	DISPOSITION OF PUBLIC COMMENTS ON DRAFT POLICY STATEMENT ANM-03-112-16, INTERIM POLICY ON HIGH ALTITUDE CABIN DECOMPRESSION INTERIM POLICY: Ref Amendment 25-87	
Commenter:	**Comment:**	**Disposition:**

Boeing:	Boeing requested the following changes (Summarized). In addition, Boeing provided more detailed changes to text. Requested changes: (1) Much of the policy is unnecessarily prescriptive in nature and should be replaced with performance based requirements. (2) Inclusion of any physiological considerations should be deleted. As proposed in the policy, these are more stringent than the current rule as well as proposals currently being developed by the ARAC working group. Any policy to require that the physiological considerations be met should be deferred until completion of ARAC. (3) The attachment on physiological considerations should be deleted.	FAA response: (1) Industry asked FAA to provide interim policy to permit the development and certification of new transport category airplanes. FAA agrees that wherever possible the regulations should be performance based. However, this policy is unique in that (a) it states that an applicant must follow the exemption process and (b) it allows manufacturers to observe how the FAA technical specialist will evaluate an applicant's petitions for exemption. As such, it permits industry with unprecedented access to the process. Performance-based standards state regulatory requirements in terms of objective safety performance rather than specific design requirements. However there are circumstances where FAA regulations need to be more specific. Historical precedent has been established in previous published material where FAA has acknowledged that, "*Performance-based standards are desirable from the standpoint that they offer the manufacturer maximum flexibility in designing equipment or systems to comply with the regulations. They can, however, be difficult to develop, particularly when involved with human performance, as is the case with emergency evacuation regulations*." FAA believes that human physiology regarding high altitude decompression falls into this category. Furthermore, as the commenter is aware, there is much controversy on the subject of high altitude human physiology. While FAA's goal is to seek a performance based rule as an outcome of the current ARAC rulemaking activity involving the Mechanical Systems Harmonization Working Group (MSHWG), FAA declines making this change in the interim policy.

		(2) FAA disagrees that the physiological considerations in the policy are more stringent that the current rule. The current rule restricts cabin altitude to 40,000 feet while this policy permits a maximum cabin altitude to 45,000 feet. FAA considers this to be relieving in nature. However, FAA does agree that the specific functional relationship in the means of compliance (i.e., transform function from cabin total pressure to approximate alveolar partial pressure of oxygen) is more conservative/restrictive than the means discussed within the ARAC. FAA believes that this is justified until further testing is accomplished that yields data to validate the functional relationship. It should be noted that FAA has revised the interim policy to eliminate the need to calculate the pressure-time integral. FAA has provided a simple table indicating the maximum time exposure to altitudes. This approach has been coordinated within the FAA including the office of aerospace medicine. (3) FAA disagrees. FAA believes that it is our responsibility to the traveling public to provide them with an explanation as to why we believe the course of action outlined in the memo results in reasonable passenger safety while enabling industry to develop and operate new airplanes above 40,000 feet.
UK CAA:	UK CAA provided detailed comments as follows: (1) CAA is aware of the fundamental importance of this issue and the power of the precedents that might be set in applying this policy. Under 'Interim Policy' on page 2 it states that the *"intent is not to pre-empt*	FAA response: (1) FAA and other authorities face the same challenge in this regard. Transport Canada and the Brazilian authority are other aviation authorities that have adopted these FAA requirements as conditions for the operation of airplanes at altitudes up to 51, 000 feet. Some authorities that have not adopted Amendment 25-87 do have some of their manufacturer's meet special conditions similar to those requirements that the FAA has imposed

	the ARAC activity." From our understanding of the difficulties the Mechanical Systems Harmonization Working Group (MSHWG) is experiencing it is difficult to see how this intent can be met. If issued, this policy would be used for the A380, B7E7, and other aircraft types for some years until the MSHWG report is turned into a rule. (2) "There appear to be significant difficulties faced by the MSHWG in formulating an acceptable regulatory standard as there appears to be a significant lack of data available and this might force invalid assumptions and/or extrapolations to be made. (3) It is noted that on pages 3 and 4, Technical Issues there is a very honest and accurate assessment of the lack of medical corroboration for the development of an acceptable exposure to high altitude conditions. Because of that lack of data we find it difficult to accept that the pressure-time integral method is valid, and we urge the FAA to reconsider its position on this. (4) At the top of page 5 it is stated that a research program to gain	on executive business jets for high altitude flight. However, some authorities have adopted a philosophy that sudden loss of cabin pressure need not be considered in the design of an airplane and impact on occupants per 25.841 based on the rarity of uncontained engine failures, hence a probabilistic approach. FAA philosophy does not permit the use of probability as the sole means of compliance to 25.841. FAA philosophy continues to be that we require US manufacturers, and foreign manufacturer's that seek FAA certification to consider such failures in their design and ensure that their airplane design be robust enough to retain the capability to safely perform a speedy descent to lower altitudes to ensure a reasonable level of protection to the occupants. (2) There is some data available from human and non-human primate altitude chamber studies. FAA has utilized this data and believes that we have formulated conservative limits that will enable safe high altitude flight during the interim period until a final rule is promulgated. FAA may seek funding to undertake an additional high altitude chamber study as recommended in the MSHWG report. (3) See response (2) above. In addition, FAA has revised the interim policy to eliminate the need to calculate the pressure-time integral. FAA has provided a simple table indicating the maximum time exposure to altitudes. This approach has been coordinated within the FAA including the office of aerospace medicine. (4) See response (2) and (3) above. (5) The FAA's view is that it is not possible to ensure a zero level of risk to any occupant following a rapid decompression. There is not a "new

	additional substantive data will permit a realistic numerical appraisal of the severity of the decompression environment. CAA agrees with this point and believes that the FAA should obtain such data as a prerequisite to allowing this policy to proceed. (5) CAA fully supports the page 5, 2nd bullet statement made under Exemption Process that "The applicant should also show why granting such an exemption would not adversely affect safety." The effect on occupant safety rests on the 'safe exposure time' and if this isn't established with a high degree of confidence then allowing higher altitude operations, without effective mitigations, would introduce a new hazardous, or even catastrophic, failure condition. Considering the shared goal of reducing the fatal accident rates the introduction of a new risk, rather than a lowered risk or equivalent risk, must be seriously considered by the FAA at a strategic level. (6) The page 5 Exemption Process	level of risk;" there always was a level of risk associated with such a failure. FAA was not aware of the level of risk when we promulgated Amendment 25-87 and stated the goal which was to ensure that even those individuals that were not able to properly don an oxygen mask would be protected from any permanent physiological harm. It is a laudable goal, but one that cannot be practically achieved. (6) See response (5) above. (7) At this time, FAA is waiting for recommendations from the Powerplant Installation Harmonization Working Group (PPIHWG) on the best model of the engine failure threat. With regard to the rulemaking activity, our intent is to use the recommendations from both MSHWG and the PPIHWG working groups. PPIHWG should provide a suitable means to determine the engine threat (distribution of uncontained engine fragments, trajectories, etc.) and the MSHWG for the resulting impact to the cabin environment. For the period of time until the rulemaking is completed the assumption that the FAA recommends is that the manufacturer evaluate a rapid decompression as noted in the MSHWG ARAC WG report. (8) FAA concurs with the intent of the first comment. However, the MSHWG has completed their work and recommended a new regulation and new guidance material for the cabin environment following a rapid decompression caused by an uncontained engine rotor burst. FAA has no plans at this time to revise this interim policy. Our position is that the interim policy will be replaced by the new rule.As noted in the interim policy, "This policy, while limited in scope, is consistent with the final ARAC recommendation and will serve as policy

	statement quoted above continues by stating "...the applicant should provide sufficient mitigation strategies that focus on those design features that provide some means to offset the inherent increased risk associated with exposure of occupants to high altitude conditions." This statement appears to accept that a new inherent risk would exist (see above comment), and the only mitigations or design features deemed feasible by FAA on page 4 are rapid descent systems and engine fragment containment systems. CAA considers the policy should also include a statement that the applicant should make mitigations at the individual occupant level. This would support the second part of the page 5 Conclusion, paragraph (2) statement "The petitioner should provide information about any design features that provide enhanced airplane emergency descent rates and occupant survivability." (7) At the top of page 4 it is stated "The average rate of emergency descent given above is predicated on the airplane meeting the	until a new regulatory standard is issued." Regarding the comment *"…to make Petitioners aware that approvals granted from use of this policy might be affected or even rescinded should an unsafe condition be identified from the MSHWG studies*." FAA believes that applicants for certification and those that petition for an exemption are aware that FAA may issue airworthiness directives or take other appropriate action as warranted by safety concerns. Regarding the comment "*Because of the lack of physiological data at high altitudes we find it difficult to accept the pressure-time integral method is valid, we urge the FAA to reconsider its position on this. We support FAA obtaining additional data as a prerequisite to allowing this policy to proceed."* FAA has revised the interim policy to eliminate the need to calculate the pressure-time integral. FAA has provided a simple table indicating the maximum time exposure to altitudes. This approach has been coordinated within the FAA including the office of aerospace medicine.

	provisions of 25.903(d) and that the airplane is designed such that in an event of an UEF the airplane structure, systems and other engine(s) function to enable an emergency (i.e., VMO/MMO) rate of descent." CAA considers the policy should include a statement that the applicant should take due account of maximum hole size caused by fragments, including those from of one-third disc and intermediate disc failure (harmonized AC/AMJ 20-128A d(2) refers). (8) Page 2, Impending Rulemaking, rightly states that an ARAC working group is considering a new regulatory standard and that *"This memorandum may be updated based on the final ARAC recommendation."* The memorandum also, rightly, describes some of the fundamental technical issues on which there is controversy. CAA considers therefore that another statement should be added to make Petitioners aware that approvals granted from use of this policy might be affected or even rescinded should an unsafe condition be identified from the	

	MSHWG studies. Because of the lack of physiological data at high altitudes we find it difficult to accept the pressure-time integral method is valid, we urge the FAA to reconsider its position on this. We support FAA obtaining additional data as a prerequisite to allowing this policy to proceed.	
AFA:	AFA provided detailed comments which are summarized here as issues: (1) 40,000 foot cabin altitude limit specified in Amendment 25-87 is generally recognized as necessary to protect public safety. (2) Pressure-time integral methodology proposed as a means of compliance lacks sufficient support and evidence. (3) Proposed interim policy is bad public policy, as it circumvents existing regulation and significantly diminishes the motivation to obtain new research data.	FAA response: (1) FAA's internal review and discussion within the MSHWG working group regarding the 40,000 feet limit and 2 minutes above 25,000 feet limit indicate that there is much debate over these numbers. The basis for the 40,000 feet limit per Amendment 25-87 was a paper by Dr. J. Gaume in which his criteria were associated with time of useful consciousness. TUC may be appropriate for occupants with necessary functions in a sudden decompression (i.e., cockpit crew) but is not appropriate for all occupants (i.e., passengers). FAA position is that any such altitude limit must inherently consider the risk of exposing occupants to such an environment. For example, some specialists will cite any altitude above 15,000 feet as dangerous in that an exposure to such a pressure could result in morbidity or mortality to a small sector of the traveling public. They believe that the risk to occupants should be "zero." FAA's position is to base our decision on risk assessment weighing in safety and health concerns against industry's requirements. (2) FAA acknowledges the lack of exhaustive data on this. FAA may elect to perform this testing. However, the completion of our internal review

		indicates that the risk to the occupants of short duration exposure to altitudes above 40,000 feet but below 45,000 feet indicates survival for all but a small number of occupants. Should the results of additional research prove that this is not the case, FAA may modify this interim policy as needed. However, it is more likely FAA would utilize such information in the rulemaking activity. (3) FAA disagrees. The procedure outlined in the policy memo clearly states the need for the applicant to pursue the exemption process. All applicants may avail themselves of this process on any regulation. The exemption process does not circumvent regulations but, rather provides a complementary alternative to them when an applicant can establish that the alternative is in the public interest.
Airbus	Airbus provided detailed comments which are summarized here: (1) In Table 1 – Descent Speed versus Altitude, an average emergency descent speed of 7,000 ft/min should be 42,500 feet instead of 42,250 in order to be in line with the other values. (2) Request clarification on text in paragraph below Table 1, regarding when redundant spoiler/speed brake deployment and automatic descent systems are required. (3) Noted that the attachment describing the use of a transform function that is not the selected function per the ARAC.	FAA response: (1) FAA accepts this change. However, FAA has revised the interim policy and eliminated Table 1. FAA has provided a simple table indicating the maximum time exposure to altitudes in lieu of the more complex pressure-time integral. It was felt that the inclusion of Table 1 was redundant. (2) FAA has received other comments on this issue as well and has taken it into consideration in the final version. FAA believes that incorporation of the noted design features is at the discretion of the manufacturer in order to ensure successful compliance to the intent of the requirement. The intent of mentioning these systems was to denote that there are state-of-the art design features which are available and could be incorporated into a design to enhance survivability of the occupants. The issue of when they should be incorporated, depends upon the specific performance characteristics of an airplane. The

		successful applicant will incorporate those features that ensure even with the loss of an engine and associated (i.e., engine driven) systems that the airplane retains sufficient descent speed capability to enhance occupant survivability. Note that the FAA has revised the interim policy and the table 1 that appeared in the draft policy is no longer present in this final policy. (3) The ARAC direction does not limit the FAA in the interim policy nor final rulemaking activity. FAA elected to use a transform function that was more conservative than that proposed by the ARAC group for the approximation of the pressure. However, FAA has revised the interim policy to eliminate the need to calculate the pressure-time integral. FAA has provided a simple table indicating the maximum time exposure to altitudes. This approach has been coordinated within the FAA including the office of aerospace medicine.
FAA-CAMI	FAA-CAMI provided detailed comments directly to Transport Airplane Directorate (TAD) Management which are summarized here: (1) Have used the Brierley & Nicholson data (Interim Policy Reference 2) for monkeys but excluded their conclusions that "the maximum cabin altitude should not exceed 36,000 feet, as above this severe disturbances in the spontaneous activity of the brain are produced," and that "maintenance of pulmonary ventilation is	FAA-Transport Airplane Directorate (TAD) response: (1) The authors of "Neurological Study of Simulated Decompression in Supersonic Transport Aircraft," Aerospace Medicine, J.B. Brierley and A. N. Nicholson, August 1969, clearly state that there were no signs of permanent physiological harm to any subjects exposed to a peak chamber altitude of 42,500 feet pressure altitude. In the results section of this reference the authors state, "There was no evidence of locomoter impairment in any animal following the various decompressions." In addition, they state that, "There was no evidence of brain damage in any animal." We elected not to use their conclusions because they are predicated on the assumptions that the authors used in defining their experiment which are functions of the

	required for survival from exposures up to 42,500 feet." In a second publication, Nicholson wrote that the monkeys had permanent neurological injury. (2) Have been based on the results of older tests with animals, and have not used the results of more recent research with humans who were tested to the "brink of physiological incapacitation" by Dr. Mohler (OAM Report AM 70-12, Physiologically Tolerable Decompression Profiles for Supersonic Transport Type Certification, July 1970). Since their exposures were limited to 2 minutes at 25,000 feet, no human subject had permanent neurological injury. Dr. Mohler also provided data on human accidental exposures in which the parachutist died, and on page 7 of AM 70-12, he reproduced Boeing Company Tables that were proposed to update FAR 25.841(a) and that recommend the "Cabin altitude may not exceed 37,000 feet, assuming passenger supplemental oxygen is present." (3) Have been based on the erroneous assumption that the FAA believes the severity of the	airplane design. Some of their assumptions were wrong. TAD elected to exclude much of the text from the paper for the sake of brevity but included the complete reference so that any interested reader could review the entire report. TAD was not aware that one of the authors recanted the stated conclusion in a later report. However, TAD elected not to include all of the conclusions from the paper because the authors made assumptions about airplane performance and rate of decompression that are not representative of a worst case decompression in the real world. The rate of decompression (ascent of the chamber) took much longer than a rapid decompression. This exposed the animals to a longer duration of hypoxia than would occur in a real airplane sudden decompression. In addition the rate of re-pressurization (descent of the chamber) was slower than many airplanes (in terms of their average rate of descent to 25,000 feet) are capable of providing. This also increased the duration of the exposure. The author's conclusions are based upon their observations of subjects during a "triangular profile." While this represents the best available data, it is not representative of a sudden decompression on a real commercial airplane. A more correct representation of such a profile would be to say "half-a-triangular profile." This is not trivial for it represents a significant lessening of the duration of the exposure. The time that it took the chamber to go from initial pressure to minimum pressure was much longer than a rapid decompression of an actual large commercial airplane. The time spent above 10,000 feet pressure altitude for the chamber was much longer than an

	neurological injury can be determined by the pressure field and the duration of a decompression event. Dr. Ernsting (Interim Policy Reference 3) stated that "the calculations used to develop the pressure-time integral approach were wrong," "the assumptions were unsound," and the tests to validate the pressure-time integral approach would be "unethical." He also stated "As I commented previously, there is no way in which the actual alveolar PO_2-time profile can be predicted with any degree of accuracy – certainly not that would be required to produce any valid correlation between the alveolar PO_2-time Integral and the incidence of cerebral damage/death (if one exists!)." "I have emphasized in my previous comments that there are at present no grounds either theoretical or experimental to support the use of the time integral of the alveolar PO_2 below 30 mm Hg (altitudes above 25,000 feet) even if it could be determined, to distinguish quantitatively between exposures which will produce brain	actual large commercial airplane would spend. The time spent above 25,000 feet pressure altitude for the chamber was much longer than an actual large commercial airplane would spend. The time spent above 40,000 feet pressure altitude for the chamber was much longer than an actual large commercial airplane would spend. FAA/TAD believes that this makes the animal data, conservative in that the risk to human beings on a large commercial airplane subject to a rapid loss of cabin pressure would be less than if they were subjected to the "triangular profile" in the paper. (2) CAMI is correct that Dr Mohler Chief, Aeromedical Applications Division, authored a FAA Aviation Medical Report (AM 70-12) on the "Physiologically Tolerable Decompression Profiles for Supersonic Transport Type Certification," July 1970. In the report he cites observations from 4 depressurization tests conducted at CAMI and he describes a particular test where subjects were taken to 25,000 feet chamber altitude for 1 minute without oxygen (page 11). TAD views this as only an opinion expressed and not a conclusion. TAD notes that some humans can climb to Mount Everest at 29,035 feet without oxygen. At that altitude the blood saturation level is near 30% capacity but they function for an extended period of time and they survive. That is above the point of Dr Mohler's "brink" comment. While the issue of acclimatization certainly enters into the scenario, the fact is that people can and do function, albeit poorly, for an extended period of time at this altitude. In addition, CAMI should recall during the MSHWG activity that (a) Dr Mohler wrote a letter to the Boeing Company expressing his support of their challenge

	damage and those which will not." "I conclude therefore that in the absence of relevant experimental studies and the known complexities of the relationship in acute hypoxia between the time course of alveolar PO_2 and the PO_2 in vulnerable areas of the brain that it is not warranted to employ the Alveolar PO_2 Time Integral Method which you have developed to measure the severity of hypoxia produced by a decompression."	to the specific requirements of 25.841 during failure events and (b) Dr Mohler (a member of the MSHWG ARAC working group) is fully supportive of this pressure-time integral approach. However, FAA has revised the interim policy to eliminate the need to calculate the pressure-time integral. FAA has provided a simple table indicating the maximum time exposure to altitudes. This approach has been coordinated within the FAA including the office of aerospace medicine. (3) As previously noted, FAA has revised the interim policy to eliminate the need to calculate the pressure-time integral. FAA has provided a simple table indicating the maximum time exposure to altitudes. This approach has been coordinated within the FAA including the office of aerospace medicine.