based on control-program risk level alone. In some cases, the practicalities of specific corrective-action timeframes have been contested, however, those types of disagreements predated TARAM use, and the rate of such disagreements has not changed. Boeing has monitored the same ~~rates and~~ issues in the two ACOs. It would be helpful if Boeing provided specific examples of the TARAM-related disagreements that would support a different conclusion.

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B-12 Page 21 Figure 6 Life Risk Comparing per hour fatality rates for events that vary widely in total long-term exposure as a criterion for establishing acceptable risk thresholds is not appropriate. As an example, most rodeo riders spend many hundreds of hours each year as an automobile occupant, but spend less than one hour actually riding a rodeo bull. Although bull riding presents far more risk on a per-hour basis, it is statistically more likely that a bull rider will die in an automobile accident than in a bull-riding accident. Similarly, most members of the public spend far more time travelling in an automobile than they spend as a passenger on a transport airplane – therefore, setting the TARAM threshold for individual risk for a transport airplane at a level that is lower than the per-hour risk for automobile travel is not logical. Boeing strongly encourages the formation of a joint government-Industry forum to develop and recommend appropriate individual risk thresholds for use in managing fleet safety. Proposed individual risk guidelines have significant potential Industry impact, and appear to have been derived without appropriate Industry participation or assessment of the potential cost to Industry.		The risk of various life events are shown in the TARAM handbook to provide a contrast between individual risk calculated according to the guidance in this handbook, and the risk associated with various aspects of daily life. The individual-risk guidelines were selected based on the ***present level*** of commercial-airplane individual risk. The present level is indicated in Figure 6, and is currently much lower than the risk for automobile travel. See G-6, above. The FAA is very much interested in understanding Boeing's position on individual-risk-level guidance for determining an unsafe condition, and particularly what risk levels Boeing believes are appropriate for commercial passengers within the context of other life risks.

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B-13 Page 21 Section 6.4 Aviation Safety Engineer (ASE) Risk Management The proposed text states: ***6.4 Aviation Safety Engineer (ASE) Risk Management** …* Within the overall direction and guidance of the applicable FAA Orders, processes, and work instructions, the ASE is expected to accomplish the following risk management actions: ………………… 3. Develop COS control program requirements commensurate with TARAM control program fleet risk results and risk level guidance. Coordinate these activities with the certificate holder. Ensure that corrective actions are accomplished as soon as reasonably practical, but within the maximum time indicated by the risk results.	Section 6.4 identifies six risk management actions for the FAA ASE. Boeing is concerned that the action to coordinate with the certificate holder doesn't occur until step three. Boeing contends that coordination must occur at step one to ensure both the certificate holder and FAA have accurate, consistent data upon which to make decisions. To avoid misunderstandings between the certificate holder and the FAA, as well as to improve the efficiency of the process and avoid unnecessary rework.	The FAA concurs with the commenter. The lead-in statement in the responsibility list will be changed to: "Within the overall direction and guidance of the applicable FAA Orders, processes, and work instructions, the ASE, in coordination with the responsible certificate holder, is expected to accomplish the following risk management actions:"
B-14 Page 22, Section 6.5 Aircraft Certification Office (ACO) Risk Management, Item 1.e. ***6.5 Aircraft Certification Office (ACO) Risk Management*** *1(e) Ensures that ASEs responsible for resolving COS issues—Understand that the TARAM is intended to result in risk values that represent the best estimate (at the time of analysis) of actual risk with no intentionally introduced conservatism.*	To avoid unnecessary and undue hardship for certificate holders and airline operators caused by overly conservative application of individual risk. Guidance in item 1.e. contradicts guidance advising use of highest frequency for individual risk. Boeing agrees that statistical data to support risk assessments should be based on the best estimates without introducing conservatism, Boeing recommends that the individual risk guidance around using the largest probability and highest frequency be readdressed as this practice will produce an unrealistically conservative individual risk number.	The FAA partially concurs with the commenter. See GE-6, GE-7, G-6, B-1d-ii, and B-1f-i, above. The FAA will reinforce the guidance that ASEs are not to use the "largest probability" and "highest frequency" when calculating individual risk, but to use actual probability that will occur on a number of known future flights if applicable. As already outlined in the TARAM handbook, we have never intended that ASEs choose a worst-case scenario for calculation of individual risk.

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Comment	Requested Change	Disposition
B-15 Page 22, Section 6.5 ACO Risk Management, Item 1 The proposed text states: ***6.5. Aircraft Certification Office (ACO) Risk Management*** *To standardize the way risk is managed for transport airplanes, each ACO, with reference to the applicable FAA orders and work instructions, does the following:* *1. Ensures that ASEs responsible for resolving COS issues—*	To emphasize that this is a critical task that requires a significant level of understanding to accomplish successfully. Another bullet should be added under Item 1 of ASE responsibility that states: ***"1. h. Are trained in the ability to identify and logically model (via event tree or other means) the contributing factors and relationships between them that are necessary for the catastrophic top event to occur."***	The FAA partially concurs with the commenter. As stated in B-6, above, the FAA agrees wholeheartedly with the spirit of this comment and recommendation. The suite of training provided to ASEs includes a course in root-cause analysis. The TARAM handbook can emphasize the importance of this training in understanding the causal chain associated with the analyzed condition and associated outcome, and this section will be reworded for greater emphasis, although not in the exact words shown, as the training requirements are governed by the higher-level MSAD Order.
B-16 Page 23, Section 6.6 Transport Airplane Risk Management ***6.6 Transport Airplane Risk Management*** *To standardize how risk is managed for transport airplanes, the following TAD organizations will take these actions in support of the TARAM:……………* *2(b). Works toward achieving and maintaining the* ***lowest practical transport airplane risk values,*** *consistent with the safety goals of the agency.* TARAM should not represent an attempt to "raise the bar" on the acceptable level for fleet safety. Recent fleet performance demonstrates that the current fleet risk levels are acceptable, and guidance to attempt to control risk to a greater degree is inappropriate without a corresponding assessment of the resulting impacts.	Use of the term "lowest practical transport airplane risk values" is inappropriate, and should be changed. Wording should reflect maintaining an "acceptable level of risk," not achieving the "lowest practical risk." A proposal for these acceptable levels is defined by the risk thresholds outlined in the Handbook.	See G-1, G-3, G-4 and G-6 above. The statement was solely intended to convey TAD commitment to "*the safety goals of the agency"* as published in the FAA Flight Plan, 2009-2013: "Target: Commercial Air Carrier Fatality Rate. Cut the rate of fatalities per 100 million persons on board in half by FY 2025." No definitive "bar" represents acceptable risk in the United States transport-airplane fleet, and neither do the risk guidelines in the TARAM handbook establish such a "bar." The TARAM handbook provides guidance for considering risk within the Order 8110.107 process. That guidance is structured within the context of the currently achieved safety level of the U.S. transport fleet, and FAA safety goals with respect to that fleet, which include reducing the fatality rate.

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Comment	Requested Change	Disposition
B-17 Page 25, Appendix A Definitions The proposed text states: ***Appendix A Definitions*** ***Foreseeable—****A qualitative expression of likelihood. It signifies a greater likelihood than "physically possible," but less likelihood than "not expected to occur in the life of the affected fleet." An event or condition is foreseeable if it is theoretically possible, and if knowledgeable persons cannot reasonably rule out its occurrence during the exposure in question.* Webster defines "**foreseeable**" as "*being such as may reasonably be anticipated.*" The term "foreseeable" is used six times in 14 CFR part 25 regulations and in 31 different Advisory Circulars. In none of these writings is the term "foreseeable" defined. Boeing considers it highly likely that, if published in this Handbook, the definition proposed may be misused to interpret all of the referenced regulations and ACs in the future. While not explicitly defined, some AC material provides guidance in the use of the term "foreseeable;" for example, AC 25.981-2A (Fuel Tank Flammability) states, *"in the context of this guidance, foreseeable causes are those that have occurred in service in the past or those that engineering judgment predicts could compromise the critical feature of a part or component of a fuel tank system."*	We are concerned that the broad definition as proposed in the Handbook will change the intended meaning of "foreseeable" as used in other guidance and regulations. We therefore recommend that the definition be removed from the TARAM Handbook, which should rely on the established interpretation of the term as it is used in each specific application.	Concur: See GE-8, above.

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<table>
<tr><th>Comment</th><th>Requested Change</th><th>Disposition</th></tr>
<tr><td colspan="3">Commenter: Bombardier, Letter AW-CON/11/158, dated February 25, 2011</td></tr>
<tr><td colspan="3">The Bombardier comments contain numerous statements regarding the intent and interpretation of the 14 CFR regulations; the meaning and application of the means-of-compliance guidance associated with those rules; and the intent and scope of FAA findings associated with those rules. Those same Bombardier comments, as a whole, do not reflect the FAA rules as they pertain to safety determinations and certification, nor the difference between the two. More specifically, the comments appear to misinterpret the scope and intent of AC 25.1309-1. (See G-3 and G-4, above.)

The comments also appear to reflect an erroneous belief that the abstract hazard categories and the limited, quantitative, analytical risk-analysis methods, contained in AC 25.1309-1A and similar documents, represent the absolute definition of risk and the only risk-analysis methodology that can or should be used to characterize risk as part of airplane certification, COS, and/or aviation-related safety-management systems. See G-1 and G-4, above.</td></tr>
<tr><td>BO-1a

Unfortunately, we find the proposed document to be problematic for use as a guide to performing aircraft safety risk assessments. As will be detailed in the attached review, the handbook adopts a philosophy for a continuing airworthiness risk assessment process that will be inconsistent with that used during initial type certification, leading to significantly different safety requirements throughout the life of an aircraft. The introduction of the injury ratio has no relation to the methods used to design and maintain the COS of the aircraft and is litigious. We also find the proposed methodology to be lacking a structure that would allow it to be readily applied to the risk assessment workflow, and overly-dependent on assumptions based on limited field data.</td><td></td><td>See MSAD Order 8110.107, the TARAM handbook, and G-1, G-3, and G-4, above.</td></tr>
</table>

Comment	Requested Change	Disposition
BO-1b In our opinion, any risk assessment methodology for continuing airworthiness should be based on a philosophy in line with the existing §25.1309 requirements used during type certification. For ease of use, the handbook should include guidance on how to apply the results of its analyses to reach a decision on how to address a risk once it has been assessed. This document does not provide this essential guidance and is in conflict with the regulations and guidance material of the FAA and other authorities.		See MSAD Order 8110.107, the TARAM handbook, and G-1, G-3, and G-4, above.

Comment	Requested Change	Disposition
BO-2a TARAM outlines a process for calculating risk as it affects the transport airplane fleet and explains how to use such risk analysis calculations when making determinations of unsafe conditions and resulting corrective actions. This methodology is intended for use by analysts performing risk analysis as part of the Monitor Safety-Analyze Data (MSAD) process. The MSAD process is required by FAA Order 8110.107 and is a safety management process to promote continuing operational safety throughout the life cycle of aviation products. The Methodology Handbook is not structured in a way that is in line with a risk assessment process used in safety analysis for design or safety management systems. In the handbook section 2, no description is made to how systems and structures are analyzed in the design phase to produce a safe and compliant design and how this is a risk management process to have a design that meets an acceptable level of safety. The section 3 introduction of risk starts immediately with specific definitions of the calculations but not basic definitions that risk is the chance of injury, damage or loss over a specific period. The risk can then be expressed qualitatively or quantitatively as the probability of occurrence (likelihood) for a hazard or event of a given severity (consequence). These concepts are the basis for Risk Management, which is the process to manage risks to acceptable levels.		The FAA considers the comment to be outside the scope of this TARAM review. See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above. The FAA agrees that the TARAM handbook does not describe how to analyze systems and structures in the design phase. To do so would be outside the scope of the handbook. Higher-level orders and processes cover risk management in total. The TARAM handbook describes only one small portion of risk management, as intended.

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BO-2b There seems to be no sequential logic in the methodology handbook but more a compilation of a number of tools and definitions. The application of these tools and definitions need to be structured in the same way as a risk assessment and analysis. It needs to describe the process from the hazard or event identification and classification through the data analysis to determine the probability of occurrence and the acceptance levels and determining the acceptable corrective action timeline. These process steps and applicable methodologies are not evident in the way this handbook is constructed.		See MSAD Order 8110.107, TARAM handbook paragraphs 1 and 2, and G-1, above. The higher-level MSAD Order covers the continued-operational-safety process. The TARAM handbook is only intended to supply a method for performing a risk assessment after an issue is determined to be potentially unsafe, and to supply a set of guidelines to assist in safety determinations. The MSAD Order provides the process for making safety determinations.

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Comment	Requested Change	Disposition
BO-2c Current BA practice is based on a Risk Assessment (RA) methodology developed internally 7 to 8 years ago using recommendations from aviation authorities (TCCA, FAA and EASA) and other available guidelines and references. The BA RA is based on the probability of occurrence and the severity of the failure condition, both defined according to AC 25.1309. The determination of an unsafe condition is through §25.1309 safety requirements while the risk level is determined by the risk category matrix defined in relationship to the certification safety level. The necessary time for corrective action is assessed based on recommendations taken from EASA GM 21A.3B (d) (4) Defect Correction – Sufficiency of proposed corrective action (originally ACJ 39.3(b)(4)). Our experience has shown this process to be relatively simple and easy to apply in practice. It is an efficient tool to detect and analyze unsafe conditions, and to take appropriate corrective actions.		See, G-1, G-2, G-3, G-4, G-7, and FS-4, above. As described in TARAM handbook paragraph 1.2, the operational safety of the Bombardier fleet, except those manufactured in the United States, will continue to be the responsibility of Transport Canada, per ICAO Annex and bilateral agreement.
BO-3a A. TARAM is based on the AC39-8 Continued Airworthiness Assessment of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes. This advisory circular (AC) describes the Continued Airworthiness Assessment Methodologies (CAAM). TARAM is a more in depth and details development of the concepts from the Appendix 6 of this AC.		The FAA considers the comment to be outside the scope of this TARAM review. See MSAD Order 8110.107, the TARAM Handbook, and AC 39-8. The risk-analysis methodology defined in the TARAM handbook is not related to the guidance of AC 39-8 and has no relationship to AC 39-8 Appendix 6. The only similarity is that both AC 39-8 and the TARAM handbook outline risk-analysis processes that, in some part, rely on statistical methods and tools.

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BO-3b B. TARAM requires the computation of 5 different probabilities for any potentially unsafe condition (the condition under study): a. Total uncorrected fleet risk, expressed by the number of "weighted events", i.e. expected number of fatalities in remaining fleet life. The safe/unsafe threshold is arbitrarily established to be 0.02. b. Uncorrected individual risk, expressed by the probability of having "fatalities per flight hour". The safe/unsafe threshold is arbitrarily established to be lower than 1.0E-07 individual fatalities per flight hour. c. 90-days fleet risk, expressed by the number of fatalities. There is no related safety threshold defined for this metric. d. Control program risk, expressed by the number of fatalities. The control program decision threshold is arbitrarily established to be lower/equal than 3 fatalities in control program time frame. e. Control program individual risk, expressed by the probability of having "fatalities per flight hour". The control program individual risk urgent action threshold is arbitrarily established to be higher than 1.0E-6 individual fatal injury probability per flight hour in the control program time frame. The arbitrary threshold for "Not Airworthy" is defined as higher than 1.0E-05.		See MSAD Order 8110.107, the TARAM handbook, and G-1, above. The risk-value computations outlined in the TARAM handbook are required by the MSAD Order, except for 90-day fleet risk, which is easily calculated from the variables used to derive the other risk factors. Note: The commenter's paraphrased descriptions of the risk factors are incorrect. Refer to the TARAM handbook for the actual definitions, calculation units, and explanatory material. Regarding statements such as, "The safe/unsafe threshold is arbitrarily established to be 0.02," per explicit wording in the TARAM handbook, the risk values contained in Table 3 are *guidelines* provided, as required by the MSAD Order, for consideration during unsafe-condition determination. They are not, and cannot be, "thresholds" (see G-3, above, and TARAM handbook paragraph 6.2). Further, the guidelines were not "arbitrarily established" (see TARAM handbook paragraph 6.3, and G-6 and B-12, above).

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BO-3c C. The required probabilities are computed by taking into account the typical probability of the occurrence of a potentially unsafe condition (the condition under study) but also the conditional probabilities of the potential events chain scenario, the fleet size and a parameter defined as “injury ratio” which accounts for the size of the aircraft (the number of passengers exposed at risk). Introduction of conditional probabilities is not a new approach; there are some instances in the BA practice where conditional probabilities are used in risk assessment (e.g. risk assessment of lightning strike with incorrect paint thicknesses applied to an aircraft with a tail fuel tank). However, the conditional probabilities can only be applied to specific risk assessment issues. In most cases they are conservatively assumed to have a value of 1. From a practical point of view, it is extremely difficult to evaluate most conditional probabilities due to a lack of data. The solution suggested by TARAM – to use existing generic databases (see page 51, E.2.5 - ASIAS database) – is a highly questionable approach due to the lack of similarity between this data and the specific conditions under study. The level of confidence in these computations will be very low. Certification requirements in §25.1309 are based on the normalized probability per flight hour. The fleet size and aircraft size factors introduced by TARAM are not present in the existing certification requirements. An introduction of these size factors to the in-service risk assessment could lead to conflicting interpretations and discrepancies between OEM, suppliers and authorities and will unjustifiably penalize larger fleet sizes and smaller aircraft models.		See the TARAM handbook, and G-1, G-3, and G-4, above. Regarding the statement, “a parameter defined as ‘injury ratio,’ which accounts for the size of the aircraft (the number of passengers exposed at risk)”: This statement is not correct. Refer to the TARAM handbook for the actual definition, derivation, and usage of the injury-ratio risk variable. Note: The certification requirements in § 25.1309 are *not* based on the normalized probability per flight hour. The requirements in § 25.1309 are qualitative, as is the means-of-compliance guidance in AC 25.1309-1A. See G-4, above.

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BO-3d D. The fundamental object of the risk assessment is the clear definition of the severity level related to the potential output of the unsafe condition under study. The current BA risk assessment methodology has adopted the same severity classification as is used for certification and is based on AC/AMC 25.1309 definitions. Risk assessment is based on the evaluation of the delta between the certification level and current safety level in the fleet. This risk assessment usually evaluates unsafe conditions of all severity levels: catastrophic, hazardous, major and minor. This approach is accepted by the engineering community and provides a solid input to airworthiness and engineering management processes. This allows the appropriate actions to be taken to restore fleet safety to the original certification level or as close as is reasonably practical. TARAM is intentionally disconnected from the §25.1309 definitions and does not provide clear definitions of the output severity. Based on the definition of the Injury Ratio (IR), as the average probability to suffer fatal injury, it can be concluded that TARAM methodology covers only catastrophic and hazardous failures conditions. TARAM also combines these two criticality levels and applies the same strategies to assess their risks, disregarding that from a certification perspective, catastrophic and hazardous levels are separated by a probability interval of two orders of magnitude (i.e. 1.0E-09 - 1.0E-07). Consequently, any corrective action will require the same level of effort for both categories and might either result in a response that is too aggressive for a hazardous risk or not aggressive enough for a catastrophic one. From the published TARAM methodology, it is impossible to conclude which would be the case.		See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above.

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BO-3e E. This significant weakness of the TARAM concept with respect to the severity definition results in a large ambiguity in the definition of a safe/unsafe threshold and the associated strategy for a corrective action. As mentioned above (see B) the safe/unsafe thresholds were adopted arbitrarily and have no relationship with the certification requirements. It might be that the threshold for “Total uncorrected fleet risk” of 0.02 is extremely low (compared to the CAAM value of 0.1—an order of magnitude difference), and the fleet-grounding threshold for “Control program individual risk” of 1.0E-05 is too high. Particularly for the catastrophic failure condition, this value will lead to unacceptable risk exposure and will put the fleet into an unsafe condition.		See MSAD Order 8110.107, the TARAM Handbook, and G-1, G-3, and G-4; above. Note: The contention the TARAM risk values can be directly compared to values that were derived using different risk-analysis methodologies, different severity characterizations, and are expressed in different mathematical units, is not correct.

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BO-3f F. TARAM methodology is asking to compute five different metrics to assess the risk level, yet does not provide any guidance on how to use those metrics to reach a final conclusion. The results presented on the page 52, Example 2 show: a. Total uncorrected fleet risk - exceeds normally accepted value b. Uncorrected individual risk - within normally accepted value c. 90-day fleet risk - don't know d. Control program fleet risk - exceeds normally accepted value e. Control program individual risk - within normally accepted value Based on the above results, it is unclear what conclusion to make—whether it is necessary to take corrective action ("a" and "d") or if no action is required ("b" and "e").		See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, G-4, and G-6, above.
BO-3g G. TARAM was developed from the CAAM methodology which was formerly extensively used by engine and APU manufacturers. Powerplant certification under Part 33 was until quite recently excluded from a requirement to comply with §25.1309. There is no question that the CAAM methodology was effective and generally accepted in the field of the engine risk assessment. However the extension of the CAAM approach to risk assessment of aircraft systems already certified under §25.1309 is not acceptable. The safety requirements should not be changed after aircraft certification and entry into service.		See MSAD Order 8110.107, the TARAM Handbook, and G-1, G-2, G-3, G-4, G-5, and BO-3a, above.

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BO-3h H. The TARAM document presents its approach as a strong, objective and structured method to assess risk, to determine unsafe conditions within a fleet, and to determine necessary corrective actions to mitigate risk. TARAM is packaged in a "scientific" cover but in fact is based on a mixture of a few different probability calculations, associated with a large number of assumptions, hypotheses and unsupported conclusions. Examples of these types of issues are found in the probability calculations provided on page 50, paragraph E.2.3. This paragraph contains a number of errors, unsupported assumptions, and arbitrary numbers taken for different probability computations. Therefore, the example does not provide any clarity as it is intended to.		See MSAD Order 8110.107, the TARAM handbook, and G-1, G-3, and G-4, above. Regarding TARAM handbook paragraph E. 2.3: Several reviewers have found an inconsistency in the paragraph calculations that can be traced to a single typographical error, i.e., the fifth sentence in the paragraph will be changed to read, "Since each Acme 10P airplane has *four* PECUs…" The FAA is interested in understanding where the reviewer believes additional errors exist in the paragraph.
BO-3i I. The TARAM is not founded as a methodology on a coherent system of well-established hypotheses, but rather is a collection of independent probability calculations. When combined with arbitrarily adopted thresholds (despite being described in TARAM as "normally accepted"), this will lead to a variety of unrelated conclusions that will be difficult to interpret or apply to a corrective action process.		See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above.

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BO-3j J. TARAM focuses on probabilistic risk analysis, however recent development and researches indicates that a probabilistic risk assessment approach has serious limitations. A better approach would be to adopt the Risk-Informed Decision Making (RIDM) concept which involves the integration of probabilistic, deterministic and non-quantifiable elements in a way that, overall, leads to a resolution of the safety issues being considered that relates to their risk-significance.		Non-Concur: See MSAD Order 8110.107, the TARAM handbook, and G-1, G-3, and G-4, above. The FAA maintains that the MSAD Order is consistent with RIDM: “Risk-informed decision making is distinguished from risk-based decision making in that RIDM is a fundamentally deliberative process that uses a diverse set of performance measures, along with other considerations, to inform decision making. The RIDM process acknowledges the role that human judgment plays in decisions, and that technical information cannot be the sole basis for decision making. This is not only because of inevitable gaps in the technical information, but also because decision making is an inherently subjective, values-based enterprise. In the face of complex decision making involving multiple competing objectives, the cumulative wisdom provided by experienced personnel is essential for integrating technical and nontechnical factors to produce sound decisions.” NASA/SP-2010-576 The TARAM handbook provides a method to measure risk, as well as guidelines to assist in decision-making. MSAD provides the framework for making COS decisions. MSAD and TARAM encourage risk-informed decision-making based on all considerations, not solely based on risk.
BO-3k K. Implementation of TARAM will impose an increased workload that will provide neither any benefit compared to currently-used risk assessment methods, nor any consistent improvement to fleet safety. In summary, the TARAM methodology is not sufficiently credible for implementation.		See MSAD Order 8110.107, the TARAM handbook (particularly paragraph 6.3), and G-1, G-2, G-3, and G-4, above.

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BO-4 1. This handbook appears to be written for personnel with a limited exposure to systems safety and risk assessments. Many of the calculations and tools presented require reliability knowledge and training to correctly use. Weibull analysis in itself is a tool which requires substantial knowledge to use correctly even with software tools or the results will be erroneous. Many reliability experts have unintentionally made errors using this analysis tool obtaining completely inaccurate results. Risk Assessments and Safety Analysis must be conducted by persons with the appropriate experience and training. Expertise in structural analysis is of little value when analyzing system failures and vice versa.	Conflict(s) with the FAA Regulations regarding the development of a safe design. §25.1309. Revise to reference current guidance, regulations, SAE ARP 5150 standard applicable to system safety and COS. State backgrounds and training that is required for personnel to correctly implement the guidance provided in this manual.	The FAA partially concurs with the commenter. We concur that analysis must be conducted by persons with the appropriate experience and training. However, the TARAM handbook describes competency requirements for those performing risk analyses. (See TARAM handbook paragraphs 6.4 and 6.5). Likewise, TAD has provided TARAM training to all FAA Aircraft Certification Offices and to interested certificate holders. Also, as an adjunct to the MSAD-process training, formal Weibull training has been made available to all ASEs with COS duties. We do not concur that TARAM conflicts with § 25.1309. See Order 8110.107, the TARAM handbook, and G-1, G-3, and G-4, above.

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BO-5 P.6, 2.1 2. AIR SMS performance measures are not only the statistical expectation of a fatal accident but of the impact to safety of issues before accidents or incidents occur. All severity classifications from Catastrophic to Minor have an impact on Safety. To be inline with the proactive component of a SMS all safety risks (Hazards or events) should be reduced to acceptable levels including those that have a minor severity. Aviation accidents are rarely the result of a single event but of many contributing factors that create holes in multiple safety barriers per the James Reason model. Many latent failures are of a Minor consequence in isolation but degrade the number of safety barriers to prevent an accident or incident. If the minor and major severity events are not considered, they in combination with other conditions and events may and have resulted in accidents. This is the rationale behind why all safety issues must be evaluated and prioritized to mitigate the risk of the event to the acceptable levels. Nuisance failures may become a distraction (Human Factors) leading to a procedural lapse that escalates into a more severe event than predicted.	Measures of statistical expectations of events from Catastrophic to Minor should be monitored.	See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above. The FAA agrees that all aspects of a safety system must be monitored, and that accidents result from many contributing factors; however, we do not write airworthiness directives to correct nuisance issues. We use means other than ADs, such as advisory materials, information bulletins, etc., to address these issues. The purpose of TARAM is to only aid in determining when and how expeditiously we write airworthiness directives. The FAA is developing other SMS initiatives to address other aspects of safety systems.
BO-6 P4, Sec. 1.1 3. Why does this guideline not correspond with or correlate to any airworthiness rule, standards or guideline? Risk assessment forms the basis of safe design and safe operation and is the foundation of an SMS. It would seem logical to maintain that standard for a safe design and operation to be used as the standard for the aircraft in service. If this guidance is not in line with the CFR then it will be in conflict.	Use system safety guidance as defined in AC25.1309 and SAE ARP5150.	The intent of this statement is to reassure the public that TARAM risk results would not be used to “re-certify” designs, and would have no effect on findings of compliance to § 25.1309. The FAA has clarified this statement. See MSAD Order 8110.107, the TARAM handbook, and G-1, G-3, and G-4, above.

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BO-7 P4 Sec., 1.1 4. Why is the term "extremely improbable" not comparable? The 14 CFR terms for probabilities and severities are internationally recognized and well defined. Changing terms leads to confusion and the lack of standardization to allow determination of a safe to unsafe condition.	Use standard probability and severity terms as defined in AC 25.1309 and ARP5150.	See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above.
BO-8 P7, Sec. 3 5. This section is entitled "Introduction to Risk", however the text does not reflect this title. Risk is the measure of the chance of injury, damage or loss over a specific period. Risk in a system safety assessment is the probability of occurrence for a given event severity. Probabilities are determined as the average probability for the affected fleet.	Change definition of risk to one in line with the §25.1309, AC and SMS risk assessment methodologies in ARP5150.	The FAA partially concurs with the commenter. The title and wording in TARAM handbook paragraph 3.1 do not align. The title and wording will be corrected. The FAA does not concur with the commenter's recommended action. See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above.
BO-9 P7, Sec. 3.1 6. 90-day uncorrected risk serves what purpose if the Control Program Uncorrected Risk is determined acceptable for a period greater than 90 days. If the Control Program Risk is less than that then immediate mitigation action is necessary or a fleet grounding is considered. Individual risk is not sufficiently defined and more detail is required. Is not necessary to calculate multiple times as the Risk Control program will give the main time constraint that all actions must remain within.	Require a calculation to determine the time to correct the condition back to the acceptable level of risk. This calculation must be based on the same criteria that are used to design a safe aircraft as that is the baseline acceptable level of risk. Alignment with AC 39-8 and EASA GM 21A.3B (d) (4) Defect Correction – Sufficiency of proposed corrective action should be considered.	See MSAD Order 8110.107, the TARAM handbook, AC 39-8, and G-1, G-2, G-3, and G-4, above. TARAM does result in a calculation showing whether a given compliance time results in a compliance-program risk within the guidelines. The FAA does not agree that this calculation should be the same as that in EASA GM 21A.3B(d)(4). See G-7, above. The 90-day uncorrected risk value, as defined and outlined in the TARAM handbook, is only used as an administrative prioritization value within the TAD. Corrective action, as also clearly defined in the TARAM handbook, should be accomplished "as soon as reasonably practical within the timeframe associated with the control program fleet risk level guidance."

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BO-10 P7, Sec. 3.2 8. The introduction of the "injury ratio" is not defined before being introduced in the text. New terms unknown to the reader are used before being defined.	Definitions on page 17 should be moved to the beginning of the document	The FAA partially concurs with the commenter. We added an explanation of the concept of injury ratio in section 3.2 where the term was first used, but we did not move the definitions. The Table of Contents directs readers to the definitions, should the readers want to see them.
BO-11 P8, Sec.3.5 9. Non-Fatal injuries have acceptable risk levels when designing an aircraft and therefore should remain the same in service. The Hazardous and Major severity categories address a low number of fatalities and injuries. These severities have an acceptable level of risk confirmed by the FAA in the design and this is the same standard that should be maintained in service.	Revise text to utilize the world wide accepted standards for a safe aircraft design.	See MSAD Order 8110.107, the TARAM handbook, AC 25.1309-1A, and G-1, G-2, G-3, and G-4, above.
BO-12 P9 Sec 3.6 Paragraph after Figure 3 10. "…. The analyst would obtain quantitative data to define the frequency of occurrence (Pc…". This is not a frequency but a probability. Inconsistent use of frequency.	Use consistent terminology. Rates and frequencies are not probabilities. See page 17 definitions.	The FAA concurs with the commenter. We will review and amend the document for proper term usage.

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BO-13 P11 Sec 5.1 11. Risk calculations presented in this section are not in line with those used to determine a safe design for introduction into service. The design considers random and wear out failure modes at a defined acceptable probability of occurrence of significant events to defined severity levels. This is accepted and defined by the FAA as acceptable risk. Unless the assessment was in error or failure modes and effects were not sufficiently assessed then maintaining the safe design is the objective. The data obtained from fleet experience validates the estimates used in the assessment of the safe design. If the data contradicts the original estimate then the risk needs to be reassessed. If the new probability does not meet the acceptable level then the delta between the current probability and the acceptable probability should determine the control program at an acceptable risk. Prioritization by injury ratio is not in line with an SMS as the objective is to minimize the less severe events that can contribute to a catastrophic event.	Alignment with AC 39-8 and EASA GM 21A.3B (d) (4) Defect Correction – Sufficiency of proposed corrective action should be considered and SAE ARP 5150 and ICAO SMS handbook is required. Remove the concept of Injury Ratio.	See MSAD Order 8110.107, the TARAM handbook, and G-1, G-2, G-3, and G-4, above.
Bob Mattern, Pratt & Whitney Fellow - Operational Safety Risk Analysis, Email dated January 11, 2011		
BM-1 (From Email) We do SRAs differently by using a simulation model that allows us to include most of the parameters/variables that are experienced in field operations. This handbook does a good job in the discussion and explanation at a basic level, but some words should be added to discuss how complex modeling can be done and such models will improve the accuracy of predictions.		The FAA partially concurs with the commenter. For transport-airplane COS, the level of complexity of analysis that is necessary varies widely, and the techniques required in each particular application of the process vary so much, that it would not be practical to attempt to address them all adequately in the guidance. As a result, discipline-related analytical techniques and differences are covered in TARAM training or on a case-by-case basis.
(Excerpted from TARAM Handbook mark-up)		

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BM-2 (Here and a number of other comments not reproduced) **3.1 The Concept of Risk** To properly use the TARAM, you must understand the concept of risk. This handbook defines the following measures of risk: • **Total uncorrected fleet risk.** The number of weighted events statistically expected in a defined timeframe (the remaining life of the affected fleet) if no corrective action is taken as a result of the identified potential unsafe condition. The events are weighted by the injury ratio (IR). I think this is just different wording, or a slightly different method. AC39-8 guides the ASE to predict engine-level events and then multiply that # by an aircraft hazard ratio (Level 3+ and then Level 4) to get the predicted aircraft events, which I think is what is meant by “weighted” I assume this (Injury Ratio) is the same as a CAAM hazard ratio.		: The “weighting” in the definition of total uncorrected fleet risk is the Injury Ratio, which is a direct measure of the severity of specific airplane-level outcomes or conditions. The injury ratio is the historical, single-event probability of death based on the actual number of people fatally injured (on the airplane and on the ground), divided by the number of people exposed (airplane passengers and crew) in specifically defined transport-airplane outcomes or conditions that occurred from 1970 to the present.
BM-3 (Here and a number of other comments not reproduced) Para. 3.1 • **Total uncorrected fleet risk.** The number of weighted events statistically expected in a defined timeframe (the remaining life of the affected fleet) if no corrective action is taken as a result of the identified potential unsafe condition. The events are weighted by the injury ratio (IR). AC39-8 uses 20 years because our engines and aircraft last far more than 20 years or 60,000 flight hours. (= malfunction Rates)	Para: 3.1 (Change to) • **Total uncorrected fleet risk.** The number of weighted events statistically expected in a defined timeframe (the remaining life of the affected fleet *or 20 years whichever comes first)* if no corrective action is taken as a result of the identified hazard. The events are weighted by the injury ratio (IR).	In TARAM, the estimated remaining operating life of the fleet is used. The estimate is based on the anticipated remaining production time plus the average retirement age. If the average retirement age isn’t known, the analyst can use 35 years as a default average.

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BM-4 (Here and a number of other comments not reproduced**)** **3.2 Individual Risk** Individual risk, as used in the TARAM, is the largest result of the number of times a condition under study is likely to occur, the conditional probability of an outcome as a result of that condition**,** and the fatality rate per outcome, that will occur on future flights, (e.g. the largest frequency coupled with the largest conditional probability expected to occur together during a reasonable number of actual flights.) This concept of risk is shown in This concept of risk is shown in ……… I know later in Sec 5.3 Table 1 gives the choice of largest or average if there is low variation. But AC39-8 just has average, so this is a significant difference.	**3.2 Individual Risk (Change to)** Individual risk, as used in the TARAM, is the *average* result of the number of times a condition under study is likely to occur, the conditional probability of an outcome as a result of that condition**,** and the fatality rate per outcome, that will occur on future flights, (e.g. the largest frequency coupled with the largest conditional probability expected to occur together during a reasonable number of actual flights.) This concept of risk is shown in ………..	See G-6, above. In TARAM, total uncorrected fleet risk and corrective-action fleet risk are average risk values. The per-hour flight risk calculated in AC 39-8 is also a fleet risk value. The individual risk factors in the TARAM handbook are not comparable to any AC 39-8 risk value. The values represent the risk of fatal injury to a random individual passenger during a known number flights that will occur in the remaining fleet life (if nothing is done) and the average corrective-action time period.
BM-5 (Here and a number of other comments not reproduced) **Table 1** Provides a long-term forecast of future risk if no corrective action is taken. This helps determine whether an unsafe condition might exist and is used to guide the decision for corrective action. Us at Pratt and the AC use the malfunction rates (L3+ is 1E-08 and L4 is 1E-09) to determine if we have to do corrective action or not		See G-5, above. In TARAM, the risk values are based on fatality probabilities and relate to specific airplane outcomes or conditions, and not to functional-hazard categories, so these risk values and guidelines are not the same or comparable to AC 39-8 values.

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BM-6 **Table 1** This computation is performed for each reasonably expected outcome for which an injury ratio is known. In case there is no data and an injury potential is known, it should be estimated from similar data or engineering judgment	**Table 1** (Change to) This computation is performed for each reasonably expected outcome for which an injury ratio is known or can be estimated.	The FAA concurs with the commenter. Transport-airplane injury ratios are known for all high-level airplane outcomes, and the injury ratio of most important lower level outcomes are also known or can be calculated from past data, so the need to estimate the value will be infrequent but, as suggested, may sometimes be necessary.
BM-7 (Here and a number of other comments not reproduced) **3.6 The Causal Chain** I have never seen the phrase "casual chain", but we have used for years "event sequence". I think we are talking about the same thing	(Change to) **3.6 The *Event Sequence***	The FAA maintains that the terms are analogous. Other reviewers have offered different, analogous terms. Accordingly, the FAA will keep the term, "causal chain." We do not believe that the term will reduce understanding of the concepts presented.
BM-8 **Figure 4** I rarely have seen it where while monitoring the control program of one issue that leads to the identification of another hazard. I understand the thought of continuously looking, but it is not a closed-loop process, in my opinion.		This figure was removed from the final TARAM Handbook, as it did not add to the explanation of the TARAM, and was more distracting than helpful. However, that figure is used in other AIR SMS documents. That figure is a concept diagram rather than a flowchart. The concept depicted is that COS needs to be continuous, and that the FAA cannot assume that our control programs work perfectly – we need to monitor the fleet to ensure that we fix what we intend to fix, as well as identify new issues.

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BM-9 **Table 2. Basic Risk Formulas and Variables** This approach is fine for the "Basic", simple method, not using inspections, scrap parts, repairs, retirements, etc. in the risk model. It should be mentioned that the ideal risk model simulates everything that happens in the field.	**Table 3. Basic *(No inspections, Scraps, Repairs, or Retirements)* Risk Formulas and Variables**	The FAA partially concurs with the commenter. As annotated throughout the handbook, the intent of the process is that everything that happens in the field is included in the basic risk variables, and particularly the Conditional Probability (CP) and Not-Detected (ND). Chapter 4 shows how to include retirements in the risk equations. In ANM-117's one-on-one consultations with the ACOs, we teach engineers how to include inspection programs and other factors in their risk analysis. However, a specific description within the handbook of the analytical approaches that can be used to account for all considerations, for each discipline and application, is not feasible.
BM-10 **5.5 Analysis Validation** I always calibrate my risk model to accurately predict the past before I try to predict the future.	**5.5 Analysis Validation** (add) ………*If the risk model does not predict the past events, adjust the appropriate risk variables until they calibrate.*	The FAA partially concurs with the commenter. See GE-3, above.
BM-11 (Here and a number of other comments not reproduced) **6.1 Fail-Safe Design** TARAM guidelines must NOT be the only means of determining the safety of discovered single failures that could foreseeably result in an unsafe outcome with an injury ratio greater than 0.1 (10%). (Foreseeably) Redundant with "could".	**6.1 Fail-Safe Design** TARAM guidelines must NOT be the only means of determining the safety of discovered single failures that could ~~foreseeably~~ result in an unsafe outcome with an injury ratio greater than 0.1 (10%).	The FAA partially concurs with the commenter. The sentence will be amended to read, "…single failures that foreseeably result in an unsafe outcome…" As used in TARAM, "foreseeable" has a specific qualitative meaning and allows engineering judgment to be used when determining the scope of issues that need to be considered for safety implications. The FAA has agreed, based on other comments, to refer back to the formal definition of "foreseeable." However, either way the word is defined, it is not as general or global as the word "could."

Comment	Requested Change	Disposition
BM-12 (Here and a number of other comments not reproduced) **Table 4. Risk Guidelines** Why is Total Unc. Risk >0.02 but CP Risk >3, and why isn't Ind Risk >1E-09. Also not clear if these are Level 3+ or 4. I am really confused with this table. AC39-8 has 0.10 as the criteria for Level 4 risk. I assume that is what the 0.02 is suppose to be, but then the ind risk criteria is 1E-07 while the AC uses 1E-09. Again I don't understand how the risk criteria make sense relative to uncorrected vs. control program and to AC39-8. Then during the Control Program the risk can be up to 3.0?????? Should be the same 0.02, unless I am missing the understanding of the criteria.		See G-5 and BO-6, above. The TARAM risk values and guidelines are based on fatality probabilities associated with actual airplane outcomes and not on functional hazards. They are not the same, nor comparable with the AC 39-8 guidelines. Total Uncorrected Fleet Risk is calculated in terms of "weighted" outcomes, i.e., outcome-related fatality rate. Control Program Fleet Risk is calculated in terms of predicted fatalities (which represents a risk level and not a predicted occurrence), hence the difference in the guidelines.
BM-13 **B.1 Understanding the Causal Chain** If more than one unsafe outcome is foreseeable for the condition under study, a TARAM worksheet must be filled out for each unsafe outcome and Part 2 of an additional constant failure rate summary worksheet prepared.	**B.1 Understanding the Causal Chain** If more than one unsafe outcome is foreseeable for the condition under study, a TARAM worksheet, *or acceptable substitute form*, must be filled out for each unsafe outcome and Part 2 of an additional constant failure rate summary worksheet prepared.	The FAA concurs with the commenter. Use of the form is not prescribed, but it aids understanding if the data is organized in a standard fashion.
BM-14 Various punctuation, grammatical, word use, and spelling suggestions		The FAA will consider the commenter's various punctuation, grammatical, word use, and spelling suggestions when incorporating the revisions related to overall review of the TARAM handbook.

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Comment	Requested Change	Disposition
Commenter: AIA/GAMA Letter dated February 28, 2011		
A/G-1a The Aerospace Industries Association (AIA) and General Aviation Manufacturers Association (GAMA) represent manufacturers of commercial and general aviation aircraft, engines, avionics and components who also provide airworthiness and maintenance services to nearly every commercial and general aviation operator in the U.S. We have reviewed the subject draft policy and handbook; we appreciate the time and opportunity to provide the FAA with feedback. In addition to providing specific comments that reference the TARAM Handbook, AIA/GAMA would like to raise a broader concern regarding this approach to risk analysis and the relation to safety management systems for the design and manufacturing industry. In general, the industry is supportive of FAA movement towards formalized risk analysis methodology connected to establishment of a regulated safety management system (SMS). In SMS, risk analysis is a critical step following the identification of a hazard and it must be done correctly to insure adequate controls or mitigation steps are put in place.		See G-1 and G-2, above. Note that MSAD Order 8110.107 describes the requirements for an internal FAA SMS process. The order places no requirements on certificate holders that are not already annotated on 14 CFR part 21. Likewise, the TARAM handbook defines how the risk-analysis step in the MSAD Order process will be accomplished within the FAA during the resolution of transport-airplane continued-operational-safety issues. Again, the TARAM handbook contains no requirements that apply to certificate holders (industry).
A/G-1b Through discussions with the FAA regarding future implementation of SMS, the design and manufacturing industry has remained encouraged by a commitment from the FAA that existing industry methodologies will be considered as a starting point for further refinement of hazard identification and risk analysis, therefore giving credit for, and due recognition to, systems currently in place. These systems have unarguably played a key role in the steady improvement of safety in our industry.		See G-2 and A/G-1a, above.

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A/G-1c In review of the TARAM handbook, the FAA has not clearly defined how this tool will be applied. In several instances, the memorandum accompanying the handbook identifies TARAM as part of the implementation of SMS within the Aircraft Certification Services (AIR), yet how SMS will be applied to type design certificate holders, through regulation, is far from being defined. The memorandum goes farther to say the handbook is meant to be used by FAA aerospace engineers; however, use by FAA personnel would almost certainly result in changes to practices or decisions that will affect the regulated industry.		See G-1, G-2, and A/G-1a, above.
A/G-1d The industry has worked closely with the FAA via the SMS Aviation Rulemaking Committee and has begun a series of Part 21 SMS pilot programs that will help shape application of SMS in the future. Meanwhile, the TARAM policy and handbook appears to be driven by SMS goals internal to the FAA, not in coordination with application of SMS to the industry.		The FAA began implementation of an internal SMS a few years ago, the goal of which is to introduce risk-informed decision-making into FAA internal processes. MSAD is a key component of the AIR internal SMS. MSAD governs the safety decision-making within AIR for COS issues. We have developed other tools to implement SMS in other FAA internal processes, such as type certification, and designee oversight. All of these activities are part of a higher-level SMS goal, and all are interconnected and implemented in concert. We are working to ensure that requirements that are established for our internal SMS are consistent with those that are defined for industry. Where differences exist, we will fully define the rationale for a decision before proceeding. The FAA defined specific processes and methodology for MSAD, an internal process, but when it comes to SMS implementation in industry, we will identify performance-based requirements and avoid prescriptiveness wherever possible. See G-1 and G-2, above.

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A/G-1e In absence of clear understanding of its application criteria, AIA/GAMA are concerned the policy and handbook is moving ahead of rulemaking it is meant to support (ie..-SMS for Part 21). If the FAA recognizes the successful functioning of current methods to make risk assessments, with emphasis towards continued operational safety, and the FAA has not yet defined the next level of regulatory framework that will change or enhance current methods by applying SMS to this industry sector, AIA/GAMA struggle to see what benefit TARAM will bring to aviation safety.		See A/G-1d, G-1, and G-2, above.
A/G-1f Lastly, the use of fatality based thresholds for issue prioritization and for establishing allowable compliance intervals should be reviewed closely. It is not logically consistent to argue that a compliance interval for a 300 passenger airplane should be an order of magnitude shorter than the compliance interval for a 30 passenger airplane (assuming the basic probability of the event of interest is the same for both airplanes) simply because the theoretical probability of producing 3 fatalities is greater for the larger airplane. In either instance, there will be 0 fatalities until there is an actual accident event. If the probability for the basic event is the same for both airplanes, and if it is controlled to a sufficiently low probability of occurrence, neither airplane fleet will experience any fatalities, irrespective of the theoretically calculated differences in expected fatality count. Thus, TARAM should not be the exclusive consideration for determination of an unsafe condition, or for corrective action accomplishment timeframes.		See G-2 and B-8, above

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A/G-2 **Uncorrected risk:** The workbook is framed to address the necessity for FAA action to control risk. The role of the TC holder and operator in controlling the risk should also be taken into consideration. The TC holder may have instigated their own risk control program before the FAA addresses the issue, such as by issuing a service bulletin or changing the production design. If this is the case, then calculating an “uncorrected risk” as though these measures were not in place will artificially inflate the apparent risk. This question has led to considerable debate in the past. AIA/GAMA also suggests the risk assessment take into account normal fleet maintenance processes, even if not mandated by CMR or AD, provided that a realistic effectivity or compliance percentage is assigned to those processes.	Handbook; 3.1 and other paragraphs: AIA/GAMA suggest the phrase “uncorrected risk” not be used, since it introduces ambiguity, and that some other phrase such as “current risk” be used..	The FAA partially concurs with the commenter. See GE-2, above.
A/G-3 AIA/GAMA would like stronger emphasis to be placed on consistency of the risk model with the events which have actually occurred.	Handbook section 5.5: AIA/GAMA propose the following wording from AC 39-8 be incorporated into the handbook.” *If a quantitative method is used, it is essential that the analysis calibrate with the experience to date. A quantitative risk analysis cannot be expected to credibly predict into the future if it does not calibrate to actual experience*.”	The FAA partially concurs with the commenter. See GE-3, above.

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A/G-4 “90-day uncorrected risk” and “Control program uncorrected risk.” The number of *fatalities* statistically expected in a defined timeframe (90 days & throughout the control program) as the result of an identified hazard. The requirement to estimate 90 day risk should be re-evaluated. When a potential safety issue initially arises, the technical details – root cause, failure mode and statistical failure characteristics – are often unknown, and a period of data-gathering is necessary before risk analysis can be performed. The “90 day risk” concept assumes that all the data necessary for a risk assessment is immediately available, which is generally not the case.	Handbook 3.1 and elsewhere: Add the wording from AC39-8, “*It is quite possible that, immediately following a potentially severe event, the likelihood of its recurrence cannot be adequately estimated. If it is possible to take immediate, practical, mitigating action while an initial assessment is being made, that action should be taken.*”	See GE-4, above.
A/G-5 “The risk guidelines described here do not, and are not intended to, correspond with or correlate to any airworthiness rule, standard, or guidance” The risk guidelines should be compatible with initial certification; the intention is to control risk until the product can be returned to the level of safety intended at certification. In particular, a newly certified product with no identified concerns should not immediately require an AD to meet the TARAM guidelines. It appears that the guidelines, by attempting to address instantaneous peak risk on individual tail numbers, may conflict with the initial certification requirements.	Handbook 1.1 and elsewhere: The risk guidelines should be reviewed to ensure that they are compatible with initial certification requirements for risk.	See G-1, G-2, G-3, G-4, G-6, and GE-5, above.

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A/G-6 Handbook table 1, "uncorrected individual risk : "The highest probability per flight hour that an exposed individual will be fatally injured that is expected to occur during a reasonable number of future flights." The intent not to expose any passenger at any time to undue risk is clear. However, the ability of statistical tools to estimate risk degrades as finer discrimination is requested, either by time or by sub-population (the confidence bands expand rapidly to the point where prediction is impracticable). Fleet or sub-fleet average risk is likely to be more meaningful (a closer estimate to reality) than is an attempt to estimate individual aircraft risk.	Remove the expectation of calculating risk to individual aircraft. We also request that the phrase "*reasonable number*", which appears several times in the handbook, be clarified, since what is "reasonable" varies greatly between individual perceptions.	The FAA partially concurs with the commenter. See G-6 and GE-6 above
A/G-7 Handbook section 5.3, footnote: "The term "fleet" refers to all airplanes on which the condition under study could occur and that are similar enough in equipage, design, and/or operation that they can be considered together in a risk analysis. The term can refer to all transport category airplanes or to a single, identifiable airplane." Statistical approaches are inherently based on addressing a population rather than an individual. Estimates of risk applied to very small populations acquire very large confidence bands, so that the estimate becomes of very limited use. In particular, we do not believe that management of risk by selecting an individual perceived as "high risk" for corrective action is an effective strategy. We recommend that the proposal to assess risk for an individual airplane be removed, to ensure statistical validity.	Replace by "the term can refer to all transport category airplanes or to a much smaller subfleet; attempts to estimate risk should address populations rather than individuals."	See G-6 and GE-7, above

Comment	Requested Change	Disposition
A/G-8 Handbook Appendix A, definitions: ***"Foreseeable—****A qualitative expression of likelihood. It signifies a greater likelihood than "physically possible," but less likelihood than "not expected to occur in the life of the affected fleet." An event or condition is foreseeable if it is theoretically possible, and if knowledgeable persons cannot reasonably rule out its occurrence during the exposure in question."* Defining "foreseeable" as so unlikely that it would never occur in the life of the fleet appears contrary to normal usage and historic practice. A foreseeable event is defined (Merriam-Webster Legal) as "*such as reasonably can or should be anticipated: such that a person of ordinary prudence would expect to occur or exist under the circumstances*" Since the proposed definition appears to introduce significant controversy, and since the term foreseeable has been used extensively within the regulations, it would be better to avoid introducing a new understanding of the term by a handbook definition. If a definition is desired, Chapter 1 would be an appropriate location for a generally used term.	Remove definition of "foreseeable"	The FAA concurs with the commenter. See GE-8, above.

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Comment	Requested Change	Disposition
Commenter: George Powell Letter, PA-10-0246, dated 2-28-11		
GP-1 1) Would a brief preamble to the Handbook help assure direction? It could touch on the TARAM risk assessment as applied to product or article failures or malfunctions caused by *design* or *manufacturing*. It might touch also on who and how safety issues caused by *human operational errors* are addressed, and by whom.		The FAA believes that, taken together, the MSAD Order and TARAM handbook address the intent of the comment. Please note that the calculation of risk described in the TARAM handbook is intended to include the contribution of human operational errors. As outlined in the MSAD Order, if it is determined, based on the risk and/or other considerations, that an unsafe condition exists, the corrective action chosen may include changes to the airplane, changes to the operational procedures associated with the airplane, or both.
GP-2 2) The Graph on Page 21 is a superb key to relative risk. Could a bit more be added with note to identify and explain the ordinate?		The FAA does not concur with the commenter about the ordinate. The ordinates of the graph relate to the social security mortality lines for men and woman, i.e. age versus probability of death per hour and are properly annotated. The risk associated with the life activities are shown without respect to age and we explain that in the notes that directly follow the graph.